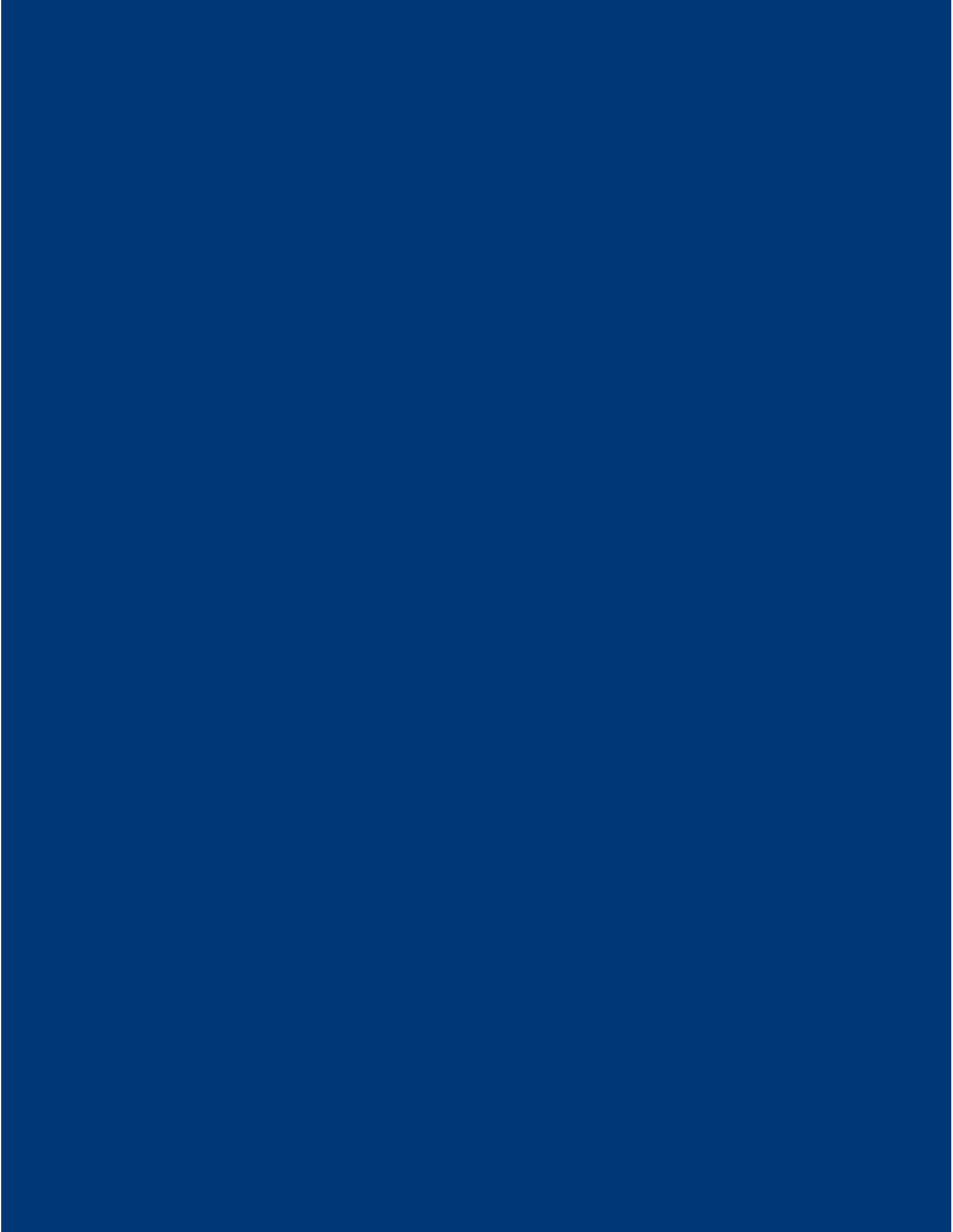


HANDBOOK ON THE IMPLEMENTATION OF EU ENVIRONMENTAL LEGISLATION

Handbook

on the Implementation
of EU Environmental Legislation





Handbook on the Implementation of EU Environmental Legislation

Edited by Hulla & Co Human Dynamics
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Disclaimer

This fourth edition and update of the Handbook covers the period 1 January 2012 until 1 January 2016. It introduces some new pieces of legislation and amendments in the environmental sector. Major updates have also been made to the whole handbook in terms of inserting cross-references to new legislation, adding new, available Commission guidance or other resource documents, checking hyperlinks, reviewing national implementing measures and national good practices. Due to the volume of the Handbook (1500 pages) and the level of detail and versatile sources, it has not been possible to cross-check all information. Hence, the consultant Hulla & Co Human Dynamics, party to the contract with the EU, do not take legal responsibility for possible information that may be out of date or faulty. It is important to note that the main purpose of the Handbook is to provide a source of guidance in transposition and implementation endeavours of the candidate and potential candidate countries. These countries are strongly advised to always first consult the official legal texts (i.e. texts of primary and secondary legislation and guidance from the Commission) and the case-law of the Court of Justice of the European Union and mainly use the Handbook as complementary information and source of unofficial guidance. The content and implementation advice are those of the authors and do not necessarily represent those of the European Commission itself, it cannot be quoted as reflecting the European Commission's position. Equally the consultant Hulla & Co Human Dynamics do not take responsibility for ensuring the accuracy of the information covering EU environmental legislation for the period prior to 1 January 2008 being the work of previous contractors.

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The Handbook, in its original format of 1999, was the result of a collaborative effort between the European Commission (Directorate General for Environment) and the Phare-funded DISAE programme (a Phare environmental approximation facility). The first revision of the Handbook was carried out in 2002 by Project Management Group (PM Group), under the Phare-funded project EUROPEAID/113417/D/SV/R20. In 2007, the Regional Environmental Center for Central and Eastern Europe (REC) carried out a major second update and revision covering all legislative developments in the area of EU environmental law for the period 1 January 2003 to 31 December 2007, but also covering *acquis* from 2008 under the project. The last revision of the Handbook was carried out in 2011 by Human Dynamics, under the RENA project EUROPEAID/128906/C/SER/Multi covering the period 1 January 2008 to 31 December 2011, but also some *acquis* passed in 2012.

The Handbook was written by external legal expert in EU matters Jasmina Kostelac Bjegovic under the overall supervision of Team Leader, Mihail Dimovski in the framework of a service contract. Sectoral expertise and input on water management was provided by Mihaela Popovici (coordinator of the WG on water management in the framework of a service contract). Acknowledgement also goes to Olivera Raicevic for the design and formatting.

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TABLE OF CONTENTS

INTRODUCTION.....	7
SECTION 1 – HORIZONTAL LEGISLATION	41
SECTION 2 – AIR QUALITY - OVERVIEW	211
SECTION 3 – WASTE MANAGEMENT	437
SECTION 4 – WATER PROTECTION	714
SECTION 5 – NATURE PROTECTION	935
SECTION 6 – INDUSTRIAL POLLUTION CONTROL AND RISK MANAGEMENT	1070
SECTION 7 – CHEMICALS	1265
SECTION 8 – NOISE	1505
ANNEX 1 – LIST OF ACRONYMS	1543
ANNEX 2 – LIST OF ENVIRONMENTAL ACQUIS.....	1549
ANNEX 3 – LIST OF CASES IN THE COURT OF JUSTICE	1561

INTRODUCTION

Section

1. OBJECTIVE OF THE HANDBOOK.....	10
2. TARGET GROUP	11
3. STRUCTURE OF THE HANDBOOK.....	12
4. CONTENTS OF THE HANDBOOK.....	15
4.1. Part 1 – Introduction	15
4.2. EU Environmental Legislation by Sector.....	15
IMPLEMENTATION AND THE ACCESSION PROCESS.....	20
1. OVERVIEW.....	21
1.1. Scope of This Section	21
1.2. Taking Account of Implementation.....	21
1.3. Planning for Accession.....	25
2. IMPLEMENTATION	27
2.1. General Considerations	27
2.2. Legal Issues.....	28
2.3. The Specific Position regarding Regulations.....	29
2.4. Institutional Issues.....	31
2.4.1. Administration	31
2.4.2. Public Participation	31
2.4.3. Enforcement	32
3. MANAGING THE IMPLEMENTATION PROCESS.....	34
4. IMPLEMENTATION MANAGEMENT CHECKLIST	36

INTRODUCTION

1. OBJECTIVE OF THE HANDBOOK

The objective of the Handbook on the Implementation of EU Environmental Legislation is to provide a planning framework and step-by-step guidance on the approaches, measures and specific activities that may contribute to ensure the effective and legally compliant implementation of EU environmental legislation. It targets candidate countries and the potential candidate countries, but can also provide a source of information for the existing Member States, especially in the implementation of completely new legislation. Although, the Handbook aims at being a useful planning and guidance tool it should not be seen as a binding document. Candidate countries and Member States are first obliged to check the wording and spirit of primary and secondary legislation, official guidance and the case-law of the Court of Justice of the European Union (CJEU).

2. TARGET GROUP

The Handbook is primarily aimed at officials (legislators, civil servants, planners, environmental advisers, etc.) in national, regional and local government agencies in candidate countries and potential candidate countries (hereinafter referred to as candidate countries), who are responsible for the planning, management and implementation of environmental laws and programmes. However, it is hoped that the Handbook may also be of interest to other parties in candidate countries, such as people working in the industrial and commercial sectors who are affected by the legislation, and non-governmental organisations (NGOs) - in fact, all relevant stakeholders in the candidate and potential candidate countries. Similarly, the Handbook will provide useful information, guidance, and sense of direction for existing Member States in their transposition and implementation of recently adopted legislation. The Handbook can similarly serve as an important information source for scholars, and practitioners in environmental law.

3. STRUCTURE OF THE HANDBOOK

The Handbook covers eight policy sectors and main chapters which each provides:

- an introduction to each environmental sector setting out a framework for planning the implementation of the legislation contained within that particular environmental sector;
- separate fiches for each legal act, providing a summary of the main requirements, their implications for implementing entities and affected parties, cost implications;
- guidance for smooth and cost-efficient implementation, comprising the establishment of the necessary institutional, policy and legislative frameworks;
- inspirational examples of implementation in existing Member States, providing for good practices regarding legal, technical or policy approach.

Table 1. Structure of the Handbook

Section 1	Introduction — Implementation of the Environmental Acquis and the Accession Process
Section 2	Horizontal Legislation
Section 3	Air Quality Legislation
Section 4	Waste Management Legislation
Section 5	Water Protection Legislation
Section 6	Nature Protection Legislation
Section 7	Industrial Pollution Control and Risk Management Legislation
Section 8	Chemicals Legislation
Section 9	Noise Legislation
Annexes	List of acronyms List of environmental acquis covered in the Handbook List of the CJEU environmental cases

This Handbook is based on the environmental acquis up to 1 January 2016., The content is based on a list of environmental legislation, approved by DG ENV, the European Commission, in May 2015. The overall scope of the Handbook has been reduced somewhat with the chief objective to focus on environmental legislation which is of key importance for the candidate and potential candidate countries. Secondly, the Handbook reflects the policies and mandates of DG ENV. Given that civil protection and GMO legislation is no longer dealt with

by DG ENV is should no longer be part of the Handbook. Similarly, climate acquis, which is the responsibility of DG CLIMA, is covered in a separate Handbook on the Implementation of the EU Climate Acquis.

Access to all the legal instruments contained in this Handbook is available through:

<http://eur-lex.europa.eu/>, which is the official provider of EU legislation. It is a service provided free of charge in all the official EU languages. This website provides direct access to all legal instruments (Decisions, Regulations and Directives). It provides the official texts of the EU legislation as well as a bibliography with details on all amendments, corrections or repealing acts, the legal basis and references to consolidated versions of the legislation as well as to repealed legislation. The Eur-lex search engine allows both simple and more advanced searches using different type of parameters including the natural number of the legal act, words in the title of the measure or other key words relevant to the measure.

In addition, Eur-lex contains case law from the European Courts, mainly from the the Court of Justice of the European Union (CJEU), which is the new name for former European Court of Justice (ECJ). These cases often concern situations where a Member State has failed to implement an EU Directive on time or has failed to implement it correctly and adequately (e.g. implementation did not satisfy the objectives and aims of the relevant EU legislation). These rulings provide important information on what action Member States are required to take to ensure full implementation and adequate application of EU environmental legal acts. The specially designated site for European Court rulings is CURIA: <http://curia.europa.eu/>

This website provides details on past but also ongoing cases brought before the European Courts. This website also provides references to court opinions and opinions of the Advocate-General.

In addition to these two main sites, summaries of EU environmental legislation and policy can be obtained at the „Summaries of EU Legislation” website: <http://eur-lex.europa.eu/browse/summaries.html>

The “Summaries of EU legislation” website presents the main aspects of EU legislation in a concise, easy-to-read and unbiased way. It provides summaries of European legislation, divided into 32 subject areas, including environment. This website is available in all EU languages and provide a general overview of the policy and legislative framework in each sectoral areas followed by separate fiches on each policy and legislative measure. The summaries are normally one to three pages long and include references to legislative proposals and policy documentation such as communications and guidelines. The summaries set out the main objectives of the acts, the key provisions and responsibilities of the Member States, as well as implementation deadlines. These summaries are organised in a sectoral order (e.g. air, chemicals, waste, water, horizontal legislation).

Another source of information is PreLex: <http://eur-lex.europa.eu/collection/eu-law/pre-acts.html>. PreLex follows all Commission proposals (legislative and budgetary dossiers), Council common positions, European Parliament legislative and budgetary resolutions and initiatives, European Economic and Social Committee opinions and Committee of the Regions opinions.

It is also important to mention the website of Directorate General Environment (DG ENV): (http://ec.europa.eu/dgs/environment/index_en.htm) as well as that of Directorate General for Climate Action (DG CLIMA): http://ec.europa.eu/dgs/clima/mission/index_en.htm

These websites are well structured (e.g. divided into policy areas, linking to other EU policies) and containing all the essential information necessary for understanding the environmental policies and legislation. These sites contain reference to legislative texts, official guidance, best practices, information on draft legislation, relevant events, projects, funding opportunities etc. The candidate countries are strongly advised to consult these

websites regularly to stay abreast of new developments and tools which are helpful in the transposition and implementation of environmental legislation. The Table below shows the distribution of Directives, Regulations and Decisions covered in separate fiches in the Handbook until 1 January 2015.

Table 2. Summary of EU environmental legislation covered in the Handbook

Sector	Directives	Regulations	Decisions	Total
Horizontal	7			7
Air quality	8	2	1	11
Waste management	10	2		12
Water protection	9			9
Nature protection	3	5		8
Industrial pollution control	4	3		7
Chemicals management	2	6		8
Noise	1			1
TOTAL	34	18	1	53

4. CONTENTS OF THE HANDBOOK

4.1. Part 1 – Introduction

The introductory section of the Handbook cover firstly the objective and structure of the Handbook itself and secondly the requirements and role of the process for implementing the environmental acquis and how implementation relates directly to the accession process.

4.2. EU Environmental Legislation by Sector

For each environmental sector (e.g. waste management, water management, industrial pollution control) there is an overview of the sector, followed by a separate fiche for each legal instrument addressed. For strongly interrelated legislation these are grouped together in one fiche to allow for easier understanding and integrated approach.

Sector Overview

The objective of the sector overview is to provide a description of the overall policy and legislative framework and the most essential implementation issues for the legislation considered in the sector. The overview describes a planning framework for the effective implementation of the legislation. Each sector overview has a common structure, which is illustrated in the Table below.

Table 3. Sector overview

Structure and Content of the Sector Overviews
Introduction and Overview Introduces EU policy and legislative framework in the specific environmental sector, listing the relevant legal instruments covered in the Handbook with links to other interlinked legislation.
Development of a Sectoral Strategy and Implementation Plan Outlines the steps which need to be taken to prepare a plan to implement the legislation within that sector.
Institutions and Relevant Parties Describes the key stakeholders affected by the legislation and their role in implementation, and discusses the role of competent authorities and government at national, regional and local level, public versus private involvement, communications and consultation.

EU environmental legislation is increasingly interrelated, both between the various environmental sectors and with other EU policy areas such as energy, agriculture, transport, industry reflecting the EU overriding objective of promoting sustainable development. This approach is in accordance with specific Treaty obligations (constitutional law) regarding the integration of environmental protection requirements into the definition and implementation of other EU policies, as well as with the inherent integrated nature of effective environmental legislation. The Treaty of the Functioning of the European Union (TFEU) requires all proposals by the Commission to be based on a high level of environmental protection. Member States can where EU legislates harmonisation measures maintain or introduce stricter environmental standards. Article 115 (former Art. 95 of the EC Treaty) of the Treaty draws distinction between two separate cases, Member States may: 1) either maintain existing national provisions to protect the environment or 2) introduce new national provisions to protect the environment. In both cases Member States have to notify the Commission for the reasons maintaining/introducing such provisions. In terms of new provisions, these have to be justified on scientific basis. The entry into force of the TFEU on 1 December 2009 has taken environmental protection further up the political agenda with specifically defined EU action and priorities also in the field of energy and climate change.

The concept of integration can be seen within each sector covered in the Handbook, as well as between sectors. Cross-references to different legal instruments in different sectors have been made to facilitate an integrative, efficient and cost-effective approach to implementation. As a result, it is recommended that individual EU legal measures should not be implemented in isolation. In this way, an environmental legislative, administrative and enforcement system administered with efficient competent authorities with sufficient capacities and powers is likely to better mirror and implement the EU environmental law in the candidate and potential candidate countries. Further benefits also follow from adopting this approach, such as economies of scale in setting up a single regulatory authority to deal with the implementation, application, supervision and enforcement of several Directives and Regulations.

This practical solution may, in addition, reduce costs for those directly affected and for other stakeholders, who will have to deal with only a single regulatory body within the particular areas of activity covered by any one group of Directives. It may also promote better application, enforcement and level of cooperation with the regulatory body due to a good overview and understanding of operations and activities.

Overall, the importance of advance and realistic planning is essential in implementing and applying EU legislation. Such planning will minimise situations of overlapping or conflicting provisions, where the solving of one problem under one piece of legislation leads to difficulties in another sector. Directive. One example: implementation of the Urban Waste Water Directive (91/271/EEC) (see Section 5 - Water Sector) might lead to increased volumes of sewage sludge, which then need to be disposed of and possibly reused in accordance with Directive 86/278/EEC on Sewage Sludge, Directive 2008/98/EC on Waste and Directive 1999/31/EC on Landfilling (see Section 4 - Waste Sector). These Directives do not exactly take the same approach to managing and disposal of sludge.

Table 4. Overview of the issues dealt with in the Handbook sectoral chapters

<p>Technical Issues</p> <p>Addresses technical issues in the legislation. These issues may require expertise and specialised equipment and models, for example in the air quality sector to set guideline emission standards, monitor air emissions and prepare technical guidance notes. Sometimes these technical issues will require fixed cooperation framework with operators and</p>

stakeholders such as the industry in extended producer responsibility legislation applicable for batteries, waste electrical and electronic equipment, end of life vehicles etc.

Regulation and Enforcement

Describes some of the key issues arising from control and supervision of the implementation of the legislation. This covers licensing and permitting procedures, monitoring, inspection, enforcement, data collection and reporting. The role of enforcement in ensuring compliance in practice with EU environmental legislation should not be underestimated, especially not since the adoption of Directive 2008/99/EC on the protection of the environment through criminal law, which emphasizes the importance of enforcing environmental law and sanctioning environmental criminal offences. It is expected that the Directive in the medium term will ensure higher regard to infringements of environmental law and thus, a reducing number of cases of insufficiently implemented environmental measures ending up in the European Courts.

Priorities and Timing

Discusses ways of prioritising the implementation tasks based on legal, institutional, and economic and financial aspects. It also provides guidance on which tasks are most likely to affect the implementation programme, due, for example, to the need for planning, institutional strengthening, and the design and construction of new facilities. For complicated and investment intensive legal instruments, where the process of implementation is likely to be complex, lengthy and involve many actors, a timetable for action by Member States is set out (see, for example, under the Water Framework Directive [2000/60/EC] or under the INSPIRE Directive [2007/2/EC]).

Economic and Financial Issues

Discusses the types of costs arising from the implementation of the legislation, who would bear them, and economic and financial tools for recovering costs. Estimates of the cost of implementing environmental legislation are provided where these were available from various studies and analysis. The most comprehensive cost analysis undertaken to date is by EDC¹, while some of the projects funded under the DISAE programme provide up-to-date estimates for some environmental sectors and countries. In general, it is difficult to obtain precise cost estimations, partly due to variable factors and local circumstances. Hence, the cost estimations should be seen as illustrative examples which can help authorities with the financial planning of implementation.

Summary of Key Issues

Each sector ends with a summary of key implementation issues.

Implementation Fiches

The purpose of each fiche is to provide information about implementation issues specific to the legal instrument addressed.

¹ EDC, 1997. Compliance Costing for Approximation of EU Environmental Legislation in the CEEC. The report concluded that total investment costs of bringing environmental protection in CEECs up to the EU level amounts to ECU 100-120 billion or ECU 1100 per capita. This translates to 2.9% of 1994 GDP in CEECs. However, the relevance for the approximation process is limited because several cost studies analyzed in the report are not related to EU approximation, and, different assumptions and cost indicators make results hard to compare. This is mainly because presented total cost probably overestimate the additional costs required to meet EU obligations, and, the presented costs may also overestimate the true economic costs to society because they do not take the economic sectors and environmental improvements into account. In addition, not all environmental sectors are adequately covered by the studies reviewed

Some sectors include a framework Directive or Regulation, such as the Directive 2008/50/EC on ambient air quality and cleaner air and the Water Framework Directive (2000/60/EC), which provide the general legal and policy context whereas more specific legal measures and guidance detail implementation in the Member States. To the extent possible these measures are grouped together to allow for a concise, stepped and integrated to implementation. However, in some cases it is necessary to split up the measures to avoid too massive fiches. In that case, the general information and legal context is not repeated for the consequent fiches. The fiches are presented in a common format, as described in the Table below.

Table 5. Structure and content of the fiches

<p>Short Title</p> <p>Each fiche is given an abbreviated title with key words from the legislation. This is used in the footer on each page of the fiche to help the reader locate a fiche quickly. The short form of the title is also used in the text.</p>
<p>Summary of the Main Aims and Provisions</p> <p>An introductory paragraph describes the main aims and requirements of the legislation. A larger picture is given of the background to the legislation, the main rationale of the legislation and its relation with other similar legal measures.</p>
<p>Principal Obligations of Member States</p> <p>This section summarises the principal legal obligations on Member States (with the associated legal provision in brackets for easy reference). These obligations are grouped under standard headings reflecting the key stages in the implementation process and, where possible, are listed in the order in which they should be considered for the practical purposes. This section omits legal obligations of other non-national regulatory bodies, for example the Commission itself, EU standard setting bodies, and optional arrangements. Readers should refer to the full text of the legislation, which is provided in a hyperlink, for further details.</p> <p>This section also includes cross-references to other EU environmental sectoral legislation and, where relevant, international conventions and agreements that should be considered in conjunction with the particular piece of EU legislation in question. Where a cross-reference to another section of the Handbook is appropriate, this is indicated by the section number in brackets following the mention of the associated EU legal act.</p>
<p>Implementation</p> <p>This section sets out the main tasks to be undertaken to implement the legislation, phasing recommendations and the key constraints to smooth implementation.</p> <p>The key implementation measures are summarised in the form of a checklist. Where possible, the structure of the table is based on the sub-divisions of the legal obligations. However, sometimes the structure is developed to take account of additional steps required to meet the obligation in question, and other issues raised in the legislation. The key tasks are arranged as far as possible in chronological order of implementation, which often also reflect the order from a more practical perspective. This range from setting up the relevant competent authority to establishing a system for efficient monitoring and enforcement.</p>

The phasing considerations identify factors affecting the implementation programme having regard to the most time consuming and cost intensive tasks as well as considers the likelihood of the legislation being superseded or significantly revised and whether the legislation refers to a fixed programme of events.

Implementation Guidance

This section brings together the collective experience of Member States to provide general observations, examples of good practice, and lessons learnt in implementing the legislation. This information may be further illustrated with case studies and examples of national implementation measures from Member States (presented in text boxes) to provide examples of good practice, legal approaches, technical and/or practical solutions to certain key obligations.

Costs

This section provides a qualitative analysis of the costs likely to be incurred through implementation of the legislation, for example capital expenditure, operation and maintenance costs, costs for hiring staff and experts, costs for equipment, etc. Specific information on costs is given where available, based on existing literature. However, given that the cost implications greatly vary from country to country and the local context, the cost analysis should be seen as an illustrative example aiming at providing a sense of cost implications which can help the Candidate and Potential Candidate Countries in planning, phasing and financing implementation. This section also identifies the entities on which the costs may fall, e.g. public sector, private sector, state or municipalities.

Implementation Experience in Member States

The implementation issues discussed in the fiches are drawn from the collective experience of the Member States comprising legislative, administrative framework, guidance documents and tools. For implementation issues covering the period until 31 December 2007, examples are primarily taken from eight Member States: France, Portugal, Sweden, the United Kingdom, Malta, Hungary, Denmark and Austria. In the current version of the Handbook spanning the period 1 January 2012 until 1 January 2015, examples have been extended to include even more countries, including Romania, Bulgaria and Croatia. The fact there are more examples from one or two countries mainly means that it is easier to obtain good examples from these locations. It does not mean necessarily that these countries produce the best examples.

IMPLEMENTATION AND THE ACCESSION PROCESS

1. OVERVIEW

1.1. Scope of This Section

This section discusses the importance and ways of taking implementation issues into account when preparing for accession. It looks at a number of implementation issues that are common to many Directives and goes on to consider how implementation planning can be incorporated into a government's broader planning for accession also aligning with the short to medium term priorities the EU has set for the accession countries in the annual progress reports². This section also briefly addresses issues common to all EU legislation in relation to the accession process, and contains particular information in relation to EU Regulations, which do not have to be nationally transposed and implemented in the Member States to have direct effect producing rights and obligations for public and private entities. The section concludes with an implementation management checklist providing a useful tool for governments for planning and tracking their implementation progress.

1.2. Taking Account of Implementation

Implementation of European Union environmental legislation is to be ensured in the first place by Member States. Over the past decades the European Union has put in place a broad range of environmental legislation, much of it long-established. However, effective implementation still presents a major challenge to the Member States. This is recognized in the Communication Improving the delivery of benefits from EU environment measures: building confidence through better knowledge and responsiveness adopted in 2012³. The Communication sets out ideas aimed at providing Member States with tools to improve implementation on the ground. It complements 2008 Commission Communication on implementing European Community Environmental Law, which sets out Commission's enforcement strategy to tackle breaches of European Union environmental protection laws.

Better implementation is in the focus of the General Union Environment Action Programme to 2020 „ Living well, within the limits of our planet” (7th EAP). Thus, maximising the benefits of Union environmental legislation by improving implementation is set as a priority objective of the EU environmental policy. In this context, the 7th EAP recognizes importance of improving the knowledge about implementation through greater public access to information. It also recognises the need to improve and enhance inspection and surveillance of environmental law, as well as better access to justice in environmental matters. In addition, it stresses the need to improve the mechanisms at national level for handling of complaints about implementation of Union environmental legislation. Beside improving implementation, the 7th EAP lists priority objectives to be achieved by 2020, which are:

- to protect, conserve and enhance the Union's natural capital
- to turn the Union into a resource-efficient, green, and competitive low-carbon economy

² Website with progress reports: http://ec.europa.eu/enlargement/countries/strategy-and-progress-report/index_en.htm

³ <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52012DC0095>

- to safeguard the Union's citizens from environment-related pressures and risks to health and wellbeing
- better information by improving the knowledge base
- more and wiser investment for environment and climate policy
- full integration of environmental requirements and considerations into other policies
- to make the Union's cities more sustainable
- to help the Union address international environmental and climate challenges more effectively.

The process of approximating the legal and administrative systems in the candidate countries to the large and complex body of EU law is a huge task that requires careful planning and management on an ongoing basis. As deadlines for implementing certain Directives and Decisions or certain provisions thereof do not arise until after EU accession, it is important that measures proposed and adopted now are adequate to meet the future compliance demands that such countries will face as Member States.

Candidate countries should have in place a framework for co-ordinating legislative and administrative practice across different ministries and legislative units with a view to achieving full and harmonious implementation in law and practice streamlined and coherent with the regulatory activities. As candidate countries adopt legislation and establish implementation frameworks giving effect to EU Directives, Decisions and Regulations in their national legal system, they should consider which areas of existing national law will be affected by the new legislation and subsequent requiring legislative amendment or repeal. Candidate countries will also need to ask what nature of legal provisions is appropriate in their national constitutional and legal order so as to give effect to EU law in national binding law. For example, would a framework Directive be better implemented in the national legislative set-up by way of primary legislation, and the daughter Directives implemented by secondary legislation under the "umbrella" of the primary legislation; or is primary legislation appropriate for all such Directives? Furthermore, bearing in mind the prospect of technical amendments to Directives, candidate countries should consider what parliamentary or other law making mechanism should be provided in order to allow for an effective, transparent but also time-efficient adoption of implementing legislation. Here it should be noted that the delegation of legislative powers to the Commission⁴ and the growing adherence by the Commission to using the so-called comitology procedure⁵ with particularly technical amendments adopted in

⁴ The Lisbon Treaty gives two kinds of powers to the Commission: delegated powers to adopt “non-legislative acts of general application” intended to “supplement or amend certain non-essential elements” of a basic legal act, and implementing powers to adopt acts which are intended purely to execute the basic legislative act. In the past, all these acts were submitted to so-called comitology procedures. While the Treaty provision on delegated acts (Article 290) is self-executing, entails no comitology procedures and has been in force since 1st December 2009, the Treaty provision on implementing powers (Article 291) has been implemented by Regulation (EU) No 182/2011, which replaces Decision 1999/468/EC (old Comitology Decision).

⁵ The Lisbon Treaty introduces major changes in the comitology procedure by which the implementation of EU legislation is reviewed and controlled by committees of Member State experts.

Under Article 291 TFEU, the Commission can be given the power to adopt implementing acts, which are intended purely to execute the basic legislative act. The control of implementing acts will remain with the Member States through the use of comitology committees. The New Comitology Regulation (EU) 182/2011 simplifies comitology by reducing the number of procedures to only two, i.e. *examination procedure* – used especially for (a) measures with general scope and (b) measures with a potentially important impact (e.g. in taxation or EU agricultural policy) and *advisory procedure* – generally

a legislative fast-track procedure, candidate countries are normally recommended to make use of similar efficient and fast-track national legislation processes for these types of EU legislative measures. This is typical for Directives and Regulations requiring regular update and adjustment due to scientific and technical advancements, such as the case for Directives restricting emissions of dangerous substances to air or water, Directives on electronic and electrical equipment and chemicals legislation. However, the candidate countries should also be mindful of ensuring transparency and careful planning to allow for public involvement and engagement.

Implementation of whole areas of EU environmental law is likely to cause significant change in the national law in the candidate and potential candidate countries. It is, thus, crucial that the implementation process involves a wide range of stakeholders, especially prior to introducing completely new legislation, as part of ensuring an open dialogue, allowing stakeholders and those potentially directly or indirectly affected by the new legislation to be involved in and get acquainted to the new requirements and the manner the new requirements are being practically implemented and in general necessary modifications to how regulatory practice is being managed. In addition, legislative change to give effect to EU law requirements may lead to additional expenditure across the country at central, regional and local government level, for the regulatory authorities, for industries and commercial operations, and for the public. Public information and focused discussion assists in easing this process, and public consultation on legislative drafts facilitate the identification of matters of national, regional or local or sectoral interest as regards the implementation process relating to given areas of activity. Consultation also raises awareness of the legislative topic and strengthens the sense of legal certainty and the public acceptance for changes.

It may, as a result, be advisable for candidate countries to consider whether transitional periods should be sought from the EU to avoid significant disruption to particular areas of industrial, commercial or social activity and to allow for an overall integrative approach to certain sectoral areas. Transitional periods may mitigate the risk of a candidate country being in breach of EU obligations in the first period of EU membership. It is undesirable to be in breach of EU obligations in any event, but the risk of fines being imposed and the awards of damages for breaches against EU obligations by the European Courts set a strong incentive for compliance (described below).

It should be noted that there are a significant and growing number of EU Regulations and Decisions in the environmental sector. These legal instruments present their own problems for the accession process, and their treatment must likewise be accorded the same level of care as Directives. Specific comments concerning Regulations are set out below.

As regards Directives, the process of approximation is usually described as involving three elements: transposition (of legislation), implementation and enforcement. Although this sequential listing of the elements appears logical and straightforward, the elements are, in fact, dependent on one another.

Effective transposition will require, firstly, an understanding of the legal requirements, implementation and enforcement practices and capabilities (application in practice); and, secondly, that the actual legal text properly takes into account the obligations relevant to effective implementation and that it provides for real and effective enforcement.

A new national law which simply repeats the text of a Directive without ensuring that it is integrated into the

used for all other implementing measures. Both procedures require an opinion to be issued by a committee of representatives from every EU country (chaired by the Commission).

national system of environmental, legislative and administrative law will probably be ineffective for this purpose. Such an approach may fail to implement in full the spirit and wording of the Directive. It may also fail to communicate to relevant stakeholders their rights and responsibilities according to the objectives and terms of the Directives. EU law requires Member States to implement Directives with unquestionable binding force and with the specificity, precision and clarity required in order to satisfy the need for legal certainty and in such a way that the national implementing law is accessible to those affected by it and that it is clear as to its legal effect. This means, for example, that legislative provisions amending national law in a particular area should not be adopted by way of amendment to legislation covering another area of activity. Likewise, implementation of a Directive addressing a very specific area of activity should not be effected across a wide range of pieces of disparate national secondary legislation. Any such opaque system of implementation can result in difficulties in effective application and enforcement.

Where governmental bodies already have competence and experience in areas covered by a Directive, a national law transposing the Directive that does not take into account any need to amend these institutions and procedures is likely to remain unimplemented in practice. However, if the new law attempts to change institutional structures without careful consultation and planning in advance, it risks becoming the subject of subsequent debate about competencies and procedures. The new law may therefore also be unimplemented and unimplementable because the responsible institutions lack the motivation, know-how, staff and budgets to carry out their new responsibilities.

A new law setting out a system of governmental responsibilities, such as that on integrated environmental permitting needs to contain a clear picture of how these responsibilities; e.g. enforcement of the permits will be carried out. The text of the new law needs to express a clear understanding of the new system of institutions, procedures and responsibilities.

As indicated above, developments in EU law have resulted in an emerging and growing body of rules as to when Member States may be held judicially liable for failures to comply with their obligations under EU law. Lack of implementation and inadequate or erroneous implementation are examples of such failure. If such failure is detected by the Commission or reported in a complaint, the Commission begins a bilateral dialogue with the Member State⁶, which is invited to solve the problem quickly and efficiently in compliance with the EU law. If these efforts are not successful, the Commission may launch formal infringement procedure pursuant to Article 258 of the TFEU. In cases where Member State fails to comply with the Commission's opinion in the context of the reasoned opinion procedure, the Commission may bring the case before the Court of Justice. Financial penalties may be imposed if Member States do not comply with the Court rulings or fail to transpose EU directives on time.

Assuming that the government has a well-planned and well-designed legal programme, effective implementation and enforcement will require:

- reliable data collection systems;
- effective systems and institutions for monitoring and reporting on emissions and environmental quality and inspection;
- procedures and tools for raising the environmental awareness of industry and the public in order to secure understanding, co-operation and support for environmental measures;

⁶ This process is referred to as «EU Pilot».

- institutions and procedures facilitating public participation in environmental management;
- administrative and judicial recourse in relation to (actual and threatened) violations of environmental laws, accompanied by appropriate systems of adequate and dissuasive fines and penalties and including provision for liability under criminal jurisdiction for serious violations (in line with the Directive 2008/99/EC on the protection of the environment through criminal law);
- training of staff of competent authorities and other relevant affected public and semi-public bodies as well as general training of and awareness raising for the affected sectors of society;
- encouraging participation of local and regional authorities;
- adequate funding of and support for implementing and enforcement institutions.

1.3. Planning for Accession

The accession planning process is carried out in the context of the Accession Partnership Agreement and is driven by the national programme for the adoption of the *acquis* (NPAA). In its environmental chapter, and for each environmental sector and each individual legal instrument, this sets out:

- the current situation (transposition as well as implementation and enforcement);
- short-term priorities in line with the accession partnership;
- medium-term priorities in line with the accession partnership;
- institution-building needs;
- estimates of financial needs in the short and medium term.

The NPAA provides a focal point for the overall co-ordination of approximation activities and will be supported at the working level by a range of other activities to prepare implementation plans at the Directive level. Implementation plans will set out the actions required, draw up the timetable according to which activities are to be completed, assign responsibilities and allocate resources. Questions concerning implementation deadlines arising after accession need to be considered in detail. In addition, candidate countries should bear in mind any transitional periods provided for in their accession treaties.

The European Commission has outlined a number of basic issues, which need to be incorporated into approximation planning considerations⁷:

- environmental approximation activities need to be integrated into other policy areas;
- all new investments should comply with the *acquis*.

The experience of the CEE countries, Malta and Cyprus, which acceded to the EU in 2004, and that of the Romania, Bulgaria and Croatia which joined the EU more recently (2007 and 2013), demonstrates that the following measures are valuable in preparing for accession:

⁷ Commission Communication, *Accession Strategies for the Environment: Meeting the Challenge of Enlargement*.

- establishment of cross-ministerial working groups to develop co-ordinated approaches to certain environmental issues. In this context it is necessary to develop a strong internal coordinating mechanism;
- development of long-term programmes to recruit and train staff for public sector organisations in each sector;
- improving knowledge about the environmental acquis and its financial implications on both national and regional/local level;
- ensuring participation of regional and local authorities;
- use of the new "twinning" schemes whereby environmental administrative structures in the candidate countries are matched with corresponding administrations in Member States to facilitate the transfer of administrative know-how.

2. IMPLEMENTATION

2.1. General Considerations

Accession is likely to result in major alterations to the structure and operation of law for new Member States. It is important that acceding states are properly equipped for the change. This process may be facilitated by following the guidance in this Handbook as regards the environmental sector. However, the environmental sector is just one area of policy of the EU, and some general observations may be useful in ensuring that acceding states are prepared as fully as possible for accession as regards the environmental sector.

Accession is likely to raise constitutional issues in all acceding states. It is important that a mechanism of constitutional status for giving effect to accession and obligations on accession guarantees the supremacy of EU law over conflicting national measures. This result must be guaranteed whether the relevant EU instruments were adopted prior to or after accession, and likewise as regards any national laws. Such a mechanism should also provide for the full effect of all EU acts able to have legal effect, and cover rulings of the courts of the European Union.

EU law, in furtherance of the principle of legal certainty, requires implementation to be carried out by way of legally binding provisions to ensure full effect of the rights and obligations the EU provisions give rise to for various legal and non-legal entities in the Member States. Therefore, in general, attempted implementation of EU environmental legal acts by way of government circulars or guidance will not suffice. Steps will be required in acceding states ahead of accession to ensure that government circulars etc. are not the sole means relied upon for implementation. It is advisable to aim to have them revoked and replaced by binding legal provisions.

In addition, it is important to note the need to ensure that implementing measures in law and practice comply with the principles derived from the European Convention on Human Rights. There is a growing body of law in this area within the EU's legal system that is also applicable in the environmental sector, whereof one stream is linked to the right to a healthy environment, providing certain protection and rights for people living in the vicinity of hazardous activities for instance.

Practical steps to increase the effectiveness of EU environmental law on accession include public awareness programmes for affected industries as well as for the general public, and legal training for persons within the administration, including staff in environmental protection agencies, environmental supervisory bodies, environmental inspectors, customs officers, as well as for lawyers and judges.

This Handbook is predominantly concerned with the implementation of Directives. However, there are a number of Regulations and Decisions addressed within the Handbook and in fact in some environmental sectors such as chemical management the dominant legal instrument is Regulation. Regulations and Decisions not requiring any particular transposing measures as they have direct effect as from date of entry into force, present their own challenges as regards implementation and effect after accession.

It is important to ensure that regulations have their full force as EU legal instruments in candidate countries' national legal systems. Regulations, in principle, take effect on adoption and publication in the EU's Official Journal. They are of general application -- that is, every legal person can rely on their provisions whether against the state or against other individuals/companies. Member States are prohibited in principle from adopting national rules in place of the rights or obligations provided in EU Regulations.

Candidate countries may have national rules relevant to the scope or operation of EU environmental regulations. On accession, as indicated above, it is the terms of the Regulations that should, as a matter of EU law, apply in the acceding states. Conflicting national provisions lead to confusion at the national level, may make enforcement more difficult in practice, and may lead to sanctions at EU level from the European Courts. At the level of national law, the "immediate" direct legal effect⁸ of Regulations may be given in the first instance by a measure of constitutional status providing for the supremacy of EU law. Legal certainty is a general principle of EU law. Hence, as indicated above, "parallel" or conflicting national provisions may cloud or seem to contradict the immediate legal effect to be derived from Regulations. As a general rule, national provisions that apply to an area within the specific scope of a Regulation should be repealed. Repealing such national provisions may be a very time-consuming and intricate exercise. Acceding states should already have programmes in place to meet this challenge. If they do not, such programmes with concise scoping and time planning, should be put in place in the very near future. Reference should also be made in this regard to individual accession treaties for applicable transitional periods. To assist acceding states with their obligations concerning Regulations, relevant Regulations within the environmental acquis are addressed in the Handbook. However, when reading the fiches for regulations it is important to bear in mind the comments in this introduction as regards the legal nature and effect of Regulations.

2.2. Legal Issues

The following measures can help reduce the risks associated with rapid transposition:

- Determine the implementation strategies and structures first. When the decisions have been taken about actually implementing and enforcing a law, then drafting is relatively simple.
- Involve the stakeholders. A successful law is one that can be implemented and applied in practice. Thus, it needs to take into account the situation and experience of all persons who will be involved in its implementation or affected by it in practice. This includes regional and local authorities, industry and the public, as well as the national ministries concerned. Consultation periods of new legislation is a basic requirement for involving directly affected parties and stakeholders.
- Adopt the framework before the details. Compliance with the law is undermined if many laws are introduced in a short time. It is important to adopt framework legislation establishing administrative systems and the appropriate fundamental rights and obligations prior to the introduction of more detailed legal requirements, particularly those that will impose a heavy administrative burden on the competent authorities. Such an approach also helps to give advance notice of new legal requirements, which itself allows operators to plan and make relevant economic provision for future compliance. Introducing the framework in advance of more specific detailed provisions also allows the affected parties to channel their experiences with application to the competent authorities allowing these observations to be taken into account when introducing further, supplementary provisions.

⁸ That is, Regulations are applicable law in Member States without national implementing legislation needing to be adopted.

2.3. The Specific Position regarding Regulations

About 10% of EU environmental laws take the form of Regulations. Regulations are directly binding in Member States and have legal effect over and in place of any conflicting national laws. Member States may not transpose the provisions of Regulations into national law, even if the resultant national law is identical to the Regulation.⁹ The constitutional arrangements for accession in each candidate country should provide that Regulations have their full force as required under EU law in their country on and as from the date of accession. Nevertheless, EU environmental Regulations often do require further national measures for their implementation as regards certain matters and so cannot be wholly ignored as part of the "approximation" process before accession. For example, the types of measures that states have to adopt in order to make Regulations apply in practice include the appointment of competent authorities to inspect and control trade in severely restricted chemicals or in endangered species, the publication of guides and notification forms, and the designation of national sanctions for violations of the law.

With respect to Regulations, countries should be aware that:

- Some Regulations require the designation or establishment of authorities or bodies responsible for their implementation. Depending on the national legal system this may be done by administrative order or decree.
- Some Regulations (and Directives) expressly require countries to specify penalties in national law - in civil or criminal codes, for example -- for non-compliance with EU regulations. Even if there is no such express provision, EU law may require effective national sanctions as part of the process for ensuring compliance with regulations. Applying effective sanctions is a general obligation on Member States to make EU law effective in their territories.

Hence, accession countries should ensure that the necessary administrative and institutional measures are in place by the date of accession and that any overlapping or conflicting national laws are repealed. Where the EU legislation in an environmental sector comprises a mixture of Directives and Regulations, countries must take particular care to ensure that national measures, including those implementing Directives, are fully integrated and do not conflict with EU Regulations. There are fewer steps required in general to implement Regulations than Directives, as illustrated below.

Table 6. Steps to implement Regulations

1	Identify a national competent authority or authorities to ensure practical implementation of the Regulation.
2	Identify what legislation (if any) is necessary (e.g. to prescribe sanctions or designate competent authorities). In addition, identify possible national legislation conflicting with the provisions of the Regulation, and adopt a strategy for eliminating these conflicts.
3	Establish a legislative timetable (as appropriate).
4	Prepare administrative instructions and procedures for the relevant authorities.

⁹This ban on transposition may also be justified on the basis that attempted transposition disguises the "immediate" legal effect of the Regulation as a EU legal instrument.

5	Consult with other government departments concerned and with groups affected by the Regulation (e.g. importers and exporters; major industries; environmental organisations; consumer groups; local communities; and trade unions).
6	Provide adequate staff and technical resources
7	Train staff
8	Inform affected industrial sectors and companies as to what standards and targets will be required.
9	Provide the relevant documents, forms and certification to the groups concerned.
10	After accession, monitor implementation and report to other Member States and the European Commission as needed.
11	Take enforcement action as necessary.

2.4. Institutional Issues

2.4.1. Administration

Successful implementation of the environmental acquis depends to a large extent on the administration. Effective and efficient administrations may be regarded as those having a number of strengths, such as:

- clear competencies for the administration of environmental and related legislation;
- clear and efficient procedures for Decision making and the implementation of Decisions;
- skilled professionals ranging from environmental scientists, engineers and ecologists to environmental law experts;
- sufficient staff and funding to carry out tasks; strong enforcement rights and capabilities.

2.4.2. Public Participation

The public plays an important role in achieving priority objectives set by the European Union's current Seventh Environmental Action Programme (7th EAP), which lasts until 2020. Hence, it is necessary to ensure that public is properly informed about the environmental policy. The 7th EAP has made it clear: „In order to maximise the benefits of Union environment legislation by improving implementation, the 7th EAP shall ensure that by 2020 the public has access to clear information showing how Union environment law is being implemented consistent with the Aarhus Convention.” Furthermore, better information by improving the knowledge base is also recognized as the priority objective.

Public participation rights are detailed in Directive 2003/35/EC providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC as well as other horizontal legislation such as Directive 2011/92/EC on the assessment of the effects of certain public and private projects on the environment, the Directive 2001/42/EC on the assessment of the effects of certain plans and programmes on the environment and the Directive 2003/4/EC on public access to environmental information.

Governments and local authorities must create the conditions that allow the public to play a significant role in environmental protection. They must provide public access to most information about the environment, and are advised to conduct information campaigns to raise awareness, and provide services which facilitate environmentally responsible behaviour, such as separate waste collection and reliable public transport.

Non-governmental organisations (NGOs) concerned with the environment and consumer issues, trade unions, industry and professional associations all play an important role in building public awareness, in representing the interests of their members, and in mobilising public opinion and should therefore be consulted before introducing major legal changes.

2.4.3. Enforcement

The 7th EAP recognizes the need for an enhanced system of implementation and enforcement at all administrative levels. It requires extending binding criteria for effective inspection and surveillance to wider body of Union environmental acquis and complementing these with with support for network of professionals, reinforcement of peer reviews and best practice sharing.

Enforcing the law is sometimes more difficult than making it. Strong enforcement implies strong and committed environmental inspectorates with adequate resources, systems of fines and penalties, and criminal liability for serious violations. Underpinning the effectiveness of any such enforcement action are matters such as providing effective training for inspectors generally and in relation to the specific industrial sectors they regulate. Inspectors should have adequate and reliable monitoring equipment. There should be effective and transparent protocols and rules for the taking of evidence and its presentation in judicial proceedings. There should be provision, with respect for due process considerations, for the proper acceptance of such evidence in enforcement proceedings as proof of the matters presented. Given the growing number of cases of non-compliance with EU provisions, enforcement issues are of high priority for the EU, which also resulted in Directive 2008/99/EC on the protection of the environment through criminal law, where the EU is seeking to ensure that at least some violations of EU provisions have to be prosecuted as criminal law and result in effective, proportionate and dissuasive fines.

It is therefore important to design regulatory systems that can monitor and control the implementation of the environmental acquis in a practical and cost-effective manner and to ensure that they operate as intended. Governments are increasingly turning to a range of policy instruments, including economic and market-based instruments and incentives, administrative sanctions (e.g. environmental sanction fees confiscating possible gains or savings from non-compliance with environmental sanctions) to promote legal compliance, as well as systems of administrative, civil and criminal sanctions.

In this regard, national rules providing for third parties to challenge decisions of public authorities in the environmental sector or to participate in open and transparent decision-making processes are a vital part of assisting environmental compliance. The same applies to the existence of national legal aid rules providing for individuals and NGOs to bring actions in relation to actual or threatened adverse environmental effects concerning themselves or for violations of environmental rules. Such national legal aid provisions should allow for participation in relevant legal processes. The right for NGOs to access challenge environmental Decisions has been enshrined by rulings of the Court of Justice of the European Union, for instance Case C-115/09: Trianel Kohlekraftwerk Lünen. In a preliminary ruling by the Court of Justice of the European Union, the court stated that, even if contrary to domestic law, NGOs must nevertheless be able to challenge projects likely to have a significant effect on the environment. Member States' procedural laws should be in line with the objective of 'wide access to justice' as laid down in the 1998 Aarhus Convention, and the Environmental Impact Assessment (EIA) Directive (2011/92/EU). Special rights are afforded in the EIA Directive to NGOs promoting environmental protection. They are deemed to automatically have sufficient interest and rights capable of being impaired.

The European Union continues to be active in promoting compliance with the Union environmental law through use of instruments such as public information access, shared files and resources between governments and environment specialists.

To support the implementation and enforcement of Union environmental law the European Union has adopted the Directive on environmental liability 2004/35/EC, the Recommendation providing for minimum criteria

for environmental inspections 2001/331/EC and the Directive on the protection of the environment through criminal law 2008/99/EC.

3. MANAGING THE IMPLEMENTATION PROCESS

Managing the approximation process generally, and the implementation of the environmental acquis in particular, has meant developing comprehensive and advanced approaches to environmental management. This Handbook is intended to assist this work by highlighting common approaches that will facilitate the monitoring of progress.

Strong environmental management, set out in instruments such as ISO 14001 and in Regulation (EC) No 1221/2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) provide a management tool for companies and other organisations to evaluate, report and improve their environmental performance. Such management schemes involve:

- listing tasks and identifying the key implications for implementation (e.g. the legal, administrative, technological, human resources and financial implications);
- prioritising tasks on the basis of agreed criteria;
- designating a Competent Body (EMAS);
- assigning responsibility for accomplishing tasks to various authorities;
- set up registration and accreditation system and an audit trail;
- set up evaluation system of Competent Bodies;
- have the registered organisations draw up environmental policy, environmental review, management system, audit procedures (relevant for EMAS in particular);
- identifying cross-sectoral implications and facilitating inter-ministerial co-ordination, particularly in relation to implementation;
- identifying data needed to support decision makers;
- establishing work programmes and timetables that indicate any deadlines or external time constraints; and
- monitoring and measuring progress both for management purposes (e.g. to monitor aspects of environmental quality and the effectiveness of implementation) and to report to the European Commission.

Strengthening the administrative structures for environmental management is likely to involve:

- establishing new institutions, such as a Competent Body for EMAS, or substantially restructuring existing institutions;
- improving inter-ministerial communication and co-ordination;
- developing regional and local environmental institutions;
- providing technical infrastructure and sufficiently trained staff;
- improve the supervisory powers of environmental supervisory authorities;
- designating a number of officials to participate in formal and informal EU working groups; and

- building partnerships and platforms of efficient cooperation with municipal authorities, business enterprises and non- governmental organisations to implement environmental laws and to promote the adoption of environmental management schemes such as ISO or EMAS.

4. IMPLEMENTATION MANAGEMENT CHECKLIST

An implementation management checklist (see Table below) has been prepared to provide an overview of the issues that need to be considered in preparing a plan to implement environmental legislation. Each candidate country should modify the checklist to suit its own institutional needs, structures and capacities. For example, the powers and roles of regional and local authorities may vary considerably in the candidate countries, with different implications for the distribution of competencies and resources. Planning implementation requires information and decision making at four levels:

- for each item of legislation;
- for each environmental sector and block of legislation;
- for the whole environmental acquis;
- for links with other EU policy areas ensuring an integrative and holistic approach supporting the endeavours for sustainable growth and development in line with EU2020 Strategy¹⁰ and EU Sustainable Development Strategy (EU SDS)¹¹

Detailed information is built up from the basic building block represented by each piece of legislation. This information is required to provide accurate estimates of requirements such as institutional framework, staffing needs, technical equipment, capital investment and operational costs. At the sectoral level, it becomes important to consider the inter-relationships between legislation within a sector and between sectors. This is necessary in order to prioritise the legislation required, rationalise competing resources, and identify economies of scale. For example, within a sector some pieces of legislation may be judged to have a higher priority for implementation based on legal, environmental or economic grounds. The checklist is divided into ten major tasks, each of which is divided into a series of sub-tasks arranged in chronological order as far as possible. However, several of these tasks may be ongoing concurrently, particularly where the overall programme for implementation is relatively short.

Table 7. Generic implementation management checklist for Directives (noting the points made above as regards Regulations)

Activity		Responsibility level		
		For each Directive	For each environmental sector	For the overall acquis
1	Ensure objectives are clear and understood			
1.1	Objectives of the approximation process			

¹⁰ EU2020 Strategy has five ambitious objectives relating to on employment, innovation, education, social inclusion and climate/energy. More information on EU2020 on website: http://ec.europa.eu/europe2020/index_en.htm

¹¹ More information on EU SDS also comprising a recent report and Commission review on website: <http://ec.europa.eu/environment/eussd/>

1.2	Objectives of the sector			
1.3	Objectives of the Directive			n/a
1.4	Principal obligations arising from Directives			n/a
2	Define responsibilities and identify responsible individuals			
2.1	Overall	n/a	n/a	
2.2	For each sector	n/a		
2.3	For each Directive			n/a
2.4	Define clear lines of communication	n/a	n/a	
2.5	Follow agreed protocols on communications			
3	Prepare a diagnostic study of the current situation			
3.1	Understand the technical issues involved and prepare a comprehensive list of key issues and stakeholders			n/a
3.2	Catalogue all facilities			n/a
3.3	Establish current levels of compliance for all facilities			n/a
3.4	Establish criteria for prioritisation			
3.5	Prioritise the issues to be addressed			
3.6	Prioritise the facilities for compliance			n/a
3.7	Evaluate the scope of effort required for compliance			n/a
3.8	Evaluate current practices and where changes/ improvements are required			n/a
4	Establish Policy			
4.1	Identify what policy tools are necessary to effect implementation		n/a	n/a
4.2	List policy requirements within the sector	n/a		n/a

4.3	Develop policy			
5	Financial Implications			
4.5	Develop and agree methodologies for calculating the cost of compliance			
4.6	Estimate costs for compliance			
4.7	Identify and quantify existing sources of funds			
4.8	Estimate shortfall in funds available			
4.9	Identify other mechanisms for revenue Generation			
5	Institutional Capacity			
5.1	Clarify current institutional arrangements and responsibilities			n/a
5.2	Quantify current staff resources and future requirements			n/a
5.3	Compare current institutes with those required by legislation			n/a
5.4	Develop a proposal for institutional reform to reflect the requirements of the Directive			n/a
5.5	Compare this Directive-level proposal with others within the sector			
5.6	Consult with other sectors and compare respective sector-level proposals for commonality			
5.7	Consult extensively to reach a consensus on institutional reform			
5.8	Estimate costs of any reforms			
5.9	Communicate the agreed way forward to all parties			
6	Prepare a preliminary programme for implementation			
6.1	Define institutions and responsibilities			

6.2	Propose a programme and timescales			
6.3	Ensure integration between legislation and sectors			
6.4	Establish priorities			
6.5	Present cost estimates			
6.6	Identify potential sources of funds			
6.7	Quantify any shortfall in funds			
7	Consult with the Ministry of Finance (MoF) or equivalent			
7.1	Assess the self-sufficiency and sustainability of each sector for adequate revenue generation	n/a	n/a	
7.2	Estimate shortfalls in funds	n/a	n/a	
7.3	Compare funding requirements and sources for all sectors	n/a	n/a	
7.4	Identify multi-sector commonalities in terms of potential sources of funds or revenue-generation schemes	n/a	n/a	
7.5	Develop a proposal to raise revenue to support all sectors	n/a	n/a	
7.6	Estimate the true availability of funds per sector	n/a	n/a	
7.7	Develop criteria for prioritisation	n/a	n/a	
7.8	Make recommendations for priorities	n/a	n/a	
8	Establish a timetable to develop the implementation programme			
8.1	Establish provisional priorities	n/a	n/a	
8.2	Define a timetable for the development of the programme	n/a	n/a	
8.3	Consult with each sector on the programme and priorities			
8.4	Revise priorities in consultation			

8.5	Confirm and communicate agreed priorities and timetable	n/a	n/a	
8.6	Define the table of contents for the formal implementation programme to submit to DG Environment	n/a	n/a	
9	Prepare an implementation programme			
9.1	Summary of the existing situation and current areas of compliance			
9.2	Qualitative and quantitative analysis of areas of non compliance			
9.3	Explanation of criteria by which priorities were made and list of priorities			
9.4	Detailed cost analysis with identified sources of funds			
9.5	Detailed list of tasks to be undertaken			
9.6	Detailed programme showing targets/milestones			
9.7	Justification to support all elements of the programme			
9.8	Evidence to show that sectoral and cross-sector issues have been addressed within an overall framework			

HORIZONTAL LEGISLATION

Section 2

1. INTRODUCTION AND SECTOR OVERVIEW.....	47
1.1 EU Policy.....	47
1.2 EU Legal Instruments.....	47
1.2.1 Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment, as amended by Directive 2014/52/EU	48
1.2.2 Strategic Environmental Assessment Directive (SEA) (2001/42/EC)	49
1.2.3 Directive on Access to Environmental Information (2003/4/EC).....	49
1.2.4 Directive 2003/35/EC providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending, with regard to public participation and access to justice	50
1.2.5 Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage	50
1.2.6 Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an infrastructure for spatial information in the EU (INSPIRE)	51
1.2.7 Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law	51
1.2.8 Inter-relationships with other environmental legislation	51
2. DEVELOPMENT OF A SECTORAL STRATEGY AND IMPLEMENTATION PLAN	53
3. INSTITUTIONS AND RELEVANT PARTIES	54
3.1. Stakeholders.....	54
3.2 National Government Institutions	58
3.3 Competent Authorities	59
3.3.1 Environmental Impact Assessment.....	62
3.3.2 Strategic Environmental Assessment.....	62
3.3.3 Environmental Information	62
3.3.4 Public Participation Directive.....	63
3.3.5 INSPIRE Directive	63
3.3.6 Environmental Liability Directive	63
3.3.7 Environmental Crimes Directive	64
3.4 Regional and Local Government	64
3.5 Private Sector Involvement.....	65
3.6 Communication and Consultation.....	66
4. TECHNICAL ISSUES	67
5. REGULATION AND ENFORCEMENT.....	69
5.1 Overview.....	69

5.2	Data Collection and Reporting.....	69
6.	PRIORITIES AND TIMING.....	72
6.1	Prioritising the Implementation Tasks	72
6.2	Timescale	73
7.	ECONOMIC AND FINANCIAL ISSUES	74
7.1	Introduction.....	74
7.2	Institutional Development	74
7.3	Facilities.....	75
7.4	Cost Recovery	75
8.	SUMMARY OF KEY ISSUES	76
	THE ENVIRONMENTAL IMPACT ASSESSMENT DIRECTIVE	78
1.	SUMMARY OF THE MAIN AIMS AND PROVISIONS.....	79
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	82
2.1	Planning.....	82
2.2	Regulation	83
2.3	Consultation	84
2.4	Reporting/notification.....	85
2.5	Additional Legal Instruments	85
3.	IMPLEMENTATION	87
3.1	Key Tasks.....	87
3.2	Phasing Considerations	89
4.	IMPLEMENTATION GUIDANCE	91
4.1	Planning.....	92
4.2	Regulation	98
4.3	Guidance and Training	102
4.4	Consultation	103
5.	COSTS.....	113
	THE STRATEGIC ENVIRONMENTAL ASSESSMENT DIRECTIVE	114
1.	SUMMARY OF THE MAIN AIMS AND PROVISIONS.....	115
2.	PRINCIPLE OBLIGATIONS OF MEMBER STATES	118
3.	IMPLEMENTATION	124
3.1.	Key Tasks.....	124
3.2.	Phasing Considerations	125

4. IMPLEMENTATION GUIDANCE	126
4.1. Planning.....	128
4.2. Regulation	129
4.3. Guidance and Training	130
4.4. Reporting	130
4.5. Consultation	131
4.6. Monitoring.....	132
5. COSTS.....	133
THE DIRECTIVE ON ACCESS TO ENVIRONMENTAL INFORMATION.....	134
1. SUMMARY OF THE MAIN AIMS AND PROVISIONS	135
2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	136
3. IMPLEMENTATION	140
3.1. Key Tasks.....	140
3.2. Phasing Considerations	141
4. IMPLEMENTATION GUIDANCE	142
4.1. Planning.....	142
4.2. Guidance	147
4.3. Reporting	147
5. COSTS.....	150
THE PUBLIC PARTICIPATION DIRECTIVE.....	151
6. SUMMARY OF THE MAIN AIMS AND PROVISIONS	152
2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	153
2.1 Planning.....	153
2.2 Regulation	153
2.3 Reporting	154
2.4 Additional Legal Instruments	155
3. IMPLEMENTATION	156
3.1 Key Tasks.....	156
3.2 Phasing Considerations.....	157
4. IMPLEMENTATION GUIDANCE	158
6.1. Planning.....	158
4.2 Regulation.....	158
5. COSTS.....	160

THE ENVIRONMENTAL LIABILITY DIRECTIVE.....	161
1. SUMMARY OF THE MAIN AIMS AND PROVISIONS.....	162
2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	165
2.1. Planning.....	165
2.2. Regulation	166
2.3. Monitoring.....	166
2.4. Information and Reporting.....	167
2.5. Additional Legal Instruments	167
1. IMPLEMENTATION	169
3.1. Key Tasks.....	169
2. IMPLEMENTATION GUIDANCE	171
4.1. Planning.....	173
4.2. Regulation.....	174
4.3. Guidance and Training.....	176
3. COSTS.....	178
THE ENVIRONMENTAL CRIMES DIRECTIVE	180
1. SUMMARY OF THE MAIN AIMS AND PROVISIONS.....	181
2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	183
2.1. Regulation.....	183
2.2. Enforcement.....	184
2.3. Information and Reporting.....	184
2.4. Relevant Legal Instruments	185
3. IMPLEMENTATION	191
3.1. Key tasks	191
4. IMPLEMENTATION GUIDANCE	194
4.1. Planning.....	194
4.2. Regulation	195
THE INSPIRE DIRECTIVE	197
1. SUMMARY OF THE MAIN AIMS AND PROVISIONS.....	198
2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	199
3. IMPLEMENTATION	203
4. IMPLEMENTATION GUIDANCE	205
5. COSTS.....	210

HORIZONTAL LEGISLATION - OVERVIEW

1. INTRODUCTION AND SECTOR OVERVIEW

This section of the Handbook deals with horizontal EU legislation. It contains an introductory overview of the sector followed by individual fiches for selected pieces of legislation.

1.1 EU Policy

The horizontal sector is concerned with environmental legislation on various matters which cut across different environmental subject areas, as opposed to Regulations which apply to a specific sector, e.g. chemicals or waste. Rather than to regulate a specific area, these items of legislation are more procedural. They provide for methods and mechanisms aimed at improving decision making and legislative development and implementation. The legislation in this sector covers:

- Environmental impact assessment (EIA) of proposed development projects;
- Strategic environmental assessment of proposed plans and programmes;
- Public access to environmental information;
- Public participation in drawing up certain plans and programmes;
- Environmental liability;
- Infrastructure for spatial information (INSPIRE Directive);
- Environmental criminal law.

1.2 EU Legal Instruments

Seven legal instruments are given particular consideration in the horizontal sector, comprising seven Directives, which are listed in the Box below.

Legislation Considered in the Horizontal Sector

Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (consolidating and repealing Directive 85/337/EEC as amended by Council Directive 97/11/EC and by Directive 2003/35/EC) as amended by Directive 2014/52/EU.

Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment.

Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC.

Directive 2003/35/EC, providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending, with regard to public participation and access to justice, Council Directives 97/11/EC and 96/61/EC amended by Directive 2011/92/EU.

Directive 2004/35/CE on environmental liability with regard to the prevention and remedying of environmental damage, as amended by Directive 2006/21/EC, Directive 2009/31/EC and 2013/30/EU.

Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an infrastructure for spatial information in the EU (INSPIRE).

Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law.

The following text provides a brief synopsis of the main requirements of each instrument. More detailed information on specific obligations is given in the fiches following this chapter.

1.2.1 Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment, as amended by Directive 2014/52/EU

The aim of the EIA Directive is to ensure that projects, which are likely to have a significant effect on the environment are adequately assessed before they are approved. Hence, before any decision is taken to allow such a project to proceed, its possible impacts on the environment are identified and assessed. Developers can then adjust projects to minimise negative impacts before they actually occur, or the competent authorities can incorporate mitigation measures into the project approval.

Environmental assessment is a procedure that ensures that the environmental implications of projects – e.g. dams, motorways, airports, factories and energy projects – are assessed and taken into account before the relevant Member State authority makes a decision on project approval. The Directive ensures early public participation in the environmental decision-making procedures. During the project assessment period, members of the public concerned must be kept informed and have the ability to comment on developers' proposals, thus enabling competent authorities and developers to make well-informed decisions.

The common principles for the environmental assessment of individual public and private projects were initially defined in the 1985 EIA Directive and amended in 1997, 2003 and 2009. This Directive was codified in early 2011 (Directive 2011/92/EU) and was subject to larger review in 2012-2013 resulting in adoption of the Directive 2014/52/EU introducing simplified rules for assessing the potential effects of projects on the environment. It is in line with the principle of smart regulation thus reducing the administrative burden. Newly adopted amendments improve the level of environmental protection, with a view to making business decisions on public and private investments more sound, more predictable and sustainable in the longer term.

1.2.2 Strategic Environmental Assessment Directive (SEA) (2001/42/EC)

This Directive, (known as the “SEA” Directive for “Strategic Environmental Assessment”) supplements the above EIA Directive. The SEA Directive requires certain public plans and programmes to undergo an environmental assessment before they are adopted.

This assessment includes the introduction of an environmental report (describing the likely significant environmental effects and reasonable alternatives), as well as carrying out public consultations involving citizens, the public or semi-privatised authorities with environmental responsibilities and other Member States in the case of significant cross-border effects. The report on environmental effects and the results of consultations shall be considered before the plan or programme is adopted. Once they are adopted the authorities with environmental responsibilities, the public and any consulted Member State shall be informed and the relevant information made available to them. In order to determine any unforeseen adverse effects as early as possible, it is necessary to ensure that the significant environmental effects of the plans and programmes are monitored pursuant to Article 10. In deciding on which plans and programmes to be subject to an SEA assessment, Annex II of the Directive offers assistance in evaluating significant effects. Annex I provides guidance as to information to be included in the assessment. The decision-making process at the planning level aims at a high level of transparency and procedural similarities exist between the SEA Directive and the EIA Directive.

The Strategic Environmental Assessment contributes to the integration of environmental concerns in planning process and to better integration of environmental requirements in plans and programmes. Proper implementation of the SEA Directive is an important tool in achieving priority objective related to improving environmental integration and policy coherence as determined in the 7th EAP.

1.2.3 Directive on Access to Environmental Information (2003/4/EC)

This Directive was adopted to fully comply with the requirements of the Aarhus Convention. It guarantees the right of access to environmental information held by or for public authorities upon request (Article 3, so-called passive dissemination) and provides for the obligation for public authorities to progressively disseminate the environmental information they hold by means of computer telecommunication and/or electronic technology (Article 7, so-called active dissemination). Upon request, the information must be provided to any natural or legal person, without them having to prove an interest (thus including those residing outside the Member States), as soon as possible and, at the latest, within one month after the receipt of the request. Under certain circumstances (depending on the volume and complexity of the information), the deadline may be extended to up to two months from the date on which the request was made. The Directive allows the authorities to charge reasonable costs for making the information available to the public. A request for information may be refused only on grounds provided for in Article 4, when it affects certain interests defined in an exhaustive way by the

Directive itself — e.g. public security, commercial and industrial confidentiality or international relations. The grounds for refusal have to be interpreted in a restrictive way, taking into account, for the particular case, the public interest served by disclosure. Where it is possible to separate out any information falling within a refusal from the rest of the information requested, partial access has to be guaranteed. A refusal to make available all or part of the requested information has to be notified in writing (if the request was in writing or if the applicant so requests), state the reasons for the refusal and include information on the review procedures. In fact, Member States have to provide access to judicial or administrative review where a person considers that a request for information was not adequately dealt with. In active dissemination of environmental information, Member States have to ensure that it is accurate, updated and comparable. A minimum content is provided for by Directive in its Article 7, Paragraph 2.

1.2.4 Directive 2003/35/EC providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending, with regard to public participation and access to justice

The Directive was adopted in order to fully comply with the requirements of the Aarhus Convention. It sets up common requirements for the participation of the public in the preparation by public authorities of a number of plans and programmes in the environmental field, e.g. under Directives 2008/98/EC on waste, 2006/66/EC on batteries, 94/62/EC on packaging, Directive 2008/50/EC on ambient air quality and Directive 91/676/EEC on nitrate pollution from agricultural sources.

1.2.5 Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage

The Directive establishes a framework for environmental liability, with a view to preventing and remedying environmental damage. The Directive applies to the following environmental damage:

- direct or indirect damage to the aquatic environment covered by EU Water Framework Directive (2000/60/EC) and by the Marine Strategy Framework Directive (2008/56/EC);
- direct or indirect damage to species and natural habitats protected at EU level by the Birds Directive (2009/147/EC) or by the Habitats Directive (92/43/EEC);
- direct or indirect contamination of the land that creates a significant risk to human health.

It covers both actual environmental damage and the imminent threat of damage resulting from occupational activities, in cases where it is possible to establish a causal link between the damage and the activity in question. The Directive provides for two different liability schemes, that is, one for the occupational activities specifically mentioned in the Directive (mainly agricultural and industrial activities requiring a permit), for which the liability is strict, meaning that the operator may be held liable even if he is not at fault, and one for all other occupational activities (not listed in the Directive) where there is damage or the imminent threat of damage to species and natural habitats protected by EU legislation. In the later case, operator will be held liable if he is at fault or negligent.

1.2.6 Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an infrastructure for spatial information in the EU (INSPIRE)

This Directive lays down the rules for establishing, within the European Union (EU), an infrastructure for spatial information (INSPIRE), the main aim of which is to make it possible for interoperable spatial and environmental data and services related to these data to be exchanged, shared, accessed and used. INSPIRE will facilitate co-ordination between users and suppliers of information in order to combine and disseminate information originating from different sectors. INSPIRE deals with spatial information such as environmental observations, statistics, etc. that are held in electronic form normally by public authorities. It covers themes such as administrative borders, air, soil and water quality observations, biodiversity, land use, transport networks, hydrography, altitude, geology, population and species distribution, habitats, industrial facilities and natural risk zones (Annexes I, II and III to the Directive contain the complete list of information subject to INSPIRE).

1.2.7 Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law

With Directive 2008/99/EC the EU is aiming to ensure minimum harmonisation of the national criminal law systems pertaining to offences against EU environmental legislation. Member States shall ensure that certain conduct, as set out in Article 3, constitutes a criminal offence, when unlawful (that is infringing EU legislation contained in the annexes of the directive or national law implementing it) and committed intentionally or with at least serious negligence. Inciting, aiding and abetting any intentional Article 3 conduct is considered as a criminal offence.

Member States shall take the necessary measures to ensure that the offences referred to in the Directive are punishable by effective, proportionate and dissuasive criminal charges.

Member States shall also ensure that legal persons can be held liable for offences referred to in Articles 3 and 4 where such offences have been committed for their benefit by any person who has a leading position within the legal person, acting either individually or as part of an organ of the legal person. The liability of a legal person may be of a criminal or administrative nature, depending on the national legal system in question.

1.2.8. Inter-relationships with other environmental legislation

The legal acts described in this sector have close links with much of the legislation in other sectors of the environmental acquis.

The EIA Directive covers a broad range of activities ranging from industrial to infrastructure projects. Its main purpose is to ensure that development consent for public and private projects, which are likely to have significant effects on the environment is granted only after an assessment of the likely significant environmental effects of those projects has been carried out. However, overlaps between the EIA and other EU environmental directives, which require specific environmental assessments may have negative implications on the effective implementation of environmental legislation.

In particular, the recent amendments of the EIA Directive were driven with the necessity to ensure coherence and synergies with other Union legislation and policies. Thus, the amended EIA Directive strives at setting up co-ordinated or joint procedures for projects that are simultaneously subject to assessment under the EIA Directive and Habitats Directive 92/43/EC, Birds Directive 2009/147/EC. Amended Article 2(3) of the EIA

Directive has introduced main obligation to ensure coordinated or integrated procedure, where appropriate, for assessments under the EIA and/or Habitats/ Birds Directive, whereas for assessments under EIA and other Union legislation Article 2(3) introduces possibility to apply coordinated or joint procedure.

As regards the strategic environmental assessment of plans and programmes relations with other Union legislation is regulated by Article 11 of the Directive 2001/42/EC, which allows Member States to provide coordinated or joint procedures, which fulfil the requirements of the relevant Union legislation, i.e. EIA Directive 2011/92/EU, Habitats Directive 92/43/EC, Water Framework Directive 2000/60/EC, Directive on Waste 2008/98/EC, Air Quality Framework Directive 2008/50/EC, Nitrates Directive 91/676/EEC.

As already said above Habitats 92/43/EC and Birds Directives 2009/147/EC have strong links with EIA and SEA Directives since the procedures must ensure protection of protected sites and species. Also the Environmental Crimes Directive obliges Member States to ensure that activities harming sites or species under Habitats and Bird Directives are sanctioned. The Habitats Directive 92/43/EC, Birds Directive 2009/147/EC, Water Framework Directive 2000/60/EC and Marine Strategy Directive 2008/56/EC are major reference points for the prevention and remediation of damage to protected species and natural habitats and water as two categories of environmental damage under the Environmental Liability Directive.

The Environmental Crime Directive 2008/99/EC applies to each of 72 Directives and Regulations concerning waste and environment listed in Annex A to the Directive 2008/99/EC, the more notable of which include: Directive on Waste 2008/98/EC, WEEE Directive 2012/19/EU, Industrial Emissions Directive 2010/75/EU, Seveso III Directive 2012/18/EU, Nitrates Directive 91/676/EEC, Bathing Water Directive 2006/7/EC, Habitats 92/43/EC and Birds Directive 2009/147/EC, Air Quality Framework Directive 2008/50/EC, Waste Shipments Regulation (EC) 1013/2006.

2. DEVELOPMENT OF A SECTORAL STRATEGY AND IMPLEMENTATION PLAN

The implementation management checklist presented in Part 1, Section 2 of the Handbook, provides an overall framework for preparing a strategy to implement the legislation contained within this sector. The following text focuses on key issues pertinent to this sector, which are developed in the remainder of this section. Further guidance on implementation is provided in the relevant fiches on specific pieces of legislation.

The horizontal sector discussed in this Handbook comprises a relatively small but growing body of legislation.

Most of the activities involved in planning the implementation of the legislation in this section will probably focus on the EIA, SEA, Access to Environmental Information, INSPIRE (spatial information) and Environmental Crimes Directives. These Directives are predominately concerned with administrative procedures, e.g. permitting procedures, approvals at the planning level, as well as the collection, processing, sharing and provision of data held by public bodies. Consequently, the key activities to implement these Directives are likely to focus upon institutional issues such as:

- a study of the existing arrangements for permitting procedures, plan and programme approvals, enforcement and sanction system and the collection and storage of environmental data;
- an assessment of whether the existing arrangements are compatible with the requirements of the Directives;
- restructuring administrative procedures, including public participation provisions in relation to development consent regarding development plans and programmes;
- restructuring internal environmental information flow processes;
- reviewing arrangements to allow public access to information;
- collating and organising data to put it into a format suitable for public consumption;
- financing.

These Directives also have implications for public participation — for example, developers need to be aware of any new requirements for seeking development consents and the public need to be aware of their rights to inspect and comment on environmental impact assessment reports and to access environmental data held by public authorities. Under the EIA and SEA Directive the public should be afforded the opportunity to comment on the environmental report and for their comments to be taken into consideration. The public may also play an active role in plan and programme monitoring activities.

3. INSTITUTIONS AND RELEVANT PARTIES

3.1. Stakeholders

All authorities with environmental responsibilities, be they public bodies, privately or commercially funded enterprises, non-government organisations interested in environment protection and the informed public, are likely at some stage to be affected by this legislation. A survey of these principal stakeholders and their roles is given below.

Table 1. Principal Stakeholders and Their Roles in the Horizontal Sector

Principal Stakeholders and Their Roles in the Horizontal Sector	
Stakeholders	Roles
Central government (e.g. a ministry or department)	<ul style="list-style-type: none"> – Transposition of Directives into national legislation. – Provision of services for implementing the EIA and SEA Directives. – Overseeing and conducting transboundary consultations related to EIA and SEA. – Internal consultation among relevant ministries/departments related to EIA and SEA approval processes. – Establishment of appropriate and cost-effective procedures for administering the instruments, which includes procedures for ensuring environmental remediation carried out or at least financed by the industrial polluter. – Designation of competent authorities according to Article 11(1) of the Environmental Liability Directive, and ensuring the tasks allocated to them (e.g. Articles 5, 6, 7, 11, 12, 13 ELD) – Ensure that activities described in Article 3 of the Environmental Crimes Directive are regarded as criminal offence. Ensure that inciting, aiding and abetting the committing of a criminal act is also punishable. An overview and revision might be needed to ensure that procedures are effective, there is sufficient capacities to monitor activities falling under Article 3 and that such legal persons referred to in the Environmental Crimes Directive can be held liable. – Establishment of efficient procedures for investigating and sanctioning of at least those environmental crimes listed in the Environmental Crimes Directive (2008/99/EC). – Reporting to the Commission as required by the instruments. – Where appropriate, requiring and enforcing alterations to development proposals and mitigation measures resulting from the EIA and SEA processes.

	<ul style="list-style-type: none"> - Ensure public access to environmental information held by or for central government such as a ministry or central department. - Take measures and practical steps to make it possible for interoperable spatial and environmental data and services related to these data to be exchanged, shared, accessed and used in accordance with the INSPIRE Directive on spatial planning.
<p>Environmental agencies working on behalf of central government (e.g. nature conservation bodies and national research centres)</p>	<ul style="list-style-type: none"> - Supporting the execution of the central government's responsibilities in achieving compliance with EU policies and legislation. This includes delegated executive powers for permitting procedures, the provision of access to environmental information, supervising compliance and ensuring corrective measures in case of non-compliance with the Environmental Liability Directive. - Environmental agencies are also likely be closely involved in the implementation of the INSPIRE Directive on infrastructure for spatial data. - These agencies often complement the relevant ministry in carrying out supervisory duties over industrial installations needing a permit under Directive 2010/75/EU on industrial emissions. They should insure that environmental inspections are in line with the criteria and objectives set out in Recommendation 2001/331/EC on minimum criteria for environmental inspection. - These agencies are also normally involved in the monitoring and supervision regarding the nature protection and conservation. - In some Member States, environmental agencies oversees the compliance with the EU provisions and will at least launch an investigation in case of non-compliance which can lead to prosecution of legal persons committing a criminal offence according to the Environmental Crimes Directive. - Competent authorities according to the Environmental Liability Directive have a range of responsibilities. For instance, they will require the operator to take the necessary preventive measures or restorative measures (in case of actual environmental damage), or they will have to take such measures themselves and recover the costs incurred at a later date. . Further, their task is to identify the liable operator, determine the significance of the damage and approve the remediation plan (remedial measures pursuant to Annex II). - The competent authority maps out and decides the order of remediation of multiple sites of environmental damage.

	<ul style="list-style-type: none"> – Environmental agencies and other delegated public authorities are also likely to be charged with implementing measures under the INSPIRE Directive such as collection, assembling of spatial information and prepare for reporting towards the Commission.
Selected national institutions e.g. for research activities funded wholly or partly by central government.	<ul style="list-style-type: none"> – Acting as statutory consultees and providers of information within the EIA process. – Providing access to environmental information. – Collecting, processing, and analysing data under INSPIRE Directive
Regional and local authorities	<ul style="list-style-type: none"> – Provision of permitting services. – Provision of administrative arrangements to meet public participation requirements. – Ensure public access to environmental information held by or for them. – Establishing and administering cost-effective arrangements for providing access to environmental information. – Application of SEA to plans and programmes at regional and local levels, in accordance with national law. – Where appropriate, requiring and enforcing alterations to development proposals and mitigation measures resulting from EIA and SEA. – Take part in remediation planning and undertaking under Environmental Liability Directive in case the responsible legal person cannot undertake it itself. – Involved in supervision, monitoring activities, especially relating to point sources and protected nature sites, also with a view to detect non-compliance, which can lead to sanctions under Environmental Crimes Directive. – Depending on the designation of the competent authorities under the Environmental Liability Directive, the list of responsibilities provided above under "environmental agencies" may apply to regional or local authorities instead or in addition to environmental agencies.
Developers of infrastructure or other projects, plans, programmes likely to have an environmental impact and private enterprises.	<ul style="list-style-type: none"> – Undertaking EIA and/or SEA where applicable, draft an environmental report, consult the public and environmental authorities and monitor implementation. – Collect and ensure public access to certain information, especially relating to EIA and SEA infrastructure developments. – Private enterprises conducting activities which can negatively affect the environment has to ensure diligent behaviour ensuring compliance with the relevant EU rules and in case of problems inform the relevant authorities. – Consider responsibilities under the Environmental Liability Directive in case of certain environmental damage.

NGOs	<ul style="list-style-type: none"> – Conveying public concerns with regard to projects, plans and programmes likely to have a significant environmental impact under the EIA and SEA Directives. – Act as public watchdog raising concerns towards public authorities in case of public complaints regarding activities affecting environment and/or public health. – Ensuring efficient participation in certain public procedures under Directives 2003/35 and 2003/4/EC and 2004/35/EC. – Supporting the activities by central government and delegated bodies in regard to enforcing environmental legislation. For instance, NGOs can on the basis of information on pollutants or non-diligent behaviour issue „black lists” of particularly polluting companies.
Public	<ul style="list-style-type: none"> – Making requests to access environmental information held by or for public authorities. – Participating in public consultation organised in the framework of the EIA and SEA procedures. – Requesting from central and regional authorities meta-data and other spatial information covering themes such as administrative borders, air, soil and water quality observations, biodiversity, land use, transport networks, hydrography, altitude, geology, population and species distribution, habitats, industrial facilities and natural risk zones. – Contribute to ensuring compliance with EU environmental legislation, providing useful information regarding polluting activities in the vicinity.
Industry	<ul style="list-style-type: none"> – Industry is concerned by most of the horizontal legislation, especially the EIA Directive and the Environmental Liability Directive. Also legal entities, especially industrial plants, are likely to be the ones mostly affected by the sanctions and penalties to be imposed by the Environmental Crimes Directive. – Industry will also be affected by the Environmental Liability Directive, in particular facilities falling under the Industrial Emissions (former IPPC) Directive and those located in the vicinity of nature reserves, biospheres or other sensitive areas. Industry should take all possible preventive measures to avoid operational or incidental releases that are not covered by the permit. – Industry will have to consider insurance or other appropriate schemes to ensure financial coverage in case of environmental damage that will have to be remediated.

3.2 National Government Institutions

National government will have responsibility for achieving and maintaining compliance with EU legislation and agreed programmes. Overall responsibility for implementing the legislation in this sector is usually assigned to the national government ministry or department responsible for the environment.

Other national government ministries or departments and their expert institutes are likely to be involved at various stages in the planning and implementation of horizontal legislation. This is especially necessary for SEA as it covers plans and programmes that are developed and implemented by government bodies, but it also applies to the establishment of infrastructure on spatial data (INSPIRE Directive). It also applies to the procedures to be followed in case of environmental remediation (Environmental Liability Directive) and the enforcement of environmental provisions and ensuring that non-compliance with Article 3 leads to effective, proportionate and dissuasive sanctions pursuant to the Environmental Crimes Directive and the collection and reporting of environmental data such as industrial discharges and emissions to various media.

In the context of EIA, the lead ministry should consult with other relevant ministries or government departments, e.g. those with responsibilities for local government, land use development, housing, urban development, transport, trade and industry, the national economy, energy, environmental protection regulation and permitting, enforcement and supervision, nature conservation efforts, foreign affairs (due to potential trans-border implications for developments requiring EIA and SEA), transport and communications and public health. For example, the development of a new motorway or expressway is likely to require specific inputs from:

- the ministry responsible for the environment or other public authority with environmental supervisory responsibilities (to ensure that an EIA is undertaken and evaluated prior to adjudicating the application for development consent and that the consent and mitigation measures are complied during the implementation phase);
- the ministry responsible for transport (as the national transport policy maker, the developer, or the body responsible for setting design and construction standards);
- ministries responsible for urban and rural development (to assess the implications of the new road on the regional economy, secondary development, and the quality of life for residents in the road corridor);
- local highway authorities (to consider the implications for traffic on the local road network); and
- authorities permitting land development (to adjudicate the application for development consent and enforce necessary amendments resulting from the SEA).

It is recommended that the lead ministry briefs other ministries with an interest in the subject on the requirements of the legislation e.g. the different types of development which will require an EIA for projects or SEA of plans and programmes, or the type of data which has to be made available to the public and any exemptions to this. The lead ministry could ensure that a diagnostic study of existing arrangements (administrative, human resources, technical, financial) is undertaken and evaluate the need to alter existing arrangements and procedures. The lead ministry should also consult with interested parties so that they can contribute to the debate on, and formulation of, implementation proposals. For the EIA and SEA Directives this could include local and regional government authorities or regulatory bodies where they have responsibilities for adjudicating applications for development consent or formulating plans and programmes,

as well as the private sector, representatives of environmental organisations and affected neighbouring states and their publics (for transboundary environmental matters).

The consultation period should be sufficient to allow time for other ministries to consider the implications of the new legislation in their sector and respond to the lead ministry with comments, suggestions or requests for additional information. These comments should be considered by the lead ministry in finalising the new procedures and drafting the legislation. The lead ministry should establish and maintain close links with other ministries to avoid any conflicts between environmental and other national policy.

With regard to the implementation of the Directive on Public Access to Environmental Information, the lead ministry or department should identify all the public authorities and institutions that hold or collect environmental information and consult with them on the proposals concerning the implementation of the Directive at national level (noting the extended definition of "public authorities" for these purposes in Directive 2003/4/EC, for instance a private firm supplying water). The lead ministry should ensure that these bodies are aware of, and have facilities for, providing access to environmental information in a uniform manner. Where this does not exist, it is advisable to draw up a programme which would include an appropriate procurement or development budget to ensure compliance. Attention should be paid not only to access upon request, but also to the active dissemination of environmental information through IT communications.

Once the legislation is in place, government ministries and departments may be involved either as main actors in implementing the legislation (for example, as competent authorities such as a regulatory body; as statutory consultees under EIA legislation; or as providers of environmental data) or could be affected by the proposals in their role as developers for publicly funded projects (for example a public authority with responsibility for highways, water supply or flood defence). Government ministries or other relevant national authorities will also have a main role, along with the regional and local authorities in implementing the Environmental Liability Directive to investigate potential cases of environmental pollution falling under the scope of the Directive and to see to that the polluter is identified, and measures are taken to assess the extent of the damage and plan the remediation action. Deciding on the consequences of the implementation of the Environmental Liability Directive (e.g. mandatory insurance against environmental damage, optional defences, biodiversity damage scope, etc.) falls under the responsibilities of the national decision makers.

It is assumed that institutional arrangements for implementation of the Environmental Crimes Directive are already in place. However, instructions and training of environmental inspectors, police, customs officers, prosecutors and judges is recommended in order to ensure that offences referred to in Article 3 and 4 of the Environmental Crimes Directive are punishable by dissuasive, effective and proportionate sanctions.

Also the Ministry has to ensure adequate supervision of industrial installations and other potential legal persons with activities covered by the Environmental Liability Directive to ensure that environmental pollution (e.g. damaged sites, water bodies, polluted soil) is being remediated by the polluter.

3.3 Competent Authorities

Competent authorities are those bodies, usually in the public sector, which are given the responsibility to implement and enforce the legislation. The competent authorities, especially where they have permitting, supervisory, monitoring or sanctioning responsibilities should normally be public bodies or agencies of some sort, such as the Ministry of Environment or an Environmental Protection Agency. Competencies may be

divided among several institutions at the same or at different levels, especially if this is more efficient and leads to better implementation due to higher specialisation, institutional set-up and access to resources. For example, a ministry of public works may have responsibilities for the implementation of the EIA Directive. Local, regional and national authorities may all have competence for issuing environmental permits controlling emissions to air, water or land. Monitoring and enforcement may be partially or wholly delegated to regional or local authorities.

A list of the types of functions to be undertaken by competent authorities to implement the legislation in this sector is provided in the list below. Some of the expertise required by competent authorities to undertake their duties in the area of horizontal legislation may already exist in one or more agencies or institutions. Similarly some of the tasks may already be implemented within the candidate countries such as the preparation of a state of the environment report. Where expertise or sufficient staff resources are lacking, the competent authorities will need to be strengthened to cope with either a different type of task or an additional workload. The staff may need to be trained in the new methods, techniques and skills required if the legislation is to be implemented effectively.

List of examples of activities that are specifically required to be undertaken by a competent authority in respect of EU legislation in the horizontal sector

Planning and Implementation

- Surveying the available expertise, staff and office systems and resources.
- Designing, deciding, promulgating and commissioning new procedures.
- Co-operating with central government over the appointment of responsible persons and institutes for responding to the EEA.
- Training staff and augmenting or upgrading existing office systems and resources.
- Designing and developing databases.
- Creating efficient internal communication strategies related to the dissemination of environmental information and related decision-making processes.
- Providing comprehensive electronic communication, including Internet and intranet infrastructures.
- Consulting and maintaining continuous dialogue with relevant stakeholders including industrial sectors.
- Carrying out periodic and ad hoc environmental inspections at industrial installations, including designating competent authorities and minimum criteria and ensuring follow-up measures.
- Publicising new arrangements for the benefit of potential developers, users of environmental information
- Monitoring compliance with horizontal legislation.
- Deciding EIA exemptions.
- Developing procedures to streamline environmental impact assessment of projects that are subject to EIA Directive and Habitats/Birds Directive.
- Deciding whether to apply streamlining to the EIA Directive and other Union legislation (e.g. Water Framework Directive or Industrial Emissions Directive).

- Dealing with and deciding administrative appeals for access to environmental information (in particular refusal, in full or in part, of access to information or requests not dealt with in accordance with the Directive) (2003/4/EC).
- Designing the SEA approvals system robustly so that approval for the plan or programme is only given once the environment assessment has been conducted and the reporting and consultation requirements thoroughly fulfilled.
- Determining protocols for advising public authorities and bodies on the scope of SEA and ensuring that the staff of the competent authority are suitably qualified to provide such advice.
- Establishing the order of priority for requesting the remediation of multiple sites of environmental damage (in accordance with the Environmental Liability Directive).
- Establishing or planning the modification of existing infrastructure for spatial data to be kept up to date and made accessible to various authorities and agencies as well as the public.
- Deciding on the implementation and consequences of the Environmental Liability Directive (preventive measures, primary/complementary/compensatory remediation in cooperation with the liable operator, recovery of costs from liable operator).

Permitting Procedures (EIA)

- Providing advice to developers on the scope of EIA.
- Ensuring that other organisations with responsibilities for the environment, local and regional authorities and the public have an opportunity to view and comment upon the environmental information provided by the developer.
- Evaluating applications for development consent, taking into consideration the environmental information provided by developers and the public participation process.
- Ensuring objectivity in order to avoid any conflict of interest.
- Publicising decisions on applications for development consent, the reasons behind the decisions including information on the public participation process, any environmental and other conditions attached to the decisions, and measures to mitigate adverse impacts.

Technical Standards

Co-operating with central government in drawing up technical guidance for implementing the Directives.

Reporting

To the Commission on exemptions from the EIA (provide the information needed to central government).

To the Commission on the implementation of the horizontal Directives (2001/42/EC, 2003/35/EC, 2003/4/EC).

Provide information to the government for the national state of the environment report.

Ensure that operators falling under the ambit of the Environmental Liability Directive promptly inform the competent authority about the situation, factors and consequences of environmental damage, including of an imminent threat of such damage, which cannot be dispelled.

3.3.1 Environmental Impact Assessment

Several institutional models exist for handling EIA procedures in Member States. These range from options in which the central government department or ministry is appointed the competent authority for all permitting procedures, to one in which the majority of the responsibility is delegated to regional and local authorities. This second approach would also make arrangements for public consultation more practical as it would bring the process closer to the main protagonists. Issues of national versus regional government involvement are discussed further in Section 3.4. The EIA procedures may be integrated with the process for granting development consent.

Legislation adopted in 2014, namely Directive 2014/52/EU aims to strengthen effectiveness of EIA and reduce an administrative burden by improving its quality, enhancing its efficiency through closer synergies with other Union legislation and simplifying procedures. Member States now have a mandate to simplify their different environmental procedures.

3.3.2 Strategic Environmental Assessment

In general, a focal point for SEA implementation tends to be the ministry of the environment or the ministry of spatial planning. The planning authority must be supported by relevant environmental authorities and other experts, but also ad-hoc working groups may be established depending on the nature and complexity of the plan/programme in question with an aim to facilitate the procedure and provide support in a decision making process. The co-ordinating role largely depends on the national system. With regard to sectoral plans and programmes, including the development of relevant guidance documentation, co-ordination with other lead ministries is vital (e.g. transport plans require close co-ordination with the transport ministry or department). Some Member States have chosen to designate the responsible authorities that must be consulted in SEA procedures in their legislation, while in other Member State authorities, which must be consulted, are designated on a case-by-case base.

The Commission's Guidance on the implementation of Directive 2001/42/EC on the assessment of the effects of certain plans and programmes on the environment may be of use for general approaches to SEA. In addition, valuable information is contained in Strategic Environmental Assessment Better Practice Guide - Methodological guidance for strategic thinking in SEA prepared by Maria do Rosário Partidário, Professor at IST-UTL for the Portuguese Environment Agency and Redes Energéticas Nacionais (REN), SA.

3.3.3 Environmental Information

The main tasks of the competent authorities are to make available environmental information at the request of an applicant; to ensure that environmental information progressively becomes available in electronic databases that are easily accessible to the public; to report on the implementation of Directives according to requirements suggested by the Commission in guidance documents; to disseminate information on the environment, in particular by producing reports on the state of the environment.

A large number of national public bodies may hold environmental information and be given responsibilities for reporting, or at least for forwarding information to a central data co-ordination unit. The types of organisations involved include national and local government, environmental protection agencies, statistical offices, meteorological offices, government research and development institutes, and agencies with a specific

environmental remit such as water resources, forestry, nature conservation, or conservation of archaeological sites and built heritage.

These institutions could be required to make their own arrangements to allow public access to information, based upon guidelines prepared by central government. Alternatively, central government could provide one or more central co-ordinating units, depending on the type of data, to collate, process, and publish information for public use, to forward to the EEA or to send to the Commission.

3.3.4 Public Participation Directive

The main task of the competent authorities is to ensure effective public participation in the decision-making procedure. Public should be able to express, and the decision-maker should take account of, opinions and concerns which may be relevant to those decisions. A quite number of national public bodies may be involved in implementation depending on their competence over development of plans and programmes referred to in Annex I. Authority responsible for the implementation of this Directive is usually ministry responsible for environment.

3.3.5 INSPIRE Directive

The competent authorities will be involved in making network services available to users, allowing them to search for, view and download spatial information. The competent authority may have to impose a reasonable fee for some services and may need to limit public access to spatial information on the grounds of international relations, public security, national defence, confidentiality related to the proceedings of public authorities and certain commercial or industrial information, intellectual property rights, personal data or environmental protection. The main ministry and the competent authority shall contribute to ensuring that representatives at national, regional and local level (local government) as well as other natural or legal persons with an interest in the spatial data concerned by virtue of their role in the infrastructure for spatial information, including users, producers, added value service providers or any co-ordinating body, shall be given an opportunity to participate in the development of implementing rules.

3.3.6 Environmental Liability Directive

The main responsibility of the competent authority is to supervise and enforce the provisions of the Environmental Liability Directive, especially relating to defining the necessary preventive measures to respond to an imminent threat of environmental damage, and to give instructions to the operator on how to take these measures. It is also responsible for determining the remedial measures for operators in case of actual environmental damage and to enforce the necessary remedial action. The competent authority can also take such measures itself and require that the operator covers the associated costs at a later date. In addition, the competent authority is responsible for giving the operator instructions to control, contain, remove or manage relevant contaminants or other damage factors to avoid further damage and negative effects on human health, as well as to remedy environmental damage.

3.3.7 Environmental Crimes Directive

Directive 2008/99/EC does not specifically request Member States to designate a competent authority as it presumes that in most Member States the normal criminal procedures and enforcing authorities can ensure implementation of the Directive. However, some Member States, such as Sweden have already established systems and bodies for environmental offences, which include environmental prosecutors.

3.4 Regional and Local Government

The role of regional and local government in permitting and EIA and SEA procedures, dissemination of environmental information and in identifying breaches of EU legislation is very important. Experience in Member States suggests that the permitting of land-use development, the supervision and monitoring of polluting activities and the dissemination of environmental information is best organised at the regional or local level.

It may be necessary to develop new administrative arrangements and procedures when the administrative structure of candidate countries does not allow the competent environmental authority to address EIA, SEA and environmental remediation requirements as well as to monitor activities and report cases of non-compliance which will require imposition of sanctions under the Environmental Crimes Directive. This will require careful planning at the beginning of the implementation process, to identify the institutions required, their roles and responsibilities, measures ensuring sufficient coordination and how these arrangements can be developed.

In the case of EIA and SEA, decisions will have to be made on the degree of decentralisation that should be arranged for permitting and approval procedures. Development projects, plans and programmes are distributed throughout the country, and regional and local authorities will be most familiar with local issues. Thresholds of size, area and perceived impact may have a bearing on whether all or some categories of projects, plans or programmes are handled regionally compared with locally. The possibility of cross-border impact represents a special case.

In terms of the Environmental Information Directive, regional and local authorities are in a good position to obtain information from industrial facilities and other relevant parties and to collect and disseminate this information, for instance throughout internet services, databases, and helpdesks.

Local authorities can also play a major role in identifying cases of environmental pollution, which will be subject to remediation measures or sanctioning pursuant to the Environmental Liability Directive and the Environmental Crimes Directive. For instance, authorities involved in permitting and supervision of industrial activities are also in a good position to determine cases of pollution, identify and prioritise remediation cases, also comprising historic pollution or cases where the polluter cannot be established or has gone insolvent.

3.5 Private Sector Involvement

The private sector is a significant player in development projects in Member States, and is becoming increasingly involved in development in candidate countries. Hence, the private sector has a major involvement in the EIA Directive, especially in infrastructure or other major development projects which require an EIA assessment and ensuing procedures. The sector needs to ensure compliance with the procedures, taking into account the interpretations and guidance established by the Commission and the Court of Justice of the European Union (CJEU)¹².

Developers will be responsible for undertaking EIAs and for ensuring that suitable mitigation measures are taken, as required. Implementation of the EIA Directive may provoke considerable debate with the private sector, through its representative associations and spokespersons. It will be necessary to consult with the private sector during the implementation planning phase, and to provide guidance to developers once the EIA procedures have been established¹³. Developers are likely to welcome guidance on the procedures and technical aspects involved. Competent authorities responsible for implementing the EIA Directive should develop good liaison with the private sector so that the administrative processes that are set up are effective.

There are options for the production of environmental information required under the EIA Directive. Developers may make their own arrangements for producing an environmental impact report using whatever approach appeals to them, or they may be encouraged or required by legislation to use preferred institutions to produce the report for them. The former approach is the most common solution, with developers either undertaking the work themselves or subcontracting it to specialised consultants. The latter approach introduces a basic quality standard and degree of uniformity to EIA and reporting. The preparation of guidelines or a code of practice should be a responsibility of the lead department or ministry consulting with stakeholders.

The private sector has a less significant role in applying the SEA Directive as this mainly relates to public plans and programmes. However, the private sector has a major role in applying the Access to Environmental Information Directive as the various concerned sectors, especially the industrial sector, has an obligation to provide the relevant authorities with the required information. This information will constitute the basis for the environmental information to which the public later will have access.

The private sector's role in implementing the Environmental Liability Directive is significant. Operators have to prevent environmental damage in case of imminent threat and to remedy the already occurred environmental damage in cooperation with the competent authority to ensure that the site or polluted medium is restored. These are self-executive obligations. They have for instance also to provide the relevant supervisory or permitting authorities with information on cases of environmental pollution or risk for environmental pollution covered by the Directive. Finally the private sector, such as industrial facilities, infrastructural development companies and companies trading in wild species of flora or fauna or specimens/products thereof has to ensure compliance with the environmental legislation and in case of non-compliance ensure that sanctions imposed are being complied with.

¹² Compilation of the rulings of the CJEU is available at: http://ec.europa.eu/environment/eia/pdf/eia_case_law.pdf

¹³ New EIA guidance document on interpretation of definitions of project categories of annex I and II is available at: http://ec.europa.eu/environment/eia/pdf/cover_2015_en.pdf

3.6 Communication and Consultation

Communication and consultation activities are common to the horizontal Directives at two levels. However, there is likely to be a greater degree of communication and consultation during implementation of the EIA and SEA Directives than for the Access to Environmental Information and, the Environmental Liability Directive. First, during the process to transpose the Directives into national law, the government should set out its views on the legal provisions and how they will be introduced into national legislation. This will generate discussion for and against the provisions and the government should consider the points made and amend their views as they think fit, bearing in mind the fact that candidate countries are under an obligation to transpose Directives into national law. This process will continue until the proposals become national law.

The second level of consultation refers to the application of the law once it has been passed. The EIA and SEA Directives require consultation with statutory consultees and the public on development proposals and environmental impact assessment report and proposed plans and programmes and approvals, as well as consideration of the results of these consultations when making a decision as to whether or not to grant development consent or approval. This will generate exchanges of views during the period set for consultation, often in the media and possibly at public meetings. This will especially be the case if there are objections to the proposed development. Communication will be necessary between the private sector as the potential polluter, but also with civil society organisations and NGOs, which provide an important function as collecting and disseminating information with the authorities and the public on potential breaches. Regarding the Environmental Liability Directive and the Environmental Crimes Directive it is reasonable to expect consultation between central authorities, environmental agencies, permitting authorities, prosecutor, police, customs officers, CITES Secretariat, and regional authorities to acquire information and to decide on responsibilities and measures to ensure full implementation of the Directives. In this context the rights of legal or natural persons affected by environmental damage and of environmental NGOs to request an action taken by the competent authority upon submission of observations as regards instances of environmental damage including the right to review such decisions taken by the competent authority are noticeable.

Member States should take measures to encourage the use by operators of any appropriate insurance or other forms of financial security and the development of financial security instruments and markets in order to provide effective cover for financial obligations under this Directive. In general, stakeholder and practitioner dialogue between the main stakeholder groups (operators/industry, authorities/government, insurance/financial security providers and affected persons/NGOs) play an important role for the good implementation of the ELD.

Where environmental damage affects or is likely to affect several Member States, those Member States should cooperate with a view to ensuring proper and effective preventive or remedial action in respect of any environmental damage. Member States may seek to recover the costs for preventive or remedial actions.

The INSPIRE Directive will also require communication and coordination between the competent authority and other relevant authorities and bodies to ensure adequate collection and use of spatial information.

4. TECHNICAL ISSUES

There are no common technical standards, such as emission limits or quality standards, laid down in the legal acts in the horizontal sector.

Guidelines on undertaking environmental impact assessments and preparing environmental impact assessment reports are available from a number of sources.

The Commission has prepared a number of guidance reports on EIA and SEA issues, for example on screening, scoping, checklist for impacts, and the assessment of cumulative impacts (see the fiche on the EIA Directive). These guidance documents however are not binding to the Member States and without prejudice to Commission competence to ensure Member States' compliance with the respective environmental legislation. Last but not the least the Court of Justice of the European Union is the sole source of definitive interpretation of EU law.

Guidelines on EIA and SEA are available, from a variety of sources within Member States such as:

- government departments with responsibility for implementing EIA and SEA legislation;
- government departments with responsibility for infrastructure development: these include guidelines on preferred methodologies to be followed by consultants undertaking EIAs or SEAs on behalf of government;
- environmental protection agencies;
- EIA/SEA institutes;
- bodies representing industry and professionals in various sectors of industry;
- universities and research bodies.

Much of the legislation in this sector is connected to data collection and organisation.

Consequently, the competent authority or authorities need to consider existing arrangements for handling potentially very large volumes of data. The last decades has seen a rapid growth in the use of computer software to store, manipulate and analyse data and present the results in a variety of forms such as maps, charts and diagrams. In the context of the INSPIRE Directive on spatial information, competent authorities should adopt one or more database management systems, e.g. based on a geographical information system (GIS), complete with facilities which allow data to be interrogated and reported. The entire database need not be at one location, but could be networked among the various authorities and institutions involved in data collection and reporting. Spatial data such as meta-data, geo-data, statistics and other similar information will most likely be increasingly standardised and subject to technical specifications to facilitate and streamline their collection, handling, dissemination and exchange.

Regarding the Environmental Liability Directive, the main technical issues include various sampling and methodologies to assess the environmental damage, and determine the necessary remediation measures which also involve technical aspects in terms of techniques, use of materials etc. The actual remediation will require the assistance of technical experts. Other technical issues linked to this Directive is the estimation of the cost of remediation and financial securities such as insurances necessary for ensuring adequate resources for remediation measures.

While no guidance at EU level has been issued yet, nine Member States have so far adopted technical and/or legal guidance documents including electronic tools (more information on: http://ec.europa.eu/environment/legal/liability/eld_guidance.htm). The Commission has developed a training package and is supporting ELD training measures: http://ec.europa.eu/environment/legal/liability/eld_training.htm.

5. REGULATION AND ENFORCEMENT

5.1 Overview

In the horizontal sector, regulation and enforcement is largely concerned with ensuring that the procedures set out in the legislation for EIA, SEA, and the corrective measures set out in the Environmental Liability Directive, as well as adequate access to environmental information to the public, reporting etc. are adhered to. The Environmental Crimes Directive 2008/99/EC provides for minimum rules relating to criminal law. The Directive obliges Member States to provide for criminal penalties in their national legislation in respect of serious infringements of provisions of Union environmental law. The competent authorities subsequently have to ensure a regulatory framework, sufficient human and financial resources to ensure enforcement and sanctions for non-compliance.

In terms of concrete examples, under the EIA Directive, Member States have to ensure that procedures are put in place so that applications for development consent for projects subject to EIA are evaluated following the submission of environmental information to the competent authority prior to issuing a permit. With regard to the Directive on Access to Environmental Information, Member States have to define the practical arrangements under which information is to be made available, and those making requests for information must be able to appeal (by way of judicial or administrative review) if their request for information is refused or is not adequately answered. However, the last couple of years have seen new horizontal legislation being adopted, which is not directly linked with the EIA, SEA and environmental information requirements. This legislation includes, notably, the INSPIRE Directive on the establishment of spatial information infrastructure and Directive 2004/35/EC on environmental liability. Although the INSPIRE Directive again, to a certain extent, concerns the collection, maintenance and dissemination of environmental information, the Environmental Liability Directive has a different character.

5.2 Data Collection and Reporting

There are limited provisions for the collection of new data, but several requirements for the collection, management and reporting of existing environmental data in the legal instruments considered in the horizontal sector. Under the EIA Directive, developers are required to provide environmental information to the competent authorities, a proportion of which may be original data, specifically collected as part of the EIA. Under the SEA Directive, authorities are required to submit to the competent authority data contained in the environmental report outlining the significant environmental effects of proposed plans and programmes along with any steps to mitigate and monitor such effects. Public bodies are required to provide the public with environmental data under the Directive to Access on Environmental Information. Regarding the Environmental Liability Directive, Member States must communicate and report to other Member States on environmental damage of cross-border nature. Also a general requirement under most environmental Directives, is the duty of competent authorities to report to the Commission on their experiences on applying the legislation, which forms the basis for further improvements. A summary of reporting requirements for the legislation in the horizontal sector is provided in the Table below.

Table 2. Reporting Requirements for the Horizontal Sector Instruments

Table - Reporting Requirements for the Horizontal Sector Instruments		
Institution Responsible	Receiver of Information	Typ of information required
International level		
European Commission	European Parliament	Report on the implementation of Directives.
European Commission	Member States	Report on implementation of Directives across Member States. Make available to competent authorities of Member State information from other Member States.
Member States	European Commission	How the Directives have been transposed also showing table of correspondence with national legislation Exemptions granted (various Directives). Experience gained in implementation (various Directives). Member State that identify damage within its borders which has not been caused within them it may report the issue to the Commission and any other Member State concerned (Environmental Liability Directive)
Within Member States		
Member States	Other Member States	Although the EIA Directive does not introduce a reporting obligation in the strict sense it includes several provisions relating to information to other Member States if a project is likely to have significant transboundary effects. Procedures for information exchange and consultation apply (Directives 2011/92/EU, 2001/42/EC and 2003/35/EC). Where environmental damage of a cross-border nature has occurred, the Member State in whose territory the damage originates shall provide sufficient information to the potentially affected Member States (Directive 2004/35/EC). Member State that identify damage within its borders which has not been caused within them it may report the issue to the Commission and any other Member State concerned (Environmental Liability Directive)
Member States	Public	Requests for development consent and information gathered must be made available, as well as information supplied at an early stage, in order that the public can give an opinion before consent is granted (Directives 2011/92/EU and 2003/35/EC). Results of the public consultation must be taken into consideration in decision-making process. The competent authority must inform the public of a decision to grant or refuse development consent or approval of a plan or programme and provide certain information (Directives 2011/92/EU, 2001/42/EC and 2003/35/EC). General information on the state of the environment in Member States must be provided at regular intervals (Directive 2003/4/EC).

Member States	Private sector	<p>The competent authority may require the relevant operator to carry out his own assessment and to supply any information and data necessary, pursuant to the Environmental Liability Directive.</p> <p>Competent authorities must notify a „polluter” under the Environmental Liability Directive about decisions to undertake assessment and remediation, the grounds for this decision and the existence of available legal remedies</p>
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6. PRIORITIES AND TIMING

6.1 Prioritising the Implementation Tasks

In preparing their implementation plans, candidate countries will need to prioritise the various major tasks to be undertaken for each legal act. This aspect is discussed in the fiches for the various environmental Directives. However, as candidate countries must transpose all of the Directives into national legislation by the date of accession, consideration should be given to the order in which the various items of legislation are transposed.

The implementation of the EIA Directive (2011/92/EU) should be considered as a priority within the horizontal sector, and implemented in conjunction with certain key Directives requiring EIA consent, e.g. the Habitats Directive (92/43/EC), Birds Directive (2009/147/EC), Industrial Emissions Directive 2010/75/EU, the Seveso II Directive (96/82/EEC), the Carbon Capture and Storage Directive (2009/31/EC), Waste Directive (2008/98/EC), Urban Waste Water Treatment Plant Directive (91/271/EEC) and Mining Directive, given that this legislation covers activities which are subject to EIA requirements. The Directive on Access to Environmental Information (2003/4/EC), the Public Participation Directive (2003/35/EC) and the Environmental Crimes Directive (2008/99/EC) should also be considered with this group of legislation, as at least the two first Directives are linked to the application and implementation of the EIA and SEA Directives requiring public access to environmental information, extensive public consultation; which might require considerable institutional and administrative steps to ensure well construed, easy to use and transparent institutional structures and systems. Also putting into place the sanctions called for in the Environmental Crimes Directive will also help ensure a more efficient implementation, linked with adequate monitoring and efficient, dissuasive and proportionate sanctions for environmental offences. Another important Directive to implement as soon as possible is the INSPIRE Directive (2007/2/EC) which also sets out certain requirements in terms of data format and content having implications for a number of other EU Directives.

However, it is also essential to correctly implement the SEA Directive (2001/42/EC) especially as regards establishing structure planning and consultation procedure. Again, the implementation of SEA should be coordinated with directly related legislation covering plans and programmes such as the River Basin Management Plans under the Framework Water Directive (2000/60/EC), Waste Management Plan under the Waste Directive (2008/98/EC). The candidate countries should also take into account national measures on plans and programmes in the agricultural, fisheries, telecommunications, energy, transport, and land planning sectors even though they might not be covered by concrete EU legislation. It is also important to carefully plan implementation of the Environmental Liability Directive (2004/35/EC), enshrining the polluter pays principle in more practical terms for industrial and other main polluters, which will involve consultations with industry, civil society organisation, insurance companies and possibly other actors such as technical experts on remediation issues. It is likely that very few of the candidate countries have already introduced liability rules for environmental polluters. In relation to this process, candidate countries should review its criminal law provisions to ensure that the Environmental Crimes Directive can smoothly be implemented after EU accession, ensuring efficient, dissuasive and proportionate sanctions for environmental offences. This system will normally work best, if there is awareness raising and planned consultation with sectors and parties likely to be affected as well as those having a particular interest in its application such as environmental NGOs.

6.2 Timescale

It is not possible to give specific guidance on the length of time required by candidate countries to implement and comply with the legislation in this sector. Some indications of the duration of the implementation programme are provided in the Directives, which stipulate transposition periods within which Member States must have implemented and complied with the legislation. These have ranged from six months to four years. However, other factors will affect the implementation programme as illustrated below.

- Institutional capacity building will be fundamental to the implementation of the horizontal sector Directives.
- The environmental acquis has been developed over a period of some 40 years and existing Member States have had a relatively long time period to transpose the legislation and adopt effective environmental policies and institutional set-up. Compared to this, the candidate countries have to implement the same environmental instruments in a much shorter timescale.
- The costs of implementing and complying with the provisions are likely to be more onerous in the candidate countries, for example in countries which are reorganising their administrative structures from a centralised to a decentralised system.

Implementation of the legislation in the horizontal sector has one advantage compared with the other environmental sectors in that virtually no capital investment is required, with exception of INSPIRE Directive. The legislation is concerned with implementing administrative and consultation procedures and adopting an effective regulatory system for sanctioning non-compliance. However, the candidate countries should carry out a needs assessment based on the existing administrative arrangements so that there is a clear understanding of the areas to be addressed for the purposes of implementing the instruments.

7. ECONOMIC AND FINANCIAL ISSUES

7.1 Introduction

This section discusses the economic and financial issues that candidate countries should understand and take into account in implementing the instruments.

7.2 Institutional Development

With the main thrust of the implementation of the instruments leading to the need for new administrative procedures, internal staffing requirements and training should be reviewed at the various institutions being given responsibility for the implementation of these items of legislation. Regardless of whether additional staff are required, training courses will be needed, tailored to the tasks of implementing and administering the new procedures. Consequently, it will be necessary to ensure that adequate budgets are available to finance the commitments to be made to enable the responsible institutions to operate effectively. Salaries will also need to be reviewed if it is considered that various tasks will command greater responsibility and if the necessary staff are to be recruited. It will be vital for the training to be phased according to the desired take-up of the new procedures so that management and skills may be improved over a period of time.

In summary, human resources are required for:

- preparing the consultation documents for transposing provisions of the Directive into national legislation and dealing with the legislative process;
- establishing procedures as requested by the Directives to ensure effective implementation;
- developing and implementing internal and external environmental communication frameworks;
- developing detailed environmental databases;
- creating and implementing information technology frameworks for communicating environmental information and decisions;
- producing guidelines and codes of practice on applying the legislation to development projects;
- making arrangements for providing access to environmental information;
- designing and commissioning systems for managing environmental information that will be made available to the public;
- producing reports as required by the Directives; and
- supervising compliance with the horizontal legislation make possible adaptations to the enforcement and sanctioning system to ensure full compliance with the Environmental Crimes Directive (2008/99/EC)

Costs for establishing the institutional structure will depend on various factors such as the size of the candidate country; the degree of decentralisation arranged to administer the legislation and the choice of organisational structure; the likely number of development projects; the size of the population; and the anticipated interest in environmental information. The aspects that are likely to require the greatest incremental costs are:

- staffing and capacity building;
- training;
- data and information management systems and office equipment;
- preparation of reports;
- provision of information to the public.

7.3 Facilities

Studies prepared on behalf of DG ENV have shown that the cost of implementing the horizontal legislation in candidate countries will be relatively low compared with some of the other instruments for which major capital expenditure is required to update the performance of treatment installations to the standards set in the Directives. For example, implementation costs for the horizontal sector were estimated at EUR 10 million in Slovenia and EUR 18 million in Romania.

7.4 Cost Recovery

Limited cost recovery is provided for in the Access to Environmental Information Directive (2003/4/EC), where public authorities will be allowed to levy charges to cover administrative costs for supplying information to those making enquiries (as long as the costs are "reasonable"). Charges can also be imposed for EIA reports as well as meta-data, statistics, GIS data and other spatial information under the INSPIRE Directive. However, the costs should be reasonable and justifiable. Full cost recovery is provided by the Environmental Liability Directive in case where the competent authority has taken (preventive or remedial) action instead of the liable operator, depending of course on the liable operator's financial solvency. Such costs include also the costs of assessing environmental damage or imminent threat of such damage, alternatives for action as well as the administrative, legal and enforcement costs, the costs of data collection and other general costs, monitoring and supervision costs.

8. SUMMARY OF KEY ISSUES

Most of the tasks associated with the implementation of horizontal legislation focus on reviewing and, if necessary, revising administrative arrangements for integrating EIA into development consent procedures and providing information to the public. Furthermore, the Environmental Liability Directive (2004/35/EC) require Member States to ensure full compliance with the polluter pays principle enshrined in the Treaty on the Functioning of the European Union and that there is a minimum level of harmonisation in terms of sanctioning criminal offences under the Environmental Crimes Directive (2008/99/EC). Key issues to be addressed by government in planning the implementation of the legislation in this sector are summarised in the following checklist.

Table 3. Checklist of Key Questions to Be Considered in Preparing the Implementation of Horizontal Legislation

Checklist of Key Questions to Be Considered in Preparing the Implementation of Horizontal Legislation	
1	Have methodologies been developed for implementing SEA and EIA?
2	Has SEA been sufficiently developed to provide for an environmental framework for plans and programmes? <ul style="list-style-type: none"> • Does it provide a comprehensive and clear framework for preventing and mitigating environmental effects in connection with projects and existing activities? • Is there sufficient knowledge on how the land-use planning and permitting system operates at present? • Are the existing institutional arrangements for assessing and permitting different types of projects to be affected by EIA legislation clearly understood? • Are there existing SEA procedures, and if so what are they?
3	Are there any problems with the existing arrangements that need to be considered in reorganising the administrative arrangements, e.g. lack of resources, national versus local conflicts, absence of appeals process or enforcement powers, public consultation?
4	Do the proposed arrangements for implementing the EIA Directive address any existing problems in the permitting process?
5	Have the requirements of the EIA Directive been addressed? <ul style="list-style-type: none"> • Does government wish to combine EIA with other relevant permitting procedures, e.g. under Waste Framework Directive, Industrial Emissions Directive, Seveso III Directive, etc.? • Does the revised permitting process ensure that development consents for projects requiring an EIA are only considered after prior evaluation of the EIA? • Are there adequate guidelines in place for the competent authorities to evaluate environmental information provided by developers? • Are there appropriate arrangements for consultation with statutory consultees and the public?
6	Have adequate mechanisms been established for transboundary consultations and decision-making processes?
7	Have adequate measures been provided for resourcing the new administrative arrangements, e.g. staffing, training and computing resources?
8	Do the competent authorities have appropriate enforcement powers?
9	Have all the public authorities in the large meaning of Directive (e.g. firms supplying water) that hold environmental data been identified and consulted about the requirements of the legislation?
10	Have adequate measures been designed and resourced to meet the new administrative arrangements (e.g. staff numbers and training, physical access to public buildings, computers, database systems)?

11	Have guidelines been prepared to advise public authorities (e.g. on the type of information that has to be made public, the presentation of the material, charging for information, reasons to refuse requests for information)?
12	Is there a system of appeals in cases of information being refused, in full or in part, or requests not dealt with in accordance with the Directive?
13	Have arrangements been made to inform the general public, NGOs and the private sector of the service?
14	Have requirements for preparing state of the environment reports been addressed and linked in with the Access to Environmental Information Directive as well as the Reporting Directive also through participating in Eionet?
15	Has the government put into place a legislative framework and procedure to implement the INSPIRE Directive? <ul style="list-style-type: none"> • Reviewed the existing infrastructure for spatial data, including legislation, networks and information channels between ministries, agencies and other concerned authorities? • Mapped out gaps and shortcomings and addressed them to ensure efficient infrastructure for various spatial data, e.g. GIS, meta-data and statistics and ensured that this information has been made available to the concerned authorities as well as the public (ensuring that some services are provided free of charge)?
16	Has the government taken steps to implement the Environmental Liability Directive? <ul style="list-style-type: none"> • Created procedures for the competent authority to carry out environmental assessments in order to determine the extent of environmental damage and the measures needed to remedy it? • Determined a procedure for determining when the measures should be taken by the relevant operator or by the competent authority on their behalf? • Identified, at an early stage of implementation, key actors and stakeholders who will be involved in or impacted by the implementation of the Directive? • Considered various options for ensuring financial means in cases of environmental damage covered by the Environmental Liability Directive, such as financial guarantees, securities? • Ensured that all the activities listed in Annex III to the Directive are being subject to the provisions of the Directive, ensuring liability in case of damage (including mining waste, geological storage of CO₂ and offshore drilling as introduced by Directives 2006/21/EC, 2009/31/EC and 2013/30/EU)? • Taken measures, such as providing guidance and assistance, to ensure that industrial operators or other directly or indirectly parties are fully aware of their rights and obligations under the Directive, including if possible, that operators are better able to calculate their risks?
17	Is the government carrying out periodic and ad hoc inspections in industrial installations subject to Industrial Emissions Directive or other similar environmental or operational permit?
18	Is the government and decentralised governmental bodies (e.g. EPAs, municipalities, regional environmental councils) taking measures to implement the Environmental Crimes Directive (2008/99/EC)? <ul style="list-style-type: none"> • Ensured that all the activities listed in Article 3 of the Directive are considered environmental criminal offences and are subject to efficient, proportionate and dissuasive penalties? • Ensured that legal persons can be held accountable for the environmental criminal offences referred to in Article 3 and that also the inciting, aiding and abetting the intentional conduct is subject to sanctions? • Ensured that the sanctioning system is extended and that all relevant parties are duly informed? • Ensured monitoring and supervision in addition to supervision pursuant to industrial emissions or SEVESO activities to ensure detection of criminal offences? • Ensured guidance to environmental supervisory authorities, governmental bodies, (environmental) prosecutors, judges on how to monitor and proceed in case of suspected criminal offences?

THE ENVIRONMENTAL IMPACT ASSESSMENT DIRECTIVE

Official Title: Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment Text with EEA relevance (OJ L 26, 28.1.2012)¹⁴

Amended by:

Directive 2014/52/EU of the European Parliament and of the Council of 16 April 2014 amending Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment (OJ L 124, 25.04.2014)

¹⁴ Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment, OJ L 26, 28.1.2012, pp.1-21, as amended by Directive 2014/52/EU of the European Parliament and of the Council of 16 April 2014, OJ L 124, 25.4.2014, pp. 1-18. Directive 2011/92/EU is a codification of the Council Directive of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, amended by Directive 1997/11/EC, Directive 2003/35/EC and Directive 2009/31/EC.

1. SUMMARY OF THE MAIN AIMS AND PROVISIONS

Directive 2011/92/EU sets out the general principles of the assessment of environmental effects of public and private projects that are likely to have significant effects on the environment due to, inter alia, of their nature, size or location. The assessment should be carried out before development consent is given. It codifies four earlier Directives, namely, the initial EIA Directive 85/337/EEC and its three amendments 97/11/EC, 2003/35/EC and 2009/31/EC.

The EIA Directive of 1985 has been amended three times, in 1997, in 2003 and in 2009. Below is a summary of the amendments:

- Directive 97/11/EC brought the Directive in line with the UN ECE Espoo Convention on EIA in a Transboundary Context. The Directive of 1997 widened the scope of the EIA Directive by increasing the types of projects covered, and the number of projects requiring mandatory environmental impact assessment (Annex I). It also provided for new screening requirements, including new screening criteria (at Annex III) for Annex II projects, and established minimum information requirements, including the obligation to take into consideration, in the development consent procedure, the results of consultation. The 1997 amendments strengthened the requirements on consultation with other Member States on projects that may have a transboundary impact, obliged competent authorities to advise developers on the scope of the EIA if requested and require developers to provide information on alternatives they have considered and the main reasons for their choice.
- Directive 2003/35/EC on public participation in decision-making and access to justice in environmental matters aligned the provisions on public participation with the Aarhus Convention. It sets out more detailed requirements and procedures regarding the participation of the public in EIA procedures (for more information, see the separate record on Directive 2003/35/EC below). Directive 2003/35/EC introduced new definitions (of "the public" and the public concerned"). A provision allowing Member States to exempt projects serving national defence purposes was introduced. Furthermore, the Directive provided more details on the rules for public participation in the decision-making procedure comprising rules on notification (timing, methodology and content); rules for information servicing during the procedure; and the requirement of early and effective participation, consultation methods and reasonable time-frames for all phases of public participation. The provisions on transboundary EIA procedures were further strengthened. New provisions were introduced on access to justice, including the determination of the legal forums to be ensured for legal remedies, the minimum circle of concerned persons to have access to them.
- Directive 2009/31/EC amended the Annexes I and II of the EIA Directive, by adding projects related to the transport, capture and storage of carbon dioxide (CO₂), pursuant to Article 31 of this Directive. Annex I (point 16 and 23) of the EIA Directive include the following new projects: 1) Pipelines with a diameter of more than 800 mm and a length of more than 40 km: for the transport of gas, oil, chemicals, and for the transport of carbon dioxide (CO₂) streams for the purposes of geological storage, including associated booster stations and CO₂ storage sites. These projects require an environmental impact assessment within the capture permit process. Article 7(8) requires that the application contains the information set out in Art. 5 of the EIA Directive. Also no substantial change to CO₂ capture can be carried out unless a new or updated storage permit is issued in accordance with Directive 2009/31/EC taking into account Annex II, point 13, first indent of the EIA Directive.

In summary, Directive 2011/92/EU lays down rules for the environmental impact assessment of projects by introducing minimum requirements, with regard to the type of projects subject to assessment, the main obligation of developers, the content of the assessment and the participation of the competent authorities and the public. It should be noted that Member States are free to lay down more stringent protective measures as long as they are in line with the Treaty on the Functioning of the European Union.

The environmental impact assessment must identify the direct and indirect effects of a project on the following factors: human beings, the fauna, the flora, the soil, water, air, the climate, the landscape, the material assets and cultural heritage, as well as the interaction between these various elements. Projects listed in the Directive are classified in two groups: projects listed in Annex I are always subject to an assessment; while for projects listed in Annex II, it is required to determine whether they should be made subject to an assessment. This determination should be made by competent authorities either through a case-by-case examination; or according to thresholds or criteria set by the Member States. Member States may also decide to apply both approaches. The selection criteria set out in Annex III should be taken into account if the case-by-case examination is applied, or if thresholds or criteria are applied.

The developers must prepare an environmental assessment report, which details information on the project's site, design and size, possible measures to avoid, reduce or remedy significant adverse effects, the main alternatives considered by the developer.

Another important aspect of the environmental impact assessment procedure is public consultation. Thus, information must be provided as early as possible in the decision-making process to the competent authorities likely to be consulted on the authorization of the project, the public and other Member States if the project is likely to have transboundary effects. The public must be informed by appropriate means (electronically, by public notices or via local newspaper). Detailed arrangements for consulting the public concerned should be established.

Finally, authorities have to decide within the reasonable time limits whether authorize the project or not. They must make available to the public, competent authorities and other Member States concerned the approval or rejection of the project and any conditions associated with it. Reasons and considerations upon which the decision was based must also be made available to the public.

Member States must ensure that the interested parties can challenge the decision in the court.

The Directive 2011/92/EU was subject to a major revision¹⁵, which led to adoption of the Directive 2014/52/EU of the European Parliament and of the Council of 16 April 2014 amending Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment. The main objective of the revision was to correct identified shortcomings, reflect ongoing environmental and socio-economic priorities and challenges, align the environmental assessment procedure with the principles of smart regulation and reflect recent ECJ case-law. The Report from the Commission of 23 July 2009 on the application and effectiveness of the EIA Directive (COM(2009)378) highlighted the main areas where improvements are needed. The following specific problems were addressed: insufficient screening process, insufficient quality of environmental impact assessment and the risk of inconsistencies due to overlaps with new environmental

¹⁵ More information about the revision process can be obtained at DG ENV's website: <http://ec.europa.eu/environment/eia/review.htm>

assessment requirements set out in e.g. Habitats Directive 92/43/EC, Industrial Emissions Directive 2010/75/EU, Strategic Environmental Assessment Directive 2001/42/EC, etc.

Directive 2014/52/EU of the European Parliament and of the Council of 16 April 2014 amending Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment entered into force on 15 May 2014, whereas full application of the revised environmental impact assessment procedure must be achieved by Member States by 16 May 2017.

Below is a summary of the amendments:

Directive 2014/52/EU clarifies some general principles by introducing a definition of an environmental impact assessment in order to reflect the case-law (C-50/90 European Commission v Ireland). Amended Article 1(3) referring to exemptions now allows Member States, where appropriate, not to apply EIA Directive in cases of projects, or parts of project serving defence purposes or projects having the response to civil emergencies as their sole purpose. Stricter conditions have been introduced for projects approved in detailed by law.

It improves the screening process, i.e. the procedure for determining whether a project should be subject to an environmental impact assessment through modification of Annex III criteria as well as through inserting Annex II.A containing list of information to be provided by the developer on the project listed in Annex II. In addition, an obligation to better justify negative screening decision has been introduced.

The Directive further strengthens the rules for the EIA procedure to ensure that they lead to better decisions. It requires the impacts of projects relating to new environmental challenges (e.g. impacts on climate change and biodiversity, measures to address risks from natural and man-made disasters, etc.) to be adequately assessed. Furthermore, a quality control mechanism of the data contained in the EIA report must be introduced. Assessing reasonable alternatives for projects is now obligatory and mandatory monitoring is required for projects that appear to have significant adverse effects on the environment. Competent authorities must better justify their final decisions. The grounds for final decision must be clear and more transparent for the public. Member States may also set timeframes for the validity of any reasoned conclusions or opinions issued as part of the EIA procedure. As regards the public consultation some new arrangements have been introduced. Thus, local and regional authorities are clearly spelled out as bodies given an opportunity to participate in the EIA consultation.

Specific timeframes are introduced for some steps of the EIA process (e.g. screening, public participation), as well as a mechanism to facilitate the assessment process when several assessments and permits are required. In particular, coordinated and/or joint procedure, where appropriate, must be provided for projects where the obligation to carry out assessments of the effects on the environment arises simultaneously from the EIA Directive and the Habitats and/or Birds Directive. Possibility to apply one-stop shop for assessments under EIA and other Union legislation (e.g. SEA, Water Framework, IED, Waste Framework, Seveso III, etc.) is left at discretion of the Member States. However, where coordinated or joint procedures are set up, Member States should designate an authority responsible for performing the corresponding duties.

Provisions on the transboundary consultations are also improved by introducing a possibility to conduct consultations through an appropriate joint body. Additional emphasis has been put to time-frame for such consultations.

The Directive introduces new provisions referring to the conflict of interest and the obligation to ensure the objectivity of the competent authorities, in particular, in cases where the competent authority is also the developer. It also requires Member States to lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1 Planning

The main obligations are listed below:

- Designating the competent authorities and setting up the institutional framework ensuring coordination and cooperation of the various central and delegated authorities.
- Develop a policy in connection with „exceptional cases”, especially in connection with projects serving national defence purposes or having response to civil emergencies as their sole purpose (Arts. 1(3), 2(4) and 2(5) taking into account the provisions in Article 7).
- Decide on the manner of integration of the environmental impact assessment into the national procedure. Hence, the reasoned conclusion by which the competent authority finalises its examination of the environmental impact of the project may be part of an integrated development consent procedure or may be annexed to another binding decision required in order to comply with the aims of this Directive.
- Provide coordinated and/or joint procedure in case of projects for which the obligation to carry out assessment arises under the EIA Directive and/or Habitats/Wild Birds Directive, where appropriate (Art. 2(3)).
- Decide on a mechanism for ensuring quality control of the EIA information (Art. 5(3))
- Decide on the option to introduce „one-stop shop” allowing the coordination or integration of assessment procedures under the EIA Directive and EU legislation (listed in recital 37 of the Directive 2014/52/EU), other than Council Directive 92/43/EC (Habitats Directive) and Directive 2009/147/EC (Wild Birds Directive) (Art. 2(3)). In this context, Member States need to decide whether to apply coordinated or joint assessment procedure. (Art. 2(3)).
- Determine whether the decision on the Annex II project should be based on a case-by-case examination, on a generally binding threshold or criteria, or on a combination of these two methods (Art. 4(2)).
- Design ways and methodologies of public notification and consultation (Art. 6).
- Develop IT systems, databases and other software facilitating the submission of information referred to in Art. 5, taking into account all relevant Commission guidance.
- Determine which legal remedies and judicial review to be made available to members of the public and public organisations carried out in harmony with the national system and procedures of administrative and judicial remedies (Art. 11).

2.2 Regulation

The main obligations are listed below:

- Ensure that no projects likely to have significant effects on the environment are allowed to proceed unless the developer has carried out an EIA and obtained development consent (Art. 2(1)).
- Ensure that coordinated and/or joint procedure are provided for where the obligation to carry out assessments related to environmental issues arises simultaneously from the EIA Directive and Directive 92/43/EEC and/or Directive 2009/147/EC (Art. 2(3)).
- Determine, for projects listed in Annex II, which of them should be subject to EIA. This can be done through a case-by-case examination or by setting thresholds or criteria. In both cases, the Member States should take into account selection criteria defined in Annex III of the Directive (Art. 4).
- Ensure that the screening process is designed in a way which allows competent authorities to identify projects likely to have significant effects on the environment.
- Ensure that every EIA identifies, describes and assesses the direct and indirect effects of the project on the environmental factors listed in the Directive (Art. 3).
- Ensure that developers provide the competent authority with information relevant to the EIA procedures, including the information specified in Article 4 and Article 5 (Art. 4, Art. 5, Annex II.A and Annex IV).
- Ensure that the determination whether the project must be subject to environmental impact assessment or not is well justified and available to the public (Art. 4(5) and (6)).
- Ensure that the competent authority gives the developer an opinion on the information to be supplied, where such an opinion is requested (Art. 5(2)).
- Ensure that, if necessary, any authorities holding relevant information make this information available to the developer (Art. 5(4) and Annex IV).
- Ensure high quality of EIA reports (Art. 5(3)).
- Ensure the inclusion in the process of the relevant authorities and the concerned public both at national level and in transboundary relations (Arts. 6-8, 9,10 and 11).
- Ensure objectivity of the competent authorities when performing duties arising from this Directive (Art. 9a).
- Ensure that final decision to grant or refuse development consent are duly and fully justified (Art. 8 and 8a) and made available to the public (Art. 9(1)).
- Ensure the enforcement of the provision on environmental impact assessment (Art. 10a).
- Ensure post-EIA monitoring for projects with significant adverse effects (Art. 8(4)).

2.3 Consultation

- Where a project is subject to an EIA, ensure that the public, as well as the authorities likely to be concerned by the project due to their specific environmental responsibilities or local and regional competencies, are consulted on the request for development consent and on the information gathered in the assessment process (Art. 6).
- Member States shall define the detailed arrangements for information and consultation, including (Arts. 6 and 9):

the definition of the public concerned;

the methods used to inform the public of the onset of the procedure (notification);

the content of the notification;

the content of the information to be made available during the procedure;

the way the consultation will be carried out, including public hearing if appropriate; and

the time limits for the different stages of the procedure.

- Where a project subject to an EIA is likely to have a significant effect on the environment of another Member State, ensure that specified procedures are followed concerning information exchange, participation in the assessment procedure, and consultation in connection with all the decision-making procedures referred to in Article 2(2) of the Directive (Arts. 7 and 9).
- Ensure that the results of consultations, as well as the information gathered in the assessment process, are duly taken into account in the development consent procedure, which comes at the end of the process (Art. 8).
- After a decision has been made as to whether or not to grant development consent, ensure that the competent authority informs the public and the competent authorities referred to in Article 6(1) of that decision, together with the reasons for the decision and other specified information, including the summary of results of the consultations and how those results have been incorporated or addressed (Art. 9).
- In cases where the country is the affected country and was consulted by another Member State, it shall ensure that the information on the final decision is made available to the public concerned in an appropriate manner (Art. 9).
- If it is decided to exempt a specific project from the provisions of the Directive, consider whether another form of assessment would be appropriate. In this case, the public shall be informed about the exemption and the reasons for granting it. The information collected from the other form of assessment should be made available to the public (Art. 2(4)).

It should be stressed that the Articles 3 and 8 are of key importance relating to the "assessment" role of the competent authorities ensuring efficient application and adequate cooperation and coordination in case responsibilities are divided over two or more authorities (e.g. see C-50/09¹⁶).

¹⁶ In Case C-50/09, the court ruled on the importance of authorities sharing responsibilities for applying the EIA Directive to ensure a complete fulfilment of the requirements, avoiding overlaps and shortcomings. In this case, the Commission

2.4 Reporting/notification

The EIA Directive does not require reporting, but exchange of information including:

- exemptions from the Directive, granted in exceptional cases (Art. 2(4)).
- experience gained in applying the Directive (Art. 12);
- transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 13).

Every six years from 15 May 2017 MSs shall inform the Commission, where such data are available, of (Art. 12):

- the number of projects referred to in Annexes I and II made subject to an environmental impact assessment in accordance with Articles 5 to 10;
- the breakdown of environmental impact assessments according to the project categories set out in Annexes I and II;
- the number of projects referred to in Annex II made subject to a determination in accordance with Article 4(2);
- the average duration of the environmental impact assessment process;
- general estimates on the average direct costs of environmental impact assessments, including the impact from the application of this Directive to SMEs.

2.5 Additional Legal Instruments

The implementation of this Directive should be considered in conjunction with a number of other legal acts from the environmental acquis and international agreements. Firstly, the EIA is strongly related to the SEA Directive (2001/42/EC) on the assessment of the effects of certain plans and programmes on the environment. The purpose of the SEA Directive is to ensure that the environmental consequences of plans and programmes are identified and assessed before they are adopted. The public will be able to give its opinion on the plans and programmes, and all results are to be taken into account during the adoption procedure of the plans and programmes. SEA is intended to contribute to a more transparent decision-making system for planning and sustainable development, especially through the realisation of the principle of early participation when all options are still open.

Other examples of related legislation that need to be taken into account:

- Legislation concerning the authorisation and operation of installations:
 - Directive on Industrial Emissions (2010/75/EU).

stated that it had “concerns” relating to the precise manner in which duties on those different decision-makers, being Irish planning authorities and the EPA, are framed. In particular, it took the view that Irish legislation contains no obligation on decision-makers to coordinate with each other effectively

- Waste Directive (2008/98EC).
- Urban Waste Water Treatment Directive (91/271/EEC).
- Seveso III Directive (2012/18/EU).
- Directive 2009/31/EC on the geological storage of carbon dioxide.
- Legislation concerning the protection of habitats and species:
 - Birds Directive (2009/147/EC).
 - Habitats Directive (92/43/EEC).
- Legislation concerning water management and marine pollution:
 - Water Framework Directive (2000/60/EC)
 - Marine Strategy Directive (2008/56/EC).
- Legislation concerning consultation and access to information:
 - Directive on Access to Environmental Information (Directive 2003/4/EC).
 - Reporting Directive (91/692/EEC)
 - Directive on public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending, with regard to public participation and access to justice, (2003/35/EC).
- International conventions:
 - Convention on Environmental Impact Assessment in a Transboundary Context (the Espoo Convention), 1991.
 - Convention on Wetlands of International Importance Especially as Waterfowl Habitat (Ramsar Convention), 1971.
 - Convention on Biological Diversity, 1992.
 - Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters (Aarhus Convention), 1998.

3. IMPLEMENTATION

3.1 Key Tasks

Table 4. Environmental Impact Assessment Directive - Key Implementation Tasks

ENVIRONMENTAL IMPACT ASSESSMENT DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	<p>Establish/designate the competent authorities of first and second instance to be consulted under this Directive.</p> <p>Establish/designate the competent authorities for facilitating and managing the development consent procedure where coordinated or joint procedure are set up.</p> <p>Also, ensure adequate financial, human and technical resources for these authorities.</p>
1.2	<p>Consider whether to integrate EIA into existing consent procedures and whether to introduce a mechanism, a sort of EIA one-stop shop for assessments required under EIA and other EU legislation (except for Habitats and/or Wild Birds Directive where the obligation to establish coordinated and/or joint procedure is a mandatory requirement).</p> <p>In relation to this decision, determine the timing of the EIA procedure in the line of permitting procedures (siting, construction, usage etc.), taking into consideration that certain options (alternatives) shall still be open, while sufficient data shall be available for the decision-making.</p>
1.3	<p>Design the development consent system robustly so that an application for development consent is only evaluated once the developer has provided the required information. Consider the establishing of a list of facts in the event that development consent is refused (e.g. due to lack of convincing evidence of being able to comply with the relevant emission standards, or in the case of contradiction with the national, regional or local environmental, spatial planning etc. plans and programmes).</p>
1.4	<p>Adopt a concept of project, which is sufficiently large and in line with established CJEU case law providing a broad interpretation of the concept of 'project'. Even though „mobile installations” are not mentioned explicitly in the EIA Directive, the scope of the Directive also covers these as well as „temporary installations”. When mobile and/or temporary installations have the characteristics (and associated impacts) of project categories included in Annex I and II of the EIA Directive, they must be subject to its requirements. Furthermore, the definition of 'project' has been complemented by the Court, which concluded that “demolition works come within the scope of Directive 85/337 and, in that respect, may constitute a 'project' within the meaning of Article 1(2) thereof” (C-50/09, paragraphs 86-107).</p> <p>Guidance to CJEU law is available at: http://ec.europa.eu/environment/eia/pdf/eia_case_law.pdf</p>
1.5	<p>Determine whether to define Annex II projects that require an EIA:</p> <ul style="list-style-type: none"> • on a case-by-case basis; • by setting thresholds or criteria; • by combining the above procedures. <p>Where a case-by-case examination is carried out or thresholds or criteria are set for determining whether the project shall be made subject to an assessment, the relevant selection criteria set out in Annex III must be taken into account. In this process authorities can consult on screening methodology developed in the 2001 “Guidance on EIA- Screening”, available at: http://ec.europa.eu/environment/archives/eia/eia-guidelines/g-screening-full-text.pdf</p> <p>In applying the above the candidate countries should consult the relevant case-law relevant to Annex II projects. It is imperative to avoid using exclusion thresholds based exclusively on the size of a project as the likely environmental impact is of essence.</p> <p>For instance the CJEU case-law has addressed the issue of ‘salami-slicing’ i.e. the practice of splitting of territory, dividing the projects into sub-projects, stretching activities over time or doing several smaller rounds of project modifications so that each of these fall below screening thresholds or criteria and</p>

	therefore avoid the obligation to undergo an EIA (See cases C-142/07 and C-205/08). In case C-227/01, <i>Commission v Spain</i> , the Court confirmed that a long-distance project cannot be split up into successive shorter sections in order to exclude both the project as a whole and the sections resulting from that division from the requirements of the Directive (paragraph 53). A publication with reference to relevant cases: http://ec.europa.eu/environment/eia/pdf/eia_case_law.pdf
1.6	Develop a procedure for providing screening opinions to developers and informing the public and the concerned authorities.
1.7	Where relevant, define the thresholds or criteria for determining whether Annex II projects require an EIA, taking into account the selection criteria in Annex III of the Directive. Provide for the determination made by competent authorities to be made available to the public and for public opinion to be made available to the concerned authorities.
1.8	Determine procedure for advising developers on the scope of the EIA if so requested, and ensure that staff are suitably qualified to provide such advice. These protocols could refer to the "Guidance on EIA - Scoping", as approved by the European Commission.
1.9	Consider how environmental information provided by the developer will be reviewed and set up any special procedures for technical assistance from other authorities or independent organisations.
1.10	Determine the method for the selection of experts designated to prepare the EIA reports, with a view to ensuring their independence as far as possible. Also determine the minimum professional conditions (training, experience etc.) and discipline rules for experts taking part in preparing the EIA report or in the EIA procedure. Ensure that competent authority is equipped with sufficient human and financial resources to review the environmental impact assessment reports. Staff involved in reviewing the EIA report should have sufficient expertise to carry out this task.
1.11	If not already available, set up a system for collecting and assessing information on applications for development consent and environmental information received from developers.
1.12	Giving appropriate attention to Directive 2014/52/EU Give specific attention to the following topics: 1) new definitions; 2) special cases (exemptions); 3) coordinated or joint procedure (EIA one-stop shop); 4) additional environmental issues (climate change, disaster risks, etc.); 5) modification of Annex III and IV; 6) justification of negative screening decision; 7) quality control of the EIA information; 8) mandatory assessment of reasonable alternatives; 9) justification of final decision; 10) mandatory post-EIA monitoring for projects with significant adverse effects; 11) specific time-frame for public consultations; 12) maximum time-frame for decision making on screening.
2	Regulation
2.1	Implement procedures for the competent authority to review applications for development consent and environmental information to ensure that the EIA has been undertaken adequately and that the report includes all the information specified in the Directive.
2.2.	Implement a coordinated or joint administrative procedure to deal with requirements under the EIA and Habitats/Wild Birds Directive.
2.3	Member States must ensure that the other authorities likely to be concerned by the project by reason of their specific environmental responsibilities or local and regional competencies are given an opportunity to express their opinion on the application and information supplied by the developer. These authorities can be identified in general terms or on a case-by-case basis, or by a combination of the two methods (e.g. certain authorities, like public health, nature protection, catastrophe prevention etc. shall always be included, while others shall be included only when the subject of the case falls under their specific competences).
2.4	Ensure that, where relevant, consultations with Member States and their affected citizens/stakeholders are effective in implementing these parties' rights to participation under the Directive.

2.5	Ensure that any authorities holding relevant information make this information available to the developer (see Art. 5(4) of the EIA Directive).
2.6	Ensure that potentially significant environmental effects are being mitigated or prevented through post EIA-monitoring. The participation of the environmental authority in the latter stages of the permitting procedure is one possible solution.
2.7	Ensure effective enforcement. In this context also ensure that the public has a legal instrument at its disposal allowing third parties to challenge the legality of decisions. This right to have access to justice has been reinforced by the ECJ in the Djurgården (C-263/08) and the Trianel (C-115/09) rulings, in which the ECJ confirmed that the members public concerned are to have access to a review procedure.
3	Guidance and Training
3.1	Candidate countries should prepare and issue detailed guidance on the procedures to comply with the Directive and on the preparation of the environmental impact assessment report.
3.2	Candidate countries should provide training to staff in the competent authorities on EIA preparation and review. This should include detailed instruction in screening and scoping and review procedural methodologies in accordance with best EU practice.
4	Consultation
4.1	Identify the relevant bodies (environmental and other) to act as statutory consultees and establish procedures for consulting them.
4.2	Inform the public about any specific projects to be exempted from the EIA requirements.
4.3	Inform the public about applications for development consent requiring an EIA in their area, consultation during the EIA, and measures for reviewing and commenting on the environmental impact assessment.
4.4	Establish procedures with neighbouring Member States to exchange information and consult with them regarding projects with potential transboundary impacts.
4.5	Ensure that the competent authority (or authorities) takes into consideration the responses from the consultation process prior to making a decision on the application for development consent.
4.6	Notify the public of the outcome of decisions on applications for development consent.
5	Reporting
5.1	Although the EIA Directive does not require Member States to report information in the strict sense, it calls for exchange of information, mainly on the basis of Articles 2.3, 12 and 13 This includes: <ul style="list-style-type: none"> • informing the Commission of the reasons justifying exemptions from the Directive; • experience gained in applying the Directive; • communicating the transposition of the Directive.

3.2 Phasing Considerations

The most demanding and time-consuming tasks related to the implementation of this Directive are likely to be:

- Strengthening the institutional structures. This work may include:
 - staff recruitment to improve capacity, should the implementation of the Directive increase workloads, and the widening of specialist expertise to support the evaluation of environmental

reports, together with the possibility to establish multidisciplinary groups of officials that enable them to give their expertise to the evaluation of the environmental reports;

- staff training to improve capability and technical knowledge;
 - the extension of existing training curricula to include topics encouraging effective public participation;
 - the development of databases tracking the progress of individual projects;
 - the development of information technology to support access to environmental information related to EIA documentation and consultation procedures;
 - internal communication approaches to integrating other environmental acquis environmental standard-based requirements into EIA approval processes;
 - the installation or modification of computer systems for handling applications and improving communications;
 - changing and improving existing permitting procedures, taking into account the key issue of cross-references and procedural guarantees (e.g. introducing additional rules into the laws and regulations on construction permitting, for example that attaching an EIA development consent with full legal force is a condition for submitting a request for a permit).
- Preparing and disseminating information on the procedural requirements for EIA internally and on an inter-ministerial basis, this should ensure sufficient coordination and cooperation of ministries responsible for IED permitting, authorising infrastructural or other projects, or the geological storage of CO₂.
 - Plan and put into place structures and capacities to ensure effective coordination and consultation with other Member States' competent authorities, third parties, in regard to projects having cross-border effect.
 - Encouraging developers to make changes in the way they prepare applications for development consent. This will focus particularly on the preparation of EIA reports.
 - Preparing guidance notes to competent authorities, developers and the general public.
 - Ensuring public participation. Amongst other measures under this topic, regular trainings should be designed and offered to the leading environmental NGOs concerning the main substantial and procedural features of EIA in order to harness the role of these NGOs in mediating and supporting the concerned local communities and municipalities.
 - Fostering a market in EIA-related expertise so that it is available to the developer and other stakeholders, and perhaps to government authorities as well. Regular monitoring of the professional level and independence of these experts should be carried out in co-operation with the chambers of experts where appropriate.
 - Making the environmental information held by public authorities and institutions available to the public (see Directive 2003/4/EC).

4. IMPLEMENTATION GUIDANCE

The EIA Directive (2011/92/EU consolidating and repealing Directive 85/337/EEC as amended by 97/11/EC/EEC and Directive 2003/35/EC) has been around for almost 30 years and there is now considerable experience related to the implementation of this Directive throughout Member States.

Detailed procedural guidance on the main stages of EIA is set out in a number of publications, reports, studies and guidance all available on DG Environment's website:

Commission guidance document on streamlining environmental assessments conducted under Article 2(3) of the Environmental Impact Assessment Directive (Directive 2011/92/EU of the European Parliament and of the Council, as amended by Directive 2014/52/EU), available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2016:273:TOC>. The most recent guidance document published by the European Commission in July 2016 concerns streamlining environmental impact assessment procedure pursuant to Article 2(3) of the EIA Directive:

Guidance on the application of the EIA procedure for large-scale transboundary projects (16/05/2013), available at: <http://ec.europa.eu/environment/eia/pdf/Transboundary%20EIA%20Guide.pdf>

Guidance on integrating climate change and biodiversity into environmental impact assessment (03/2013), available at: <http://ec.europa.eu/environment/eia/pdf/EIA%20Guidance.pdf>

Interpretation of definitions of project categories of annex I and II of the EIA Directive (05/2015), available at: http://ec.europa.eu/environment/eia/pdf/cover_2015_en.pdf

"Guidance on EIA – Screening" (2001), available at <http://ec.europa.eu/environment/eia/eia-guidelines/g-screening-full-text.pdf>. This guidance also comprises a screening checklist available at: http://ec.europa.eu/environment/eia/eia-guidelines/screening_checklist.pdf

"Guidance on EIA – Scoping" (2001), available at: <http://ec.europa.eu/environment/eia/eia-guidelines/g-scoping-full-text.pdf>. This guidance comprises a scoping checklist available at: http://ec.europa.eu/environment/eia/eia-guidelines/scoping_checklist.pdf

"Guidance on EIA – EIS Review" (2001), available at: <http://ec.europa.eu/environment/eia/eia-guidelines/g-review-full-text.pdf>

"Guidelines for the Assessment of Indirect and Cumulative Impacts as well as Impact Interactions (1999)", available at: <http://ec.europa.eu/environment/eia/eia-studies-and-reports/guidel.pdf>

"Clarification of the Application of Article 2(3) of the EIA Directive", which deals with Article 2(4) (former 2(3)) of the 'EIA' Directive which provides that Member States may, in exceptional cases, exempt specific projects in whole, or in part, from the provisions of the Directive. This guidance is available at: http://ec.europa.eu/environment/eia/pdf/eia_art2_3.pdf

There are also a number of guidance focusing on certain project categories affected by the EIA Directive such as:

- Streamlining environmental assessments procedures for energy infrastructure Projects of Common Interest (PCIs) (24/07/2013), available at: http://ec.europa.eu/environment/eia/pdf/PCI_guidance.pdf
- Rehabilitation of landfills (2012) available at: http://ec.europa.eu/environment/eia/pdf/eia_landfills.pdf

- Interpretation suggested by the Commission as regards the application of the EIA Directive to ancillary/associated works (05/03/2012), which regarded the question whether a Finnish cement coating factory needed an EIA, available at: <http://ec.europa.eu/environment/eia/pdf/Note%20-%20Interpretation%20of%20Directive%2085-337-EEC.pdf>
- Further guidance from 2012 addressing projects related to the exploration and exploitation of unconventional hydrocarbon. This guidance is available at: <http://ec.europa.eu/environment/eia/pdf/Annexe%202.pdf.pdf>

Quite a few rulings of the European courts have concerned the application and interpretation of the EIA Directive. Among these rulings are also preliminary rulings where the national courts ask the European Courts for guidance on how to interpret certain provisions of a specific piece of legislation.

A compilation of such rulings is available at: http://ec.europa.eu/environment/eia/pdf/eia_case_law.pdf

In July 2009, the Commission published a report on the application and effectiveness of the EIA Directive¹⁷ (available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52009DC0378:EN:NOT>).

The report outlines the strengths of the EIA Directive, highlights the main areas where improvements are needed and provides recommendations, where relevant.

4.1 Planning

- Candidate countries could undertake a detailed review to identify the current development consents as well as permitting procedures for development consents and industrial pollution control permitting for industrial sites and processes. This review should also encompass existing overlaps between environmental assessments required by EU law, in particular as regards SEA Directive, Industrial Emissions Directive, Seveso III Directive, etc. In addition, the study could include an institutional assessment to examine the interrelationships between national, regional and local government, and other institutions or authorities involved in the control of land development and permitting procedures. It could also review staffing and office resources including office equipment, computers, databases and software systems for storage and dissemination of information. The survey should record any weaknesses in the current arrangements and propose appropriate follow-up steps.
- Candidate countries could develop databases tracking the progress of individual projects and keep them available on the Internet. This would allow all stakeholders to track the progress of projects that are subject to EIA procedures, thus facilitating their understanding of how to contribute strategically to the process while maintaining a check on competent authority efficiency in advancing project approval processes. This arrangement could prevent or mitigate criticism of the lengthy, complicated and expensive nature of the EIA procedures that is frequently raised by representatives of the developers who are not fully aware of the tasks and procedural steps of EIA, including procedural guarantees protecting the interests of the parties.
- Acquisition of information technology and strategic implementation should enhance access to environmental information related to EIA documentation and consultation procedures.

¹⁷(COM(2009)378).

- An internal communication strategy could be devised for integrating other environmental acquis environmental standard-based requirements into EIA approval processes.
- Candidate countries need to decide whether to develop a coordinated and/or joint administrative procedure to deal with environmental assessment requirements required under the EIA and other EU Directives, such as Water Framework Directive 2000/60/EC, SEA Directive 2001/42/EC, Directive on Waste 2008/98/EC, Industrial Emissions Directive 2010/75/EU and Seveso III Directive 2012/18/EU. In case of coordinated procedure various individual assessments of the environmental impact of a particular project, required by the relevant Union legislation, should be coordinated by the authority/ies designated for this purpose. On the other hand, under the joint procedure a single assessment of the environmental impact of a particular project required by the relevant Union legislation should be provided. In order to implement joint procedure candidate countries need to designate an authority responsible for performing the corresponding duties. In deciding this complex issue, a starting point could be the possible advantages in terms of administrative simplification and avoiding inconsistencies between different environmental assessments.
- Candidate countries could then draw up feasible alternatives for revising the permitting process, taking account of the existing situation, the permitting procedures set out in the EIA and other Union legislation, and the estimated numbers of development consents and their geographical distribution. Candidate countries should also consider how the new arrangements would affect the institutions involved, and prepare a plan for institutional strengthening to cover staff numbers, training, computers, financial budgets etc. The preferred approach for modifying or changing existing permitting procedures, including any changes to administrative arrangements, in order to address the EIA requirements imposed by the Directives should be developed and costed.
- Member States have followed two main alternatives for administrative arrangements —that is, centralised or decentralised land development control. Under centralised control, central government retains responsibility for the development and implementation of strategic land development policy and decides on development consents. Under decentralised control, central government usually retains responsibility for strategic land development, but the evaluation of development applications is undertaken by regional or local authorities. Some countries adopt a mixture of the two approaches, with central government deciding on development consents for major infrastructure projects such as transport infrastructure or power stations. The preferred approach will depend mainly on the existing institutional arrangements for granting development consents.
- Candidate countries have to decide which approach to take to determine whether Annex II projects require an EIA. The options are (a) a case-by-case examination; (b) by the definition of thresholds and criteria; or (c) by a combination of (a) and (b). All these approaches have to take into account the selection criteria given in Annex III of the Directive. In deciding whether to apply EIA to specific projects, competent authorities should also consider implementing the screening guidance methodology. The screening process addresses the specific task of determining whether an EIA is required for given projects. This could happen either upon notification by the developer of its intention to make a development consent application or upon the developer's request for a screening opinion from the competent authority. In some countries, after the screening decision there is an obligatory delay within which the developer cannot submit the request for development consent. This arrangement prevents the developer from rushing the process by preparing the environmental report, or parts of it, before the screening procedure. The developer is obliged to prepare the whole

environmental report after a positive screening decision, once they are fully aware of the requirements thereof.

- To prepare for project screening, the developer should be able to describe the relevant characteristics of the project and its likely significant effects on the environment. Minimum information to be supplied by the developer in the screening stage is regulated in Annex II.A.
- Once the screening process is complete, guidance on the scoping process should be given to parties, if requested by the developer. It should be noted, however, that in several countries screening and scoping take place in one procedural step. Although, as a rule, scoping is not a mandatory procedure, it is wise to make it a key methodological step so as to avoid mistakes and the loss of time in environmental impact study submissions. A further step can be to introduce mandatory scoping in accordance with the last sentence of Article 5(2) of the Directive. Subsequent implementation of the requirement of early public participation (Art. 6(2)) might make it necessary to ensure public participation in the screening/scoping procedure(s), although not mandatory under the EIA Directive.
- Developers can seek advice on the scope and content of the EIA from the competent authorities, who should ensure that their staff members are sufficiently trained in the EIA process to advise developers. Developers can usually also obtain guidance on the contents of the environmental impact report from the legislation, published literature and advisory institutions (see subsection Guidance and Access to Information below). Procedural principles such as transparency and accountability, and also the principle of fair procedure (an even-handed attitude towards all participants in the administrative procedure), make it necessary for all correspondence and discussions between the developer and the authorities to be accessible to the rest of the participants and to be duly documented.
- If the screening and scoping procedures have been adequately carried out, then the developer should be fully aware of the environmental information to be provided in the environmental impact report itself. This prevents the developer and other participants in the cases from wasting resources on unnecessary research and studies and enables them to focus on the most important environmental features of the planned activity. Thus the procedure should be designed to codify this objective.
- Further to the screening and scoping procedures is the imperative to prepare and disseminate the relevant information about the project to the competent authority in connection with the environmental impact report. This legal requirement should be legislated and planned through the development of an electronic database that standardises the information and makes it publicly accessible.
- As the EIA review and consultation procedures are necessary legal requirements, transparent and accountable consultation with statutory environmental authorities, other interested parties and the public is vital. The points of view expressed in these procedures must be considered in determining whether or not to grant development consent. Once a decision is taken it must be published with reasons and a description of the measures required to mitigate adverse environmental impacts. This will require detailed logging of opinions expressed and a methodology for incorporating them into decision-making processes. Bearing in mind the large amount of paperwork required, it would be preferable to use electronic communication and reporting tools as often as possible, perhaps by encouraging, e-mail and web usage to the maximum extent appropriate to the level of technology access among stakeholders.

- It is necessary to take account of the public participation and access to information procedures. The new and more detailed notification, information servicing and consultation rules require, in particular, greater scrutiny and careful planning efforts in terms of ensuring the proper institutional (including the necessary training and supervision), procedural and budgetary arrangements. In addition to these, the transposition of the provisions on access to justice requires wide-scale discussions with representatives of the judiciary and, as a result, the need for legal or practical changes might arise. Such changes might concern the procedural rules of the administrative court supervision of EIA cases and also the issuance of guideline from those organisations (e.g. the Supreme Court or a chief administrative tribunal) that are entitled to form the court practice.
- The national legislation should set out the procedures for appeals against the decision by the competent authority to require or not an EIA (although the Directive does not explicitly require this)¹⁸. The national legislation may also decide that only a negative decision (ceasing the procedure) can be subject to appeal procedures, while positive ones are not (since a legal remedy will be available at the end of the substantial procedure).
- Member States may exempt specific projects from the provisions of the Directive under exceptional circumstances. These are likely to be projects to which special security and strategic considerations (e.g. response to civil emergencies) apply.

Alternative procedures for Annex II projects

A number of Member States (e.g. Austria, Denmark, Sweden, Italy, Greece) have adopted alternative procedures for Annex II projects, mainly for small-scale activities and projects, which are often carried out by SMEs. Prior to or during the screening process, the developer modifies the project at an early stage to reduce any negative impacts; hence an EIA is not needed. Moreover, during the screening stage, if it appears that a project impacts on a few environmental media and appropriate solutions are identified to avoid or mitigate such effects, an EIA will not be required. For instance, in Denmark, almost 50 % of projects are changed as a result of this process.

Source: European Commission (2012) Commission Staff Working Paper Impact Assessment accompanying document Proposal for a Directive of the European Parliament and of the Council amending Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52012SC0355>

¹⁸ See recent ruling of the CJEU in a case C-570/13 Gruber (ECLI:EU:C:2015:231) where the Court concluded that an administrative decision not to carry out an EIA taken on the basis of national legislation cannot prevent an individual, who is part of the ‘public concerned’ within the meaning of the directive and satisfies the criteria laid down in national law regarding ‘sufficient interest’ or, as the case may be, ‘impairment of a right’, from contesting that administrative decision in an action brought against either that decision, or against a subsequent development consent decision. The CJEU confirmed that Member States dispose of a wide margin of discretion when implementing Art 11 of the EIA Directive. However, it underlined that this discretion is limited by the need to respect the objective of ensuring wide access to justice for the public concerned, expressed in Art 11(3) EIA Directive and Art 9(2) Aarhus Convention.

Application of one-stop shop

Austria

Austria has introduced an integrated one-stop shop approach, which combines the assessment and permit requirements of the EIA, the Industrial Emissions Directive, the Habitats Directive and the national legislation on water, air and waste licensing, etc. The SEA Directive is not part of this process, as SEAs are seen to be part of the responsibility of planning authorities, not permitting ones.

Regional agencies are responsible for an integrated assessment and permitting procedure in each of the nine regions. These provisional authorities correspond to the regional tier of a system including also a national and a regional tier. In this integrated procedure, the EIA has been combined with the IED, the Habitats Directive, the national legislation on water, air and waste licensing, etc. However, EIAs for federal roads and railways are not part of this consolidated process but dealt with by the Ministry of Transport. In this integrated approach, the developer only needs to fill in one application for all permits with the possibility of assistance from the provisional authority, even in the form of meetings.

Source: European Commission (2012) Commission Staff Working Paper Impact Assessment accompanying document Proposal for a Directive of the European Parliament and of the Council amending Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52012SC0355>

Due Consideration of Public Comments

Hungary: According to the regulation of Hungary, the reasoning part of both the screening/scoping and the final decision shall contain a detailed evaluation of the comments from members of the public and public organisations, including the municipality councils on the territory affected by the planned project. This evaluation shall comprise three parts: a factual, a professional and a legal analysis of the comments. This legal arrangement ensures the detailed consideration of the public input and a satisfactory explanation to members of the public and public organisations, even if the decision-making authority does not share their opinion. Finally, the formal structure of the evaluation of public comments makes the administrative and court remedies simpler and more focused.

Examples of Approaches in Implementing Requirements Relating to Annex II Projects

In a study of the implementation of the EIA Directive in the „old” 12 EU Member States, only three

Member States had adopted a single approach to deciding whether Annex II projects require an EIA. Two Member States adopted the thresholds approach (AT and IE), and one adopted an approach based on general criteria (SE). The remainder adopted a combined approach. Five of the Member States also decided to assess the need for an EIA for Annex II projects on a case-by-case basis. Further examples:

UK adopted a combined approach to identifying Annex II projects requiring an EIA. Certain projects will always require an EIA, namely Annex I projects and development applications in Sites of Special Scientific Interest (SSSIs), World Heritage sites, scheduled ancient monuments, national parks and areas of outstanding natural beauty that are designated as such under national legislation for nature conservation, landscape protection and cultural heritage reasons. EIAs will not be required for projects that do not meet the screening criteria. Those projects for which an EIA may be required will be examined on a case-by-case basis, by applying general criteria and indicative thresholds. The general criteria are whether a project is (i) of more than local importance; (ii) in a particularly sensitive location; or (iii) involves particularly complex environmental effects. Indicative thresholds are being prepared for specified types of projects. In exceptional cases, the competent ministry retains the power to require an EIA for a project that does not meet the screening criteria.

Portugal adopted the threshold approach to determine whether a project should be subject to an EIA. The competent authority for transposing and implementing the new EIA Directive, the Directorate General of the Environment, consulted with other government entities and interested parties from various sectors (e.g. industrial and agricultural associations) to determine the nature of the thresholds. In order to minimise the likelihood of unfair competition between projects in Member States, they then compared their threshold criteria with those adopted in two other Member States (ES and FR) before reaching a final decision.

In Romania, the competent authority uses a combination of thresholds, a methodology for determining "significant environmental impacts" and the project screening process prescribed in the Commission's 2001 "Guidance on EIA - Screening". This selection process is based, in part, on a review of best practices among Member States and a conscious decision to apply the Commission's guidance, based on the understanding that this would become the state of the art with respect to screening methodologies. The process also allows developers to seek screening opinions from the competent authority. The basis of the competent authority opinion on whether a project should be subject to EIA must be stated with reasons.

4.2 Regulation

- Responsibility for undertaking and/or paying for the EIA and the environmental impact report lies with the developer, who may decide to undertake the work in-house, or, as happens in many cases, to subcontract the EIA and the preparation of the report to specialist consultants. This arrangement, however, results in EIAs that may, to a certain extent, be biased (non-objective). It is often difficult to trace back and amend this in material up to several thousands of pages long. Another important aspect to be addressed is reinforcing the quality of the EIA reports. Two main possibilities should be considered here: use of accredited consultants or a creation of a quality control committee; these two possibilities may be implemented simultaneously. The use of accredited consultants to prepare or to verify EIA reports appears to be easiest way to address the quality issues. However, this option requires an accreditation process to be put in place (developing accreditation criteria, including provisions on duration of its validity, cancellation criteria, etc.). Another, more complex option, entails creating separate body responsible for quality control and providing expert advice to the competent authority before this authority issues its final decision. Members of this advisory body may be drawn from the competent authorities with the participation of independent external experts.

Countries may also consider an option to design systems where the preparation of the EIA is not the task of the developer, who remains responsible for providing information about the planned project and who pays for the work of the independent experts. Such experts can be either hired by the environmental authorities on a case-by-case basis or employed by them. Guarantees of transparency and accountability shall also be developed in such systems.

- Competent authorities required to review EIAs may need to seek technical expertise and assistance from other government bodies (such as the ministry with environmental protection responsibilities if it is not the main decision-making body). Co-ordination of technical expertise between the competent authority and other authorities with environmental responsibilities is important in order to ensure that EIAs are adequately reviewed (see also the subsection Consultation below).
- The competent authority should ensure that, where relevant, consultations with Member States and their affected citizens/stakeholders are directly effective in implementing these parties' rights to participation under the Directive. While it is the responsibility of the potentially affected neighbouring state to ensure that its affected people are given consultation opportunities, this should be checked by the state initiating the EIA procedures. Such a check can be performed by a simple exchange of letters or other form of confirmation. The consultations concerning possible transboundary effects and measures envisaged to eliminate and reduce such effects may be conducted through an appropriate joint body.
- The EIA Directive requires competent authorities to publicise the conditions attached to successful applications for development consents and the measures required to mitigate the environmental effects of the development, including monitoring measures. Monitoring requirements for developers are to be set by the competent authorities and defined in the development consent. Developers and/or project operators will only be required to monitor the significant adverse environmental impacts of projects identified during the EIA process, once projects are implemented; they will be required to evaluate the results and take any measures required to correct deviations from the expected effects

The monitoring procedure (parameters, frequency, methods, etc.) will be specified by the competent authority. Monitoring results should also be evaluated by the competent authorities (e.g. during random inspections) and any remedial action considered necessary should be imposed to the developer of the project. Governments need to ensure that the competent authorities have the legal powers to enter sites, stop construction and possibly remove structures where developers have not complied with the permit conditions.

- Penalties for breaches of the national provisions on EIA need to be set. Countries are free to decide the kind or form of those penalties (e.g. administrative sanctions, fines) provided that the penalties imposed are effective, proportionate and dissuasive.
- Countries must ensure “wide access to justice” by ensuring that the public has a legal instrument at its disposal that allows third parties to challenge the legality of decisions made by the authorities. In developing rules for access to justice related to EIA procedure countries should bear in mind jurisprudence of the *Djurgarden* (C-263/08) and *Trianel* (C-115/09) rulings. Thus, in the *Trianel* case the Court concluded that the environmental NGOs have standing right of their own to challenge decisions according to rules in national laws implementing EU environmental law, as well as provisions under that EU law having direct effect. In *Djurgarden* case the Court ruled that when defining rules for NGOs standing use of numerical criterion for the minimum of members is allowed, but only in order to ensure that NGOs does in fact exist and is still active. The most common criteria for NGOs standing are requirements for registration, length of existence or activity and its non-profit organisation character. When using time criterion, countries may be guided by provision of the Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies which requires NGOs to have been active for at least two years to have standing in the CJEU. Another important judgement is the *Altrip* case (C-72/12), where the Court made clear that the public must be able to invoke any procedural defect in support of an action challenging the legality of decision, unless it can be clearly established that the contested decision would not have been different without the procedural defect invoked.

Examples for ensuring high quality of EIA information- national committee

France: An environmental authority (“Autorité Environnementale”) was created in 2009 to provide advice on the quality of certain EIA reports, when the project/programme developer is the Ministry of the Environment or a public organisation under its supervision (e.g. large infrastructure projects) or when the final decision is taken by the Ministry itself (e.g. nuclear installations). The main purpose of this measure was to provide a guarantee for impartiality but also a guarantee for quality and transparency towards the public. This authority includes 17 persons, 12 of which are part of the evaluation services of the Ministry of the Environment (CGEDD) and 5 are external qualified experts.

Netherlands: A specific agency, the Netherlands Commission for Environmental Assessment (NCEA), which is independent from the Ministry of Environment, provides advice to the competent authority on the quality of EIA reports, upon request from the competent authority. The NCEA is composed of a pool of 700 experts, working for governmental organisations, research institutes or universities and private companies. They are hired on a project-by-project base. For every EIA/SEA, a working group is created, usually counting 3-6 experts. The Commission for EIA is lump sum funded by central government.

Environmental Supervision - A Legal Tool for the Systematic Analysis of Existing Facilities

Hungary: In Hungary there is a legal institution that the environmental authorities can use when they experience that:

- a facility subject to EIA is being operated without an environmental permit (because of failure to request one, even though the law prescribed it, or because, due to changes in the legal situation or changes in the practical situation, the project has become subject to EIA);
- the validity of the environmental permit has expired;
- significant changes have occurred in the operation of a facility that otherwise possesses a valid environmental permit;
- a facility damages or seriously endangers the environment

Example of the EIA Process

Portugal: In Portugal, the developer submits their proposal for the project, including the environmental impact report, to the appropriate government sector body, for example the Directorate General for Energy for power generation projects; or the Directorate General for Transport for road projects. This body retains responsibility for the evaluation and overall approval of the proposal, but sends the proposal and environmental impact report to the Ministry of Environment.

The competent authority for evaluating the environmental impact report is either the Directorate General for the Environment of the ministry (DGA) itself or one of the regional directorates for the environment (DRARNs), depending on whether the proposal is for a national (Annex I) or regional (Annex III) project (annex numbers refer to the national legislation and not the Directive). For Annex I projects, the DGA nominates and co-ordinates an evaluation commission composed of its own representatives and also the Institute for Nature Conservation (ICN), the National Institute for Water (INAG) and the Institute for Environmental Promotion (IPAMB).

Regarding Annex III projects, the DGA nominates the DRARN to be in charge of co-ordinating the respective evaluation commission. The DGA and the DRARNs are supported by the IPAMB, which makes arrangements for public consultation. The Evaluation Commission's decision, in both cases, is made available to the appropriate ministry but is not binding. However, a ministry's decision not to comply must be justified and impact mitigation measures, proposed by the evaluation commission, must be undertaken. Final approval of the proposal requires consent by the minister of environment (which is binding, contrary to the proposal of the Evaluation Commission) and the other relevant sector entity. For major projects, such as large infrastructure or dams, a regulation commission may be nominated by the minister of environment, comprising representatives from the DGA, INAG and ICN, to control and supervise the implementation of the project. The requirement to nominate a regulation commission will be mandatory under the new legislation.

The DGA maintains a database with a standard entry form for Annex I and III projects that is used as a tool for monitoring the process of evaluation and approval of projects subject to an EIA. The DGA is currently revising the form and database to include an "Observations" field to summarise any impacts and the measures proposed to minimise them. Some 80 environmental impact reports are produced each year.

4.3 Guidance and Training

- The range of technical skills required for preparing and reviewing EIAs is diverse and can include specialisation in visual and landscape assessment, noise and vibration, air quality, contaminated land remediation, waste disposal, water resources and hydrology, ecology, traffic impact assessment, archaeology and socio-economics. This potentially poses problems for developers in ensuring that the EIA is carried out to an appropriate standard, and for the competent authorities who have to evaluate the EIA presented by the developer. This is why steps should be taken to ensure that a viable market for professional EIA expertise exists in the relevant candidate country.
- There is a strong case for including in the programme for implementation the effective education and training of administrators in the competent authorities. This should include training in EIA screening, scoping and review procedures.
- Various organisations prepare guidance on the EIA permitting system and the preparation of EIA reports. The European Commission has published various guidance documents. Central governments often produce guidance on the requirements of the national legislation, advice on permitting procedures, best-practice guidelines for preparing an EIA, methodologies for assessing environmental impacts, advice on the preparation of environmental impact reports, and guidelines on public consultation procedures. Professional bodies in the construction and environmental sectors often provide guidance to their members. Research institutes and universities also undertake studies, for example on developing impact assessment methodologies.
- A number of Member States have EIA centres, which are active in providing support on the carrying out of EIAs. They all offer training on various aspects of EIAs.
- Some Member States have adopted obligatory or voluntary schemes to control the quality of environmental impact reports.

Example of Training on EIA

Portugal: In Portugal, the Directorate General for Environment (DGA) ran workshops on the requirements for bodies interested in preparing EIAs immediately after the transposition of the Directive into national legislation. The DGA has issued guidance materials to the relevant government sectors for dissemination to developers interested in proposing projects and to bodies within that sector, and has published a booklet on the evaluation of impact assessments every three months since April 1999.

The Netherlands: In the Netherlands, a statutory EIA commission provides advice, for example on the treatment of alternatives to the proposal, scoping, the review of environmental reports and the monitoring of the impacts of the construction and operation of projects. In the UK, the Institute for Environmental Assessment accredits consultancies for undertaking EIAs, publishes guidelines on EIA methodologies, and reviews environmental impact reports. The Institute raises revenue from membership subscriptions and fees for services provided.

4.4 Consultation

- Member States have to set up procedures to ensure that authorities that may have an interest in a project due to their environmental responsibilities or local and regional competencies are given an opportunity to express their opinion on the information supplied by the developer and on the request for development consent.
- Member States have to designate those authorities in general terms or on a case-by-case basis, and must set out detailed arrangements for access to information and consultation. The same applies to states affected by potentially significant transboundary environmental impacts.
- The EIA Directive does not specify the maximum duration of consultation periods with statutory consultees, whereas the time-frame for consulting the public concerned on the EIA report may not be shorter than 30 days. The maximum period allowed to competent authorities to reach a decision on the application for development consent is not determined either. Thus, the Member States may set deadlines and time limits for these activities within their national legislation, or may make such recommendations in government guidance, in order to avoid extensive delays in reaching a decision on development consent.
- In designing the EIA procedure, consideration should be given to parallel rather than consecutive procedural steps (e.g. the decision-making body, the co-operating authorities and members of the public and public organisations can study the EIA report at the same time).
- Information on the development consent, the decision to require an EIA, and environmental impact assessment reports has to be made available to the public. This may be done through announcements in the press and through the Internet, as well as by placing the relevant information on a register of applications for development consents. In addition to these methodological solutions, municipalities can play an important mediatory role in forwarding information to and from the concerned local communities.
- Relevant information concerning the arrangements for informing the public and for consulting the public concerned must be electronically accessible to the public, through at least a central portal or easily accessible points of access, at the appropriate administrative level.
- Public access to information is more easily achieved where the development consent is processed in the region or the locality where the development is planned to take place. In this case, consideration should be given to the de-centralisation of EIA-related information sources (i.e., they should be provided both in hard copy and by electronic means). Sub-national government offices may wish to have their own Internet sites for distributing EIA-project information.
- Developers have different approaches to making information available to the public. The most common approach is to deposit the EIA report at one or more key sites accessible to the public in the affected area (for example at the office of the competent authority, or at a local library or school) and to inform the public about the opportunity to view the EIA via announcements in the press. Where the developer decides to put on a public exhibition, or consult with local groups, they may make one or more copies of the EIA report available for inspection for a limited period.
- It is usually too expensive to reproduce EIA reports in large numbers, which precludes their wide circulation to the general public. Developers can disseminate information about the project more

widely to the general public by preparing a separate leaflet containing a non-technical summary for distribution at public exhibitions, for delivery to properties in the area affected by the proposals etc.

- Certain types of projects, for example projects affecting downstream river flow or quality, port developments, or industrial and power developments, may impact upon neighbouring countries. The impact is not determined exclusively by physical distance from the border, although the general practice among countries shows that planned installations within a 10 to 50 km zone from the border usually trigger at least the first phases of transboundary EIA procedures. Candidate countries need to set up protocols to facilitate the exchange of information and the involvement of the neighbouring state in the consultation process. Candidate countries may need to involve their ministries with responsibilities for foreign affairs in this aspect of implementing the Directive, or appoint a joint body to facilitate consultations in a transboundary context.

Example of Arrangements for Consultation as Part of the EIA Process

United Kingdom: here the implementing legislation identifies the statutory consultees who have to be consulted by the competent authority responsible for the permitting procedures prior to reaching a decision on the development application. The statutory consultees reflect the range of potential environmental concerns and include government departments responsible for the environment and transport; the national body responsible for health and safety; the national environment agency; and organisations concerned with the conservation of the countryside, nature, and cultural heritage.

In the UK, notices of applications for development consent are published weekly in local newspapers. Applications can be viewed at the office of the local planning authority, and fluorescent posters are displayed either at, or in the vicinity of, the proposed development site to attract people's attention. During the course of the EIA, the developer may make arrangements for the dissemination of information about the project through leaflets distributed to the local community, meetings with individuals and local groups, and public meetings. Once the EIA has been completed, the planning authority publishes a notice in the local newspapers (at the developer's expense) explaining where the environmental report can be reviewed. Members of the public can submit an objection to the planning authority which is then responsible for deciding whether to approve the application for development consent. Alternatively, the secretary of state may call for an application to be subject to a public inquiry.

Portugal: the Institute for Environmental Promotion (IPAMB) was appointed the Competent Authority tasked to organise public consultations during the evaluation of the proposal. The developer has to bear the costs of the public consultation and notification, which are specifically regulated by the law. Public meetings are mandatory for national projects and meetings at several locations may be required for projects that cover a large geographical area, for example motorways and pipelines. For regional projects, the requirement to hold public meetings depends on the level of public interest. The IPAMB also disseminates information about the proposed project through the local, regional and national press, letters to municipalities, NGOs and the Internet. The IPAMB also informs the public of the decision on the application for development consent through these media. Records taken at public meetings and correspondence from interested parties are used to identify any individuals or organisations to which specific information should be sent directly. The effective dissemination of information about proposed projects is essential in order to ensure the adequate participation of the public and other interested parties. Experience in this Member State has shown that the consultation process also benefits the competent body by providing local information that it might not otherwise obtain.

Example of fundamental principles as laid down by the Court of Justice of the European Union (former European Court of Justice)

1. The purpose of the EIA Directive

In rulings related to the EIA Directive, the Court has consistently emphasised the fundamental purpose of the Directive as expressed in Article 2(1), i.e. those projects ‘likely to have significant effects on the environment by virtue, *inter alia*, of their nature, size or location are made subject to a requirement for development consent and an assessment with regard to their effects’.

2. Interpreting the project categories set out in the annexes

CJEU has held that ‘the Directive has a wide scope and a broad purpose’ (for example in case C-72/95, *Kraaijeveld and others*, paragraph 31; case C-227/01, *Commission v Spain*).

3. Uniform interpretation, different language versions

In case C-72/95, *Kraaijeveld and others*, referring to previous case-law the Court held that the interpretation of a provision of EU law involves a comparison of the language versions. Where these versions diverge, the need for a uniform interpretation requires that the provision in question be interpreted by reference to the purpose and general scheme of the rules of which it forms part (paragraph 28). This issue is again referred to in the Court’s ruling in case C-227/01, *Commission v Spain*.

4. Exclusion of salami-slicing (project splitting)

In case C-227/01, *Commission v Spain*, the Court confirmed that a long-distance project cannot be split up into successive shorter sections in order to exclude both the project as a whole and the sections resulting from that division from the requirements of the Directive (paragraph 53). If that were possible, the effectiveness of the Directive could be seriously compromised, since the authorities concerned would need only to split up a long-distance project into successive shorter sections in order to exclude it from the requirements of the Directive.

5. The concept of ‘project’

The jurisprudence of the European Court of Justice provides a broad interpretation of the concept of ‘project’. The term ‘project’ refers to works and physical interventions (C-2/07, *Abraham and Others*, C-275/09, *Brussels Hoofdstedelijk Gewest and Others*). The term ‘installation’ is not defined in the EIA Directive. The definition of this term in the IED Directive is not appropriate for the purposes of the EIA Directive.

Even though mobile installations are not mentioned explicitly in the EIA Directive, the scope of the Directive also covers these as well as temporary installations. Furthermore, when a mobile installation is moved elsewhere, the need for a new EIA has to be considered. Interpretation of the definition “project” was subject to several rulings of the CJEU. Thus, the term ‘project’ refers to works and physical interventions in Article 1(2) of Directive 85/337 as confirmed in the cases C-2/07 *Abraham and Others* and C-275/09, *Brussels Hoofdstedelijk Gewest and Others*.

In its case-law, the Court has given a broad interpretation of the concept of ‘construction’, accepting that works for the refurbishment of an existing road may be equivalent, due to their size and the manner in which they are carried out, to the construction of a new road (Case C-142/07 *Ecologistas en Acción-CODA* [2008] ECR I-6097, paragraph 36). Similarly, the Court has interpreted point 13 of Annex II, read in conjunction with point 7 of Annex I, to Directive 85/337 as also encompassing works to alter the infrastructure of an existing airport, without extension of the runway, where they may be regarded, in particular because of their nature, extent and characteristics, as an alteration of the airport itself (*Abraham and Others*, paragraph 40).

In the case C-121/11, *Pro-Braine and Others* the Court concluded that the definitive decision relating to the carrying on of operations at an existing landfill site, taken on the basis of a conditioning plan, pursuant to Article 14(b) of Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste, does not constitute a ‘consent’ within the meaning of Article 1(2) of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, as amended by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003, unless that decision authorises

a change to or extension of that installation or site, through works or interventions involving alterations to its physical aspect, which may have significant adverse effects on the environment within the meaning of point 13 of Annex II to Directive 85/337, and thus constitute a 'project' within the meaning of Article 1(2) of that Directive.

The renewal of an existing permit (to operate an airport) cannot, in the absence of any works or interventions involving alterations to the physical aspect of the site, be classified as a 'project' within the meaning of the second indent of Article 1(2) of Directive 85/337 (C-275/09, Brussels Hoofdstedelijk Gewest and Others, paragraph 24; C-121/11, Pro-Braine and Others, paragraph 31).

The ruling of the Court (Case C-50/09) established that the demolition works come within the scope of the Directive and may constitute a 'project' within the meaning of Article 1(2).

Source: European Commission publication: „Interpretation of definitions of certain project categories of annex I and II of the EIA Directive”, 2015, http://ec.europa.eu/environment/eia/pdf/cover_2015_en.pdf and Compilation of the rulings on EIA of the CJEU, http://ec.europa.eu/environment/eia/pdf/eia_case_law.pdf

Court of Justice of the European Union (CJEU)-Case Law

Relevant Jurisprudence of the CJEU concerning Standing

1) Case C-115/09, REFERENCE for a preliminary ruling Bund für Umwelt und Naturschutz Deutschland, Landesverband Nordrhein Westfalen eV V Bezirksregierung Arnsberg, intervening party: Trianel Kohlekraftwerk Lünen GmbH & Co. KG

Background: Trianel – the intervener in the main proceedings – intends to construct and operate a coal-fired power station in Lünen. Within eight kilometers of the project site, there are five areas designated as special areas of conservation within the meaning of the Habitats Directive. A preliminary decision and a partial permit for the project by the CA, NGO challenged this based on the Habitats Directive. The German law provided standing only in cases where individual rights are infringed, which was found by the national court not to be the case.

Operative part of the judgment:

Article 10a of Directive 85/337/EEC precludes legislation which does not permit NGOs promoting environmental protection for the purposes of Article 2(1) of that Directive to rely before the courts, in an action contesting a decision authorising projects 'likely to have significant effects on the environment' for the purposes of Article 1(1) of Directive 85/337, on the infringement of a rule flowing from EU environment law and intended to protect the environment, on the ground that that rule protects only the interests of the general public and not the interests of individuals. Such a NGO can derive, from the last sentence of the third paragraph of Article 10a of Directive 85/337, the right to rely before the courts, in an action contesting a decision authorising projects 'likely to have significant effects on the environment' for the purposes of Article 1(1) of Directive 85/337, as amended, on the infringement of the rules of national law flowing from Article 6 of Directive 92/43/EC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, even where, on the ground that the rules relied on protect only the interests of the general public and not the interests of individuals, national procedural law does not permit this.

2) Joined Cases C-128/09 to C-131/09, C-134/09 and C-135/09, REFERENCES for a preliminary ruling from the Conseil d'État (Belgium), Boxus-case

Background:

The references have been made in the course of proceedings brought by persons living near Liège-Bierset and Brussels South Charleroi airports and the Brussels to Charleroi railway line against the Région wallonne (Walloon Region) concerning consents for works granted in respect of those installations. The Conseil d'État had six proceedings before it that challenged a series of consents and authorisations adopted by the competent administrative authorities concerning the carrying out of works or the operation of installations in connection with those airports and transport links to them. In the proceedings before the referring court, the applicants argued that, since an act of a legislative nature has replaced the contested administrative acts and that legislative act can be challenged only before the Cour constitutionnelle, the effect of the adoption is to deprive them of effective remedies, as required by the Directive.

Operative part of the judgment:

Article 1(5) of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, as amended by Directive 2003/35/EC must be interpreted as meaning that only projects the details of which have been adopted by a specific legislative act, in such a way that the objectives of that Directive have been achieved by the legislative process, are excluded from the Directive's scope. It is for the national court to verify that those two conditions have been satisfied, taking account both of the content of the legislative act adopted and of the entire legislative process which led to its adoption, in particular the preparatory documents and parliamentary debates. In that regard, a legislative act which does no more than simply 'ratify' a pre-existing administrative act, by merely referring to overriding reasons in the general interest without a substantive legislative process enabling those conditions to be fulfilled having first been commenced, cannot be regarded as a specific legislative act for the purposes of that provision and is therefore not sufficient to exclude a project from the scope of Directive 85/337, as amended by Directive 2003/35.

Article 9(2) of the Convention on access to information, public participation in decision making and access to justice in environmental matters, concluded on 25 June 1998 and approved on behalf of the EU by Council Decision 2005/370/EC of 17 February 2005, and Article 10a of Directive 85/337, as amended by Directive 2003/35, must be interpreted as meaning that:

- when a project falling within the scope of those provisions is adopted by a legislative act, the question whether that legislative act satisfies the conditions laid down in Article 1(5) of that Directive must be capable of being submitted, under the national procedural rules, to a court of law or an independent and impartial body established by law;
- if no review procedure of the nature and scope set out above were available in respect of such an act, any national court before which an action falling within its jurisdiction is brought would have the task of carrying out the review described in the previous indent and, as the case may be, drawing the necessary conclusions by disapplying that legislative act.

3) Case C-182/10 Judgment of the Court – on a reference for a preliminary ruling from the Cour constitutionnelle (Belgium)) - Marie-Noëlle Solvay and Others v Région wallonne

Background: Before the Cour constitutionnelle a number of actions were seeking annulment of the decree of the Walloon Parliament of 17 July 2008 which 'ratified' the building consents for various works relating to Liège-Bierset airport, Brussels South Charleroi airport and the Brussels-Charleroi railway, that is to say, authorised them in view of 'overriding reasons in the public interest'. In each of the cases, the Cour constitutionnelle is asked *inter alia* to rule on whether it was possible for the contested decree to withdraw the consents in question from review by the Conseil d'État and subject them to review by the Cour constitutionnelle, even though the possibilities of review before that court are less extensive than before the Conseil d'État. By so doing, the legislature is said to have infringed the Belgian Constitution, read in conjunction with Article 9(2) to (4) of the Aarhus Convention and Article 10a of Directive 85/337.

Main elements of the reference: Whether a procedure leading to the granting of consents which can be challenged only by an action brought before the Cour constitutionnelle and the ordinary courts is compatible with the Convention and with EU law.

Operative part of the judgment

For the interpretation of Articles 2(2) and 9(4) of the Convention on access to information, public participation in decision-making and access to justice in environmental matters, it is permissible to take the Implementation Guide for that Convention into consideration, although it has no binding force and does not have the normative effect of the provisions of that Convention.

Article 2(2) of the Convention on access to information, public participation in decision-making and access to justice in environmental matters and Article 1(5) of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, as amended by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003, must be interpreted as meaning that only projects the details of which have been adopted by a specific legislative act, in such a way that the objectives of the Convention and the Directive have been achieved by the legislative process, are excluded from the scope of those instruments. It is for the national court to verify that those two conditions have been satisfied, taking account both of the content of the legislative act adopted and of the entire legislative process which led to its adoption, in particular the preparatory documents and parliamentary debates. In that regard, a legislative act which does no more than simply 'ratify' a pre-existing administrative act, by merely referring to overriding reasons in the public interest without a substantive legislative process enabling those conditions to be fulfilled having first been commenced, cannot be regarded as a specific act of legislation within the meaning of the latter provision and is therefore not sufficient to exclude a project from the scope of that Convention and that Directive as amended.

Articles 3(9) and 9(2) to (4) of the Convention on access to information, public participation in decision-making and access to justice in environmental matters and Article 10a of Directive 85/337, as amended by Directive 2003/35, must be interpreted as meaning that:

- when a project falling within the scope of those provisions is adopted by a legislative act, the question whether that legislative act satisfies the conditions laid down in Article 1(5) of that Directive as amended must be capable of being submitted, under the national procedural rules, to a court of law or an independent and impartial body established by law, and
- if no review procedure of the nature and scope set out above were available in respect of such an act, any national court before which an action falling within its jurisdiction is brought would have the task of carrying out the review described in the previous indent and, as the case may be, drawing the necessary conclusions by disapplying that legislative act.

Article 6(9) of the Convention on access to information, public participation in decision-making and access to justice in environmental matters and Article 9(1) of Directive 85/337, as amended by Directive 2003/35, must be interpreted as not requiring that the decision should itself contain the reasons for the competent authority's decision that it was necessary. However, if an interested party so requests, the competent authority is obliged to communicate to him the reasons for that decision or the relevant information and documents in response to the request made.

4) Case C 263/08, REFERENCE for a preliminary ruling, Djurgården-Lilla Värtans Miljöskyddsförening

Background:

The Municipality of Stockholm concluded a contract with an electricity company for the construction of a tunnel approximately one kilometre in length through the hills of Sweden in order to house electric cables replacing overground high tension cables. The implementation of that project required, first, works on

abstraction on groundwater. Decision delivered by the Stockholm Regional Authority, concluded, on the basis of the environmental impact assessment carried out for that project, that the works concerned were likely to have significant effects on the environment particularly with respect to groundwater. Judgment of Environmental Chamber of the District Court of Stockholm granted the Municipality of Stockholm development consent to carry out the works at issue. Swedish environmental NGO appealed the decision, but it was not granted standing and appeal was held to be inadmissible on the ground that the NGO (Miljöskyddsförening) had not fulfilled the condition laid down in the Environmental Act that it must have at least 2 000 members to be entitled to appeal against judgments and decisions covered by that act. The Miljöskyddsförening brought an appeal against that decision before the Högsta domstolen, which court then issued the preliminary reference.

Main elements of the reference:

Whether such standing rules are compatible with EU law and the Aarhus Convention.

Operative part of ruling and main elements:

- A project such as that at issue in the main proceedings, concerning abstraction of water leaking into a tunnel which houses electric cables and its recharging into the ground or rock in order to compensate for any reduction in the amount of groundwater, and the construction and maintenance of facilities for the abstraction and recharging, are covered by point 10(l) in Annex II to Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, as amended by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003, irrespective of the ultimate destination of the groundwater and, in particular, of whether or not it is put to a subsequent use.
- Members of the ‘public concerned’ within the meaning of Article 1(2) and 10a of Directive 85/337, as amended by Directive 2003/35, must be able to have access to a review procedure to challenge the decision by which a body attached to a court of law of a Member State has given a ruling on a request for development consent, regardless of the role they might have played in the examination of that request by taking part in the procedure before that body and by expressing their views.
- Article 10a of Directive 85/337, as amended by Directive 2003/35, precludes a provision of national law which reserves the right to bring an appeal against a decision on projects which fall within the scope of that Directive, as amended, solely to environmental protection associations which have at least 2 000 members.

5) Case C-72/12, Reference for a preliminary ruling, Gemeinde Altrip and others v. Land Rheinland-Pfalz

Background: The applicants in the case sought annulment of a decision by the Rheinland-Pfalz region approving plans to construct a flood retention scheme. They argued that the environmental impact assessment had been inadequate. The Administrative Court and the Administrative Court of Appeal dismissed the appeal, but the applicants appealed further to the Federal Supreme Administrative Court. As that court was uncertain whether the case law in Germany was compatible with the access to justice rights under Article 10a of the EIA Directive, it requested a preliminary ruling from the CJEU.

Main elements of the reference: whether a national system which allows an individual to appeal a permit decision only if there is a causal link between the deficiency in the EIA and the final approval of the project, and if, at the same time, the procedural irregularity substantively affected a legal position of the appellant.

Judgment:

The CJEU held that Article 10a of the EIA Directive precludes the Member States from granting access to justice solely in cases in which the legality of a decision is challenged on the ground that no environmental impact assessment was carried out, while not extending that possibility to cases in which such an assessment was carried out but was defective. Instead, as a matter of principle, in accordance with the aim of granting broad access to justice, the public concerned must be able to invoke any procedural defect in support of an action challenging the legality of decisions covered by that directive.

Nevertheless, it is unarguable that not every procedural defect will necessarily have consequences that meaningfully affect decision making, and thereby impair the rights of the party alleging it. Therefore, the CJEU stated, it could be permissible for national law not to allow standing if it is established that it is conceivable that the contested decision would not have been different without the alleged procedural defect. However, the burden of proof may not fall on the applicant and the court must make its ruling, where appropriate, on the basis of the evidence provided by the developer or the competent authorities and, more generally, on the basis of the case-file documents, taking into account, *inter alia*, the seriousness of the defect invoked. In particular, it should be ascertained whether that defect has deprived the public concerned of the right to access to information and to be empowered to participate in decision making, in accordance with the objectives of the EIA Directive.

Relevant Jurisprudence of the CJEU concerning Costs

Case C- C-260/11, Reference for a preliminary ruling, Edwards/Pallikaropoulos v Environment Agency

Background: Ms Pallikaropoulos brought an action for judicial review of a permit for a large cement work. She lost the case and was ordered to pay the respondent's litigation cost at the appeal stage, in total GBP 90,000. When the cost order was appealed, the Supreme Court decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

- (1) How should a national court approach the question of awards of costs against a member of the public who is an unsuccessful claimant in an environmental claim, having regard to the requirements of Article 9(4) of the Aarhus Convention, as implemented by Article 10a [of Directive 85/337] and Article 15a of [Directive 96/61]?
- (2) Should the question whether the cost of the litigation is or is not “prohibitively expensive” within the meaning of Article 9(4) of the Aarhus Convention as implemented by [those] directives be decided on an objective basis (by reference, for example, to the ability of an “ordinary” member of the public to meet the potential liability for costs), or should it be decided on a subjective basis (by reference to the means of the particular claimant) or upon some combination of these two bases?
- (3) Or is this entirely a matter for the national law of the Member State subject only to achieving the result laid down by [those] directives, namely that the proceedings in question are not “prohibitively expensive”?
- (4) In considering whether proceedings are, or are not, “prohibitively expensive”, is it relevant that the claimant has not in fact been deterred from bringing or continuing with the proceedings?
- (5) Is a different approach to these issues permissible at the stage of (i) an appeal or (ii) a second appeal from that which requires to be taken at first instance?

Judgement

The requirement, under the fifth paragraph of Article 10a of Directive 85/337 on the assessment of the effects of certain public and private projects on the environment and the fifth paragraph of Article 15a of Directive 96/61 concerning integrated pollution prevention and control, as amended by Directive 2003/35, that judicial proceedings should not be prohibitively expensive means that the persons covered by those provisions should not be prevented from seeking, or pursuing a claim for, a review by the courts that falls within the scope of those articles by reason of the financial burden that might arise as a result, taking into account all the costs

borne by the party concerned. The prohibitive nature of costs must therefore be assessed as a whole, taking into account all the costs borne by the party concerned (paras 27 and 28). The assessment of what must be regarded as prohibitively expensive is not a matter for national law alone (paras 29 and 30). The objective of the EU legislature is to give the public concerned 'wide access to justice' in order that they may play an active part in protecting and improving the quality of the environment. The requirement that costs should be 'not prohibitively expensive' pertains to the observance of the right to an effective remedy enshrined in Article 47 of the Charter of Fundamental Rights of the European Union, and to the principle of effectiveness, in accordance with which detailed procedural rules governing actions for safeguarding an individual's rights under European Union law must not make it in practice impossible or excessively difficult to exercise rights conferred by European Union law (paras 31-33).

The assessment as to what is prohibitively expensive cannot be carried out solely on the basis of the financial situation of the person concerned but must also be based on an objective analysis of the amount of the costs, particularly since members of the public and associations are naturally required to play an active role in defending the environment. To that extent, the cost of proceedings must not appear, in certain cases, to be objectively unreasonable. Thus, the cost of proceedings must neither exceed the financial resources of the person concerned nor appear, in any event, to be objectively unreasonable (paras 40-41).

In deciding the figure, other factors are relevant, including: (i) the situation of the parties concerned; (ii) whether the claimant has a reasonable prospect of success; (iii) the importance of what is at stake for the claimant and the protection of the environment; (iv) the complexity of the relevant law and procedure; (v) the potentially frivolous nature of the claim at its various stages; and (vi) the existence of a national legal aid scheme or a costs protection regime (paras 42 and 46).

The fact that the claimant has not been deterred, in practice, from asserting his or her claim is not in itself sufficient to establish that the proceedings are not, as far as that claimant is concerned, prohibitively expensive (para 43).

The requirement that judicial proceedings should not be prohibitively expensive cannot be assessed differently by a national court depending on whether it is adjudicating at the conclusion of first-instance proceedings, an appeal or a second appeal (para 44 and 45).

Relevant Jurisprudence of the CJEU concerning Injunctive Relief

Case C-416/10, Reference for a preliminary ruling, Jozef Krizan and Others v Slovenska inspekcia zivotneho prostredia

Background: Josef Krizan and others challenged a permit for the Pezinok landfill issued according to IPPC Directive by the environment inspection authority in Bratislava. In 2006, the regional urban planning service of Bratislava adopted an urban planning decision concerning the establishment of a waste landfill site in a trench used for the extraction of earth for use in brick-making, called 'Nova jama'. Subsequently, the Slovak environment inspectorate initiated an authorisation procedure in the course of which residents of the town of Pezinok requested publication of the urban planning decision. That body authorised the construction and operation of the landfill site without having first published the decision in question. Following an appeal brought through administrative channels, the environmental protection body at second instance confirmed that decision, after having published the urban planning decision. The concerned parties then brought an action before the Slovak courts and the Supreme Court of the Slovak Republic (Najvyšší sud Slovenskej republiky) has requested the Court of Justice to explain the extent of the public's right to participate in procedures for the authorisation of projects having significant effects on the environment.

Judgement

In its judgment, the Court notes first of all that a national procedural rule cannot call into question the discretion of national courts to submit a request to the Court of Justice for a preliminary ruling in cases where they have

doubts as to the interpretation of EU law. The national court therefore retains that option – even though a national rule obliges it to follow the legal position of the Slovak Constitutional Court – and it must set aside the assessments made by that latter court if they prove to be contrary to EU law. As a supreme court, the Najvyšší sud Slovenskej republiky is even required to submit a request for a preliminary ruling to the Court of Justice.

The Court states, next, that the urban planning decision on the establishment of the landfill site at issue is one of the measures on the basis of which the final decision whether or not to authorise that installation is taken. Moreover, it includes information on the environmental impact of the project, on the conditions imposed on the developer to limit that impact, on the objections raised by the parties to the urban planning decision and on the reasons for the choices made by the competent authority to issue that decision. It thus includes relevant information on the authorisation procedure to which the public concerned must be able to have access in accordance with the

Aarhus Convention and the IPPC Directive setting out its provisions. In that context, the CJEU states that the refusal to make the urban planning decision available to the public cannot be justified by invoking the protection of the confidentiality of commercial or industrial information.

In its judgement, CJEU also points out that the public concerned must have all of the relevant information as from the stage of the administrative procedure at first instance, before a first decision has been adopted, to the extent that that information is available at that stage of the procedure. However, EU law does not preclude the possibility of rectifying, during the administrative procedure at second instance, an unjustified refusal to make an urban planning decision available to the public concerned during the administrative procedure at first instance, provided that all options and solutions remain possible and that such rectification allows that public effectively to influence the outcome of the decision-making process.

Next, the Court states that the purpose of the IPPC Directive, namely to ensure pollution prevention and control, could not be attained if it were impossible to prevent an installation which may have benefited from a permit awarded in infringement of that directive from continuing to function pending a definitive decision as to the lawfulness of that permit. Consequently, the Directive requires that members of the public concerned should have the right to request the adoption of interim measures designed to prevent that pollution, such as temporary suspension of the disputed permit.

Finally, the Court rules that the decision of a national court which annuls a permit granted in infringement of the abovementioned directive is not capable, in itself, of constituting an unjustified interference with the developer's right to property as determined in Article 17 of the Charter of Fundamental Rights of the European Union.

5. COSTS

Table 5. Checklist of the Types of Cost Incurred to Implement the Directive

Checklist of the Types of Cost Incurred to Implement the Directive

Initial set-up costs:

- establishment of complex professional teams within the competent authorities for the evaluation of environmental impact assessment reports and comments thereto;
- establishment of contact points within the authorities included in the EIA procedure according to Article 6 of the Directive;
- devising systems and procedures;
- provisions for initial training;
- preparation of technical and legal guidance material;
- costs of public participation (e.g. costs of newspaper advertisements or posters, costs of public hearings).

Capital expenditure

- information technology for the EIA databases within the relevant authorities.

Ongoing running costs

- continuous (annual or biannual) training of the relevant officials;
- capacity building of relevant NGOs.
- providing guidance materials for public and private sector, including land developers, EIA experts and operators of industrial installations, waste management facilities, geological storage of CO₂, etc.
- supervision and monitoring of EIA compliance, application procedures
- enforcement and sanctioning system

THE STRATEGIC ENVIRONMENTAL ASSESSMENT DIRECTIVE

Official Title: Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment (OJ L 197, 21.7. 2001)

1. SUMMARY OF THE MAIN AIMS AND PROVISIONS

The Strategic Environmental Assessment Directive (2001/42/EC) requires Member States to assess the effects of certain plans and programmes on the environment during their preparation and has to be completed before their adoption. To assist with conceptualising the goals of the Directive, reference may be made to a common definition of Strategic Environmental Assessment (SEA)¹⁹: "The formalised, systematic and comprehensive process of evaluating the environmental impacts of a [...] plan or programme and its alternatives, including the preparation of a written report²⁰ on findings of that evaluation, and using the findings in publicly accountable decision making."

The SEA Directive aims for a "high level of protection of the environment" and promotes the integration of environmental considerations into planning and programming by requiring that the environmental consequences of certain plans and programmes that are "likely" to have significant environmental effects are identified and assessed during the preparation and before the adoption of plans and programmes (but not policies) covered by the Directive (Art. 4 (1)). All this is with a view to achieving the goals of sustainable development and improving the plan or programme from this perspective. Thus, the SEA Directive lays down the procedure for undertaking an "environmental assessment" of plans and programmes that fall within its scope (see Recitals, Para. 9). This is the key element of the Directive.

An "SEA assessment" should aim to identify strategic options that make a plan or programme more sustainable. Environmental objectives must include the topics listed in the Directive. It takes place much earlier in the decision-making process than EIA and allows for the identification and possible prevention of adverse environmental impacts before the beginning of the formal decision-making process.

The information contained within the environmental assessment and the information received during mandatory consultations with relevant environmental authorities and the public must be taken into consideration before the plan or programme is allowed to proceed (Art. 8). Hence, the public must be endowed with the right to know about plans and programmes and the right to comment; their comments must be taken into account; and, after the adoption of the plan or programme, they must be informed about the decision and the way in which it was made.

Any likely significant transboundary effects of potential plans and programmes must also be taken into account by competent authorities. The potentially affected Member State and its public are likewise to be informed before a decision is made. Their comments are also to be integrated into the relevant national decision-making process, and they should also be notified of the ultimate decision.

An SEA is required in order for a plan or programme to be given approval and is part of the national planning process. The decision-making process at the planning level aims at a high level of transparency.

In summary, the key stages of the SEA procedure are:

¹⁹ Although the word "strategic" does not appear in either the title or the text of the Directive, it is often referred to as the "strategic environmental assessment" Directive (or SEA Directive) because it deals with environmental assessment at a higher, more strategic level than that of projects (which are dealt with in the Environmental Impact Assessment [or EIA] Directive [Directive 2011/92/EU/85/337/EEC, as amended by Directive 97/11/EC]). Source: Commission guidance on the implementation of Directive 2001/42/EC on the assessment of the effects of certain plans and programmes on the environment (http://ec.europa.eu/environment/archives/eia/pdf/030923_sea_guidance.pdf).

²⁰R. Thérivel, E. Wilson, S. Thompson, D. Heaney & D Pritchard, Strategic Environmental Assessment, Earthscan Publications Ltd, London, UK, 1992. 14 See Article 1 - Objectives.

- Screening

The categories of plans and programmes that should be subject to determination of whether they should be subject to an environmental assessment through a so-called screening procedure:

- Plans and programmes adopted for the use of small areas at local level or where plans and programmes are only minor modifications to the plans and/or programmes for which the SEA is mandatory should be assessed only where Member States determine that they are likely to have significant effects to the environment.
- Other plans and programmes which set the framework for future development consent of projects may not have significant effects on the environment in all cases and should be assessed only where Member States determine that they are likely to have such effect.

The screening procedure is based on criteria set out in Annex II of the Directive, but it is left to the Member States to choose between different screening models. The models employed may be case-by-case examination or by specifying types of plans and programmes or by combining both models.

- Scoping

Scoping is a mandatory activity referred to in Articles 5(1) and 5(4). However, organisation of the scoping process is entirely left to the discretion of the Member States with the exception of the obligation to consult concerned authorities - as defined in article 6(3) - on the scope of the environmental assessment (Article 5(4)).

- Alternatives

Article 5 (1) of the SEA Directive lay down a requirement to identify, describe and evaluate the reasonable alternatives taking into account the objectives and the geographical scope of the plan or programme. The alternatives proposed must be realistic. The ultimate goal of studying alternatives is to find ways of reducing or avoiding the significant adverse environmental effects of the proposed plan or programme.

- Baseline reporting

The description of the likely evolution of the relevant aspects of the environment without the implementation of the plan or programme is important as a frame of reference for the assessment of the plan or programme. It follows from Annex I (b) that the information to be provided under Article 5 (1), subject to Article 5(2) and (3) is the relevant aspects of the current state of the environment and the likely evolution thereof without implementation of the plan or programme.

- Forecast of impacts

At this stage, authorities need to assess the likely effects on the environment of the plan and programme and assess proposed alternatives. The assessment methods applied will usually depend on the nature, character and level of abstraction of the plan or programme in question.

- Monitoring and evaluation

Monitoring of the significant environmental effects of the implementation of plans and programmes is a requirement set by Article 10. This allows any unforeseen adverse effect to be recognized at an early stage and dealt with.

- Preparation of environmental report

The Environmental Report is the key output of the SEA process, which will identify, describe and evaluate the likely significant effects on the environment of implementing the plan or programme as well as reasonable alternatives. It forms the basis for monitoring the significant effects. Annex I sets out a broad spectrum of issues that may be addressed in the environmental report. The environmental report and its integral non-technical summary has to be made available to the public.

- Consultation and public participation

Consultation constitutes an integral part of the environmental assessment procedure and taking into account of the results of consultation in decision making. Article 6 of the Directive is concerned with consultation and participation. Consultation must be carried out at all the stages of SEA.

A significant difference between the SEA Directive and the EIA Directive is that the SEA Directive is wider in scope and focuses on decision-making in the context of public plans and programmes. The EIA Directive, on the other hand, is concerned with a particular type of development or project per se, whether it is by a private or public developer, and is applied to focus more narrowly on the type of development or project in question.

The table below shows some of the key differences between the two Directives (table available at: http://sea.unu.edu/course/?page_id=30)

Table 6. Some Comparisons between EIA and SEA

Some Comparisons between EIA and SEA	
<i>Source: UNEP (2002) Environmental Impact Assessment Training Resource Manual, 2nd Edition, UNEP, Geneva. Amended from CSIR (1996)</i>	
EIA of Projects	SEA of Policies, Plans and Programmes
Takes place near the end of decision-making cycle: aims to minimise impacts	Takes place at earlier stages of decision-making cycle: aims to prevent impacts
Reactive approach to development proposal	Pro-active approach to development proposals
Considers limited number of feasible alternatives	Considers broad range of potential alternatives
Limited review of cumulative effects	Cumulative effects assessment is key to SEA
Emphasis on mitigating and minimizing impacts	Emphasis on meeting environmental objectives, maintaining natural systems
Narrow perspective, high level of detail	Broad perspective, lower level of detail to provide a vision and overall framework
Well-defined process, clear beginning and end	Multi-stage process, overlapping components, policy level is continuing, iterative
Focuses on standard agenda, treats systems of environmental deterioration	Focuses on sustainability agenda, gets at sources of environmental deterioration

2. PRINCIPLE OBLIGATIONS OF MEMBER STATES

Member States should ensure that the implementing legislation adopted to give effect to the Directive provides for at least those matters set out in Sections 2.1 to 2.5.

2.1. Planning

- Decide on the institutional arrangements, i.e. on the responsibility to carry out the SEA procedure.
- Determine the plans and programmes to which SEA shall apply. Article 2 contains a broad definition as to plans and programmes; and Article 3, on the scope of the Directive, indicates to the Member States, which plans and programmes are to be made subject to the requirements of the Directive.

The plans and programmes covered by the Directive are (Art. 2.a):

- those that are required by legislative, regulatory or administrative provisions;

and which

- are subject to preparation and/or adoption by an authority at national, regional or local level;

or which

- are prepared by an authority for adoption, through a formal procedure, by a legislative procedure by parliament or government.

- Determine whether environmental assessments required under Article 3(3) and (4) are to be made subject to the requirements of the Directive (screening) through a case-by-case examination; by specifying types of plans or programmes; or by combining both of these approaches (Art. 3(5)), and in either case provide for the relevant threshold determining factors to be set out clearly in the implementing national law. Annex II of the Directive provides relevant criteria to be taken into consideration by the Member States in order to determine the likely significant environmental effects and the need for an environmental assessment (Art. 3(5)).
- Design ways and methodologies for public notification and consultation (Art.6).
- It might be useful for the competent authority to create an electronic database to be uploaded and maintained on the competent authority website for the purposes of identifying and reporting on the specific plans and programmes that are undergoing strategic environmental assessment, including the relevant SEA procedural stage for each plan or programme.
- Consider creating a review procedure in order to ensure that plans or programmes referred to in Article 3(3) and 3(4) do not escape SEA.
- Decide whether to apply co-ordinated joint procedures of assessment when the obligation to carry out an environmental assessment of a plan or programme under this Directive and other EU legislation arises simultaneously so as to, inter alia, avoid duplication of assessment (Art. 11(2)) as long as the assessment requirements of the legislation in question are fully met.

2.2. Regulation

- Set out the definition and scope of plans and programmes to be covered by the national legislation in accordance with the Directive also taking into account exceptions to the scope (i.e. plans and programmes the sole purpose of which is in relation to national defence or civil emergency and financial or budget plans and programmes (Arts. 2 and 3).
- Ensure that all plans and programmes likely to have significant environmental effects are not allowed to proceed unless an environmental assessment has been carried out (Art. 4(1)).
- Ensure that also modifications to plans and programmes are subject to SEA procedure if significant. Also minor modifications will require an assessment if the assessing authority considers that these modifications will have significant environmental effects.
- Determine the extent to which certain matters are more appropriately assessed at different levels in the above process in order to avoid duplication of the assessment where plans and programmes form part of a hierarchy (Arts. 4(3), 5(2) and (3)), where the plan/programme being assessed forms only one level in a planning hierarchy.
- Ensure that the environmental assessment includes the production of a report (Art. 5), consultation and public participation (Art. 6), including in a transboundary context (Art. 7), ensure the provision of information on the decision (Art. 9), and also for monitoring implementation of the plan or programme with provision for remediation efforts in the event of significant adverse environmental impacts (Art. 10).

2.3. Consultation

- Identify and designate the authorities that are to be consulted as a result of their specific environmental responsibilities and likelihood of being concerned by the environmental effects of implementing plans and programmes (Art. 6(3)).
- Provide that authorities with relevant environmental responsibilities and the public are given early and effective opportunity to express their opinion on the draft plan or programme and the accompanying environmental report before the adoption of the plan or programme or its submission to the legislative procedure (Art. 6(2)).
- Define the detailed arrangements for the information to be provided and manner of consultation of the authorities and public, including (Art. 6(4) and 6(5)):
 - definition of the public and public concerned;
 - the ways of identifying public concerned, including non-governmental organisations;
 - the time limits for the different stages of the procedure;

- methods by which information shall be made available;
 - requirements for informing/notifying the public and authorities concerned on the final decision, including the content of such notification;
 - methods applied for public consultation.
- Ensure that the relevant environmental authorities and/or public are informed and given opportunity to participate in the SEA decision-making procedure. Information and consultation requirements depending on the stages of the SEA are as follows:
 - during procedure of determination if a plan or programme requires an SEA: Consultation of authorities must be provided (Art. 3(6)) and information must be made available to the public about the conclusion and reasons whether plan or programme concerned should be subject to SEA or not (Art. 3(7)).
 - consultation of authorities must be ensured when deciding on the scope and level of detail of the information, which must be included in the environmental report (Art. 5(4)).
 - the environmental report and the draft plan or programme must be made available to the public and the authorities and should be given an opportunity to express their opinion on the draft plan or programme and the accompanying environmental report before the adoption of the plan or programme or its submission to the legislative procedure (Art. 6(1) and 6(2)).
 - during preparation of plan or programme environmental report and opinions expressed under Article 6 must be taken into account (Art.8).
 - the public and authorities concerned must be informed about the final decision, including the statement referred to in Article 9(1)(b) and measures concerning monitoring (Art. 9(1)).
 - Member States likely to be affected by the significant effects of a plan or programme in another Member State are to be consulted (Art. 7(1)).
 - The Member State preparing the plan or programme shall forward a copy of the draft plan or programme and the environmental report, and measures envisaged to reduce or eliminate such effects, to such Member State before the plan or programme is to be submitted for adoption (Art. 7(2)). Such information has to be supplied to the Member State likely to be affected if so requested.
 - If consultation takes place between the Member States concerned, at the request of the Member State likely to be affected by the plan or programme detailed arrangements shall be made to ensure that the authorities and the public in the affected Member State are informed and provided with the opportunity to submit their opinions within a reasonable time-frame (Art. 7(2)). Member States shall agree in advance a reasonable time-frame for the duration of the consultations (Art. 7(3)).
 - After a decision has been made as to whether or not to adopt a plan or programme, consulted Member State should be informed and information on the plan or programme shall be made available, along with an environmental statement and information on the monitoring of the plan or programme (Art. 9(1)).

Key court cases to be considered

Judgment of the Court (Fourth Chamber) of 22 September 2011 (reference for a preliminary ruling from the Lietuvos vyriausiasis administracinis teismas — Republic of Lithuania), C-295/10:

Concerns: Whether or not it is necessary to carry out an assessment under Directive 2001/42/EC after an assessment has been carried out under Directive 85/337/EEC — National legislation which provides that it is not necessary to carry out a strategic environmental impact assessment of documents relating to land planning at local level if those documents relate to only one subject of economic activity

Ruling: Article 11(1) and (2) of Directive 2001/42 must be interpreted as meaning that an environmental assessment carried out under Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, as amended by Council Directive 97/11/EC of 3 March 1997, does not dispense with the obligation to carry out such an assessment under Directive 2001/42. However, it is for the referring court to assess whether an assessment which has been carried out pursuant to Directive 85/337, as amended, may be considered to be the result of a coordinated or joint procedure and whether it already complies with all the requirements of Directive 2001/42. If that were to be the case, there would then no longer be an obligation to carry out a new assessment pursuant to Directive 2001/42. (Text of the case is available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:331:0005:0006:EN:PDF>)

C-567 / 10: Judgment of the Court (Fourth Chamber) of 22 March 2012

Concerns: The Constitutional Court of Belgium sent the following question to Luxembourg: "Must the definition of 'plans and programmes' in Article 2(a) of Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment be interpreted as excluding from the scope of that Directive a procedure for the total or partial repeal of a plan such as that applicable to a 'plan particulier d'affectation du sol' (specific land-use plan), provided for in Articles 58 to 63 of the Code bruxellois de l'Aménagement du Territoire (Brussels Town and Country Planning Code)?"

Ruling:

- The concept of plans and programmes 'which are required by legislative, regulatory or administrative provisions', appearing in Article 2(a) of Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment, must be interpreted as also concerning specific land development plans, such as the one covered by the national legislation at issue in the main proceedings.
- Article 2(a) of Directive 2001/42 must be interpreted as meaning that a procedure for the total or partial repeal of a land use plan, such as the procedure laid down in Articles 58 to 63 of the Brussels Town and Country Planning Code, as amended by the Order of 14 May 2009, falls in principle within the scope of that Directive, so that it is subject to the rules relating to the assessment of effects on the environment that are laid down by the Directive.

C-474/10: Judgment of the Court (Fourth Chamber) of 20 October 2011.

Concerns: The interpretation of Article 6 of Directive 2001/42/EC on the assessment of the effects of certain plans and programmes on the environment. The reference was made in proceedings between the Department of the Environment for Northern Ireland and Seaport (NI) Ltd and Magherafelt District Council, F P McCann (Developments) Ltd, Younger Homes Ltd, Heron Brothers Ltd, G Small Contracts and Creagh Concrete Products Ltd, concerning the validity of the 'Draft Northern Area Plan 2016' and 'Draft Magherafelt Area Plan 2015'

Article 6(3) of Directive 2001/42/EC on the assessment of the effects of certain plans and programmes on the environment does not require that another authority to be consulted as provided for in that provision be created or designated, provided that, within the authority usually responsible for undertaking consultation on environmental matters and designated as such, a functional separation is organised so that an administrative entity internal to it has real autonomy, meaning, in particular, that it is provided with administrative and human resources of its own and is thus in a position to fulfil the tasks entrusted to authorities to be consulted as provided for in Article 6(3) and, in particular, to give an objective opinion on the plan or programme envisaged by the authority to which it is attached.

Ruling: Article 6(2) of Directive 2001/42 must be interpreted as not requiring that the national legislation transposing the Directive lay down precisely the periods within which the authorities designated and the public affected or likely to be affected for the purposes of Article 6(3) and (4) should be able to express their opinions on a particular draft plan or programme and on the environmental report upon it. Consequently, Article 6(2) does not preclude such periods from being laid down on a case-by-case basis by the authority which prepares the plan or programme. However, in that situation, Article 6(2) requires that, for the purposes of consultation of those authorities and the public on a given draft plan or programme, the period actually laid down must be sufficient to allow them an effective opportunity to express their opinions in good time on that draft plan or programme and on the environmental report upon it.

2.4. Monitoring

- Monitor the significant effects of the implementation of the plan or programme so as to identify at an early stage any unforeseen adverse effects, and so as to be able to take appropriate remedial action (Art. 10).

2.5. Information, Reporting and Review

Report to the Commission on:

- measures taken to ensure the environmental assessment reports produced are of a sufficient quality (Art. 12(2));
- plans and programmes identified as being subject to an environmental assessment under the Directive (Art. 13(4));
- transposition and implementation of the Directive including texts (Art. 13(1));
- experience gained under this Directive (Art. 12(1));
- proposals for amendment of the Directive (Art. 12(3)).

2.6. Additional Legal Instruments

The implementation of this Directive should be considered in conjunction with a number of other legal acts from the environmental acquis (Art. 11(1)) and international agreements. The key examples highlighted in the Commission's guidance on the SEA Directive (refer to http://ec.europa.eu/environment/archives/eia/pdf/030923_sea_guidance.pdf) include the following:

- Environmental Impact Assessment Directive (2011/92/EU) as amended;
- Water Framework Directive (2000/60/EC) require programmes and planning for water management zoning and protection, including the River Basin Management Plans (Arts. 11 and 13);
- Waste Framework Directive (2008/98/EC) especially regarding Waste Management Plans;
This Directive requires waste management plans to be established by Member States;
- Directive 2009/31/EC on geological storage of CO₂, which also is subject to EIA application under the EIA Directive;
- Nitrates Directive (91/676/EEC). This Directive requires action programmes for areas affected or threatened by nitrate pollution. The targets of these action programmes are mainly certain agricultural practices rather than projects. These action programmes may, in certain situations, set the framework for future development consent of projects such as intensive livestock units;
- Directive 2008/50/EC on ambient air. This Directive requires Member States to prepare and implement a plan for attaining the limit value within the specific time limit in zones and agglomerations

in which levels of one or more pollutants exceed certain limit values. If the level of more than one pollutant is higher than the limit values, Member States must provide an integrated plan covering all the pollutants concerned.

- The Habitats Directive (92/43/EEC). This Directive aims to set up a coherent European ecological network of special areas of conservation. It requires Member States to propose sites as special areas of conservation and transmit a list of such sites to the Commission. The purpose is to recognise that the site hosts nature values worth protecting. Thus, the essence of such a proposal is to recognise the environmental value of the site.

Further to above-mentioned directives, relevant are also: Industrial Emissions Directive (2010/75/EU), Floods Directive (2007/60/EC), the Seveso III Directive (2012/18/EU), Marine Strategy Framework Directive (2008/56/EC), etc. Other policy areas could be relevant for the application of the SEA Directive, e.g. Regulation (EU) 236/2014 for financing external action and Common Provisions Regulation (EU)1303/2013).

International conventions:

- Convention on Environmental Impact Assessment in a Transboundary Context (the Espoo Convention), 1991;
- UNECE Protocol on Strategic Environmental Assessment, 2003;
- Convention on Wetlands of International Importance Especially as Waterfowl Habitat (Ramsar Convention), 1971;
- Convention on Biological Diversity, 1992;
- Convention on Access to Environmental Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Aarhus Convention), 1998.

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the following checklist.

The tasks are arranged under subheadings and organised in chronological order of implementation wherever possible.

Table 7. Strategic Environmental Assessment Directive - Key Implementation Tasks

STRATEGIC ENVIRONMENTAL ASSESSMENT DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Identify the competent authorities that will have responsibility for implementing the Directive and ensure that adequate financial, human and equipment resources are provided.
1.2	Design inclusive, participatory and transparent consultation procedures with well-conceived information/advertising.
1.3	Develop a co-ordinated communication and decision-making framework, one that accounts for non-environment ministry/agency authority participation as well.
1.4	Consider the extent to which SEA can be integrated into existing environmental assessment procedures and where one can combine the SEA and other EIA-related methodologies.
1.5	Develop SEA-related transboundary consultation procedures.
1.6	Design the approvals system robustly so that approval for the plan or programme is only given once the environment assessment has been conducted and the reporting and consultation requirements thoroughly fulfilled.
1.7	Determine how to identify those plans and programmes that may have significant effects on the environment and thus require an environmental assessment: <ul style="list-style-type: none"> • on a case-by-case basis; • by specifying types of plans or programmes; or • using both procedures.
1.8	Determine protocols for advising public authorities and bodies on the scope of SEA and ensure that staff are suitably qualified to provide such advice.
1.9	To the extent practical and efficient aim at integrating monitoring protocols with requirements stemming from EIA.
2	Regulation
2.1	Determine the competent authority responsible for overseeing the SEA process.
2.2	Develop thorough definitions for "plans" and "programmes".
2.3	Provide a mechanism for blocking approval of plans and programmes that have not had SEA-related approvals.
2.4	Codify the environmental report production, review and approval procedure. Ensure high quality of the environmental reports.
2.5	Take measures to legally codify transboundary consultation processes.
2.6	Implement procedures for the competent authority to review the plan/programme in order to ensure that the SEA has been carried out in an appropriate manner and that the report is of a high enough standard and includes all the information required under the Directive.
3	Guidance and Training
3.1	Prepare and issue detailed guidance on the procedures required to comply with the Directive, the nature of SEA and the preparation of an environmental assessment report.
3.2	Develop regulatory guidance on the "significance of environmental effects".
3.3	Provide training to staff in the competent authorities on SEA preparation, consultation and

	related review procedures.
3.4	Consider creating sectoral SEA guidance documents (e.g. transport, land-use planning, waste management etc.).
4	Consultation
4.1	Identify the relevant bodies (environmental and others) to act as statutory consultees and establish procedures for consulting with them.
4.2	Ensure that the other authorities likely to be concerned by the project by reason of their specific environmental responsibilities (i.e. authorities responsible for transport) are given an opportunity to express their opinion on the SEA. These authorities can be identified either in general terms or on a case-by-case basis.
4.3	Ensure that the public is informed and/or consulted at all appropriate stages: screening, scoping, review, decision.
4.4	Ensure that other countries are consulted in the case of potential transboundary impacts.
4.5	While the public only has to be consulted when the report has been completed, the environmental authorities have to be consulted in two instances: firstly, at the scoping stage; and then when the environmental report has been completed at the decision-making stage.
4.6	Follow, or if need be established, protocols with neighbouring Member States to provide for the exchange of information and to integrate respective national consultation processes regarding plans and programmes with potentially significant environmental effects.
4.7	Implement measures to ensure that the competent authority (or authorities) take into consideration the responses from the consultation process prior to approving a plan or programme.
4.8	Implement measures to notify the public of the outcome of approving plans or programmes.
5	Reporting
5.1	Pursuant to Articles 12 and 13 provide information to the Commission on: <ul style="list-style-type: none"> • measures taken to ensure the environmental assessment reports produced are of a sufficient quality; • experience gained under this Directive; and • transpositional legal measures.

3.2. Phasing Considerations

The most demanding and time-consuming tasks to implement this Directive are likely to be:

- Strengthening the institutional structures. This work may include:

staff recruitment to improve capacity, should implementation of the Directive increase workloads, and to widen specialist expertise to support the evaluation of environmental reports;

staff training to improve capability and technical knowledge.

- Preparing and disseminating information on the procedural requirements of SEA.
- Encouraging public authorities to make changes in the way they prepare plans and programmes, particularly the preparation of the environmental assessment report.
- Preparing detailed sectoral guidance notes to those bodies that are responsible for drawing up plans and programmes.
- Ensuring public participation and raising public awareness.
- Making environmental information held by public authorities and institutions available to the public in methods and forms ensuring transparency and accuracy (see Directive 2003/4/EC).

4. IMPLEMENTATION GUIDANCE

The SEA Directive was adopted and entered into force on 21 July 2001. It had to be implemented by Member States by 21 July 2004.

The Commission has published several guidance documents to facilitate the interpretation and understanding of the SEA Directive and the requirements involved. This guidance includes:

- Guidance on Integrating Climate Change and Biodiversity into SEA, 2013: <http://ec.europa.eu/environment/eia/pdf/SEA%20Guidance.pdf>
- Manual on Strategic Environmental Assessment of Transport Infrastructure Plans, 2005, prepared by DG Energy and Transport: http://ec.europa.eu/environment/eia/sea-studies-and-reports/beacon_manuel_en.pdf
- Guidance on the implementation of Directive 2001/42/EC on the assessment of the effects of certain plans and programmes on the environment: http://ec.europa.eu/environment/eia/pdf/030923_sea_guidance.pdf
- Commissions' Guidance document on ex-ante evaluation (2014): http://ec.europa.eu/regional_policy/sources/docoffic/2014/working/ex_ante_en.pdf
- SEA and Integration of the Environment into Strategic Decision-Making²¹ (2001): http://ec.europa.eu/environment/archives/eia/sea-studies-and-reports/pdf/sea_integration_main.pdf

The Commission has also published a number of helpful documents pertaining to certain sectors such as:

- Strategic Environmental Assessment in the Transport Sector: An overview of the legislation and practices in the Member States (2000): http://ec.europa.eu/environment/eia/sea-studies-and-reports/sea_transport.pdf
- Strategic Environmental Assessment in Transport Corridors: lessons learned comparing methods of five Member States: http://ec.europa.eu/environment/eia/sea-studies-and-reports/sea_transport2.pdf

In addition, there are a number of published reports and studies dealing with various aspects of the SEA procedure (further information can be obtained at <http://ec.europa.eu/environment/eia/sea-support.htm>).

One such report, relating to the general overhaul of the EIA Directive, is the report on the effectiveness of the SEA Directive²² as well as the „Study concerning the report on the application and effectiveness of the SEA Directive” (2009), available at: <http://ec.europa.eu/environment/eia/pdf/study0309.pdf>. Another useful document is the Strategic Environmental Assessment Better Practice Guide- Methodological guidance

²¹European Commission Contract No. B4-3040/99/136634/MAR/B4, Imperial College Consultants Ltd (William Sheate, Suzan Dagg), Babbie Allott & Lomax, UK (Jeremy Richardson), Wissenschaftsladen Graz/Austrian Institute for the Development of Environmental Assessment (Ralf Aschemann) and ECA, Spain (Juan Palerm)

²²COM/2009/0469 final.

for strategic thinking in SEA²³ (2012) available at:

http://ec.europa.eu/environment/eia/pdf/2012%20SEA_Guidance_Portugal.pdf

Candidate countries can benefit from the experience gained through the implementation of the EIA Directive, given the similarities in scope and procedure. The candidate countries may find that some of the administrative implementation requirements that are already in place due to the EIA Directive can be adapted to incorporate the provisions of the SEA Directive. They will also benefit from the best practice of Member States in implementing the related EIA Directive. Finally, the jurisprudence of the CJEU on the implementation of the SEA Directive is the main source for interpreting the SEA Directive.

Member States had to prepare national legislation that considered transboundary impacts and access to information and consultation requirements. The existing frameworks might be adapted to meet the requirements of the SEA Directive. If, in the case of candidate countries, there are no existing frameworks of this nature, the best practice of Member States, relevant EU Directives and relevant international laws can offer guidance. As regards consultation on plans or programmes that are likely to have significant effects in other Member States SEA Directive follows the general approach taken by the UNECE Convention on Environmental Impact Assessment in a Transboundary Context (Espoo Convention). Experience of the Member States²⁴ shows that the main barrier in carrying out transboundary consultations is the language issue, i.e. the costs of translating the documents and not systematically translated documentation.

Some Member States will already have legislative frameworks that require environmental assessments to be carried out in a similar vein to the SEA Directive — for example, the UK requirements for sustainability appraisals. Such existing frameworks will provide implementation guidance and could be adapted to meet the requirements of the Directive.

One of the most difficult practical aspects of the new SEA Directive is the monitoring of significant environmental effects of the implementation of plans and programmes. The Directive requires Member States: "...to monitor the significant environmental effects of the implementation of plans and programmes in order, inter alia, to identify at an early stage unforeseen adverse effects, and to enable Member States to undertake appropriate remedial action." In many Member States, specific monitoring systems for evaluating the environmental effects of plans and programmes do not exist at present. The Directive allows Member States to use existing monitoring arrangements, but it is not yet clear what types of monitoring systems exist in different Member States that could be used or developed for that purpose. Practical guidance on monitoring is contained in Annex I of the Guidance on the implementation of Directive 2001/42/EC on the assessment of the effects of certain plans and programmes on the environment. More detailed information on the practical implementation of Article 10 can be obtained from the report 'Implementing Article 10 of the SEA Directive' prepared in the framework of the IMPEL Network, available at: http://ec.europa.eu/environment/archives/eia/pdf/impel_final_report.pdf

²³ Prepared by Maria do Rosário Partidário, Professor at IST-UTL for the Portuguese Environment Agency and Redes Energéticas Nacionais (REN), SA, Lisbon, 2012

²⁴ Report from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on the application and effectiveness of the Directive on Strategic Environmental Assessment (Directive 2001/42/EC) (COM/2009/0469)

4.1. Planning

- The procedural implementation methodology, in line with the main aims and requirements of the SEA Directive, could include:
 - identify other relevant plans and programmes and environmental protection objectives and how they relate to the plan;
 - identify relevant environmental and sustainability visions and problems and how they relate to the plan;
 - devise draft SEA objectives, indicators and targets;
 - collect baseline information including data on likely future trends;
 - identify environmental options for dealing with issues raised;
 - prepare a scoping report;
 - consult on the scoping report;
 - assess the effects of the plan or programme options on the SEA objectives and targets;
 - choose draft prepared options;
 - test the compatibility of the draft preferred options against other relevant plans and programmes;
 - assess the cumulative and synergistic effect of the draft preferred options;
 - finalise the preferred options;
 - screen plan/programme proposals for significance;
 - assess the effects of plan/programme proposals on the SEA objectives and targets;
 - tier assessments and link them to EIA (if relevant);
 - propose SEA monitoring measures;
 - prepare an environmental report;
 - consult environmental and other authorities and the public on the environmental report;
 - take the consultation results into account;
 - integrate environmental considerations into changes, amendments and modifications to the plan/programme.
- Details of the tasks required to implement the SEA Directive and associated legislation will be influenced to a great extent by the nature of existing procedures for approving plans and programmes, and for granting development consent under the EIA Directive, in particular to the extent in which the SEA requirements can be integrated into these existing procedures.
- Candidate countries should undertake a detailed review of existing plans and programme approvals. The study could include an institutional assessment to examine the interrelationships between national, regional and local government and those bodies that undertake responsibilities on behalf of public authorities, such as utility companies. The study could also review staffing and office resources

including office equipment, computers and related software systems. The study should identify any weaknesses in current arrangements and propose mitigating measures.

- Member States and candidate countries could consider nominating a central competent authority staff member(s) that will have responsibility for advising other authorities (i.e. regional, local and other centralised bodies) on the methods and procedures for implementing the Directive. This can include providing advice as to the extent of the environmental assessment, the content of the report, the means of consulting the public and how to undertake monitoring of the significant effects of the implementation of the plan or programme.
- In some jurisdictions there may be a need for a centralised competent authority with legislative powers or some form of legal enactment by the central legislature relating to SEA as concerns the defined roles of respective competent authorities. Otherwise, there may be conflict between responsible bodies/ministries as to whether an SEA needs to be conducted and by whom. This will allow for clear lines of communication and implementation responsibilities where they may be dealt with on an inter-ministerial basis (i.e. ministry of environment/agency and ministry of transport for transport plans).
- Member States should consider that the scope of plans and programmes could include those plans and programmes that are not explicitly so called but that fit within the scope of the Directive. They may be strategies, schemes, guidelines and so forth.
- In some Member States a plan is thought of as a document that identifies how it is proposed to carry out or implement a scheme — for example, land-use plans identifying how land should be developed. Other examples include transport plans, waste management plans and energy plans. In some Member States a programme is thought of as a plan covering a set of projects for a given area (i.e. a regional development plan or a road project). Whatever difference in definition is ultimately decided, the difference should be codified in legal terms.

Example of how SEA and the environment are integrated in a Member State

Ireland: In Ireland, planning and development legislation provides for greater environmental integration through a number of new requirements. They include, but are not limited to: sustainable development and planning in sub-national development plans; and data on likely environmental impacts of a plan to be included in a draft development plan, all of which provides a basis for strategic environmental assessment that attends the implementation of EIA in the main environmental legislation.

4.2. Regulation

- Candidate countries will have to determine the scope of application of the Directive (Art. 3(2)). In this context, particular attention should be given to definition of sectoral plans, interpretation of the terms ‘administrative provisions’ as well as “setting framework for future development consents”.
- Candidate countries will have to determine, on a case-by-case basis or through specifying types of plans or programmes, based on the criteria provided in Article 3(5) and Annex II of the Directive, the types of plans and programmes that will be subject to the Directive.

- Candidate countries may need to devise systems for monitoring the environmental effects of plans and programmes, where these do not presently exist. Existing systems may need to be amended.
- Public authorities that have to undertake SEA may wish to consider seeking technical expertise from, among others, consultants, academics, policy experts and so forth.
- The competent authority could set up a review and advisory panel to evaluate SEAs. This would help to standardise the evaluation of the environmental reports and provide technical expertise. Members of such a review panel could potentially be drawn from within the competent authority and/or include other relevant public authorities, independent external experts and typical stakeholder representatives. Alternatively, SEAs could be reviewed with external assistance by accredited companies or institutions. SEA accreditation procedures and standards could be legislated along with other distinctly environmental technical expertise.
- Conflict resolution between different commercial and environmental aspects of plans/programmes could have regard to the application of the proportionality principle as well as traditional principles of EU environmental law, which generally favour environmental protection goals.

4.3. Guidance and Training

- Successfully undertaking an SEA would potentially require input from a variety of skilled technical specialists (i.e. SEA in the water sector would require skilled biologists, ecologists, hydrologists, engineers etc.). For competent authorities that have responsibility for evaluating SEAs, the level of technical expertise required on their behalf may pose a problem.
- There would be a strong case for including effective education and training of those government officials and experts that are involved in undertaking and/or evaluating SEAs. The resulting expertise could be supported and enhanced with the use of external accredited SEA/EIA specialists.
- Various Member States are in the process of producing guidance, consultation papers and other documentation. Candidate countries may benefit from this and from producing their own guidance. Research institutions, universities and consultants may also produce useful guidance, for example based on a study into developing methodologies for carrying out an SEA, while external experts can provide training on various aspects of SEA. A number of Member States have EIA/SEA centres that may be of use in providing assistance on SEA.
- Some Member States adopted obligatory or voluntary schemes to control the quality of EIA reports. Member States and candidate countries may wish to do the same for SEA reports.

4.4. Reporting

- Report to the Commission on matters concerning the quality of the environmental reports. The Directive does not specify what "sufficient quality" (Art. 12) is as regards the environmental report. Nevertheless, Article 5 and Annex I will provide guidance, as will past practical experience of reporting

under the EIA Directive. This practical experience has shown that in some instances the information provided in the impact assessment has been inadequate. In addition, Member States should consider whether and how the environmental report would provide information on the relationship of the proposed plan/programme with other existing plans/programmes and any environmental objectives relevant to those plans and programmes.

4.5. Consultation

- The SEA Directive does not specify the duration of the consultation periods with authorities and the public, nor the maximum period allowed for competent authorities to reach their decision on approving the plan or programme. Member States and candidate countries may set deadlines and time limits for these activities within their national legislation, or make such recommendations in government guidance. They may wish to adopt the same time limits that have been agreed for the EIA Directive. In any event, these time-lines must be of reasonable duration and represent sound administrative practice.
- In contrast to the EIA Directive, the SEA Directive does not specify any details about how the public should be informed (i.e. methods for disseminating information, venues for consultation and so forth). It is at the discretion of Member States to determine the methods of consultation, although to some extent they could follow those based on the EIA Directive.
- Directive 2003/35/EC on public participation in respect of the drawing up of certain plans and programmes relating to the environment may offer guidance as to the level of public consultation to be undertaken and on the implementation of public consultation provisions at the national level. The provisions of this Directive do not directly concern the SEA Directive but are nevertheless useful in highlighting key elements of public participation.

Table 8: Overview of the SEA Directive information and consultation requirements

Stage of SEA	Information and Consultation Requirements
Deciding whether the plan or programme requires an SEA	Consultation of authorities (Art. 3(6)) Information made available to the public (Art. 3(7))
Decision on scope and level of detail of the assessment	Consultation of authorities (Art. 5(4))
Environmental report and draft plan or programme	Information made available to the public (Art. 6(1)) Consultation of authorities and of the public concerned (Art. 6(2))
During preparation of the plan or programme	Take account of environmental report and opinions expressed under Article 6 (Art. 8)
Adopted plan or programme; Statement referred to in Art. 9(1)(b); Measures concerning monitoring Art. 9(1)(c)	Information made available to the authorities and to the public (Art. 9(1))

Source: *Guidance on the implementation of Directive 2001/42/EC on the assessment of the effects of certain plans and programmes on the environment* (http://ec.europa.eu/environment/archives/eia/pdf/030923_sea_guidance.pdf)

4.6. Monitoring

- Article 10 gives Member States flexibility as to monitoring the significant environmental effects of plans and programmes that are implemented. Member States have the discretion to decide whether monitoring should be for each programme or plan individually or not. Significant effects are also not defined but should be taken to include effects that can be negative, positive, foreseen, unforeseen, adverse, minor, major and so on.
- Monitoring requirements could be implemented into existing planning procedures.
- Issues to consider could include identifying what types of environmental effects should be monitored. The environmental report, and thus the criteria in Article 5 and Annex I, should assist in identifying such effects (which are likely to be the same as those considered in the environmental assessment — except for unforeseen effects etc.) and the type of remedial action required.
- Staff should be trained to specifically carry out SEA monitoring compliance activities at their respective jurisdictional (i.e. transnational, national, regional, local) levels.

5. COSTS

Table 9. Checklist of the Types of Cost Incurred to Implement the Directive

Checklist of the Types of Cost Incurred to Implement the Directive

Initial set-up costs:

- establishment of complex professional teams within the competent authorities for the evaluation of environmental impact assessment reports and comments thereto;
- establishment of contact points within the authorities included in the SEA procedure according to Article 6(3) of the Directive;
- devising systems and procedures;
- provisions for initial training;
- preparation of technical and legal guidance material;
- costs of public participation (e.g. costs of newspaper advertisements or posters, costs of public hearings).

Capital expenditure

- information technology for the SEA databases within the relevant authorities.

Ongoing running costs

- continuous (annual or biannual) training of the relevant officials;
- capacity building of relevant NGOs.
- providing guidance materials.
- supervision and monitoring of SEA compliance
- enforcement and sanctioning system

THE DIRECTIVE ON ACCESS TO ENVIRONMENTAL INFORMATION

Official Title: Council Directive 2003/4/EC on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L41, 14.2.2003)

1. SUMMARY OF THE MAIN AIMS AND PROVISIONS

The three primary aims of this Directive are:

- to guarantee the right to access to environmental information held by or for public authorities and to set out the basic terms and conditions of, and practical arrangements for, the exercise of this right;
- to ensure that environmental information is progressively made available and disseminated to the public in order to achieve the widest possible systematic availability and dissemination to the public of environmental information;
- to further the goals of contributing to a greater awareness of environmental matters, a free exchange of views, more effective participation by the public in environmental decision making and, ultimately, to a better environment.

This Directive repealed and replaced Directive 90/313/EEC to give effect to the Aarhus Convention of 1998, to which the EU is a party. Directive 2003/4/EC had to be implemented by 14 February 2005. It should be noted that the European legislator makes it unambiguous that the new Directive aimed to expand the previously existing access to information and that Member States have the right to go further down this path by providing for even broader access to information than that required by the new Directive (Recitals 2 and 24). This should be borne in mind in all cases when the need to interpret the text of the Directive arises.

There are strong links with Directive 2003/35/EC on providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

The planning obligations include:

- Designing and implementing a procedure and related institutional responsibilities in order to address requests for environmental information (requests must be processed in a timely manner, which demands administrative efficiency), including an additional procedure for reviewing requests for environmental information that are not satisfied (Arts. 3 and 6).
- Setting out the practical arrangements necessary for the organisation and dissemination of environmental information, including methods for compiling and analysing information, of the kind described in Articles 7 and 8. Environmental databases and the related dissemination of information derived from monitoring responsibilities in relation to environmental effects must be designed and implemented (Art. 7).
- In relation to both key tasks set out above, those bodies added to the scope of the Directive by the extended definition of "public authorities" (Art. 2(2)) must be informed and must have sufficient resources to meet the obligations created under the Directive.
- Plan capacity-building measures both for officials regularly working with information request cases and for members of the public and public organisations covering, inter alia, the range of available environmental information, the authorities that provide the information, the best procedures for requesting and providing information, the time needed to supply the information, the form in which it is supplied and the cost of providing it, and an accurate definition of the exemptions (Arts. 3(3), 3(5), 4, 7 and 8(2)).

2.2. Regulation

The regulatory obligations include:

- Member States must require public authorities to make information relating to the environment available:
 - to any natural or legal person (including persons residing outside the Member States);
 - on request;
 - in the form requested, if available, unless it is already publicly available in another form or it is reasonable for the authority to make it available in another form;
 - for a reasonable cost;
 - within a reasonable time (as soon as possible and not exceeding one month. This deadline may be extended to up to two months, depending on the volume or complexity of the information); and
 - without the person having to state an interest (Arts. 3 and 5).

- Provide access to expeditious and either free or inexpensive administrative and judicial review for any person who considers that their request for information has been unreasonably refused, in full or in part, ignored, inadequately answered or otherwise not dealt with (Art. 6).
- Allow requests for information to be refused on grounds not broader than those set out in the Directive, and require the authority to state reasons for refusal and to indicate the review procedure (Recital (16) and Art. 4). In assessing refusals of access, consider publishing the relevant criteria: the grounds for refusal shall be interpreted in a restrictive way, taking into account the public interest served by disclosure against the interest served by refusal and also, in certain cases, if the request relates to information on emissions into the environment (Art. 4(2)).
- Ensure that lists of public authorities as defined in Article 4 (i.e. (a) government or other public administration, including public advisory bodies, at national, regional or local level; (b) any natural or legal person performing public administrative functions under national law, including specific duties, activities or services in relation to the environment; and (c) any natural or legal person having public responsibilities or functions, or providing public services, relating to the environment under the control of a body or person falling within (a) or (b).) are publicly accessible
- Ensure that the practical arrangements for guaranteeing the effective exercise of the right to access to environmental information are defined, including designating information officers, and that facilities for the examination of information are established and maintained (Art. 3).
- Provide for the active dissemination of environmental information related to applicable environmental laws, policies, plans, programmes, progress reports, state of the environment reports, monitoring data, authorisations with a significant impact on the environment and environmental agreements, environmental impact studies and risk assessments concerning the environmental elements. Ensure that environmental information progressively becomes available in electronic databases that are easily accessible to the public through public telecommunication networks (Art. 7).
- Inform applicants as to where information, if available, can be found on the measurement procedures, including the methods of analysis, sampling and pre-treatment of samples used, or those standardised procedures used in compiling certain relevant elements of environmental information (Art. 8).

2.3. Reporting

Report to the Commission on:

- experience gained in implementing the Directive (Art. 9(1));
- adopted laws, regulations and administrative provisions necessary to the implementation of the Directive (Art. 10).

2.4. Additional Legal Instruments

Pursuant to Article 2 of the Directive, authorities have to ensure access to a wide range of environmental information, which apart from policies, programmes and legislation on environment include the state of the

elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites including wetlands, coastal and marine areas, biological diversity and its components, GMOs as well as on factors, such as substances, energy, noise, radiation or waste, including radioactive waste, emissions, discharges and other releases into the environment, affecting or likely to affect the environment. The Directives that are most relevant to these issues, apart from this Directive, the EIA Directive, the SEA Directive and Directive 2003/35/EC on public participation) are:

- Directive 2010/75/EU Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions
- Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste
- Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)
- Directive 2006/21/EC of the European Parliament and of the Council of 15 March 2006 on the management of waste from extractive.
- Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for EU action in the field of water policy
- Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for EU action in the field of marine environmental policy
- Directive 2001/80/EC of the European Parliament and of the Council of 23 October 2001 on the limitation of emissions of certain pollutants into the air from large combustion plants (to be repealed by the Directive 2010/75/EU as of 1 January 2016)
- Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe
- Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) 1907/2006
- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise
- Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC

Countries should be aware of the case law relevant for the relationship with other EU legislation. This concerns in particular relationship between Article 4 on exemptions and provisions on access to information in sectoral EU legislation. As a general rule, the sector-specific act as *'lex specialis'* overrules the general access provisions in the Environmental Information Directive. However, many sector-specific acts contain provisions on their

relationship to the Directive, either allowing general access to information subject to the Directive or further specifying the scope of the Directive within their ambit. Nevertheless, it can be difficult to ascertain which legal instrument applies to a specific case²⁵.

Case law to be consulted on this subject²⁶:

In its judgment of 17 February 2009 in Case C-552/07, *Commune de Sausheim v Pierre Azelvandre*, the Court held that a Member State cannot invoke an exemption provided for by Article 4(2), including 'public security', in order to refuse access to information which should be in the public domain under the GMO Directive. The transparency requirements arising from the GMO Directive therefore take precedence over the exception to protect public order or other interests under the Directive.

In its judgement of 22 December 2010 in Case C-524/09, *Ville de Lyon v Caisse des dépôts et consignations*, the Court dealt, in particular, with whether data on greenhouse gas emission allowance trading had to be considered as 'information on emissions into the environment' within the meaning of Article 4 in which case 'the confidentiality of commercial or industrial information' could not be invoked. However, it found that provision of such information was governed by the specific rules on confidentiality in the emission trading scheme.

** Source: Report From the Commission to the Council and the European Parliament on the Experience Gained in the Application of Directive 2003/4/EC on Public Access to Environmental Information (COM 2012/0744/final), page 9.

²⁶ As above.

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the following checklist.

The tasks are arranged under subheadings and organised in chronological order of implementation wherever possible.

Table 10. Access to Environmental Information - Key Implementation Tasks

ACCESS TO ENVIRONMENTAL INFORMATION - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Define the practical arrangements under which public authorities are required to make information relating to the environment available to the public. Provide an overview of the technical possibilities for determining the maximum duration for providing information and the format of the information disclosed.
1.2	Consult all the relevant stakeholders (state authorities relevant to the topics, economic chambers, experts and relevant non-governmental, non-profit organisations) in order to collect viewpoints regarding the concrete definitions of the extent of and limitations to the confidential information categories in Article 4 of the Directive.
1.3	Determine whether active relevant environmental information, particularly monitoring- related data, is available through databases. Then consider constructing web links to a web home page for environmental information.
1.4	Develop Internet and intranet pages for passive and active information dissemination respectively.
1.5	Develop environmental information web links and electronic databases that explain the status of applications vis-à-vis development approval and environmental consent/permit/licence procedures. Where databases provide data derived from measuring or other scientific methodologies, explain how these methodologies work.
1.6	In the interests of economic efficiency, consider the planning measures that are necessary to implement and publish a uniform system of charges for the dissemination of environmental information (if charges are applied). Countries might consider introducing different charging policies for information that is legally required to be made available and for information the compilation of which requires additional person-days on the part of the authority in order to serve certain economic interests of the requester.
2	Regulation
2.1	Ensure that public authorities make environmental information available to the public in accordance with the conditions laid down in the Directive and that environmental information progressively becomes available in electronic databases that are easily accessible.
2.2	Ensure that the practical arrangements for guaranteeing the effective exercise of the right to access to environmental information are defined, including designating information officers, and ensure that facilities for the examination of information are established and maintained.
2.3	Establish procedures for dealing with appeals from the public following refusals of requests for information. Member States may refuse a request inter alia when the request is, unreasonable, or if the material is in the course of completion or certain private and the public interest would be adversely affected by disclosure. Ensure that, in the appeal process, as in the initial procedure, the grounds for refusal are interpreted in a restrictive manner bearing in mind for the particular case the public interest in disclosure. Also ensure that the notification for the refusal states the reasons for the refusal and include information on the review procedure.
2.4	Ensure that there is a legal basis for the system of charges to be applied by competent authorities in connection with the dissemination of information, if charges are imposed.

2.5	As the codification of access to environmental information legislation may overlap with access to information legislation in general, ensure that uniformity exists as far as possible regarding the proper implementation of the Directive, while also taking account of the need to make clear that in environmental cases the specific access to environmental information laws prevail.
2.6	Ensure co-ordination between the relevant environmental competent authority and other public authorities that hold environmental information so that dissemination takes place smoothly within the specified strict timelines. Amendment of the relevant laws regulating the activities of these other authorities might be necessary in order to ensure compliance, in their practical implementation, with the rules for implementing the Directive.
2.7	Ensure that information is up to date, accurate, well organised, easy to access and comparable.
3	Guidance and Training
3.1	Prepare and publish guidance on the duties of public authorities to provide proactive access to environmental information, including transferring incorrectly addressed requests to the correct public authority and detaching parts containing information falling under the exceptions in order to be able to disclose the remaining information.
3.2	Provide communication skills training to enable environmental information officers to use the best means of providing information to stakeholders and of representing the relevant competent authorities. Such training should also assist trainees in internal information management processes. Some of the training events might be organised jointly with relevant organisations that are interested and experienced in access to environmental information matters ("cross training").
4	Reporting
4.1	Report to the Commission on: <ul style="list-style-type: none"> • transposition; • measures taken to comply with the Directive; • the experience gained in implementing the Directive.

3.2. Phasing Considerations

Candidate countries are likely already to possess a large body of environmental data in numerous public organisations. These organisations may need a substantial amount of time to put their information into a format suitable for public access and dissemination. This may necessitate the setting up of an additional unit specifically responsible for public information. The relevant competent authorities (i.e. the national environment ministry or agency and their regional or local counterparts, as well as providers of public services relating to the environment under the control of a public administrative body) should ensure that the competent authority personnel dealing with environmental information are familiar with procedures and best practices when communicating with stakeholders as regards the provision of environmental information, noting that such information can, at times, be sensitive in nature.

The most time-consuming tasks related to the implementation of this Directive are likely to be:

- organising the information services in public bodies and other organisations so as to provide an acceptable level of service to those wishing to access information (e.g. in terms of staffing, databases and reporting facilities), and publicising the services provided;
- supervision and monitoring to ensure sufficient, reliable and timely input from industry, developers, nature protection bodies providing the basis for state of the environment reports;
- organising the production of state of the environment reports and other publications; and
- organising, and where appropriate formatting, the data (particularly monitoring-related data) for public access.

4. IMPLEMENTATION GUIDANCE

Public authorities hold data on a wide range of environmental matters that have often been collected over long periods. Data are collected on, for example, rainfall and other climate events, water quality, flora and fauna, development approval, licensing, permitting and related consents, air and water pollution from emissions and discharges of dangerous substances and land contamination. Public authorities collect information in order to carry out their various legal responsibilities.

The public does not usually have the means to collect and process environmental data. However, access to environmental information will provide them with knowledge of the quality of the environment in which they live and the effectiveness of competent authorities in delivering environmental protection and related human health requirements. On the basis of this information they can (i) make decisions about their way of life, (ii) contribute to informed debate about environmental protection activities, and (iii) support measures to improve the environment. Indeed, such informed participation is a primary goal of the Directive. This conclusion can be reached especially taking into account that the Information Directive is part of the systematic implementation of the pillars of the Aarhus Convention within EU law. However, access to information, including access to environmental information, also has a more general legislative role: ensuring transparency and accountability on the part of authorities dealing with environmental cases, therefore enhancing good governance within a basic cross-cutting legal branch of the public administration.

The Commission has published several guidance documents to facilitate the interpretation and implementation of specific requirements under the Environmental Information Directive. This guidance includes:

- Guidance Document on Reporting About the Experience Gained in the Application of Directive 2003/4/EC Concerning Public Access to Environmental Information http://ec.europa.eu/environment/aarhus/pdf/guidance_en.pdf
- Report From the Commission to the Council and the European Parliament on the Experience Gained in the Application of Directive 2003/4/EC on Public Access to Environmental Information (COM/2012/0774 final) <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52012DC0774>

The following sections draw upon the experience of Member States and present a number of general observations and comments relevant to the implementation of this Directive.

4.1. Planning

- During the transposition phase, careful consideration has to be given to a number of legal issues, for example instances of confidentiality, conditions under which to allow a request for information to be refused, and procedures for appeal against refusals for environmental information. The exceptions to disclosure of environmental information are explicitly provided in Article 4 of the Directive.

- Article 4(1) d) and e) state that a request for information may be refused where it would involve the supply of unfinished documents or data, or internal communications. (Requests may also be refused, pursuant to Article 4(1) b) and c), if they are manifestly unreasonable or formulated in too general a manner.) Member States may introduce restrictions to free access to information based on the instances of confidentiality of proceedings of public authorities or for public security reasons as per Article 4(2). It is necessary to underline that this group of exemptions from the disclosure of public interest environmental data shall not be interpreted in practice in a way that would hinder the right to legal remedies.
- The primary, national competent authority for implementing this Directive is usually the ministry with responsibility for the environment, although regional and/or local competent authority participation will often be vital as accountability and everyday communications with stakeholders will also almost inevitably exist at the regional and/or local level. However, central, regional or local levels of other types of authorities shall also play an important role in the implementation of the Directive. These include authorities responsible for water management, forestry, fishery, game management, soil and arable land protection, catastrophe prevention, public health and chemical safety, mining, traffic etc.
- Environmental information may be held by a large number of public bodies within a country. At the level of central government, these may include government ministries with responsibility for agriculture, the environment, planning, transportation etc. Other types of national bodies that may hold relevant information include environmental protection agencies, meteorological offices, central statistics offices, research institutions etc. At the regional and local level, environmental information may be held by sub-national or local environmental inspectorates or environment agency offices, local government offices, local planning authorities, municipalities etc. Consideration may have to be given to the recruitment of trained environmental information officers at these levels. Given the expanded definition of "public authorities" in Article 2, the providers of public services relating to the environment under the control of public administrative bodies are also to be placed under the access provision obligations, at least to forward requests for information on to any relevant public administrative body.
- Where information relating to the environment is held by bodies that have responsibilities for the environment and that are under the control of public authorities, ensure that lists of public authorities are publicly accessible. Meta-databases listing the type of information they hold might be a useful tool for supporting effective access to environmental information.
- Member States need to define the practical arrangements under which environmental information is made available to the public. In practical terms, given the potentially large number of public bodies involved, if different public authorities make their own arrangements to comply with the Directive, guidance from central government will be required to ensure that the Directive is implemented consistently.
- Practical arrangements for guaranteeing the effective exercise of access to environmental information can include the designation of information officers and the creation and maintenance of facilities specifically to provide and hold environmental information.
- In the case of a national public body with a number of regional offices, the organisation will need to decide whether to supply information centrally through a publications office or through its network of regional offices. In the latter case, the organisation needs to consider which offices can conveniently

provide a service to the public based on a network for handling enquiries and meeting requests for information.

- Where environmental information is held centrally, consideration might be given to the establishment of an electronic network comprising all authorities holding environmental information. In conjunction with creating this network, Member States could develop and implement a protocol for the regular supply of appropriately formatted information to the relevant central Internet or intranet site. Alternatively, where sub-regional authorities have a key stakeholder interface role with regard to the provision of electronically held environmental information, this could be accomplished through regional and/or local controlled websites.
- In some circumstances a single organisation will have responsibility for data collection and assessment, for example a meteorological office, a research institute or a statistical office. This type of institute may be directly under the responsibility of a government ministry or have a quasi-independent status. The institute may either (a) arrange to make the data available through the relevant ministry, or (b) provide its own service.
- Some research institutes hold databases on environmental quality, for example on observations of flora and fauna, which are available to the public on request.
- Where various agencies are collecting data in a particular environmental sector, it may be necessary to establish a framework to co-ordinate data collection and management. Such a framework may be provided by a single environment agency. In other cases, a single organisation may need to be appointed as the appropriate authority for collecting data in a particular area.
- Public bodies should periodically review the staffing arrangements for the service responsible for providing information in order to ensure that staff can deal with requests for information and that the response times are in compliance with the legal provisions. The organisation may wish to publicise performance criteria for dealing with requests, that is, response times for providing information.
- Public bodies may need to consider how the data collection, storage and reporting can be harmonised to facilitate data collection from different sources. They may also need to set up standardised data collection and reporting formats.
- Quality control is vital in order to ensure the reliability and accuracy of data. This is particularly important where data are to be used in environmental analysis or for assessing compliance with environmental quality standards, or are to be made available to the public. Quality control procedures need to be developed for all stages of data collection, database preparation, analysis and reporting.
- Where the information service is to be supported by a database facility, it may be necessary to decide whether the existing system needs to be updated or modified to enable the service to be as efficient as possible. Particular consideration should be given to cost effectiveness and flexibility for future modification. Consideration must also be given to providing data to the public electronically, for example on the Internet. The Directive encourages the use of technology to make information available to the public.
- Public authorities should have a procedure, database and internal communications strategy for processing requests for information in situ or via websites that explain how measurement procedures are applied in compiling environmental information.

- Certain Directives require information to be made available for public inspection – for example the outcome of applications for development consent under the EIA Directive, IED/IPPC applications, or data concerning the application of sewage sludge to agricultural land (Sewage Sludge Directive, 86/278/EEC). The relevant competent authorities need to consider how this information is to be made available to the public, for example in registers to be held by the competent authorities themselves, or by local government offices.
- Under the Directive, public bodies are required to supply information to any person, on request, for a reasonable cost and within a reasonable time (Art. 3). A "reasonable time" takes into account any timeline specified by the applicant, and also the circumstances of the case that the information concerns (e.g. information shall be given before an imminent decision-making procedure starts or certain procedural or substantial deadlines expire). Further, if the volume and complexity of the information requested makes it impossible to comply with the request within the usual one-month deadline, the turnaround time may not exceed two months. Therefore, arrangements for supplying information should be practical and efficient and, as far as possible, should not present a significant ongoing financial burden to the organisation concerned.
- Charges to the public for information must not exceed the reasonable costs for supplying the information (Art. 5). Public authorities need to avoid any suggestion that they are imposing a barrier to the availability of the information through pricing. Charges should be consistent within organisations and must be publicised (Art. 5(3)). A "reasonable" charge implies that, as a general rule, it may not exceed actual costs of producing the material in question. Instances where advance payment will be required should be limited. In particular cases, where public authorities make available environmental information on a commercial basis, and where this is necessary in order to guarantee the continuation of collecting and publishing such information, a market based charge is considered to be reasonable; an advance payment may be required. A schedule of charges should be published and made available to applicants together with information on the circumstances in which a charge may be levied or waived. (Recital 18)
- Information shall always be made available except under the conditions set out in the Directive. Information shall be disclosed in part when it can be detached from the part of the information that falls under the exceptions.
- The national legislation should set up an administrative appeal procedure (if not already established) to deal with cases in which requests for information are refused (Art. 6). Such a procedure shall be expeditious and either free of charge or inexpensive (Art. 6). In addition, public authorities shall ensure that an applicant has access to a review procedure before a court.

Examples of Legal Provisions Implementing Directive 2003/4/EC

Sweden: In Sweden the implementation of Directive 2003/4/EC did not require changes in national legislation. According to the Freedom of the Press Act, which is part of the national constitution, everyone has the right to access documents kept by the public authorities. This right is limited only in specified cases according to the Secrecy Act. Anybody who is refused access to a document can appeal against the refusal.

Portugal: In Portugal, the Directive on Access to Environmental Information was transposed through the Law on Access to Administrative Information. The national law contained a general reference to access to environmental information and stated that the Directive should be applied. This raised the issue that simply legislating that that Directive should apply without specifying any further regulation was not considered to be sufficient for its transposition.

Also, the lack of response by the public authorities within a given time period was regarded as a refusal under national law, when under Article 3(4) of Directive 90/313/EEC (as with this Directive), an answer should be given to the applicant and, in the event of a refusal to provide the information, the grounds for the decision must be given.

Example on Uniform Codes for Operators

Hungary: the Ministry of Environment has initiated the issuance of governmental decrees about using uniform codes for operators (Environmental Operators Code) and for activities (Environmental Activity Code) for the relevant branches of administrative bodies. With the help of these codes, several dozens of databases of significant environmental relevance can be interconnected and searched, in order to obtain a complex picture of certain environmental problems and situations

Examples of Arrangements for Charging the Public for Information Provided

United Kingdom: In the UK, existing charges for information vary between organisations and depend on the nature of the information. Data and other information are often charged at a nominal fee reflecting the administrative time and photocopying costs involved in collating the information. Documents can be purchased through the state publications office.

Sweden: In Sweden public authorities may charge an amount equivalent to the actual cost of providing a copy. Charges for documents are regulated in the Service Charge Ordinance.

The Netherlands: In the Netherlands, a system of charges is prescribed through a published schedule applicable to ministries of the national government. Local authorities are free to create their own charging systems.

4.2. Guidance

- Governments may prepare guidance notes for public authorities to explain their duties under the legislation. Such guidance notes could cover:
 - an introduction to the issues raised, including a clarification of the specific laws on access to environmental information and the laws, if any, on general access to public interest administrative information;
 - a list of the types of organisations affected; that is, public authorities such as government departments, all statutory bodies, or any body with public responsibilities for the environment that is under the control of public authorities, an environmental protection agency or public services provider;
 - the scope of the environmental information available to the public (e.g. the state of water, air, soil, flora, fauna, land and natural sites), and activities or measures that have an environmental impact, as well as environmental protection activities or measures;
 - environmental information for dissemination on the Internet and the intranets of competent authorities;
 - publicising the type of information held;
 - the release of reports;
 - the availability of registers of relevant information;
 - response times;
 - charges;
 - refusals of requests, judicial or administrative reviews, and appeals;
 - how to handle information exempt from disclosure (e.g. information related to national defence or public security, commercially sensitive data and data on individuals);
 - protocols for stakeholder interaction.
- Candidate countries should also consider how to inform the public about their rights to access to environmental information. This could be done through the Internet and through information packs prepared by local government offices or the relevant competent authorities. NGOs also play an important role in obtaining, checking and analysing information held by public bodies. NGOs disseminate their interpretation of the data in a wide variety of ways, including newsletters to members, publications, articles in the press, and via the Internet.

4.3. Reporting

- Candidate countries are required to publish general information on the state of the environment, for example through the periodic publication of descriptive reports. The Directive gives certain guidance

on the frequency (at regular intervals not exceeding four years), scope (national and, where appropriate, regional and local) and depth of information (information on the quality of, and pressures on, the environment) to be contained within these reports (Art. 7, Para. 3). In addition, Article 5(4) of the Aarhus Convention gives guidance: "Each Party shall, at regular intervals not exceeding three or four years, publish and disseminate a national report on the state of the environment (...)."

- Many Member States do routinely publish reports on the state of the environment. The value of the information disclosed in this way might depend on the variety of the information suppliers and the formats used by the publishers. In some countries, the ministry of environment develops a series of products connected to the annual environmental reports, ranging from lengthy and detailed reports to simple leaflets drawing the attention of the public to the most important facts and trends.
- The ministry with responsibility for the environment or another national organisation such as a statistical office or environment agency may publish the state of the environment report. Governments will often wish to have overall responsibility for the production of the state of the environment report. However, organisations such as environment agencies often have the easiest access to the type of information required for a state of the environment report. Such organisations may also be identified as national focal points under the European Environment Agency Regulation (No. 401/2009) and may receive environmental information from the national Eionet for forwarding to the European Environment Agency. Such organisations are likely to have at their disposal a complement of trained staff collecting, analysing and assessing environmental data on a regular basis, together with other staff, involved with planning programmes to improve the environment, that require up-to-date information to assist them. Consequently, an environmental protection agency is often best placed to prepare a state of the environment report, albeit under the auspices of the ministry with responsibility for the environment.

Examples from Member States

Most Member States publish a State of the Environment report annually. This is also coordinated partly through EOINET and Member States (EU States) as well as EEA countries participate and provide information to the work of the European Environment Agency (EEA) whose main task is to provide the State of the Environment reports. Some of the discussions focus on common indicators according to which Member States are advised to reflect, plan and evaluate environmental data. Candidate countries can follow these discussions, work on producing indicators, Member States' experience at: http://forum.eionet.europa.eu/nrc-state-environment/login/login_form?came_from=http%3A//forum.eionet.europa.eu/nrc-state-environment/library/nrc-soe-meetings/nrc-state-environment-workshop-26-27-september-2011/index.html&retry=&disable_cookie_login=1. Regarding the EEA State of the Environment report is from 2010 („The European environment – state and outlook 2010: Synthesis”), available at: <http://www.eea.europa.eu/soer/synthesis/synthesis>

Example from a Member State:

In Sweden the Environmental Code requires legal entities carrying out certain commercial and industrial activities to submit environmental reports (miljörapporter). The EPA has established an Environmental Reporting Portal with the formats for the reporting. There is also guidance available at: http://www.naturvardsverket.se/upload/03_lagar_och_andra_styrmedel/tillsyn_och_egenkontroll/Egenkontroll/Miljorapportering/Vagledning-miljorapportering-ver8.pdf (in Swedish). In addition, the Swedish Environmental Protection Agency (Naturvårdsverket) publishes annual State of the Environment reports. In addition, EPA is operating a screening programme financed by the EPA, aiming at alleviating the lack of knowledge by estimating the occurrence of different chemicals in the environment in relevant matrices (soil, water etc.). The result from the screening studies typically consists of the concentrations of various substances in various matrices at, or close to, different anthropogenic sources as well as concentrations unaffected background localities. An important part of the screening program is to evaluate these results, which partly is contracted out to external experts. Swedish consultant SWECO carried out to analysis in 2006 and 2008 („SWECO Environment Screening Report 2008:8, Evaluation of results from Swedish screening studies, Suggestions for a methodology”)

5. COSTS

The implementation of this Directive may involve additional costs to public organisations, related to the provision of information services and reporting requirements. The main cost areas are listed in the checklist below, although some may already be covered if a state has taken active practical steps to give effect to Directive 2003/4/EC.

The authority with responsibility for producing the state of the environment report will incur additional costs, unless they already prepare reports that meet the reporting requirements. A charge is normally made for the reports. However, the decision as to whether the charge should cover the costs involved is a matter of government policy. There is a strong case for limiting the cost so that as many members of the public as possible can have access to the reports.

Table 11. Checklist of the Types of Cost Incurred to Implement the Directive Initial set-up costs

<p>Checklist of the Types of Cost Incurred to Implement the Directive Initial set-up costs:</p> <ul style="list-style-type: none">• improvements to procedures for data collection, storage and retrieval;• provision of, or improvements to, databases, including computer systems and PCs;• improvements to, or new, office facilities;• training of information officers in communications and information dissemination methods;• information technology for running relevant databases, information networks and• websites. <p>Ongoing costs:</p> <ul style="list-style-type: none">• provision of information service (staffing, consumables, etc);• reporting to the public and the Commission;• information technology maintenance and updating, as necessary and• running of an information centre, helpdesk or other assistance service facilitating the public's access to environmental information

THE PUBLIC PARTICIPATION DIRECTIVE

Official Title: Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending, with regard to public participation and access to justice, Council Directives 97/11/EC/EEC and 96/61/EC (OJ L 156, 25.6.2003)

6. SUMMARY OF THE MAIN AIMS AND PROVISIONS

On 25 June 1998 the European Community signed the Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (the Aarhus Convention). Reflecting the general aim of properly aligning EU law with the Aarhus Convention, the primary aims of this Directive is to provide for public participation in respect of the drawing up of certain plans and programmes relating to the environment, meaning that Member States must guarantee that the public (natural and legal persons, associations, organizations or groups) is given early and effective opportunities to participate in the preparation and modification or review of the plans and programmes referred to in Annex I.

Initially, another objective of the Directive was to improve public participation and making rules on access to justice within Directives 85/337/EEC and 96/61/EC. These two Directives were subject to a major overhaul. As a result rules on public participation were included in sector specific legislation. Thus, Directive 2003/35/EC has been amended by Directive 2011/92/EU repealing Article 3 of the Directive. In addition, Directive 2010/75/EU has repealed Directive 2008/1/EC as of 7 January 2014, which has repealed Article 4 and Annex II of the Public Participation Directive.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1 Planning

- A list of plans and programmes shall be put together taking into consideration Annex I of the Directive:
 - all levels of waste management plans, including plans in international co-operation;
 - four-year programmes in connection with batteries and accumulators, including a reduction in quantity, in the dangerous materials they contain, and in their proportion in household waste etc.;
 - action programmes in relation to water protection in zones vulnerable to nitrate pollution;
 - hazardous waste management plans, if separate from general waste management plans;
 - management plans for waste from packaging materials (as part of the general waste management plan);
 - plans or programmes related to air pollution in zones and agglomerations where pollution levels are higher than the limit values plus the margin of tolerance.
- There shall be a systematic examination of whether there are other plans or programmes according to national law that shall be subject to public participation in harmony with the Directive.
- During the planning phase it should also be ensured that parallel or contradictory rules are avoided in relation to the SEA Directive (Directive 2001/42/EC) and the Water Framework Directive (Directive 2000/60/EC). In fact, this Directive (Art. 2) does not apply to plans and programmes for which a public participation procedure is carried out under Directives 2001/42/EC and 2000/60/EC.
- A decision shall be made as to whether the new provisions on public participation concerning certain plans and programmes are better suited:
 - to a separate piece of legislation;
 - to an already existing piece of legislation (and, if yes, to general environmental law: the environmental code, the law on general rules for environmental protection etc.); or
 - to a specific environmental law.

2.2 Regulation

- The rules on scope shall encompass all the kinds of plans and programmes in Annex I
 - and, if any, other specific plans and programmes or a general description of environmental plans and programmes that are covered by the regulation. The list in Annex I may be incorporated into the main text or may be attached as an annex to the text.
- Exemptions shall be determined as concerns plans and programmes designed for the
 - sole purpose of serving national defence (it should be noted that this is not mandatory)

- and plans or programmes that have already undergone an SEA or WFD procedure.
- The definitions shall include "the public" in harmony (word by word is the best solution)
 - with Article 2(2) of the Directive. Other definitions are also possible, such as definitions of "the designer", "environmental plan or programme" (this is necessary only if the scope of regulation is wider than that of the Directive), or "relevant non-governmental organisations".
- Notification rules shall contain the following provisions (usually in separate paragraphs):
 - the exact timing of the notification, with guarantees of the earliest possible notification;
 - the identification of the persons and organisations to be notified;
 - the methodology(ies) of minimum use in all cases;
 - suggested further methodologies of notification;
 - the minimum content of the notification.
- The rules of participation shall contain the following procedural steps:
 - issuance and reception of comments from members of the public and public organisations;
 - provision of information to the public during the planning procedure;
 - public discussions (trial, hearing etc.) as a binding rule;
 - time-frames for each participation step.
- Rules regarding due consideration of public comments shall cover the procedural rules of evaluation and the inclusion of the results of the evaluation into a written document that accompanies the plan or programme, or other method of informing the public about the consideration given to their inputs.
- Rules regarding the participation of relevant non-governmental organisations shall contain a clear description of the conditions for participation in the planning and programming procedures, such as the scope of activity or the territorial scope of the activity of the NGOs.
- All the relevant laws concerning general waste management planning, programmes for batteries and accumulators, action programmes for the protection of water against nitrate pollution, hazardous waste management plans, management plans for packaging waste, plans and programmes for tackling air pollution in certain zones and agglomerations, and others, if any, shall be supplemented with an additional paragraph with a reference to the new legislation on public participation concerning plans and programmes.

2.3 Reporting

- Reporting to the Commission within the framework of Article 5 of the Directive
- Member States shall inform the Commission on the laws, regulations and administrative provisions drawn up in order to comply with the Directive in harmony with Article 6(1) of the Directive.

2.4 Additional Legal Instruments

- The Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters (the Aarhus Convention), 1998.
- Directive 2008/50/EC on ambient air quality.
- Directive 2008/98/EC on waste.
- Packaging Waste Directive 94/62/EC.
- Batteries Directive 2006/66/EC.
- Nitrates Directive 91/676/EEC.
- Environmental Information Directive 2003/4/EC.
- Council Directive 2011/92/EU on Environmental Impact Assessment (consolidating and repealing Directive 85/337/EEC).
- Council Directive 2001/42/EC of the European Parliament and of the Council on the assessment of the effects of certain plans and programmes on the environment (the SEA Directive).
- Directive 2010/75/EU on industrial emissions.

3. IMPLEMENTATION

3.1 Key Tasks

The key tasks involved in implementing this Directive are summarised in the following checklist.

The tasks are arranged under subheadings and organised in chronological order of implementation wherever possible.

Table 12. Public Participation Directive - Key Implementation Tasks

PUBLIC PARTICIPATION - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Putting together the list of plans and programmes that must be included in the new regulation (Annex I of the Directive).
1.2	Collecting the relevant laws and regulations on these plans and programmes.
1.3	Deciding if other plans and programmes shall be subject to regulation either by adding to the list or by determining the basic features that establish the necessity for inclusion under the scope of the new regulation.
1.4	Determining steps to eliminate parallel procedures with SEA and WFD (Art. 2(5)).
1.5	Deciding on the legal technique for the codification of the new regulation (separate or incorporated, incorporated into general environmental law or into a specific law).
2	Regulation
2.1	Creating a preamble containing the goal of the regulation and the basic principles of the regulation, such as the protection of personal health and well being, accountability and the transparency of the planning and programming procedures, public awareness and support, the promotion of environmental education among the public and effective and early participation (Preamble of the Directive, Recitals 3, 4 and 6, Art. 2(2)).
2.2	Determining the scope of legislation (with a list in the text or in an annex) (Art. 2(2) and Annex I).
2.3	Determining the exemptions (national defence and SEA or WFD) (Art. 2(4) and (5)).
2.4	Providing definitions (mandatory: "the public"; optional: "non-governmental organisations", "designer", "environmental plan", "environmental programme" etc.) (Art. 2(1)).
2.5	Establishing the details of the notification rules (including the identification of the persons and organisations notified) (Art. 2(2) and (3)).
2.6	Determining the detailed procedure for participation, including the rules for disclosing relevant information during the planning and programming procedure, and for due consideration of the comments (Art. 2(2)).
2.7	Establishing specific rules for the participation of NGOs (Art. 2(3)).
2.8	Developing a section on separate rules for the modification or review of the plans and programmes subject to the new legislation on public participation (Art. 2(3)).
2.9	Inserting reference rules into all of the relevant laws and regulations on planning and programming (see 2.2. above).
3	Guidance and Training
3.1	Generating guidance and training materials for officials dealing with waste management planning (including hazardous waste and packaging waste management planning), air protection and hazardous materials (only batteries and accumulators if they belong to a separate unit).
3.2	Designing guidance and training materials for members of the public and public organisations. Considering the production of a range of materials from detailed procedural descriptions to simple leaflets, and the use of electronic information tools. Considering the organisation of cross trainings (joint

	trainings for relevant officials and NGO representatives with opportunities for mutual exchange on the schedule). (In harmony with the Preamble, Recital 4 of the Directive.)
4	Reporting
4.1	Reporting to the Commission upon request (Art. 5).
4.2	Reporting to the Commission on the laws, regulations and administrative provisions drawn up in order to comply with the Directive (Art. 6).

3.2 Phasing Considerations

The planning phase might be time-consuming, bearing in mind the need to contact several branches of the administration that are concerned with the new regulation on public participation in designing certain plans and programmes. The actual legislative work might be made more complicated by the possible (suggested) decision on public participation in the legislative procedure of the new regulation itself.

4. IMPLEMENTATION GUIDANCE

6.1. Planning

- When determining the extent of the list subject to the regulation on public participation in planning and programming, the countries should take into consideration that this list shall be broader than that of the SEA regulations, since the public participation regulation is much less demanding (e.g. it does not require an environmental evaluation or report), while the possible direct or indirect environmental effects might make public participation necessary in connection with a wide range of plans and programmes.
- The definition of environmental information in Article 2(3) of the Aarhus Convention and the identical definition in the Environmental Information Directive 2003/4/EC might be relevant when determining the list. Definition elements such as certain factors (substances, energy, and radiation), measures and economic analyses, as well as the state of human health and safety, conditions of human life, cultural sites and built structures might be used to design the scope of the regulation.

Examples of Legal Provisions Used for Implementing Directive 2003/35/EC

Hungary: In this Member State the scope of the so-called environmental analysis is defined in a very broad way. All strategic-level decisions, draft laws and regulations, national or regional concepts that include all plans, programmes or policies shall be examined by the National Environmental Council (which includes seven environmental NGO representatives) if they have any impact on the quality of the environment or on human health. Economic instruments such as customs, tax, or court or administrative fee regulations shall always be subject to this legal institution.

4.2 Regulation

- When designing the definition part of the national legislation the countries should ensure that the definitions do not contain substantial provisions (e.g. the definition of "non- governmental organisations" should not in itself determine which organisations are entitled to participate and which not in the design procedure of the plans or programmes).
- The circle of persons and organisations to be notified can be determined according to a particular geographical area (the whole country, regions, counties, neighbouring municipalities or the territorial scope of the effects) or by other types of connection to the subject of the planning and programming procedure.

- The earliest time for notification can be the onset of the conceptual phase of the planning or programming in cases when the procedure is divided into conceptual and substantial (detailed) planning/programming phases. The legislator should also take into consideration that the notification might reasonably take place when sufficient information is available about the substance of the planning/programming procedure. Such information, however, can also be disclosed at later stages of the procedure and might not be a reason for delaying the notification.
- The methodologies for notification may include: the Internet home page of the designer; a local or national daily newspaper; public notices at regularly visited places; circular letters to NGOs with a potential interest in the subject of the planning/programming procedure etc.
- The minimum content of the notification is prescribed by Article 2(2), Point a) of the Directive:
 - information that the notified persons and organisations have the right to participate in the decision-making procedure (this should be accompanied by information about the technical details and deadlines for participation); and
 - information on the competent authority to which comments or questions may be submitted (this should include the name and address of the authority, the possibility to use electronic communication tools, the contact person or the person charged with the planning/programming itself etc.).
- Reasonable time-frames shall be provided allowing sufficient time for each of the stages of public participation required by the Directive (Art. 2(3)). When determining the time-frames or deadlines, the legislator (or the designer if the legislator gives general instructions rather than exact times) should take into consideration the content and level of complexity of the information necessary for effective participation. In the case of participation of organisations or local communities, the time-consuming nature of internal discussions and decisions, and also the necessity to require the help of external experts, shall also be taken into consideration.

Example of Public Participation Processes Concerning Plans and Programmes

National reports submitted by the parties to the Aarhus Convention to the Third Meeting of the Parties (Riga, 2008) in connection with Article 7 of the convention, concerning public participation in plans, programmes and policies relating to the environment, contain several good examples:

- In defining the scope of application of Article 7 (plans and programmes relating to the environment), the definition of environmental information in Article 2(3) is applied (DK).
- In establishing policies and strategies, preliminary idea meetings and workshops are extensively utilised, during which the public has an opportunity to have a say in the decision-making process (DK).
- Principles and examples of good practice with respect to the involvement of the public have been elaborated by the State Chancellery to be followed by all public authorities (ES).
- Within the framework of Local Agenda 21, sustainable development programmes are discussed in a consultative forum where the public and the stakeholders are represented (IT).
- In order to identify NGOs having an interest, the Ministry of the Environment maintains a list of organisations willing to participate in consultations on certain issues (PL).

5. COSTS

Table 13. Checklist of the Types of Cost Incurred to Implement the Directive

Checklist of the Types of Cost Incurred to Implement the Directive

Initial set-up costs:

- studies and analyses on the possible extent of the scope of the new regulations;
- consultations with the relevant branches of environmental and other administration;
- initial training of the relevant personnel involved in air protection and of waste management and water protection officials within the environmental protection authorities;
- editing and printing training manuals (both for officials and for the general public) and leaflets (for the public).

Ongoing costs:

- provision of office time and resources on the part of the designer (staffing, consumables, etc);
- reporting to the public and to the Commission;
- information technology maintenance and updating, as necessary.

THE ENVIRONMENTAL LIABILITY DIRECTIVE

Official Title: Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage (OJ L 143, 30.4.2004)

Amended by:

Directive 2006/21/EC of the European Parliament and of the Council of 15 March 2006 on the management of waste from extractive industries and amending Directive 2004/35/EC (OJ L 102, 11.4.2006)

Directive 2009/31/EC of the European Parliament and of the Council of 23 April 2009 on the geological storage of carbon dioxide and amending Council Directive 85/337/EEC, European Parliament and Council Directives 2000/60/EC, 2001/80/EC, 2004/35/EC, 2006/12/EC, 2008/1/EC and Regulation (EC) No 1013/2006 (OJ L 140, 5.6.2009)

Directive 2013/30/EU of the European Parliament and of the Council of 12 June 2013 on safety of offshore oil and gas operations and amending Directive 2004/35/EC (OJ L 178, 28.6.2013)

1. SUMMARY OF THE MAIN AIMS AND PROVISIONS

Directive 2004/35/EC (hereafter referred to as the „Environmental Liability Directive”) is the first secondary EU legislation whose main objectives include the application of the "polluter pays" principle as set out in the Treaty on the Functioning of the European Union (Article 191(2) TFEU). The Directive establishes a common legal framework for liability with a view to preventing and remedying damage to animals, plants, natural habitats and water resources, and damage affecting the land. The liability scheme applies to certain specified occupational activities covered by strict liability and to other activities in cases where the operator is at fault or negligent. The public authorities are also responsible for ensuring that the liable operators take or finance the necessary preventive or remedial measures themselves. The Environmental Liability Directive deals with the "pure ecological damage", and it is subsequently based on the powers and duties of public authorities ("administrative approach") as distinct from a civil liability system which is more appropriate for "traditional damage" (damage to property, economic loss, personal injury). This approach has been welcomed by the Member States.

The Directive was preceded by the White Paper on Environmental Liability of 9 February 2000²⁷ and aspires to meet the commitment in the Commission's Sustainable Development Strategy, which aimed to have "EC legislation on strict liability in place by 2003". The newly adopted Environmental Crimes Directive (2008/99/EC), further supports the legal approach of this Directive, as it requires that the Member States impose sanctions for certain environmental criminal offences.

The Environmental Liability Directive was already amended three times through Directive 2006/21/EC on the management of waste from extractive industries, Directive 2009/31/EC on the geological storage of carbon dioxide and through Directive 2013/30/EU on safety of offshore oil and gas operations. Directive 2006/21/EC broadened the scope of strict liability by adding one more dangerous activity ("management of extractive waste") to the list of dangerous occupational activities in Annex III of the ELD. Directive 2009/31/EC adds another dangerous activity ("operation of storage sites pursuant to Directive 2009/31/EC") but includes also genuine responsibility and financial security provisions separate from the ELD, whereas Directive 2013/30/EU clarifies that holders of authorisations for offshore oil and gas operations pursuant to Directive 94/22/EC are also the liable 'operators' within the meaning of Directive 2004/35/EC. In this context, definition of water damage in Directive 2004/35/EC has been amended to cover also damage to marine waters.

The elementary foundations of the Environmental Liability Directive comprise:

- Covers environmental damage -- or any imminent threats of damage -- under three categories:
 - damage to protected species and natural habitats as defined by the Directive, that is damage to protected species and natural habitats that has significant adverse effects on reaching or maintaining the favourable conservation status of such species or habitats;
 - water damage, that is, damage that has a significant adverse effect on ecological, chemical and/or quantitative status and/or ecological potential, as defined in the Water Framework Directive 2000/60/EC and the Marine Strategy Framework Directive 2008/56/EC;

²⁷COM(2000) 66 final

- land damage, that is, any land contamination that creates the significant risk of an adverse effect on human health as a result of the direct or indirect introduction in, on or under the land, of substances, preparations, organisms or micro-organisms.
- Imposes strict liability on operators who undertake an activity covered by the EU legislation listed in Annex III of the Directive for the above three types of environmental damage. In 2006 and 2009 this Annex was amended to include mining waste activities and the geological storage of CO₂.
- Imposes fault-based liability on operators of non-listed occupational activities. These operators can be held liable for damage to protected species and natural habitats and not for other types of damage.
- Shall apply to environmental damage and any threat of such damage (see above) occurring by reason of occupational activities that are listed in Annex III.
- Shall also apply to damage that adversely affects biodiversity and that results from occupational activities not listed in Annex III.
- Does not cover environmental damage resulting from armed conflict, national defence, a natural disaster, or pollution that is of a widespread or diffuse character where a causal link to an individual operator cannot be established.
- Does not apply to environmental damage caused by activities covered by the international conventions (mainly IMO Conventions) listed in Annex IV relating mainly to maritime transport and by nuclear activities covered by the Treaty establishing the European Atomic Energy Community or activities covered by the international conventions listed in Annex V.
- Shall require the operator (the potential polluter) to take necessary preventive and restorative measures (the latter based on rules and principles contained in Annex II) for environmental damage.
- Shall require that, in cases where the operator is not in a position to take preventive or restorative measures, these could be undertaken by the competent authority and the costs recovered at a later date, within five years at the latest.
- Leaves it open to Member States to provide for the so-called permit defence. The permit defence would allow operators under certain circumstances to escape from bearing the costs of measures if they demonstrate that they were not at fault or negligent and that the damage was caused by an emission or event expressly authorised under applicable national laws.
- Leaves it open to Member States to provide for the so-called state of the art defence. The state of the art defence would allow operators to escape from bearing the costs of measures if they demonstrate that they were not at fault or negligent and that the damage was caused by an emission or activity or any manner of use of a product in the course of an activity that the operator demonstrates was not considered likely to cause environmental damage according to the state of scientific and technical knowledge at the time the emission was released or the activity took place.
- Does not provide for specific cost allocation mechanisms in case of multi-party causation, but leaves the issue to the Member States to decide.
- Provides investigative and related powers for competent authorities.
- Establishes a "request for action" procedure for addressing third-party requests and provides related access to courts or comparable decision-making bodies as a means of redress where requests for action are not satisfactorily addressed.

- Third parties are defined as natural or legal persons affected or likely to be affected by environmental damage; or having a sufficient interest in environmental decision making relating to damage; or alleging the impairment of a right where this is required under national law. Any non-governmental organisation promoting environmental protection and meeting any national law requirements is deemed to have sufficient interest/impairment of a right.
- Sets out the rules and procedures for remedying environmental damage (Annex II).
- Requests Member States to encourage the development of financial security/insurance mechanisms.
- Requires co-operation between mutually affected States in matters of environmental damage prevention or remediation.
- Being prospective as of its effective implementation date (30 April 2007) and not retroactive.
- Provides detailed reporting requirements to be met by Member States in 2013 and the Commission in 2010 and in 2014.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Designate competent authorities and other bodies to implement the requirements of the Directive.
- Create the procedures required for the competent authority to carry out environmental assessments in order to determine the extent of environmental damage and the measures needed to remedy it.
- Determine a procedure for determining when the measures should be taken by the relevant operator or by the competent authority on their behalf.
- At the earliest stage of implementation, identify key actors and stakeholders who will be involved in or impacted by the implementation of the Directive. This might also comprise a preliminary assessment of the type of activities carried out which are covered by the Directive.
- Generate discussion and consultation with stakeholders that should focus on prevention, mitigation and remediation/restoration issues, and identify areas where environmental damage may occur or has occurred.
- Identify, and hold initial discussions with, all potential polluter sectoral representatives in order to help achieve the most efficient path to approximation, to avoid costly errors (for example, in drafting legislation and regulations and in setting up institutions), and to encourage the co-operation of operators in complying with the national legal instruments.
- Discuss approaches to cost allocation, noting the range of mechanisms that would appear to be permitted by the Directive and national law. This is particularly important in multiple party causation circumstances.
- The lead competent authority could be the ministry with responsibility for environmental protection or the national environmental protection agency, but designation as competent authority actually varies from Member State to Member State. The authority should be able to take a nationwide view of the issues, co-ordinate nationwide actions and report on a nationwide basis, but this is not actually the case in all Member States, since in several Member States regional authorities or even local municipalities have been designated as competent authorities.
- It is important to have effective co-ordination between the competent authority with primary responsibility for the implementation of this Directive, and those local and regional bodies that may play a monitoring, enforcement and overseeing role.
- The competent authorities of bordering/neighbouring Member States may wish to collaborate and co-operate on procedures to ensure the proper and effective prevention of cross-border environmental damage and to implement procedures for restoring the environment in cases where environmental damage is of a cross-border nature.

To the extent activities are planned on geological storage of CO₂, the specific provisions set out in Directive 2009/31/EC have to be observed as it removes environmental liability from private operators in certain circumstances.

2.2. Regulation

- Establish the legal basis for addressing environmental damage including biodiversity damage as prescribed by the Directive.
- Provide a clear understanding of the breadth and scope of the exception provisions of the Directive, including as to persons and circumstances within the prescribed exemptions from liability including the transfer of responsibilities from private operator to the competent authorities in certain cases, such as those prescribed for in Directive 2009/31/EC on geological storage of CO₂.
- Determine the definitions and procedures that apply with respect to prevention, mitigation, remediation and restoration activities.
- Set up procedures for cost recovery where the competent authority had implemented preventive or restorative measures on behalf of the operator or undertook an environmental assessment related to the damage.
- Decide upon the introduction of exceptions from cost recovery, particularly permit defence and state of the art defence.
- Decide upon the possible establishment of mandatory financial security or create procedures for encouraging operators to have financial security, such as insurance, and for assessing the adequacy of such insurance provision.
- Provide procedures for legal and natural persons and qualified entities likely to be adversely affected by environmental damage to make requests for and to take legal action as appropriate.
- Establish procedures for cross-border co-operation with other Member States in cases where preventive or restorative measures are required.
- Establish procedures for judicial review and challenges to action or inaction taken for legal and natural persons and qualified entities.
- Ensure that the legal position on non-retrospectivity is codified in law (bearing in mind that transposition could be stricter than required by the minimum standards of the Directive).
- In the light of the latest amendments it is necessary to ensure that holders of authorisations for offshore oil and gas operations pursuant to Directive 94/22/EC are also the liable ‘operators’ within the meaning of this Directive and should not delegate their responsibilities in this regard to third parties contracted by them.

2.3 Monitoring

- Designate competent authorities to carry out monitoring and enforcement and to bring non-compliance actions.

- Devise a system for identifying potential and actual environmental damage.
- Ensure that monitoring activities address prevention, mitigation and remediation activities.

Ensure that monitoring duties falling upon industrial operators pursuant to Directives 2010/75/EU on industrial emissions and 2009/31/EC on geological storage of CO₂ are being carried out adequately.

2.4 Information and Reporting

- Report to the Commission on:
 - The main provisions of national law that Member States adopt in the field covered by this Directive, together with a table showing how the provisions of the Directive correspond to the national provisions adopted.
 - Damage identified within a Member State's borders not caused by itself (the issue may be reported to the Commission and any other Member State concerned), pursuant to Art. 15(3)

2.5 Additional Legal Instruments

A number of other legal instruments are relevant to the Environmental Liability Directive and should be borne in mind when implementing it. These are:

- Directive 2010/75/EU on industrial emissions.
- Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law.
- Directive 2006/11/EC on the discharge of dangerous substances into the aquatic environment.
- Directive 2006/118/EC on the protection of groundwater from dangerous substances.
- Directive 2008/98/EC on waste.
- Directive 1999/31/EC on the landfill of waste.
- Regulation (EC) 1013/2006 on the shipment of waste.
- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
- Regulation (EC) No 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH).
- Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury
- Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods.

- Directive 2002/59/EC of the European Parliament and of the Council of 27 June 2002 establishing Community vessels traffic monitoring and information system
- Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (Seveso III Directive).
- Directive 2008/50/EC on ambient air quality and cleaner air for Europe.
- Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein.
- The Habitats Directive (92/43/EEC).
- The Wild Birds Directive (2009/147/EC).
- The Water Framework Directive (2000/60/EC).
- Directive 2008/56/EC establishing a framework for EU action in the field of marine environmental policy.
- The Lugano Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment.
- The Basel Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and their Disposal.
- The Helsinki Convention on the Transboundary Effects of Industrial Accidents.
- The Helsinki Convention on the Protection and Use of Transboundary Watercourses and International Lakes.
- The Nagoya – Kuala Lumpur Supplementary Protocol to the Cartagena Biosafety Protocol to the Convention on Biological Diversity.
- The Convention on Access to Environmental Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Aarhus Convention).

1. IMPLEMENTATION

3.1 Key Tasks

The key tasks involved in implementing this Directive are summarised in the following checklist.

The tasks are arranged under subheadings and organised in chronological order of implementation wherever possible.

Table 14. Environmental Liability Directive - Key Implementation Tasks

ENVIRONMENTAL LIABILITY DIRECTIVE - KEY IMPLEMENTATION TASKS	
1.	Planning
1.1	Identify the competent authority (or authorities) that shall have responsibility for implementing the Directive and ensure that adequate financial, human and technical resources are provided. Due to the wide scope of activities covered several authorities are likely to be involved both in regard to the various sectors (waste, mining, geological storage of CO ₂) as well as overall supervisory and enforcement authorities.
1.2	In determining the allocation of competent authority responsibilities, determine the balance between harmonised rules, procedures and standards and sub-national implementation responsibilities. Ensure sufficient coordination and cooperation mechanisms.
1.3	Consider whether to integrate the Directive into existing environmental liability procedures, whether to combine procedures, or whether to have separate procedures.
1.4	Design the assessment procedure by which the competent authority can evaluate whether environmental damage has taken place and an operator is liable.
1.5	Develop a procedure for determining when the competent authority should take remedial action.
1.6	Identify, within the competent authority, those persons that shall be responsible for overseeing clean-up operations.
1.7	Design the procedure by which a competent authority can determine which preventative or restorative measures should be taken and how.
1.8	Develop detailed consultation procedures with stakeholders on prevention, mitigation and remediation strategies as well as cost recovery measures, etc.
1.9	Determine the protocols and institutional responses to transboundary co-operation and consultation requirements.
1.10	In general assess the types of financial securities most likely to be accepted by industry and being effective, e.g. insurance funds, bonds, self-insurance.
1.11	Consider possible options for market-based instruments to finance remediation and prevention measures (especially where polluter cannot be held liable or has gone insolvent), such as taxes, fees.
2	Regulation
2.1	Provide clear legal rules and guidance on the scope of the Directive with respect to environmental including biodiversity damage as well as the permissible exceptions. Ensure implementation of correct thresholds for biodiversity damage as well as water damage and soil damage.
2.2	Create a procedure and guidelines for dealing with prevention and mitigation activities while ensuring that the restoration/remediation of the environment take place in an effective manner ensuring that the relevant restoration objectives are achieved.
2.3	Implement procedures for the competent authority to assess the environmental damage and determine what remediation/restoration measures are required.
2.4	Create a procedure by which the competent authority can recover costs from the operator for assessing environmental damage or the threat of damage. In the implementing national legislation it will have to be decided whether the permit defence and the state of the art defence (Art. 8, Para. 4) should be allowed, as the Directive leaves open both options.
2.5	Create a procedure for ensuring that the liable operator restores the damaged environment.
2.6	Create a procedure for the competent authority to restore the damaged environment, in cases where a liable operator cannot be found and the polluter pays principle cannot be applied.

2.7	Where the competent authority has had to take on the responsibility of restoring the environment on behalf of a liable operator, create a procedure for the competent authority to recover the costs from the operator.
2.8	In cases where there are several instances of environmental damage that cannot all be remediated at the same time, create procedures by which the competent authority can prioritise remediation and clean-up.
2.9	Create a procedure for channelling funds received back into clean-up and remediation operations in cases where funds have been set up.
2.10	Create a procedure for apportioning clean-up costs between operators in cases where there is joint and several liabilities, if foreseen by applicable national law.
2.11	Create a procedure for informing person(s) or qualified entities adversely affected or likely to be adversely affected by environmental damage of the process for asking the competent authority to take action.
2.12	Create a procedure by which the competent authority should inform the interested party when it is not possible to take a decision within a reasonable period of time.
2.13	Create a procedure for review of the competent authority's decision, acts or failures to act.
2.14	Create a procedure by which the competent authority can require an operator to take preventative or remedial measures to prevent imminent danger to the environment or to remedy the damage.
2.15	Determine the procedure for transboundary co-operation and consultation as regards the potential or actual transboundary threats of environmental damage.
2.16	Create a procedure by which the operator under investigation has to supply information and data for the purpose of the investigation
2.17	Create a procedure and clarity in regard to the legal liability (also relating to monitoring and corrective measures) relating to geological storage of CO ₂ , which in certain cases (such as during the process of a new storage permit or after closure), is temporarily or permanently transferred from the (private) operator of the storage to the competent authorities. In these cases, the competent authority shall recover any costs incurred from the former operator, including by drawing on the financial security referred to in Article 19.
3	Guidance and Training
3.1	Train staff to advise on suitable forms of insurance/financial security for operators.
3.2	Train staff to assess whether environmental damage has taken place ('significance').
3.3	Train staff to bring liability actions against offending operators.
3.4	Train staff to oversee clean-up and remediation operations.
3.5	Train non-legal staff responsible for implementation in the legal concepts and obligations set by the Directive as transposed into national law.
3.6	Develop technical guidelines to support the competent authorities in recognizing and determining environmental damage.
4	Consultation
4.1	Consult with potential operators so that they can take precautionary environmental protection measures and/or financial and insurance-related measures in light of this proposed Directive.
4.2	Consult with liable operators about required remediation measures and method of approach.
4.3	The competent authorities should take the required steps to raise the awareness of operators of the ELD and its related liabilities. The most efficient means of communication should be taken such as through industry associations in regard to communication with operators. The communication should include general responsibilities but also highlight the option of alternative financial security instruments. Specific information and communication strategy might be necessary for SMEs.
4.4	Consult with stakeholders as per sub-point 1.8 (above).
5	Reporting
5.1	Report to the Commission on: The main provisions of national law, which Member States adopt in the field covered by this Directive, together with a table showing how the provisions of the Directive correspond to the national provisions adopted.

2. IMPLEMENTATION GUIDANCE

The Environmental Liability Directive entered into force on 30 April 2004 and the Member States had three years to complete transposition. However, only four Member States met the transposition deadline of 30 April 2010 and the transposition was completed by the last Member State in July 2010. The main reasons for such long delay in transposition²⁸, which can be translated as the main obstacles for meeting the requirements of this Directive by the candidate countries, are:

- existing liability rules on environmental issues. Countries may find it difficult to incorporate new liability rules arising from this Directive to existing liability schemes.
- challenging technical issues, i.e. introduction of novelties such as economic valuation of environmental damage, different types of remediations, damage to protected species and natural habitats.
- framework character of the Directive giving wide margin of discretion to the Member States. Range of options to be discussed require wide debate among all stakeholders.

As a result, operators were often unaware of the specific legal obligations. Insurers and other institutions offering financial security were not sufficiently familiar with the requirements their products had to meet to be ELD-compliant.

The Commission reported on 12 October 2010 on the effectiveness of the Directive in terms of actual remediation of environmental damages and on the availability at reasonable costs and on conditions of insurance and other types of financial security: Report from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions under Article 14(2) of Directive 2004/35/EC on the environmental liability with regard to the prevention and remedying of environmental damage (COM/2010/0581 final), available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52010DC0581>

The abovementioned Report has proposed several measures to improve the effectiveness of the Directive, which should be taken into account by the candidate countries during implementation:

- improving information exchange and communication between stakeholder/practitioner groups;
- carry out awareness raising actions in order to promote awareness of industrial operators and financial security providers;
- develop guidelines on the application of the Environmental Liability Directive, in particular its Annex II. Provide interpretation of the key concepts of the ELD, such as 'environmental damage', 'significant damage', 'baseline conditions'.
- establish records and registers of ELD cases. Such registers may provide support to ELD stakeholders, but also help the competent authorities in fulfilling the reporting obligations.

On the basis of the national reports submitted in 2013 by the Member States to the Commission and of other relevant information, the Commission had to report in 2014 on the experience gained in the application of the Directive. Due to delays in reporting and evaluation and due to the changes at EU political level in 2014, the

²⁸ Source: Report from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions under Article 14(2) of Directive 2004/35/EC on the environmental liability with regard to the prevention and remedying of environmental damage COM/2010/0581

report has been adopted in April 2016. This second implementation report on Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage (COM/2016/0204) presents the experience gained in applying the Directive between 2007 and 2013 and it is available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2016:204:FIN>. It contains conclusions and recommendations on how to improve the implementation. The document must be read in conjunction with a Staff Working Document (SWD (2016)121) available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016SC0122>

The main Commission's recommendations stipulated in the second implementation report (COM/2016/0204) are the following:

- support the implementation efforts with proactive initiatives (such as guidance documents, training, electronic tools for risk analysis, baseline setting, financial security models, etc.) as some Member States have done already;
- exchange administrative experiences and best practices and support each other in capacity-building efforts;
- review the interpretation of key provisions of the Directive, in particular in relation to 'significance';
- record data on ELD incidents and publish ELD registers if they have not done so already;
- systematically gather the necessary data that can document that the application of the Directive in their country is effective, efficient and in line with the overall situation in the EU.

The Commission has launched two studies in 2012 and three studies in 2013 evaluating the Directive. Although experience is limited the following studies and reports are available on DG ENV's website (available at: <http://ec.europa.eu/environment/legal/liability/index.htm>).

- Study on ELD implementation:
- Implementation challenges and obstacles of the Environmental Liability Directive (ELD) (16 May 2013)
- Feasibility study regarding a fund:
- Study to explore the feasibility of creating a fund to cover environmental liability and losses occurring from industrial accidents (17 April 2013)
- ELD effectiveness study:
- Study on ELD Effectiveness: Scope and Exceptions (19 February 2014)
- ELD biodiversity damage study:
- Experience gained in the application of ELD biodiversity damage (February 2014)
- Legal Analysis:
- Study on Analysis of integrating the ELD into 11 national legal frameworks (16 December 2013), hence completing the legal analysis for 16 Member States in the respective annex to the above listed Study on ELD implementation.

The Commission organised also a Stakeholder and Practitioner Workshop on the implementation of the ELD on 8 November 2011 in Brussels. Materials are available at: <http://ec.europa.eu/environment/legal/liability/workshop081111.htm>

Further Stakeholder Workshops took place on 11 June 2013, 26 November 2014 and 24 May 2016, cf: <http://ec.europa.eu/environment/legal/liability/workshops.htm>

As a consequence of the ascertained need for more information and better understanding of the Environmental Liability Directive's provisions and requirements, in particular regarding Annex II (primary, complementary, compensatory remediation; baseline condition; economic valuation of damage etc.), an ELD training material for operators, competent authorities and other stakeholders and interested persons has been developed in 2012/2013, which are available at: http://ec.europa.eu/environment/legal/liability/eld_training.htm The Commission continues also to promote and subsidise ELD trainings.

Furthermore, a certain amount of experience in liability issues, especially in cases of cross-border dimension can be gained from the Lugano Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment and the Basel Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and their Disposal.

4.1 Planning

The Directive requires quite a deal of planning in terms of the legal system and financial aspects and involves engagement and cooperation with several sectors, especially industry, the insurance and financial security market. In general, the reliance on public law mechanisms has been welcomed. Member States and candidate countries are likely to have at least some elements of such systems in place and this will assist in the implementation of the Directive. Provisions of the ELD leave a great margin of discretion to Member States in shaping national environmental liability regime. Thus, the ELD contains optional provisions such as: extension of biodiversity damage to nationally protected biodiversity, permit defence, state-of-the-art defence; mandatory financial security, exemption for the spreading of sewage sludge for agricultural purposes from Annex III and procedures in the event of environmental damage in a Member State from outside its borders.

Attention should be given to method of transposition, i.e. the countries should decide on how will provisions on ELD be incorporated in the national legal system. It is advisable to carry out the analysis of the existing national legal framework on liability in environmental matters in order to avoid duplication of liability regimes, overlapping of competencies and procedures.

Another important aspect that requires careful planning is designation of competent authorities. Recent analysis²⁹ has shown *“that it is more likely that the designation of multiple authorities will result in less implementation and enforcement of the ELD, as it is more difficult for personnel in many authorities to become experienced in implementing the ELD regime, compared to personnel in a single authority or a limited number of authorities.”*

²⁹ BIO Intelligence Service (2013), Implementation challenges and obstacles of the Environmental Liability Directive, Final report prepared for European Commission – DG Environment. In collaboration with Stevens & Bolton LLP.

Experience from Member States

One of the major issues when planning the national system for the implementation of the Directive is the question of whether or not to allow permit defence and state of the art defence. Member States have chosen different approaches. Another issue is whether insurance or other means of financial guarantee should be obligatory. Countries could also consider the extension of liability for biodiversity damage to nationally protected biodiversity. Such option has been introduced in Belgium, Cyprus, Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Luxemburg, Poland, Portugal, Slovenia, Spain, Sweden, United Kingdom (England, Wales, Northern Ireland).

In Germany, the Directive was transposed by the so-called Law on Environmental Damage at federal level. The name was chosen because there is already a law on (civil law) environmental liability from 1990. According to the federal system in Germany, the provinces will have to decide in their implementing legislation whether or not to apply permit defence and state of the art defence. German federal law does not contain provisions on insurance and financial guarantees.

Spain, alike seven other Member States, has chosen a compulsory insurance system, targeting the largest potential polluters, in order to protect the nation's natural resources.

4.2 Regulation

Pursuant to the report by Bio Intelligence Service³⁰, some of the most common country-specific features of the implementation comprise:

- an extension of the scope of biodiversity beyond that of the Directive (the case for Belgium (Federal level and Brussels), Cyprus, the Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Luxemburg, Poland, Portugal, Slovenia, Spain, Sweden and the UK)
- the obligation of a competent authority to take remedial action if no operator can be identified (as transposed into national law by Bulgaria, Czech Republic, Latvia and Lithuania).

Legal solutions introduced in some Member States may provide valuable guidance in developing effective regulatory framework on environmental liability in candidate countries. Here are some examples discussed in Report on Implementation challenges and obstacles of the Environmental Liability Directive³¹:

- Consider introducing an obligation to establish a register or database of ELD incidents. Such obligation exists for example in Poland and Ireland and in several other countries. Denmark has gone a step further and requires details of property that is affected by an imminent threat of, or actual, environmental damage and for which a preliminary or final notice has been issued to be included in the land register for that property at the cost of the liable operator.
- Consider introducing offences and sanctions for breaches of the legislation transposing ELD. These may range from administrative to criminal sanctions (imprisonment and fines).

³⁰ Stevens & Bolton LLP (2013), The Study on Analysis of integrating the ELD into 11 national legal frameworks, Final Report prepared for the European Commission – DG Environment

³¹ BIO Intelligence Service (2013), Implementation challenges and obstacles of the Environmental Liability Directive, Final report prepared for European Commission – DG Environment. In collaboration with Stevens & Bolton LLP.

- Enact legislation to ensure access to third-party property to carry out preventive and remedial measures.
- Provide for the publication of information on the implementation and enforcement of the ELD regime. This may include publishing of planned remedial measures for ELD incidents and ensuring consultation with the public or annual publication of the report.

Examples on Member States' implementation of the provisions of mandatory financial security schemes

Bulgaria, Portugal, Spain, Greece, Hungary, Slovakia, Czech Republic and Romania had decided to set up mandatory financial security schemes at national level, while the other Member States preferred a voluntary markets approach. Insurance (General Third Party Liability or Environmental Impairment Liability policies) had proven to be the most popular instrument, followed by bank guarantees and other market based instruments, such as funds or bonds.

- Bulgaria introduced compulsory financial security from January 2011 on covering all operators under Annex III. The scheme allows for insurance, pools, bank guarantees, and financial guarantees as proof of liability cover. It is envisaged that an operator will have to have financial security commensurate to the cost of potential remediation measures. A determination of financial security that is 'commensurate' will be determined through risk assessment.
- In the Czech Republic financial security for all Annex III operators became compulsory from January 2013 on. Insurance and bank guarantees are acceptable means to provide evidence that liabilities are covered. Further details about the scheme, such as the level of indemnity that needs to be covered, is specified in the Government Order. As already discussed, a number of exceptions to the mandatory financial security scheme will be introduced:
 - when the potential cost of remediation is less than 20 million CZK (approximately €800k) based on a risk assessment;
 - when the company in question is Eco-management and Audit Scheme (EMAS) registered, even if the potential remediation costs exceed the above mentioned amount.
- Spain is introducing a limited mandatory financial security scheme from April 2010 onward. It will cover the most important operators in Annex III but it is not intended to cover all costs potentially arising from the Law. The security provided by the guarantee covers the costs of primary remediation and a small percentage of prevention and avoidance costs. The compulsory guarantee refers only to damage caused by 'pollution', despite the Law being based on the concept of 'damage to natural resources' irrespective of whether the damage is caused by pollution or not (i.e.; fire, aquifer depletion).

In all the above-mentioned cases, mandatory financial security is understood in an ex-ante manner, which means that it must be established in anticipation of a potential incident rather than after an incident has occurred.

Source: Bio Intelligence Europe, Final Contract Reference: 070307/2008/516353/ETU/G.1. Available at: <http://ec.europa.eu/environment/legal/liability/pdf/ELD%20Study%20November%202009.pdf>

4.3 Guidance and Training

In 2012/2013 an ELD training material for operators, competent authorities and other stakeholders and interested persons has been developed to address the need for more information and better understanding of the Environmental Liability Directive's provisions and requirements, in particular regarding Annex II (primary, complementary, compensatory remediation; baseline condition; economic valuation of damage etc.). The material exists in three versions: a half day training material, a one day training material and a two days training material. The training material (all three versions) is available at: http://ec.europa.eu/environment/legal/liability/eld_training.htm.

Example of EU-funded Project Assisting Implementation

The EU-funded REMEDE project was designed to support Annex II of the Directive, which lists different methodologies that can be used for this common framework.

The goal of the REMEDE project is to develop, test and disseminate methods for determining the scale of the remedial measures necessary to adequately offset environmental damage. The project draws from both US experience, in terms of methodological developments and implementation issues encountered, and the experiences of EU Member States. It aims to apply and develop these in accordance with the requirements of the Environmental Liability Directive and the Environmental Impact Assessment, Habitats and Wild Birds Directives, in order that a standard toolkit can be applied in all cases of damage in the EU. The project brings together ecologists, economists and legal experts from the USA and Europe to review experience in the application of resource equivalency methods, to draft a toolkit document for the EU, to test the toolkit through application in case studies in different Member States, and to disseminate the toolkit to relevant stakeholders.

For further information, see www.envliability.eu

Importance of developing national guidelines for the implementation of the ELD has been stressed out in the Commission's second implementation report.

Some Member States have published guidance to accompany national transposing legislation. These include Belgium (Walloon Region), Denmark, Finland, France, Ireland, the Netherlands, Portugal, Spain, and the United Kingdom. Such guidance typically elaborates on provisions of the national legislation and, in addition, provides case studies and guidelines for determining whether the threshold for biodiversity damage has been exceeded and methods for quantifying such damage. The available national guidance documents are available from the European Commission's Environmental Liability website; see http://ec.europa.eu/environment/legal/liability/eld_guidance.htm.

Guidance for the insurance business

Different stakeholders in the insurance business have taken initiatives to develop guidelines. However, these efforts are largely restricted to national efforts that might not be applicable to other MS. In Germany, the main insurance industry association (GDV) adapted a 1993 model for insurance policies covering environmental risks to cover the new requirements under the German transposition of the ELD. Institutions providing for reinsurance of environmental

risks such as ASSURPOL in France and the Pool Español de Riesgos Medioambientales in Spain have established guidelines for their members. A common view among stakeholders in the insurance industry is that the working relationship with competent authorities should cover the development of methodologies to assist in determining and calculating the level of compensatory remediation required.

By the end of 2009, only Austria, France, and Germany had some kind of national guidelines on product development in their country, although these guidelines had not been developed by the national authorities themselves however.

Source: Tanja Munchmeyer, Valerie Fogleman, Leonardo Mazza, and Shailendra Mudgal. Implementation Effectiveness of the Environmental Liability Directive (ELD) and related Financial Security Issues. Bio Intelligence Service, Report for the European Commission (DG Environment), 2009.

<http://ec.europa.eu/environment/legal/liability/pdf/ELD%20Study%20November%202009.pdf>

3. COSTS

Costs incurred largely depend on the size of the country, the constitutional and administrative system (e.g. centrally organised administration or decentralised/federal administration) and on the existing structure. Most Member States already have in place a system for the cleaning up of environmental damage by the polluter.

Table 14. Checklist of the Types of Cost Incurred to Implement the Directive

Checklist of the Types of Cost Incurred to Implement the Directive	
Initial set-up costs:	
<ul style="list-style-type: none"> • costs of organisational changes, set-up costs of inspection units; • improvements to procedures for data collection, storage and retrieval; • provision of, or improvements to, databases, including computer systems and PCs; • training of inspectors in communications and information dissemination methods; • information technology for running relevant databases, information networks and websites. 	
Ongoing costs:	
<ul style="list-style-type: none"> • provision of the inspections unit (staffing, office space, etc) • reporting to the public and to the Commission; • compliance promotion; • information technology maintenance and updating, as necessary. 	

Table 15. Examples of administrative costs from Member States

Cost Estimations from Member States	
<ul style="list-style-type: none"> • the Flemish Region of Belgium indicated €55,000/year (gross) of annual administrative costs, • Bulgaria: €135,613 per year • Spain: overall €20,000 per year in staff costs, and between €684,000 and €2 million of administrative costs of the autonomous communities and cities in Spain. 	
<p><i>Source: COMMISSION STAFF WORKING DOCUMENT REFIT Evaluation of the Environmental Liability Directive Accompanying the document Report from the Commission to the European Parliament and to the Council pursuant to Article 18(2) of Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage (SWD/2016/0121 final)</i></p>	

Table 16. Average remediation costs per Member State in EURO

Belgium	Bulgaria	Estonia	Greece	Hungary	Latvia
111,052	20,958	11,922	60,000	3,559	37,919
Lithuania	Malta	Romania	Spain	Sweden	UK

369,375	42,000	295,171	615,250	1,070,341	361,007
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Source: COMMISSION STAFF WORKING DOCUMENT REFIT Evaluation of the Environmental Liability Directive Accompanying the document Report from the Commission to the European Parliament and to the Council pursuant to Article 18(2) of Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage (SWD/2016/0121 final)

THE ENVIRONMENTAL CRIMES DIRECTIVE

Official Title: Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law (OJ L 328, 6.12.2008)

1. SUMMARY OF THE MAIN AIMS AND PROVISIONS

Directive 2008/99/EC on the protection of the environment through criminal law, adopted on 19 November 2008, was the first EU Directive to contain provisions with regard to criminal law. The years leading up to its adoption were marked by long and often heated discussions among the EU institutions and the Member States concerning the role of criminal law in enforcement of EU obligations and the appropriate legal basis for the EU to act in this area, i.e. whether an EU legal act setting in place criminal law provisions in certain areas of environmental protection should be in the third pillar (unanimous vote, no European Parliament co-decision power, little control by the Court of Justice of European Union) or in the first pillar (majority vote, European Parliament co-decision, control by the the Court of Justice).

The Lisbon Treaty has now clarified the issue of EU competence with respect to criminal law. Article 83(2) of the TFEU expressly enables the EU legislator to adopt Directives establishing “*minimum rules with regard to the definition of criminal offences and sanctions in the area concerned*” if this “*proves essential to ensure effective implementation of a Union policy in an area which has been subject to harmonisation measures*”.

Directive 2008/99/EC obliges Member States to provide for criminal sanctions in their national legislation for certain serious infringements of EU law on protection of the environment.

Article 2 of the Directive defines as ‘unlawful’ any infringements of the EU acts listed in the Directive’s annexes A and B, or any infringements of a Member State law, administrative regulation or decision taken by one of its competent authorities to give effect to the EU acts listed in the aforementioned annexes.

The Directive lays down a list of environmental offences that must be considered criminal offences by all Member States, if committed intentionally or with at least serious negligence. These offences include:

- discharge, emission or introduction into air, soil, water of dangerous materials;
- collection, transport, recovery or disposal of hazardous waste;
- shipment of noticeable quantities of waste;
- operation of an industrial plant conducting dangerous activities or storing dangerous substances;
- manufacture, treatment, storage, use, transport, import, export, or disposal of nuclear material/hazardous radioactive materials;
- killing, possession or trafficking of noticeable amounts of protected animal and plant species;
- damage to protected habitats;
- production, trade in or use of substances that deplete the ozone layer.

Directive also requires Member States to consider inciting, aiding and abetting any intentional Article 3 conduct as a criminal offence. Member States have to ensure that legal persons can be held liable for the commission of an Article 3 or Article 4 offence.

Article 5 requires Member States to ensure that Article 3 and Article 4 offences are punishable by criminal sanctions that are effective, proportionate and dissuasive. However, pursuant to Article 7, the sanctions for legal persons held liable under Article 6 – while required to be effective, proportionate and dissuasive – need not be criminal sanctions.

The Directive only sets a minimum standard of environmental protection through criminal law to be adopted by the Member States. The Member States are free to maintain or introduce more stringent protective measures. The Directive does not lay down measures concerning the procedural part of criminal law nor does it touch upon the powers of prosecutors and judges.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Regulation

A summary of the regulatory obligations:

- Member States should take the necessary measures to ensure that the following conducts, constitute a criminal offence, when unlawful³² and committed intentionally or with at least serious negligence:
 - the discharge, emission or introduction of a quantity of materials or ionising radiation into air, soil or water, which causes or is likely to cause death or serious injury to any person or substantial damage to the quality of air, the quality of soil or the quality of water, or to animals or plants;
 - the collection, transport, recovery or disposal of waste, which causes or is likely to cause death or serious injury to any person or substantial damage to the quality of air, the quality of soil or the quality of water, or to animals or plants;
 - the shipment of waste, where this activity falls within the scope of Article 2(35) of Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste (1) and is undertaken in a non-negligible quantity, whether executed in a single shipment or in several shipments which appear to be linked;
 - the operation of a plant in which a dangerous activity is carried out or in which dangerous substances or preparations are stored or used and which, outside the plant, causes or is likely to cause death or serious injury to any person or substantial damage to the quality of air, the quality of soil or the quality of water, or to animals or plants;
 - the production, processing, handling, use, holding, storage, transport, import, export or disposal of nuclear materials or other hazardous radioactive substances which causes or is likely to cause death or serious injury to any person or substantial damage to the quality of air, the quality of soil or the quality of water, or to animals or plants;
 - the killing, destruction, possession or taking of specimens of protected wild fauna or flora species, except for cases where the conduct concerns a negligible quantity of such specimens and has a negligible impact on the conservation status of the species;
 - trading in specimens of protected wild fauna or flora species or parts or derivatives thereof, except for cases where the conduct concerns a negligible quantity of such specimens and has a negligible impact on the conservation status of the species;
 - any conduct which causes the significant deterioration of a habitat within a protected site;
 - the production, importation, exportation, placing on the market or use of ozone-depleting substances.

³² Note that Article 2 of the Directive defines as ‘unlawful’ any infringements of the EU acts listed in the Directive’s Annexes A and B, or any infringements of a Member State law, administrative regulation or decision taken by one of its competent authorities to give effect to the EU acts listed in the aforementioned annexes.

- Member States have to take the necessary measures to ensure that legal persons held liable pursuant to Article 6 are punishable by effective, proportionate and dissuasive penalties (Art. 7), which can be of a criminal or non-criminal nature.
- Member States should ensure that legal persons can be held liable for offences referred to in Articles 3 and 4 where such offences have been committed for their benefit by any person who has a leading position within the legal person, acting either individually or as part of an organ of the legal person, based on:
 - a power of representation of the legal person;
 - an authority to take decisions on behalf of the legal person;
 - an authority to exercise control within the legal person. (Art. 6(1))
- Member States shall also ensure that legal persons can be held liable where the lack of supervision or control, by a person referred to in paragraph 1, has made possible the commission of an offence referred to in Articles 3 and 4 for the benefit of the legal person by a person under its authority. (Art. 6(2))
- Member States shall ensure that the liability of legal persons under paragraphs 1 and 2 of Article 6 shall not exclude criminal proceedings against natural persons who are perpetrators, inciters or accessories in the offences referred to in Articles 3 and 4. (Art. 6(3))

2.2. Enforcement

Candidate countries should designate competent authorities to enforce the Environmental Crimes Directive through detection, investigation and prosecution of criminal offences against the environment. To reach this aim, it is important that environmental authorities are obliged to monitor whether environmental offences are committed and to report suspected cases to the prosecution office. In this context, candidate countries should strengthen the roles of the inspection and cooperation with the bodies responsible for prosecution.

2.3. Information and Reporting

Candidate countries should report to the Commission on the main provisions of national law that Member States adopt in the field covered by this Directive, together with a table showing how the provisions of the Directive correspond to the national provisions adopted.

2.4. Relevant Legal Instruments

Annex A and B of the Directive set out a list of EU Directives and regulations, the infringement of which constitutes unlawful conduct pursuant to Article 2(a)(i) and 2(a)(ii), respectively.

Below is an up-dated list of all EU legal acts listed in Annexes A and B. Legal acts, which have been repealed since the adoption of Directive 2008/99/EC, are duly recognized. It should be noted that Environmental Crime Directive needs to be implemented in respect of all obligations in the repealed legal instruments that were carried-over into the new legislation that have replaced them.

- Council Directive 70/220/EEC of 20 March 1970 on the approximation of the laws of the Member States on measures to be taken against air pollution by emissions from motor vehicles³³
- Council Directive 72/306/EEC of 2 August 1972 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in vehicles³⁴
- Council Directive 75/439/EEC of 16 June 1975 on the disposal of waste oils³⁵
- Council Directive 76/160/EEC of 8 December 1975 concerning the quality of bathing water³⁶
- Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations³⁷
- Council Directive 77/537/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in wheeled agricultural or forestry tractors³⁸
- Council Directive 78/176/EEC of 20 February 1978 on waste from the titanium dioxide industry³⁹
- Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances⁴⁰
- Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds⁴¹
- Council Directive 82/176/EEC of 22 March 1982 on limit values and quality objectives for mercury discharges by the chlor-alkali electrolysis industry⁴²
- Council Directive 83/513/EEC of 26 September 1983 on limit values and quality objectives for cadmium discharges⁴³

³³ Repealed by Regulation (EC) 715/2007 as from 1 January 2013

³⁴ As above.

³⁵ Repealed by Directive 2008/98/EC as from 12 December 2010

³⁶ Repealed by Directive 2006/7/EC as from 31 December 2014

³⁷ Repealed by Regulation (EC) 1907/2006 as from 1 June 2009

³⁸ Repealed by Regulation (EU) 167/2013 as from 1 January 2016

³⁹ Repealed by Directive 2010/75/EU as from 7 January 2014

⁴⁰ Repealed by Regulation (EC) 1107/2009 as from 14 June 2011

⁴¹ Repealed by Directive 2009/147/EC as from 15 February 2010

⁴² Repealed by Directive 2008/105/EC as from 22 December 2012

⁴³ As above

- Council Directive 84/156/EEC of 8 March 1984 on limit values and quality objectives for mercury discharges by sectors other than the chlor-alkali electrolysis industry⁴⁴
- Council Directive 84/360/EEC of 28 June 1984 on the combating of air pollution from industrial plants⁴⁵
- Council Directive 84/491/EEC of 9 October 1984 on limit values and quality objectives for discharges of hexachlorocyclohexane⁴⁶
- Council Directive 85/203/EEC of 7 March 1985 on air quality standards for nitrogen dioxide⁴⁷
- Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture
- Council Directive 86/280/EEC of 12 June 1986 on limit values and quality objectives for discharges of certain dangerous substances included in List I of the Annex to Directive 76/464/EEC⁴⁸
- Council Directive 87/217/EEC of 19 March 1987 on the prevention and reduction of environmental pollution by asbestos
- Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms⁴⁹
- Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment
- Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market⁵⁰
- Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources
- Council Directive 91/689/EEC of 12 December 1991 on hazardous waste⁵¹
- Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora
- Council Directive 92/112/EEC of 15 December 1992 on procedures for harmonising the programmes for the reduction and eventual elimination of pollution caused by waste from the titanium dioxide industry⁵²
- Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft: the provisions amended by Directive 2003/44/EC

⁴⁴ As above

⁴⁵ Repealed by Directive 2001/80/EC, which is subsequently repealed by Directive 2010/75/EU as from 1 January 2016

⁴⁶ Repealed by Directive 2008/105/EC as from 22 December 2012

⁴⁷ Repealed by Directive 1999/30/EC, which is subsequently repealed by Directive 2008/50/EC from 11 June 2010

⁴⁸ Repealed by Directive 2008/105/EC as from 22 December 2012

⁴⁹ Repealed by Directive 2009/41/EC as from 10 June 2009

⁵⁰ Repealed by Regulation (EC) 1107/2009 as from 14 June 2011

⁵¹ Repealed by Directive 2008/98/EC as from 12 December 2010

⁵² Repealed by Directive 2010/75/EU as from 7 January 2014

- European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste
- European Parliament and Council Directive 94/63/EC of 20 December 1994 on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations
- Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail⁵³
- Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT)
- Council Directive 96/62/EC of 27 September 1996 on ambient air quality assessment and management⁵⁴
- Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances⁵⁵
- Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery
- Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein
- Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁵⁶
- Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels
- Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
- Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations⁵⁷
- Council Directive 1999/30/EC of 22 April 1999 relating to limit values for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead in ambient air⁵⁸
- Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste
- Council Directive 1999/32/EC of 26 April 1999 relating to a reduction in the sulphur content of certain liquid fuels

⁵³ Repealed by Directive 2008/68/EC as from 30 June 2009

⁵⁴ Repealed by Directive 2008/105/EC as from 22 December 2012

⁵⁵ Repealed by Directive 2012/18/EU as from 1 June 2015

⁵⁶ Repealed by Regulation (EU) 528/2012 as from 1 September 2013

⁵⁷ Repealed by Directive 2010/75/EU as from 7 January 2014

⁵⁸ Repealed by Directive 2008/105/EC as from 22 December 2012

- Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end of life vehicles
- Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy
- Directive 2000/69/EC of the European Parliament and of the Council of 16 November 2000 relating to limit values for benzene and carbon monoxide in ambient air⁵⁹
- Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste⁶⁰
- Regulation (EC) No 2037/2000 of the European Parliament and of the Council of 29 June 2000 on substances that deplete the ozone layer⁶¹
- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms
- Directive 2001/80/EC of the European Parliament and of the Council of 23 October 2001 on the limitation of emissions of certain pollutants into the air from large combustion plants⁶²
- Directive 2002/3/EC of the European Parliament and of the Council of 12 February 2002 relating to ozone in ambient air⁶³
- Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment⁶⁴
- Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)⁶⁵
- Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air
- Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents
- Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants
- Directive 2005/55/EC of the European Parliament and of the Council of 28 September 2005 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from compression-ignition engines for use in vehicles, and the emission of gaseous pollutants from positive-ignition engines fuelled with natural gas or liquefied petroleum gas for use in vehicles⁶⁶

⁵⁹ Repealed by Directive 2008/105/EC as from 22 December 2012

⁶⁰ Repealed by Directive 2010/75/EU as from 7 January 2014

⁶¹ Repealed by Regulation (EC) 1005/2009 as from 1 January 2010

⁶² Repealed by Directive 2010/75/EU as from 1 January 2016

⁶³ Repealed by Directive 2008/105/EC as from 22 December 2012

⁶⁴ Repealed by Directive 2011/65/EU as from 3 January 2013

⁶⁵ Repealed by Directive 2012/19/EU as from 15 February 2014

⁶⁶ Repealed by Regulation (EC) 595/2009 as from 31 December 2013

- Commission Directive 2005/78/EC of 14 November 2005 implementing Directive 2005/55/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from compression-ignition engines for use in vehicles, and the emission of gaseous pollutants from positive ignition engines fuelled with natural gas or liquefied petroleum gas for use in vehicles and amending Annexes I, II, III, IV and VI thereto⁶⁷
- Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality
- Directive 2006/11/EC of the European Parliament and of the Council of 15 February 2006 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community⁶⁸
- Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste⁶⁹
- Directive 2006/21/EC of the European Parliament and of the Council of 15 March 2006 on the management of waste from extractive industries
- Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 relating to emissions from air conditioning systems in motor vehicles
- Directive 2006/44/EC of the European Parliament and of the Council of 6 September 2006 on the quality of fresh waters needing protection or improvement in order to support fish life⁷⁰
- Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators
- Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration
- Regulation (EC) No 842/2006 of the European Parliament and of the Council of 17 May 2006 on certain fluorinated greenhouse gases⁷¹
- Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste
- Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information
- Commission Regulation (EC) No 1418/2007 of 29 November 2007 concerning the export for recovery of certain waste listed in Annex III or IIIA to Regulation (EC) No 1013/2006 of the European Parliament and of the Council to certain countries to which the OECD Decision on the control of transboundary movements of wastes does not apply

⁶⁷ Repealed by Regulation (EC) 595/2009 as from 31 December 2013

⁶⁸ Repealed by the Directive 2000/60/EC as from 22 December 2013

⁶⁹ Repealed by Directive 2008/98/EC as from 12 December 2010

⁷⁰ Repealed by the Directive 2000/60/EC as from 22 December 2013

⁷¹ Repealed by Regulation (EU) 517/2014 as from 1 January 2015

- Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control⁷²
- Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation⁷³
- Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources⁷⁴
- Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel

⁷² Repealed by Directive 2010/75/EU as from 7 January 2014

⁷³ Repealed by Directive 2013/59/Euratom with effect from 6 February 2018

⁷⁴ As above.

3. IMPLEMENTATION

3.1 Key tasks

The key tasks involved in implementing this Directive are summarised in the following checklist.

The tasks are arranged under subheadings and organised in chronological order of implementation wherever possible.

Table 17. Environmental Crimes Directive - Key Implementation Tasks

ENVIRONMENTAL CRIMES DIRECTIVE - KEY IMPLEMENTATION TASKS	
1.	Planning
1.1	Identify the competent authority (or authorities) that shall have responsibility for implementing the Directive and ensure that adequate financial, human and technical resources are provided. Due to the wide scope of activities covered several authorities are likely to be involved, such as environmental inspectorate and enforcement authorities (prosecutors and judges)
1.2	In determining the allocation of competent authority responsibilities, determine the balance between harmonised rules, procedures and standards and sub-national implementation responsibilities. Ensure sufficient coordination and cooperation mechanisms.
1.3	Prepare a cost assessment for implementing the directive and envisage strategies for financing and cost recovery (where reasonable).
1.4	Develop detailed consultation procedures with stakeholders to help achieve the most efficient path to approximation, to avoid costly errors (for example, in drafting legislation and regulations, and to encourage the co-operation of operators in complying with the national legal instruments.
1.5	Integrate the Directive into existing criminal sanctioning system.
1.6	Devise or build on existing system for inspection and other compliance monitoring procedures for identifying potential and detecting actual environmental offences.
1.7	Monitor and take stock of the number and type of criminal offences to be able to also introduce other incentive systems for greater compliance. Collect statistical information on environmental crime based on clear parameters.
1.8	Consider whether to extend the number of offences to which environmental penalties will be attached, since the Directive only stipulates the minimum scope of activities, which must be considered unlawful and linked to penalties. For example, several Member States criminalize the conduct of articles 3 and 4 of the directive wherever a legal provision has been infringed, regardless whether this provision is covered by the annexes of the directive 2008/99; this both is a better protection of the environment and makes the legal provision easier to understand and apply. Consider the type of penalties attached for each criminal offence.
1.9	Design the assessment procedure by which the competent authority can evaluate whether environmental damage has taken place and an operator is liable. This can partly be combined with the procedure applicable for the Environmental Liability Directive, as several of the criminal offences are the same or similar.
1.10	Develop procedure and measures to ensure that identified criminal offences are prosecuted and that effective, dissuasive and proportionate sanctions are imposed.
1.11	Decide on the statute of limitation periods, which must not be too short. Decide on rules, which must be clear on what acts interrupt these statute of limitation periods. Particular focus should also be on establishing an effective procedure of cooperation and coordination between the administrative authorities/inspectorates and the prosecutors office especially addressing: <ul style="list-style-type: none"> • time of handing over files • action to take when a crime cannot be proven but the conduct could still amount to an administrative offence • whether the prosecutor should send back the file back to the administrative authority

1.12	Plan an awareness raising campaign to inform the general public, public authorities and the private sector about the implications of the Environmental Crimes Directive and the rationale behind the Directive (achieve overall improved compliance leading to improved environment and health conditions).
2	Regulation
2.1	Provide clear legal rules and guidance on the definitions, scope, aim and implications of the Directive with respect to the relevant environmental offences. For this reason, it should be avoided to implement the several offences contained in the directive by few very general offences, such as "endangering the environment", since the rule of law makes it necessary that the boundaries of criminal behaviour can be recognised clearly.
2.2	Ensure compliance with the relevant definitions of the Directive, i.e. 'unlawful', 'protected wild fauna nad flora species', 'habitat within the protected site' and 'legal person'.
2.3	Ensure that the transposing legal instrument refers to the illegal conducts set out in the EU legislation in the Annex to the Directive and that the offences referred to in Arts. 3-4 are punishable with effective, dissuasive and proportionate penalties. In order to avoid gaps, it is recommended not to split the conduct contained in articles 3 and 4 of the directive into too many different offences, since this creates the danger that some parts of the offences of the directive are not covered.
2.4	Review and amend, if appropriate existing legal and administrative procedures and regulations for dealing with environmental offences to ensure detection, prosecution, sanctioning and enforcement.
2.5	Establish procedures and guidance for the judiciary system that take into account the peculiarities of environmental crimes including the option of specialized prosecutors/judges
2.6	Ensure that the national legal system recognises the liability of legal persons and that also instigation, aiding and abetting of environmental offences is seen as an environmental offence and subject to sanctions
2.7	Ensure harmony and synergy between the procedures and legal provisions relating to the Environmental Crimes Directive and Environmental Liability Directive to achieve an optimised effect of the polluter pays principle
2.8	Ensure a procedure for legal review of the competent authority's (normally a national court with or without specialisation in environmental cases) decision regarding potential offences and sanctions.
2.9	Determine the procedure for transboundary co-operation and consultation as regards the potential or actual transboundary threats of environmental damage.
2.10	Provide procedures for legal and natural persons and qualified entities likely to be adversely affected by the Directive for cooperation with the competent authority and staff involved in implementing the legislation transposing the Directive.
2.11	Establish procedures for judicial review and challenges to action or inaction taken for legal and natural persons and qualified entities.
3	Guidance and Training
3.1	Train environmental inspectors to detect environmental offences through regular monitoring and supervision and also through effective cooperation with citizens that might submit complaints or important information i.e. effective complaint-handling mechanisms; train judges and prosecutors on the relevance and particularities of environmental crimes.
3.2	Train staff to assess whether the environmental offence has been done by intent or negligence.
3.3	Train staff in procedures to ensure efficient cooperation with the perpetrators, authorities or other third parties in collecting and assessing information and evidence material
3.4	Train non-legal staff responsible for implementation in the legal concepts and obligations set by the Directive as transposed into national law.
4	Consultation
4.1	Wide stakeholder process to inquire about the various options including the types and size of criminal sanctions to ensure that they are effective, dissuasive and efficient. Also consult on ways to ensure that offences are detected, contemplating some kind of incentive system for third parties to submit complaints to enforcement authorities. Also raise debate whether to introduce more stringent provisions such as additional offences being added to the offences listed in Arts. 3-4.
4.2	Information campaign to inform directly affected natural and legal persons about the rationale and consequences of the Directive.
5	Reporting

5.1	Report to the Commission on the main provisions of national law, which Member States adopt in the field covered by this Directive, together with a table showing how the provisions of the Directive correspond to the national provisions adopted.
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4. IMPLEMENTATION GUIDANCE

The Environmental Crime Directive had to be transposed in national law by 26 December 2010 by the existing Member States. For some Member States, that already had a very elaborated protection of the environment through criminal law, the Directive did not constitute major legal changes and implementation efforts. However, for some Member States which did not have an elaborate protection awarded to the environment via criminal law yet, the Directive may have brought important changes.

Various studies have been published, which may assist the candidate countries in developing their planning, phasing and implementation measures. These materials are available at: http://ec.europa.eu/environment/legal/crime/studies_en.htm

The European Commission has developed training tools in support to all training structures and trainers with an interest in EU environmental law that can be accessed at: http://ec.europa.eu/environment/legal/law/training_package.htm

Various approaches in transposition of Environmental Crimes Directive

Member States have transposed the Environmental Crimes Directive in various ways, in particular through a catch-all provision in the Criminal Code (e.g. Croatia), through various provisions in framework environmental legislation or through provisions in all sectoral laws which transpose the EU legal acts listed in Annexes A and B to Directive 2008/99/EC (e.g. UK).

4.1 Planning

The Directive may involve planning in terms of the criminal law system and the judiciary branch also in terms of ensuring the sufficient expertise, which will require training for prosecutors and judges. It also will require the engagement and cooperation with several public authorities, the private sector, civil society organisations and the public in general. Candidate countries are likely to have at least some elements of such systems in place and this will assist in the implementation of the Directive.

In most jurisdictions, whether based on common law or civil law systems, a mixture of criminal and administrative sanctions (such as the removal of a licence or the imposition of an administrative penalty) can be brought into play. But they stem from different legal principles and are often in the hands of different public agencies, with little in the way of effective coordination.

Experience from Member States

Sweden: In Sweden, the criminal sanction system for environmental offences is complemented with an administrative charge– the „environmental sanction charge (miljöskyddsavgift)” – which aims at further ensure high compliance with environmental regulations. This system has worked since several decades already but is continuously adapted to ensure that the charges are well targeted and their rationale achieved. The environmental sanction charges are imposed on more „minor” environmental offences, one typical example being non-submission of the annual environmental report for industrial operators. These charges are regulated through the Environmental Code, Chapter 30 and the ordinance (1998:950) on environmental sanction charges as well as through NFS decree (2002:16) on payment of environmental sanction charges. This decree contains a list of offences that are subject to charges and this list is gradually being extended. Since 2007 not only legal entities can be subject to environmental sanction charges but also natural persons. Also measures have been taken lately to avoid double sanctioning.

4.2 Regulation

The Directive contains a number of definitions and notions that might become subject to different interpretation by the Member States. For example, Articles 3(c), (f) and (g) of the Directive refers to “(non) negligible quantities or impacts” and Article 3(d) of Directive 2008/99 refers to “dangerous activities and substances”. The use of these notions in (national) criminal law has to take into account the *lex certa* requirement which follows from the legality principle in criminal law, requiring that the law should be sufficiently precise for the potential perpetrator to know whether he will commit a crime or not. Candidate countries will mitigate this risk where they use the established definitions set out in the EU environmental legislation (set out in Annex A and B) and to follow the jurisprudence as developed by the European courts.

It is useful if the national legislation implementing the Environmental Crimes Directive provide more precision and guidance in the implementation of these notions of the Directive. This may on the one hand better satisfy the *lex certa* principle and on the other hand also provide the harmonising effect desired by the legislator. In doing this, the candidate countries should have regard to available reports, studies, guidance firstly at EU level and then at Member State level.

5. COSTS

Costs incurred largely depend on the size of the country, the constitutional and administrative system (e.g. centrally organised administration or decentralised/federal administration) and on the existing structure. Whereas some candidate countries may already have in place a sanctioning system for environmental offences, which is efficient and dissuasive some candidate countries might need to undertake a more holistic overhaul of the sanctioning system, which also will entail resources incurred for consultation, information, awareness raising and training. Very limited capital costs are expected.

THE INSPIRE DIRECTIVE

Official Title: Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the EU (INSPIRE) (OJ L 108, 25.04.2007)

1. SUMMARY OF THE MAIN AIMS AND PROVISIONS

The INSPIRE Directive serves to establish the necessary infrastructure for spatial information within the EU to ensure the better integration of environmental policy making into other policies as specified in the Sixth Environmental Action Programme adopted by Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 (OJ L242 10.09.2002 p1).

The INSPIRE Directive responds to the need for quality geo-referenced information to support understanding of the complexity of, and interactions between, human activities and environmental pressures and impacts. It addresses the current general situation with respect to spatial information in Europe, where there is an urgent need to fill in gaps in availability and to eliminate the duplication of information collection, as well as to compensate for the fragmentation of existing datasets and sources. All these problems make it difficult to identify, access and use the data that are available, to the detriment of environmental integration, given the importance of data to a large number of policy and information themes across various levels of public authority. The INSPIRE Directive is complementary to related policy initiatives, such as Directive 2003/98/EC on the re-use and commercial exploitation of public sector information (which will be amended) and to the Directive on Public Access to Environmental Information (2003/4/EC).

The implementation of the Directive is challenging because of the current problems outlined above and also because there are many stakeholder interests to be addressed. The target users of INSPIRE include policy makers, planners and managers at European, national and local level, as well as citizens themselves and their organisations.

INSPIRE is based on a number of common principles:

- Data should be collected only once and kept where it can be maintained most effectively.
- It should be possible to combine seamless spatial information from different sources across Europe and share it with many users and applications.
- It should be possible for information collected at one level/scale to be shared with all levels/scales; detailed for thorough investigations, general for strategic purposes.
- Geographic information needed for good governance at all levels should be readily and transparently available.
- Easy to find what geographic information is available, how it can be used to meet a particular need, and under which conditions it can be acquired and used.

In order to reach its objective, the Directive provides a legal framework that involves: removing obstacles that stall the exchange of data; harmonising structures to promote the standardisation of data interfaces; and increasing the interoperability of data acquisition systems. The Directive also provides for the pooling of spatial information from a variety of sources in order to disseminate it in a user-friendly format, and for the creation of a single network that will integrate all available data providers that are currently not interconnected within a single system. The Directive also ensures that the infrastructure established provides spatial data services across various levels of public authority and across different sectors.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1 Planning

Member States should:

- Identify spatial datasets that meet the conditions established under Article 4(1) of the Directive.
- Identify the national authorities that hold such data.
- Identify international standards, especially with respect to the validation of meta-data and any existing initiatives.
- Identify stakeholders for the purposes of Article 22(1) of the Directive and assess user requirements.

2.2 Regulation

- Regulate the collection and dissemination of all spatial data that fulfils the conditions stipulated under Article 4 of the Directive and provide for legal obligations with respect to the spatial data's:
 - availability;
 - updating;
 - quality;
 - organisation;
 - accessibility;
 - sharing; and
 - compatibility when used at EU level.

There is no obligation under the Directive to collect new spatial data or to regulate spatial data in accordance with the INSPIRE Directive if it lacks any of the conditions stipulated under Article 4.

- Establish meta-data for spatial datasets and services. This entails the obligation to include information describing spatial datasets and spatial data services as well as making possible their:
 - discovery;
 - inventory; and
 - use.
- Establish a competent authority or authorities that have regulatory powers to:
 - Co-ordinate the provision of spatial datasets and services at the intergovernmental level, specifying:
 - the type of contributions to be considered;

- the designated authority responsible for co-ordination; and
 - the distribution of powers between various co-ordinating entities.
 - Provide for the continuous updating of meta-data, spatial datasets and services.
 - Facilitate the exchange of spatial data and related services between national authorities and with other Member State institutions.
 - Monitor compliance with the obligations of the Directive, as well as quality control and reporting requirements.
- Formulate legal instruments with implementation rules for the interoperability and harmonisation of spatial data. These implementation rules must provide for:
 - the identification of spatial objects through a common framework where identifiers can be mapped to ensure interoperability;
 - the relationship between the spatial objects;
 - key attributes and multilingual thesauri used in policies having an environmental impact;
 - information on the temporal dimension of the data; and
 - data updates.
 - Establish under national legislation a network of services for spatial datasets and services for which meta-data have been created and provide for its operation.
 - The network must provide all of the services referred to in Article 11(1) of the Directive and take into account:
 - relevant user requirements;
 - user friendliness; and
 - public availability and accessibility via Internet or other means of telecommunication.
 - The network must provide the discovery, view, download and transformation services referred to in Article 11(1)(a), which implement all of the search criteria in Article 11(2).
 - The network must combine the transformation services referred to in Article 11(1)(d) with other services to ensure that all services are operated in compliance with the implementation rules referred to Article 7(1).
 - Legislation must remove all obstacles, legal or otherwise, in order to ensure unrestricted access to the network for public authorities and third parties whose spatial datasets and services comply with the implementing rules, whenever they request it. The only exceptions to obstacles to access may be those listed in Article 13. Compliance with Directive 95/46/EC must also be ensured.
 - Legislation must ensure that network services relating to the discovery services and view services referred to in Article 11(1) (a) and (b) must be available to the public free of charge. Proportionate charges or licenses to gain access to, exchange and use spatial data and services may be levied or imposed in accordance with Article 14.
 - National legislation must set obligations to facilitate data sharing.

- National legislation must set up measures to render it legally obligatory for public authorities to be able to gain access to, and also to share, spatial datasets and services in accordance with the Directive.
- National legislation must provide for obligations that prohibit restrictions at point of use and the sharing of such datasets and services.
- National legislation should provide for obligations setting parameters for a licensing mechanism to which public authorities that are obliged to provide and exchange spatial data must adhere.
- National legislation must allow the sharing and exchange of data with other EU institutions and Member States.

2.3 Monitoring

Competent authorities established by law shall be legally responsible for monitoring:

- various sources of spatial data holders according to the themes listed in Annex I, II and III, and their role in distributing spatial data and services;
- meta-data according to Article 5, ensuring its updating and quality control;
- stakeholders' involvement;
- accessibility, or limitations thereto, in accordance with Article 13;
- the implementation and use of spatial data and services.

According to Commission Decision 2009/442/EC of 5 June 2009 implementing the INSPIRE Directive, EU Member States have to report annually a number of indicators for monitoring the implementation and use of their infrastructures for spatial information. The information provided includes a list of spatial data sets and services belonging to those infrastructures.

2.4 Reporting

Summary of main reporting obligations:

- Candidate countries must ensure that their competent authorities have the necessary capacity to fulfil, within the appropriate time-frames and on a permanent basis, their reporting requirements to the Commission. This is a legal obligation, which is binding upon competent authorities of candidate countries.
- Candidate countries must, however, provide for legal instruments that make it obligatory to report/provide information to the public both upon request and also at regular intervals such as, for example, in state of the environment reports.
- The competent authority must be in a position to provide, upon request, information to the public and to the Commission about the implementation rules adopted.

According to Commission Decision 2009/442/EC of 5 June 2009 implementing the INSPIRE Directive, a report including inter alia information on the coordinating structures, on the use of the infrastructure for spatial information, on data-sharing agreements and on the costs and benefits of implementing the INSPIRE Directive, is prepared and submitted every three years, starting in 2010.

2.5 Additional Legal Requirements

To ensure that the spatial data infrastructures of the Member States are compatible and usable in a Community and transboundary context, the Directive requires that common Implementing Rules (IR) are adopted in a number of specific areas (Metadata, Data Specifications, Network Services, Data and Service Sharing and Monitoring and Reporting). These IRs adopted so far are listed below:

- Commission Regulation (EC) No 1205/2008 of 3 December 2008 implementing Directive 2007/2/EC of the European Parliament and of the Council as regards metadata
- Commission Decision 2009/442/EC of 5 June 2009 implementing the INSPIRE Directive
- Commission Regulation (EC) No 976/2009 of 19 October 2009 implementing Directive 2007/2/EC of the European Parliament and of the Council as regards the Network Services, as amended by Commission Regulation (EU) No 1088/2010 as regards download services and transformation services and Regulation (EU) No 1311/2014 as regards the definition of an INSPIRE metadata element
- Commission Regulation (EU) No 268/2010 of 29 March 2010 implementing Directive 2007/2/EC of the European Parliament and of the Council as regards the access to spatial data sets and services of the Member States by Community institutions and bodies under harmonised conditions
- Commission Regulation (EU) No 1089/2010 of 23 November 2010 implementing Directive 2007/2/EC of the European Parliament and of the Council as regards interoperability of spatial data sets and services, as amended by Commission Regulations (EU) No 102/2011, (EU) 1253/2013, (EU) 1312/2014
- The Directive is without prejudice (supplementing) to Directive 2003/4/EC on public access to environmental information and Directive 2003/98/EC on the re-use of public sector information.
- The provision of network services under the Directive must be in full compliance with Directive 95/46/EC on the protection of individuals with regard to the processing of personal data.
- In implementing the Directive, international and European standards must be taken into consideration in accordance with the procedure laid down in Directive 2015/1535/EU laying down a procedure for the provision of information in the field of technical standards and regulations.

3. IMPLEMENTATION

3.1 Key Tasks

The key tasks involved in implementing this Directive are summarised in the checklist below. The tasks are arranged under subheadings and organised in chronological order of implementation wherever possible.

Table 18. INSPIRE Directive – Key Implementation Tasks

INSPIRE - CHECKLIST OVER IMPLEMENTATION ISSUES	
1	Planning
1.1	Locate spatial data covered by the Directive and the holders of such data (Art. 4).
1.2	Assign duties to the competent authority or authorities that will carry out regulatory, co-ordination and co-operation measures (various articles and Art. 18).
1.3	Devise memoranda of understanding for various competent authorities that will work together to set up and co-ordinate networks.
1.4	Conduct a feasibility analysis for implementing rules with respect to the interoperability of spatial datasets and estimate their cost effectiveness.
1.5	Organise stakeholder meetings to facilitate the exchange of information, to ensure the participation of stakeholders in preparatory work and to identify user needs.
2	Regulation
2.1	Publish legal instruments for the collection and dissemination of spatial data and meta-data (Arts. 4, 5 and 6). Compile meta-data corresponding to the themes listed in Annexes I, II and III. Devise quality control for meta-data.
2.2	Establish implementation rules for the harmonisation and interoperability of spatial datasets and services (Art. 7) corresponding to the themes in Annexes I and II (Arts. 8, 9 and 10).
2.3	Establish network services (Arts. 11-16) that provide for discovery, view, download and transformation services and for services allowing spatial data services to be invoked. The services must operate using search criteria in accordance with Article 11(2). Quality control assessment shall include accessibility, user friendliness and compatibility with the implementation rules in Article 2(2).
2.4	Provide access to the network services to public authorities and third parties whose spatial datasets and services comply with the implementing rules. The only exceptions to obstacles to access may be those listed in Article 13. Compliance with Directive 95/46/EC must also be ensured.
2.5	Conclude memoranda of understanding identifying which public authorities are involved, and for which tasks, in order to ensure that the network facilitates the exchange of spatial data and related services.
2.6	Ensure that national infrastructure will enable access to the services referred to in Article 1(1) through the INSPIRE geo-portal that will be established and operated by the EU.
2.7	Set up e-commerce services if the view and download services and access to spatial data services are available against payment.
2.8	Devise national measures to ensure access to data sharing and to facilitate the exchange of data (Art. 17) for all public tasks that may have an impact on the environment. Measures must include the issuing of guidelines for setting up licensing systems or the stipulation of fees for the provision of spatial datasets and services to ensure that they do not create obstacles to data sharing.
3	Training and Capacity Building
3.1	Prepare and publish guidance on the duties and the roles of the various public authorities that are obligated under the Directive to provide access to spatial datasets and services.
3.2	Provide user guides and a list of user rights with respect to access to spatial datasets and services, including transferring incorrectly addressed requests to the correct public authority.
3.3	Provide technical training to officers in public authorities involved in the provision of spatial data services in order to optimise their services. Train a selected group to ensure quality control. Provide training in communication skills for officers who handle user claims and queries.

3.4	Provide information to stakeholders, including those representing the relevant competent authorities. The said training should also assist trainees in internal management processes.
4	Reporting
4.1	Provide information at regular intervals on a national level and set up an infrastructure to handle demands upon request by the public or public authorities, whether national or from other Member States.
4.2	Set up the necessary infrastructure to report to the Commission any information in accordance with the Directive, including: <ul style="list-style-type: none"> • experience gained in implementing the Directive; • measures taken to comply with the Directive; • transposition; • obstacles met within implementing the Directive.
4.3	Given the importance of good co-ordination amongst public authorities to implement this Directive, consider the appointment of one contact point responsible for co-ordination supported by a co-ordination structure.

3.2 Phasing Considerations

Candidate countries are likely already to possess a large body of spatial data in numerous public organisations that fulfil the conditions under Article 4 and are therefore subject to regulation in accordance with the Directive. These organisations may need a substantial amount of time not only to transpose the Directive but also to ensure the necessary capacity building both logistically and in terms of human resources. The major tasks involved that are likely to be time-consuming are: to create meta-data, to ensure the interoperability of spatial datasets and services, to set up network services and facilitate data sharing, and to ensure better co-ordination at the national and EU level.

The national competent authorities, (i.e. the national environment ministry or agency and their regional or local counterparts, providers of public services related to the themes listed in the three annexes to the Directive, as well as all public authorities whose activities have an environmental impact must ensure appropriate and efficient co-ordination). Whilst the nature of the Directive itself involves many stakeholders even amongst public authorities, the creation of one authority to regulate and monitor compliance and to be responsible for co-ordination and reporting to the Commission should be considered.

All competent authorities must train personnel in procedures and best practices for interfacing with stakeholders as regards the provision of spatial datasets and services, bearing in mind that such information can, at times, be sensitive.

The Directive provides specific time-frames for compliance by Member States, such as those in Article 6. Preparations must also be made to provide national links with the EU's geo-portal referred to in the Directive.

Detailed implementation roadmap is available at: <http://inspire.ec.europa.eu/index.cfm/pageid/44>.

4. IMPLEMENTATION GUIDANCE

Several technical guidance documents to facilitate implementation of the INSPIRE Directive and understanding of the requirements involved are published and available at: <http://inspire.ec.europa.eu/index.cfm/pageid/6/list/1>

These technical guidance documents define how Member states might implement the Implementing Rules. Below is the list of the latest guidance documents:

Technical Guidance for INSPIRE Spatial Data Services and services allowing spatial data services to be invoked (17.12.2014)

- INSPIRE Data Specification on Address - technical guidelines 3.1 (17.04.2014)
- INSPIRE Data Specification on Administrative units - technical guidelines 3.1 (17.04.2014)
- INSPIRE Data Specification on Cadastral Parcels - technical guidelines 3.1 (17.04.2014)
- INSPIRE Data Specification on Coordinate Reference Systems - technical guidelines 3.2 (17.04.2014)
- INSPIRE Data Specification on Geographical Grid Systems - technical guidelines 3.1 (17.04.2014)
- INSPIRE Data Specification on Geographical Names - technical guidelines 3.1 (17.04.2014)
- INSPIRE Data Specification on Hydrography - technical guidelines 3.1 (17.04.2014)
- INSPIRE Data Specification on Protected Sites- technical guidelines 3.2 (17.04.2014)
- INSPIRE Data Specification on Transport Networks - technical guidelines 3.2 (17.04.2014)
- Guidelines for the Encoding of Spatial Data – framework document (08.04.2014)

In addition, there are a number of published reports and studies dealing with various aspects of the INSPIRE implementation

(further information can be obtained at <http://inspire.ec.europa.eu/index.cfm/pageid/6/list/1>)

4.1 Planning

The INSPIRE Directive came into force on 15 May 2007 and will be implemented in various stages, with full implementation required by 2019.

During the transposition phase, careful consideration must be given to a number of legal and organisational issues to ensure compliance and better co-ordination. Legal issues that need to be addressed, given the nature of the obligations of the Directive, include: principles of confidentiality, conditions under which to allow a request for spatial data information to be refused, co-ordination between public authorities involved in the network set up when providing access to spatial datasets and services as well as meta-data or in exchanging such data and services. It is essential to give consideration to training officers in all public authorities regarding compliance with the INSPIRE Directive. Training officers in all public authorities that will be involved in the implementation of the INSPIRE Directive is essential, both for compliance purposes and good governance.

Another issue that has been highlighted by research institutes and consultancies is that there is a need for clearer guidelines regarding the separation of public duties and commercial activities. Furthermore, the following aspects need to be dealt with in order to mitigate the negative consequences for private sector providers of meta-data:

- inconsistent legislation and policies;
- the fact that public sector bodies often have a monopoly on collecting and disseminating certain meta-data;
- inconsistent fees and conditions;
- lack of transparency regarding costs.

Enforcement is a complex issue in the INSPIRE Directive, since it does not contain provisions stipulating sanctions. It is unlikely that states will provide for penalties since it is the public authorities, in this case, that would be non-compliant. Despite the lack of obligation to provide sanctions, the Member States are still subject to infringement procedures if they do not comply with the Directive's provisions, therefore some form of deterrent, such as reporting, is recommended in order to name and shame non-compliant authorities. However, this is an optional measure.

Examples of Implementation in Member States

United Kingdom:

The Department of Environment, in its assessment of the INSPIRE Directive and its consequences at national level, estimated that the regional development agencies (RDAs) could have enhanced responsibility for co-ordinating public sector business support and advice in certain flood data management and dissemination activities. This would include post-flood event recovery initiatives. RDAs could take direct responsibility for capturing, or for being the repository of, certain datasets from business. They should also take steps to improve the quality and consistency of data on flood issues in order to support and advice business and support services.

4.2 Regulation

The definitions of the Directive must be carefully transposed and abided by in order to ensure compliance. Special attention must be given to Article 4(1), as this establishes the type of spatial data to which the obligations of the Directive apply. Candidate countries must also draw up parameters in order to determine the criteria to regulate licensing by public authorities with respect to access to data, the kind of charges that may be levied, and the circumstances under which the derogations referred to in the Directive regarding access to spatial data should be applied.

National legislation should leave as little discretion as possible to the public authorities in order to ensure smooth implementation and uniform application. Provision should also be made in legal instruments to establish when requests may be refused — for example when they are manifestly unreasonable or likely to be used and availed of for commercial purposes. In the event that it is considered inappropriate to include certain measures in a legal instrument because of their predominantly administrative nature, it is recommended that memoranda of understanding be drawn up to ensure smooth and uniform implementation given the large number of public authorities that may be involved. Transparency is of vital importance and the competent

authority, as the regulator, must provide lists of public authorities and the type of spatial data and services falling within the scope of Article 4(1) of the Directive, as well as the type of data and services that they hold and that they are legally bound to provide and exchange.

National legislation must provide the necessary steps to ensure that existing spatial datasets and corresponding spatial services falling under the themes listed in Annexes I, II and III of the Directive are compiled into meta-data and are in conformity with the implementation rules specified in the Directive. It must be decided whether this is to be done via adaptation or through transformation in accordance with Article 11(1)(d). Where spatial datasets correspond to one or more of the themes listed in Annex I or II, the implementing rules provided for in Article 7 must address the aspects of spatial data listed in Article 8(2), ensure information consistency in accordance with Article 8(3), and ensure comparability in accordance with Article 8(4).

National legislation must provide for links between the spatial datasets and services to the network, identify who is responsible for ensuring that this happens, and provide this information to the public. Any limitations to access and any derogations on any grounds must be interpreted in a very strict manner. Any charges for access to services referred to in Article 11 1(a) and (b) may only be levied where permitted by the Directive. The provision of e-commerce services is obligatory when charges are made, in accordance with Article 11 (1) (b) (c) (e).

Examples from Practical Implementation in Member States

Sweden:

A new Act and Ordinance for Geographic Environmental Data (Lag och förordning för geografisk miljöinformation) entered into force on 1 January 2011. The Ordinance distributes responsibilities among 20 authorities, including the Swedish EPA, which is responsible for geodata quantities within 5 themes: 1) protected areas, 2) facilities and locations affected by environmental monitoring/supervision, 3) locations with specific administration, 4) biogeographic regions, nature types, 5) extension of species.

The Ordinance and the responsibilities was scheduled for a review in 2012, which as a result will lead to responsibilities of the EPA being transferred to the newly established Sea and Water Authority (Havs- och vattenmyndigheten). This national implementation work is undertaken in parallel with the EU proposals for further implementing provisions (for instance Annex 3).

One of the main authorities in charge of implementing the Inspire Directive is „Lantmäteriet”. This authority has developed an activity model for geodata coordination which includes a business model and cooperation agreement which was entered by some 20 authorities. This latter agreement is applicable as from 1 January 2011 and concerns a number of authorities including those that have been designated informative responsibilities. The agreement has resulted in extended possibilities to access geo data from public authorities and municipalities in a simple and uniform manner. All participating authorities, including Swedish EPA, have to make accessible all geographic data for the contracting parties. This service is prepaid and profits shared according to a predetermined model.

More information on the coordination and cooperation between authorities with responsibilities for implementing the INSPIRE Directive can be obtained from: <http://www.naturvardsverket.se/sv/Start/Tillstandet-i-miljon/Miljoovervakning/Samordning-av-miljoovervakningen/Miljoovervakning--hur-styrs-samordningen/INSPIRE/>

The Swedish Environmental Data Portal (Miljödataportalen) constitutes on element of the implementation.

This portal provides access to environmental reports, maps with information on nature and environment, including network over national environmental supervision. Other more hard data is available through the national Geodata Portal and the services can be used directly in independent GIS programs. These two portals can be accessed at: <http://gpt.vic-metria.nu/GeoPortal/> and <http://www.geodata.se/sv/>

4.3 Monitoring and Reporting

The primary competent authority for implementing this Directive is usually the ministry for the environment, or an agency for environment protection, which shall be the regulator responsible for monitoring compliance and enforcement. Sub-national competent authority participation, however, will often be vital since accountability and everyday communications with stakeholders will also almost inevitably occur at the sub-national level. However, spatial data may be held by a large number of public bodies within a state. At the central government level, these may include government ministries for agriculture, spatial planning, transportation, statistics, forestry, water resources, post, telecommunications etc. Other types of national bodies that may hold relevant spatial data and provide related services include environmental protection agencies, meteorological offices, research institutions, universities etc. At the regional and local level, spatial data may be held by sub-national or local environmental inspectorates or environment agency offices, local government offices, local planning authorities and municipalities etc.

Although the lead ministry or the focal point for the purposes of the Directive may be the environment ministry or the environment agency that would have the necessary regulatory and monitoring powers, implementation is likely to be exercised by all other public authorities. Given the expanded definition of "public authorities" in Article 2, the providers of spatial data relating to the themes referred to in Annexes I, II and III of the Directive that are under the control of the public administration are also to be placed under the obligations imposed by the Directive, at least to forward requests for information on spatial datasets and services as well as the compilation of meta-data to the relevant public administrative body.

Monitoring follows a quantitative approach and is based on a list of spatial data sets and services of the Member States. The list should cover already conformant data sets and services as well as those that still have to be brought into conformity. This list should basically reflect the Member State's plans for the implementation of INSPIRE. Based on the information collected for all the items of the list, indicators can be calculated to evaluate:

- Existence of metadata for spatial data sets and services
- Conformity of metadata for spatial data sets and services with the implementing rules on metadata
- Geographical coverage of spatial data sets
- Conformity of spatial data sets with the data specifications and of their metadata with the implementing rules on metadata
- Accessibility of metadata for spatial data sets and services through discovery services
- Accessibility of spatial data sets through view and download services
- Use of network services

- Conformity of network services to the implementing rules on network services
- Reporting follows a qualitative approach. Member states will provide information on five main areas:
- Coordination and quality assurance, including information on the Member State contact point and the coordination structure, as well as a description and evaluation of the quality assurance procedure, including measures taken to improve it
- Contribution to the functioning and coordination of the infrastructure, including an overview of the stakeholders and of their roles, the measures taken to facilitate sharing and a description on how they cooperate
- Use of the infrastructure for spatial information, in general and by public authorities in particular; examples of cross border use and efforts made to improve it
- Data sharing arrangements between public authorities of the Member State, between public authorities and Community institutions and bodies as well as barriers to sharing
- Cost and benefit aspects, that is an estimate of the costs related to INSPIRE Directive and examples of the observed benefits.

5. COSTS

The INSPIRE Directive itself states that implementing rules should be based, where possible, on international standards and should not result in excessive costs for Member States.

Costs will depend largely on the size of the country, the constitutional and administrative system (e.g. centrally organised administration or decentralised/federal administration), and on the already existing structure for the collection, dissemination and exchange of geo-data and meta- data. Candidate countries that already have in place a functioning system for this data will incur substantially lower costs than those for which this is a new area.

Some of the costs of setting up and maintaining geo-data portals can be offset by charging a proportionate and reasonable fee. Charges for using datasets are often higher in the initial stages and become lower over time.

One consequence of providing access to geo-data free of charge is that it is likely to have a negative financial impact on companies in the private sector that are selling similar datasets. The private sector could therefore view the dominant position of agencies in terms of collecting and disseminating geo-data at low prices as being unfair competition.

AIR QUALITY – OVERVIEW

Section 3

1. INTRODUCTION AND OVERVIEW	219
1.1. EU Policy on Ambient Air.....	219
1.2. General Approach and Principles	224
1.3. EU Legal Instruments.....	226
1.4. Summary of Air Quality Legislative Framework.....	229
1.4.1. Ambient Air Quality Directive 2008/50/EC and Heavy Metals Directive 2004/107/EC	229
1.4.2. The National Emission Ceilings Directive (2001/81/EC).....	231
1.4.3. Directive on Sulphur Content in Certain Liquid Fuels (EU) 2016/802.....	231
1.4.4. Directive on Petrol Vapour Recovery from Storage and Distribution – Stage I (94/63/EC)	232
1.4.5. Directive on Petrol Vapour Recovery from Refuelling at Service Stations - Stage II (2009/126/EC)	232
1.4.6. Directive on Pollutants from Non-road Mobile Machinery (97/68/EC).....	232
1.4.7. Regulation 595/2009 on Type-approval for Heavy Duty Vehicles	233
1.4.8. Regulation (EC) No 715/2007 on Type-approval of Light Duty Vehicles	233
1.4.9. Decision 86/277/EEC on Monitoring and Evaluation of the Long-Range Transmission of Air Pollutants in Europe (EMEP)	234
1.4.10. Decision 2003/507/EC on the Accession of the European Community, to the Protocol to the 1979 Convention on Long- Range Transboundary Air Pollution to Abate Acidification, Eutrophication and Ground-Level	234
1.5. Implementation of ambient air quality legislation.....	234
1.5.1. Zoning.....	235
1.5.2. Assessment	235
1.5.3. Management	238
1.5.4. Reporting	239
1.5.5. Time extensions	239
1.6. Links with other sectoral legislation	240
2. DEVELOPMENT OF A SECTORAL STRATEGY AND IMPLEMENTATION PLAN	243
3. INSTITUTIONS AND RELEVANT PARTIES.....	247
3.1. Stakeholders.....	247
3.2. National Government Institutions	247
3.3. Competent Authorities	249
3.4. Regional and Local Government	250
3.5. Private Sector Involvement.....	251
3.6. Communication and Consultation.....	252
4. TECHNICAL ISSUES	254

4.1.	Adoption of Technical Standards	254
4.2.	Monitoring Ambient Air Quality	255
4.3.	Quality Assurance and Control	258
5.	REGULATION AND ENFORCEMENT.....	259
5.1.	Overview	259
5.2.	Authorisations and Permitting	259
5.3.	Monitoring, Inspection and Enforcement.....	260
5.4.	Data Collection and Reporting.....	261
6.	PRIORITIES AND TIMING.....	263
6.1.	Prioritising the Implementation Tasks	263
6.1.1.	Legislative Considerations.....	263
6.1.2.	Cost-effectiveness.....	263
6.1.3.	Economic Considerations.....	264
6.1.4.	Environmental Considerations	265
6.2.	Timescales.....	266
7.	ECONOMIC AND FINANCIAL ISSUES	268
7.1.	Introduction.....	268
7.2.	Main Cost Areas	268
7.3.	Institutional Development	271
7.4.	Facilities.....	271
7.5.	Application of Other Economic Tools.....	272
7.5.1.	Economic tools at national level.....	272
8.	SUMMARY OF KEY ISSUES	275
	THE AIR QUALITY FRAMEWORK DIRECTIVE.....	278
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	282
2.1.	Planning.....	282
2.2.	Regulation	284
2.3.	Monitoring.....	288
2.4.	Information and Reporting.....	289
2.5.	Additional Legal Instruments	292
3.	IMPLEMENTATION	296
3.1.	Key Tasks.....	296
3.2.	Phasing Considerations	299

4. IMPLEMENTATION GUIDANCE	300
4.1. Planning.....	301
4.2. Assessment and Classification.....	302
4.3. Plans and Programmes to Achieve Compliance.....	303
4.4. Monitoring, Information and Reporting.....	307
5. COSTS.....	309
HEAVY METALS IN AMBIENT AIR DIRECTIVE.....	311
1. SUMMARY OF MAIN AIMS AND PROVISIONS.....	312
2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	315
2.1. Planning.....	315
2.2. Monitoring.....	316
2.3. Regulation and Enforcement.....	317
2.4. Consultation, Reporting and Information.....	317
3. IMPLEMENTATION	319
3.1. Key Tasks.....	319
4. IMPLEMENTATION GUIDANCE	321
4.1. Planning.....	321
4.2. Regulation.....	321
4.3. Monitoring and Enforcement.....	322
4.4. Monitoring, Information and Reporting.....	323
5. COSTS.....	324
THE NATIONAL EMISSION CEILINGS DIRECTIVE	325
1. SUMMARY OF MAIN AIMS AND PROVISIONS.....	326
2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	328
2.1. Planning and Programmes	328
2.2. Emission Inventories	328
2.3. Reporting by Member States	328
2.4. Additional Legal Instruments	329
2.5. Co-operation with Third Countries.....	329
3. IMPLEMENTATION	330
3.1. Key Tasks.....	330
4. IMPLEMENTATION GUIDANCE	331
4.1. National programmes	331

4.2.	Reporting	331
4.3.	Examples of Implementing Measures.....	331
5.	COSTS.....	340
THE DIRECTIVE ON SULPHUR CONTENT OF CERTAIN LIQUID FUELS		341
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	342
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	344
2.1.	Regulation	344
2.2.	Monitoring.....	345
2.3.	Reporting	345
2.4.	Enforcement.....	346
2.5.	Additional Legal Instruments	346
3.	IMPLEMENTATION	349
3.1.	Key Tasks.....	349
3.2.	Phasing Considerations	350
4.	IMPLEMENTATION GUIDANCE	351
4.1.	Regulation	352
4.2.	Monitoring.....	353
4.3.	Enforcement.....	353
5.	COSTS.....	354
THE DIRECTIVES ON VOC EMISSIONS RESULTING FROM STORAGE AND DISTRIBUTION OF PETROL		355
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	356
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	358
2.1.	Regulation.....	358
2.1.1.	Obligations linked to Stage I Directive:.....	358
2.1.2.	Obligations linked to Stage II Directive:	358
2.2.	Monitoring and Enforcement.....	359
2.2.1.	Obligations linked to Stage I Directive:.....	359
2.2.2.	Obligations linked to Stage II Directive:	360
2.3.	Reporting	360
2.3.1.	Obligations linked to Stage I Directive:.....	360
2.3.2.	Obligations linked to Stage II Directive:	361
2.4.	Additional Legal Instruments	361
3.	IMPLEMENTATION	363

3.1.	Key Tasks.....	363
3.2.	Phasing Considerations	365
4.	IMPLEMENTATION GUIDANCE	367
4.1.	Planning.....	367
4.2.	Regulation.....	367
4.3.	Monitoring and Enforcement.....	370
5.	COSTS.....	371
THE DIRECTIVE ON EMISSIONS FROM ENGINES TO BE INSTALLED IN NON-ROAD MOBILE MACHINERY		372
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	373
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	377
2.1.	Regulation.....	377
2.2.	Monitoring and Enforcement.....	379
2.3.	Reporting	380
2.4.	Additional Legal Instruments	381
3.	IMPLEMENTATION	383
3.1.	Key Tasks.....	383
3.2.	Phasing Considerations	384
4.	IMPLEMENTATION GUIDANCE	386
4.1.	Regulation.....	386
4.2.	Monitoring and Enforcement.....	388
5.	COSTS.....	389
REGULATION ON EMISSIONS FROM HEAVY DUTY VEHICLES.....		391
1.	MAIN AIMS AND PROVISIONS	392
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	393
2.1.	Planning.....	393
2.2.	Regulation.....	393
2.3.	Monitoring and Enforcement.....	398
2.4.	Reporting	398
2.5.	Additional Legal Instruments	399
3.	IMPLEMENTATION	401
3.1.	Key Tasks.....	401
3.2.	Phasing Considerations	404
4.	IMPLEMENTATION GUIDANCE	405

4.1.	Regulation	405
4.2.	Monitoring and Enforcement.....	405
5.	COSTS.....	407
REGULATION ON TYPE APPROVAL OF MOTOR VEHICLES REGARDING EMISSIONS FROM VEHICLES.....		
408		
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	409
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	414
2.1.	Planning.....	414
2.2.	Regulation	417
2.3.	Monitoring and Enforcement.....	422
2.4.	Information	422
2.5.	Reporting	423
2.6.	Additional Legal Instruments	424
2.6.1.	Directly related acts:.....	424
2.6.2.	Other relevant acts:	424
3.	IMPLEMENTATION	426
3.1.	Key Tasks.....	426
3.2.	Phasing Considerations	428
4.	IMPLEMENTATION GUIDANCE	429
4.1.	Regulation	429
4.2.	Monitoring and Enforcement.....	429
5.	COSTS.....	431
THE DECISION ON THE PROTOCOL ON LONG-TERM FINANCING OF EMEP		
432		
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	433
2.	PRINCIPAL OBLIGATIONS.....	434
3.	IMPLEMENTATION	435
4.	IMPLEMENTATION GUIDANCE	436

AIR QUALITY - OVERVIEW

1. INTRODUCTION AND OVERVIEW

This section of the Handbook deals with EU legislation in the air quality sector. It contains an introductory overview of the sector followed by individual fiches for selected pieces of legislation.

This section of the Handbook is an updated version of a previous edition. It covers legislation until 31 December 2014. It should be noted that with the establishment of DG CLIMA, this Directorate-General took over and specialised in certain areas which previously were dealt with by DG ENV; e.g. fluorinated greenhouse gases, the greenhouse gases emission trading system, ozone depleting substances, fuel quality and CO₂ emissions targets for cars and vans. However, it should be noted that the *acquis* presented in this chapter is closely related to the climate *acquis* (published in a separate Handbook on the Implementation of the EU Climate *Acquis*) as well as industrial pollution *acquis* (e.g. combustion of waste, the Industrial Emissions Directive (2010/75/EU) and transport and energy *acquis* given that mobile sources and electricity production give rise to significant air emissions. Hence, the candidate countries should implement the air quality *acquis* in conjunction with these other sector specific legislation.

As a result of the ample policy, legislative and organisational changes in the area of air quality *acquis*, this chapter has undergone a major revision aiming at presenting the historical policy background as well as the current policy and legislative context. EU's policy on air quality aims to develop and implement appropriate instruments to improve air quality. The control of emissions from mobile sources, improving fuel quality and integrating environmental protection requirements into the transport and energy sector are part of these aims.

1.1. EU Policy on Ambient Air

EU environmental policy focuses on developing and implementing a clean air policy framework that reinforces national policies for those aspects of the air quality problem that Member States cannot handle effectively or efficiently alone. EU policies also aim at implementing the Union's international obligations in the field of air pollution, and on integrating environmental protection requirements into, for example, the industry, energy, transport and agriculture sectors.

Air pollution has been one of Europe's main political concerns since the late 1970s. Environment Action Programmes have guided the development of EU environment policy. During this period, environment legislation was consolidated and completed to cover almost all environmental media, with the exception of soil. The Commission continues to pursue an ambitious environment policy aimed at ensuring a high level of environmental protection and guided by the principles enshrined in the Treaty of the Functioning of the EU on 'precaution', 'prevention', 'rectifying pollution at source' and 'polluter pays'.

In 1992, the EU set itself the objective of laying the foundations in the last years of the 20th century for achieving sustainable development in the 21st century. The long-term goal of transforming the European economy into one whose development would be sustainable for generations to come was set out in the 5th Environmental Action Programme "Towards Sustainability" (5th EAP). The general approach and strategy was to set longer-term objectives and focus on a more global approach.

In 2002 the Sixth Environment Action Programme (EAP), "Environment 2010: Our future, Our choice" (2002-2012), was adopted. It included Environment and Health⁷⁵ as one of the four main target areas where further effort was needed. The objective of the 6th EAP was to achieve levels of air quality that do not give rise to unacceptable impacts on, and risks to, human health and the environment. In 2005, the Commission launched the Thematic Strategy on Air Pollution⁷⁶ and Clean Air For Europe (CAFE)⁷⁷, the first of seven Thematic Strategies in the EU's 6th EAP. The Thematic Strategy on Air Pollution set out interim objectives for health and the environment to be attained by 2020. It was accompanied by a proposal to merge and update the main body of legislation on ambient air quality, which establishes health-based standards and targets. As a result, the new Air Quality Directive 2008/50/EC (on ambient air quality and cleaner air for Europe) merged together most of the existing legislation on air quality and introduced a range of binding and non-binding objectives for fine particulate matter (PM2.5) the pollutant associated with the most damaging impacts for human health.

Long-term objective for air quality: to achieve 'levels of air quality that do not give rise to significant negative impacts on and risks to human health and the environment' is confirmed in the new General Union Environment Action Programme to 2020⁷⁸ (the 7th EAP). The 7th EAP is a strategic document providing an overarching framework for recent environment policy initiatives and setting out priority objectives to be attained over the period up to 2020, in the context of the Europe 2020 Strategy⁷⁹. The 7th EAP priority objectives are:

1. Natural capital: "Nurturing the hand that feeds us"

Natural capital refers to the biodiversity that provides goods and services we rely on, from fertile soil and productive land and seas to fresh water and clean air. It includes vital services such as pollination of plants, natural protection against flooding, and the regulation of our climate. In this context the new EAP commits the EU and its Member States to speed up the implementation of existing strategies, fill gaps where legislation doesn't yet exist, and improve existing legislation.

2. Resource-efficient economy: "Doing more with less"

The EAP sets out the conditions that will help transform the EU into a resource-efficient, low-carbon economy. This requires:

- Full delivery of the climate and energy package to achieve the 20-20-20 targets and agreement on the next steps for climate policy beyond 2020;
- Significant improvements to the environmental performance of products over their life cycle;
- Reductions in the environmental impact of consumption, including issues such as cutting food waste and using biomass in a sustainable way.
- There is a special focus on turning waste into a resource and to move towards more efficient use of our water resources.

⁷⁵ Background information on pollutants and their effects on health can be found in the Air Quality Guidelines of the WHO (http://www.who.int/phe/health_topics/outdoorair_agq/en/index.html) and information on other air pollution effects and data can be obtained from the European Environmental Agency (<http://www.eea.europa.eu/themes/air>).

⁷⁶ (COM(2005) 446) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2005:0446:FIN:EN:PDF>

⁷⁷ <http://ec.europa.eu/environment/archives/cale/general/keydocs.htm>

⁷⁸ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32013D1386>

⁷⁹ http://ec.europa.eu/europe2020/index_en.htm

3. Healthy environment for healthy people: "Taking care of the environment is taking care of ourselves"

The third key action area covers challenges to human health and wellbeing, such as air and water pollution, excessive noise, and chemicals. This requires:

- updating air quality and noise legislation;
- improving implementation of legislation relating to drinking and bathing water;
- tackling hazardous chemicals, including nanomaterials, chemicals that interfere with the endocrine system and chemicals in combination, as part of a broader, strategic approach for a non-toxic environment.

4. Improved implementation: "Good for the environment, our health and our wallets"

Better implementation of existing legislation will bring numerous benefits for the environment, our health and the economy.

5. Increased information: "Best decisions based on latest data"

Scientific research, monitoring and reporting environmental developments mean that our understanding of the environment is constantly increasing. This knowledge base should be made more accessible to citizens and policymakers to ensure policy continues to draw on a sound understanding of the state of the environment.

The EAP aims to:

- improve the way data and other information is collected, managed and used across the EU;
- invest in research to fill knowledge gaps;
- and develop a more systematic approach to new and emerging risks

6. Secured investments: "Green incentives mean green innovations"

Adequate investments and innovation in products, services and public policies will be needed from public and private sources, in order to achieve the objectives set out in the programme.

This can only happen if impacts on the environment are properly accounted for and if market signals also reflect the true costs to the environment. This involves:

- applying the polluter-pays principle more systematically;
- phasing out environmentally harmful subsidies;
- shifting taxation from labour towards pollution;
- and expanding markets for environmental goods and services

7. Better integration: "Tackling multiple challenges with one approach"

Better integration of environmental concerns into other policy areas, such as regional policy, agriculture, fisheries, energy and transport will ensure better decision-making and coherent policy approaches that deliver multiple benefits.

Two further priority objectives complete the programme: tackling local and global challenges together.

8. Sustainable cities: "Working together for common solutions"

Cities often share a common set of problems such as poor air quality, high levels of noise, greenhouse gas emissions, water scarcity, and waste.

The EAP aims to:

- help cities become more sustainable;
- promote and expand initiatives that support innovation and best practice sharing in cities;
- ensure that by 2020, most cities in the EU are implementing policies for sustainable urban planning and design, and are using the EU funding available for this purpose

9. Tackling international challenges: "Living well, within the limits of our planet" is a global aim

Many of the priority objectives in the EAP can only be achieved in cooperation with partner countries or as part of a global approach. The EU and its Member States are committed to:

- engage more effectively in working with international partners towards the adoption of Sustainable Development Goals as a follow-up to the Rio+20 conference;
- further steps that could be taken to reduce impacts on the environment beyond EU border.

To this end, the EU acts at many levels to reduce exposure to air pollution: through legislation, through work at the wider international level in order to reduce cross-border pollution, through working with sectors responsible for air pollution and with national, regional authorities and NGOs, and through research and innovation. Despite the continuous efforts air pollution is the number one environmental cause of death in the EU. In addition, the European Union is not on track to meet its long-term air quality objective and the air pollution guidelines of the WHO are generally not being met.

The next corner stone in air quality policy is the adoption of the Air Quality Policy Package in 2013 as a result of a major review of the air policy that begun in early 2011. The Air Quality Policy Package has several components. They include:

- New Clean Air Programme for Europe⁸⁰ with measures to ensure that existing targets are met in the short term, and new air quality objectives for the period up to 2030. The package also includes support measures to help cut air pollution, with a focus on improving air quality in cities, supporting research and innovation, and promoting international cooperation.
- Revised National Emission Ceilings Directive⁸¹ with stricter national emission ceilings for the six main pollutants.
- Proposal for a new Directive to reduce pollution from medium-sized combustion installations⁸², such as energy plants for street blocks or large buildings, and small industry installations, and

⁸⁰ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions A Clean Air Programme For Europe, COM(2013)918 final, 18.12.2013.

⁸¹ Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the reduction of national emissions of certain atmospheric pollutants and amending Directive 2003/35/EC (COM/2013/0920 final) - 2013/0443 (COD)

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013PC0920>

⁸² Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the limitation of emissions of certain pollutants into the air from medium combustion plants (COM/2013/0919 final) - 2013/0442 (COD)

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013PC0919>

- Proposal for ratification of the 2012 Gothenburg Protocol⁸³.

New Clean Air Programme for Europe is built upon measures proposed in the 2005 Thematic Strategy on Air Pollution and it is aimed at achieving long term objectives set in the 6th and 7th EAP. Measures proposed and timelines for emissions reductions are coherent with the new climate and energy policy.

The new air protection strategy is focused on two priorities: to achieve broad compliance with existing legislation by 2020 at the latest, and to set a pathway for the EU to meet the long-term objective, i.e. no exceedence of the WHO guideline levels for human health and no exceedence of the critical loads and levels which mark the limits of ecosystem tolerance. Thus, new strategic air policy objectives until 2030 have been set in table below.

New air policy objectives for 2030 relative to 2005 (Source: COM(2013) 918)

Impacts	Health impacts (premature mortality due to PM and ozone)	Ecosystem area exceeding eutrophication limits
2030	-52%	35%

The Clean Air Programme for Europe proposes a combination of regulatory and non-regulatory measures for meeting the above targets. Full compliance with the existing legislation is set as a priority, whereas the targets for 2030 will require action to reduce emissions at source.

Proposed regulatory measures

- Revising National Emission Ceilings Directive

The proposal for a revised NEC Directive sets a new policy targets for 2030, with two interim milestones: for 2020, transposition of the EU's new international commitment agreed under the amended Gothenburg Protocol; and for 2025, intermediate reduction obligations to maintain the trajectory towards 2030.

The proposal includes cost- effective national emission reduction commitments ("NERCs") expressed as a percentage reduction of annual emissions of sulphur dioxide (SO₂), nitrogen oxides (NO_x), ammonia (NH₃), volatile organic compounds other than methane (NMVOC), fine particulate matter (PM_{2,5}) and methane (CH₄) as compared to the total of emissions of each of those pollutants discharged by each Member State in 2005. It also includes enhanced provisions on inventory, projections, ecosystems monitoring and drawing-up national air pollution programmes.

- Adoption of a Directive on Medium Combustion Plants

Recently adopted Directive (EU) 2015/2193 of the European Parliament and the Council of 25 November 2015 on the limitation of emissions of certain pollutants into the air from medium combustion plants regulates

⁸³ Proposal for a COUNCIL DECISION on the acceptance of the Amendment to the 1999 Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution to Abate Acidification, Eutrophication and Ground-level Ozone (COM/2013/0917 final) - 2013/0448 (NLE)

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013PC0917>

pollutant emissions from the combustion of fuels in plants with a rated thermal input equal to or greater than 1 megawatt (MWth) and less than 50 MWth.

It is thus aimed to fill out the gap in the EU source legislation concerning emissions from combustion installations of a thermal capacity between 1 and 50 MW and to help deliver a significant part of Member States' emission reduction obligations. The Directive on the limitation of emissions of certain pollutants into air from medium combustion plants (MCP) provides an effective instrument to further reduce pollution of NO_x, SO₂ and PM through appropriate limit values for new and existing installations, coupled with a simple registration scheme. The Directive entered into force on 18 December 2015 and will have to be transposed by Member States by 19 December 2017.

- Exploiting the full potential of existing source control legislation: Industrial Emissions, Ecodesign and Non-Road machinery
- Measures to abate ammonia emissions from agriculture
- Controlling emissions from shipping

Non-regulatory measures

A range of non-regulatory measures are presented to support policy implementation, targeting in particular the urban, agriculture and international dimensions while promoting closer links between policy-makers and the research and innovation community. They include measures such as: active engagement with the farming sector, mobilising international action and promoting research and innovation.

1.2. General Approach and Principles

European legislation on air quality is built on certain key approaches and principles. One important approach is that the Member States divide their territory into a number of zones and agglomerations. In these zones and agglomerations, the Member States should undertake assessments of air pollution levels using measurements and modelling and other empirical techniques. Where levels are elevated, the Member States should prepare an air quality plan or programme to ensure compliance with the limit value before the date when the limit value formally enters into force. In addition, information on air quality should be disseminated to the public.

EU Principles for Air Quality Management

- For ambient air quality standards:
 - Effects-based approach. Ambient air quality standards for pollutants are set according to their scientifically observed or estimated effects on human health and/or on the environment.
- Technologically and economically feasible standards: regarding product control, material handling, and emissions standards
- Best available techniques not entailing excessive cost (BAT). This principle seeks a balance between using state-of-the-art techniques to minimise emissions, and the cost of doing so.
- Polluter pays principle. Potential polluters should in general bear the costs of pollution prevention and control measures attributable to them, as well as of remediation. In the context of air quality

management, this means that potential emitters of air pollutants should bear the full costs of carrying out their activities in an environmentally sound manner, i.e. taking air quality into account.

- Integrated approach. Measures taken to reduce air pollution at one point or in one area should not lead to an increase in air pollution elsewhere, or to an increase in pollution of another environmental medium. Specific mitigation measures for all atmospheric pollutants in all economic sectors contributing to air pollution should be identified in order to achieve environmental objectives at least costs
- International approach. International coordination of air pollution policy is considered crucial since air pollution does not recognize borders. Joint efforts on the local, national and regional levels to combat air pollution and improve air quality have been successfully achieved through the Convention on Long-range Transboundary Air Pollution (CLRTAP) signed in 1979 and accompanied by eight protocols identifying specific measures to be taken by Parties to cut their emissions of air pollutants.
- Communication and information. Member States are required to inform the Commission about air quality issues in their territory and to inform the public. This requirement has been reinforced through the Environmental Information Directive and the Public Participation Directive. This horizontal legislation is crucial in ensuring the effective implementation of the air quality legislation

1.3. EU Legal Instruments

In this chapter on air pollution, 10 legislative instruments are described in separate sections. These instruments may usefully be grouped into:

(a) Ambient air quality

Legislation which aims at the establishment and maintenance of an air quality standard which does not adversely affect human health or the environment. This is partly achieved by setting limits on levels of specified pollutants in ambient air, together with requirements for monitoring and reporting on pollution levels. In line with the EU's on-going review and streamlining of EU legislation, the EU adopted Directive 2008/50/EC in 2008, which recast and consolidated most of the existing Directives on ambient air quality⁸⁴ into one piece of legislation, except for Directive 2004/107/EC, which remained intact. This Ambient Air Quality Directive (hereinafter referred to as the AQD) should, hence, be implemented together with Directive 2004/107/EC and Commission Implementing Decision 2011/850/EU on the reciprocal exchange of information and reporting on ambient air quality. In addition, this legal framework on air quality control also has strong links with the EU legislation on national emission ceilings.

(b) Automotive exhaust and type-approval

Concerns the type-approval of certain standard engines (Euro 5 and 6) and other control measures restricting the pollutants from the automotive sector. This bulk of legislation stemming back to the 70's include Directive 97/68/EC, Directive 2005/55/EC, Directive 2005/78/EC, Regulation (EC) No 715/2007. In addition, three new Regulations came into force in 2009 and 2011 (Regulation 595/2009, Regulation 582/2011 and Regulation 566/2011), respectively, which introduce Euro VI standard for heavy-duty vehicles. These Regulations phased out and subsequently repealed Directives 2005/55/EC and 2005/78/EC from 31 December 2013. The EU is currently focused on establishing an ambitious and robust real driving emissions (RDE) testing scheme. The RDE testing procedure is starting from 1 January 2017 and is phased-in through several stages. More information on RDE testing scheme is available at: <http://ec.europa.eu/environment/air/transport/road.htm> and https://ec.europa.eu/growth/sectors/automotive/legislation/motor-vehicles-trailers_nn

(c) Sulphur content of certain liquid fuels

Directive (EU) 2016/802 of the European Parliament and of the Council of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels concerns measures to reduce the emissions of sulphur dioxide resulting from the combustion of certain types of liquid fuels and to reduce the harmful effects of such emissions on man and the environment. However, it should be noted that most of the fuel quality acquis addressing mainly fuels for road transport is now dealt with in the separate Handbook on the Implementation of the EU Climate Acquis.

(d) Emission of Volatile Organic Compounds (VOCs)

The VOC control concerns two main areas:

⁸⁴ This decision repealed Commission Decision 2004/461/EC of 29 April 2004 laying down a questionnaire to be used for annual reporting on ambient air quality assessment under Council Directives 96/62/EC and 1999/30/EC and under Directive 2000/69/EC and 2002/3/EC of the European Parliament and of the Council and Commission Decision 2004/224/EC of 20 February laying down arrangements for the submission of information on plans or programmes required under Council Directive 96/62/EC in relation to limit values for certain pollutants in ambient air.

- Control of VOC in the production, storage or refilling of fuels regulated by Directive 94/63/EC of 20 December 1994 on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations, Directive 2009/126/EC on Stage II petrol vapour recovery during refuelling of motor vehicles at service stations (which was adopted to extend and complement the scope of Directive 94/63/EC)
- Control of VOC emissions in the use of solvents in certain industrial activities and in varnish and paints. The legal measures concerned are Directive 2010/75/EU and Directive 2004/42/CE. However, these two Directives will be dealt with under the chapter on industrial pollution control. .

(e) Long-Range Air Transboundary Air Pollution

Council Decision 86/277/EEC on the conclusion of the protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on the long-term financing of the co-operative programme for the monitoring and evaluation of the long-range transmission of air pollutants in Europe (EMEP).

Council Decision 2003/507/EC of 13 June 2003 on the accession of the European Community, to the Protocol to the 1979 Convention on Long- Range Transboundary Air Pollution to Abate Acidification, Eutrophication and Ground-Level.

The LRTAP Convention provides for extensive provisions for monitoring of air quality, emissions and policy implementation. To date, the Convention has been extended by eight Protocols, including the 1999 Protocol to Abate Acidification, Eutrophication and Ground-level Ozone (the Gothenburg Protocol). The CLRTAP and in particular the Gothenburg Protocol has been instrumental in the policy development of effective air pollution strategies across Europe.

The Gothenburg Protocol promotes a multi-pollutant approach to prevent or minimize exceedances of critical loads of acidification and nutrient nitrogen and critical levels of ozone for human health and vegetation. To that effect, it sets national emission ceilings for each Party to be met by 2010 and thereafter for the following four air pollutants: sulphur oxides (mainly sulphur dioxide, SO₂), nitrogen oxides (NO_x), ammonia (NH₃) and volatile organic compounds other than methane (VOC). To support the achievement of the national emission ceilings, the Annexes of the Protocol establish emission limit values to control emissions of air pollutants generated at source from relevant categories of stationary and mobile sources. Within the EU the Gothenburg Protocol is implemented through the National Emission Ceilings Directive 2001/81/EC.

The Protocol was successfully amended in 2012 to strengthen the existing reductions commitments for SO₂, NO_x, NH₃ and VOC and introduce new reduction commitments for PM_{2.5}, to be attained from 2020 onwards. The amendment also updated the minimum performance standards for industrial emissions, which are now broadly in line with existing EU legislation. It is also the first Multilateral Environment Agreement to include binding obligations to monitor and abate short-lived climate pollutants, such as black carbon.

Ambient air quality assessment and management:

- Directive 2008/50/EC on ambient air quality and cleaner air for Europe, as amended by Commission Directive (EU) 2015/1480 of 28 August 2015 amending several annexes to Directives 2004/107/EC and 2008/50/EC.
- Directive 2004/107/EC relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air, as amended by Commission Directive (EU) 2015/1480.
- Council Directive 2001/81/EC on national emission ceilings for certain atmospheric pollutants, as amended by Council Directive 2006/105/EC and 2013/17/EU.
- 2011/850/EU: Commission Implementing Decision laying down rules for Directives 2004/107/EC and 2008/50/EC of the European Parliament and of the Council as regards the reciprocal exchange of information and reporting on ambient air quality.

Quality of Fuels:

- Directive (EU) 2016/802 of the European Parliament and of the Council of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels (*Note that most of the Fuel Quality acquis is now dealt with in the separate Handbook on the Implementation of the EU Climate Acquis*).

Automotive exhaust and type-approval:

- Directive 97/68/EC relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, as amended by Commission Directives 2001/63/EC, 2010/26/EU, 2012/46/EU, Council Directive 2006/105/EC, Directives of the European Parliament and of the Council 2002/88/EC, 2004/26/EC, 2011/88/EU and Regulation (EC) 596/2009.
- Regulation (EC) No 595/2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC, amended by Regulations (EU) 582/2011 and (EU) 133/2014.
- Regulation 566/2011 amending Regulation 715/2007 and Regulation 692/2008 as regards access to vehicle repair and maintenance information.
- Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type-approval of vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information, amended by Commission Regulations (EC) 692/2008, (EU) 566/2011, (EU) 459/2012 and Regulation (EC) 595/2009.

Emission of VOCs:

- European Parliament and Council Directive 94/63/EC on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations, amended by Regulations (EC) 1882/2003 and (EC) 1137/2008.
- European Parliament and Council Directive 2009/126/EC of 21 October 2009 on Stage II petrol vapour recovery during refuelling of motor vehicles at service stations, amended by Commission Directive 2014/99/EU.

Long-range transboundary air pollution:

- Council Decision 86/277/EEC on the conclusion of the protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on the long-term financing of the co-operative programme for the monitoring and evaluation of the long-range transmission of air pollutants in Europe (EMEP).
- Council Decision 2003/507/EC of 13 June 2003 on the accession of the European Community, to the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution to Abate Acidification, Eutrophication and Ground-Level.

1.4. Summary of Air Quality Legislative Framework

1.4.1. Ambient Air Quality Directive 2008/50/EC and Heavy Metals Directive 2004/107/EC

In 2008, Directive 2008/50/EC on ambient air quality and better air for Europe (referred to as the AQD) was adopted to modernise, consolidate and streamline the former Framework Directive on Air (96/62/EC) and three of its four daughter Directives. The AQD, however, did not introduce major changes to the air quality values and the other substantial requirements on assessment, plans, monitoring and reporting. In brief, the AQD:

- Merged the former daughter Directives into a single Directive (except for the fourth daughter Directive) but with no changes to the air quality objectives.
- Sets out new air quality objectives for PM_{2.5} (fine particles), including the limit value and exposure-related objectives — exposure concentration obligation and exposure reduction target.
- Allowed for the possibility to discount natural sources of pollution when assessing compliance against limit values.

The remaining part of the core legislation on air quality objectives and limit values consists of the Heavy Metals Directive (2004/107/EC): This is the fourth „daughter Directive” regulating heavy metals; e.g. mercury (Hg), cadmium (Cd), arsenic (As), nickel (Ni) and polycyclic aromatic hydrocarbons (PAH). (In terms of future implementation of this Directive, it should be noted that the 1998 Heavy Metals Protocol to the Convention on Long-Range Transboundary Air Pollution could provide some guidance as to implementation.)

On 18 September 2015 Commission Directive (EU) 2015/1480 entered into force, laying down the rules concerning reference methods, data validation and location of sampling points for the assessment of ambient

air quality. Member States need to align the national provisions with the requirements of this Directive by 31 December 2016 at the latest.

The applicable standards and objectives set out in these Directives are summarised in the table 1 below. These apply over differing periods of time because the observed health impacts associated with the various pollutants occur over different exposure times.

Table 1.

Pollutant	Concentration	Averaging period	Legal nature	Permitted exceedences each year
Fine particles (PM2.5)	25 µg/m ³	1 year	Target value entered into force 1.1.2010 Limit value enters into force 1.1.2015	n/a
Sulphur dioxide (SO ₂)	350 µg/m ³	1 hour	Limit value entered into force 1.1.2005	24
	125 µg/m ³	24 hours	Limit value entered into force 1.1.2005	3
Nitrogen dioxide (NO ₂)	200 µg/m ³	1 hour	Limit value entered into force 1.1.2010	18
	40 µg/m ³	1 year	Limit value entered into force 1.1.2010*	n/a
PM10	50 µg/m ³	24 hours	Limit value entered into force 1.1.2005**	35
	40 µg/m ³	1 year	Limit value entered into force 1.1.2005**	n/a
Lead (Pb)	0.5 µg/m ³	1 year	Limit value entered into force 1.1.2005 (or 1.1.2010 in the immediate vicinity of specific, notified industrial sources; and a 1.0 µg/m ³ limit value applied from 1.1.2005 to 31.12.2009)	n/a
Carbon monoxide (CO)	10 mg/m ³	Maximum daily 8 hour mean	Limit value entered into force 1.1.2005	n/a
Benzene	5 µg/m ³	1 year	Limit value entered into force 1.1.2010**	n/a
Ozone	120 µg/m ³	Maximum daily 8 hour mean	Target value entered into force 1.1.2010	25 days averaged over 3 years
Arsenic (As)	6 ng/m ³	1 year	Target value entered into force 31.12.2012	n/a
Cadmium (Cd)	5 ng/m ³	1 year	Target value entered into force 31.12.2012	n/a
Nickel (Ni)	20 ng/m ³	1 year	Target value entered into force 31.12.2012	n/a
Polycyclic Aromatic Hydrocarbons	1 ng/m ³ (expressed as concentration of Benzo(a)pyrene)	1 year	Target value entered into force 31.12.2012	n/a

Title	Metric	Averaging period	Legal nature	Permitted exceedences each year
PM2.5 Exposure concentration obligation	20 µg/m ³ (AEI) ⁸⁵	Based on 3 year average	Legally binding in 2015 (years 2013,2014,2015)	n/a
PM2.5 Exposure reduction target	Percentage reduction* + all measures to reach 18 µg/m ³ (AEI)	Based on 3 year average	Reduction to be attained where possible in 2020, determined on the basis of the value of exposure indicator in 2010	n/a

Source: DG ENV: <http://ec.europa.eu/environment/air/quality/standards.htm>

1.4.2. The National Emission Ceilings Directive (2001/81/EC)

The National Emissions Ceilings Directive (2001/81/EC, as amended by Council Directive 2006/105/EC and 2013/17/EU hereinafter referred to as the NEC Directive) establishes national emissions ceilings for sulphur dioxide (SO₂), nitrogen oxides (NO_x), volatile organic compounds (VOC) and ammonia (NH₃) with a view to improving the protection of the environment and human health against adverse effects from acidification, soil eutrophication and ground-level ozone. Member States have to achieve their national ceilings by 2010 at the latest, and thereafter continuously stay below them.

Annex I of the NEC Directive, as amended, lists emissions ceilings for each of the current 28 Member States. Member States are competent for determining the cost-effective means by which to comply with the ceilings laid down in the Directive.

The NEC Directive is the main instrument at EU level to transpose the 1999 Gothenburg Protocol to the Convention on Long-Range Transboundary Air Pollution.

Following the 2012 amendment of the Gothenburg Protocol and as part of the review of the EU air quality policy, Directive 2001/81/EC is being subject to a revision. The amended NEC Directive will set revised emission ceilings to be met by 2020 and beyond for SO₂, NO_x, VOC and NH₃, as well as a new ceiling for the primary emissions of PM_{2.5} and methane CH₄.

1.4.3. Directive on Sulphur Content in Certain Liquid Fuels (EU) 2016/802

In May 2016 Directive (EU) 2016/802 of the European Parliament and of the Council of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels has been adopted. The Directive (EU) 2016/802 is

⁸⁵ Depending on the value of AEI in 2010, a percentage reduction requirement (0, 10, 15, or 20%) is set in the Directive. If AEI in 2010 is assessed to be over 22 µg/m³, all appropriate measures need to be taken to achieve 18 µg/m³ by 2020

a codification of Council Directive 1999/32/EC, which has been substantially amended several times. The Council Directive 1999/32/EC is repealed with the effect from 9 June 2016.

The Directive (EU) 2016/802 on reduction of sulphur content of certain liquid fuels aims to reduce the emissions of sulphur dioxide resulting from the combustion of certain types of liquid fuels and thereby to reduce the harmful effects of such emissions on human health and the environment. The reductions of sulphur dioxide emissions under the scope of the Directive shall be achieved by imposing limits on the sulphur content of certain liquid fuels as a condition for their use within the territory of the Member States.

1.4.4. Directive on Petrol Vapour Recovery from Storage and Distribution – Stage I (94/63/EC)

Directive 1994/63/EC aims to prevent emissions to the atmosphere of volatile organic compounds (VOCs) during the storage of petrol at terminals and its subsequent distribution to service stations. The Directive contains measures that terminals should employ such as floating roofs and reflective coatings so as to reduce evaporative losses from storage tanks. In addition, when petrol is loaded into tankers and transported to service stations the Directive requires that any vapours are recovered and returned to the tanker or terminal.⁸⁶

1.4.5. Directive on Petrol Vapour Recovery from Refuelling at Service Stations - Stage II (2009/126/EC)

Directive 2009/126/EC aims to recover petrol vapour that would otherwise be emitted to the air during the refuelling of vehicles at service stations. The Directive requires Stage II petrol vapour recovery (PVR) technologies to be fitted to petrol pumps at all service stations with an annual petrol throughput greater than 500 cubic metres per year when they are newly constructed or substantially refurbished. All service stations situated under residential accommodation also need to install this equipment when the annual petrol throughput is greater than 100 cubic metres per year. The largest existing stations, with a throughput greater than 3000 cubic metres per year, have to implement Stage II PVR by 2020 at the latest. Stage II PVR equipment is already installed in petrol stations.⁸⁷

1.4.6. Directive on Pollutants from Non-road Mobile Machinery (97/68/EC)

Since 1997 EU legislation has required new diesel engines to meet certain environmental standards for air pollutants before they are placed on the market. Engines in non-road mobile machinery contribute to emissions of air pollutants. Diesel engines in excavators, bulldozers, front loaders, back loaders, compressors etc. emit nitrogen oxides (NOx) and particulate matter. Emissions from these engines are regulated before they are placed on the market by Directive 97/68/EC on the approximation of the laws of the Member States relating

⁸⁶ More information can be obtained at DG ENV: <http://ec.europa.eu/environment/air/transport/petrol.htm>

⁸⁷ More information can be obtained at DG ENV: <http://ec.europa.eu/environment/air/transport/petrol.htm>

to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery.

1.4.7. Regulation 595/2009 on Type-approval for Heavy Duty Vehicles

This pieces of legislation concern the type-approval of certain standard engines (Euro 5 and 6) and other control measures restricting the pollutants from the automotive sector.

Regulation 595/2009 was adopted in June 2009 and repealed Directives 2005/55/EC and 2005/78 as of 31 December 2013. It introduces the new norm called Euro VI, aimed at reducing emissions of nitrogen oxides and particulate matters from trucks and buses as of January 2013.

Regulation 595/2009 is implemented through two further acts:

- Regulation 582/2011 ("the first comitology package") implementing and amending Regulation 595/2009 and amending Annexes I and III to Directive 2007/46/EC, establishes the detailed technical aspects needed for certification, like the requirements for the conduction of the tests to be performed at type-approval and during in service conformity,
- Regulation (EU) No 64/2012 ("the second comitology package") amends Regulation 582/2011 in the field of vehicles repair, PEMS systems and type approval.

In parallel, a series of amendments to UNECE Regulation 49, carrying over the European Euro VI legislation into the UNECE acquis, has been approved in the January 2012 session of the Working Party on Pollution and Energy (GRPE). This will allow, in the near future, to accept type-approval certificates awarded according to UNECE Regulation 49, as equivalent to certificates based on the European legislation.

1.4.8. Regulation (EC) No 715/2007 on Type-approval of Light Duty Vehicles

New emission limits (Euro 5 and Euro 6) have been introduced for cars and light commercial vehicles with respect to a number of pollutants, especially nitrogen oxides (NO_x) and particulate matter.

The new standard known as Euro 5 applies as of 1 September 2009 for the approval of new vehicles and as of 1 January 2011 for the registration and sale of all types of cars and vans in the EU market. In practice, this makes the introduction of particle filters for diesel cars obligatory. The main effect of Euro 5 is to reduce the emission of particulate matter from diesel cars from 25mg/km to 5mg/km.

Euro 6 will set even lower emission limits. It will be binding for the type approval of vehicles as of 1 September 2014 and for the registration and sale of new types of cars and vans as of 1 September 2015. Euro 6 will mainly reduce the emissions of NO_x from diesel cars further, from 180mg/km to 80mg/km⁸⁸. Regulation 566/2011 amends Regulation 715/2007 and Regulation 692/2008 as regards to vehicle repair, on board diagnosis systems, particulate matter test procedures and reference fuels.

⁸⁸ More information available at: http://ec.europa.eu/growth/sectors/automotive/environment-protection/index_en.htm

Commission Regulation (EU) No 459/2012 amends the Euro 6 legislation and sets threshold limits for on board diagnostic systems. It also sets temporary limits for Particle Numbers emitted by direct injection gasoline engines.

1.4.9. Decision 86/277/EEC on Monitoring and Evaluation of the Long-Range Transmission of Air Pollutants in Europe (EMEP)

The Decision approves, on behalf of the EU, the EMEP Protocol, adopted under the 1979 Convention on Long-Range Transboundary Air Pollution. The Protocol lays down the long-term financing arrangements for the co-operative programme for monitoring and evaluation of the long-range transmission of air pollutants in Europe (EMEP). The Decision commits the EU to paying its share of the costs of EMEP, which are allocated to the Member States in accordance with an agreed formula.

1.4.10. Decision 2003/507/EC on the Accession of the European Community, to the Protocol to the 1979 Convention on Long- Range Transboundary Air Pollution to Abate Acidification, Eutrophication and Ground-Level

The Decision approves, on behalf of the EU, the Gothenburg Protocol adopted under the 1979 Convention on Long-Range Transboundary Air Pollution. The Protocol sets national emission ceilings for 2010 up to 2020 for four pollutants: sulphur dioxide (SO₂), nitrogen oxides (NO_x), volatile organic compounds (VOCs) and ammonia (NH₃). It also sets tight limit values for specific emission sources (e.g. combustion plant, electricity production, dry cleaning, cars and lorries) and requires best available techniques to be used to keep emissions down. VOCs emissions from such products as paints or aerosols also have to be cut. Finally, farmers have to take specific measures to control ammonia emissions. Guidance documents⁸⁹ adopted together with the Protocol provide a wide range of abatement techniques and economic instruments for the reduction of emissions in the relevant sectors, including transport.

1.5. Implementation of ambient air quality legislation

There are ample benefits of aiming at a holistic integrated policy and legislative framework covering the AQD, the Heavy Metals Directive and the NEC Directive. Such an approach will be cost-effective, provides a clearer and more transparent framework for the affected parties, the competent authorities and the public. Hence, an integrated, consolidated framework is desired.

The legislation dealing with air quality standards and monitoring sets the framework for identifying and prioritising air quality planning needs, whilst the legislation dealing with the control of vehicle and petrol

⁸⁹ <http://www.unece.org/environmental-policy/conventions/air/guidance-documents-and-other-methodological-materials/gothenburg-protocol.html>

emissions and fuel content lays down more regulatory controls (such as prohibitions on the use of certain types of fuels).

Implementation phase can be categorised by four different phases, which mainly pertain to AQD and Directive 2004/107/EC:

- Zoning;
- Assessment;
- Management;
- Reporting.

1.5.1. Zoning

The EU air quality legislation requires the Member States to report on zones designated under the AQD. Information on zoning and the concentrations in the zones in comparison to air quality objectives is provided through an annual assessment report. New reporting of zones was developed under the new Directive to be able to aggregate and use zoning information by GIS system.

1.5.2. Assessment

1) Understanding the relevant pollutants and their impact

It is essential for an accurate assessment to understand the impact of individual pollutants, their sources and evolution of concentrations. Such understanding helps develop air quality policy and decided on effective abatement. The Commission has produced a number of so-called position papers which are linked to the former 1st (1990/30/EC), 2nd (2000/69/EC) and 3rd (2002/3/EC) daughter Directives as well as the current 4th daughter Directive (2007/107/EC). These position papers are obtained at: <http://ec.europa.eu/environment/air/quality/legislation/assessment.htm>. Note though, that this website is currently being updated with new information and guidance being published.

2) Selecting the monitoring sites

One of the first measures to take, where monitoring is being used for the assessment, is to select the site of the monitoring station. The siting affects the ability to use the monitoring information to assess compliance in the specific area as well as to obtain further information as regards exposure and source apportionment. The AQD provides detailed rules on the location and number of monitoring stations to be placed in each zone. For more information on this Member States should consult [Commission Staff Working Paper establishing guidelines for the agreements on setting up common measuring stations for PM2.5 under Directive 2008/50/EC](#)⁹⁰.

For more guidance on selecting monitoring sites, candidate countries may consult a study that was conducted for the Commission by the UBA that would facilitate more harmonized approach to monitoring stations. The

⁹⁰ Available from DG ENV at: http://ec.europa.eu/environment/air/quality/legislation/pdf/sec_2011_77.pdf

interim report of this study is available at:
http://ec.europa.eu/environment/air/quality/legislation/pdf/report_uba.pdf

3) Taking into account natural sources and sanding and salting of roads

The AQD provides new possibilities to take into account natural sources and effects of winter sanding and salting of roads in the assessment of emissions of certain limit values and PM10.

- Member States may choose to subtract the contribution of natural sources under certain conditions before comparing the ambient air pollutant concentrations to the limit values. For more information on this possibility Member States could consult: [Commission Staff Working Paper establishing guidelines for demonstration and subtraction of exceedances attributable to natural sources under the Air Quality Directive](#)⁹¹
- Member States may indicate that, for designated zones or agglomerations within which limit values for PM10 are exceeded in ambient air, such exceedance is due to the re-suspension of particulates following winter sanding or salting of roads. The Commission adopted a [Staff Working Paper establishing guidelines for determination of contributions from the re-suspension of particulates following winter sanding or salting of roads under the Directive](#)⁹²

4) Prescribing measurement methods

- Reference measurement methods

For each regulated pollutant a reference measurement method has been prescribed. At the time of the adoption of the Directives standardised methods had not been developed for all pollutants.

Provisions of the Directive (EU) 2015/1480 have updated the reference measurements methods for pollutants covered by the AQD (Annex VI) and the 4th Daughter Directive (Annex V).

The most up-to-date list of reference measurement methods are available at:
<http://ec.europa.eu/environment/air/quality/legislation/assessment.htm> as well as through CEN or the national standardisation organisation (<http://www.cen.eu/cenorm/members/members/index.asp>).

4. SO₂: EN 14212:2012
5. NO₂ and NO_x: EN 14211:2012
6. Pb, Cd, As, Ni: EN 14902:2005
7. PM₁₀: EN 12341:2014
8. PM_{2,5}: EN 12341:2014
9. Benzene: EN 14662:2005
10. CO: EN 14626:2012
11. O₃: EN 14625:2012

⁹¹ Available from DG ENV at: http://ec.europa.eu/environment/air/quality/legislation/pdf/sec_2011_0208.pdf

⁹² W. Spangl, J. Schneider, L. Moosmann and C. Nagl, (UBA), Draft Final Report - Representativeness and classification of air quality monitoring stations, 2007, provides further guidance in taking a harmonized approach to monitoring stations. This study is available at: http://ec.europa.eu/environment/air/quality/legislation/pdf/report_uba.pdf

The Commission has entrusted ESOs with the following work: establishing of three European standards for 1) automated measuring systems for particulate matter (PM10 and PM2.5), 2) determination of elemental carbon and organic carbon in PM2.5 and 3) the determination of anions and cations in PM2.5 .

<https://law.resource.org/pub/eu/mandates/m503.pdf>

- Non-reference measurement methods

Non-reference measurement methods can also be used provided they respect provisions for equivalence set out in the Directives (see for example 2008/50/EC, Annex VI). A Commission Working Group on Equivalence has prepared a document describing principles and methodologies to be used for the demonstration of the equivalence of alternative (non-reference) measurement methods to the reference methods described by the EN Standard methods. A guidance document on equivalence methods and a tool to facilitate the use of the guidance were prepared in 2010 ([Guidance for the Demonstration of Equivalence of Ambient Air Monitoring Methods](#))⁹³. A tool to facilitate the use of the guidance (in particular for checking the equivalence of non-reference methods for PM-monitoring) is available in excel format: [Test the equivalence](#).

- Modelling

Modelling is an assessment tool which provides supplemental information and to air quality monitoring as regards public exposure, supports identification of sources and future projections based on different measures scenarios. Use of modelling has also been developed under specific initiatives such as HARMO (Harmonisation within Atmospheric Dispersion Modelling for Regulatory Purposes)⁹⁴. The 15th International Conference on Harmonisation within Atmospheric Dispersion Modelling for Regulatory Purposes, took place in Madrid, in May 2013⁹⁵. Under the 6th Research Framework programme an Air4EU project has been concluded which facilitates combined use of monitoring and modelling for the air quality assessment through the developed guidance and IT tools.

A Forum for AIR quality MODElling (FAIRMODE)⁹⁶ of modellers and users has been established to support the widespread and harmonised use of models through model validation and intercomparison exercises and through the management of the modelling network.

- Objective estimation

Objective estimation is reserved for the air quality zones with very good air quality and no large conurbations. It is usually combined with modelling. By identification of local pollution sources and information of regional air quality an estimation of concentration of a regulated pollutant is made.

5) Ensuring quality of assessment information

It is crucial to be able to verify the quality of assessment of information, whether generated through monitoring, modelling or objective estimation. The EU Air Quality Directive prescribes data quality objectives defining maximum allowed uncertainty, time coverage and data coverage and introduced some streamlining and further quality requirements and assessment requirements for fine particulate matter PM2.5.

The quality assessment is carried out by the Member States together with the Commission and the Joint Research Centre. The main task of the Member States is to ensure appropriate quality assurance of the assessment as well as the appropriate quality control of the information provided to the public and the issuing

⁹³ Guidance for the Demonstration of Equivalence of Ambient Air Monitoring Methods from January 2010. The guidance and the tool kit are available at: <http://ec.europa.eu/environment/air/quality/legislation/assessment.htm>

⁹⁴ More information on the HARMO Initiative is available at: <http://www.harmo.org/>

⁹⁵ More information on this conference at: <http://titanio.lma.fi.upm.es/harmo15/node/14>

⁹⁶ FAIRMODE webpage contains links to current activities: <http://fairmode.ev.eea.europa.eu/>.

of the assessment reports. The Commission established an EU-wide quality assessment process, which is managed by the JRC. For instance, JRC organises intercomparison exercises for the national reference laboratories and manages [AQUILA](#)⁹⁷ – the network of national reference laboratories which follows the implementation of assessment by monitoring, serves as exchange forum and provides expert advice to the Commission. More information on the roles and responsibilities of the national reference laboratories and the network itself, the quality assurance procedures and comparative studies can be obtained at: <http://ec.europa.eu/environment/air/quality/legislation/pdf/aquila.pdf>

Further information, including best practices, can be obtained through the European Environment Agency and its Topic Centre.

1.5.3. Management

Structural Plans and Programmes

Member States need to ensure that limit values are complied with throughout the territory by their respective attainment dates, and that target values are respected to the extent possible. Action is required before the attainment dates when certain assessment thresholds set in the Directives are exceeded, generating a requirement to prepare and implement air quality plans or programmes. Minimum requirements of such plans are given in the Air Quality Directive. The plan or programme needs to be available to the public and reported to the Commission within 2 years after the exceedance has been observed. A number of guidance documents and standards have been produced:

- [Guidance on drafting plans and programmes](#)⁹⁸
- [Report assessment of Plans and Programmes reported under 1996/62/EC](#)⁹⁹
- [Overview of reports on plans or programmes for reducing air pollution submitted under Decision 2004/224/EC](#)¹⁰⁰
- [Particle reduction plans in Europe](#)¹⁰¹
- [The impact of changes in vehicle fleet and treatment technology on the attainment of the ambient air quality limit value for nitrogen dioxide in 2010](#)¹⁰²
- [Air quality and ancillary benefits of climate change policies](#)¹⁰³

Short term Plans and Programmes

Upon the attainment date, Member States have to draw up action plans indicating the measures that they will take in the short term where there is a risk of the limit values and/or alert thresholds being exceeded, in order to reduce that risk and to limit the duration of such an occurrence. A guidance document from 2003 provides

⁹⁷ More information on AQUILA at: <http://ies.jrc.ec.europa.eu/aquila-homepage.html>

⁹⁸ http://ec.europa.eu/environment/air/quality/legislation/pdf/recommendation_plans.pdf

⁹⁹ http://ec.europa.eu/environment/air/quality/legislation/pdf/assessment_report.pdf

¹⁰⁰ http://ec.europa.eu/environment/air/quality/legislation/pdf/report_plans_tno_2007.pdf

¹⁰¹ http://ec.europa.eu/environment/air/quality/legislation/pdf/eeb_report.pdf

¹⁰² http://ec.europa.eu/environment/air/quality/legislation/pdf/eeb_report.pdf

¹⁰³ http://ec.europa.eu/environment/air/quality/legislation/pdf/eea_report.pdf

advice on the preparing of action plans to reduce the duration of exceedances of alert thresholds (Art 7(3), 96/62/EC)¹⁰⁴.

Also available is the Report for the Commission on the Best practices for Short term action plans¹⁰⁵ prepared in 2011 by AEA Technology plc and Umweltbundesamt GmbH.

1.5.4. Reporting

Commission Implementing Decision 2011/850/EU of 12 December 2011 lays down rules for Directives 2004/107/EC and 2008/50/EC of the European Parliament and of the Council as regards the reciprocal exchange of information and reporting on ambient air quality. Directive 2008/50/EC introduces new reporting provisions which take into account the previous implementation experience, IT development and legislative frameworks such as INSPIRE. As the Directive also embeds the Council Decision 97/101/EC on Exchange of Information (EoI), it includes both mandatory and voluntary information streams on ambient air quality assessment and management. This Decision applies as from 1 January 2014.

The Commission with the extensive support of the Member States and European Environment Agency has prepared a guidance (IPR guidance part I¹⁰⁶ and IPR guidance part II¹⁰⁷) to facilitate the implementation of the Decision 2011/850/EC.

More details about the new mechanism of reporting can be found at the Ambient Air Quality Portal (<http://www.eionet.europa.eu/aqportal>) managed by the European Environment Agency with the support of the ETC/ACM and the IPR pilot group.

1.5.5. Time extensions

The Air Quality Directive (2008/50/EC) introduced certain flexibility for achieving compliance with the limit values for particulate matter (PM10), nitrogen dioxide and benzene. Member States having particular difficulties in meeting these values had the possibility to notify the Commission and ask for postponing the attainment deadline for the limit values for nitrogen dioxide and benzene, or for being exempt from the limit values for PM10. For PM10, the exemption from the limit value ended in June 2011, whereas for nitrogen dioxide and benzene ended in January 2015.

¹⁰⁴ http://ec.europa.eu/environment/archives/cafe/pdf/working_groups/action_plans_necessity.pdf

¹⁰⁵ http://ec.europa.eu/environment/air/quality/legislation/pdf/SC5_Task%201_report.pdf

¹⁰⁶ http://ec.europa.eu/environment/air/quality/legislation/pdf/IPR_guidance1.pdf

¹⁰⁷ http://ec.europa.eu/environment/air/quality/legislation/pdf/IPR_guidance2.pdf

1.6. Links with other sectoral legislation

There are several other EU legal instruments covering other environmental sectors that must be taken into account when implementing legislation regulating air quality. The main legal instruments are set out in the Table below.

Table 2. Summary of key interrelationships between EU air acquis and other relevant EU legislation

Related Sector Legislation	Relevance
HORIZONTAL	
Environmental Impact Assessment Directive (2011/92/EU)	Requires an EIA for new projects that are judged to have a significant impact on the environment.
The Strategic Environmental Assessment Directive (2001/42/EC)	The SEA Directive lays down the procedure for undertaking an environmental assessment of plans and programmes that fall within its scope.
INSPIRE Directive (2007/2/EC)	The INSPIRE Directive requires that some spatial data, including meta-data and statistics regarding air pollution (e.g. from ambient air monitoring stations), are stored and made accessible in a certain way. The INSPIRE requirements are particularly reflected in Commission Implementing Decision of 12 December 2011 laying down rules for Directives 2004/107/EC and 2008/50/EC of the European Parliament and of the Council as regards the reciprocal exchange of information and reporting on ambient air quality.
The Regulation on the European Pollutant Release and Transfer Register (EC) No. 166/2006)	Requires operators to provide periodic information to the national competent authority about operational and accidental releases of certain pollutants to various environmental media including ambient air. Member States must collect information (data reported by the operators and information on releases from diffuse sources) at national level and report to the Commission within 15 months of the end of each reporting year.
The Directive on Environmental Liability (2004/35/EC)	Establishes strict or causal liability for certain damage caused to the environment, including damage arising from air pollution, particularly deriving from an IPPC permitted plant. Art. 5 calls for preventive action: Where environmental damage has not yet occurred but there is an imminent threat of such damage occurring, the operator shall, without delay, take the necessary preventive measures.
Environmental Crimes Directive (2008/99/EC)	Art. 3 stipulates that Member States shall ensure that the following conduct constitutes a criminal offence, when unlawful and committed intentionally or with at least serious negligence: (a) the discharge, emission or introduction of a quantity of materials or ionising radiation into air, which causes or is likely to cause death or serious injury to any person or substantial damage to the quality of air.
Access to Environmental Information (2003/4/EC)	Requires public authorities and installations emitting pollutants to keep certain information relating to the monitoring and emissions available to interested parties. This Directive gives the right of everyone to receive environmental information that is held by public authorities ("access to environmental information"). This can include information on the state of the environment, but also on policies or measures taken, or on the state of human health and safety where this can be affected by the state of the environment. Applicants are entitled to obtain this information within one month of

	the request and without having to say why they require it. In addition, public authorities are obliged, to actively disseminate environmental information in their possession
CLIMATE CHANGE	
Fuel Quality Legislation (Directive 98/70/EC and Directive 2009/30/EC)	The Directives on fuel quality will ensure better quality fuels, which in turn lead to less toxic emissions from vehicles and other mobile sources.
F-gases Regulations (No 517/2014, 303/2008, 304/2008, 305/2008, 306/2008, 307/2008 and No 308/2008 ¹⁰⁸)	These Regulations will reduce the emissions of fluorinated gases through precautionary and control measures and training and certification for technical staff dealing with f-gases and equipment containing these gases.
CO2 in cars Regulations (Regulation 443/2009, Regulation 63/2011, Regulation, No 725/2011 and Regulation 510/2011)	These Regulations aim at reducing overall CO2 emissions from light-duty vehicles by setting emission performance standards for new passenger cars and vans
WASTE MANAGEMENT	
Directive on Waste Management (2008/98/EC)	The waste management plans will have to be coordinated with the air strategies, plans and programmes to ensure synergies.
Waste Landfill Directive (1999/31/EC)	Controls the emissions of pollutants and gases (e.g. methane) from landfills, prescribing measures to reduce leakage during operation and after closure)
INDUSTRIAL POLLUTION CONTROL	
Directive on Industrial Emissions (2010/75/EU)	The Directive on industrial emissions 2010/75/EU (IED) IED combines a strengthened BAT-based approach with EU wide emission limit values for certain sectors (waste incineration and co-incineration, titanium-dioxide production, large combustion plants of rated thermal input of 50MW and more.)
SEVESO III Directive (2012/18/EU)	Aims to prevent major accidents at establishments involving dangerous substances and to limit their impacts on people and the environment. Such accidents often cause major air pollution.
CHEMICALS	
The Asbestos Directive (87/217/EEC)	Requires measures to prevent and reduce emissions of asbestos into the air.
REACH Regulation (EC) No 1907/2006	Sets out procedures and requirements aimed at safe control and use of substances and mixtures which in turn will control the emissions of these substances to ambient air.
Metallic Mercury Transport Ban and Safe Storage Regulation (EC) No 1102/2008	This is one of several measures at EU level to reduce the risk of exposure to mercury. This Regulation bans certain mercury transports and regulates storage so as to reduce, as far as possible to exposure to mercury, through air or other ways.
Persistent Organic Pollutant Regulation (EC) No 850/2004	The Regulation contains provisions regarding production, placing on the market and use of chemicals, management of stockpiles and wastes, and measures to reduce unintentional releases of POPs. Furthermore, Member States must set up emission inventories for unintentionally produced POPs, national implementation plans (NIPs) and monitoring and information exchange mechanisms.

¹⁰⁸ While the new Regulation repeals the original Regulation from 2006, implementing Regulations adopted under the original Regulation remain in force and continue to apply until new acts are adopted.

ENERGY LABELLING AND ECODESIGN	
<p>Eco design Directive (2009/125/EC) and Directive 2010/30/EU on energy labels as well as the implementing measures resulting from these Directives. (For a list of the implementing measures regarding Directive 2010/30/EU, setting out energy labelling requirements for a large range of household products, consult website: http://ec.europa.eu/energy/efficiency/labelling/doc/overview_legislation_energy_labelling_household_appliances.pdf)</p>	<p>The Eco design and Energy Labelling framework Directives and the implementing measures, especially the Regulations under the Eco design Directive will set product requirements for relevant environmental parameters, such as emissions in the case of central heaters, local room heaters and water heaters.</p>

2. DEVELOPMENT OF A SECTORAL STRATEGY AND IMPLEMENTATION PLAN

The implementation management checklist presented in Section 2.4 of the introductory section of the Handbook provides an overall framework for preparing a strategy to implement the legislation contained within this sector. The following text focuses on key issues pertinent to this sector, which are developed in the remainder of this section. Further guidance and examples of Member States' practices on implementation is provided in the fiches for individual legal instruments.

The air quality sector consists of a diverse body of legislative instruments, which form complementary strands within an overall framework.

The principal tasks are:

- Designating competent authorities at both national and regional/local levels and ensuring sufficient financial and human resources and coordination mechanisms between relevant ministries, authorities, laboratories, agencies etc.
- Planning the setting up of measurement stations, also identifying hot spot pollution areas.
- Introducing statutory ambient air quality standards and alert thresholds. Central government will need to set standards and incorporate them either in primary or secondary legislation. The various Directives on air quality standards allow Member States to set more stringent standards than those contained in the Directives. For example, in areas with ecologically sensitive sites, more stringent air quality standards may be required in order to protect such sites. Member States may also wish to set air quality standards for different averaging periods or for pollutants not covered by the Directives. There will, therefore, be a need for scientific advice on what standards should be set, based on knowledge of standards in other countries and health considerations, and what is technically realistic in relation to emission standards (as opposed to ambient air quality standards). Such advice may come from government institutes, scientific advisors or independent consultants.
- Establishing and co-ordinating an ambient air quality monitoring and assessment programme, taking into account the available measurement standards, modelling and Commission guidance and templates (see Section 4.2 below).
- Reporting annually to the Commission and the public on the results of ambient air quality and monitoring taking into account the common reporting templates also taking into account reporting and consultation obligations falling under other Directives (Industrial Emissions Directive (2010/75/EU), EIA Directive (2011/92/EU), SEA Directive (2001/42/EC), Public Participation Directive (2003/35/EC) and Access to Environmental Information (2003/4/EC). Also the INSPIRE Directive (2007/2/EC) is important to consult as it provides templates and methods for the collection of certain spatial data (see Section 5.4 below).
- Putting in place a system to ensure that the public is notified when alert thresholds are exceeded. Also the structural plans or programmes on air quality adopted in case of exceedance of assessment thresholds need to be available to the public and reported to the Commission within 2 years after the exceedance has been assessed.

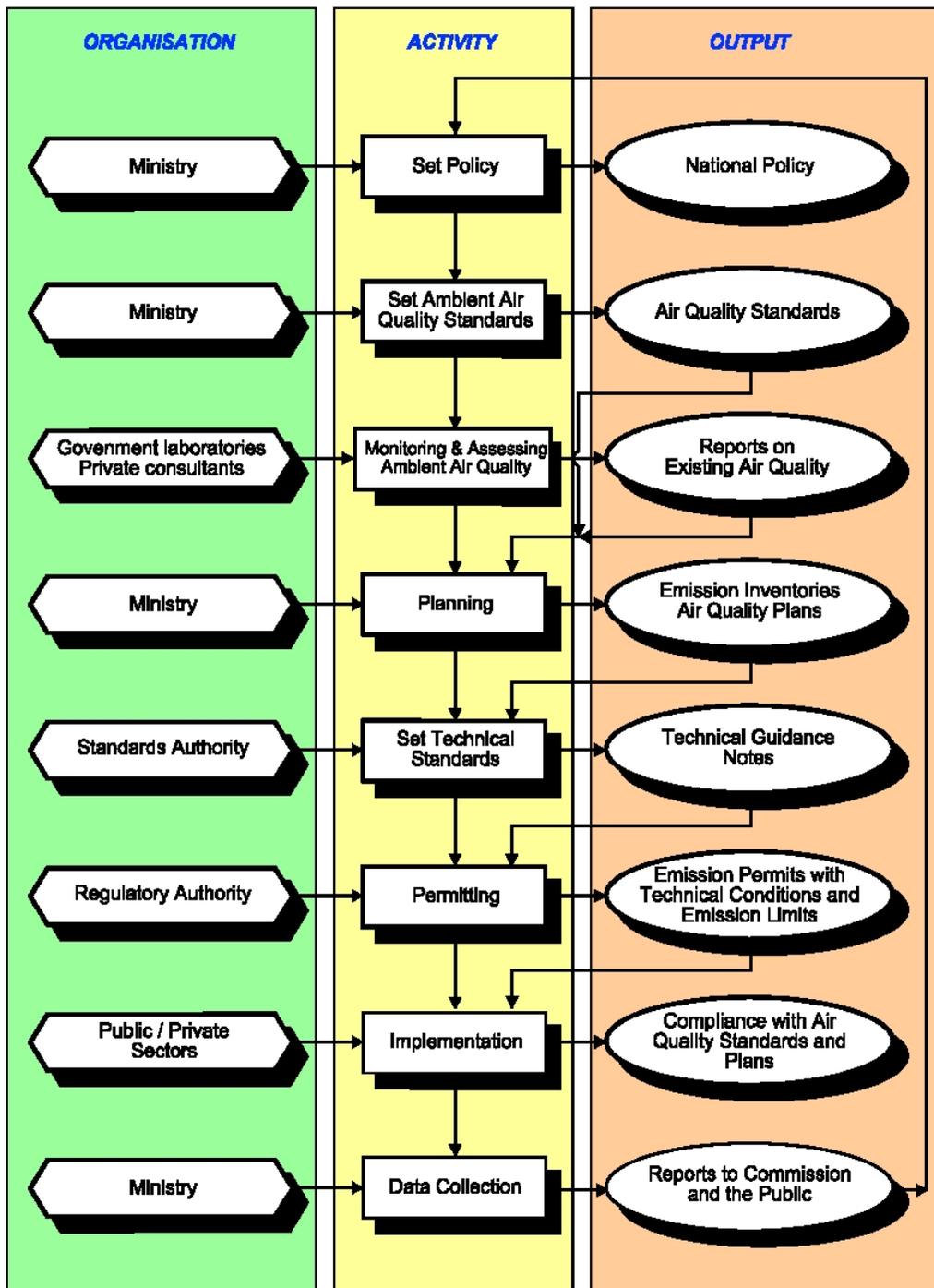
- Preparing the air quality plan or short-term action plans to improve air quality in areas where it does not meet the ambient air quality standards. This will be a task for central government in co-ordination with local authorities. Plans will need to focus on areas of poor air quality and will need to identify major emission sources, preferably by setting up an emissions inventory. Operators and suppliers of major emission sources (whether industry, household boilers or motor vehicles) and local authorities will need to be consulted, to determine technically and financially realistic approaches to reducing emissions to prescribed standards. There can be a certain amount of overlap between the measurements (and modelling) and the plans. Plans to deal with serious and obvious breaches of air quality limit values may be prepared even before all measurements have been completed, provided that it is certain that it will not be necessary to re-formulate any of the plans after more information has been obtained. This consideration applies mainly to significant local sources of air pollution.
- Implementing plans for improving air quality. The competent authority must maintain an overseeing role in relation to the results of air quality monitoring and modelling and the permitting process. Achieving compliance with air quality standards is likely to be brought about through the use of legislation, economic instruments, education and voluntary agreements. It will also require co-operation between the competent authorities and operators in the private sector. The competent authority will need to monitor the success of the various approaches, in order that they can be adjusted as and when necessary.
- Setting and implementing technical and emissions standards for different classes of emitters such as motor vehicles, industry, domestic boilers etc. (see Section 4.1 of the overview).
- Planning the measures needed to ensure compliance with the VOC legislation on the storage, transport and refill of petrol in service stations. This requires periodic monitoring and supervision as well as certain measures to verify compliance with technical and safety standards.
- Implementing Regulations on the composition of motor vehicle (engine standards and emission exhausts), non-road machinery and other fuels, which will involve technical measures and capital investments for laboratories or other facilities for testing and verification of vehicles and fuels.
- Undertaking permitting and enforcement of standards (see Sections 5.2 and 5.3 of the overview).
- Ensuring efficient supervision, monitoring and sanctioning in case of non-compliance
- Ratifying the 1979 Convention on Long-Range Transboundary Air Pollution (LRTAP) and the 1999 Gothenburg Protocol to LRTAP including recent 2012 amendment.

The government will also need to set overall policy within the context of the EU Directives, Regulations and Decisions — for example establishing the role that taxation or other fiscal measures will have in implementing air quality objectives. In addition, the instruments concerned with product control, materials handling and emissions standards for mobile sources will require action, including significant expenditure, by industry and the public to bring about compliance.

The strategy needs to carefully consider the relationship between ambient air quality criteria and emission limits from individual sources. There is likely to be a role for emissions inventories and dispersion modelling to establish the interrelationships and enable air pollution priorities to be identified. Modelling not only enables the contribution of different sources to existing air pollution levels to be quantified, it also allows an estimate to be made of the benefits of reducing specific emissions at source. A process flow chart identifying the sequence of activities and responsibilities involved in implementing the Directives in the air quality sector is

shown in Figure 1. Communications have not been shown, since they are involved with most, if not all, tasks. In practice, the roles of the standards authority and the regulatory authority are likely to be combined within an environmental protection agency, which will also be involved in planning and data collection. It is not possible to show all the organisational options in a single flow chart, and the actual model adopted will depend upon the existing institutional structures in place.

Figure 1: PROCESS FLOW CHART



3. INSTITUTIONS AND RELEVANT PARTIES

3.1. Stakeholders

A large number and great variety of stakeholders have an interest in, or may be affected by, air quality issues. The principal stakeholders and their roles in the process of developing and implementing a sectoral strategy to achieve compliance with EU policies and legislation on air quality are identified in Table 3 below.

3.2. National Government Institutions

National governments are ultimately responsible for achieving and maintaining compliance with EU policies and legislation on air quality issues. They have a duty and an obligation to secure compliance in a manner and within a programme either stipulated in the relevant EU instrument or agreed with the responsible EU institution.

A few candidate countries may choose to delegate a large part of the responsibility for achieving and maintaining compliance to a single national institution, e.g. a ministry, department or government agency with responsibility for the environment. This is often the case in smaller countries. The lead ministry should identify and appoint the competent authority (or authorities) required to take responsibility for functions and tasks prescribed in the legislation. The lead ministry must ensure that the competent authorities have the required legal powers, expertise and resources (financial, technical, administrative and logistical) to meet their obligations. Competent authorities are discussed further in Section 3.3 below.

Other ministries or departments in national government will inevitably need to be involved in some way at various stages in the planning and implementation process, depending on the Directive or Decision concerned, e.g. ministries with responsibilities for energy, transport, industry, agriculture, tourism, labour and finance.

The lead ministry (usually the ministry with responsibility for the environment) should identify which other ministries, national government agencies and bodies need to be involved and given competence in the process of planning and implementing EU air quality legislation. For example, the development of an air quality management strategy to carry out the tasks described in Section 2 is likely to require technical inputs from other government organisations such as local authorities, a national standards or accreditation institute, a national meteorological institute and existing public regulatory bodies. The role and input of each type of organisation to be involved must be carefully identified and agreed between the lead ministry and the organisation concerned.

The level of control and delegation ultimately depends on the political and administrative structure of a Member State, e.g. to what extent the administration is decentralised. The approach can, hence, vary a great deal between the EU Member States. The most essential, though, is that the approach allows for the effective and timely implementation of the EU provisions.

Table 3. Principal Stakeholders and Their Roles in the Air Quality Sector

Principal Stakeholders and Their Roles in the Air Quality Sector	
Stakeholders	Roles
Central government (e.g. a ministry or department)	<ul style="list-style-type: none"> • Implement and maintain compliance with EU policies and legislation on air quality; • Determine national policy on the environment, energy, transport etc.; • Transpose and implement legislation; • Set technical standards or in case of existing EN standards, ensure that they are fully reflected in national standardisation organisations; • Determine fiscal incentives or taxes; • Monitoring duties; • Coordination with other line ministries; • Coordination and consultation with ministries/authorities from neighbouring Member States (especially for hot spots transgressing national borders); • Set framework for public awareness campaigns and public consultation procedures; • Responsibilities for verifying certain technical standards (fuel, Euro 5 and 6 engines, VOC control technology); • Establish enforcement and ensure efficient, dissuasive and proportionate sanctions in case of non-compliance.
Environmental and other agencies working on behalf of central government; e.g. <ul style="list-style-type: none"> • Regulatory authority; • National standards body or accreditation laboratory; • Meteorological office; • Institute responsible for vehicle type-approvals; • Institute carrying out regular vehicle testing and roadside vehicle inspections; • Fuel testing agencies; • Occupational health and safety authorities; • Supervisory and monitoring agencies (e.g. EPA); • Statistical office. 	<ul style="list-style-type: none"> • Provide planning, Regulation and technical assistance; • Industrial pollution control; • Monitor weather, collect data on meteorological conditions and air quality, • Compile data inventories and collect air quality and pollution statistics, • Modelling; • Measurement and accreditation services; • Supervision of compliance with air quality standards and requirements in air quality acquis; • Regular inspections (also ad-hoc if need be);
Police and judiciary branch	<ul style="list-style-type: none"> • Investigate serious breaches of air quality provisions. • Ensure that non-compliance is subject to sanctions including criminal penalties at least for those environmental offences listed in the Environmental Crimes Directive (2008/99/EC).

Public utilities	<ul style="list-style-type: none"> • Use fuels; • Emit air pollutants.
Regional and local government	<ul style="list-style-type: none"> • Traffic management; • Regulation of emissions from small sources (including building codes); • Undertaking local air quality assessment including monitoring; • Possible delegated powers for inspection, supervision and monitoring; • Regional air quality planning, which should also reflect the regional waste management plans (in terms of combustion activities)
Industry, commercial organisations and trade associations involved in: <ul style="list-style-type: none"> • Metals and mining; • Chemicals; • Production/processing/distribution of fuels e.g. petroleum, fuels for power generation, industrial, transport (vehicular) and domestic use, including petrol and petrol additives (e.g. tetra-ethyl lead); • Power generation; • Products; e.g. domestic heating appliances, motor vehicles and pollution abatement technology, air quality monitoring stations; • Waste collection and disposal. 	<ul style="list-style-type: none"> • Significant emitters of air pollutants; • Provision of pollution control equipment; • Provision of air quality monitoring equipment, solutions and software; • Provision of waste management and disposal services; • Users of fuels; • Producers and suppliers of fuels and motor vehicles and non-road machinery.
Consultants	<ul style="list-style-type: none"> • Advise the private and public sector.
NGOs, media and trade unions	<ul style="list-style-type: none"> • Represent the public or workers' interest or specialists or experts in the field of air quality; • Public watchdog, detecting cases of non-compliance; • Provide guidance and important data for public authorities.
Public, including motorists and householders	<ul style="list-style-type: none"> • Significant emitters of air pollutants (heating fuels, fuels for motor vehicles and other non—road machinery); • Able to choose vehicles, fuels, heating systems and to purchase goods e.g. refrigerators.
Research institutions, academic and other	<ul style="list-style-type: none"> • Research on e.g. pollution abatement technology

3.3. Competent Authorities

Some of the required technical expertise may already exist in one or more agencies or authorities in the candidate country. However, in some areas the expertise or sufficient staff resources may not be readily available.

Existing public bodies that may have suitable characteristics include environmental protection agencies and local authorities. There may be a need to define working relationships between different bodies in order to fulfil legislative requirements or, alternatively, to bring together expertise presently existing in different bodies. New roles may be created for specialist staff, requiring training or recruitment.

Competent authorities can be appointed for one or more functions across several environmental sectors. For example, the drafting of legislation and Regulations may be undertaken, or at least co-ordinated, by a single body. Again in the area of Regulation, various Directives across the environmental sectors require the permitting of installations and their emissions to air. Therefore, consideration should be given to the interaction between the competent authorities appointed in the air quality sector, and those operating in other sectors, particularly waste, water and industrial pollution control. These functions would fall naturally to an integrated environmental protection agency. There may also be a role for local authorities in the management of air quality.

The closest form of integration for cross-sectoral competent authorities would be provided either by a single national body, or by regional bodies operating under the same management system. This type of structure would help to avoid duplication in many areas and provide economies of scale through shared facilities and resources. Alternatively, a sectoral approach could be adopted, but mechanisms would be required to ensure close co-operation and co-ordination between the different sectoral authorities. Most countries have found that integrated environmental protection agencies provide the most effective regulators of pollution sources.

Competent authorities with strategically important roles or requiring specialised technical expertise should be established at the national level in order to provide consistency of approach and make efficient use of scarce resources. Examples are functions for legal work (analysis and drafting), national planning, and setting technical standards. Where local experience or local accountability is important, competent authorities can be established at the regional or local level, for example in local planning, permitting and the inspection of facilities. In the air sector, integration of functions at local level between the environment agency and local authorities is an important consideration.

3.4. Regional and Local Government

The role of regional and local government in the context of air quality management is important for two reasons. Most countries have a tiered administrative structure in which certain powers are devolved to the regional (county, département, Länder) or local level of government (local planning authority or municipality). This decentralisation is stronger in federal countries but exists elsewhere and usually includes at least some air quality management functions, for example those relating to road traffic and domestic heating boilers. Consequently, the implementation of central government functions would not in itself be sufficient to implement EU requirements on air quality. Certainly, some air quality issues are most easily and efficiently detected and resolved at local level. The same goes for the efficient monitoring and supervision of polluting activities from fixed sources.

EU legislation does not stipulate the division of powers and responsibilities between national, regional and local administration. However, it is logical and practical for some functions (for example, drafting the air quality plans, drafting transposing legislation, setting technical standards, and introducing penalties for non-compliance) to be undertaken at national level, and others (for example, inspection of small air pollution sources, services verifying compliance with technical standards and monitoring of local air monitoring stations)

to be undertaken at local level. A range of tasks between these two extremes could be undertaken either nationally or locally, largely depending on whether the overall results are sufficient, cost-effective and meeting the overall air quality principles and objectives.

Where regional or local government takes on more than one role, there is a potential for conflicts of interest to arise. This could happen where local government has responsibility for certain air quality Regulation tasks and also for operating communal facilities such as district heating schemes or waste incineration facilities.

Some countries may have a large number of small municipalities with individual responsibility for managing air quality. These may be too small to achieve the high standards demanded by EU legislation, either because they do not have relevant specialist staff or technologies, or because they are mainly affected by air pollution from beyond their boundaries. In this case, inter-municipal co-operation can be very beneficial in achieving geographical groupings with enough mobile and stationary air quality sources to make co-operation cost effective.

If the regional approach is to be promoted, the existing policy, legal and administrative framework governing local government bodies needs to be reviewed to ensure that there is an adequate basis for inter-municipal co-operation. It is necessary to examine carefully the nature of any forms of voluntary agreements, joint ventures or associations between local government bodies to ensure that issues such as resource sharing and liability are addressed appropriately.

3.5. Private Sector Involvement

Private sector organisations may have a variety of interests in air quality management, for example:

- Actual and potential emitters of pollutants to air (the predominant case);
- Manufacturers of non-road machinery and road vehicles;
- Manufacturers and suppliers of fuels (fuel quality legislation, VOC from petrol stations);
- Manufacturers of and service providers related to air monitoring and measurement stations (units, systems, components);
- Service providers (also public service, e.g. schools, kindergartens, hospitals, recreational and sports facilities) requiring clean air to conduct their business;
- Innovators and developers of new products, prototypes, materials, models, monitoring and measurement methods, IT systems and technologies.

The private sector may be able to provide valuable finance and offer substantial improvements in efficiency in privatised industries and utilities which own or operate stationary or mobile sources (e.g. power stations, passenger or freight transport). Where, candidate countries choose to separate polluters from regulatory authorities, where both are publicly owned, with the objective to ensure effective regulation and enforcement in relation to polluting emissions, these privatisation efforts should be accompanied by an effective system of regulation (enforcement). Also, all polluting entities must be regulated under the same terms, regardless of their ownership and administration.

3.6. Communication and Consultation

Planning and implementation of air quality management legislation will require co-ordination between government, competent authorities, regional and local authorities, private entities (e.g. industry, electricity producers) and other relevant stakeholders. All these key players and stakeholders will be directly or indirectly involved in the implementation and application of the air quality acquis. Consequently, efficient and timely communications are important for effective implementation of the legislation.

During the development of an air quality strategy, a communication strategy/programme is recommended whereby the views and opinions of interested and affected parties are solicited by national government in order to assess the acceptability and practicability of all aspects of air quality legislation and the proposals for its implementation. Parties which should be consulted, at least initially, include all those listed as stakeholders. Nowadays, it is common practice in the EU for national governments to conduct a wide consultation on new standards or regulations. This provides the key actors and stakeholders, including industry, with an opportunity to inform government about the potential impact of the proposals on the viability of their business; to provide technical advice which may not be available to government, for example on the practicalities of procedures or techniques; and to start planning for the introduction of the new regime.

Once an air quality management strategy has been determined, clear lines of communication are needed among the competent authorities to support the roles and activities of the various public bodies and other actors involved.

Government will also need to continue a dialogue with interested parties such as industry, NGOs and the public, for example to update guidance notes on the control of emissions to air, encourage emitters to improve their performance, and disseminate information on existing, revised or new government air quality management policies and legislation.

In the longer term, achieving compliance with the EU's principles of air quality management, the air quality values and the requirements on fuel quality, type approvals for vehicles etc. may require changes in values and attitudes to the environment by different entities within government and by industry and consumers. A programme should be developed for education and raising awareness, suggesting measures that the general public can take and also environmental components of the school curricula. It is, further, recommended to promote the national air quality strategy in terms of its main objectives, expected results and short to medium term measures, particularly focusing on polluting entities and public authorities. In this information to polluters, it should also be made clear that non-compliance with air emission regulations, especially that resulting in environmental damage is considered a criminal offence under the Environmental Crimes Directive (2008/99/EC). NGOs and civil society groups can be expected to contribute positively to public debate on air quality and should be encouraged to do so. In the UK, for example, a leading specialist NGO, the National Society for Clean Air and Environmental Protection, maintains a website with support from the Environmental Action Fund of the Department of Environment, Transport and the Regions.

The EU and its Member States are parties to the Aarhus convention on access to information, public participation in decision-making and access to justice. Two pillars of the Convention related to the access to information and public participation have been implemented in the EU through the various directives. Thus, the AQD specifically calls for public access to information on ambient air quality.

Public consultation forms another element of communication. Several Directives specifically require Member States to consult and make information available to the public. Such requirements are found in the

Environmental Impact Assessment Directive (2011/92/EU), the Strategic Environmental Assessment Directive (2011/42/EC), the Access to Environmental Information (2003/4/EC) and the Public Participation Directive (2003/35/EC), which set out clear and transparent procedures and substantial requirements on how stakeholders and the public are to be consulted and how their opinions must be taken into account in final projects, plans, decisions etc.

4. TECHNICAL ISSUES

4.1. Adoption of Technical Standards

To ensure a uniform approach, national technical standards must be adopted, ranging from standards for certain products, techniques or reference measurement methods. These standards should comply with the requirements of EU legislation regulating emissions from motor vehicle fuels, engine standards (Euro 5 and 6) for light and heavy duty vehicles as well as ambient air emissions from industrial facilities and other activities (see the industrial pollution control section of the Handbook). Standards need to take account of Best Available Technology (BAT), but also to a certain extent significant economic constraints on the operators of emission sources, which may result in instead complying with BAT. In some cases, national authorities have discretion to determine the technical standards that are to be applied, provided that the standards adopted are at least as stringent as those contained in the Directives and that the intended result is achieved. In other cases (for example, the Directives relating to the composition of motor vehicle fuel), the Directives specify exact standards and there is no discretion for more stringent standards to be adopted, since variations between Member States would interfere with the functioning of the single market.

It has to be noted that for certain product groups harmonised EU emission requirements are established in Regulations under the Eco design Directive (2009/125/EC). These include central heaters, local room heaters, solid fuel boilers and water heaters. As these Regulations are addressing the internal market they will be accompanied by EU measurement methods developed by the European Standardisation Organisation CEN/CENELEC. Therefore for such products no national measurement method has to be developed, but each MS will have to perform market surveillance. Only in cases justified by a specific environmental situation Member States or regions might go beyond these product requirements, as stipulated in the Lisbon Treaty.

Other important technical requirements important in overall air quality assessment policy and legislation stem from the Eco design requirements, e.g. from the Eco design Directive (2009/125/EC) but also Directive 2010/30/EU on energy labels as well as the implementing measures resulting from these Directives. For instance, the Eco design Directive will set product requirements for relevant environmental parameters, such as emissions in the case of central heaters, local room heaters and water heaters.

For instance, the Air Quality Directive's requirements on monitoring of air quality call for certain measurement standards for each regulated pollutant. Such standards exist for all regulated pollutants:

Reference methods under the Directive 2008/50/EC & 2004/107/EC	Reference methods under Commission Directive (EU) 2015/1480 (<i>transposition deadline 31.12.2016</i>)
SO ₂ : EN 14212:2005	SO ₂ : EN 14212:2012
NO ₂ and NO _x : EN 14211:2005	NO ₂ and NO _x : EN 14211:2012
Pb, Cd, As, Ni: EN 14902: 2005	Pb, Cd, As, Ni: EN 14902: 2005
PM ₁₀ : EN 12341:1999	PM ₁₀ : EN 12341:2014
PM _{2,5} : EN 14907:2005	PM _{2,5} : EN 12341:2014

Benzene: EN 14662:2005	Benzene: EN 14662:2005
CO: EN 14626:2005	CO: EN 14626:2012
Ozone: 14625:2005	Ozone: 14625:2012

Such standards have to be incorporated in the national standardisation organisation and translated into the national language. Non-reference measurement methods can also be used provided they respect provisions for equivalence set out in the Directives (see for example 2008/50/EC, Annex V). However, this procedure will entail consultation of the Commission and the Member State will have to submit sufficient evidence to demonstrate the equivalence to the reference method. More information on this can be obtained at DG ENV: <http://ec.europa.eu/environment/air/quality/legislation/assessment.htm>

See the following website for information on EN standards: <http://www.cen.eu/cenorm/members/members/index.asp>

4.2. Monitoring Ambient Air Quality

Accurate information on existing air quality is essential for effective management and for planning air quality improvements, and for maintaining air quality where it is already satisfactory. Monitoring can be undertaken by government laboratories, private consultants, local authorities or meteorological institutes. It is common that funding for monitoring and quality control is provided from the central government. Central government has a key role in defining and approving the monitoring strategy, in particular the location of monitoring stations and the monitoring procedures to be used, and in ensuring quality control/assurance. Although, Member States have a certain margin of discretion in deciding on monitoring programmes and strategies, it is important to comply with the harmonised requirements and reference to various technical standards set at the EU (or international) level. EN standards have been adopted at EU level defining the measurement methods for monitoring of individual pollutants. Also, Decision 2011/850/EU further ensures uniform implementation of Directives 2004/107/EC and 2008/50/EC through setting out common rules for the reciprocal exchange of information and reporting on ambient air quality.

Modelling techniques may also be used (although they are not mandatory) to assess existing air quality. Models have the advantage of being able to calculate the concentration of pollutants from a source of known characteristics at hundreds of locations for the same cost as a single set of measurements. The Air Quality Directive allows the use of modelling techniques and the use of modelling is even encouraged as modelling will provide information supplementary to measurements, by providing indicators of the efficiency and results of the monitoring and measurements. Modelling is becoming a principal assessment tool that is validated by monitoring and provides much more comprehensive information as regards public exposure, and it supports identification of sources and future projections. A number of forums and guidance documents are available to guide the work of the Member States on modelling, e.g. the HARMO initiative, the Air4EU project and FAIRMODE (a forum for air quality modelling).

Pursuant to Article 3 of the Air Quality Directive, Member States must designate competent authorities and bodies responsible for assessment of ambient air quality, approval of measurement systems, ensuring the accuracy of measurements; analysis of assessment methods; coordination on their territory if EU-wide quality assurance programmes are being organised by the Commission; and for cooperation with the other Member States and the Commission.

In the context of quality assurance, these competent authorities/bodies must comply with Section C of Annex I (Quality assurance for ambient air quality assessment: data validation). Such standards have to be incorporated in the national standardisation organisation. For instance, these authorities have to ensure that:

- All measurements undertaken in relation to the assessment of ambient air quality pursuant to Articles 6 and 9 are traceable in accordance with the requirements set out in Section 5.6.2.2 of the ISO/IEC 17025:2005;
- That institutions operating networks and individual stations have an established quality assurance and quality control system which provides for regular maintenance to assure the accuracy of measuring devices;
- That a quality assurance/quality control process is established for the process of data collection and reporting and that institutions appointed for this task actively participate in the related E-wide quality assurance programmes;
- That the national laboratories, when appointed by the appropriate competent authority or body designated pursuant to Article 3, that are taking part in EU-wide intercomparisons covering pollutants regulated in this Directive, are accredited according to EN/ISO 17025 (reference methods referred to in Annex VI).

Recent amendments to the Directive 2008/50/EC have introduced new rules on quality assurance for ambient air quality assessment. Thus, competent authorities and bodies designated pursuant to Article 3 shall ensure the following:

- that all measurements undertaken in relation to the assessment of ambient air quality pursuant to Articles 6 and 9 are traceable in accordance with the requirements set out in the harmonised standard for testing and calibration laboratories,
- that institutions operating networks and individual stations have an established quality assurance and quality control system which provides for regular maintenance to assure the continued accuracy of measuring devices. The quality system shall be reviewed as necessary and at least every five years by the relevant National Reference Laboratory
- that a quality assurance/quality control process is established for the process of data collection and reporting and that institutions appointed for this task actively participate, in the related Union-wide quality assurance programmes,
- that the National Reference Laboratories are appointed by the appropriate competent authority or body designated pursuant to Article 3 and are accredited for the reference methods referred to in Annex VI, at least for those pollutants for which concentrations are above the lower assessment threshold, according to the relevant harmonised standard for testing and calibration laboratories, the reference to which has been published in the Official Journal of the European Union pursuant to Article 2(9) of Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance. These laboratories shall also be responsible for the coordination in Member State's territory of the Union-wide quality assurance programmes to be organised by the Commission's Joint

Research Centre and shall also be responsible for coordinating, on the national level, the appropriate use of reference methods, and the demonstration of equivalence of non-reference methods. National Reference Laboratories organising intercomparison on the national level should also be accredited according to the relevant harmonised standard for proficiency testing.

- that the National Reference Laboratories, take part at least every three years in the Union-wide quality assurance programmes organized by the Commission's Joint Research Centre. If this participation produces unsatisfactory results then the national laboratory should demonstrate at the next participation in the intercomparison satisfactory remediation measures, and provide a report to the Joint Research Centre on these.
- that the national reference laboratories support the work done by the European network of National Reference Laboratories set up by the Commission.

These laboratories are involved in the coordination on Member States territory of the EU wide quality assurance programmes organised by the Commission and shall coordinate, on the national level, the appropriate realisation of reference methods and the demonstration of equivalence of non-reference methods. The Air Quality Directive has further established the role of these national air quality reference laboratories. The initiative AQUILA, operated by the Institute for the Environment and Sustainability under the Joint Research Centre, provide for a network of these laboratories; AQUILA (National Air Quality Reference Laboratories and the European Network).- With the adoption of the new Air Quality Directive, the importance of the National Air Quality Reference Laboratories has grown significantly and this has been acknowledged by the AQD and through AQUILA since their role and responsibilities have been more formally established. For instance the National Air Quality Reference Laboratories are legally responsible for the quality assurance of air pollutant measurements in their Member State, which implies the organisation of national QA/QC programmes and the participation to European QA/QC programmes. They may also be involved in standardisation activities, in the validation of measurement methods and the type approval of instruments. (More information on AQUILA is provided below under section 4.3 on Quality Assurance and Control.

Careful selection of monitoring equipment is essential. A primary requirement is that the principle of operation should permit compliance with the limit and target values laid down in the Directives and Regulations to be assessed. This means that detection limits and averaging times must be suitable. Likely future needs for monitoring, in terms of shorter averaging periods and/or lower detection limits, should be borne in mind. These may be related to human health and other environmental effects reported in the literature. The need to use data for purposes other than the estimation of compliance, e.g. the assessment of air quality in relation to health effects, the dispersion of pollutants and the validation/calibration of models, should also be borne in mind. Other important factors to be considered in the selection of monitoring equipment are:

- Ease of use;
- Expandability (mainly for data processing equipment);
- Reliability;
- Durability;
- Compatibility with any existing hardware or software;
- Availability of training and documentation (including circuit diagrams); and
- Availability of spares, warranties and after-sales services (maintenance and possibly calibration).

It is advisable to ensure that the data processing and storage systems used for all monitoring have sufficient capacity to deal with all likely future requirements for running and fixed means. This should include sufficient provision for raw data storage at the sites themselves for at least several days of monitoring, and preferably several weeks, in case the telecommunications linking the sites with a central control and data storage facility break down. The monitoring and data collection system may also have to take into account the requirements on spatial data prescribed by the INSPIRE Directive (2007/2/EC).

Meteorological data, especially wind speed and wind direction, and if possible solar radiation and air temperature, should be obtained in order to trace high levels of relevant pollutants back to their sources. These data are not specifically required by the Directive, but are essential for modelling and useful in identifying sources of pollutants, which may originate from outside the air quality zone or Member State.

4.3. Quality Assurance and Control

Regarding quality assurance and control in the fuel quality sector, measurements of the quality of samples of fuel and of the performance of individual vehicles will determine whether or not they are acceptable.

The AQD and various EU legal instruments in the fuel quality sector, safeguard that all verifying, measuring, monitoring procedures are subject to objective and independent quality assurance and control. The AQD sets out requirements on quality assurance and control of data, which are detailed in Annex 1.C. Annex 1.C ensures that quality of assessment information either generated through monitoring, modelling or objective estimation is uniform in all the Member States. Data quality objectives are prescribed in Annex 1.C, which define maximum allowed uncertainty, time coverage and data coverage.

Member States, mainly through their national reference laboratories, ensure appropriate quality assurance of the assessment as well as the appropriate quality control of the information provided to the public and through the assessment reports. This work is guided through an EU-wide process, which is established by the Commission and managed by the Joint Research Centre. JRC organises intercomparison exercises for the national reference laboratories and manages AQUILA – network of national reference laboratories which follows the implementation of assessment by monitoring, serves as exchange forum and provides expert advice to the Commission. Candidate countries should consult the document¹⁰⁹ prepared by AQUILA, which summarises the roles and responsibilities of the national reference laboratories and of the network itself as well as describes the quality assurance procedures and EU-wide comparisons.

¹⁰⁹ National Air Quality Reference Laboratories and the European Network – AQUILA: Roles and Requirements for Measurement Traceability, Accreditation, Quality Assurance/Quality Control, and Measurement Comparisons, at National and European Levels National and European Levels, Version 2, December 2009. Available at: <http://ec.europa.eu/environment/air/quality/legislation/pdf/aquila.pdf>

5. REGULATION AND ENFORCEMENT

5.1. Overview

Laws and regulations governing air quality are not in themselves sufficient to ensure their success. In order to be effective, such measures must be implemented and enforced, which in turn requires that adequate systems, procedures and resources are deployed.

The regulatory function consists of four primary tasks:

- Setting standards and limit values for ambient air quality and for emissions to air from specified sources;
- The issuing of licences or permits for certain activities which cause emissions to air;
- Monitoring and inspecting activities to ensure that licence or permit conditions and limit values are being adhered to;
- Taking enforcement action and impose sanctions (including penalties for offences covered by the Environmental Crimes Directive) in cases of non-compliance.

5.2. Authorisations and Permitting

A variety of potential sources of air pollution need to be subject to one form of licensing, permitting or approval system. The type of system that applies should depend mainly on the type of source and activities involved. Some Member States integrate the control of air emissions with the permitting required under the Industrial Emissions Directive (IED) and the authorisation and permitting system may be an integral part of the system established for the implementation of the IED. Although, the IED requires an integrated approach, it is not mandatory to have one single permit for each installation.

Permitting of fixed emission sources will usually be undertaken by the national environmental protection agency, but responsibilities may be divided between the agency and any local branches it may have (dealing with large emission sources) and local authorities (dealing with small sources, including domestic emissions). The division should be clear and should be made on the basis of the type of source involved, the scale (expressed in terms of the rate of energy or material inputs), and the type of materials being processed. Where local authorities have a responsibility, it is advisable to issue clear technical guidance at a national level in order to ensure a uniform approach throughout the country. In larger countries with many large emission sources, it may also be advisable to issue guidelines to the officials who are responsible for the permitting of such sources.

Vehicle (and fuel) type-approvals need to be handled by a testing laboratory and implemented as part of the national vehicle registration process. Regular motor vehicle emission testing will be handled as part of regular vehicle roadworthiness checks. Where roadworthiness checks are not already in place, arrangements will need to be made for testing centres to be set up and for the integration of testing procedures with vehicle licensing.

In some countries, certain sources of air pollution are only allowed to operate when air quality is sufficiently good; this approach has been used in Paris, where only low-emission motor vehicles (registered with a green

disc) are allowed to operate on days when air pollution levels are high. A similar approach is being used increasingly in EU (including newer Member States such as Hungary).

In some countries national or local authorities may include provisions in building codes, notably for emissions from central heaters, local heaters and water heaters. In future such provisions may have to be reconciled with European Eco design requirements regarding emissions.

Checks on the composition of imported fuels will be implemented by customs authorities, which need to be provided with sufficient information and testing facilities. The quality of fuels manufactured in the Member State itself, and vehicle fuels on retail sale, will also need to be tested, which may, for example, be done by local authority inspectors — typically trading standards officers.

5.3. Monitoring, Inspection and Enforcement

The monitoring, inspection and enforcement regimes to ensure compliance with the requirements of EU legislation activities and installations covered by the air quality acquis, should be an integral part of the legislative and policy framework to ensure compliance with the requirements of the IED Directive (2010/75/EU). A requirement to ensure that ambient air quality standards are not breached may be included in the operating licence issued to a stationary potential pollution source. In practice, however, attributing a breach of such a standard to a particular source may not be straightforward, because it may be difficult to obtain adequate meteorological and background data as evidence against a particular operator. Installations should also pay attention to the IED and its Article 18 which establishes a link between permits and adhering to BAT and the compliance with the environmental quality standards.

Operating licences can, therefore, usefully include limits on the rate of emission of one or more pollutants of concern. Indeed, for some sources and pollutants, they must do so in order to ensure compliance with EU Directives. Operating licences may include a requirement for operators of sources to carry out, or to have carried out on their behalf, monitoring of emission rates. Such monitoring must be carried out within a quality assurance regime to ensure that the data obtained are valid.

The type of monitoring required must be appropriate to the nature and size of the source and the pollutant under consideration. In certain cases, non-continuous (intermittent or "spot check") monitoring at intervals of some months may be satisfactory. This would be appropriate especially where the process operating parameters are reasonably constant over time, and where the pollutant (e.g. a heavy metal) is of concern to human health in terms of its long-term average, not peak, concentration. Where a process varies significantly over time in its potential emissions to air (e.g. a batch process with raw materials which may vary significantly in quality) or where the pollutant can affect human health or the environment in the short term (e.g. sulphur dioxide), then continuous monitoring may be necessary. In certain cases, parameters measured in order to control the process (for example, oxygen levels or fuel quality) may be used as surrogates (substitutes) for measuring emission rates. The competent authority will need to ensure, as part of the inspection procedure, that monitoring is being carried out to an acceptable standard and that the emission rates are within the limits specified in the licence.

If there is any breach of a licence, the competent authority will need to have at its disposal an appropriate range of options to ensure compliance. These may range from unofficial warnings to formal requests for improvement in performance (regarding monitoring procedures or emission rates or both) to closure of the plant and/or prosecution. A graduated approach, with enforcement options chosen to suit the magnitude of the breach is

probably the best. The inspector or inspection team needs to have a thorough technical understanding of the process, in order to be able to understand any technical problems encountered by the operator and to evaluate the proposed solutions in terms of timescale, practicality and cost.

It may be useful to separate the technical inspection function of the competent authority from an enforcement function. This will help to allow the technical inspectors to maintain a good working relationship with the operator and to avoid the strain on the relationship that the inspectors' being directly responsible for a closure notice or for a prosecution might cause.

Monitoring, inspection and enforcement can also affect small combustion installations far below the IED threshold. In many Member States there is local or national legislation regarding maintenance of heating equipment and chimneys, the installation and operation of catalytic converters or filters, and/or regarding the quality of fuel allowed on the market (e.g. the water content in biomass). These measures often support or are part of air quality plans to comply with the values in AQD, but they also require follow-up.

5.4. Data Collection and Reporting

Complete and efficient data collection and reporting are essential components of air quality management. Most Directives impose a duty to report to the Commission on their implementation, and, in the case of Directives requiring air quality monitoring to be undertaken, to report the results and the degree of compliance to both the Commission and the public.

Commission Implementing Decision 2011/850/EU of 12 December 2011 lays down rules for Directives 2004/107/EC and 2008/50/EC as regards the reciprocal exchange of information and reporting on ambient air quality. AQD introduces reporting provisions which take into account the previous implementation experience. Also the reporting procedures for data provision, assessment and reporting of air quality have been adapted to enable electronic means and the internet to be used as the main tools to make information available, and in such a way that these procedures are compatible with Directive 2007/2/EC establishing an infrastructure for spatial information in the European Union (INSPIRE). The new requirements with regard to reporting and exchange of air quality information apply as from 1 January 2014.

Data should be subject to quality control before they can be accepted as part of database, which can then be used for the analysis of high pollution episodes or the detection of trends in air quality over time. For instance, Annex I of Directive 2008/50/EC lays down provisions on data quality objectives and requires the national competent authorities and bodies designated pursuant to Article 3 of the Directive to comply with Section C of Annex I (see under Chapter 4.2 above Monitoring Ambient Air Quality).

Where data need to be supplied rapidly (for example, to warn the public regarding ozone levels) it may be impossible to complete all the quality assurance procedures. Where this occurs, the data should be accompanied by a statement to this effect.

Data on emission rates from sources (and surrogate data such as traffic flows) are also of value, for example in building up a picture at the national and regional level of the causes of high pollution episodes. Major stationary sources should be required, under the terms of their licences to operate, to obtain, check, store and supply to the authorities data on their emissions.

There are also provisions in some Directives for informing other Member States about certain technical issues relating to transboundary air pollution, and for consulting each other about it.

6. PRIORITIES AND TIMING

6.1. Prioritising the Implementation Tasks

Candidate countries must agree with the Commission a timetable for transposing the entire EU legislation into national legislation. However, consideration should be given to prioritising the order in which the various items of legislation are transposed and implemented.

6.1.1. Legislative Considerations

Within the air quality sector, implementation of AQD, Directive 2004/107/EC (Heavy Metals Directive), Decision 2011/850/EU and the NEC Directive (2001/81/EC) must be given a high priority, as these legislative measures provide the structure for meeting overall EU air quality objectives, setting limit values, setting up the air emission monitoring and reporting framework and taking action on individual pollutants. Most of the monitoring and reporting obligations fall on the government and public sector and this legislative core should be reflected directly in the national air pollution strategy. Also, implementation of the air quality framework legislation should be carried out in conjunction with implementation of key legislation in other sectors e.g. Directives on IED/IPPC, waste and reporting.

The next core areas for implementation are VOC control in industrial installations and in petrol fuel stations and fuel quality and specifications for engines for the exhaust system of light and heavy duty vehicles. This bulk of legislation has to be implemented in close cooperation with industry and the public as many of the requirements fall on industry but also on vehicle owners. The legislative framework must be supported with ample information and consultation to ensure that all key actors are aware of their responsibilities, the cost implications and the relevant timetable.

6.1.2. Cost-effectiveness

Cost-benefit discussions are relevant in deciding on national priorities provided that all the EU provisions are fully implemented within the given deadlines. Cost-benefit analysis is the prerogative of the Member States, permitted under the principle of subsidiarity. However, the bottom-line is that all EU provisions have to be implemented on time. Also, legislation that is likely to require major investments in new facilities must, however, not be ignored or postponed, as the candidate countries will need to plan for their development, financing and construction, and prepare the public and industry for the eventual introduction of this legislation. Overall, the cost of implementing legislation on the quality of ambient air is reduced where candidate countries have already undertaken great efforts under the existing legislation, on the basis of one piece of legislation on ambient air that includes all the relevant limit values. The logic and provisions are very similar, the main differences being the pollutants regulated. Further, cost-effectiveness can be gained through contemplating, to the extent realistic, manageable and feasible, an integrative framework for reporting and monitoring which partly covers other reporting obligations under IED or for certain legislation now falling in the area of climate acquis.

A key consideration for cost-effectiveness is phasing the implementation of the air quality acquis so that industries have a defined time period to respond to the new requirements. With the AQD, the implementation is more straightforward with one legislative and institutional context comprising all the pollutants apart from certain heavy metals regulated by the fourth daughter Directive 2004/107/EC. This simplified legislative format also supplemented with Commission Implementing Decision 2011/850/EU

laying down rules for the AQD and the Heavy Metals Directive as regards the reciprocal exchange of information and reporting on ambient air quality provides a much more cost-effective regulatory framework in itself. This allows investment to be focused on particular pollution hotspots in the early stages of implementation.

A further cost-effectiveness issue is the case where certain legislation is scheduled to be replaced by more stringent requirements. Where this is the case, it is usually more cost effective to move directly to the more stringent standards, applying these to new installations, while scheduling implementation of the existing Directive as a lower priority. For cost-effectiveness reasons Directive 94/63/EC on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations could be implemented together with Directive 2009/126/EC on Stage II petrol vapour recovery during refuelling of motor vehicles at service stations.

It is important to note that the EU also performs a cost-efficiency assessment covered by the impact assessment process for EU legislation. This assessment is useful to consider to better understand the concrete costs but also assessed benefits (translated into the economic terms) of the legislation.

6.1.3. Economic Considerations

A significant part of the costs for implementing the AQD and the related legislation constitutes expenditures and investments for setting up the regulatory framework with system for data collection, reporting towards the Commission, and public information dissemination as well as for putting into place monitoring stations and to supervise compliance and sanction non-compliance. These costs are mainly covered by the public sector. Also a part of the polluting activities can have public or semi-public owners like energy and electricity production and hence the costs for taking polluting abating measures have to be covered by the public sector.

The industry on the other hand, and then notably the industrial sectors emitting the pollutants listed in the AQD and the Heavy Metals Directive, has to make investments into polluting abatement equipment and monitoring systems, which will be necessary to ensure compliance with the limit values but also provide evidence of compliance in case of inspection and claims of non-compliance. Pollution abatement measures also stem from the IED, and in particular the integrated pollution permit required under this Directive. These sectors should also look into the possibility of cleaner production systems and cleaner products as this might be economically viable in the medium to long-term and provide market advantages as well. The government can assist the industry here by informing them well in advance of their obligations and the financial implications suggesting an implementation road map gradually phasing in the new requirements in line with the timeline given in the EU legislation. The government can also choose to be more pro-active and consider introducing incentives for the industry for investing into cleaner production systems, with provide tangible economic and health benefits.

For the fuel quality legislation, Euro5 and Euro6 Regulations and the two Directives on the control of volatile organic compound (VOC) emissions resulting from the storage, distribution and refilling of petrol at service stations, the costs are mainly falling on industry (the producers and suppliers of fuel and motor vehicles) as they have to ensure that they comply with new emission reduction standards, engine standards etc. To a certain extent, these costs can be shared with the public in large and especially the consumers of these products but in general this is not normally the case. However, regarding the implementation of legislation implying significant costs for domestic and foreign industrial actors, it is beneficial to ensure a phased implementation schedule with a clear road map, supplemented with guidance documents, information exchange and constructive

dialogue. This approach will lessen the economic blow, give more opportunities for various upgrading solutions and enhance the compliance.

Also, in the case of the Directives on emissions from mobile sources, vehicle manufacturers may need a period of several years to adapt their products to the new Regulations if they are to compete successfully with manufacturers whose vehicles already comply. Older vehicles are replaced by new models as part of normal economic activity, with the result that over ten years or so the whole vehicle fleet will be upgraded, without high costs falling on existing vehicle owners.

6.1.4. Environmental Considerations

In setting ambient air quality standards, any zones that require special environmental protection should be identified, to avoid new or continued damage to sensitive ecosystems. Such protection may be needed to maintain biodiversity and the integrity of nature protection areas. Similarly, zones where it is considered necessary to limit or prevent a foreseeable increase in air pollution in the wake of development, especially urban or industrial, must be identified. These zones will include hot-spot areas where the air pollution is particularly significant.

The AQD requires Member States to measure the ambient air quality both in urban and rural areas. Densely populated „agglomerations” should normally be given the first priority because in general air quality problems are likely to be greatest here. Some agglomerations or heavily industrialised areas are so-called hot spots calling for particular preventive and control measures to limit adverse health effects and environmental damage. To avoid the waste of resources and the production of potentially misleading erroneous data, monitoring should not be carried out before quality assurance procedures have been designed and put in place. All data used for assessment purposes must be quality assured, because of the high potential expenditure that may hinge on such results. From the results of these initial monitoring activities, other areas where limit values may be exceeded or where it is unlikely that they are exceeded can be identified, and monitoring or other forms of assessment undertaken where necessary. It is not necessary to carry out monitoring or even modelling of ambient air quality throughout the territory, but it must be assessed. This assessment must clearly be objective but need not be time-consuming. It could, for example, be based on data on stationary emission sources, on population and on transport and on comparisons with the results from other geographic areas where more detailed assessments have been carried out. However, such comparisons should be made with diligence as many factors have to be weighed in to draw conclusions about findings and results. To facilitate for the Member States and candidate countries, there are projects on-going to improve the exchange of best practices in air quality assessments.

Planning should be carried out as a first priority in any areas where air quality needs to be improved, i.e. where prescribed limit values are exceeded and structural plans and programmes and short-term plans and programmes are needed. If there are many such areas, prioritisation could be carried out on the basis of the number of people exposed in each area and the magnitude of the difference between the limit value and the actual ambient level in that area. In many cases, modelling can be used to predict the effect of different emission reduction scenarios and to assist in the selection of the most acceptable solution. Models will need to be based on up-to-date and accurate inventories of emissions. Acceptability of the possible solutions will need to be judged against national, regional and/or local criteria which may be expressed in terms of cost-effectiveness, social factors (such as employment) and/ or speed of implementation.

The setting of technical standards (e.g. for emissions monitoring or fuel quality measurements) and the formulation of the corresponding quality assurance procedures need to be carried out before such standards

are published or imposed on sources or other entities which need to be regulated. International standards should be referred to and used wherever possible, to save time and resources and to ensure acceptability by the Commission, by other countries and by the public. Technical standards should be well publicised among stakeholders so that all of them are aware of the future regulatory climate in which they will operate. For example, those operating sources without a permit should be made aware at the earliest possible opportunity of the standards with which they will be expected to comply in due course.

Where a significant number of sources are being operated without permits or without satisfactory permits, they need to be brought under the control of the competent authority and some degree of prioritisation to do this may be necessary. Large sources that are thought both to be exceeding emissions standards and to be causing breaches of ambient air quality standards in highly populated or environmentally sensitive areas should clearly be given the highest priority. The early publication of technical standards and the official issuing of them to all sources to which they could apply, together with a timescale for action, could help to achieve compliance at an earlier date than might be achieved by initially approaching sources on an individual basis with a view to giving them a permit or requiring them to make improvements.

Implementation of those measures to improve air quality or to prevent deterioration which are centred on stationary or mobile sources should be prioritised, if necessary, in a fashion similar to that used for permitting. Implementation should be required only where quality-assured results for emissions or for ambient air quality shows that it is necessary. Stationary sources may typically need up to about five years to implement changes without excessive costs. Changes in the emissions from mobile sources other than those obtained by changes in fuel quality may take even longer, depending on the legal and economic penalties and incentives employed. The effects of implementing changes should therefore be viewed against the likely future, as opposed to the present, air pollution background due to other sources. Data collection must, as a minimum, be sufficient to satisfy Commission requirements. An early review of the amount of data on ambient air quality and on emissions which is likely to be generated should assist in planning the means by which it will be archived and accessed. Data collection will occur at all stages of the approximation process.

6.2. Timescales

It is not possible to give specific guidance on the dates by which the candidate countries must, or may be able to, implement and comply with EU air quality legislation. Some indications are provided in the Directives that stipulate the transposition periods within which Member States must have implemented and complied with the legislation. However, these periods may not provide appropriate indications of the transposition periods that will apply to candidate countries. Timetables will need to be agreed between the candidate countries and the European Commission in the accession negotiations, taking into account the level of existing development of air quality management and the costs involved.

Implementation tasks that will tend to be especially time-consuming are:

- Making air quality plans and setting emission standards to be reflected in national air strategies;
- Monitoring and assessing ambient air quality;
- Identifying facilities within the priority areas whose problems need to be addressed through the national strategy;

- Consultation and information dissemination also putting in place procedures for information public on various strategic documents but also in case of exceedance of certain pollution thresholds;
- Supervision and ensuring implementation of improvements at facilities and in mobile sources and sanctions in case of non-compliance.

Some improvements will need to be phased, for example the mandatory introduction of three-way catalytic converters on motor vehicles depends on the availability of unleaded fuel. Hence, Directives relating to fuel quality and type-approvals for Euro 5 and 6 engines need to be transposed prior to those relating to vehicle emissions.

There may be instances where implementation of a specific requirement cannot be achieved by the date of accession, for example due to the long lead times associated with planning, financing and constructing certain types of air pollution abatement facility. Candidate countries must be in a position to negotiate appropriate transitional arrangements with the Commission, such as extended periods for implementing, and achieving compliance with, specific requirements of EU legislation. The need for any transitional arrangements should be identified and taken into account when developing the air quality strategy and implementation plan. The AQD provides further time-limited derogations for certain of the pollutants, especially for countries with specific climate conditions. However, the timelines provided in the Directive may not be achievable under the accession process. But these could be studied in detail and provide suggestions for the accession negotiations (see separate fiche on AQD below). Candidate countries in their negotiations with the Commission on the timetable for implementing the air quality legislation, could also study the examples of the latest Member States.

7. ECONOMIC AND FINANCIAL ISSUES

7.1. Introduction

This section provides guidance on economic and financial issues relating to the implementation of the EU legislation on air quality. The first two subsections indicate the types of costs that will be incurred during implementation, while the last two subsections discuss cost recovery and the use of economic tools. Examples of unit costs related to specific items of legislation are provided in the fiches where appropriate.

7.2. Main Cost Areas

The costs for implementing EU air quality acquis, especially heavy investment legislation such as the AQD is considerable. Table 5 lists examples of the main costs and some case studies on the costs incurred by the latest Member States at their time of accession as well as some examples from the founding Member States. However, it is also important to realise that implementing EU environment law is cost-effective. This is underpinned by the Commission Communication of 2012 – „Communication on Improving the delivery of benefits from EU environment measures: building confidence through better knowledge and responsiveness”¹¹⁰ (following up on an earlier Communication of 2008)¹¹¹, which refers to studies showing that when factors such as health costs are taken into account, non-implementation actually costs more than implementation.¹¹² For instance, 20 % - 50 % of the European population lives in areas where the air quality limits are exceeded and the estimated annual costs in terms of health expenditure or days of work lost through illness run into billions of Euros. Several ideas in the Communication represent approaches that have stand-alone economic benefits. For instance, placing more environmental information online, for example, should contribute to the knowledge economy and fit with a wider emphasis on e-government.

Table 5. Some other examples illustrating that implementation of EU environment law is cost effective:

	Benefits from implementation	Costs of implementing legislation
General example The phase-out of dangerous chemicals has significant environmental and health benefits.	Prudent assumptions are that the total health benefits would be in the order of magnitude of €50 billion over the next 30 years.	The costs of implementing the legislation are estimated to be €4-5 billion in total.

¹¹⁰ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Improving the delivery of benefits from EU environment measures: building confidence through better knowledge and responsiveness (COM/2012/095 final)

¹¹¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on implementing EU Environmental Law {SEC(2008) 2851} {SEC(2008) 2852} {SEC(2008) 2876}

¹¹² More information can be obtained at:

<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/220&format=HTML&aged=0&language=EN&guiLanguage=en>

Location specific examples Implementation of the Natura 2000 network in France	Benefits were estimated to be seven times higher than the costs.	€142 per hectare and year.
A programme to restore several wetlands in the Danube river basin	Benefits of retaining vital adaptive ecosystem functions will likely lead to earnings of €85.6 million per year.	€183 million

The value of the benefits of implementing environmental legislation has to be kept in mind when estimating the costs.

The main costs imposed by the legislation in the air quality sector will be those incurred by:

- Establishing and maintaining a network of air quality monitoring stations and associated monitoring, data verification equipment, and reporting the monitoring results. The maintenance cost can be high and should not be underestimated. These costs will generally be partly borne by central government but more likely to a greater extent by local government for the operation of local monitoring stations and the reporting of collected data;
- Preparing plans and programmes to achieve compliance with ambient air quality limits and to arrange for consultation and public awareness raising campaigns; These costs will be borne by central or more likely by local government;
- Compliance with emission limits and technical requirements under the Directives, or by the implementation of plans and programmes designed to improve ambient air quality. These costs will be partly borne by the polluters themselves (industry, households, motorists etc) but also to a large extent by the local government. (and its citizens) (e.g. roads and traffic management systems, public transport, parks and trees, awareness campaigns etc.;
- Establishing verification, certification, analysing and testing systems, with laboratories, trained staff and the necessary equipment for the fuel quality, type approval of vehicles and road worthiness legislation. These costs will mainly be born by the central government, apart from cases where these tasks are carried out by accredited private or semi-public entities;
- Monitoring, supervising and sanctioning of non-compliance. These costs will mainly be borne by the central government.

These costs are all considerable. A part of these costs is initial capital investments (e.g. air monitoring stations, laboratories) whereas other costs are operational in character.

A few studies on the costs of implementing EU legislation in the Central and Eastern European Countries (CEECs) were undertaken. The EDC¹¹³ estimated total investment for abatement of SO₂, NO_x and particulates at combustion plants to be EUR 48.2 billion for the CEECs, varying between EUR 0.7 billion for Estonia to EUR 13.9 billion for Poland. In one of the projects funded by DISAE to estimate compliance costs for several

¹¹³ EDC, 1997. Compliance Costing for Approximation of EU Environmental Legislation in the CEEC.

environmental sectors in Latvia¹¹⁴, the capital cost for implementing the Directive on VOC emissions (94/63/EC) was estimated at EUR 22.8 million, while the capital cost of implementing the previous Air Quality Framework Directive was estimated at EUR 0.9 million.

In the case of Poland, a DISAE mini-project (POL-101)¹¹⁵ on the costs and financial analysis of environmental approximation took place. The estimates relating to vehicles were based on a fleet of 9.6 million vehicles in 1996 rising to a projected 18.7 million vehicles in 2010 (an increase of 95%). The cumulative capital investment cost of compliance with the Directives relating to emissions from motor vehicles was estimated at EUR 0.7 billion in the year 2000, EUR 4.2 billion in 2005 and EUR 10.9 billion in 2010. This last estimated investment cost for 2010 is about 43% of the estimated total for investment for implementing environmental legislation in Poland, excluding the nitrates and IPPC Directives, of EUR 25.4 billion by 2010. For the same years, the annual (operating) cost of compliance was estimated to be EUR 0.4 billion, EUR 1.3 billion and EUR 2.6 billion respectively. This last estimated annual cost for 2010 is about 48% of the estimated total annual cost for implementing environmental legislation in Poland, namely EUR 5.3 billion in that year.

The case of Estonia provides a useful additional example from a smaller candidate country. The DISAE mini-project EST-101/1 on the Estonian approximation strategy¹¹⁶ provided estimates relating to vehicles. These estimates were based on a fleet of 0.5 million vehicles in 1997, rising to a projected 0.8 million vehicles in 2010 (an increase of 53%). The cumulative capital investment cost of compliance with the Directives relating to emissions from motor vehicles was estimated to be EUR 0.05 billion in the year 2000, EUR 0.25 billion in 2005 and EUR 0.61 billion in 2010. For the same years, the annual (operating) cost of compliance was estimated at EUR 0.03 billion, EUR 0.08 billion and EUR 0.13 billion respectively.

Further estimated costs for the implementation of the Large Combustion Plants Directive (2001/80/EC) to meet its requirements in the new Member States are indicated in table 6, taken from the Technical Report on Enlargement, RIVM¹¹⁷, November 2001.

Table 6. Costs for the implementation of the Large Combustion Plants Directive

Country	Population in 2000	Est. cost of large combustion plant requirements	Per capita cost
Bulgaria	8 million	MEUR 1,627	EUR 203
The Czech Republic	10 million	MEUR 1,858	EUR 186
Estonia	1 million	MEUR 312	EUR 312
Hungary	10 million	MEUR 878	EUR 88
Latvia	2 million	MEUR 43	EUR 21
Lithuania	4 million	MEUR 74	EUR 18
Poland	39 million	MEUR 3,456	EUR 89

¹¹⁴ DISAE Project LAT-103. Development of the Latvian Approximation Strategy and Programme. 1998. Halcrow

¹¹⁵ Agriconsulting Europe, 1998. Costing and Financial Analysis of Approximation in Environment

¹¹⁶ DISAE Project EST-101/1: Approximation Strategy and Institutional Support. 1998. AgriConsulting

¹¹⁷ National Institute of Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu -RIVM), the Netherlands.

Romania	22 million	MEUR 402	EUR 18
The Slovak Republic	5 million	MEUR 796	EUR 159
Slovenia	2 million	MEUR 180	EUR 90

Source: RIVM

7.3. Institutional Development

Implementation of the air quality Directives will require staff training. Without sufficient and suitably trained staff, systems for air quality monitoring, modelling, management, planning, Regulation and enforcement cannot be effectively implemented. It is therefore important to ensure that adequate budgets are provided to enable the responsible institutions to perform their functions effectively. Salaries need to be set at levels that enable staff with the necessary experience and training to be attracted and retained, taking account of the competition for such staff from the private sector. An assessment of training needs should be carried out to ensure that, once staff is recruited and working, any deficiencies in skills can be remedied within a reasonable period of time.

Human resources are required for:

- Developing and setting environmental and technical standards and guidelines;
- Air quality management strategy development and implementation of air quality plans at central and local levels;
- Issuing of licenses, permits or approvals;
- Supervision, monitoring and inspection of facilities and activities that have a potential for pollutant emissions to air;
- Initiating and pursuing enforcement actions;
- Data collection, analysis and reporting.

It is not possible to generalise the costs of establishing the institutional structure, which will depend on the size of country, the existing organisational structures and existence of technical units, the degree of industrialisation, the existence of the regulated activities, the choice of organisational structure and local salary levels. These costs will be borne by central government, in some cases shared by local government, but some of these may be recovered from source operators.

7.4. Facilities

The significant share of the costs of implementation of the AQD, Heavy Metal Directive and the NEC Directive will fall on source operators, who will need to pay for emission abatement equipment, either to upgrade existing plants or to install new plants. Finance needs to be raised for capital investment and any

recurrent costs incurred during operations. Certain industrial sectors will also have significant expenses for implementing the standards set out in the legislation on VOCs, fuel quality and road worthiness (Euro 5 and 6). In countries, where there is no domestic producer of fuels, cars and non-road machinery the costs will be less although suppliers also have to share some of these costs and ensure that only compliant products are being put on the market.

The costs of facility provision and operation could partly be recovered from customers and clients (purchasers or users of goods, materials, services and energy) in the form of „green” charges. However, in this case these extra costs should be earmarked and consumer clearly is informed about the costs, the underlying legal basis and environmental objectives etc. Finance may derive from the private or public sectors (for example from "green funds") or a mixture of the two, depending on national policies for the ownership of facilities and for the improvement of the environment.

In line with this consumer oriented approach, the Eco design Directive (2009/125/EC) provides requirements and incentives for the design and production of more eco-efficient products such as more efficient and cleaner heating equipment. Consumers may, initially, pay a bit more for such products but over time the price increase tends to level out and over the medium to long-term consumers will often save costs through using these more efficient products. (More information on the Eco design Directive and its meaning for industry and consumers can be obtained at: http://ec.europa.eu/enterprise/policies/sustainable-business/ecodesign/index_en.htm)

Life-cycle costing (or LCC) is a relevant tool which evaluates the costs of an asset throughout its life-cycle. It allows costs associated with the use, maintenance and end-of-life of the supplies, services or works to be taken into account – sometimes also referred to as total cost of ownership. Four main cost categories are assessed: investment, operation, maintenance and end-of-life disposal expenses (more information on LCC from EU perspective can be obtained at: <http://ec.europa.eu/environment/gpp/lcc.htm>).

7.5. Application of Other Economic Tools

The use of economic tools or instruments in environmental policy has long been promoted by economists as a (potentially) more efficient way of achieving environmental goals. The major advantage of economic tools is that, in theory, they incorporate environmental concerns and costs directly into the market price mechanism and therefore possess all the efficiency properties of competitive market pricing. The efficiency of economic tools, however, depends crucially on (a) the flexibility and effectiveness of other related environmental policy instruments; and (b) marginal cost differentials for different air quality management/air pollution abatement options. More information on studies also partly involving the use of economic tools can be obtained at: <http://ec.europa.eu/environment/air/pollutants/stationary/studies.htm>

7.5.1. Economic tools at national level

Market based instruments for dealing with air pollution has been employed by several Member States for years already. There are ample experience and case studies that the candidate countries could take into consideration if contemplating to introduce economic tools in their national air policy.

Some common examples of economic tools are:

- Taxes and product charges (or input charges), which are added to the price of certain goods, materials, services and energy that are considered to cause adverse effects on air quality during their production, use or disposal. Taxes on vehicle fuel can be viewed as being partly of this type;
- Congestion fees or road pricing for certain built-up city areas;
- Emission trading systems (such as for greenhouse gases under the EU ETS);
- Rebates and tax incentives for new cleaner products or for replacing old dirty stock (often linked to an energy or eco-label);
- Green Public Procurement (often linked to an energy or eco-label).

Core issues to be considered when choosing and devising market based instruments:

- Should the revenue generated through economic tools should be ring fenced for environmental purposes or go into the general national budget?
- Should the role of the economic instrument be to reallocate some of the costs borne by the polluters?
- Will the fees/charges bring about benefits greater than those produced by binding EU legislation (e.g. IED, Air Quality Directive, NEC Directive); i.e. will the market based instrument go beyond binding emission limits and BAT standards?
- Is the regulatory framework and enforcement system sufficiently adapted and supportive of market-based instruments?
- Will the taxes/subsidies bring expected results in dealing with air pollution?

Examples from Member States – NOX fee:

Sweden: In 1990 the Swedish Parliament decided to introduce a tax of 40 SEK (4,43 EUR) per kilogram of NO_x emitted from all combustion plants producing at least 50 GWh useful energy per year. The tax came into effect on January 1992, and affected about 200 plants, excluding smaller plants partly due to the high costs of metering and the abatement costs which were considered unreasonable. The setting of the charge level at 40 SEK/kg NO_x was based on the results of a study by the Swedish Environmental Protection Agency (SEPA, 1987). The Swedish NO_x charge has remained constant (in nominal terms). On the other hand the charge is distributed back to the polluting companies in relation to the amount of energy produced by the specific plant. This means that the polluting industry as a whole does not pay anything to society – and it is presumably this fact that has made the charge politically feasible.

The unique design of the NO_x charge is referred to as output-based refunding of emission payments (Sternier and Höglund 2000, Gersbach and Requate 2004, Fredriksson and Sternier 2005, Sternier and Höglund-Isaksson 2006, and Bernard, Fischer and Fox 2007). Within a refund system, plants compete for the lowest emissions per unit of output produced within the regulated group of plants. Plants emitting exactly the group average emissions per unit of output produced pay the emission charges equal to what they receive back as refunds. Plants performing worse than the group average have to make a net payment and plants performing better than the average receive a positive net refund. This system makes it economically beneficial to improve their environmental performance relative other plants in the system.

Source: Höglund-Isaksson, L., International Institute For Applied Systems Analysis (IIASA), Laxenburg, Austria and Sternier, T., the Department of Economics, Gothenburg University, Sweden, „Innovation Effects of the Swedish NOX Charge (available at: <http://www.oecd.org/greengrowth/consumptioninnovationandtheenvironment/43211635.pdf>

In some instances, there may be a role for economic instruments to reallocate some of the costs borne by polluters. Differential taxation as a tool to encourage cleaner transportation has been successfully adopted in some EU countries. In some countries, financial incentives are given for purchasing electric, plug-in hybrid or hybrid vehicles. In general, taxes on fuels have led to an overall introduction of higher concentrations of ethanol in petrol. For instance, since 2006 the new vehicle tax in Sweden is based on the concentrations of certain pollutants in the exhaust fumes rather than on weight. Another example is introducing special environmental charges for motor vehicles, where higher charges are introduced for vehicles with higher pollution potential.

Taxes can also be levied on industry according to the emission levels of specified air pollutants.

Financial subsidies are available in some countries for implementing emission reductions, for example in France through the Agency for Environment and Energy (ADEME) and financing companies (SOFERGIES).

The costs of emission permitting and associated enforcement can be recovered from polluters by charging fees for issuing and renewing permits.

8. SUMMARY OF KEY ISSUES

Achieving and maintaining compliance with EU policies and legislation on air quality management presents a major challenge to the candidate countries which, in order to minimise the associated administrative burden and costs, needs to be managed in a systematic and cost-effective manner. With this in mind, the governments of the candidate countries should endeavour to focus their efforts and actions on addressing those issues and requirements that are fundamental to the implementation of the legislation in this sector, in particular by ensuring that:

- Air quality management and regulation is effectively integrated with that for other environmental sectors such as water, IED/IPPC, climate change and waste, preferably through the supervision and coordination of a single environmental protection agency;
- A thorough quality-assured assessment of ambient air quality is undertaken as a prelude to formulating a strategy for air quality improvement, and mapping/inventory of pollution sources;
- Action is taken to identify the concerned industrial facilities or other economic actors and ensure that they are adequately informed about their obligations, and to draw up a roadmap for phasing in new abatement technologies, meeting new product and technical standards etc;
- A comprehensive plan (air quality management strategy) is drawn up for improving and maintaining air quality, addressing all pollutants of concern and focusing on issues of immediate concern in terms of complying with air quality criteria;
- Arrangements are put in place for the effective involvement and participation of all bodies or interest groups that have a significant role or function to perform in relation to air quality management;
- The necessary monitoring infrastructure and data collection systems are set up;
- Adequate provision is made for the monitoring, regulation and enforcement of the legislation, permits and licenses. In particular, sufficient human and technical resources need to be allocated to enable all functions to be properly performed;
- Record keeping, reporting and information dissemination is performed to meet the requirements of the Directives and to inform the public; and
- The air quality management plan is regularly reviewed and updated to ensure that it remains relevant to the key issues of concern.

A well-prepared, integrated strategy provides the means by which these and all other significant issues relating to air quality management can be systematically identified and addressed. A checklist of the key questions that should be considered in preparing and implementing such a strategy is presented in Table 7.

Table 7. Checklist of Key Questions to be Considered in Preparing and Implementing an Air Quality Management Strategy

Checklist of Key Questions to be Considered in Preparing and Implementing an Air Quality Management Strategy	
1	Have key actors and stakeholders been identified for each Directive, Regulation or Decision and have discussions been held between them, especially on the choice of competent authority (-ies), the necessary guidance materials and the possible need for temporary derogations?
2	For each Directive or Decision, have suitable administrative, technical, legal and financial arrangements been made? In particular: <ul style="list-style-type: none"> • Has a competent authority been appointed that is appropriate in terms of its technical expertise, its relationships with other governmental and non-governmental bodies, its enforcement powers and its authority to report to the Commission? • Has a competent authority been appointed that is appropriate in terms of its technical expertise, its relationships with other governmental and non-governmental bodies, its enforcement powers and its authority to report to the Commission? • Have appropriate institutions for carrying out air quality assessment (including monitoring), modelling, the compilation of inventories and independent quality assurance in all these areas been identified and appointed? • Have all the necessary laws, regulations etc. been passed to allow the competent authority to carry out its functions as required under each Directive or Decision (including international protocols)? • Have any necessary additional air quality or related standards been regulated for? • Have sufficient financial resources for all the necessary activities, including staff recruitment and training, been allocated?
3	For each pollutant that requires air quality assessment (especially monitoring): <ul style="list-style-type: none"> • Have suitable quality assurance procedures been set up for all stages and activities? • Is technical advice available? • Is monitoring being carried out at suitable locations? • Have suitable arrangements for data handling and storage been made and implemented?
4	Have all significant existing and potential future air quality problems been identified and, where possible, prioritised?
	Regarding the drawing up of plans: <ul style="list-style-type: none"> • Are the plans based on emissions inventories, modelling results or other objective and verified data? • Have the plans been reviewed, discussed and agreed on at an appropriate local, regional and/or national level with key stakeholders? • Have all technical and economic options been reviewed? • Have all social and economic effects been considered? • Are the plans based upon feasible techniques (e.g. BATNEEC/BAT)? • Has plan identified competent authorities, including clear definition of their responsibilities and administrative capacities for the implementation of measures? • Have reasonable time lines for complying with the air quality objectives been determined? • Have the possible sources of funding been assessed and allocated?
5	Has sufficient measures been taken to ensure full compliance with public consultation requirements, requirements for cross-border consultation, ensuring access to environmental information, allowing for public participation in certain Decisions and procedures including: <ul style="list-style-type: none"> • Consultations with adjoining Member States where necessary; • Using efficient means and channels of information to reach the public; • Applying efficient means of generating reports for the Commission and the public.
6	Have all the competent authorities and technical representatives been appointed and has the Commission been informed where necessary?
7	Has sufficient information been submitted to the Commission: <ul style="list-style-type: none"> • Details of the implementation of each Directive or Decision;

	<ul style="list-style-type: none">• Data on alternative methods;• The results of air quality assessment, including monitoring.
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THE AIR QUALITY FRAMEWORK DIRECTIVE

Official Title:

Directive 2008/50/EC of the European Parliament and the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L152/1, 11.6.2008)

Amended by:

Commission Directive (EU) 2015/1480 of 28 August 2015 amending several annexes to Directives 2004/107/EC and 2008/50/EC of the European Parliament and of the Council laying down the rules concerning reference methods, data validation and location of sampling points for the assessment of ambient air quality (OJ L 226, 29.08.2015)

2011/850/EU: Commission Implementing Decision of 12 December 2011 laying down rules for Directives 2004/107/EC and 2008/50/EC of the European Parliament and of the Council as regards the reciprocal exchange of information and reporting on ambient air quality (OJ L 335, 17.12.2011)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

This Directive merged most of previous air quality legislation¹¹⁸ into a single directive (except for the fourth daughter Directive) and includes following key points:

- Defining and establishing air quality objectives for ambient air quality designed to reduce harmful effects on health and the environment up to 2020;
- Assessing the ambient air quality in Member States on the basis of common methods and criteria;
- Obtaining information on ambient air quality in order to monitor long-term trends;
- Ensuring that such information on ambient air quality is made available to the public;
- Maintaining air quality where it is good and improving it in other cases;
- Promoting increased cooperation between the Member States in reducing air pollution.

One of the key implementation features is designation of zones and agglomerations covering whole Member States' territory. The zones represent basic areas for which assessment and management provisions are prescribed. The Directive sets thresholds, limit values and target values for pollutants: sulphur dioxide, nitrogen dioxide, particulate matter, lead, benzene and carbon monoxide. It also sets target values and long term objectives for ozone in ambient air.

Member States need to ensure that limit values are complied with throughout the territory by their respective attainment dates, and that target values are respected to the extent possible. Action is required before the attainment dates when certain assessment thresholds set in the Directives are exceeded, generating a requirement to prepare and implement air quality plans or programmes. Plan or programme need to be available to the public and reported to the Commission within 2 years after the exceedance has been assessed.

The national authorities must ensure that not only the public, but also environmental, consumer and other relevant organisations, including health care bodies and industry federations, are kept informed of the ambient air quality. Detailed information must be published on exceedance, type of population concerned, recommended behaviour and on preventive measures in case where alert thresholds and information thresholds are exceeded.

Member States must lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties imposed must be effective, proportionate and dissuasive.

The Directive introduces possibility to discount natural sources of pollution when assessing compliance against limit values.

In August 2015 the European Commission adopted Directive (EU) 2015/1480 amending several annexes to Directives 2004/107/EC and 2008/50/EC of the European Parliament and of the Council laying down the rules concerning reference methods, data validation and location of sampling points for the assessment of ambient air quality. Thus, the Directive amends certain provisions of Annexes I, III, VI and IX to the Directive 2008/50/EC. The amendments concern, in particular:

¹¹⁸ Framework Directive 96/62/EC, 1-3 daughter Directives 1999/30/EC, 2000/69/EC, 2002/3/EC and Decision on exchange of information 97/101/EC

- Section C of Annex I laying down criteria for the quality assurance for ambient air quality assessment. Provisions are clarified and complemented taking into account the quality assurance programmes organised by the Commission's Joint Research Centre and introducing the obligation of reviewing the quality control system in order to ensure the continued accuracy of monitoring devices.
- Sections C and D of Annex III laying down criteria for the siting of sampling points. Provisions are updated in order to reflect experience gained in implementing the Directive
- Section A of Annex VI laying down the reference method for the measurement of certain pollutants. Reference methods are adapted based on the experience gained in implementing the Directive and taking into account the most recent standards for the sampling and measurement of particulate matter.

Member States must align their national law with the requirements of this Directive by 31 December 2016 at the latest.

Rules for the reciprocal exchange of information and reporting on ambient air quality for the AQD and the Heavy Metals Directive are set out in the Commission Implementing Decision 2011/850/EU. The scope of this Decision covers the annual reporting on ambient air quality assessment and the submission of information on plans and programmes in relation to limit values for certain pollutants in ambient air as well as reciprocal exchange of information concerning networks and stations, and the measurements of air quality obtained from those stations that are selected by Member States for the purpose of reciprocal exchange from amongst existing stations.

This Decision repeals and replaces former Commission Decisions 2004/224/EC¹¹⁹ and 2004/461/EC¹²⁰. It applies from 1 January 2014, although Member States should have made available the information required pursuant to Articles 6 (zones and agglomerations) and 7 (assessment regime) for the first time no later than 31 December 2013.

For more information see <http://aqportal.eionet.europa.eu/>

- Website of DG ENV (chapter air) on general information, guidance and supportive documentation: http://ec.europa.eu/environment/air/quality/legislation/existing_leg.htm, and http://ec.europa.eu/environment/air/quality/legislation/time_extensions.htm. Here are also links with forms in excel such as the questionnaire for reporting (available at: http://ec.europa.eu/environment/air/quality/legislation/pdf/2008_2132_forms_en.xls)
- Communication from the Commission on notifications of postponements or attainment deadlines and exemptions from the obligation to apply certain limit values pursuant to Article 22 of Directive 2008/50/EC on ambient air quality and cleaner air for Europe¹²¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52008DC0403:EN:NOT>

¹¹⁹ Commission Decision 2004/224/EC of 20 February 2004 laying down arrangements for the submission of information on plans or programmes required under Council Directive 96/62/EC in relation to limit values for certain pollutants in ambient air

¹²⁰ Decision 2004/461/EC laid down a questionnaire for annual reporting on ambient air quality assessment under Council Directives 96/62/EC and 1999/30/EC and under Directives 2000/69/EC and 2002/3/EC of the European Parliament and of the Council and specified the format and content of Member States' Annual Report on ambient air quality in their territories

¹²¹ COM(2008)403

- Staff working paper accompanying the Communication relating to the notification procedure¹²²
http://ec.europa.eu/environment/air/quality/legislation/pdf/sec_2008_2132_en.pdf
- Website of Curia regarding important case law:
<http://curia.europa.eu/juris/liste.jsf?language=en&num=C-237/07>

¹²² (SEC(2008)2132)

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Designate the competent authorities and bodies responsible for:
 - assessment of ambient air quality;
 - approval of measurement systems (methods, equipment, networks and laboratories);
 - ensuring the accuracy of measurements;
 - analysis of assessment methods;
 - coordination on their territory if EU-wide quality assurance programmes are being organised by the Commission;
 - cooperation with the other Member States and the Commission. (Art. 3)
- Ensure that the competent authorities and bodies comply with Section C of Annex I. (Art. 3)
- Implement the key notions of the Directive: ambient air, limit value, target value, information threshold, alert threshold and critical level. (Art. 2)
- Take into account the provisions stemming from Directive 2004/107/EC, relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air, which belongs to the air quality legislation. Candidate countries should also take into account the continuance of obligations relating to the preliminary assessments of air quality required under Directive 2004/107/EC. (Recital 4 and 27)
- Establish zones and agglomerations throughout their territory within which air quality assessment and air quality management shall be carried out. (Art. 4).
- Classify each zone and agglomeration in relation to the assessment threshold laid down for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter, lead, benzene and carbon monoxide, taking into account the upper and lower assessment thresholds specified in Section A of Annex II:
 - review classification every 5 years pursuant to procedure in Section B of Annex II;
 - review more frequently if significant changes in activities emitting the regulated pollutants. (Art. 5, AQD)
- Assess the ambient air quality for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter, lead, benzene and carbon monoxide in every zone and agglomeration taking into account the following criteria and the those set out in Annex III:
 - where the level of pollutants exceeds the upper assessment threshold, use of fixed measurements is mandatory. Member States may supplement the fixed measuring with modelling techniques and indicative information to provide adequate information on the spatial distribution of the ambient air quality;
 - where the level of pollutants is below the upper assessment threshold, Member States may use a combination of fixed measurements and modelling techniques and/or indicative measurements;

- where the level of pollutants is below the lower assessment threshold, it is sufficient to use modelling techniques or objective-estimation techniques or both;
- for all zones and agglomerations regardless of pollution level, Member States have to undertake annual measurements at rural background locations to provide information on the total mass concentration and the chemical speciation concentrations of fine particulate matter (PM_{2,5}) pursuant to the following criteria:
 - one sampling point every 100 000 km²;
 - at least one measuring station per Member State or in agreement with Member States, one or several common measuring stations, covering neighbouring zones;
 - where appropriate, monitoring shall be coordinated with the monitoring strategy and measurement programme of the Cooperative Programme for Monitoring and Evaluation of the Long-range Transmission of Air Pollutants in Europe (EMEP);
 - apply the entire Annex IV and sections A and C of Annex I on the data quality objectives for mass concentration measurements of particulate matter. (Art. 6)
- Decide on the number and location of sampling points:
 - decide on the location of sampling points for the measurement of all covered pollutants using the criteria listed in Annex III;
 - minimum number of sampling points for each zone or agglomeration where fixed measurements are the sole source of information for assessing air quality must not be less than the minimum number of sampling points specified in Section A of Annex V;
 - the number of sampling points for zones and agglomerations using a combination of fixed measurement sampling points and modelling and/or indicative measurement may be up to half of total number of sampling points specified in Section A of Annex V where certain conditions are met (see Art. 7(3), AQD) to ensure sufficient information for assessment of limit values and thresholds and information to the public and having regard to the number of sampling points necessary to establish concentration of pollutants in accordance with data quality objectives
 - the results of modelling and/or indicative measurement shall be taken into account for the assessment of air quality with respect to the limit values. (Art. 7)
- Regarding the reporting and information sharing obligations that are detailed in Decision 2011/850/EU, the definitions set out in the Decision should be read also in conjunction with Art. 2 of Directive 2004/107/EC, Article 3 of the INSPIRE Directive (2007/2/EC) and Art. 2 and Annex VII to the AQD.
- Plan the information submission procedures into the new EU repository data system, managed by the European Environmental Agency, ensuring compliance with the procedural requirements on submission and updating of information. (Art. 3, Decision 2011/850/EU)
- Designate a person to make information submissions into the EU repository system pursuant to Decision 2011/850/EU. (Art. 3(5), Decision 2011/850/EU)
- Competent authorities should prepare for change over to information and reporting system set out in Commission Implementing Decision 2011/850/EU laying down rules for Directives 2004/107/EC and 2008/50/EC as regards the reciprocal exchange of information and reporting on ambient air

quality, which applies from 1 January 2014 obliging the Member States to make available a number of information prescribed in Articles 6 and 7.

- Carry out monitoring and share information under Commission Implementing Decision 2011/850/EU laying down rules for Directives 2004/107/EC and 2008/50/EC as regards the reciprocal exchange of information and reporting on ambient air quality.
- In the planning of air quality plans contemplate to include specific measures aiming at the protection of sensitive population groups, including children. (Art. 23)

2.2. Regulation

- Ensure compliance with limit values and critical levels
 - take measures to ensure compliance with limit values for sulphur dioxide, PM10, lead, carbon monoxide, nitrogen dioxide and benzene laid down in Annex XI, taking into account the conditions set out in Annex III and the conditions for assessing the margins of tolerance laid down in Article 22(3) and 23(1). (Art. 13(1));
 - take measures to ensure compliance with the critical levels set out in Annex XIII pursuant to Section A of Annex III. (Art. 14(1));
 - where the levels of pollutants (i.e. of sulphur dioxide, nitrogen dioxide, PM10, PM2,5, lead, benzene and carbon monoxide) in ambient air are below the limit values specified in Annexes XI XIV, Member States shall maintain the levels of those pollutants below the limit values and shall endeavour to preserve the best ambient air quality, compatible with sustainable development. (Art. 12)
- Take all necessary measures to reduce exposure to PM2,5 for the protection of health:
 - to attain the national exposure reduction target laid down in Section B of Annex XIV by the year specified;
 - not to exceed the target value and limit value regarding the concentration of PM2,5 (Section D of Annex XIV and Section E of Annex XIV, respectively, from the date indicated) taking into account assessment criteria in Annex III and the margin of tolerance (Art. 16);
 - ensure that the average exposure indicator for the year 2015 does not exceed the exposure concentration obligation having regard to Sections A and C of Annex XIV;
 - assess the average exposure indicator for PM2,5 (Section A of Annex XIV);
 - ensure that the distribution and the number of sampling points on which the average exposure indicator for PM2,5 is based on Annex III, reflect the general population exposure adequately and that the number is no less than indicated in Section B of Annex V (Art. 15).
- Take all necessary measures to ensure that public is adequately informed in the event of information or alert threshold specified in Section A of Annex XII being exceeded. (Art. 19)
- Take all necessary measures to reduce the concentration of ozone in ambient air

- to attain the target values and long-term objectives (Art.17);
- to prepare a programme pursuant to Art. 6 of NEC Directive (2001/81/EC) and if needed an air quality plan, for zones and agglomerations in which a target value is exceeded to attain target values from the specified date (section B of Annex VII);
- take cost-effective measures, consistent with relevant plans and programmes, to achieve long-term objectives for zones where levels of ozone are higher than long-term objectives but below or equal to target values (Art. 17);
- where the ozone levels meet the long-term objectives, maintain those levels and preserve the best ambient air quality taking a balanced approach to sustainable development, environmental and human health protection (Art. 18)
- Establish air quality plans in case of:
 - the levels of pollutants in ambient air exceed any limit value or target value, plus any relevant margin of tolerance in each case in any given zone or agglomeration. Those plans target the relevant zones and agglomerations and aim at achieving the related limit value or target value specified in Annexes XI and XIV. (Art. 23)
 - exceedances of those limit values for which the attainment deadline is already expired. Those plans must set measures to shorten the exceedance period as much as possible and may include specific measures aiming at the protection of sensitive population groups, including children. (Art. 23)
- Ensure some minimum requirements in the drawing up and implementation of air quality plans:
 - air quality plans shall incorporate at least the information listed in Section A of Annex XV and may include measures pursuant to Article 24. Those plans shall be communicated to the Commission without delay, but no later than two years after the end of the year the first exceedance was observed;
 - where air quality plans must be prepared or implemented in respect of several pollutants, Member States shall, where appropriate, prepare and implement integrated air quality plans covering all pollutants concerned;
 - ensure consistency with other plans required under Directive 2001/80/EC, Directive 2001/81/EC or Directive 2002/49/EC.
- Draw up short-term action plans where there is a risk that the levels of pollutants will exceed alert thresholds set out in Annex XII. It is also possible and advisable (not mandatory) to draw up a short-term action plan where the risk relates to limit values or target values (Annexes VII, XI and XIV) (Art. 24(1))
 - consider whether short-term action plan is necessary for ozone, i.e. whether this plan can significantly reduce the risk, duration and severity of the exceedance;
 - consider Decision 2011/850 in preparing these plans;
 - decide on effective measures to control and, if need be, suspend activities which contribute to the limit values, target values or alert thresholds being exceeded. Consider whether the measures should have a wider focus comprising traffic Regulation, construction works, domestic heating,

- use of industrial plants and whether special measures are needed to protect sensitive population groups (e.g. measures targeting specific public institutions for elderly or children) (Art. 24(2));
- ensure that the public has access to preparatory material during the preparation of the plans as well as is involved in the implementation of the plans. (Art. 24(3))
- Take the necessary measures to address transboundary air pollution and facilitate cross border cooperation on air quality management:
 - determine the existence of exceedances of alert threshold, limit value or target value plus any relevant margin of tolerance or long-term objective due to significant transboundary transport of air pollutants or their precursors and in that case, ensure efficient cooperation in taking efficient measures, including a joint or coordinated air quality plans (Art. 23), to remove exceedances;
 - inform and involve the Commission in this cross-border cooperation, especially in regard to input from reports on results from action under the NEC Directive. (Art. 25(2));
 - Prepare and implement joint short-term action plans for neighbouring zones also providing information about the content of these plans for Member States of such zones which may not be actively cooperating in such plans. (Art. 25(3));
 - To the extent possible involve cooperation with third countries in drawing up of joint or coordinated air quality plans and informing the public. (Art. 25(5))

Case law from the Court of Justice of the European Union

Judgment of the Court of Justice in Case C-237/07 - *Dieter Janecek v Freistaat Bayern*

Pursuant to former Directive 96/62/EC, Member States are to draw up action plans indicating the measures to be taken in the short term where there is a risk that the limit values and/or alert thresholds may be exceeded, in order to reduce that risk and to limit the duration of such an occurrence.

Mr Janecek lives on the Landshuter Allee on Munich's central ring road, approximately 900 metres north of an air quality measuring station. Measurements taken at that station have shown that, in 2005 and 2006, the limit value fixed for emissions of particulate matter was exceeded much more than 35 times. Mr Janecek brought an action for an order requiring the Freistaat Bayern to draw up an air quality action plan in the Landshuter Allee district, so as to determine the measures to be taken in the short term in order to ensure compliance with the maximum permitted number of instances. As his application was dismissed at first instance, Mr Janecek appealed to the Verwaltungsgerichtshof (Higher Administrative Court), which held that residents concerned may require the competent authorities to draw up an action plan, but that they are not entitled to insist that it must include the particular measures that would guarantee compliance in the short term with emission limit values.

Mr Janecek and the Freistaat Bayern appealed to the Bundesverwaltungsgericht (Federal Administrative Court) against that judgment. According to that court, Mr Janecek cannot, under national law alone, rely on any entitlement to have an action plan drawn up. The Bundesverwaltungsgericht asked for preliminary ruling of the CJEU to inquire whether under EU law, an individual can require the competent national authorities to draw up an action plan where there is a risk that the limit values or alert thresholds may be exceeded.

The CJEU held that it is incompatible with the binding effect of the Directive to exclude, in principle, the possibility of the obligation which it imposes being relied on by the persons concerned. Therefore, where there is a risk that the alert thresholds or limit values may be exceeded, persons directly concerned must be in a position to require the competent national authorities to draw up an action plan, even though, under national law, those persons may have other courses of action available to them for requiring the competent authorities to take measures to combat atmospheric pollution.

However, pursuant to the judgement the Member States are not obliged to take measures to ensure that the limit values or alert thresholds are never exceeded. They are obliged, subject to judicial review by the national courts, only to take such measures in the short term in an action plan as are capable of reducing to a minimum the risk that the limit values or alert thresholds may be exceeded and of ensuring a gradual return to a level below those values, taking into account the factual circumstances and all opposing interests.

For the entire judgment consult: <http://curia.europa.eu/juris/liste.jsf?language=en&num=C-237/07>

2.3. Monitoring

- Ensure that the location of sampling points for the measurement of sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter (PM₁₀, PM_{2.5}), lead, benzene and carbon monoxide in ambient air is based on the criteria listed in Annex III. (Art. 7(1))
- Ensure that the number of sampling points in each zone or agglomeration is in compliance with Art. 7:
 - ensure that in each zone or agglomeration where fixed measurements are the sole source of information for assessments, the number of sampling points for each relevant pollutant shall not be less than the minimum number of sampling points specified in Section A of Annex V. (Art. 7(2));
 - ensure that for zones and agglomerations where fixed measurements are combined with information from modelling and/or indicative measurement, that the total number of sampling points specified in Section A of Annex V may only be reduced by up to 50 %, provided that the following conditions set out in Art. 7(3) are met. (Art. 7(3))
- Install, as a minimum, one rural background station every 100 000 km² for measuring PM_{2.5} in order to get data on the total mass concentration and the chemical specification. (Art. 6(5)). Member States may decide to with adjoining Member States, together, set up one or several common measuring stations (also see the Commission Staff Working Paper establishing guidelines for the agreements on setting up common measuring stations for PM_{2.5} under Directive 2008/50/EC on ambient air quality and cleaner air for Europe¹²³).
- Apply the reference measurement methods and criteria specified in Section A and Section C of Annex VI or where conditions of Section B of Annex VI are met, use other measurement methods. (Art. 8)
- Ensure that where fixed measurements are exclusively used the number of sampling points should be in accordance with Section C of Annex V. Where there is a combination of measurements, the number of sampling points may be reduced. (Art. 14(2))
- The application in Member States of the criteria for selecting sampling points shall be monitored by the Commission so as to facilitate the harmonised application of those criteria throughout the EU. (Art. 7(4))
- Carry out monitoring and share information under Decision 2011/850/EC regarding air pollutants listed in Annex I. This monitoring shall mainly cover measurement stations established to monitor air pollution;

Obligations regarding ozone assessments and sampling

- Ensure sufficient assessment of ground-level ozone to determine whether long-term objectives are being met following the below criteria:

¹²³ http://ec.europa.eu/environment/air/quality/legislation/pdf/sec_2011_77.pdf

- fixed measurements are mandatory if concentrations of ozone have exceeded the long-term objectives specified in Section C of Annex VII during any of the previous five years;
- if it is impossible to establish whether the long term objectives have been exceeded simply on the basis of the fixed measurements in the case of data scarcity during the last five years, supplement fixed measurements with emission inventories and modelling. (Art. 9)
- Establish the appropriate number and siting of sampling points
 - site of sampling points for ozone should be in accordance with Annex VIII, Section A or Section B (where concentrations have been below the long-term objective for five consecutive years) of Annex IX;
 - where fixed measurements are supplemented with modelling and/or indicative measurements the number of sampling points can be reduced provided that conditions in Article 10(3) are met (e.g. ensuring sufficient information to assess whether target values, long-term objectives information and alert thresholds are being met, whether the spatial resolution is sufficient, ensuring at least one sampling point per two million inhabitants or one sampling point per 50 000 km², may not be less than one sampling point in each zone or agglomeration and that nitrogen dioxide is measured at all remaining sampling points except at rural background stations. (Art. 10(1), (2), (3) and (5));
 - each Member States must install and operate at least one sampling point in its territory to supply data on concentrations of the ozone precursor substances listed in Annex X having regard to the objectives and methods laid down in the same annex. (Art. 10(6));
 - nitrogen dioxide shall be measured at a minimum of 50 % of the ozone sampling points required under Section A of Annex IX. That measurement shall be continuous except at rural background stations, as referred to in Section A of Annex VIII, where other measurement methods may be used. (Art. 10(4))
- Apply the reference measurement methods set out in point 8 of Section A of Annex VI or alternative methods provided that they comply with Section B of Annex VI. (Art. 11(1))

2.4. Information and Reporting

- Ensure that the public including appropriate organisations such as environmental organisations, consumer organisations, organisations representing the interests of sensitive populations, other relevant health-care bodies and the relevant industrial federations receive sufficient and timely information, regarding:
 - ambient air quality (Annex XVI);
 - any postponement Decisions (Art. 22(1));
 - any exemptions (Art. 22(2));
 - air quality plans (Art. 22(1), Article 23) and programmes (Art. 17(2));

- information by means of radio, TV, newspapers or the Internet regarding the exceedance or exceedances of information thresholds (Annex XII) or alert thresholds observed (place, type of threshold, time and duration of the exceedance, highest concentration observed) (Art. 19);
- forecasts for the following hours and days;
- information on the type of population concerned, possible health effects and recommended behaviour;
- information on preventative measures and measures to reduce the emissions;
- annual reports for all pollutants, summarising the levels exceeding limit values, target values, long-term objectives, information thresholds and alert thresholds, for the relevant averaging periods including summary assessment of the effects of those exceedances and various forecasts and assessments;
- the competent authority designated for ambient air quality assessment. (Art. 26)
- Ensure that information is provided free of charge and in an easily accessible media, taking into account the INSPIRE Directive (Directive 2007/2/EC) in terms of spatial data format. (Art. 26)
- Member States must nominate a person or persons responsible for the delivery on its behalf to the data repository of each reported and exchanged information and inform the Commission thereof (Art. 3(5), (6), Decision 2011/850/EU);
- Ensure that the database and information system is fully compliant with Decision 2011/850/EU regarding the procedure and data relevant for the EU data repository, operated by the European Environmental Agency on behalf of the Commission;
- Ensure compliance with the procedure set out in Art. 5 of the Decision 2011/850/EU regarding the manner of making information available to the data repository, which has to be in accordance with the Part A of Annex I and be automatically processed by an electronic tool aiming at facilitating check of consistency, correspondence with data quality objectives and aggregation of primary data. This procedure must also be used for information updates;
- Ensure that information on ambient air quality is made available to the Commission within the required timescale as determined by the Decision 2011/850/EU (Art. 27); In this context, ensure that all required information listed below is submitted to the data repository:
 - information on zones and agglomerations, indicating possible temporary derogations under Art. 22 of the AQD. This information has to be made available to the Commission no later than 31 December of each calendar year (Part B of Annex II, Article 6);
 - information on the assessment regime. This information has to be provided to the Commission no later than 31 December of each calendar year (Part C of Annex II, Article 7);
 - methods for the demonstration and subtraction of exceedances attributable to natural sources or to winter- sanding or –salting (referring to Arts. 20-21 of the AQD). This information has to be made available to the Commission for a previous calendar year by end of September at the latest of the following year. (Part D of Annex II, Art. 8);
 - information on the quality and traceability of the assessment methods, to be made available to the Commission for a full calendar year by latest September of the following year. Where fewer

than five years' data are available, Member States may, for the purposes of determining whether the long-term objectives referred to in paragraph 1 have been exceeded during those five years, combine the results from measurement campaigns of short duration carried out when and where levels are likely to be at their highest, with the results obtained from emission inventories and modelling (Article 9(2), AQD);

- information on primary validated assessment data and primary up-to-date assessment data, ensuring the highest possible resolution in case of modelling techniques being used. Information on contribution from natural sources from winter-sanding or salting of roads have to be specified with supplementary information. In addition, primary up-to-date assessment data and primary validated assessment data for the networks and stations selected by the Member States for the specific purpose of making has to be made available amongst the networks and stations selected by the Member States for the purpose of the reciprocal exchange of information. This information has to be made available to the Commission for a full calendar year by latest September of the following year (Art. 10, Part E of Annex II)
- information on the attainment of environmental objectives, to be made available to the Commission for a full calendar year by latest September of the following year. This information shall include a declaration of attainment of all environmental objective in each zone or agglomeration and information on exceedance of any applicable margin of tolerance, declaration of exceedances attributable to natural sources or to the re-suspension of particulates due to winter-sanding or –salting of roads, information on the attainment of PM_{2,5} exposure concentration target, where exceedance occurred information on areas of exceedances and number of people exposed (G, Annex II, Article 12);
- information on air quality plans, e.g. the mandatory elements, references to places where the public has access to information on implementation of the plans. This information has to be made available to the Commission no later than 2 years after the end of the calendar year in which the first exceedance was observed. (Parts H, I, J and K, Annex II and Art. 23, AQD), Articles 13 and 14)
- Further ensure that the Commission is informed about:
 - texts of the main provisions of national law adopted in the field covered by the Directive (Art. 33(1) AQD);
 - information concerning levels recorded and duration during which alert thresholds or information thresholds were exceeded (Art. 19(2), AQD);
- Ensure that competent authorities of other Member States are informed about:
 - the preparation and implementation of joint short-term action plans for neighbouring zones (Art. 25(3), AQD);
 - inform the competent authorities in the neighbouring Member States concerned in case of the information threshold or alert thresholds being exceeded in zones or agglomerations close to national borders.

The guidelines on how to report are available at EIONET Air Quality Portal <http://www.eionet.europa.eu/aqportal>

2.5. Additional Legal Instruments

A number of other legal instruments are relevant to the AQD and the implementing Decision 2011/850, which should be borne in mind in implementation. These instruments may be grouped into the areas of (a) product control and material handling; (b) emissions standards for stationary sources; (c) emissions standards for mobile sources; (d) ambient air quality standards (limit values and target values); and (e) monitoring and information exchange.

- Product control and material handling:

Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC, as amended by Commission Directives 2000/71/EC, 2011/63/EU, 2014/77/EU, Directives 2003/17/EC, 2009/30/EC, (EU) 2015/1513 and Regulation (EC) 1882/2003;

European Parliament and Council Directive 94/63/EC of 20 December 1994 on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations, amended by Regulations (EC) 1882/2003 and (EC) 1137/2008;

Directive 2009/126/EC of the European Parliament and of the Council of 21 October 2009 on Stage II petrol vapour recovery during refuelling of motor vehicles at service stations, amended by Commission Directive 2014/99/EU;

Council Directive 87/217/EEC of 19 March 1987 on the prevention and reduction of environmental pollution by asbestos, amended by Council Directive 91/692/EEC and Regulation (EC) 807/2003;

Regulation (EC) 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer, as amended by Commission Regulations (EU) 744/2010, (EU) 1087/2013 and (EU) 1088/2013;

- Emissions standards for stationary sources:

Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions;

Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances;

Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC, amended by Regulation (EC) 1137/2008, Directive 2008/112/EC and Commission Directive 2010/79/EU;

Regulations for certain product groups such as central heaters, local room heaters and water heaters developed under the Ecodesign and Energy Labelling Framework Directives (2009/125/EC and 2010/30/EU respectively):

Commission Regulation (EU) 2015/1189 of 28 April 2015 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for solid fuel boilers

Commission Regulation (EU) 2015/1188 of 28 April 2015 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for local space heaters

Commission Regulation (EU) 2015/1185 of 24 April 2015 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for solid fuel local space heaters

Commission Regulation (EU) No 813/2013 of 2 August 2013 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for space heaters and combination heaters

Commission Regulation (EU) No 814/2013 of 2 August 2013 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for water heaters and hot water storage tanks

Commission Delegated Regulation (EU) No 1254/2014 of 11 July 2014 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to energy labelling of residential ventilation units

Commission Delegated Regulation (EU) No 811/2013 of 18 February 2013 supplementing Directive 2010/30/EU of the European Parliament and of the Council with regard to the energy labelling of space heaters, combination heaters, packages of space heater, temperature control and solar device and packages of combination heater, temperature control and solar device

- Emissions standards for mobile sources:

Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC, as amended by Commission Directives 2000/71/EC, 2011/63/EU, 2014/77/EU, Directives 2003/17/EC, 2009/30/EC, (EU) 2015/1513 and Regulation (EC) 1882/2003;

Directive 2009/40/EC on roadworthiness tests for motor vehicles and their trailers, amended by Commission Directive 2010/48/EU;

- Standards for engines and vehicles:

Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information, amended by Commission Regulations (EC) 692/2008, (EU) 566/2011, (EU) 459/2012 and Regulation (EC) 595/2009;

Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, as amended by Commission Directives 2001/63/EC, 2010/26/EC, 2012/46/EU, Directives 2002/88/EC, 2004/26/EC, 2011/88/EU, Council Directive 2006/105/EC and Regulation (EC) 596/2009;

- Ambient air quality standards

Directive 2001/81/EC of the European Parliament and of the Council of 23 October 2001 on national emission ceilings for certain atmospheric pollutants, amended by Council Directive 2006/105/EC, 2013/17/EU and Regulation (EC) 219/2009;

Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air, amended by Regulation (EC) 219/2009 and Commission Directive (EU) 2015/1480;

- Monitoring and information exchange

Regulation (EU) No 525/2013 of the European Parliament and of the Council of 21 May 2013 on a mechanism for monitoring and reporting greenhouse gas emissions and for reporting other information at national and Union level relevant to climate change and repealing Decision No 280/2004/EC

Decision 86/277/EEC on the conclusion of the protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on the long-term financing of the programme for the monitoring and evaluation of the long-range transmission of air pollutants in Europe (EMEP)

Commission Decision of 29 July 1996 concerning the questionnaires provided for in Council Directives 80/779/EEC, 82/884/EEC, 84/360/EEC and 85/203/EEC (96/511/EC);

Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE)

Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC

- Eco-design and energy labelling

Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products, amended by Directive 2012/27/EU;

Directive 2010/30/EU of the European Parliament and of the Council of 19 May 2010 on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products, amended by Directive 2012/27/EU;

- International Conventions

Convention on Long-range Transboundary Air Pollution (LRTAP Convention) (1979)

LRTAP Convention Protocol to Abate Acidification, Eutrophication and Ground-Level Ozone (1999)

LRTAP Convention Protocol on Persistent Organic Pollutants (POPs) (1998)

LRTAP Convention Protocol on Heavy Metals (1998)

LRTAP Convention Protocol on Further Reduction of Sulphur Emissions (1994)

LRTAP Convention Protocol Concerning the Control of Emissions of Volatile Organic Compounds or their Transboundary Fluxes (1991)

LRTAP Convention Protocol Concerning the Control of Nitrogen Oxides or Their Transboundary Fluxes (1988)

LRTAP Convention Protocol on the Reduction of Sulphur Emissions or their Transboundary Fluxes by at least 30 per cent (1985)

LRTAP Convention Protocol on Long-term Financing of the Cooperative Programme for Monitoring and Evaluation of the Long-Range Transmission of Air Pollutants in Europe (EMEP) (1984)

Convention on Environmental Impact Assessment in a Transboundary Context (Espoo Convention) (25 February 1991)

The Vienna Convention for the Protection of the Ozone Layer (1985)

Montreal Protocol to the Vienna Convention on Substances That Deplete the Ozone Layer (1987)

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1989)

Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Aarhus) (1998)

MARPOL Convention of the International Maritime Organisation, Annex VI

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the checklist below.

They are organised in chronological order of implementation wherever possible.

Table 8. Key Implementation Tasks

THE AIR QUALITY FRAMEWORK DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	<p>Identify the key stakeholders, public bodies and organisations (e.g. environmental organisations, consumer organisations, civil society organisations that will have to be involved in planning and implementation of the AQD and in particular are recipients of various information about the ambient air quality and measures taken to improve or maintain the quality.</p> <p>Also involve the key actors and stakeholders and arrange discussions between them on specific issues such as the choice of a competent authority and the identification of likely "hotspots" (areas where air pollution is worse). Take a wide definition to the notion stakeholders involving various organisations representing environmental, health and consumer interests.</p>
1.2	<p>Designate a competent authority to implement the requirements of the Directive and ensure that it complies with Section C of Annex I. The responsibilities of the authority would include:</p> <ul style="list-style-type: none"> • assessing ambient air quality; • approving measuring devices; • ensuring accuracy of measurements; • analysing assessment methods; • co-ordinating quality-assurance programmes; • ensuring compliance with air quality standards, including establishing the role of local authorities; • vehicle approval and inspection authorities; fuel-producing industries; trading standards organisations; pollution licensing bodies and other ministries; • consulting with other Member States; • reporting to the EU data repository system; • arrangements for reporting on air quality monitoring and on the implementation of the Directive.
1.3	<p>Ensure strengthening of the capacity and knowledge of CA to ensure compliance with the information and reporting system set out in Commission Implementing Decision 2011/850/EU laying down rules for Directives 2004/107/EC and 2008/50/EC as regards the reciprocal exchange of information and reporting on ambient air quality, which apply from 1 January 2014. Designate a person to make information submissions into the EU repository system pursuant to Decision 2011/850/EU (Art. 3(5), Decision 2011/850/EU).</p>
1.4	<p>Assess the ambient air quality for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter, lead, benzene and carbon monoxide in every zone and agglomeration taking into account the following criteria and the those set out in Annex III using the method of measurements indicated (i.e. fixed measurements, indicative measurement and modelling).</p>
1.5	<p>Decide on number and location of sampling points in accordance with established criteria (Annex III, V) depending on method of measurements.</p>
1.6	<p>Establish a system to divide the territory into zones and agglomerations, and prepare list of zones and agglomerations. This should include zones for ecosystem protection (against SO₂ pollution) and for the protection of vegetation (against NO_x pollution).</p>
1.7	<p>Establish a system to designate zones or agglomerations within which assessment thresholds for the purpose of assessing ambient air quality.</p>

1.8	Classify each zone and agglomeration in relation to the assessment threshold laid down for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter, lead, benzene and carbon monoxide, taking into account the upper and lower assessment thresholds specified and review the classification in case of changes or no later than every five years
1.9	Introduce Regulations to implement the limit and target values set out in the Directive.
1.10	Establish a system for the collection of data on ambient concentrations of the relevant pollutants. The system should enable information to be regularly updated and made available to the Commission, the public and appropriate organisations. Information should include: <ul style="list-style-type: none"> • the occurrence of pollutant levels that exceed the limit value (or exceed the limit value plus the margin of tolerance); • the periods when such levels occurred; • the reasons for the exceedance; • plans to achieve compliance with the limit value (this is an irregular task); • any exceedances of the target value for ozone (this is an irregular task); • the methods used for the preliminary assessment of air quality (this is a single task); • standards set for any other pollutants, and any measures adopted which are more stringent than those specified by the Directive (this is a single or infrequent task).
1.11	Ensure that the number and location of sampling points is sufficient to guarantee accurate results and adequate ambient air quality assessment and management.
2	Regulation
2.1	Draw up a list of zones and agglomerations in which the levels of pollutants are below the limit values, and take measures to maintain the best ambient air quality in these zones that is compatible with sustainable development.
2.2	Draw up a list of zones and agglomerations in which the levels of pollutants are above the limit values (including a list of zones and agglomerations in which the levels of pollutants are between the limit value and the limit value plus the margin of tolerance).
2.3	Ensure compliance with limit values and critical levels.
2.4	Take all necessary measures to reduce exposure to air pollutants for the protection of health.
2.5	Take all necessary measures to reduce the concentration of ozone in ambient air including attaining the target values and long-term objectives through preparation of programme referred to by NEC Directive, taking cost-effective measures.
2.6	Where thresholds are exceeded due to transboundary transport of air pollutants, the Member States concerned shall cooperate and coordinate their work in order to remove the exceedance.
2.7	Ensure that appropriate measures to inform the public are taken in case of information or alert threshold being exceeded.
3	Monitoring
3.1	Establish an ambient air quality monitoring programme. This should include sampling and analytical methodologies and could include modelling techniques to supplement monitoring.
3.2	Define the locations at which preliminary assessment is to be undertaken.
3.3	Set up suitable quality assurance and technical advice and guidance for the air quality assessment/monitoring programme, to include third-party accreditation for the analytical services.
3.4	Where there are no representative measurements for all zones and agglomerations, undertake a preliminary assessment of air quality.
3.5	Carry out preliminary assessment of air quality throughout the territory of the Member State. This is to be done by monitoring in agglomerations and in zones where limit values are approached or exceeded.
3.6	Carry out monitoring and share information under Decision 2011/850/EU, using the guidelines provided at Air Quality Portal http://www.eionet.europa.eu/aqportal
3.7	Provide for monitoring and compliance activities to be linked to database development and updating processes for Commission Decision 2011/850/EU reporting purposes.
3.8	Take the necessary measures to address transboundary air pollution and facilitate cross border cooperation on air quality management: <ul style="list-style-type: none"> • determine the existence of exceedances of alert threshold, limit value or target value plus any relevant margin of tolerance or long-term objective due to significant transboundary transport

	<p>of air pollutants or their precursors and in that case, ensure efficient cooperation in taking efficient measures, including a joint or coordinated air quality plans (Art. 23), to remove exceedances;</p> <ul style="list-style-type: none"> • inform and involve the Commission in this cross-border cooperation, especially in regard to input from reports on results from action under the NEC Directive (2001/81/EC) (Art. 25(2), AQD); • prepare and implement joint short-term action plans for neighbouring zones also providing information about the content of these plans for Member States of such zones which may not be actively cooperating in such plans (Art. 25(3), AQD); • to the extent possible involve cooperation with third countries in drawing up of joint or coordinated air quality plans and informing the public.
3.9	Ensure sufficient assessment of ground-level ozone to determine whether long-term objectives are being met following the prescribed criteria regarding use of fixed measurements and supplementing modelling and emission inventories.
3.10	Establish the appropriate number and siting of sampling points considering the choice of measurement methods and the combination of fixed measurements, modelling, indicative measurements and emission inventories.
3.11	Apply the reference measurement methods set out or alternative methods in compliance with the provisions of AQD.
4	Plans and Programmes
4.1	<p>Establish air quality plans in case of:</p> <ul style="list-style-type: none"> • the levels of pollutants in ambient air exceed any limit value or target value in each case in any given zone or agglomeration. Those plans target the relevant zones and agglomerations and aim at achieving the related limit value or target value specified • exceedances of those limit values for which the attainment deadline is already expired. <p>Those plans must set measures to shorten the exceedance period as much as possible and may include specific measures aiming at the protection of sensitive population groups, including children.</p>
4.2	Ensure that the drawing up and implementation of air quality plans cover the required information, take an integrative approach to the various pollutants, are consistent with plans required under the NEC Directive
4.3	<p>Draw up short-term action plans where there is a risk that the levels of pollutants will exceed alert thresholds (Annex XII) and also contemplate short-term action plans where the risk relates to limit values or target values (Annexes VII, XI and XIV).</p> <p>These actions plans can in particular suspend activities which contribute to the risk of exceedance (motor-vehicle traffic, construction works, the use of industrial plants etc.) These action plans may include specific measures aimed at the protection of sensitive population groups, in particular children.</p>
4.4	In the event of exceedances of those limit values for which the attainment deadline is already expired, the air quality plans shall set out appropriate measures, so that the exceedance period can be kept as short as possible and can include additional specific measures to protect sensitive population groups. Measures similar to those laid down in short-term action plans may be considered.
5	Consultation and Reporting
5.1	Ensure that information on ambient air quality is made available to the Commission within the required timescale as required by Decision 2011/850/EU.
5.2	<p>Ensure that competent authorities of other Member States are informed about:</p> <ul style="list-style-type: none"> • inform Member States about the preparation and implementation of joint short-term action plans for neighbouring zones (Art. 25(3), AQD); • inform the competent authorities in the neighbouring Member States concerned in case of the information threshold or alert thresholds being exceeded in zones or agglomerations close to national borders.
5.3	Ensure that the public including appropriate organisations such as environmental organisations, consumer organisations, organisations representing the interests of sensitive populations, other relevant health-care bodies and the relevant industrial federations receive sufficient and timely information.
5.4	Report to the Commission the texts of the provisions of national law adopted to implement the Directive.

3.2. Phasing Considerations

The required financial resources need to be estimated and allocated before any other activities can start.

A quality-assurance system should be set up before devoting resources to atmospheric dispersion modelling and to monitoring, in order to ensure that these activities produce results of known reliability. Technical training, support and guidance should accompany the quality-assurance system.

A monitoring programme should be set up as soon as possible after the precise monitoring requirements have been identified and financial resources have been made available. Clearly, a basic initial monitoring programme can be expanded in the light of assessment results. Ideally, the locations of monitoring sites should be determined on the basis of modelling results.

Where ambient air monitoring is already being carried out, it should be reviewed at national level to evaluate the extent to which each monitoring site complies with the requirements of the Directive. This review should take into account at least the location of each site, the method(s) used and the pollutant(s) monitored. Some sites may not comply with the requirements of the Directive: consideration should, however, be given to continuing the operation of some or all of such sites, with upgrading where possible, in order to identify any long-term trends in air quality.

In any case, only after quality-assured assessments of air quality have been produced should plans and programmes be drawn up. Implementation of these plans and programmes will be the most expensive and time-consuming part of achieving compliance with the Directive. The likely approximate time periods are considered in the fiches dealing with individual pollutants. There can be a certain amount of overlap between the assessments and the plans and programmes: plans to deal with serious and obvious breaches (exceedances) of air quality limit values may be prepared even before all assessments have been completed, provided that it is certain that it will not be necessary to reformulate any of the plans after more information has been obtained. This consideration applies mainly to significant local sources of air pollution.

4. IMPLEMENTATION GUIDANCE

Candidate countries are advised to implement the AQD and the fourth daughter Directive, and to check developments related to e-reporting, new guidance (notably for Decision 2011/850/EU) and a recent revision of the AQD. The AQD focuses on the maintenance and improvement of air quality with respect to the following eight pollutants:

- sulphur dioxide;
- nitrogen dioxide;
- suspended particulate matter (PM10 and PM2.5);
- suspended particulate matter;
- lead;
- ground level ozone;
- benzene;
- carbon monoxide.

Directive 2004/107/EC regulates the remaining pollutants in Annex I of the AQD, i.e. mercury, cadmium, arsenic, nickel and polycyclic aromatic hydrocarbons – making it 13 pollutants in total. The thresholds take the form of a number of different values whose purposes are defined in the Directive:

- a "limit value" (for sulphur dioxide, PM10, lead, carbon monoxide, nitrogen dioxide and benzene);
- a "target value";
- an "alert threshold";
- "critical levels";
- a "margin of tolerance".

The Directive allows Member States to set more stringent limit values than the minimum values established at EU level and to have short-term action plans covering an extended range of measures and activities. The candidate countries and their competent authority need to decide on the various possibilities as well as on temporary derogations to be negotiated during the accession process. Also another important issue to consider is whether it would be more efficient to have a large part of the air quality management and monitoring implemented in cooperation with a neighbouring EU country. This is particularly relevant in case of polluting activities in border areas, for smaller countries (cost-efficiency reasons). Hence, the candidate countries will have a significant margin of discretion in the ambient air quality management, provided that they promptly inform the Commission in advance and ensure continuous cooperation with the Commission and all relevant parties.

4.1. Planning

- At the earliest stage of implementation, it is necessary to identify key actors and stakeholders including various environmental, health, consumer organisations, which are more powerful in representing the interest of their members and the general public overall, who will be involved in or impacted by the implementation of the AQD and Decision 2011/850/EU. Discussion, consultation and involvement with them should focus on issues such as the choice of a competent authority, identifying problematic zones or agglomerations, the most relevant mobile and fixed sources of pollution in each area and the possibility to adopt supplementary cost-effective measures such as fiscal measures, taxes etc. Identification of, and initial discussion with, all potential stakeholders will help to achieve the most efficient path to approximation, to avoid costly errors (for example, in drafting legislation and regulations and in setting up institutions) and to encourage the co-operation of stakeholders in complying with the national legal instruments.
- The competent authority would probably be the ministry with responsibility for environmental protection in close co-operation with the ministry of health, whereas certain implementing obligations could fall under the competency of the national environmental protection agency. The authority needs to be able to take a nationwide view of the issues, co-ordinate nationwide actions, and report on a nationwide basis. It is important to have effective co-ordination between the competent authority with the primary responsibility for the implementation of this Directive, and the one responsible for the implementation of the IED Directive (2010/75/EU) but also with authorities responsible for road and maritime transport.
- The appropriate institution(s) to undertake air quality assessment for the thirteen above-listed pollutants may be a government laboratory, a regional or local authority, a private company, or a combination of these.
- Consider whether to take use of derogations regarding natural contributions to high pollution levels and the effect of re-suspension of particulates on PM values to due sanding and salting of winter roads. In this exercise candidate countries are advised to consult the the notifications of time extensions submitted by Member States and a list of Air Quality zones in which exceedances of PM10 and NO2 have been reported for the year 2011 including the results of the request of time extension notification (available at: http://ec.europa.eu/environment/air/quality/legislation/time_extensions.htm)
- The data collection and requirements on data quality and reporting procedures according to the new Decision 2011/850/EU has to be discussed and planned accordingly which might require investments in new software, training of IT and information processing staff.

Examples in a Member State

Sweden: An ambient air guide was published in 2011 by the Swedish National Protection Agency. This handbook updates an earlier version from 2006. The principal aim of the handbook is to support the municipalities in their implementation and supervision of environmental quality norms for ambient air. This revised handbook integrates the new provisions from the AQD, which has been implemented through the Air Quality Ordinance (Luftkvalitetsförordning (2010:477) och the EPA Regulation on Control of Air Quality (Naturvårdsverkets föreskrifter om kontroll av luftkvalitet (2010:8)). The handbook provides extensive guidance from application procedures to assessment, supervision and compliance with the information and reporting procedures also comprising how to develop programmes of measures. The Handbook reflects the policy change from mid-2010 and gives the overall structure for environmental protection work in Sweden. Some of the changes include some modifications of the environmental objectives and their implementation at national, regional and local levels as well as extended competences for the EPA in the coordination of public authorities' implementation of environmental objectives.

Source: Naturvårdsverket, Luftguiden – handbok om miljökvalitetsnormer (Guidance on Ambient Air – Handbook on environmental quality norms), 2011:1, edition 1, January 2011 (<http://www.naturvardsverket.se/Start/Om-Naturvardsverket/Vara-publikationer/ISBN1/0100/978-91-620-0171-1/>)

4.2. Assessment and Classification

- When defining the locations at which preliminary assessment is to be undertaken, it should be noted that the Directive requires that the preliminary assessment of air quality should include all "zones and agglomerations" (an agglomeration being a zone with a population exceeding 250,000 or with a high population density). In general, monitoring sites should include a mixture of different types of sites such as urban, rural and industrial zones. It is not necessary for all pollutants to be monitored at all stations. In allocating resources to monitoring, priority could be given to a monitoring network for pollutants 1 to 6 as numbered in Subsection 4.1, whilst other pollutants could be monitored at a smaller number of sites.
- The purpose of the preliminary assessment of air quality is to obtain representative values by means of measurements, surveys or assessments of the concentrations of the thirteen pollutants, prior to the implementation of the daughter Directives.
- The assessment of air quality throughout the territory of the Member State is to be done by monitoring in agglomerations and in zones where limit values are likely to be reached or exceeded. The Directive allows, but does not require, for a mixture of monitoring and modelling, or modelling only, to be used to assess air quality in zones where concentrations are less than prescribed levels or lower than the limit value. It is important to emphasise that the Directive does not oblige the use of modelling but gives an option to use this as a complementing method

- The assessment/monitoring programmes may be conducted by the competent authority, or by one or more other organisations appointed for the purpose, either from the public or the private sector. In either event, a third party should be appointed to verify the monitoring methodology and to provide independent accreditation of the assessment (modelling, sampling and analytical) techniques used.
- A variety of monitoring (sampling and analysis) and other assessment techniques (modelling) will be appropriate for the thirteen different pollutants covered by the Directive. The monitoring techniques required would depend on the way in which the air quality limit values are expressed (e.g. hourly, daily or annual and in the case for PM10 percentile under certain conditions). Continuous monitoring provides the most complete method of analysis, but there is also likely to be a role for simpler methods such as diffusion tubes, which can monitor long-term average concentrations of sulphur dioxide and nitrogen dioxide at many sites at a relatively low cost. Mobile laboratories can be valuable in providing indicative baseline data, including identifying suitable locations for fixed monitoring stations. It is undesirable to move fixed stations, because that makes it much more difficult to evaluate reliably trends in air quality over time. Ideally, the locations of fixed monitoring stations should be determined by modelling, which itself can be done relatively quickly, in a matter of weeks, once input data are available.
- The Directive allows assessment of air quality to be undertaken partly or wholly by modelling or other objective estimation techniques in zones where pollutant levels are below the limit value, which are set by the Commission. This is likely to provide a more economical approach than comprehensive monitoring, since models can calculate air quality at hundreds of sites at a lower cost than that for a single set of measurements. However, calibration of results from modelling techniques will require some monitoring to be undertaken for all pollutants. Thus, few monitoring stations will always be needed.
- Take into account provisions of the Directive (EU) 2015/1480 laying down rules concerning reference methods, data validation and location of sampling points for the assessment of ambient air quality.

Examples of Monitoring Practice in Member States

France: In France monitoring of ambient air quality is solely the responsibility of local authorities. In another Member State (SE), the municipality operates monitoring sites within cities, while the government operates rural background sites. In a third Member State (UK), the main national monitoring network is the responsibility of the government, while local authorities carry out additional localised monitoring. In a fourth Member State (PT), local commissions conduct monitoring in five cities, (while regional directorates are responsible for other areas). In a fifth Member State (DK), the national network is the responsibility of the National Environmental Research Institute, an independent body that is part of the government.

4.3. Plans and Programmes to Achieve Compliance

- Candidate countries should keep fully up to date with all proposed new implementing measures adopted under the AQD, supplementing Decision 2011/850/EU on the electronic reporting system

and other documents such as the IPR guidance¹²⁴, which can assist in determining whether they qualify for temporary derogations, when to rather opt for joint air quality plans, how to efficiently inform the public etc. It is advisable to coordinate the air quality plans with NEC measures and other assessment and planning measures under other sectoral legislation (e.g. industrial and waste management). It is essential to review the air quality plans and the zoning to ensure that they reflect reality and are sufficiently effective to achieve and maintain overall good ambient air quality. Such an approach will also facilitate the quick adaptation to updated more stringent limit and target values.

- In the event that monitoring shows areas in which the limit values for specified pollutants in air are exceeded, achieving compliance will require a number of different measures and approaches in which the candidate countries have some flexibility and margin of appreciation. Firstly, the principal sources of atmospheric pollution leading to exceedance need to be identified. Sometimes this can be done by correlating measured concentrations and wind direction. These will almost certainly be different in the case of each pollutant, but in general may include emissions from industry, power stations, road vehicles and domestic heating equipment. It may be necessary to set up detailed emission inventories to supply input data to models used to evaluate various plans or scenarios to improve or maintain air quality. Also source apportionment will be necessary.
- Ozone is a special case amongst the pollutants covered by the Directive in that it is a secondary pollutant, formed from the action of sunlight on precursors (mainly volatile organic compounds and oxides of nitrogen). The reactions by which ozone is formed take place over a period of days and are influenced by emissions of primary pollutants over scales of many hundreds of kilometres. It therefore follows that co-operation between Member States is required to address the causes of ozone pollution.
- Plans and programmes to bring pollutant concentrations below limit values will need to adopt a number of approaches. They need to be integrated, in the sense that all pollutants of concern are addressed, and also need to ensure that account is taken of the need to protect other environmental media, such as land and water, from increases in pollution. Plans and programmes must be carefully prepared because they will entail high costs during their subsequent implementation.
- The types of mechanism that may be used to reduce pollution emissions include:
 - controlling or suspending polluting activities (for example, motor vehicle traffic) to control pollution levels during short-term events when limit values or alert thresholds for pollutants are in danger of being exceeded;
 - regulation of either emission levels or the type of installations allowed, using either existing or new legislation;
 - economic incentives, such as differential taxation or subsidies, to encourage reductions in emissions, for example through fuel substitution; and
 - closure of installations that cannot meet the emission standards necessary to comply with ambient air quality limits.

¹²⁴ IPR is an acronym for Implementing Provisions on Reporting. IPR guidance is available at <http://ec.europa.eu/environment/air/quality/legislation/reporting.htm>

- There is likely to be a division of responsibilities for the control of different emission sources. In many countries, control of stationary industrial sources is divided between a national authority, typically the environmental protection agency, which has responsibility for IED/IPPC, and regional or local authorities. Domestic boilers and some other combustion appliances are regulated at EU level (Ecodesign Directive and its implementing regulations) or by the department of industry, and there may also be a role for the ministry of finance in establishing economic subsidies for appliance replacement. Control of the emissions from mobile sources is likely to be organised at national level for type-approvals, with national organisation and local testing stations for inspections and tests. Fuel quality inspections need to be carried out at national and local level. Control of traffic is likely to be done at the local level. There is a need for the various agencies involved in achieving compliance to work together, and for their respective contributions to be co-ordinated by the competent authority. This co-ordinating role should include setting emission standards for different classes of polluters, which the individual authorities will be expected to enforce. The responsibilities of different organisations must be clearly set out, agreed upon and fulfilled.
- Take into account the collection of best practices for the drawing-up of short-term action plans, including examples of best practices for the protection of sensitive population groups, including children prepared by the Commission¹²⁵. Projects are on-going to help dissemination of good practice and these could be helpful for developing air quality plans.

¹²⁵ available at: http://ec.europa.eu/environment/air/quality/legislation/pdf/SC5_Task%201_report.pdf

Example from a Member State

The Netherlands: On 12 June 2008 the Minister of the Environment and Spatial Planning, the Association of Provincial Authorities and the Association of Netherlands Municipalities adopted an Action Plan on Industrial Fine Particle Emissions Summary (AVT08/VR91611). This action plan is an elaboration of the National Air Quality Cooperation Programme (NSL), which aims to improve air quality in the Netherlands in the years to come and to achieve timely compliance with the limit values for PM10 and NO2. This is necessary to reduce the negative effects of air pollution on public health and to allow spatial projects, which previously did not comply with air quality legislation, to go ahead. This action plan contains all possible measures to ensure that the Netherlands will fully comply with the appropriate values by the extended deadlines. Measures will be introduced in all sectors, including industry, to achieve these objectives.

The action plan should result in effective emission reduction techniques being used on a wider scale in the Netherlands. The action plan will be implemented in accordance with the approach prescribed by the IPPC (IED) Directive, which has been implemented in the Netherlands in the Environmental Management Act. The measures proposed in the action plan will be implemented in cooperation with all relevant authorities and the private sector. The action plan distinguishes between new and existing installations and the proposed measures will apply to new installations as soon as they are laid down in law. A transitional period will apply for existing installations, thus taking account of cost-effectiveness and performance on other environmental themes. The action plan also includes clearer regulations for emissions that occur when filters are non-operational due to, for instance, malfunction, as well as clearer provisions on emissions from diffuse sources (dispersal of fine particles from commercial buildings or during transshipment or storage).

The Dutch Emission Limits (Combustion Plants) Decree A and B (BEES-A and BEES-B) and the Dutch Emission Guidelines for Air Pollution (NeR) will need to be brought up to date as a result of the action plan. In addition, the possibility of financial incentives for adopting further emission reductions will be explored with the licensing authorities and the private sector.

The action plan was drawn up under the guidance of a working group made up of representatives of the Ministry of Housing, Spatial Planning and the Environment, the Association of Provincial Authorities (IPO, specifically the North Holland and Gelderland representatives), the environmental protection agency of the Rijnmond region (DCMR), the Environmental and Building Department in Amsterdam (DMB), the Netherlands Environmental Assessment Agency (MNP), the Confederation of Netherlands Industry and Employers (VNO-NCW), Tauw consultancy and InfoMil, the Dutch information centre for the environment. The action plan was also discussed with the NeR Advisory Group, the environment department heads in each province, the Netherlands Society for Nature and the Environment and the Ministry of Economic Affairs.

Example from a Member State

Denmark: in Denmark, environmental zones have been established to continuously improve the quality of ambient air in habitated areas. To be able to enter the environmental zones the most polluting diesel-powered buses and trucks exceeding 3,5 tons have to ensure that they are furnished with a PM filter and bear the environmental zone label to enter into these zones. So far the following municipalities/cities have environmental zones:

- Copenhagen municipality (as from 1 September 2008)
- Fredriksberg municipality (as from 1 September 2008)
- Aalborg municipality (as from 1 February 2009)
- Odense (as from 1 July 2010)
- Aarhus (as from 1 September 2010)

The environmental zone label and is specific for each vehicle. The price for the label is 89 DEK and can be purchased at: www.ecosticker.applus.dk or from certain supervisory authorities, such as those responsible for annual vehicle inspection.

A new proposed law from 2010 would allow municipalities that have introduced environmental zones to introduce more stringent rules within the zones to extend the scope of application to also cover commercial vans. Also other municipalities will be allowed to establish environmental zones where they have documented that the limit values for PM have been exceeded. This legislation also introduces the requirement to bear an environmental zone label for foreign trucks and buses. The police will have some supervisory powers and can impose certain sanctions on non-complying vehicles.

More information about the the environmental zones can be obtained at:

<http://www.miljozone.dk/index.php> and

http://www.mst.dk/Virksomhed_og_myndighed/Luft/miljoezoner/indenfor_miljoezonerne/i_miljoezoner.htm and <https://www.retsinformation.dk/Forms/R0710.aspx?id=132218>

4.4. Monitoring, Information and Reporting

- Measurements of air emissions play an important role in monitoring, in showing that an installation meets the specified emission limit values and in emissions trading. However, the performance of air emission measurements is fairly complex. Competent authorities can play a major role in promoting the reliability of measurement data. This can be done by focussing on the quality of air emission measurements during inspections and permitting.
- Details of assessment methods, modelling results and monitoring results should be made available to the public and to the Commission as soon as possible. However, care must be taken to ensure that the quality assurance status of results (e.g. "checked" or "unchecked") is included with them. This is especially applicable where information is published, for example on the Internet, on a daily basis.

- If possible, plan to use the EU data repository as soon as possible and make use of the available guidance information from the Commission, e.g. IPR guidances (references to these are found above).

Examples of monitoring practice in Member States

In the UK the institution that carries out monitoring is a former government laboratory, which has been privatised. In Portugal, monitoring is undertaken by the local air management commission in cities where such a body has been created, or by the regional environmental directorate elsewhere.

Examples from a Member State

The Netherlands: The Dutch government has produced the guidance “L40 Manual Measurement of air emissions”, which provides for concrete tools for setting quality requirements on the measurements upon issue of permits. The manual is accompanied by factsheets to be used during inspections.

This publication describes the general and quality-assurance aspects of measuring air emissions from stationary sources. The manual L40 describes the general and quality-assurance aspects of measuring air emissions from stationary sources (and therefore not air quality measurements or emission measurements). The manual is accompanied by several factsheets (i.e. Factsheet L40-1P Nitrogen oxides Nox, Factsheet L40-7C Quality assurance of automated measuring systems and L40 Measurement of air emissions), describing, per measurement standard (type of measurement), the specific quality-determining factors for the type of measurement in question.

The manual and factsheets are intended to support the competent authority. They can be used in assessing the quality of the air emission measurements that are performed to check the emission limit values specified in permits and in the law and regulations. They also serve as concrete tools for setting quality requirements on the measurements upon issue of permits.

The manual and factsheets are expressly not intended to replace the original measurement standards or to replace the accreditation of measurement bodies. The assessment of the quality of air emission measurements is fairly complex. The users of this manual and the factsheets should therefore have a certain technical background and, preferably, some practical experience.

Source: *The manual and factsheets can be obtained at the Dutch Ministry of Infrastructure and Environment:* <http://www.infomil.nl/english/subjects/air/emission>

5. COSTS

The following checklist describes the types of cost which are likely to be incurred to implement the Directive and the Decision.

Table 9. Checklist of the Types of Cost Incurred to Implement the Directive

Checklist of the Types of Cost Incurred to Implement the Directive
<p>Initial set-up cost:</p> <ul style="list-style-type: none"> • consultation with key actors and stakeholders (incurred by national government and others); • initial assessments as to whether use a combination of fixed measurements, modelling and indicative measurements determining the number and location of monitoring stations (incurred by the national government) • initial investigations and assessment to whether market-based instruments such as NOx taxes are appropriate to reduce pollution levels in a cost-efficient manner) (incurred by government) • establishment of the competent authority (CA) (incurred by national government); • devising quality assurance systems and procedures (incurred by CA); • provision of training of staff (incurred by CA); • preparing initial technical guidance documents (incurred by CA); • setting up a public information and warning system (incurred by CA) • data inventories and reporting systems (in line with format and content requirements set out in Decision 2011/850/EU and the INSPIRE Directive (2007/2/EC) .
<p>Capital expenditure:</p> <ul style="list-style-type: none"> • setting up a network of air quality monitoring stations and associated quality-assurance • equipment for assessment and classification (incurred by CA and possibly by some local authorities [LAs]); • implementation of improvements to industrial sources (changing materials, processes and/or adding abatement technology) (costs incurred by the owners of the sources).
<p>Ongoing running costs:</p> <ul style="list-style-type: none"> • ongoing air quality assessments, including running the monitoring network (incurred by CA); • updating and improving technical guidance documents and/or telephone helpline (incurred by CA); • maintenance of network (repairs, spares, consumables, rental of sites, power) (incurred by CA, and possibly by some LAs); • analysis of samples (incurred by CA, and possibly by some LAs); • maintenance of quality-assurance facilities (incurred by CA and possibly by some LAs); • compiling and checking of results from modelling and monitoring (incurred by CA, and possibly by some LAs); • preparation and updating of plans and programmes (also inventories and modelling for scenarios) (incurred by CA, possibly by some LAs and possibly by any major industrial sources); • financial incentives to use less-polluting materials and equipment (incurred by national government and possibly by LAs); • maintenance of a public information system (incurred by CA, possibly by some LAs); • consultation and information provision to neighbouring Member States (incurred by CA and sometimes LAs); • production of reports for the Commission (incurred by CA).

The initial set-up costs will be incurred chiefly by the national government, mainly through the competent authority once it has been appointed. Sometime costs are likely to be incurred by other key actors and stakeholders in attending meetings and reviewing documents. The total initial set-up costs are likely to be relatively low.

Carrying out assessment and classification will incur both capital and on-going costs. They will be incurred by the competent authority or by the government agency charged with undertaking the monitoring, and possibly also by local authorities, depending on the exact arrangements for financing assessments. This is true whether or not a consultant is employed to carry out the practical work. Costs will probably be greater than the initial set-up costs but far less than any compliance costs incurred in modifying fuels or stationary sources. They will depend on the number of agglomerations and of pollutants of concern and on the complexity of terrain (for modelling). Costs for modelling on a local scale are likely to be in the very approximate region of the capital costs of one multi-pollutant monitoring station.

The main costs of assessment and classification will be in setting up and maintaining a network of air quality monitoring stations and associated quality-assurance equipment and tasks. The main capital cost will be the purchase and siting of continuous monitoring stations, together with staff training. The main on-going (running) costs will be for the running and maintenance of the stations; for the supply (and analysis where necessary) of diffusion tubes, filters and other consumables; for mains electrical power; and for the collation and checking (for quality) of results. The preparation of plans and programmes to achieve compliance with air quality limits and to maintain air quality where it is already good will incur costs for the competent authority and possibly also for local authorities, depending on the exact arrangements for making plans. Work on inventories, the modelling of different abatement (emissions control) scenarios and the subsequent development of plans may be carried out by consultants. Evaluations will also probably need to be made of the technical and economic feasibility of achieving emission reductions from particular emission classes, to ensure cost-effectiveness.

Some costs in planning reductions of their emissions may be incurred by major industrial sources of air pollution. Overall costs for the preparation of plans and programmes will probably lie in the low to medium range (e.g. installing better equipment and filters) and/or by taxpayers (through e.g. to fund equipment and staff, financial incentives such as subsidies and rebates). The overall costs for implementation will be relatively high. The polluter pays principle should be applied as much as possible. In general, plans should be made to maximise the mass of pollutant emission abated per euro invested, except where local pollution problems are of prime importance.

The costs of achieving compliance by emitters of pollutants that cause exceedances of air quality limit values will probably be the major single cost of compliance. These costs should be borne by the polluters themselves as much as possible (industry, householders, motorists etc). In some candidate countries, this may require the polluter pays principle to be incorporated into national legislation. In some instances, there could be a role for subsidies or other economic instruments to reallocate some of these costs to the taxpayer through the national government.

The costs of reporting, providing information and consulting should not be underestimated. Developing the INSPIRE compliant IT system is proven to be expensive and long process. They will be incurred by the competent authority and possibly also by local authorities, depending on exact arrangements for monitoring and assessment.

HEAVY METALS IN AMBIENT AIR DIRECTIVE

Official Title: Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (OJ L 23/3, 26.1.2005)

Amended by:

Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Two (OJ L 87, 31.3.2009)

Commission Directive (EU) 2015/1480 of 28 August 2015 amending several annexes to Directives 2004/107/EC and 2008/50/EC of the European Parliament and of the Council laying down the rules concerning reference methods, data validation and location of sampling points for the assessment of ambient air quality (OJ L 226, 29.08.2015)

2011/850/EU: Commission Implementing Decision of 12 December 2011 laying down rules for Directives 2004/107/EC and 2008/50/EC of the European Parliament and of the Council as regards the reciprocal exchange of information and reporting on ambient air quality.

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Directive 2004/107/EC is the 4th daughter Directive passed under the 1996 air quality framework Directive (96/62/EC) on ambient air quality assessment and management.

In 2008, the old framework air Directive was repealed and replaced by the AQD, which consolidated and integrated all daughter Directives, except for this Heavy Metals Directive, into one piece of legislation.

Though it is often referred to as the Heavy Metals Directive, Directive 2004/107/EC covers not only pollutants such as arsenic, cadmium, nickel and mercury but also and some polycyclic aromatic hydrocarbons.

The objective of the Directive is to:

- Set target values, "to be attained as far as possible", for all the concerned pollutants (i.e. arsenic, cadmium, nickel and polycyclic aromatic hydrocarbons). In terms of mercury, these target values became effective from 31 December 2012 (Art.3). These values are 6 ng/m³ for arsenic, 5 ng/m³ for cadmium, 20 ng/m³ for nickel and 1 ng/m³ for PAH, represented by benzo(a)pyrene (Annex I);
- Call for measures to meet the values, which would not have to go beyond application of best available techniques (BAT), and in particular "would not lead to the closure of installations" (recital (5));
- Ensure that Member States assess levels of the pollutants throughout their territories on the basis of common methods and criteria. For all except mercury they must draw up lists of areas where they are met and areas where they are exceeded (Art.4), and ensure "clear and comprehensible" information is made publicly accessible (Art. 5(3), Art.7).
- Ensure that where the targets are exceeded, Member States identify pollution sources and demonstrate the application of "all necessary measures not entailing disproportionate costs" to meet them (Art. 3(3));
- Governments shall report to the Commission on zones and agglomerations where the target values are exceeded. (Art. 5(1));
- Ensure that the public is effectively and timely informed about concentration levels of the relevant pollutants, also in case of exceedance of values.

The Directive entered into force on 4 January 2005 and the Member States had to implement it to ensure full compliance by 15 February 2007.

The Directive, together with the AQD (2008/50/EC) is currently subject to review by the Commission, one of the first steps was the report submitted in 2010 about the results of scientific research concerning the effects of these substances on health, available BAT, current air quality and projections for the future, the possibility of further reducing pollution emissions from relevant sources and the experience acquired through the application of the Directive. In combination with the review of the Thematic Strategy on Air Pollution this could lead to a revised Directive with more stringent targets as well as regulating the deposition of arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons.

In addition to the Directive, the Commission has proposed a strategy to protect human health and the environment from the release of mercury¹²⁶.

For each regulated pollutant a reference measurement method has been prescribed: Pb, Cd, As, Ni: EN 14902: 2005 CEN standard methods are also developed for the measurement of heavy metals in ambient air.

In August 2015 the European Commission adopted Directive (EU) 2015/1480 amending several annexes to Directives 2004/107/EC and 2008/50/EC of the European Parliament and of the Council laying down the rules concerning reference methods, data validation and location of sampling points for the assessment of ambient air quality. Thus, the Directive amends Annex IV and Annex V to the Directive 2004/107/EC and provides updated data quality objectives and reference methods for assessment of concentrations of arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons. Member States must bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2016 at the latest.

The Heavy Metals Directive should be implemented taking into account:

- 2011/850/EU: Commission Implementing Decision 2011/850/EU laying down rules for Directives 2004/107/EC and 2008/50/EC of the European Parliament and of the Council as regards the reciprocal exchange of information and reporting on ambient air quality. This Decision applies from 1 January 2014. The scope of this Decision covers the annual reporting on ambient air quality assessment and the submission of information on plans and programmes in relation to limit values for certain pollutants in ambient air currently covered by Commission Decision 2004/224/EC laying down arrangements for the submission of information on plans or programmes required under Council Directive 96/62/EC in relation to limit values for certain pollutants in ambient air and Commission Decision 2004/461/EC laying down a questionnaire to be used for annual reporting on ambient air quality assessment. This Decision also cover obligations set out in Decision 97/101/EC which is repealed by Directive 2008/50/EC as from 31 December 2013.
- Council Decision 2001/379/EC of 4 April 2001 on the approval, on behalf of the European EU, of the Protocol to the 1979 Convention on Long-range Transboundary Air Pollution on Heavy Metals. On 24 June 1998 the Commission signed the Heavy Metals Protocol to the 1979 Convention on Long-range Transboundary Air Pollution. This Decision approves the Protocol on behalf of the EU. The aim of the Protocol is to reduce emissions from heavy metals caused by anthropogenic activities that are subject to long-range transboundary atmospheric transport and are likely to have serious adverse effects on human health and the environment. To this end, it stipulates the reduction of total annual emissions into the atmosphere of cadmium, lead and mercury, and the application of product control measures. Under this Protocol Parties commit themselves to: 1) apply the best available technologies described in Annex III vis-à-vis all the major sources of heavy metals existing, 2) respect the emission limit values specified in Annex V, 3) apply regulatory measures on products, as specified in Annex VI and 4) keep regularly updated cadmium, lead and mercury emission registers
- Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury This Regulation sets out an export ban, forming a fundamental part

¹²⁶ Communication from the Commission to the Council and the European Parliament - Community Strategy Concerning Mercury, COM/2005/0020 final, available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52005DC0020>

of the EU's strategy for reducing the global supply of mercury and thereby limiting emissions of the highly toxic heavy metal into the environment. The legislation requires mercury that is no longer used in the chlor-alkali industry – the chemical industry sector responsible for chlorine and caustic soda production – or that is produced in certain other industrial operations, to be put into safe storage after the export ban took effect in March 2011.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Ensure that measuring stations are operational with regard to the pollutants regulated by the Directive and that the minimum number and location of the sampling points for measurements is in accordance with the criteria set out in Annex III, Sections IV, I and II (Art. 4(7)).
- Determine the measurement methods used for measuring concentrations of the relevant pollutants, i.e. the combination of indicative measurements referred to in Annex IV and modelling techniques according to Annex II. For zones/agglomerations where the concentration levels are below the lower assessment threshold, candidate countries may mainly rely on modelling or objective estimation techniques. (Art. 4(3))
- Competent authorities should develop reporting procedures and access to information-related databases in connection with the reporting requirements of Commission Implementing Decision 2011/850/EU. In particular, databases could track the following information:
 - pollutants regulated under the Directive;
 - data on the levels of the specified pollutants in the air;
 - types of monitoring, surveys and measurements of pollutants undertaken;
 - action plans undertaken in the event of air quality limits being exceeded; and
 - plans and programmes that are in place to ensure compliance with emission limit values.
- Competent authorities should develop reporting procedures and access to information-related databases in connection with the reporting requirements set out in Articles 5 and 7 and in accordance with the questionnaire and guidance developed by the European Commission, which are accessible at:
<http://ec.europa.eu/environment/air/quality/legislation/reporting.htm>
- Competent authorities should assess the need to set up one or several common measuring stations, covering territories in neighbouring countries, in order to achieve the necessary spatial resolution. (Art. 4(9))
- Competent authorities should prepare for implementation of information and reporting system set out in Commission Implementing Decision 2011/850/EU laying down rules for Directives 2004/107/EC and the AQD, as regards the reciprocal exchange of information and reporting on ambient air quality.
- Plan the information submission procedures into the new EU repository data system, managed by the European Environmental Agency, ensuring compliance with the procedural requirements on submission and updating of information. (Art. 5, Decision 2011/850/EU)
- Designate a person to make information submissions into the EU repository system pursuant to Decision 2011/850/EU. (Art. 3(5), Decision 2011/850/EU)

- Take into account new provisions of the Directive (EU) 2015/1480 amending Annex IV and Annex V to the Directive 2004/107/EC.

2.2. Monitoring

- Take measures to ensure that concentrations of arsenic, cadmium, nickel and benzo(a)pyrene in ambient air are assessed throughout the whole territory, in accordance with the methods and criteria set out in the Directive. Fixed measurement is mandatory in zones and agglomerations where the levels are above the upper assessment threshold. Where the levels are between the upper and lower assessment threshold, a combination of fixed measurements and indicative measurements and/or modelling may be used. (Art. 4 and Annexes V to IX).
- Measurements can be taken either continuously or by random sampling and the number of measurements must be sufficient. The number of sampling sites must ensure geographical coverage and the identification of long-term trends. (Art. 4(5,9))
- The reference methods for the sampling and analysis of the relevant pollutants set out in Sections I, II and III of Annex V and the reference techniques for measuring the total deposition of these pollutants referred to in section IV of Annex V (Art. 4(13)) must be applied. Make sure that the amendments made to Sections I-IV of Annex V concerning reference method for the sampling and analysis of arsenic, cadmium, nickel, polycyclic aromatic hydrocarbons and mercury in ambient air and reference method for the sampling and analysis of the deposition of arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons are applied by 31 December 2016 at the latest.
- Candidate countries must carry out the measurements in accordance with the upper and lower assessment thresholds set out in Section I of Annex II (Art. 4(6)).
- Measurements must be made for other relevant polycyclic aromatic hydrocarbons at selected sampling sites for benzo(a)pyrene, including those compounds referred to in Article 4(8)).
- It is mandatory to install one background sampling point every 100,000 km² for the indicative measurement and the total deposition of arsenic, cadmium, nickel, total gaseous mercury, benzo (a) pyrene and the other polycyclic aromatic hydrocarbons. At a minimum, one measurement station must be established per Member State, although it is also possible to set up one or several common stations covering parts of other Member States. (Art. 4(9))
- The number and density of measurement stations also depend on the availability of reliable information from other sources, such as emission inventories, indicative measurement methods and air quality modelling. (Art. 4(11))
- Carry out monitoring and share information Commission Implementing Decision 2011/850/EU laying down rules for Directives 2004/107/EC and 2008/50/EC as regards the reciprocal exchange of information and reporting on ambient air quality.
- This monitoring shall mainly cover measurement stations established to monitor air pollution deriving from the obligations under the Heavy Metals Directive and the AQD.

- Comply with Decision 2011/850/EU regarding 1) obligations to report on the assessment and management of ambient air quality and 2) the reciprocal exchange of information concerning networks and stations, and the measurements of air quality obtained from those stations that are selected by Member States for the purpose of reciprocal exchange from amongst existing stations. Member States shall make available the information used for reporting and reciprocal exchange of information to the EU data repository (managed by the European Environmental Agency and made available through the ambient air quality portal), in accordance with Article 5.
- Ensure compliance with the reference measurement method: Pb, Cd, As, Ni: EN 14902: 2005 (this standard can be obtained through the national standardisation organisation, also see <http://www.cen.eu/cenorm/members/members/index.asp>)

2.3. Regulation and Enforcement

- Ensure that legal and administrative provisions are set down to ensure full compliance with the provisions of this Directive (Art. 10). Make sure that provisions of the Directive (EU) 2015/1480 are complied with by the 31 December 2016 at the latest (Art. 4).
- Draw up a list of zones and agglomerations in which the concentrations fall below the target values for arsenic, cadmium, nickel and benzo(a)pyrene as well as a list of zones and agglomerations where the target values are exceeded. This classification has to be reviewed when there is a significant change in activities relevant to concentrations of arsenic, cadmium, nickel and benzo(a)pyrene in ambient air or, at a minimum, every five years. This reclassification should be done in accordance with Section II of Annex II (Arts. 3(2-3)) and 4(6)).
- Take measures to maintain or reduce the level of pollutants in zones where the concentrations fall below the target values. (Art. 3(2))
- Take the measures necessary to ensure that concentrations of relevant substances (i.e. arsenic, cadmium, nickel and benzo(a)pyrene) in the atmosphere are properly assessed in accordance with Article 4 and do not exceed the target values laid down in Annex I as of 31 December 2012. (Art. 3)
- Take all appropriate measures to bring down concentrations in zones and agglomerations where the target values are exceeded. This includes measures targeting the main emission sources, including IPPC installations. (Art. 3(3))
- Put in place effective, proportionate and dissuasive penalties for breaches of national law transposing the requirements of the Directive. (Art. 9)

2.4. Consultation, Reporting and Information

- Ensure that the following information, in a clear, comprehensible and accessible form (e.g. Internet, press), is accessible and routinely made available to the public and appropriate organisations (e.g. environmental organisations, consumer organisations and health care bodies):
 - up-to-date information on concentrations of relevant substances in the atmosphere;
 - deposition rates of the relevant substances;
 - measures taken in regard to the setting of the target values, including the definition of action plans;
 - any annual exceedance of the target values as laid down in Annex I, including the reasons for the exceedance and the area affected (Art. 7).
- Report to the Commission on:
 - cases where the target values set out in Annex I are exceeded, submitting:
 - list of zones and agglomerations concerned;
 - the areas of exceedance;
 - the concentration values assessed;
 - the reasons for exceedance, identifying contributing sources;
 - the population exposed to such exceedance.
- The above-mentioned information must be submitted by 30 September of the following year (Art. 5(1)).
- Measures taken under Article 3:
 - measures to ensure that concentrations of the regulated pollutants do not exceed;
 - the target values laid down in Annex I (Art. 5(2));
 - a list of zones and agglomerations where the levels of the regulated pollutants are below the target values, and measures to keep the levels of these pollutants below the target values and otherwise preserve the best possible ambient air quality (Art. 5(2));
 - a list of zones and agglomerations where the target values are exceeded, as well as measures to attain target values, including the application of BAT for IPPC installations (Art. 5(2));
- Comply with the reporting and information requirements set out in 2011/850/EU laying down rules for the Heavy Metals Directive and the AQD as regards the reciprocal exchange of information and reporting on ambient air quality requiring the Member States to supply certain information to the EU data repository (available through the ambient air quality portal). Member States have to ensure information regarding the following:
 - information set out in Part K of Annex II to Decision 2011/850/EU on measures taken to comply with the target values as required pursuant to Article 5(2) of Directive 2004/107/EC;
 - pursuant to the procedure set out in Article 5 of Decision 2011/850/EU;

The information shall be made available to the Commission no later than 2 years after the end of the year in which the exceedance triggering the measure was observed.

3. IMPLEMENTATION

3.1. Key Tasks

This Directive should be implemented as an integral part of the AQD. This section sets out tasks that are specific to the implementation of this Directive.

Table 10. Key Implementation Tasks - Heavy Metals Directive

Key Implementation Tasks - Heavy Metals Directive	
1	Planning
1.1	Member States must designate a competent authority for the implementation and operation of the information exchange system.
1.2	Establish a system to divide the territory into zones and agglomerations, and prepare a list of zones and agglomerations. This could also include zones for ecosystem protection as well as zones shared with neighbouring countries requiring joint measurement stations.
1.3	Establish a system to designate zones or agglomerations within which assessment thresholds for one or more of the relevant pollutants are exceeded, and prepare a list of such zones and agglomerations. The system should include a mechanism for reviewing the classification every five years or more often in case of changes.
1.4	Establish a system to designate zones or agglomerations within which limit values for one or more relevant pollutants are likely to be approached or exceeded, and at representative sites where pollution is thought to be greatest. The system should include a mechanism for identifying sources of pollution so as to distinguish between natural and human-made sources of pollution and a mechanism for reviewing the classifications.
1.5	Plan the use of assessment criteria for assessing concentrations of the pollutants, also deciding on the appropriate combination of harmonised measurement methods, indicative measurements and modelling.
1.6	Plan the information submission procedures into the new EU repository data system, managed by the European Environmental Agency, ensuring compliance with the procedural requirements on submission and updating of information (Art. 3, Decision 2011/850/EU).
1.7	Decide on the location and number of sampling points in accordance with Annex III to Directive 2004/107/EC, also ensuring background sampling points to provide the indicative measurements.
1.7	Designate a person to make information submissions into the EU repository system pursuant to Decision 2011/850/EU and notify the Commission about this designation (Art. 3(5), Decision 2011/850/EU).
2	Regulation
2.1	Prepare and implement action plans in areas where limit values are exceeded. The plans should include time limits for attaining the relevant limit values; integrated plans where limit values for more than one relevant pollutant are exceeded, and justification for not taking action where limit values are exceeded.
3	Monitoring
3.1	Carry out monitoring of all concentrations including relevant polycyclic aromatic hydrocarbons in addition to benzo(a)pyrene.
3.2	Monitor the results of the sampling points including the background sampling points.
3.2	Carry out monitoring and share information under Decision 2011/850/EU.
3.3	Any aggregation of data and the calculation of statistics by a Member State shall comply with criteria at least as stringent as those indicated in Annex IV. These data have to be transmitted by 1 October for each preceding calendar year (Art. 5(3)).

3.4	Ensure compliance with the reference measurement method: Pb, Cd, As, Ni: EN 14902: 2005 (this standard can be obtained through the national standardisation organisation, also see http://www.cen.eu/cenorm/members/members/index.asp)
4	Reporting and Provision of Information
4.1	Put in place a reporting system to ensure the timely submission of the relevant information to the Commission on the exceedance of target values, monitoring measures etc. This reporting system and data format has to comply with the specifications set out in Decision 2011/850/EU.
4.2	Ensure that information on the exceedance of concentrations, the affected areas and agglomerations, and mitigating measures are made available to the population through the Internet, press or other easily accessible means of communication.
4.3	<p>Comply with Decision 2011/850/EU regarding 1) obligations to report on the assessment and management of ambient air quality and 2) the reciprocal exchange of information concerning networks and stations, and the measurements of air quality obtained from those stations that are selected by Member States for the purpose of reciprocal exchange from amongst existing stations. Member States shall make available the information used for reporting and reciprocal exchange of information to the EU data repository (managed by the European Environmental Agency and made available through the ambient air quality portal), in accordance with Article 5. Member States to ensure information regarding the following;</p> <p>(Part B of Annex II) Information on zones and agglomerations (Article 6) (Part C of Annex II) Information on the assessment regime (Article 7) (Part D of Annex II) Information on the assessment methods (Article 9) (G, Annex II) Information on the attainment of environmental objectives (Article 12) (K, Annex II) Information on measures (Articles 13 and 14)</p> <p>In accordance with the procedure referred to in Article 5 of this Decision (make information available by designated person to the EU data repository in line with general procedural steps set out), Member States shall make available the information set out in Part K of Annex II to this Decision on measures taken to comply with the target values as required pursuant to Article 5(2) of Directive 2004/107/EC. The information shall be made available to the Commission no later than 2 years after the end of the year in which the exceedance triggering the measure was observed.</p>

4. IMPLEMENTATION GUIDANCE

Candidate countries are strongly advised to transpose and apply the new legislative framework on air quality, i.e. the AQD, the Heavy Metals Directive, including respective amendments and Decision 2011/850 as soon as possible.

4.1. Planning

- One of the first planning tasks is to designate the competent authorities responsible for the implementation of the Heavy Metals Directive. Some of these could and for practical and cost-effective reasons should be the same as those designated for the AQD. The competent authority should be responsible to monitoring compliance with limit values for the regulated pollutants and ensure appropriate measures in case exceedance of these values as well as for fulfilling the obligations on collection and dissemination of information and reporting into the EU data repository in accordance with Decision 2011/850/EU.
- The competent authority should also plan the initial consultation procedure to solicit the views of directly involved stakeholders (mainly industrial facilities) and other interested parties. The central government should draw up a list of affected stakeholders (particularly the affected industrial facilities) and notify them about their monitoring, information collection and reporting obligations.
- It may also be necessary to nominate a laboratory/technicians responsible for implementing the recommended measurement methods and applying the relevant CEN standards, although, this largely is the task of the competent authority responsible for implementing the AQD. (The government and possible local government should also ensure that the objectives and provisions of the Heavy Metals Directive are reflected in the overall policy and strategy on ambient air pollution both at national and local level).

4.2. Regulation

- The ministry with primary responsibility for administering national legislation relevant to this Directive should mainly be the ministry of environment in close co-operation with the ministry of health and other relevant ministries (e.g. ministry of trade and industry). Such co-operation will be necessary both in developing the relevant national legislation and in establishing other measures to implement the requirements of the Directive.

Examples from Member States

At the national level, the Federal Government of Germany transposed the Air Quality Framework Directive into national law on 11 September 2002 through the 22 Bundesimmissionsschutzverordnung (BImSchV) as an own Directive, and through the amendment of the Federal Emission Control Act (Bundesimmissionsschutzgesetz (BImSchG)). The 22 BImSchV detail the limits on levels of carbon monoxide, nitrogen oxides, sulphur oxide, tropospheric ozone, benzene, lead, airborne particles and fine particulate matter (PM10 and PM2.5) and provides a catalogue of measures and duties for disseminating information to the public. More information: http://www.stadtklima-stuttgart.de/index.php?start_e

In the United Kingdom, Directive 2004/107/EC were initially transposed by the Air Quality Standards Regulations 2007, No. 64, which also transposed the Air Quality Framework Directive (96/62/EC); the first daughter Directive (1999/30/EC), the second daughter Directive (2000/69/EC) and the third daughter Directive (2002/3/EC). In 2010, the 2007 Regulations were repealed and replaced by the Air Quality Standards Regulations 2010 (SI 2010 No. 1001). These Regulations implement Directive 2008/50/EC on ambient air quality and cleaner air for Europe and apply in England (provisions on PM2.5 concerns the United Kingdom). In the UK, responsibility for meeting air quality limit values is devolved to the national administrations in Scotland, Wales and Northern Ireland. The Secretary of State for Environment, Food and Rural Affairs has responsibility for meeting the limit values in England and the Department for Environment, Food and Rural Affairs (Defra) co-ordinates assessment and air quality plans for the UK as a whole. These Regulations designate the Secretary of State as the competent authority both for Directive 2008/50/EC and 2004/107/EC, responsible for dividing England into zones and agglomerations. Chapter 3 concerns the pollutants covered by Directive 2004/107/EC. The Secretary of State must classify each zone according to whether or not the upper and lower assessment thresholds specified in Section I of Annex II to Directive 2004/107/EC are exceeded in relation to arsenic, cadmium, nickel and benzo(a)pyrene. The Secretary of State must review the classification of zones every five years and even more frequently if there are significant changes. In classifying zones the Secretary of State must comply with Section II of Annex II. The Secretary of State also must assess concentrations of the regulated metals in ambient air, with a combination of fixed measurements together with indicative measurements or modelling, or both, to assess the level of pollutants. In zones where levels of pollutants are below the lower assessment thresholds, modelling or objective estimation techniques may be used. In assessing levels, the Secretary of State has to apply the data quality objectives and standards set out in Annex IV to Directive 2004/107/EC and the number of sampling points must be determined as well.

More information: <https://uk-air.defra.gov.uk/air-pollution/>

4.3. Monitoring and Enforcement

- The authorities/organisations set up to carry out monitoring functions must have the necessary administrative powers and technical, human and financial resources for sampling and testing. Testing laboratories are crucial tools for the implementation of the monitoring task.

- Economic incentives can be used to encourage the further phasing out of arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in products and in industrial processes. Many of these substances are already subject to bans and user restrictions under other pieces of EU legislation.
- The authorities should ensure that required measurement and testing methods are consistently utilised, using the available CEN standards.
- Data should be regularly and consistently updated using the procedure laid down in Decision 2011/850/EU regarding the submission of data and updating of existing data in the data repository.
- Modelling for the covered pollutants should take into account the experience and knowledge acquired under initiatives such as HARMO, Air4EU (facilitates the combined use of monitoring and modelling for the air quality assessment through the developed guidance and IT tools) and forum for AIR quality MODElling (FAIRMODE) of modellers and users (to support the widespread and harmonised use of models through model validation and inter-comparison exercises and through the management of the modelling network).

4.4. Monitoring, Information and Reporting

- Measurements of air emissions play an important role in monitoring, in showing that an installation meets the specified emission limit values and in emissions trading. However, the performance of air emission measurements is fairly complex. Competent authorities can play a major role in promoting the reliability of measurement data. This can be done by focussing on the quality of air emission measurements during inspections and permitting.
- Details of assessment methods, modelling results and monitoring results should be made available to the public and to the Commission as soon as possible. However, care must be taken to ensure that the quality assurance status of results (e.g. "checked" or "unchecked") is included with them. This is especially applicable where information is published, for example on the Internet, on a daily basis.
- If possible, plan to use the EU data repository as soon as possible and make use of the available guidance information from the Commission, e.g. IPR guidances (references to these are found above).

5. COSTS

The costs of transposing and implementing this Directive include the following:

Table 11. Checklist of the Types of Cost Incurred to Implement the Directive

Checklist of the Types of Cost Incurred to Implement the Directive
Administrative tasks: <ul style="list-style-type: none"> • initial consultation of industry and other key stakeholders and put into place a cooperation and consultation mechanism, • classification of zones and agglomerations, setting target values, • establishing the assessment framework with the assessment criteria, • establishing a database system for recording the results of measurements, • follow up measures for incidents of exceedance of target values etc., • co-ordination between various national authorities including co-ordination with competent authorities in neighbouring countries for zones and agglomerations shared by these countries, • establishing an information procedures ensuring public access to certain information, • establishing a reporting system.
Capital investments for government: <ul style="list-style-type: none"> • costs of establishing measuring stations, • necessary sampling, • other monitoring and sampling equipment (including sampling points for provide the indicative measurements). Capital investments for industrial facilities: <ul style="list-style-type: none"> • abatement equipment or alternative production processes preventing or limiting emissions of the concerned pollutants.
Monitoring tasks – both incurred by the government and industrial facilities: <ul style="list-style-type: none"> • technical support, • monitoring and reporting system (database, inventory, indicators), • human resources.

As indicted above, part of the costs would fall on industrial installations, especially where target values are exceeded and reduction measures are introduced to bring down levels of pollutants from specific facilities. However, these costs should be limited for IPPC installations since they are required to apply BAT under the IED. Hence, it is not expected that the costs will pose any serious financial constraints on industrial operators. For more details on costs, see the fiche on the AQD.

Examples of Estimations of Impact and Costs in the United Kingdom

The UK government estimated that the target values were likely to be met under existing UK policy commitments and trends, and as a result no additional emission reduction measures are anticipated to be required, beyond those implemented under existing UK policy commitments. The Directive does not set specific obligations for industry and therefore the regulations do not have any additional direct regulatory effect on industry. The UK has estimated expenses for the transposition of the Directive into UK regulations, to assess levels of relevant pollutants (through the purchase, operation and maintenance of monitoring equipment), to administer and report on the implementation of the Directive, and monitoring costs (both capital and annual operating costs).

The total costs associated with additional monitoring and the demonstration of compliance were estimated to be in the range of £0.6 million to £1.8 million per year and these would mainly be costs to the government.

THE NATIONAL EMISSION CEILINGS DIRECTIVE

Official Title: Council Directive 2001/81/EC on national emission ceilings for certain atmospheric pollutants (OJ L 309/2, 27.11.2001),

as amended by:

Council Directive 2006/105/EC of 20 November 2006 adapting Directives 73/239/EEC, 74/557/EEC and 2002/83/EC in the field of environment, by reason of the accession of Bulgaria and Romania (OJ L 363, 20/12/2006)

Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Two (OJ L 87, 31.3.2009)

Council Directive 2013/17/EU of 13 May 2013 adapting certain directives in the field of environment, by reason of the accession of the Republic of Croatia (OJ L 158, 10.6.2013)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Directive 2001/81/EC of the European Parliament and the Council on National Emission Ceilings for certain pollutants (NEC Directive) sets caps to be met by 2010 at the latest applicable to Member States' total annual emissions of sulphur dioxide (SO₂), nitrogen oxides (NO_x), volatile organic compounds (VOC) and ammonia (NH₃) as pollutants responsible for acidification, soil eutrophication and ground-level ozone pollution. Directive 2001/81/EC leaves it to Member States to define which measures to implement – in addition to those required by EU legislation applicable to specific source categories to comply with the national emission ceilings. The Directive covers emissions of SO₂, NO_x, VOC and NH₃ from all sources within the Member States (Art. 2). Emissions from international maritime traffic, from beyond aircraft take-off and landing and emissions that occur in overseas departments and islands of France, Portugal and Spain are excluded (Art. 2). Directive 2001/81/EC provides relevant definitions (Art. 3).

The NEC Directive sets out three main tasks for Member States:

- To limit national emissions of SO₂, NO_x, VOC and NH₃ with a view to meeting the national emission ceilings by 2010 at the latest and to stay below these ceilings thereafter (Art. 4). National emission ceilings expressed in kilotonnes per year applicable to each Member State are specified in Annex I of the Directive. The purpose of the national emission ceilings (Art. 5) is to reduce for the EU as a whole:
 - the ground-level critical loads of acidification by 50% in each 150 km by 150 km grid cell compared to 1990;
 - the critical level of health-related ground-level ozone exposure (AOT₆₀=0) by two-thirds, so that the ground-level ozone load does not exceed 2.9 ppm.h in any grid cell;
 - the critical level of vegetation-related ground-level ozone exposure (AOT₄₀=3 ppm.h) by one-third so that the ground-level ozone load does not exceed an absolute limit of 10 ppm.h expressed as an exceedance of the critical level of 3 ppm.h in any grid cell.
- To develop and implement National Programmes by 2002 and, if needed, update them by 2006 as a means to ensure the meeting of the national emission ceilings by 2010 and thereafter. National programmes are also to be notified to the Commission and are to be made available to the public.
- To report their annual emission inventories and projections to the Commission and the European Environment Agency as a means to assess the progress made towards compliance with the national emission ceilings.

Directives 2006/105/EC and 2013/17 amend Directive 2001/81/EC to make necessary adjustments due to adjust the latest enlargement of the EU, respectively. It amends:

- Annex I: adds entries for Bulgaria, Romania and Croatia;
- Annex II: adds entries for Bulgaria, Romania and Croatia.

The comitology Regulation 219/2009 also amends the NEC Directive. It allows the Commission to update, through the regulatory procedure with scrutiny, the methodologies referred to in Annex III to be used by Member States to establish their emission inventories and projections.

The NEC Directive is currently being reviewed. The revision is aimed at addressing the highly significant remaining health risks and environmental impacts posed by air pollution in the Union, and aligning Union law with new international commitments following a revision of the Gothenburg Protocol in 2012.

The proposal repeals and replaces the current Union regime on the annual capping of national emissions of air pollutants, as defined in Directive 2001/81/EC. By doing so, it ensures that the national emission ceilings (NECs) set in Directive 2001/81/EC for 2010 onwards for SO₂, NO_x, NMVOC and NH₃ shall apply until 2020 and establishes new national emission reduction commitments (“NERCs”) applicable from 2020 and 2030 for SO₂, NO_x, NMVOC, NH₃, fine particulate matter (PM_{2,5}) and methane (CH₄) as well as intermediate emission levels for the year 2025 applicable to the same pollutants. Existing provisions related to adoption of national air pollution control programmes and establishing emission inventories are further strengthened.

The 2020 NERCs are based upon the emission reduction commitments as agreed under the 1999 Protocol to the 1979 Convention on Long Range Transboundary Air Pollution to abate acidification, eutrophication and ground-level ozone, as amended in 2012 and will be largely attained through compliance with current relevant Union and national legislation. In comparison to the NERCs applicable for the period 2020-2024, Member States must reduce their emissions substantially further from 2025 according to the percentages specified in the proposed Directive. Proposed Directive further specifies that the 2030 NERCs shall only have to be achieved if measures not entailing disproportionate costs are available.

The proposed Directive requires Member States to draw-up, adopt and to regularly update a national air pollution control programme (“NAPCP”) taking into account the wider air quality challenges of the Member State with a view to ensuring that the 2020, 2025 and potentially also the 2030 NERCs are met in time and without significantly impacting air quality in neighbouring Member States. In this context, proposed Directive sets the minimum content of the NAPCPs.

Compared to the relevant provisions of the existing NEC Directive emission monitoring and reporting requirements are extended under the proposed Directive with a view to aligning Union legislation with the LRTAP monitoring and reporting requirements and guidelines that currently are being revised.

The revision of the NEC Directive builds upon the evaluation and review of the 2002 (and 2006) National Programmes, the work performed under the Clean Air for Europe Programme and the Thematic Strategy on Air Pollution, new scientific and technical knowledge on the impacts of air pollution upon the environment and public health. The revision takes also into account EU legislation enacted to regulate specific source categories (e.g. Euro 5/6, EURO VI, Directive 2010/75/EU on industrial emissions) and the Decision of the European Council of March 2007 to reduce the greenhouse gas emissions by 20% and to have 20% renewables by 2020.

For more information about the NEC Directive and its current revision Directive and the amended Gothenburg Protocol, consult the website of DG ENV:

<http://ec.europa.eu/environment/air/pollutants/ceilings.htm>

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning and Programmes

- The Member States have to draw up programmes for the progressive reduction of the national emissions of SO₂, NO_x, VOC and NH₃ (Art. 6). These national programmes are subject to periodic updates.

2.2. Emission Inventories

- Member States shall prepare emission inventories for SO₂, NO_x, VOC and NH₃ (Art. 7). The inventories shall:
 - be updated annually;
 - be prepared using methodologies agreed upon in the Convention on Long-Range Transboundary Air Pollution and the joint EMP/CORINAIR guidebook (Annex III);
 - take into account Articles 4 and 7 of Decision 1999/468/EC (as amended by Directive 2006/105/EC) setting out a regulatory procedure for amendment of non-essential elements of the Directive.
- The Commission, assisted by the European Environment Agency and in co-operation with the Member States, shall establish EU-wide inventories and projections and these shall be made publicly available. (Art. 7)

2.3. Reporting by Member States

Member States shall:

- Report to the Commission and the European Environment Agency by 31 December each year (Art. 8) on:
 - the national emission inventories and the emission projections for 2010;
 - the final emission inventories for the previous year but one;
 - the provisional emission inventories for the previous year.
- Inform the Commission of the national programmes developed and updated.

2.4. Additional Legal Instruments

The following legislation should be borne in mind (non-exhaustive list) when implementing this Directive:

- Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions, should be taken into account when examining the need to develop EU measures for the most relevant economic sectors and products that contribute to acidification, eutrophication and ground-level ozone
- Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC, which allows the public to have access to environmental information held by public bodies
- Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC
- VOC in petrol stations Directives (European Parliament and Council Directive 94/63/EC of 20 December 1994 on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations and Directive 2009/126/EC of the European Parliament and of the Council of 21 October 2009 on Stage II petrol vapour recovery during refuelling of motor vehicles at service stations)
- Directive (EU) 2016/802 of the European Parliament and of the Council of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels
- Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law, as the NEC Directive is listed in Annex A, the infringement of which constitutes unlawful conduct pursuant to Article 2(a)(i) of Directive 2008/99/EC.

2.5. Co-operation with Third Countries

- Member States shall pursue bilateral and multilateral co-operation with third countries and relevant international organisations (UNECE, IMO, ICAO) through the exchange of information with the aim to reduce emissions. (Art. 11)

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the following checklist.

Key tasks are organised in chronological order, wherever applicable.

Table 12. National Emissions Ceilings Directive - Key Implementation Tasks

NATIONAL EMISSIONS CEILINGS DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Member States have to draw up national programmes for the progressive reduction of the national emissions of SO ₂ , NO _x , VOC and NH ₃ in line with the national emission ceilings set in Annex I to the Directive. (Member States had to draw up a the National Programme by 2002 on adopted and envisaged policies and measures and quantified estimates of their effects on the emissions in 2010). Member States were also required to update the plan, where necessary, in 2006.
1.2	The competent authority should use emission inventory methodologies referred to in Annex III to the Directive and are requested to use the joint EMEP/Corinair guidebook (now named the EMEP/EEA guidebook) for the assessment of emission inventories and projections.
2	Consultation and Reporting
2.1	Report to the Commission and the European Environment Agency by 31 December each year on: <ul style="list-style-type: none"> • the national emission projections (for 2010) and key socioeconomic assumptions used for the projections; • the final emission inventories for the previous year but one; • the provisional emission inventories for the previous year.
2.2	Inform the Commission of the programmes drawn up and updated programmes. In order to enhance comparability of the reports of the Member States, Member States were requested to base their programmes on the "Recommendations on developing and reporting National Programmes under the National Emission Ceilings Directive". The recommendations have been drawn up by the Working Group on Implementation of the CAFE-programme.
2.3	Member States are obliged to report each year their national emission inventories and projections for 2010 to the European Commission and the European Environment Agency (through the EIONET Central Data Repository). That reporting has to be based on the EMEP/EEA Emission Inventory Guidebook.

4. IMPLEMENTATION GUIDANCE

The Directive stipulates that Member States have to elaborate and implement national programmes with a view to meeting their national emission ceilings and to contributing to the achievement of the interim objectives set in Art. 5 and applicable to the EU as a whole.

National emission inventories and projections on emissions must be elaborated each year to assess the progress made in reducing emissions and to verify compliance with the national emission ceilings.

4.1. National programmes

Member States were required to draw up a national programme in 2002 on adopted and envisaged policies and measures and quantified estimates of their effects on emissions in 2010. Member States had to update them in 2006 in case where they estimated that the 2002 national programmes would not be sufficient to meet the national emission ceilings by 2010. Candidate countries are encouraged, for their own implementation of the Directive, to draw on information and experience from Member States reporting from 2002 and 2006.

More information on the programmes, analysis and recommendations is found on the Commission National Emission Ceilings Directive webpage on implementation:

http://ec.europa.eu/environment/air/pollutants/implem_nec_directive.htm

4.2. Reporting

Member States must report each year their national emission inventories (and projections for 2010) to the European Commission and the European Environment Agency (Eionet Central Data Repository, consult: <http://cdr.eionet.europa.eu/>). They must report before the end of each year the definite emissions for the previous year but one and the provisional emissions for the previous year. The emission projections for the target year should have quantitative socio-economic underpinning.

Candidate countries should base their reporting on the EMEP/Corinair (now EMEP/EEA) Emission Inventory Guidebook which is continuously updated.

4.3. Examples of Implementing Measures

There are ample examples of policies and instruments to reduce ambient air pollution, especially relating to exhaust emissions from the transport sector. Two policies aiming to reduce pollution from vehicles include:

- Road pricing, road user charging or congestion fees: This involves a charge being levied for the circulation of vehicles on certain roads or in built-up areas. It is possible to target this road charging scheme towards heavy traffic and/or lighter vehicles. Where road charging is introduced in built-up, city areas it often leads to a reduction in traffic congestion and air pollution. Road pricing is normally designed to influence the behaviour of road users, to encourage them to avoid driving at busy times and in busy places in order to allow traffic to flow more freely. The economic rationale for road pricing

is compelling. Road use generates costs which are borne by wider society instead of the motorist. These 'externalities' mean that in the absence of taxation or pricing, there is an inefficiently high level of road use. Taxes can help bring private demands into line with the socially desirable level. Several different externalities are associated with motoring. Some, like carbon emissions from burning petrol and diesel, are easily addressed through fuel duties as the costs depend entirely on fuel use. Others, notably congestion but also the costs of noise and accidents, vary enormously according to where and when someone drives. Driving in rural areas late at night imposes no congestion cost upon other motorists. Driving in conurbations at rush hour generates large congestion costs. Taxes on fuel cannot vary according to time and location, and so are fundamentally unable to account for this variation. Taxes on road use, however, would be able to do so. Examples of successful road charging can be found in the United Kingdom, Germany and Sweden. Road charging often forms part of a combination of policies and measures to tackle climate change at national level and is normally part of larger strategic plans.

- Environmental zoning: This is a concept according to which access to certain cities or areas of cities is restricted by way of certain agreed criteria. The main purpose of this policy measure is to improve the environment and, in particular, to reduce the concentration of air pollutants deriving from traffic.

Examples from the United Kingdom

A report by the Institute for Fiscal Studies (IFS), funded by the RAC Foundation, suggests the need for a „radical overhaul" of road taxes. Fuel and Vehicle Excise duties raise about £38bn a year but are set to fall. Also forecasts from the Office for Budget Responsibility predict tax revenues from duties will fall by £13bn a year, at current prices, by 2029, as cars become electrified and more fuel-efficient. To bridge the gap would require a 50% rise in fuel duty, according to the IFS. Instead of raising the fuel duty, however, IFS advocates for introducing a nationwide system of road charging, including road tolls, to account for this loss of revenue. Under this system, one option would be to charge drivers by the mile, with higher pricing in congested areas at peak times, whereas drivers in the countryside would be likely to pay less.

The potential efficiency gains from better-targeted taxes are large: the 2005 Eddington transport study (available at: <http://webarchive.nationalarchives.gov.uk/20090104005813/http://www.dft.gov.uk/about/strategy/transportstrategy/eddingtonstudy/>) estimated benefits of up to £25 billion per year.

The government is currently consulting on charging tolls to motorists, following on from the existing M6 toll road as well as is considering "shadow tolls" - a fee to the road maintenance company per driver using a road, but paid by the government rather than drivers. The Treasury and Department for Transport are carrying out a feasibility study looking at "new ownership and financing models" for the roads, with the results due in the autumn.

Source: <http://www.ifs.org.uk/publications/6174>

Examples from a Member State

Sweden: Measures that have contributed to attaining the target values in the Emission Ceilings Directive include:

1. Tax incentives: increasing taxes on polluting activities and energy consumption in exchange for reduced tax levels in areas such as the labour market.
 - Sulphur tax since 1991, targeting solid or liquid products producing sulphur when combusted. This tax has affected the price of energy and facilitated a transition from heavy to light heating oil;
 - CO₂ tax since 1991, aiming at reducing CO₂ emissions deriving from the combustion of fossil fuels;
 - NO_x tax for combustion plants.
2. Other financial incentives:
 - System of certification of electricity. This aims at promoting the production of electricity from renewable sources. The system covers all types of renewable energy sources and aims particularly at promoting the most effective renewable electricity production. The system is expected to run until 2030;
 - Tax breaks on combined heat and power plants (kraftvärme) since 2003. This tax incentive promotes increased production of electricity in combined heat and power plants to achieve more efficient energy consumption. Sweden will also have a new law on a warranty of origin for energy produced by combined heat and power plants or from renewable energy sources;
 - Programme for energy efficiency targeting particularly energy intensive industry. This programme, which has been in operation since 2005, gives participating companies a tax reduction per kWh;
 - Extended use of district heating in Swedish cities, with an increased transition from the use of fossil fuels to biofuels. Experience has shown that a reduced number of outlet sources reduces the pollution more effectively;
 - Subsidies for facilities used for public services. Such activities were eligible for financial support for investments in energy consumption savings between 2005 and 2007;
 - Subsidies for private households for transition from heating with fossil fuels to biofuels, solar heating etc. These subsidies are available for a period of five years;
 - Adoption of a new law (2006) on vehicle tax, which is now based on CO₂ discharges. This law has led to a significant increase in environmentally friendly cars since 2006, especially in Stockholm where such vehicles have been exempt from road charges in city areas;
 - Trial congestion pricing in Stockholm in 2006.

The Swedish Government also envisages the following steps to ensure timely attainment of the objectives of the National Emission Ceilings Directive:

1. Measures targeting point sources:
 - Extended and increased NO_x charge (from SEK 50 to 60);
 - Technical measures for larger combustion plants to reduce NO_x emissions.
2. Measures targeting working machines:
 - More stringent criteria for working machines in public procurement;

- Training for drivers of working machines to minimise emissions;
- Environmental labelling of working machines following more stringent environmental criteria;
- Favour more environmentally sustainable heavy vehicles in procurement;
- Temporarily reduce the vehicle tax for heavy vehicles meeting the criteria for the Environmental Category 2008 until these criteria become mandatory. It is also possible to introduce a similar tax reduction for Environmental Category 2010 regarding Euro 5.

Source: Engleryd, A, Jundén I, Implementation of the EC Directive on National Emission Ceilings (2001/81/EC) - a status report for Sweden, 2006

Examples from Germany:

Germany: German cities, under a law passed in 2006, are acquiring environmental zones (Umweltzonen); areas into which it is only possible driving a car if it bears a windshield sticker certifying that it has an acceptable emission level.



Stickers are numbered and color coded and include your license plate number



There are three different stickers:

- 1) green: certifying that the vehicle is environmentally acceptable;
- 2) yellow: for less acceptable vehicles
- 3) red: for those still less acceptable.

Under this system, yellow and red stickers will eventually be phased out, after which all vehicles permitted in the environmental zones will need a green sticker.

Gasoline- and diesel-powered vehicles without catalytic converters will be unable to get any kind of a sticker and will not be permitted in the environmental zones. All gasoline-powered cars with catalytic converters will get a green sticker. So will the best of the diesel-powered vehicles. Diesels, however, present a greater pollution hazard, and many will only get yellow or red stickers.

Environmental zones are marked clearly indicating the stickers that are allowed beyond the sign. If you have a red or yellow sticker and that sticker is not pictured on the sign you cannot enter. Cars found in an environmental zone without an appropriate sticker are subject to a €40 fine.

The first environmental zones were established on January 1, 2008 in Berlin, Cologne and Hannover. Others have since been established in Düsseldorf, Stuttgart and a group of smaller communities in the Stuttgart area. Many other cities entered the system in 2008 and early 2009. Foreign plated cars, and those of the US forces in Europe, are also required to have the stickers. Stickers can be purchased for €5 at vehicle registration offices and vehicle inspection stations (*TÜV's*) on presentation of your car's registration containing its pollution level data. They are also available online, from the cities that have environmental zones. Your car doesn't have to be registered in the city to which you apply, and a sticker, once obtained, is good for all of the environmental zones nationwide. Even a foreigner can get a sticker online, and it is advisable to seek it at least three weeks before a planned visit to Germany.

Source: <http://www.howtogermy.com/pages/environmentalzones.html>

attained in 2010. (Note that this figures only covered the actual levels in 2004 and the Swedish targets in 2010. The actual numbers for 2010 and for following years may therefore be different)¹²⁷.

Table 13. Targets given in metric tonnes per year

	Target in Directive	Swedish 2010 target	Emission levels in 2004
SO ₂	67,000	50,000	47,000
NO _x	148,000	148,000	197,000
NM _{VOC}	241,000	241,000	255,000
NH ₃	57,000	50,000	56,000

¹²⁷ Source: Engleryd, A, Jundén I, Implementation of the EC Directive on National Emission Ceilings (2001/81/EC) - a status report for Sweden, 2006 (Genomförande av EU:s utsläppstakdirektiv -, en lägesrapport för Sverige 2006).

Examples of Congestion Pricing in Member States

London:

- The main goal with London’s congestion charge is to reduce congestion in the city centre.
- To meet this goal, London installed hundreds of cameras throughout the congestion zone, charging £10 to anyone driving within it between operational hours of 7am-6pm, Monday to Friday.
- The charge has to be paid at the latest the following day.

Stockholm:

- The main aim of the charge in Stockholm was to regulate the traffic over the day to reduce peak traffic and congestions.
- Stockholm’s daily charges add up every time you enter or leave the charging zone and you pay the final bill at the end of the month.
- Installed cameras at 18 entrance points to the city – a system only possible due to the fact that central Stockholm is essentially an island with just a few possible points of entry.
- Local road users travelling in and out of the city center pay between 10-60 SEK.
- The other effect of this technical solution is that those who drive exclusively within the congestion charging zone will only get charged if they leave and re-enter, as that would be the only opportunity to catch their

There are some similarities between London and Stockholm’s congestion pricing.

- ‘green vehicles’ are exempt from the fee in both cities, as are motorcycles and taxis;
- in both cities the road tax system has been a big success. In the case of Sweden, public transport saw a [4.5% increase in ridership](#), traffic reduction of 18%, and a 50% reduction in waiting time to enter the city center during peak hours. Furthermore, carbon emissions [dropped by 14-18%](#), ownership of tax-exempt environmentally sustainable vehicles has almost tripled, and retailers have seen a [6% increase in business](#).

As summary of the results of the trial road charge system in Stockholm can be obtained at: http://www.stockholmsforsoket.se/upload/Rapporter/Expert_group_summary_060621.pdf

Examples of other successful national and local actions to address ambient air pollution are summarized in the table below:

Table 14 Example of National and Local Measures by Source (Sub) Category

Emission source/sector	Subcategories	Measures/Examples
Transport	Road management Transport/traffic	<ul style="list-style-type: none"> • Road pricing (e.g. London, Gothenburg) • Speed-limits (e.g. Rotterdam) • Low emission zones (e.g. Berlin)

		<ul style="list-style-type: none"> • Parking fees (e.g. Torino) • Car sharing (e.g. Cambio) • Bus or Heavy Occupancy Vehicles
	Road Transport/fleet management	<ul style="list-style-type: none"> • Green Public Procurement (ultra low emission or alternative fuelled vehicles) • Retrofitting standards (e.g. for buses, municipal service vehicles, trucks,..)
	Road Transport/inter-modality	<ul style="list-style-type: none"> • Kiss&Ride road and rail infrastructure • Pedestrian zones and dedicated bike lanes
	Road Transport/promoting public transport	<ul style="list-style-type: none"> • Green taxis • Green buses (LPG, CNG cars and buses) • ...
	Maritime transport/promoting clean marine ports	<ul style="list-style-type: none"> • Electricity at berth (Hamburg, ...) • Differentiated fees • Remote sensing of emissions (JRC, EMSA and Riparian States in the Emission Control Areas in North sea and Baltic Sea) • Retrofitting vessels • Discharge services • Alternative fuel infrastructure (low sulphur fuels, LNG,..) • Clean inter-modality • Intensification and improvement of port inspections/enforcement
	Maritime transport/fleet management	<ul style="list-style-type: none"> • Retrofitting (inland, SSS) • LNG (SSS, inland) • Scrubbers...
	Air transport/Clean Air Ports	<ul style="list-style-type: none"> • Public transport access • Differentiated fees
	Rail transport/fleet management	<ul style="list-style-type: none"> • Retrofitting (diesel) railcars • Electrification • ...
Energy	Large and medium sized combustion installations	<ul style="list-style-type: none"> • Permitting (upper range BAT/beyond) • Promote energy efficiency

		<ul style="list-style-type: none"> • Promote RES • District heating and cooling (Torino) • Fuel taxes (Denmark) • Carbon pricing (ETS)
	Small combustion installations	<ul style="list-style-type: none"> • Labels and/or standards for clean wood/biomass stoves (IT, DK) • Fuel switching (Dublin) • Permitting
Industry	Iron & Steel Cement ...	<ul style="list-style-type: none"> • Permitting according to best Available Technologies or beyond (national/local competence) • Joint clean air and climate change pilot projects
Agriculture		<ul style="list-style-type: none"> • Manure management conditions (BE, NL, DE) • Agriculture burning restrictions • Animal rearing criteria (CLRTAP) • Fertilizers management • Food and feeding strategies
Economic incentives/general		<ul style="list-style-type: none"> • Greening vehicle taxation (differentiated registration tax, road tax, fuel tax) • NOx funds (Norway) • Off-set systems (US) • Tradable permits (NL, California)
Public information		<ul style="list-style-type: none"> • Promotion campaigns, on-site training and inspection for energy efficiency and RES • Awareness and actions at citizen level
Other		Measures funded by the EU Cohesion Fund

Source: Commission Staff Working Document Impact Assessment, Accompanying the documents Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions -a Clean Air Programme for Europe; Proposal for a Directive of the European Parliament and of the Council on the limitation of emissions of certain pollutants into the air from medium combustion plants; Proposal for a Directive of the European Parliament and of the Council on the reduction of national emissions of certain atmospheric pollutants and amending Directive 2003/35/EC and Proposal for a Council Decision on the acceptance of the Amendment to the 1999 Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution to Abate Acidification, Eutrophication and Ground-level Ozone, SWD(2013)531; p 152-153; available at http://ec.europa.eu/environment/archives/air/pdf/Impact_assessment_en.pdf

5. COSTS

The main types of cost arising during the implementation of the National Emissions Ceilings Directive are illustrated, as far as possible, in the checklist below.

Table 14. Checklist of the Types of Cost that may Incur to Implement the Directive

Checklist of the Types of Cost that may Incur to Implement the Directive
Initial set-up costs: <ul style="list-style-type: none"> • establishment of a competent authority; • devising of systems and procedures; • provision of training; • preparation of technical guidance notes.
Capital expenditure: <ul style="list-style-type: none"> • alteration to existing plant to meet national emission ceilings; • purchase of the relevant monitoring equipment.
Ongoing running costs: <ul style="list-style-type: none"> • processing licence applications; • operating emissions abatement technology; • maintaining emissions inventory; • public information-promoting greater public awareness and guiding purchase decisions; • reporting to the Commission.

Costs will be incurred by the competent authority in administering the Directive, including for the annual assessment and reporting of the emissions and for the development of administrative measures and national programmes to meet the ceilings. However, the costs incurred by operators in complying with the Directive ceilings and reducing emissions are likely to be far higher.

In practice, most of the costs that fall on the competent authority will also arise in order to comply with the IED (2010/75/EU). If possible and realistic arrangements could be made to recover at least some of the costs from operators through fees for licensing in accordance with the polluter pays principle.

THE DIRECTIVE ON SULPHUR CONTENT OF CERTAIN LIQUID FUELS

Official Title: Directive (EU) 2016/802 of the European Parliament and of the Council of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels (OJ L 132, 21.5.2016)

Implementing acts:

Commission Implementing Decision (EU) 2015/253 of 16 February 2015 laying down the rules concerning the sampling and reporting under Council Directive 1999/32/EC as regards the sulphur content of marine fuels (OJ L 41, 17.2.2015)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Directive (EU) 2016/802 of the European Parliament and the Council of 11 May 2016 on the reduction in the sulphur content of certain liquid fuels was published in May 2016. The new Directive brings together in one single act all the provisions of the six legislative acts (the original Directive 1999/32/EC and the five acts amending it: Directives 2005/33/EC, 2009/30/EC, 2012/33/EU and Regulations (EC) No 1882/2003 and (EC) 219/2009).

The Directive on sulphur content of certain liquid fuels is intended to combat emissions of sulphur dioxide, which are one of the causes of acidification and particle formation in the European Union, and are one of the factors causing damage to ecosystems, biodiversity and human health. The Directive sets the maximum sulphur content for heavy fuel oil, gas oil and marine gas oils.

Directive 1999/32/EC of 26 April 1999 established limits for sulphur content in heavy fuel oil (1.0% after 1 January 2003) and gas oil, including marine gas oil (0.2% after 1 January 2000 and 0.1% after 1 January 2008). Following the entry into force of MARPOL Annex VI in May 2005 a new Directive, 2005/33/EC, was promulgated in July 2005, amending Directive 1999/32/EC. The amending Directive 2005/33/EC introduced rules on the sulphur content of marine fuels and therefore includes the definition of marine fuels in its Article 2(3). It introduced the following:

- a 1.5% limit for marine fuels used in SECAs and by passenger ships operating on regular services to or from EU ports in Member States' territorial seas, exclusive economic zones and pollution control zones. The application dates were: 11 August 2006 for the Baltic Sea, 11 August 2007 for the North Sea (including English Channel), and 12 months after entry into force for any other SECA, including ports, designated by the IMO
- a 0.1% limit for marine fuels used by inland waterway vessels and by ships at berth in EU ports as from 1 January 2010.

In 2009 the scope of the definition of marine fuels referred to in Article 2(3) has been extended by Directive 2009/30/EC to include any petroleum-derived liquid fuel in use on board inland waterway vessels or recreational craft only when such vessels are at sea.

The EU rendered mandatory IMO rules on marine fuels through the Directive 2012/33/EU further amending Directive 1999/32/EC as regards the sulphur content of marine fuels. The Directive 2012/33/EC regulated the sulphur limits in land and marine based fuels to be used in territorial sea areas and in ports and has updated the definition of heavy fuel oil and gas oil, as well as marine diesel oil and gas oils. Moreover, Directive 2012/33/EU transposed into EU legislation the sulphur in fuel requirements of the 2008 revision of Annex VI of the MARPOL Convention of the IMO. The key elements of this Directive are:

- stricter sulphur content standards in SO_x Emission Control Areas (SECAs) (down to 0.10% by mass in 2015 from 1.00%), and outside SECAs 0.50% in 2020 from the current 3.50%;
- allowing for compliance with the sulphur standards by using equivalent compliance methods (eg. scrubbers systems, alternative fuels, shore side electricity, ...);
- clauses ensuring availability of compliant fuel.

In addition to the MARPOL provisions (some are also referring to equally relevant land based-applications):

- 3,50% cap on sulphur content of fuels used in the EU territory (0,10% for gas oils);

- monitoring of fuel suppliers, alignment to ISO and IMO international standards (fuel technical updates, definitions and scope of application) and to latest developments in relevant directives for land based applications (industrial installations, non-road mobile machinery, road transport and inland waterways).

Following the legal mandate of Directive 2012/33/EU, Commission Implementing Decision (EU) 2015/253 was adopted on 16 February 2015 laying down the rules concerning the sampling and reporting under Council Directive 1999/32/EC as regards the sulphur content of marine fuels. The Decision sets for the EU Member States' competent authorities stricter and more specific implementation measures on sulphur in marine fuel inspections, through sampling, and on reporting.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Regulation

- Prohibit the use of heavy fuel oils used in EU territory if their sulphur content exceeds 1% by mass (Art. 3).
- Ensure that combustion plants using heavy fuel oil with sulphur concentration greater than 1% by mass operate with permits that specify emission limits (Art. 3).
- Prohibit the use of marine fuels if their sulphur content exceeds 3,50 % by mass, except for fuels supplied to ships using emission abatement methods operating in closed mode (Art. 5)
- Prohibit the use of gas oils if their sulphur content exceeds 0.1% by mass (Art.4)
- Ensure that marine fuels are not used in the areas of their territorial seas, exclusive economic zones and pollution control zones falling within SO_x Emission Control Areas if the sulphur content of those fuels exceeds 0,10% by mass (Art. 6(2)). This requirement applies as of 1 January 2015.
- Ensure that marine fuels are not used in the areas of their territorial seas, exclusive economic zones and pollution control zones if the sulphur content of those fuels exceeds (Art. 6(1)):
 - a) 3,50% as from 18 June 2014
 - b) 0,50% as from 1 January 2020
- Prohibit the use of marine fuels in their territorial seas, exclusive economic zones and pollution control zones falling outside SO_x Emission Control Areas by passenger ships operating on regular services to or from any Union port if the sulphur content of those fuels exceeds 1,50 % by mass as of 1 January 2020 (Art. 6(5)).
- Ensure that marine diesel oils are not placed on the market in their territory if the sulphur content of those marine diesel oils exceeds 1.5% by mass (Art. 6(10)).
- Ensure that inland waterway vessels and ships at berth in EU ports do not use marine fuels with a sulphur content exceeding 0.1% by mass (Art. 7).
- Ensure that marine gas oils are not placed on the market in their territory if the sulphur content of those marine gas oils exceeds 0.1% by mass (Art. 7).
- Determine penalties applicable to breaches of national provisions transposing the requirements of the Directive. The penalties must be effective, proportionate and dissuasive (Art. 18). If penalties imposed are fines they must be calculated in such a way as to ensure that the fines at least deprive those responsible of the economic benefits derived from their infringement and that those fines gradually increase for repeated infringements.

2.2. Monitoring

- Check, by sampling, that the sulphur content of gas oils used in the territory complies with the requirements of the Directive, i.e. Arts. 3, 4, 5, 6 and 7. The sampling must start on the date on which the relevant limit for maximum sulphur content comes into force, and must be carried out periodically and with enough frequency and quantities to ensure that samples are representative of fuel examined. When marine fuels are examined, samples must be representative of fuel being used by vessels while in relevant sea areas and ports (Art. 13).
- Inspections of marine fuel involves documentary verifications (ships' log books and bunker delivery notes) and, as appropriate: sampling of the marine fuel for on-board combustion while being delivered to ships, or sampling and analysis of the sulphur content of marine fuel for on-board combustion contained in tanks, where technically and economically feasible, and in sealed bunker samples on board ships (Art. 13(2)). Commission Implementing Decision (EU) 2015/253 of 16 February 2015 concerning the sampling and reporting under Council Directive 1999/32/EC as regards the sulphur content of marine fuels sets detailed rules on frequency of sampling of marine fuels being used on board ships (Art. 3) and of marine fuels while being delivered to ships (Art.4)¹²⁸. It also determines rules for on-board spot sampling of marine fuel (Art. 6).
- Use the following reference methods for determining the sulphur content: ISO method 8754 (2003) or PrEN ISO 14596 (2007) (Art. 13(3)).
- Use the fuel verification procedure set out in Appendix VI to Annex VI to MARPOL to determine whether marine fuel delivered to and used on board ships is compliant with the sulphur limits required by Articles 4, 5, 6 and 7 (Art. 13(3)).

2.3. Reporting

- Report to the Commission, by 30 June each year, on the basis of the results of the sampling, analysis and inspections carried out in accordance with Article 6, on compliance with the sulphur standards set out in this Directive for the preceding year.
- Commission Implementing Decision (EU) 2015/253 of 16 February 2015 concerning the sampling and reporting under the Directive (EU) 2016/802 as regards the sulphur content of marine fuels determines format and content of the annual report to be submitted by the Member States to the Commission on the compliance with sulphur standards for marine fuels. Minimum content of the annual report is determined in Article 7, whereas format of the report is determined in Article 8. Thus, countries may choose to use the Union information system to fulfil the relevant annual reporting obligations. Member States not using the Union information system should either facilitate a connection between the Union information system and their national system that can at least record,

¹²⁸ Please note that Article 3 and 4 of the Commission Implementing Decision (EU) 2015/253 do not apply to landlock countries (Austria, Hungary, Luxemburg, Slovakia and Czech Republic).

where applicable, the same fields as those in the Union information system, or report electronically on all items referred to in Article 7 of the Commission Implementing Decision.

- Not earlier than 1 January 2016, and subject to the availability of common shared data regarding sulphur compliance verifications and sampling, Member States may use the risk-based targeting mechanism integrated into the Union information system to prioritise ship fuel verification in a cost-effective manner.

2.4. Enforcement

- Ensure that competent authorities responsible for inspection verify the on-board ship documentation including bunker delivery notes, ships' logbooks, or abatement method documents, as appropriate. In addition, other on-board documentation may be considered by the inspectors to ascertain sulphur in fuel compliance as well as the analysis of fuel samples taken on board in case the documentation checks indicates a non compliance risk. Ships found not to be in compliance with the required standards for marine fuels not intentionally (i.e. fuel unavailability in a previous port of call), might be requested to provide additional evidence including actions taken to achieve compliance, and attempts to purchase compliant marine fuel.
- Introduce effective, proportionate and dissuasive penalties applicable to breaches of the national provisions adopted pursuant to this Directive. The penalties may include fines, which should have depriving effect and gradually increase for repeated infringements.

2.5. Additional Legal Instruments

A number of other legislative instruments have relevance to controlling atmospheric emissions from mobile sources and must be borne in mind during the implementation of this Directive.

These include:

- Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe amended by Commission Directive (EU) 2015/1480
- Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air, amended by Regulation (EC) 219/2009 and Commission Directive (EU) 2015/1480;
- European Parliament and Council Directive 94/63/EC of 20 December 1994 on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations, amended by Regulations (EC) 1882/2003 and (EC) 1137/2008;

- Directive 2009/126/EC of the European Parliament and of the Council of 21 October 2009 on Stage II petrol vapour recovery during refuelling of motor vehicles at service stations, amended by Commission Directive 2014/99/EU;
- Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions
- Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law
- Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC, as amended by Commission Directives 2000/71/EC, 2011/63/EU, 2014/77/EU, Directives 2003/17/EC, 2009/30/EC, (EU) 2015/1513 and Regulation (EC) 1882/2003;
- Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information, amended by Commission Regulations (EC) 692/2008, (EU) 566/2011, (EU) 459/2012 and Regulation (EC) 595/2009;
- Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, as amended by Commission Directives 2001/63/EC, 2010/26/EC, 2012/46/EU, Directives 2002/88/EC, 2004/26/EC, 2011/88/EU, Council Directive 2006/105/EC and Regulation (EC) 596/2009;
- Regulation (EC) No 595/2009 of the European Parliament and of the Council of 18 June 2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC, amended by Commission Regulations (EU) No 582/2011 and (EU) 133/2014
- Directive 2009/40/EC of the European Parliament and of the Council of 6 May 2009 on roadworthiness tests for motor vehicles and their trailers *(to be repealed by Directive 2014/45/EU of the European Parliament and of the Council of 3 April 2014 on periodic roadworthiness tests for motor vehicles and their trailers and repealing Directive 2009/40/EC as of 19 May 2018)*
- Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (repealing Directive 77/537/EEC on smoke emissions from diesel engines for use in agricultural or forestry tractors as of 31 December 2015)
- Regulation (EC) No 443/2009 of the European Parliament and of the Council of 23 April 2009 setting emission performance standards for new passenger cars as part of the Community's integrated approach to reduce CO₂ emissions from light-duty vehicles, amended by Commission Regulation (EU) No 397/2013, Regulation (EU) No 333/2014 and Commission Delegated Regulation (EU) 2015/6

- Regulation (EU) No 510/2011 of the European Parliament and of the Council of 11 May 2011 setting emission performance standards for new light commercial vehicles as part of the Union's integrated approach to reduce CO₂ emissions from light-duty vehicles amended by Commission Delegated Regulations (EU) 205/2012, (EU) 404/2015 and Regulation (EU) 253/2014
- Directive 2005/35 of the European Parliament and of the Council of 7 September 2005 on ship-source pollution and on the introduction of penalties for infringements.

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the table below. The tasks are arranged under subheadings and organised in chronological order of implementation where possible.

Table 15. Directive On Sulphur Content Of Certain Liquid Fuels – Key Implementation Tasks

DIRECTIVE ON SULPHUR CONTENT OF CERTAIN LIQUID FUELS – KEY IMPLEMENTATION TASKS												
1	Planning and Assessments											
1.1	Designate authorities and other organisations with responsibility for regulating the quality of heavy fuel oil, gas oils and marine fuels used in their territory. Responsibilities include: <ul style="list-style-type: none"> sampling and analysing the quality of heavy fuel oil used in plants or elsewhere, gas oils used for heating or other purposes, and marine gas and diesel oils used on board ships; penalising any breaches of national provisions transposing the requirements of the Directive. 											
1.2	Carry out assessment of the sulphur content of heavy fuel oil in plants and of gas oils used in their territory.											
1.3	Decide on the possibility to use the Union information system to fulfil the relevant annual reporting obligations as regards marine fuels.											
1.4	Plan resources to carry out the sulphur in fuel specific inspection in EU ports in accordance with Commission Implementing Decision (EU) 2015/253.											
2	Regulation and Enforcement											
2.1	Establish a regulatory system to: <ul style="list-style-type: none"> ensure that heavy fuel oil for land application with a sulphur content greater than 1% is not used; ensure that gas oil for land application with a sulphur content greater than 0.1% is not used; ensure that new sulphur limits for marine fuels are applied (1 January 2015- 1 January 2020) <table border="1" data-bbox="418 1207 1323 1386"> <thead> <tr> <th></th> <th>Inside EU SECA¹²⁹</th> <th>Outside EU SECA</th> </tr> </thead> <tbody> <tr> <td>At berth/anchor</td> <td rowspan="3">0,10%</td> <td>0,10% (not if < 2hrs or shoreside electricity)</td> </tr> <tr> <td>Passenger ships on regular service</td> <td>1,50% (until 1 January 2020)</td> </tr> <tr> <td>Other ships</td> <td>3,50 % (0.50% as of 1 January 2020)</td> </tr> </tbody> </table> <ul style="list-style-type: none"> cover exceptional circumstances when it may be difficult to apply the relevant limits on the maximum sulphur content in liquid fuels. This should set higher limits on permissible sulphur content, time limits for derogations, and a system for notifying derogations; ensure that marine diesel oils are not placed on the market if the sulphur content of those marine diesel oils exceeds 1,50 % by mass. 			Inside EU SECA ¹²⁹	Outside EU SECA	At berth/anchor	0,10%	0,10% (not if < 2hrs or shoreside electricity)	Passenger ships on regular service	1,50% (until 1 January 2020)	Other ships	3,50 % (0.50% as of 1 January 2020)
	Inside EU SECA ¹²⁹	Outside EU SECA										
At berth/anchor	0,10%	0,10% (not if < 2hrs or shoreside electricity)										
Passenger ships on regular service		1,50% (until 1 January 2020)										
Other ships		3,50 % (0.50% as of 1 January 2020)										
2.2	Determine effective, proportionate and dissuasive penalties applicable to breaches of the national provisions adopted pursuant to this Directive and ensure that they are effectively implemented.											
3	Monitoring											

¹²⁹ SOx Emission Control Area (SECA). The current EU SECAs are the Baltic Sea and North Sea as respectively defined in regulation 1.11.2 of Annex I and regulation 1.14.6 of Annex V of MARPOL Convention.

3.1	Set up a system and procedure for monitoring the sulphur content of heavy fuel oil and gas oils and marine fuels used in their territory. This includes the designation and control of laboratories for carrying out analysis of samples taken.
3.2	Provide relevant training on monitoring procedures, in particular in ISO method 8754 (2003) or PrEN ISO 14596 (2007).
3.3	Maintain a publicly available register of local suppliers of marine fuel;
4	Reporting
4.1	Set up a system (for example a database) to collect results of sampling and analysis of heavy fuel oil used in plants and gas oils. This system should include summaries of derogations and a method for producing annual reports.
4.2	Report to the Commission on transposition measures.
4.3	Where necessary, co-operate with industry and local authorities to obtain information about the difficulties in applying the fuel specifications in case of supply difficulties.
4.4	Inform the Commission of difficulties in applying the fuel specifications in case of supply difficulties.
4.5	Report to the Commission by 30 June of each year on the sulphur content of the liquid fuels falling within the scope of this Directive and used within the Member State during the preceding calendar year. This report shall contain at least information stipulated by Commission Implementing Decision (EU) 2015/253
5	Technical Advice and Guidance
5.1	Prepare and issue guidance on monitoring procedures which incorporate ISO method

3.2. Phasing Considerations

The most demanding and time-consuming task associated with implementing this Directive is the setting up of an efficient system to monitor the sulphur content of fuels being used in their territory and at sea. The planning and setting up of monitoring systems and procedures need to begin during the initial phase of implementation. Depending on the existing institutional structure, the transposition of legislation may be required before a new structure can be introduced, since it may be necessary to establish the new institutions through legislation. The institutional structures and systems for monitoring and enforcing the requirements of the Directive should involve authorities responsible for maritime affairs.

4. IMPLEMENTATION GUIDANCE

The practical implementation of the provisions of the Directive will depend on the particular needs and on the institutional and administrative structures and resources of each country. However, this section briefly gives some suggestions for implementing the Directive, drawn from the experiences of various Member States.

The Commission has developed a series of medium and long-term measures within the framework of a "Sustainable Waterborne Transport Toolbox" to foster sustainable and competitive short sea shipping¹³⁰. The new rules and, in particular the use of alternative abatement technologies, will over time significantly reduce compliance costs and stimulate innovation and resource efficiency. In September 2011, the Commission presented a staff working paper (The Sustainable Waterborne Transport Toolbox) together with the proposal amending the Sulphur Directive as a response to stakeholder concerns related to the implementation of the stricter sulphur standards. The toolbox contains a number of short-term measures aiming to reduce costs of compliance with the new low sulphur standards. In addition, the toolbox proposes a set of medium and longer-term accompanying measures aimed at addressing the environmental and other challenges faced by the shipping sector also from a broader perspective.

In June 2013 the first progress report on the toolbox was published presenting the progress to date on the implementation of the toolbox as well as outline next steps. To support the toolbox, the European Commission has launched a set of activities aiming to take forward all aspects of sustainable shipping relevant to a cost-efficient and coherent implementation of the Sulphur Directive. To serve this purpose the European Sustainable Shipping Forum (ESSF) was created (the decision establishing forum was published in September 2013) bringing together 28 Member States and 32 maritime organisations to enable a structured dialogue, exchange of best practices and coordination, including on issues related to fuel availability. The ESSF envisages to:

- provide guidance on the overall implementation of the Sulphur Directive aiming to reinforce the monitoring of compliance in the EU
- create the framework conditions for the use of marine LNG as ship fuel
- promote the use of scrubbing technology in shipping by addressing its technical, economic and operational aspects
- coordinate research and development activities and encourage innovation
- explore all available financing opportunities
- identify potential improvements in sustainability and competitiveness.
- Port reception facilities
- Monitoring Reporting Verification (under the responsibility of DG CLIMA)

¹³⁰ Commission Staff Working Paper Pollutant Emission Reduction From Maritime Transport And The Sustainable Waterborne Transport Toolbox, SEC(2011) 1052 final, available at: http://ec.europa.eu/environment/air/transport/pdf/ships/sec_2011_1052.pdf

The Commission is managing the above-mentioned wide-spectrum of activities of the sub-groups under the ESSF with the expertise of EMSA as technical secretariat. The work of the ESSF has been highly recognised in the EU and also at the international scene (IMO level and latest submissions) the stakeholders have recommended the Commission to continue the EESF activities beyond 2015 since they have recognised the value of having a forum to discuss and solve practical issues related to sustainable shipping¹³¹..

4.1. Regulation

- National Regulations to transpose this Directive in most of the Member States are part of regulations on specifications for motor fuels.
- The ministry with primary responsibility for administering national legislation which transposes the requirements for the sulphur content of heavy fuel oil and gas oil could either be the ministry responsible for energy matters or the ministry responsible for environmental matters. However, because the aim of the Directive is air quality control, whichever ministry has primary responsibility must co-operate closely with the ministry responsible for environmental issues, including water management and with other ministries such as the ministry of transport, in developing legislation to transpose the requirements of the Directive and in establishing measures to implement the requirements of the Directive.
- Countries should conduct discussions on implementation options with representatives of the oil sector as well as other interested parties in order to avoid compliance problems

Examples of Practice in Member States:

Croatia: The national transposing measures for the Directive on sulphur content in certain liquid fuels are part of the legislation adopted within the framework Law on air protection. Thus, provisions of the Law on air protection (Official Gazette no. 130/2011 and 47/2014) provide a legal basis for the implementation of this Directive, whereas detailed rules on the maximum sulphur content for heavy fuel oil, gas oil and marine gas oils and monitoring requirements are determined in the secondary legislation adopted thereof, i.e. the Regulation on the quality of liquid oil fuels (Official Gazette no. 113/2013, 76/2014, 56/2015). The Programme for monitoring the quality of liquid oil fuels is adopted annually and published in the Official Gazette.

¹³¹ COMMISSION DECISION of 7.1.2016 on amending Decision C(2013) 5984 final of 24 September 2013 on setting-up the group of experts on maritime transport sustainability - The European Sustainable Shipping Forum (ESSF)

4.2. Monitoring

- The Directive requires that the sulphur content of fuels used in EU territory is checked by sampling. The detailed organisation of the sampling regime is left to the discretion of the Member State, but the system must be efficient and ensure that the sulphur content of fuels placed on the market complies with the requirements set out in the Directive. The sampling shall be carried out with sufficient frequency and in such a way that the samples are representative of the gas oil examined. Commission Implementing Decision (EU) 2015/253 lays down detailed rules concerning the sampling of marine fuels.
- The authorities/organisations set up to carry out monitoring functions must have the administrative apparatus (sufficient human, technical and financial resources), including sampling and statistical interpretation methodologies, for testing sulphur content levels and enforcing the requirements.
- Local authorities can be made responsible for monitoring within their jurisdictions.
- Private sector actors could also be required to monitor their fuel supplies and to report the results to the relevant authorities.
- Imported fuels are monitored in most Member States by the customs and excise department, using their laboratories to carry out sampling, where these are available.
- Fuels produced within the Member State are checked during one or more of the production, wholesale or retail stages. The most appropriate and adequately equipped organisations to carry out monitoring are found within the oil sector.

The European Maritime Safety Agency has developed inspection guidance under the Directive expanding on the provisions of the Commission Implementing Decision (EU) 2015/253, which is available at: <http://www.emsa.europa.eu/news-a-press-centre/external-news/item/2407-sulphur-inspection-guidance.html>

4.3. Enforcement

- The enforcement of requirements stipulated in the Directive on sulphur content in certain liquid fuels through imposing appropriate sanctions for infringements has to be ensured. Inspection system should be set robustly in order to detect and impose sanctions to suppliers that are found delivering non-compliant fuel.
- Customs officials should report to the competent authorities on shipments of imported fuels that do not comply with the requirements of the Directive. For ensuring efficient controls, these customs officials should be adequately trained about the technical requirements under this Directive.
- Port inspectors or sulphur inspectors nominated by the competent authorities in the Member States should carry out controls in accordance with Article 13 of the Directive on sulphur content in certain liquid fuels.

5. COSTS

The main types of costs arising from the implementation of this Directive are given in the checklist below.

Table 16. Checklist of the Types of Cost Incurred to Implement the Directive

Checklist of the Types of Cost Incurred to Implement the Directive
Initial set-up costs: <ul style="list-style-type: none">• establishment of competent authorities;• devising systems and procedures;• provisions for training (also provided by the European Maritime Safety Agency);• preparation of technical guidance (also provided by the European Maritime Safety Agency).
Capital expenditure: <ul style="list-style-type: none">• fuel sulphur analyser
Ongoing running costs: <ul style="list-style-type: none">• fuel sampling equipment (kits)• labour costs for sampling activity;• labour costs for fuel analysis;• operating costs for analyser;• labour costs for processing data and reporting to the Commission.• Remote sensing technologies

THE DIRECTIVES ON VOC EMISSIONS RESULTING FROM STORAGE AND DISTRIBUTION OF PETROL

Official Title: European Parliament and Council Directive 94/63/EC on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations (OJ L 365, 31.12.1994),

as amended by:

Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty (OJ L 284, 31.10.2003)

Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part One (OJ L 311, 21.11.2008)

European Parliament and Council Directive 2009/126/EC of 21 October 2009 on Stage II petrol vapour recovery during refuelling of motor vehicles at service stations (OJ L 285, 31.10.2009),

as amended by:

Commission Directive 2014/99/EU of 21 October 2014 amending, for the purposes of its adaptation to technical progress, Directive 2009/126/EC on Stage II petrol vapour recovery during refuelling of motor vehicles at service stations (OJ L 304, 23.10.2014)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Petrol is a complex mixture of volatile organic compounds (VOC) which readily evaporate into the air where they contribute to several pollution problems. These include excessive levels of toxic benzene in ambient air and photochemical formation of ozone which is an air pollutant causing respiratory illnesses such as asthma. In addition, ozone is a greenhouse gas.

The reductions of VOC emissions achieved the two Directives reduce the levels of photochemical oxidants, e.g. ozone, for which the VOC from petrol play a vital role as precursor of pollution. Reduction in emissions from petrol storage, distribution and use also reduces exposure to substances that are carcinogenic, mutagenic and toxic for reproduction.

Directive 94/63/EC (often referred to as Stage I Directive) aims at combating air pollution by reducing VOC emissions from operations, installations, vehicles and vessels used for the storage, loading and transport of petrol from one terminal to another, or from a terminal to a service station. The Directive does not cover the refuelling of vehicles at service stations (this is instead covered by Directive 2009/126/EC, Stage II petrol). The Stage I control measures established by Directive 94/63/EC call for measures to „close” the system for storage and distribution of petrol by reducing breathing losses from storage tanks at terminals and by ensuring that the petrol vapours displaced during transport and loading operations are captured, contained and transported back to terminals where the vapours can be regenerated into petrol. A summary of the obligations follows:

- Loading and unloading equipment shall be designed and operated in accordance with the technical provisions of Annex II;
- Member States may adopt technical measures for the reduction of losses of petrol other than those set down in Annex II if such alternative measures are demonstrated to have at least the same efficiency;
- Member States shall inform the other Member States and the Commission of any existing measures or of any special measures referred to in this paragraph which they contemplate taking and of their grounds for taking them.

Directive 2009/126/EC on Stage II petrol vapour recovery during refuelling of motor vehicles at service stations (hereinafter referred to as the Stage II petrol Directive) has the following aims:

- Petrol vapour displaced from the fuel tank of a motor vehicle during refuelling at a service station is recovered;
- Petrol Vapour Recovery must capture 85% of petrol vapour;
- Directive applies to new service station or those having undergone major refurbishment which the annual throughput must be in excess of 500 m³; larger existing stations with a throughput in excess of 3000 m³ per year must apply by 31 December 2018.

In 2014 Directive 2009/126/EC Directive was amended by Directive 2014/99/EU for the purposes of its adaptation to technical progress. On 25 September 2013, CEN made available Standards EN 16321-1:2013 and EN 16321-2:2013. Standard EN 16321-1:2013 specifies the test methods for the type approval of petrol vapour recovery systems for use in service stations. Standard EN 16321-2:2013 specifies the test methods to be used at service stations to verify the operation of such vapour recovery systems. Amendments introduced concern Article 4 and 5 thus ensuring consistency with relevant standards. Transposition deadline set for the Member States to comply with the provisions of this Directive is 12 May 2016.

Commission, assisted by an external consultant, will carry out an extensive evaluation of the effectiveness, efficiency, coherence, relevance and the EU added value of the two Directives. This is part of the European Commission's Regulatory Fitness and Performance programme (REFIT) to make EU law lighter, simpler and less costly. In addition, an assessment of the implementation status will be carried out.

This work will also include the evaluation required under Article 7 of Directive 2009/126/EC, which calls for the review of implementation, in particular:

- The 100 m³ /year threshold referred to in Article 3(1)(b) and (2)(b), Stage II Directive and Article 6(3) of Stage I;
- The in-service compliance record of Stage II petrol vapour recovery systems;
- The need for automatic monitoring equipment.

The evaluation study conducted by the external consultants was published in February 2016¹³². The final Staff Working Document on the REFIT evaluation and the Commission Report on the implementation of Directive 2009/126/EC are expected to be finalised in the fourth quarter of 2016.

¹³² <http://bookshop.europa.eu/en/evaluation-of-directive-1994-63-ec-on-voc-emissions-from-petrol-storage-distribution-and-directive-2009-126-ec-on-petrol-vapour-recovery-pbKH0416107/>

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Regulation

2.1.1. Obligations linked to Stage I Directive:

- Require that storage installations at terminals be designed and operated in accordance with the technical provisions set out in the Directive. (Art. 3 and Annex I, Stage I Directive)
- Require that loading and unloading equipment of mobile containers at terminals be designed and operated in accordance with the technical provisions set out in the Directive. (Art. 4 and Annex II, Stage I Directive)
- Require that all terminals with loading facilities for road tankers be equipped with at least one gantry, which meets the specifications for bottom-loading equipment laid down in the Directive. (Art. 4 and Annex IV, Stage I Directive)
- With effect from 1 January 2005 require that all road tanker loading gantries at all terminals, unless exempted as specified in the Directive, meet the specifications for bottom-loading equipment set out in the Directive. (Art. 4 and Annex IV, Stage I Directive)
- Require that mobile containers be designed and operated in accordance with the requirements set out in the Directive. (Art. 5, Stage I Directive)
- Require that loading and storage equipment at service stations and terminals where the intermediate storage of vapours is carried out be designed and operated in accordance with the technical provisions set out in the Directive. (Art. 6 and Annex III, Stage I Directive)

2.1.2. Obligations linked to Stage II Directive:

- Upon having installed a Stage II petrol vapour recovery system at a service station, Member States must ensure that this station displays a sign, sticker or other notification on, or in the vicinity of, the petrol dispenser, informing consumers of that fact. (see below on sticker example from CECOD. (Art. 5(3), Stage II Directive (2009/126/EU)
- Ensure full compliance with Stage II Directive by 1 January 2012 and notify the Commission about the transposing legislative measures, which should provide reference to the Stage II Directive. (Art.10, Stage II Directive)
- Ensure compliance with any technical standards that may be adopted by the Commission in regulatory procedure for ensuring a harmonised application of Articles 4 and 5 of Stage II Directive. (Art. 8, Stage II Directive)
- Ensure that any new service station (in place after 1 January 2012) – unless exclusively used in relation to the construction and delivery of new motor vehicles - shall be equipped with a Stage II petrol vapour recovery system if:
 - its actual or intended throughput is greater than 500 m³ /year; or

- its actual or intended throughput is greater than 100 m³ /year and it is situated under permanent living quarters or working areas.
- Ensure that any existing service station which undergoes a major refurbishment shall be equipped with a Stage II petrol vapour recovery system at the time of the refurbishment if:
 - its actual or intended throughput is greater than 500 m³ /year; or
 - its actual or intended throughput is greater than 100 m³ /year and it is situated under permanent living quarters or working areas.
- Ensure that any existing service station (in place before 1 January 2012) with a throughput in excess of 3 000 m³ /year must be equipped with a Stage II petrol vapour recovery system by no later than 31 December 2018. (Art. 3, Stage II Directive)
- Ensure that with effect from the date on which Stage II petrol vapour recovery systems become mandatory pursuant to Article 3, and that:
 - the petrol vapour capture efficiency of such systems is equal to or greater than 85 % as certified by the manufacturer in accordance with relevant European technical standards or type approval procedures referred to in Article 8 or, if absence of such standards or procedures, with any relevant national standard;
 - where the recovered petrol vapour is transferred to a storage tank at the service station, the vapour/petrol ratio shall be equal to or greater than 0,95 but less than or equal to 1,05. (Art. 4, Stage II Directive)

2.2. Monitoring and Enforcement

2.2.1. Obligations linked to Stage I Directive:

- Ensure that road tankers are regularly tested for vapour tightness and that vacuum/pressure valves on all mobile containers are periodically inspected for correct functioning. (Art. 5, Stage I Directive)
- Ensure the establishment of measurement and analysis methods and their frequency for determining the mean concentration of vapours in the exhaust from the vapour recovery unit at loading and unloading installations at terminals. The methods and their frequency shall satisfy the conditions set out in the Directive. (Annex II, Para. 2, Stage I Directive)
- Ensure that connection lines and pipe installations at loading and unloading installations at terminals are checked regularly for leaks. (Annex II, Para. 3, Stage I Directive)
- Ensure that loading operations at terminals are shut down at the gantry in the event of a leak of vapour; and that equipment for such shutdown operations is installed at the gantry (Annex II, Para. 4, Stage I Directive)

2.2.2. Obligations linked to Stage II Directive:

- Ensure that Stage II petrol vapour recovery systems are tested at least once a year to ensure that the vapour/petrol ratio under simulated petrol flow conditions is in conformity with Art. 4(2) or through other equivalent methodology. (Art. 5(1), Stage II Directive)
- For automatic monitoring systems installed ensure:
 - that petrol vapour capture efficiency is tested for installed automatic monitoring system at least every three years;
 - that the system automatically detects faults in the proper functioning of the Stage II petrol vapour recover system and in the monitoring system itself, leading to an indication of the faults to the service station operator and an automatic stop of the flow of petrol from the faulty dispenser. (Art. 5(2), Stage II Directive)
- Service stations having installed a Stage II petrol vapour recovery system have to inform consumers about this through a sign, sticker or other suitable notification in the vicinity of the petrol dispenser (see below under implementation guidance for harmonised best practice regarding a sticker). (Art. 5(3), Stage II Directive)
- Introduce effective, dissuasive and proportionate criminal penalties for non-compliance with the Directive since the Directive is listed in Annex A to the Environmental Crimes Directive (2008/99/EC) regarding EU legislation the infringement of which constitutes unlawful conduct pursuant to Article 2(a)(i) of this Directive. (Art. 6, Stage II Directive)

2.3. Reporting

2.3.1. Obligations linked to Stage I Directive:

- Inform the Commission and other Member States of:
 - existing and contemplated measures that are more stringent than those set out in the Directive, which satisfy the conditions set out in the Directive, and the grounds for taking them (Arts. 3, 4 and 6, Stage I Directive);
 - existing and contemplated alternative technical measures demonstrated to have at least the same efficiency as the measures set out in the Directive, and the grounds for taking them. (Arts. 3,4 and 6, Stage I Directive)
- Inform the Commission of:
 - terminals subject to derogations from the specifications for loading, unloading and storage equipment (Arts. 4 and 9, Stage I Directive);
 - details of areas within which it intends to grant a derogation for specified service stations from the requirements for loading and storage equipment, and subsequently of any changes to such areas. (Art. 6, Stage I Directive).
- Report to the Commission on:
 - implementation of the Directive (Decision 2004/461/EC);

- transposition measures and the text of the provisions of national law adopted in the field governed by the Directive (Art. 10, Stage I Directive).

2.3.2. Obligations linked to Stage II Directive:

- Report to the Commission about national provisions introducing effective, dissuasive and proportionate criminal penalties for non-compliance with the Directive also taking into account the fact that non-compliance is considered an environmental offence leading to criminal penalties pursuant to the Environmental Crimes Directive. (Art. 6, Stage II Directive)
- Report to the Commission about implementation of Stage II Directive, communicating the texts of the transposing legislative measures, which should provide reference to the Stage II Directive (Art.10, Stage II Directive).

2.4. Additional Legal Instruments

A number of legislative instruments have relevance to controlling emissions from mobile sources and in relation to the quality of fuels must be borne in mind during the implementation of this Directive. These include:

- Gothenburg Protocol, as amended in 2012
- Directive 2008/68/EC of the European Parliament and the Council of 24 September 2008 on inland transport of dangerous goods, as amended by Commission Decisions 2009/240/EC, 2010/187/EU, 2011/26/EU, Commission Directive 2010/61/EU, 2012/45/EU, 2014/103/EU and Commission Implementing Decisions 2012/188/EU, 2013/218/EU, (EU) 2015/217 and (EU) 2015/974 (sets up a common regime covering all aspects of the inland transport of dangerous goods by road and rail)
- Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe amended by Commission Directive (EU) 2015/1480 (the Directive has the objective of reducing tropospheric ozone pollution to which the emissions of VOCs contribute).
- Council Directive 2001/81/EC on national emission ceilings for certain atmospheric pollutants, as amended by Council Directives 2006/105 and 2013/17/EU and Regulation (EC) 219/2009 (establishes requirements for national ceilings for VOCs, to which the controls in Directives 94/36/EC and 2009/126/EC contribute);
- Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (Chapter V addressing the other major source of VOCs, that is industrial emissions)
- Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC, as amended by Commission Directives 2000/71/EC, 2011/63/EU, 2014/77/EU, Directives 2003/17/EC, 2009/30/EC, (EU) 2015/1513 and Regulation (EC) 1882/2003;

- Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information, amended by Commission Regulations (EC) 692/2008, (EU) 566/2011, (EU) 459/2012 and Regulation (EC) 595/2009;
- Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, as amended by Commission Directives 2001/63/EC, 2010/26/EC, 2012/46/EU, Directives 2002/88/EC, 2004/26/EC, 2011/88/EU, Council Directive 2006/105/EC and Regulation (EC) 596/2009;
- Regulation (EC) No 595/2009 of the European Parliament and of the Council of 18 June 2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC, amended by Commission Regulations (EU) No 582/2011 and (EU) 133/2014
- Directive 2009/40/EC of the European Parliament and of the Council of 6 May 2009 on roadworthiness tests for motor vehicles and their trailers (*to be repealed by Directive 2014/45/EU of the European Parliament and of the Council of 3 April 2014 on periodic roadworthiness tests for motor vehicles and their trailers and repealing Directive 2009/40/EC as of 19 May 2018*)
- Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (*repealing Directive 77/537/EEC on smoke emissions from diesel engines for use in agricultural or forestry tractors as of 31 December 2015*)
- Directive (EU) 2016/802 of the European Parliament and of the Council of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels
- Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law

It needs to be considered that Directive 94/63/EC is meanwhile 20 years old. Its annexes contain technical provisions (e.g. for means of transport) which have meanwhile been complemented by specific legislation (e.g. on transport safety).

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing these Directives are summarised in the checklist below. The key tasks are arranged under subheadings and organised in chronological order of implementation (where possible).

Table 17. Directive on VOC emissions resulting from storage and distribution of petrol - Key Implementation Tasks

DIRECTIVES ON VOC EMISSIONS RESULTING FROM STORAGE AND DISTRIBUTION OF PETROL - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	<p>Designate the competent authorities with responsibility for implementing the Directives. Responsibilities would include:</p> <ul style="list-style-type: none"> • authorising terminals and services stations (possibly requiring an environmental permit); • ensure that the fuelling equipment in the service stations bear a clear label to inform the consumers about fuel recovery equipment and procedures pursuant to Art. 5(3) of Directive 2009/129/EC • monitor compliance with emissions limits for petrol vapour from storage tanks, mobile containers, and from the service stations when refuelling • appointment of competent laboratories. • enforcement action - imposing penalties in case of non-compliance (pursuant to the Environmental Crimes Directive).
1.2	Establish systems and procedures for authorising terminals and services stations in order to ensure that they comply with the Directive's requirements
1.3	Ensure full compliance with Stage II Directive by 1 January 2012 also ensure compliance with any kind of technical standards that may be adopted by the Commission in regulatory procedure for ensuring a harmonised application of Articles 4 and 5 of Stage II Directive)
1.4	<p>Ensure that any new service station (in place after 1 January 2012) is equipped with a Stage II petrol vapour recovery system if:</p> <p>(a) its actual or intended throughput is greater than 500 m³ /year; or</p> <p>(b) its actual or intended throughput is greater than 100 m³ /year and it is situated under permanent living quarters or working areas.</p>
1.5	<p>Ensure that any existing service station (in place before 1 January 2012) is equipped with a Stage II petrol vapour recovery system either</p> <ul style="list-style-type: none"> • when it undergoes a major refurbishment if: <ul style="list-style-type: none"> – its actual or intended throughput is greater than 500 m³ /year; or – its actual or intended throughput is greater than 100 m³ /year and it is situated under permanent living quarters or working areas. • But no later than 31 December 2018 for any existing service station with a throughput in excess of 3 000 m³ /year <p>Ensure that the petrol vapour capture efficiency of such systems is equal to or greater than 85 % as certified by the manufacturer in accordance with relevant European technical standards or type approval procedures referred to in Article 8 or, if absence of such standards or procedures, with any relevant national standard.</p> <p>Where the recovered petrol vapour is transferred to a storage tank at the service station, the vapour/petrol ratio shall be equal to or greater than 0,95 but less than or equal to 1,05</p>
2	Regulation and Monitoring

2.1	Establish the measurement and analysis methods and their frequency for determining the mean concentration of vapours from terminals.
2.2	Establish the systems and procedures to regularly test the vapour tightness of road tankers. Such tanks must have a high heat-reflectance paint, tanks with external floating roofs must have primary and secondary seals between the tank wall and the floating roof and fixed tanks must be connected to a vapour recovery unit or be fitted with an internal floating roof. These tanks should take into account applicable CEN/TC 296 standards for tanks designated for transport of dangerous goods governing the design, construction, inspection and testing of such metallic tanks ¹³³
2.3	Establish the systems and procedures to periodically inspect the vacuum/pressure valves on all mobile containers for correct functioning.
2.4	Establish the systems and procedures to regularly check for leaks the connection lines and pipe installations at loading and unloading installations at terminals.
2.5	Establish the systems and procedures to ensure that loading operations at terminals are in accordance with Directive 94/63/EC: <ul style="list-style-type: none"> • displaced vapours must be returned through a vapour-tight connection line to a vapour recovery unit for regeneration at the terminal; • vapours must be incinerated when loading onto vessels where vapour recovery is unsafe or technically impossible because of the volume of return vapour; • shut down at the gantry in case of vapour leaks.
2.6	Mobile containers need to be designed and operated so as to retain vapours returned from storage installations.
2.7	Where intermediate storage of vapours is carried out at terminals and during unloading of petrol at service stations and terminals, displaced vapours must be returned through a vapour-tight connection line to the mobile container delivering the petrol.
2.8	Ensure that Stage II petrol vapour recovery systems are tested at least once a year to ensure that the vapour/petrol ratio under simulated petrol flow conditions is in conformity with Art. 4(2) or through other equivalent methodology.
2.9	For automatic monitoring systems installed ensure: <ul style="list-style-type: none"> • that petrol vapour capture efficiency is tested for installed automatic monitoring system at least every three years; • that the system automatically detects faults in the proper functioning of the Stage II petrol vapour recovery system and in the monitoring system itself, leading to an indication of the faults to the service station operator and an automatic stop of the flow of petrol from the faulty dispenser. (Art. 5(2), Stage II Directive)
2.10	Service stations having installed a Stage II petrol vapour recovery system have to inform consumers about this through a sign, sticker or other suitable notification in the vicinity of the petrol dispenser.
3	Reporting
3.1	Inform the Commission of: <ul style="list-style-type: none"> • more stringent national measures; • alternative technical measures; • terminals subject to derogations; • areas within which there is the intention to grant a derogation for service stations; • implementation and transposition measures.
3.2	Inform other Member States of: <ul style="list-style-type: none"> • more stringent national measures; and • alternative technical measures.
3.3	Establish a reporting system, also taking into account the reporting framework under the Air Quality Directive (2008/50/EC) and the implementing Decision 2011/850)
4	Technical Advice and Guidance

¹³³ List of CEN standards available at: <http://www.cen.eu/cenorm/aboutus/index.asp>

4.1	Prepare and issue technical guidance to the monitoring authorities to help their application of nationally harmonised testing procedures monitoring terminals and service stations, as well as vehicles and vessels for the transport of petrol.
5	Enforcement
5.1	Introduce criminal penalties for non-compliance with the Directive since it is listed in Annex A to the Environmental Crimes Directive (2008/99/EC) regarding EU legislation the infringement of which constitutes unlawful conduct pursuant to Article 2(a)(i) of this Directive.

3.2. Phasing Considerations

Experience within Member States suggests that the most demanding and time-consuming tasks (see report of 2009¹³⁴) associated with implementing these Directives are:

- Establishing legislation for meeting the emission limits for petrol vapour from storage tanks, mobile containers: trucks, trains and inland waterway vessels and from the service stations. The transposing structure needs to be carefully considered especially in countries where the issues covered by the Directive are the responsibility of various ministries (e.g. ministry of environment for fixed installations and ministry of transport for mobile containers).
- Establishing and developing the institutional structure, as well as systems and procedures for:
 - authorising the relevant terminals and service stations covered to ensure that they comply with the Directive's requirements as regards the design and operation of their storage, loading and unloading installations;
 - monitoring and enforcing the emissions limits for petrol vapour from storage tanks, mobile containers and from refuelling equipment, as set out in the Directives, in particular the acquisition and training of sufficient personnel.

Depending on the existing institutional structure, the transposition of legislation may be required before a new structure can be introduced, since it may be necessary to establish the new institutions through legislation.

Member States are allowed to uphold or impose more stringent measures relating to evaporative losses than those set out in the Directive. These may apply to storage installations at terminals, the loading of mobile containers, unloading and loading installations at terminals, and loading and storage equipment at service stations. Such measures are permitted throughout the Member State's territory or in geographical areas where it is established that they are necessary for the protection of human health or the environment because of special conditions; and are subject to additional conditions set out in the Directive. Member States may also maintain or develop technical measures that are alternatives to those set out in the Directive. The Member State must be able to show that the alternative measures are at least as efficient as those set out in the Directive. The more stringent and alternative measures may relate to storage installations at terminals, the loading of mobile containers, unloading and loading installation at terminals, and loading and storage equipment at service stations. More stringent or alternative technical measures should in particular be considered for the Stage-I Directive which has meanwhile aged and more effective abatement technologies should be readily available on the market.

¹³⁴ ENTEC UK (contracted by the European Commission), Assessment of the Implementation of the VOC Stage I Directive (94/63/EC), Final Report, April 2009

For Directive 94/63/EC certain Member States have been given longer periods in which to adapt to the requirements of the Directive, which have presented particular problems for the arctic countries (Finland and Sweden) and several Member States were in general delay in ensuring full compliance with the requirements until the end of the implementation period. Examples of derogations for the newest Member States:

- Bulgaria and Romania: various transition periods for compliance with a final deadline for implementation of 31 December 2009;
- Cyprus: extended deadline as regards compliance with Directive 94/63/EC for five petrol stations until 2008.

Such derogations have taken account of any major environmental measures that they may already have adopted which cover issues relating to the Directive, or the particular burden imposed by the measures in the Directive owing to the structure of their networks. The implementation timetable to be applied in each candidate country should be brought up and discussed in the accession negotiations. In the Directive, implementation is staged according to the age and throughput of the installations, vehicles, vessels and service stations.

Regarding Directive 2009/126/EC (Stage II) candidate countries may start with checking the condition of existing service stations (those stations which are built or for which an individual planning permission, construction licence or operating licence was granted before 1 January 2012), as they may need to adapt existing infrastructure. It is preferable to install vapour recovery equipment when they undergo major refurbishment of the fuelling system (that is to say, significant alteration or renewal of the station infrastructure, particularly tanks and pipes), since this significantly reduces the cost of the necessary adaptations. Larger existing stations are better able to adapt and should install petrol vapour recovery earlier, given that they make a greater contribution to emissions. New service stations can integrate petrol vapour recovery equipment during the design and construction of the service station and can therefore install such equipment immediately.

In the implementation of the Directive, local actors in the Member State play a major role. The implementation of the Directive requires all operators of petrol terminals, service stations and petrol transportation to implement a range of technical and management requirements to minimise vapour losses from the handling of petrol.

4. IMPLEMENTATION GUIDANCE

Relevant information can be retrieved through the website of DG ENV on petrol vapour recovery legislation and developments (<http://ec.europa.eu/environment/industry/stationary/petrol.htm>). This includes a link to the CIRCABC interest group where all relevant documents and studies can be found.

4.1. Planning

- Consider whether to introduce stricter provisions and in particular limit values than what is provided in the Directives. For instance, Germany using carbon adsorption together with hybrid membrane is capable of meeting the 150 mg/Nm³ limit specified in German legislation.
- Discuss with industry and directly related stakeholders the types of technology employed in modern vapour recovery units that would be most suitable taking into account all general considerations and local peculiarities (e.g. climate).
- Identify the various service stations falling under the scope of the Directives, in particularly for Stage II Directive, including new stations (after 1 January 2012) and those that were established before this date but need major refurbishment of the fuelling system.
- Plan the initial consultation with stakeholders and industry and the best means to inform consumer about the petrol vapour recovery systems at the service stations

4.2. Regulation

- A number of national ministries may have some responsibility for implementing various aspects of this Directive — for example the ministries of environment, energy and transport. It is therefore essential that there is co-operation between different ministries, and also prior consultation with other interested groups (e.g. the oil industry).
- In order to ensure that the fixed terminals and service stations covered by the Directive are designed and operated in accordance with the Directive's requirements, candidate countries would be advised to establish an authorisation regime.

Examples of Practice from a Member State

Finland: In Finland, terminals and service stations need environmental permits. The permitting procedure requires compliance with the requirements set out in the Stage-I and Stage-II Directives. The competent authority that grants environmental permits for oil refineries and large petrol storage installations is the Finish Regional Environmental Centre (REC). The authority that grants the authorisations for service stations is the local environmental authority.

Examples from a Member State

United Kingdom: The Environmental Permitting Regulations were made on 9 December 2011 to transpose the Stage-II Directive into law in England and Wales. Defra has produced accompanying guidance which contains the main changes, practical implications, and the key definition of “major refurbishment” which is one of the triggers for fitting Stage-II equipment in existing petrol stations. The guidance was drawn up in consultation with the UK Petroleum Industry Association, Retail Motor Industry Petrol Retailers Association, and the Downstream Fuel Associations, and with selected local authorities.

The Stage-I and Stage-II controls in England are implemented through a requirement to hold a permit issued under the Environmental Permitting Regulations. Most terminals must obtain a permit from the Environment Agency – see EA guidance. Terminals not linked to refineries, and all relevant petrol stations, must obtain a permit from the relevant local authority.

Defra guidance:

- PG1/13: [Storage, Unloading and Loading Petrol at Terminals](http://archive.defra.gov.uk/environment/quality/pollution/ppc/localauth/pubs/guidance/notes/pgnotes/documents/pg1-13.pdf)
(<http://archive.defra.gov.uk/environment/quality/pollution/ppc/localauth/pubs/guidance/notes/pgnotes/documents/pg1-13.pdf>)
- PG1/14: [Unloading of Petrol into Storage at Petrol Stations](http://archive.defra.gov.uk/environment/quality/pollution/ppc/localauth/pubs/guidance/notes/pgnotes/documents/pg1-13.pdf)
(<http://archive.defra.gov.uk/environment/quality/pollution/ppc/localauth/pubs/guidance/notes/pgnotes/documents/pg1-13.pdf>)

This guidance give the following interpretation of the definition “major refurbishment” (produced in consultation with key stakeholders and local authorities and is issued under regulation 64 of the Environmental Permitting (England and Wales) Regulations 2010), in the absence of a precise definition in the Directive (apart from recital 9):

- The regulator should be based on the facts of each individual case, decide whether particular works fall within this term. In doing so, they should have regard to the following:
 - in the Government’s view, a major refurbishment will be one which, because of the scale of the works involved, will provide a cost-effective opportunity for installing PVRII equipment at the same time, such as when a forecourt is excavated in order to install replacement pipework and dispensers (typically necessitating temporary closure of the petrol station);
 - the Government can see no reason why rebuilding or refurbishment of a shop which is located on the petrol station site should constitute a major refurbishment if no works are being carried out on the petroleum pipework or petrol dispensers;
 - the following are unlikely to constitute a major refurbishment:
 - repair of petroleum pipes, without replacing an entire pipe
 - replacement of one or more of the petrol dispensers without any other works

Changing all the petroleum pipework and replacing all the dispensers with new ones constitutes a major refurbishment. Consideration should be given to the cumulative effect of smaller-scale refurbishments. For example, where a petrol station has undertaken works which were judged not to constitute a major refurbishment and within the next three or so years carries out further significant works, the two (or more) sets of works should be considered together when deciding whether this is a major refurbishment.

Best Practices at EU level

The Committee of European Manufacturers of Petroleum Measuring and Distributing Equipment (CECOD) has produced best practice guide on sticker referred to in Article 5(3) of Directive 2009/126/EC. CECOD considers that the most effective way to control compliance with the requirements of the Directive is by placing the marking on the dispenser. Given that Europeans travel between Member States, it makes sense to have a common indication in all countries. Given that the Directive does not define the required marking, there is a risk that individual Member States could introduce their own country specific requirements. The purpose of the sticker is to inform consumers that the dispenser is “environmentally friendly”, with petrol recovery through a unique “pictogram” that could be understood by all European citizens. Using this sticker also avoids the need for translations. The pictogram developed by the CECOD is intended to be used and promoted, however, taking responsibility for possible liability for its misuse.

First picture/sticker: OPEN LOOP SYSTEM – NO

MONITORING

Second picture/sticker: CLOSE LOOP SYSTEM – WITH

MONITORING



4.3. Monitoring and Enforcement

- The Member States' competent authorities must ensure that periodic monitoring, measurement and analysis methods and their frequency are established, taking into account available harmonised standards. Competent authorities monitoring terminals and service stations, as well as vehicles and vessels for the transport of petrol, must apply nationally harmonised testing procedures. In some cases, such as the check of the functioning of the Stage II petrol vapour recovery system (vapour/petrol ratio under simulated petrol flow condition) candidate countries can choose the measurement method referred to in the Directive or another equivalent method.
- Regional or local environmental authorities normally carry out the practical monitoring of fixed terminals and service stations to ensure compliance with the Directive's requirements. The authority with responsibility for monitoring mobile containers is often different from that with responsibility for monitoring fixed installations.
- Under the Stage II Directive the mandatory inspection interval can be increased from once every two years to every third year when a automatic monitoring system is installed.

Examples of Practice from a Member State

Finland: The Safety Technology Authority (TUKES) It is now called the **The Finnish Safety and Chemicals Agency (Tukes)** is the competent authority monitoring the conformity of road tankers with the Directive's requirements. TUKES is a technical authority placed under the Ministry of Trade and Industry. In practice, the control of conformity with VOC emission limits is performed by means of a type-approval system of road tankers, as well as their periodic inspections. TUKES is the competent authority for the administration of ADR (a European agreement concerning the international carriage of dangerous goods by road). The transposition and implementation of the Directive as regards VOC emissions from road tankers is included in the general system of requirements set for the carriage of dangerous goods by road.

Denmark: The transposed Directive prescribes sanctions for non-compliance with the Directive. In very gross cases the maximum sanction for infringing the requirements laid down for storage installations at terminals, loading and unloading installations at terminals, mobile containers and loading and storage installations at service stations may be up to two years in prison.

5. COSTS

The main types of costs arising from the implementation of this Directive are given in the checklist below.

Table 18. Checklist of the Types of Cost Incurred to Implement these Directives

Checklist of the Types of Cost Incurred to Implement the Directive
<p>Initial set-up costs (mainly for the government):</p> <ul style="list-style-type: none"> • establishment of competent authorities; • devising systems and procedures for monitoring, supervision, verification and reporting; • provisions for training; • preparation of technical guidance giving reference to CEN standards and best practices (e.g. on stickers to be affixed to fuelling equipment).
<p>Capital expenditure (mainly for the tank operators, filling stations):</p> <ul style="list-style-type: none"> • vapour recovery systems for filling stations (approx. EUR 2,000 per station); • vapour recovery systems for mobile units (tanks) during transportation, loading, and unloading; • vapour recovery systems for temporary storage (at or outside filling stations)
<p>Ongoing running costs:</p> <ul style="list-style-type: none"> • maintenance costs for vapour recovery systems (basically for the industrial operators); • monitoring and supervision (mainly for the government); • verification of tanks.

THE DIRECTIVE ON EMISSIONS FROM ENGINES TO BE INSTALLED IN NON-ROAD MOBILE MACHINERY

Official Title: European Parliament and Council Directive 97/68/EC on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998)

as amended by:

Commission Directive 2001/63/EC of 17 August 2001 adapting to technical progress Directive 97/68/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 227, 23.8.2001)

Directive 2002/88/EC of the European Parliament and of the Council of 9 December 2002 amending Directive 97/68/EC on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 35, 11.2.2003)

Directive 2004/26/EC of the European Parliament and of the Council of 21 April 2004 amending Directive 97/68/EC on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 146, 30.4.2004)

Council Directive 2006/105/EC of 20 November 2006 adapting Directives 73/239/EEC, 74/557/EEC and 2002/83/EC in the field of environment, by reason of the accession of Bulgaria and Romania (OJ L 363, 20.12.2006)

Commission Directive 2010/26/EU of 31 March 2010 amending Directive 97/68/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 86, 1.4.2010)

Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four (OJ L 188, 18.7.2009)

Directive 2011/88/EU of the European Parliament and of the Council of 16 November 2011 amending Directive 97/68/EC as regards the provisions for engines placed on the market under the flexibility scheme (OJ L 305, 23.11.2011)

Commission Directive 2012/46/EU of 6 December 2012 amending Directive 97/68/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 353, 21.12.2012)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The main aim of Directive 97/68/EC is to approximate the laws of EU Member States relating to emission type and standards approval procedures for compression-ignition engines with an engine power of 18 to 560 kW that are intended for use in non-road mobile machinery such as mobile cranes, industrial drilling rigs and compressors, snowplough equipment, fork-lift trucks and so forth. The Directive sets out the maximum permitted exhaust emissions in relation to the power of the engine. Manufacturers must ensure that new engines comply with the limits set out in the Directive before placing their products on the market. The Directive contributes to the smooth functioning of the internal market, while protecting human health and the environment. It sets out gaseous emission limit values for CO, HC, NO_x, and particulate matter through a two-step approach to regulating emission standards from power bands.

The main method of controlling emissions under the Directive is through the system of engine type-approval, a system that has stood the test of time for approvals for road vehicles and their components. A new element introduced to the engine type-approval regime by the current Directive was the approval of a parent engine on behalf of a group of engines (engine family) built using similar components according to similar construction principles.

Some of the most noteworthy amendments to Directive 97/68/EC:

- Directive 2002/88/EC extended the scope to spark ignition (petrol) engines. Following a Commission proposal (COM (2002) 765), emission standards from diesel engines used in general non road applications were further tightened¹³⁵ in light of technological developments (but standards for petrol engines were not changed)
- Directive 2004/26/EC: This Directive extends the scope of Directive 97/68/EC to cover locomotives and inland waterway vessels and small spark ignition engines (19 kW or below, also known as gasoline engines). It also reinforces the emission standards applicable to the machinery in question, in particular as regards oxides of nitrogen and particulates. These new standards will be applied in two stages.
 - The first stage started in 2006 and these new standards were re-examined by the Commission in 2007 with a view to making appropriate adjustments to the timetable and to the standards themselves in cases where technical difficulties arise with respect to special applications;
 - The second stage phases in standards which, on average, are ten times more stringent than those currently in place, between 2010 and 2014. These standards are compatible with similar requirements in the United States and this adjustment to US standards will make it possible to harmonise the types of engine being produced in the industry worldwide.

The Directive provides an additional incentive for the faster application of the new standards.

Manufacturers who comply with the requirements before the deadline can display a label on their engines to give them greater market visibility. Finally, the Directive provides for means of improving the methods for testing new engines prior to marketing.

- Commission Directive 2010/26/EU: This Directive is necessary to fully implement the the type-approval of stage IIIB engines (category L) as from 1 January 2010, as provided by Directive

¹³⁵ Standards laid down by Directive 2004/26/EC are Stage III A, Stage III B and Stage IV

97/68/EC, This Directive updates the annexes of Directive 97/68/EC to technical progress reflecting the development of electronically controlled engines which largely are replacing mechanically controlled fuel injection and control systems and thus, introducing more stringent standards (exhaust emission limits for stages IIIB and IV) The following changes are made:

- Amended Annex I on the general type- approval requirements, introducing general type-approval requirements for stages IIIB and IV;
- Amended Annex II on the technical details of the information documents that need to be submitted by the manufacturer to the type-approval authority with the application for engine type-approval;
- Amended Annex III regarding:
 - the type-approval testing procedure of engines to ensure that the simultaneous compliance with the gaseous (carbon monoxide, hydrocarbons, oxides of nitrogen) and the particulate emission limits of stage IIIB and IV is demonstrated;
 - the type approval procedure to demonstrate compliance with the exhaust emission limits of stage IIIB and IV requires the introduction of a detailed description of the cold start cycle (Point 1.3.2);
 - the test cycle for the different equipment specifications under Annex III;
 - specification to clarify which engine speed needs to be used in the type approval calculation method, ensuring compliance with the updated version of the international testing standard the emissions test run specifications is modified to take account of the cold start cycle;
 - the type approval of engines in accordance with stage IIIB and IV requires the adaptation of the calculation method for the NRTC test (appendix III).
- Amended Annex XIII: to ensure a smooth implementation of stage IIIB, an increased use of the flexibility scheme may be needed.

The Directive introduces an extension of the derogation period until 31 July 2013, within the category of top handle machines, for professional use, multi- positional, hand-held hedge trimmers and top handle tree service chainsaws in which engines of classes SH:2 and SH:3 are installed. Member States had to apply the provisions of Directive 2010/26/EU as from 31 March 2011.

- Directive 2011/88/EU:
 - Amendment to Article 4(6): Compression ignition engines for use other than in the propulsion of railcars and inland waterway vessels may be placed on the market under a flexibility scheme in accordance with the procedure referred to in Annex XIII;
 - Amendment to Article 10 with new provisions, allowing for derogation from Article 9(3g), (3i) and (4a) and temporary authorisation for the placing on the market of the certain engines for railcars and locomotives. These engines must be labelled appropriately referring to the associated derogation;
 - Art. 10(7): Member States shall permit the placing on the market of engines, as defined in points A(i), A(ii) and A(v) of Section 1 of Annex I, under the flexibility scheme in accordance with the provisions set out in Annex XIII;
 - Annex XIII is amended in accordance with the Annex to this Directive.

The Member States had to apply the provisions of this Directive as from 13 December 2011.

- Directive 2012/46/EU:
 - Amendments introduced are related to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery. Directive 2012/46/EU updated Directive 97/68/EC so as to reflect technical progress in areas such as:
 - Symbols and abbreviations, specifications and tests, specification of conformity of production assessment and parameters defining the conformity of production (Annex I).
 - Type-approval process with reference to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (Annex II).
 - Test procedures for combustion ignition engines (Annex III).
 - Analytical and sampling procedures for gaseous emissions tests (Annex IV).
 - Type approval certificate modifications (Annex VII) Data sheet for type approved engines (Annex XI) Recognition of alternative type approvals (Annex XII)

The ongoing review of the Directive 97/68/EC on emissions standards for non-road mobile machinery seeks to:

- introduce new emission limits reflecting technological progress and EU policies in the on-road sector, with a view to achieving EU air quality targets;
- extend the scope, with a view to improving market harmonisation (EU and international) and minimising the risk of market distortions;
- introduce measures for simplifying administrative procedures and improving enforcement, including conditions for better market surveillance.

The Commission adopted the Proposal for a Regulation on requirements relating to emission limits and type-approval for internal combustion engines for non-road mobile machinery¹³⁶ on 25 September 2014.

The proposal significantly upgrades the non-road mobile machinery engine type-approval system with respect to the technical requirements on emissions by adopting stricter levels, as well as introducing the “split-level approach”.

The proposal will, through the delegated acts foreseen therein, lay down in detail the new mandatory requirements for Stage V engine emission limits. In particular, the delegated acts adopted under this proposal will include, amongst others:

- detailed technical requirements of the test cycles;
- technical test and measurement procedures;

¹³⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52014PC0581>

- detailed arrangements and requirements for the exceptions granted under this Regulation;
- detailed provisions for type-approval procedures

The “split-level approach” is already used in other pieces of legislation in the area of EU type-approval of motor vehicles. This approach foresees legislation in two steps:

- first, the fundamental provisions will be laid down by the European Parliament and the Council in a Regulation based on Article 114 of the Treaty on the Functioning of the European Union through the ordinary legislative procedure;
- secondly, the technical specifications implementing the fundamental provisions will be laid down in delegated acts adopted by the Commission in accordance with Article 290 of the Treaty on the Functioning of the European Union.

The new Regulation will replace a patchwork of 28 national laws. It will also repeal the current extremely complex directive that comprises 15 Annexes and has been amended eight times, without recasting, since its adoption in 1997.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Regulation

- Ensure that measures are taken to comply with Directive 97/68/EC, as amended, for all internal combustion engines to be installed in non-road machinery including locomotives and inland water vessels. (see below for newest changes introduced by amending Directive 2010/26/EC and 2011/88/EU)
- Ensure that applications for type-approval for engines and engine families are submitted and dealt with according to the requirements of the Directive. (Art. 3, Directive 97/68/EC)
- Grant type-approval to all engine types and engine families that conform to particulars in an information folder submitted with the application. (Art. 4, Directive 97/68/EC)
- Complete and number the type-approval certificate, compile or verify the contents of the index to the information package, and deliver the certificate to the applicant. (Arts. 4 and Annexes VI and VII, Directive 97/68/EC)
- With effect from 30 June 1998, Member States may not refuse to grant type-approval or to issue the type-approval certificate, and may not impose any other type-approval requirements with regard to the scope covered by the Directive, if the engine meets the requirements of the Directive with regard to gaseous and particulate matters. (Art. 9, Directive 97/68/EC)
- With effect from specified dates, shall refuse to grant type-approval and to issue the type-approval certificate, and shall refuse to grant any other type-approval for non-road machinery in which an engine is installed, if the engine and its emissions fail to comply with the requirements of the Directive. (Art. 9(2)-(3), Directive 97/68/EC)
- After granting type-approval, take the necessary measures to ensure that it is being informed of any change in the particulars appearing in the information package.
- Ensure that applications for amendments of or extensions to a type-approval are submitted to the approval authorities that granted the original type-approval and are dealt with in accordance with the provisions of the Directive with regard to revising information packages and type-approval certificates. (Art. 5, Directive 97/68/EC)
- Ensure that manufacturers affix to each unit manufactured prescribed markings; and, where the type-approval certificate includes restrictions, deliver specified information with each unit manufactured. (Art. 6 and Annex I, Directive 97/68/EC)
- Ensure that exemptions are granted for specified end-of-series engines only where there is compliance with all conditions set out in the Directive. (Art. 10, Directive 97/68/EC)
- May not refuse the registration, where applicable, or the placing on the market of new engines, whether or not already installed in machinery, meeting the requirements of the Directive. With certain exceptions, only permit the registration or placing on the market of new engines meeting the

requirements of the Directive and approved in compliance with one of the engine categories. (Art. 8 and Art. 9, Directive 97/68/EC)

- Before granting a type-approval, verify, according to the provisions of the Directive, that adequate arrangements have been made to ensure an effective code of practice (CoP). (Art. 11, Directive 97/68/EC)
 - Pursuant to Directive 2004/26/EC, ensure that engines comply with the new emission standards (including standards for oxides of nitrogen and particulates) applicable from 2006.
 - Take measures to ensure that the more stringent emission standards are phased in between 2010 and 2014. (Directive 2004/26/EC)
 - Facilitate the marketing of engines that meet the more stringent emission standards, ensuring that manufacturers of engines complying with these standards ahead of the final deadline (2014) can label their engines with a visible label that provides them with a market advantage.
 - Ensure compliance with amending Directive 2010/26 as from 31 March 2011:
 - Annex I on the general type- approval requirements, introducing general type-approval requirements for stages IIIB and IV;
 - Annex II on the technical details of the information documents that need to be submitted by the manufacturer to the type-approval authority with the application for engine type-approval (more detailed information on the after-treatment devices installed on the engines to enable type approval authorities to assess the engine's capability to comply with stages IIIB and IV;
 - Amended Annex III regarding:
 - the type-approval testing procedure of engines to ensure that the simultaneous compliance with the gaseous and the particulate emission limits of stage IIIB and IV is demonstrated according to modified specifications for the non-road steady cycle (NRSC) and non-road transient cycle (NRTC),
 - the type approval procedure to demonstrate compliance with the exhaust emission limits of stage IIIB and IV requires the introduction of a detailed description of the cold start cycle. (Point 1.3.2)
 - the test cycle for the different equipment specifications under Annex III,
 - point 3.7.1.1 (specification A) is adapted to clarify which engine speed needs to be used in the type approval calculation method, ensuring compliance with the updated version of the international testing standard ISO 8178-4:2007.EN 1.4.2010 (Section 3.7.1)
 - the emissions test run specifications is modified to take account of the cold start cycle (section 4.5)
 - the type approval of engines in accordance with stage IIIB and IV requires the adaptation of the calculation method for the NRTC test (appendix III).
12. Amended Annex XIII: to ensure a smooth implementation of stage IIIB, an increased use of the flexibility scheme may be needed, which may be hampered by notification requirements that have not yet been adapted to stage IIIB compliant engines. Hence, this change will be complemented with future measures aimed at simplifying the notification requirements and the reporting obligations, making them more focused and tailored to the need for market surveillance authorities to respond to the increased use of the flexibility scheme that will result from the introduction of stage IIIB.
- Ensure compliance with Directive 2011/88/EU as from 13 December 2011 regarding

- Amended Article 4(6): Compression ignition engines for use other than in the propulsion of railcars and inland waterway vessels may be placed on the market under a flexibility scheme in accordance with the procedure referred to in Annex XIII,
- Amended Article 10 allowing for derogation from Article 9(3g), (3i) and (4a).
 - Member States may authorise the placing on the market of the following engines for railcars and locomotives, provided that the approval authority is satisfied that the use of a replacement engine that meets the requirements of the latest emission stage in the railcar or locomotive will involve significant technical difficulties:
 - replacement engines that meet the Stage III A limits, where they are to replace engines for railcars and locomotives that do not meet the Stage III A standard; or meet the Stage III A standard but do not meet the Stage III B standard;
 - replacement engines that do not meet Stage III A limits, where they are to replace engines for railcars without driving control and not capable of independent movement, so long as such replacement engines meet a standard no lower than the standard met by engines fitted to existing railcars of the same type.
 - A label bearing the text “REPLACEMENT ENGINE” and bearing the unique reference of the associated derogation shall be affixed to the above mentioned engines.

Member States shall permit the placing on the market of engines, as defined in points A(i), A(ii) and A(v) of Section 1 of Annex I, under the flexibility scheme in accordance with the provisions set out in Annex XIII (Art. 10(7), amending Directive 2011/88/EU);

Apply amended Annex XIII to Directive 2011/88/EU.

- Ensure compliance with Directive 2012/46/EU as from 21 December 2013 regarding:
 - Symbols and abbreviations, specifications and tests, specification of conformity of production assessment and parameters defining the conformity of production (Amended Annex I).
 - Type-approval process with reference to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (Amended Annex II).
 - Test procedures for combustion ignition engines (Amended Annex III).
 - Analytical and sampling procedures for gaseous emissions tests (Amended Annex IV).
 - Type approval certificate modifications (Amended Annex VII)
 - Data sheet for type approved engines (Amended Annex XI)
 - Recognition of alternative type approvals (Amended Annex XII)

2.2. Monitoring and Enforcement

- After granting the approval, verify that the CoP arrangements continue to be adequate and that each production engine bearing a type-approval number pursuant to the Directive continues to conform to the description given in the approval certificate and to the requirements of the Directive. (Art. 11, 97/68/EC)

- Ensure that manufacturers submit, to the approval authorities that granted the type-approvals, declarations specifying future production plans and, where requested, detailed information on engines produced in compliance with the requirements of the Directive. (Art. 6, Art. 97/68/EC)
- After granting type-approval, take the necessary measures to register and control the identification numbers of those engines produced in conformity with the requirements of the Directive. (Art. 8, Art. 97/68/EC)
- In cases of non-conformity with the approved type or family that it has granted, take measures to ensure that the engines in production again conform to the approved type or family. (Art. 12(1) and (2), Art. 97/68/EC)
- Co-operate with other Member States over disputes relating to non-conformity. (Art. 12, Art. 97/68/EC)
- Monitor the marketing of engines complying with the 2010/2014 standards to ensure that their marketing is not made more difficult than that of engines complying with the less strict standards. Such engines should bear a specific label informing consumers about the engine and its superior environmental performance.

2.3. Reporting

- Inform the other Member States:
 - on a monthly basis of type-approvals granted, refused and withdrawn (Art. 4, Art. 97/68/EC);
 - of any withdrawal of type-approval and the reasons for it (Art. 12, Directive 97/68/EC);
 - particulars of, and reasons for, the exemptions granted for the manufacturer (Art. 10, Directive 97/68/EC);
 - measures taken, and the reasons for them, in case of non-conformity with the approved type or family (Art. 12(2) and (4), Directive 97/68/EC); and
 - the approval authorities and technical services (Art. 16, Directive 97/68/EC).
- Supply to other Member States on request:
 - a copy of the type-approval certificate with/without information package, for each engine type or engine family approved, refused or withdrawn;
 - a list of engines produced according to type-approvals granted; and
 - a copy of a manufacturer's declaration specifying their production plans (Art. 4, Directive 97/68/EC).
- Inform the Commission of:
 - the engines approved (Art. 4(5), Directive 97/68/EC);
 - the exemptions granted to manufacturers and the reasons for them (Art. 10(2), Directive 97/68/EC);

- disputes between Member States relating to the non-conformity of production (Art.12(5), Directive 97/68/EC);
- details of the approval authorities and technical services responsible for implementing the Directive (Art. 16, Directive 97/68/EC);
- transposition measures, the text of the provisions of national law adopted in the field governed by the Directives and a reference to the relevant EU Directives (Art. 17 of Directive 1996/78/EC, Art. 3(2) of Directive 2010/26/EC, Art 2 of Directive 2011/88/EU, Art.2 of Directive 2012/46/EU).

2.4. Additional Legal Instruments

A number of other legislative instruments have relevance to controlling emissions from mobile sources and must be borne in mind during the implementation of this Directive. These include:

- Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe amended by Commission Directive (EU) 2015/1480
- Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air, amended by Regulation (EC) 219/2009 and Commission Directive (EU) 2015/1480;
- Council Directive 2001/81/EC on national emission ceilings for certain atmospheric pollutants, as amended by Council Directives 2006/105 and 2013/17/EU and Regulation (EC) 219/2009;
- Directive (EU) 2016/802 of the European Parliament and of the Council of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels
- Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions
- Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC, as amended by Commission Directives 2000/71/EC, 2011/63/EU, 2014/77/EU, Directives 2003/17/EC, 2009/30/EC, (EU) 2015/1513 and Regulation (EC) 1882/2003;
- Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information, amended by Commission Regulations (EC) 692/2008, (EU) 566/2011, (EU) 459/2012 and Regulation (EC) 595/2009;
- Regulation (EC) No 595/2009 of the European Parliament and of the Council of 18 June 2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC, amended by Commission Regulations (EU) No 582/2011 and (EU) 133/2014

- Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (repealing Directive 77/537/EEC on smoke emissions from diesel engines for use in agricultural or forestry tractors as of 31 December 2015)
- Directive 2009/40/EC of the European Parliament and of the Council of 6 May 2009 on roadworthiness tests for motor vehicles and their trailers *(to be repealed by Directive 2014/45/EU of the European Parliament and of the Council of 3 April 2014 on periodic roadworthiness tests for motor vehicles and their trailers and repealing Directive 2009/40/EC as of 19 May 2018)*
- Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the checklist below. The key tasks are arranged under subheadings and organised in chronological order of implementation (where possible).

Table 19. Directive On Emissions From Engines To Be Installed In Non-Road Mobile Machinery - Key Implementation Tasks

DIRECTIVE ON EMISSIONS FROM ENGINES TO BE INSTALLED IN NON-ROAD MOBILE MACHINERY - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	<p>Designate the competent authority(ies) responsible for regulating emissions from internal combustion engines in non-road mobile machinery. Responsibilities would include:</p> <ul style="list-style-type: none"> • issuing and/or withdrawing type-approval certificates; • registering and permitting the placing on the market of new engines; • regulating exemptions from the requirements of the Directive; • testing and inspecting engines; • verifying the manufacturers CoP arrangements; • ensuring compliance with labelling and information to consumer provisions; • serving as contact point with the approval authorities of other Member States.
1.2	Where it is considered necessary, appoint the organisation or body to carry out technical services as required under the Directive.
1.3	Plan for the introduction of the type-approval requirements and procedures for Stages IIB and IV (see amending Directive 2010/26/EC)
2	Regulation
2.1	<p>Adopt the systems and procedures for type-approval of engines (now Stages IIIB and IV) as required by the Directive. This includes:</p> <ul style="list-style-type: none"> • a system for initial type approval; • procedures for amending type-approval certificates (including requirements relating to notification, revision of information packages, fresh tests or checks, and issuing revised type-approval certificates); • a national database of certificates; • a system requiring sufficiently detailed information to be submitted by the manufacturer (including information on the after-treatment devices installed on engines to enable the competent authorities to assess the engine's capability to comply with Stages IIIB and IV); • type-approval testing procedures ensuring simultaneous compliance with the particulate emission limits of Stage IIIB and IV according to the modified specifications for NRSC and NRTC also comprising a description of the cold start cycle and whether they comply with international testing standard ISO 8178-4:2007.EN 1.4.2010; • a system for temporary derogations for replacement engines (under Directive 2011/88/EC); • simplified notification requirements and reporting obligations, tailored to the needs of the surveillance authorities allowing increased use of the flexibility scheme and • a system for co-operation between the competent authorities of different Member States as well as the Commission, as required under the Directive.
2.2	<p>Put in place a system for the registration and placing on the market of new engines. The systems should:</p> <ul style="list-style-type: none"> • control identification numbers; • compile information on purchasers and the identification number of the engine sold.

2.3	Allow for the placement of compression ignition engines for use other than in railcars and inland waterway vessels may be placed on the market under the flexibility scheme subject to procedure set out in Annex XIII of Directive 2011/88/EU
2.4	Adopt a system to regulate exemptions from requirements of the Directive (taking into account latest time-limited derogations under Directive 2011/88/EU, e.g. regarding certain replacement engines for railcars and locomotives, which allow for derogation from Article 9 under certain conditions (e.g. in case the approval authority is convinced that the requiring those engines to meet the requirements of Stage IIIB and IV emission limits will involve significant technical difficulties). Such engines have to be clearly labelled „replacement engines”
2.5	Adopt and publish the laws, Regulations and administrative provisions necessary to comply with amending Directives 2010/26/EC, 2011/88/EU and 2012/46/EU.
3	Monitoring
3.1	Adopt a testing/inspection system to control the quality of engine types or families. The system should: <ul style="list-style-type: none"> • control the quality of production of engines; • ensure conformity of production; • ensure and enforce compliance with the type-approval; and • ensure compliance with the emission standards.
3.2	If a private sector organisation is appointed as a technical service, establish a system for monitoring its activities.
3.3	Establish systems and procedures for requesting, receiving and handling information from the engine manufacturers.
4	Reporting
4.1	Inform the other Member States of: <ul style="list-style-type: none"> • type-approvals granted, refused and withdrawn; • any withdrawal of type-approval and the reasons for it; • particulars of, and reasons for, the exemptions granted for the manufacturer; • measures taken, and the reasons for them, in case of non-conformity with the approved type or family; • the approval authorities and technical services.
4.2	Supply to other Member States on request: <ul style="list-style-type: none"> • a copy of the type-approval certificate with/without information package, for each engine type or engine family approved, refused or withdrawn; • a list of engines produced according to type-approvals granted; and • a copy of a manufacturer's declaration specifying their production plans.
4.3	Inform the Commission of: <ul style="list-style-type: none"> • the engines approved; • the exemptions granted for the manufacturers, and the reasons for them; • disputes between Member States relating to the non-conformity of production; • the approval authorities and technical services; and • transposition measures, the text of the provisions of national law adopted in the field governed by the Directives and a reference to the applicable EU Directive (Art. 17, Directive 1996/78/EC, Art. 3(2), Directive 2010/26/EC , Art 2, Directive 2011/88/EU, Art.2 Directive 2012/46/EU).
5	Technical Advice and Guidance
5.1	Prepare and issue technical guidance to ensure a full understanding of the technical requirements for testing set out in the Directive.

3.2. Phasing Considerations

The most demanding and time-consuming tasks associated with implementing this Directive are deemed to be establishing and developing the institutional structure responsible for the type-approval and monitoring regime,

in particular the acquisition and training of sufficient personnel and the development of systems and procedures for all aspects of type-approval and monitoring.

The implementation of the Directive is staggered according to the level of power output of engines. The implementation timetable in each candidate country could be brought up and discussed in the accession negotiations.

4. IMPLEMENTATION GUIDANCE

4.1. Regulation

- In the national legal systems, the technical requirements set out for diesel engines to be installed in non-road mobile machinery structurally differ from the corresponding requirements set for those in road vehicles. This is primarily because non-road mobile machinery does not normally undergo the same kind of registration procedures as road vehicles. Consequently, type-approval provisions for non-road vehicles are not normally transposed through the same legislation as those for road vehicles that have separate type-approval Directives. The type-approval regime laid down by Directive 97/68/EC is independent from the regime set out in framework Directive 2007/46/EC. Directive 97/68/EC does not contain any referrals to the framework type-approval Directive. However, the basic principles of the type-approval system set out in the framework Directive are adopted in Directive 97/68/EC.
- Exhaust emission standards set by this Directive are technically not as demanding as those set in Regulation (EC) 595/2009 relating to measures to be taken against the emission of gaseous and particulate pollutants from compression-ignition engines for use in vehicles, and the emission of gaseous pollutants from positive-ignition engines fuelled with natural gas or liquefied petroleum gas for use in vehicles. Engines that comply with the Directive are being developed and currently produced widely in many Member States.
- It is recommended that the competent authority responsible for road vehicle type-approval is also designated the competent authority responsible for all aspects of type- approval as regards engines to be installed in non-road mobile machinery.
- Technical service means a private sector organisation or a public body that has been appointed as a testing laboratory to carry out tests or inspections on behalf of the competent authority. The competent authority may itself carry out the tests and inspections. Every Member State does not need to have its own technical service, but can use services situated in another Member State. The designation of a technical service is, thus, optional. If technical services are appointed, they must be accredited to ensure their competence.
- The accredited organisations that act as technical services in type-approval matters can be research institutes established specifically to carry out certification and type-approvals, or organisations responsible for vehicle roadworthiness testing.
- For advice on how to establish effective administrative structures, type-approval authorities and technical services, authorities in candidate countries should consult Member States that have large national automotive industries.

Example of Institutional Practice in Finland

The Finish Ministry of Environment and the Ministry of Transport agreed, for pragmatic reasons, that the Vehicle Administration Centre that is under the Ministry of Transport would be the competent authority responsible for type-approval issues regarding engines to be installed in non-road mobile machinery. However, the Ministry of Environment is the ministry with primary responsibility for administering the transposition of the Directive.

4.2. Monitoring and Enforcement

- There is usually no obligation to register non-road mobile machinery, so an alternative form of monitoring such machinery to ensure compliance with the requirements of the Directive is necessary. Information supplied to the authorities by the manufacturers will play an important role. The engine manufacturers have to notify the authorities about the engines produced in accordance with the Directive, and they have to make available relevant production planning information at regular intervals. It is recommended that the authority granting type-approval for engines regularly demands the manufacturer to provide the list containing information on the engines produced in accordance with the requirements of the Directive. With help provided by the manufacturers, the authority must register and control the identification numbers of those engines produced in conformity with the granted approval. The competent authorities should be given powers to carry out spot checks.
- The manufacturers' delivery of information to the competent authorities shall be enforced by effective administrative provisions, which could include sanctions.
- Some degree of self-Regulation within the non-road mobile machinery and engine markets can be expected, when competing manufacturers and dealers of engines and machinery act as watchdogs for the products of other manufacturers and provide the authorities with information on non-compliance.
- In case of non-conformity, the authority shall ensure (by means of guidance, administrative orders, and withdrawal of approval) that the engines in production again conform to the approved type. Appropriate penalties for non-compliance should be established.
- The enforcement requires increased staffing and training of the bodies handling the vehicle approvals and registrations, or governing technical safety of machinery. The workload expected depends heavily on the number of separate machine types being offered on the market.
- If a candidate country chooses not to use accredited technical organisations in other EU member countries to carry out testing for certificate and type-approvals, the competent national organisations responsible for testing and approvals need to also check that engine emissions conform to standards set in the Directive. These new tasks are closely related to those required by Regulation (EC) No 715/2007 and Regulation (EC) 595/2009.

5. COSTS

The main types of costs arising from the implementation of this Directive are given in the checklist below.

Table 20. Checklist of the Types of Cost Incurred to Implement the Directive

Checklist of the Types of Cost Incurred to Implement the Directive
Initial set-up costs: <ul style="list-style-type: none"> • establishment of competent authorities; • devising systems and procedures; • provisions for training; • preparation of technical guidance.
Capital expenditure: <ul style="list-style-type: none"> • test laboratory/installation for exhaust emissions measurements.
Ongoing running costs: <ul style="list-style-type: none"> • labour costs for certification testing (if not outsourced: see below); • operating costs of test laboratory (if not outsourced: see below); • acquisition costs for testing services (if testing is outsourced); • labour costs for processing of data and reporting to the Commission.
Cost sharing: <ul style="list-style-type: none"> • this cost can partly be shared with those arising from Regulation (EC) No 715/2007 and Directive 2005/55/EC.

The approximate cost of the exhaust analysis system necessary for the measurements according to this Directive is some EUR 300,000. Additionally, an engine dynamometer is needed, which would cost approximately EUR 100,000-300.000.

If a candidate country chooses to use technical services in another Member State, capital expenditure will be minimal but ongoing costs would be higher, because the acquisition of testing services shall then include the cost of depreciation for the equipment at the agency providing the testing services.

Enforcement requires increased staffing and training in the bodies handling the vehicle approvals and registrations, or governing the technical safety of machinery. The workload expected depends heavily on the number of separate machine types being offered to the market. Thus, it is very difficult even to approximate the costs.

In addition, the costs for implementing Directive 97/68/EC are expected to increase significantly as a consequence of the new requirements introduced by Directive 2004/26/EC, Directive 2010/26/EC and Directive 2011/88/EC introducing type approval for Stages IIIB and IV. Firstly, type- approval, inspection and monitoring systems now also have to be applied to locomotives and inland water vessels. Secondly, additional costs will be incurred both by industry and by the candidate country with regard to the introduction of the new emission standards applicable from 2006 and 2010-2014 respectively. Additional costs are likely to be incurred as a result of the need for additional staff requirements and the training of staff responsible for approvals and for the technical safety of small spark ignition engines for use in non-road mobile machinery. The workload expected will again depend on the number of separate machine types being offered on the market.

Candidate countries will also incur some costs with respect to the voluntary producer labelling of engines already complying with the 2010 emission standards. Ideally, the candidate country shall take measures to promote this labelling, emphasising the market advantage producers may have from early compliance with the emission standards.

Below is a list of some measures that give rise to additional costs:

- the creation or amendment of procedures for approving small spark ignition engines;
- the preparation of technical guidance and the notification of requirements to manufacturers and other interested parties;
- the creation of Commission reports;
- the provision of new or upgraded testing equipment;
- the monitoring of the latest research and developments;
- new costs for measurement and sampling procedures, calibration, and test procedures for small spark ignition engines.

REGULATION ON EMISSIONS FROM HEAVY DUTY VEHICLES

Official Title: Regulation (EC) No 595/2009 of the European Parliament and of the Council of 18 June 2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC (OJ L 188, 18.7.2009)

As amended:

Commission Regulation (EU) No 582/2011 of 25 May 2011 implementing and amending Regulation (EC) No 595/2009 of the European Parliament and of the Council with respect to emissions from heavy duty vehicles (Euro VI) and amending Annexes I and III to Directive 2007/46/EC of the European Parliament and of the Council¹³⁷ (OJ L 167, 25.6.2011)

Commission Regulation (EU) No 133/2014 of 31 January 2014 amending, for the purposes of adapting to technical progress as regards emission limits, Directive 2007/46/EC of the European Parliament and of the Council, Regulation (EC) No 595/2009 of the European Parliament and of the Council and Commission Regulation (EU) No 582/2011 (OJ L 47, 18.2.2014)

¹³⁷ Amended by Commissions Regulations (EU) 64/2012, (EU) 519/2013, (EU) 136/2014, (EU) 133/2014 and (EU) 627/2014

1. MAIN AIMS AND PROVISIONS

In 2009, Regulation (EC) No 595/2009 was adopted. This Regulation repealed and replaced Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC with effect from 31 January 2013. The legislative choice of a Regulation ensures that the detailed technical provisions are directly applicable to manufacturers, approval authorities and technical services and that they can be updated in a fast and efficient way.

The Regulation (EC) 595/2009 establishes common technical requirements for the type-approval of motor vehicles, engines and replacement parts for heavy duty vehicles with regard to their emission performance. It also lays down rules on: in-service conformity of vehicles and engines, durability of pollution control devices, on-board diagnostic (OBD) systems, measurement of fuel consumption and CO₂ emissions and accessibility of vehicle OBD and vehicle repair and maintenance information.

The Regulation applies to motor vehicles of categories M1, M2, N1 and N2 with a reference mass exceeding 2610 kg and to all motor vehicles of categories M3 and N3 as defined in Annex II of Directive 2007/46/EC.

Regulation (EC) No 595/2009 was amended by Regulation 582/2011 implementing and amending Regulation 595/2009. Regulation 582/2011 lays down measures for the implementation of Articles 4, 5, 6 and 12 of Regulation (EC) No 595/2009. Annex XV of Regulation 582/2011 also replaces Annex I to Regulation (EC) No 595/2009 regarding limit values for Euro VI engines, which have been applicable as from 15 July 2011.

Commission Regulation (EU) No 133/2014 amends Regulation (EC) No 595/2009 of the European Parliament and of the Council and Commission Regulation (EU) No 582/2011 as regards emission limits.

More information on Regulation No 595/2009 and 582/2011 and later implementing measures can be obtained at the homepage of DG for Internal Market, Industry, Entrepreneurship and SMEs:

http://ec.europa.eu/growth/sectors/automotive/legislation/motor-vehicles-trailers/index_en.htm

The Regulation is also closely linked to Regulation (EC) No. 715/2007, which covers light-duty vehicles.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Consider whether to integrate the emissions of pollutants as an additional cost for road traffic taxes on motor vehicles.
- Plan for implementing Regulation (EC) No 595/2009 and its amending Regulations (EC) 582/2011 and (EU) 133/2014 and introduce a number of new provisions including updated emission limit values for Euro VI (see Annex II of Regulation (EU) 133/2014).
- Consider introducing financial incentives for retrofitting measures, either to adapt in-use motors or for scrapping. The amount of the financial incentives must not exceed the additional cost of the technical measures used to ensure compliance with the emission limits specified in Annex I (Art. 10).

2.2. Regulation

- Ensure institutional framework to apply Regulation No 595/2009 and Regulation No 582/2011, including any subsequent amendment.
- Member States must ensure the following prohibitions (Art. 8 Regulation No 595/2009):
 - as from 31 December 2012, national authorities have to refuse to grant EC type-approval or national type-approval in respect of new types of vehicles or engines not compliant with Regulation 595/2009 and its implementing measures;
 - type-approval technical certificates corresponding to the emission stages prior to Euro VI may be granted to vehicles and engines intended for export to third countries, where certificates state that the vehicles/engines cannot be marketed in the EU;
 - as from 31 December 2013, national authorities shall, in the case of new vehicles which do not comply with this Regulation and its implementing measures, consider certificates of conformity no longer valid (referring to Article 26 of Directive 2007/46/EC) and thus, prohibit the registration, sale and entry into service of such vehicles;
 - as from 31 December 2013, national authorities must prohibit the sale or use of new engines which do not comply with Regulation No 595/2009 (exception for replacement engines for in-service vehicles);
 - even prior to the above-mentioned dates, national authorities may not (if a manufacturer so requests) not refuse to grant EC type approval or national type approval for a new type of vehicle or engine or prohibit the registration or sale of such vehicles and engines where they comply with Regulation No 595/2009.

- Prohibit the sale or installation on a vehicle of new replacement pollution control devices intended to be fitted on vehicles type approved under Regulation No 595/2009 where they are not of a type in respect of which a type-approval has been granted. (Art. 9, Regulation No 595/2009)
- *Obligations of the manufacturer*
- Manufacturers shall demonstrate that all new vehicles sold, registered or put into service within the EU, all new engines sold or put into service within the EU and all new replacement pollution control devices requiring type-approval, which are sold or put into service within the EU, are type-approved in accordance with Regulation 595/2009 and Article 3 of Regulation No 582/2011 (Article 4(1), Regulation No 595/2009). With regard to the requirements for obtaining and EC type approval of a vehicle with an improved system with regard to emissions and vehicle repair and maintenance information, manufacturers must ensure (not exhaustive list):
 - compliance with Annex I, Annexes III to VIII, X, XIII and XIV as well as with the specifications of reference fuels set out in Annex IX (Art. 3(1), Reg. No 582/2011);
 - compliance with the installations requirements set out in Annex I, section 4 (Art. 3(2), Reg. No 582/2011);
 - compliance with Annex VIII, appendix 1 for receiving an extension of the EC type-approval for vehicles with a weight between 2380-2610 (Art. 3(3), Reg. No 582/2011);
 - that the provisions for alternative approval (point 2,4,1 to Annex X and point 2,1 to Annex XIII are not used for type approval of an engine system or engine family. (Art. 3(4), Reg. No 582/2011);
 - that engine systems or elements of design that may affect the emissions are designed, constructed, assembled and installed to (in normal use) comply with Reg. 595/2009 and Reg. 582/2011 including off-cycle requirements set out in Art. 14 and Annex VI of Reg. 582/2011 (Art. 3(5), Reg. No 582/2011);
 - compliance with the requirements on fuel range (either universal fuel approval or restricted fuel approval) specified in Section 1 of Annex I to Reg. 582/2011 (Art. 3(6), Reg. No 582/2011);
 - compliance with requirements set out in Section 4,3 of Annex I regarding petrol or E85 fuelled engines (Art. 3(7), Reg. No 582/2011);
 - compliance with requirements in Point 2,1 of Annex X regarding electronic system security (Art. 3(8), Reg. No 582/2011);
 - that technical measures are taken to limit tailpipe emissions (Art. 3(9), Reg. No 582/2011);
 - that emissions test results are in conformity with limit values under the test conditions specified (Art. 3(10), Reg. No 582/2011);
 - compliance with procedures set out in Annex VII regarding demonstration that emissions of an engine family remain in conformity with emission limits set out in Annex I to Reg. No 595/2009 (Art. 3(11), Reg. No 582/2011);
 - that for positive-ignition engines, the maximum carbon monoxide content is not more than 0,3% vol (Art. 3(12), Reg. No 582/2011);
 - compliance with the specific requirements set out for crankcase, including tests in Annex V (Art. 3(13), Reg. No 582/2011);

- that the type approval authority receives information showing the deNox system retains its emission control function during all conditions and information on the operating strategy of EGR system (Art. 3(14), Reg. No 582/2011);
- that the type approval is complying with forthcoming EU legislation on measurement procedures for measuring PM numbers and on multi-setting engines.
- Manufacturers shall apply for type-approval with regard to emissions and access to vehicle repair and maintenance information and for this purpose comply with the type-approval procedures for verifying conformity of production, durability of pollution control devices and in-service conformity pursuant to the specifications laid down by Articles 5, 6, 7, 8, 9 and 10 of Regulation (No) 582/2011. (Article 4(2), Regulation No 595/2009). This applies to vehicle with an approved engine system with regard to emissions and access to vehicle repair and maintenance information (Art. 7), a vehicle with regard to emissions and access to vehicle repair and maintenance information (Art, 9), replacement pollution control devices (Catalytic converters, deNOx devices and particulate filters) intended to be fitted to EC type-approved engine systems or vehicles (Art. 15), replacement pollution control device as a separate technical unit (Art. 16) and pollution control devices (Art. 17). The requirements include:
 - submit application to the designated approval authority;
 - application is in accordance with Appendix 4 to Annex I and Appendix 1 to Annex XI in regard to replacement control devices (Reg. 582/2011, Art. 5(2));
 - provides a documentation package that fully explains any element of design which affects emissions, the emission control strategy of the engine system, the means by which the engine system controls the output variables which have a bearing upon emissions, whether that control is direct or indirect, and fully explains the warning and inducement system (refer to Sections 4 and 5 of Annex XIII and Section 8 to Annex I) and contains:
 - in the case of positive-ignition engines, a declaration by the manufacturer of the minimum percentage of misfires out of a total number of firing events that for instance, would result in emissions exceeding the limits set out in Annex X;
 - a description of the provisions taken to prevent tampering with and modification of the emission control computer(s);
 - documentation and description of the OBD system (Section 5 to Annex X);
 - OBD related information for the purpose of access to OBD and repair and maintenance information;
 - Statement of Off-Cycle Emission (Article 14 and Section 9 to Annex VI) Statement of OBD in-use Performance (Appendix 6 to Annex X); Statement of compliance with the requirements on access to OBD and repair and maintenance information;
 - the initial plan for in-service testing (point 2.4 of Annex II);
 - copies of other type-approvals with the relevant data to enable extension of approvals and establishment of deterioration factors.
 - an engine of a parent engine representative of the type to be approved (Reg. 582/2011, Art. 5(3))
 - for pollution control devices (catalytic converters, de-NOx devices and particulate filters) the type approval has to be in accordance with Art. 17, Regulation No 582/2011, comply with Annex XI (unless covered by point 3,2,12 of Appendix 4 to Annex I then only points 2,1-2,3 of Annex XI apply, bear identification markings, be subject to the specific testing requirements that will be introduced in Annex XI to Regulation No 582/2011. (Art. 17, Regulation No 582/2011)

- for replacement pollution control devices as a separate technical unit the application has to be in the form set out in Appendix 1 to Annex XI and the manufacturer has to submit an engine system equipped with a new original equipment pollution control device, one sample for the type of replacement pollution control device, which is clearly marked. Testing conditions have to comply with requirements of Section 6 of Annex 4B to UN/ECE Regulation No 49 and comply with the requirements set out in Art. 16 of Reg. 582/2011).

The approval authority must retain the documentation package and make it available to interested parties upon request;

An extended documentation package (confidential) may be kept by the approval authority, or be retained by the manufacturer, at the discretion of the approval authority, but must be made available for inspection by the approval authority at the time of approval or at any time during the validity of the approval

- Member States must not invalidate a type-approval in case of changes to the make of a system, component or separate technical unit that occur after a type-approval (only if the characteristics or technical parameters are changed so that the functionality of the engine or pollution control system is affected.
- Where the requirements are met, the approval authority must for vehicles, engines, control devices:
 - grant an EC type approval in accordance with the number system set out in Annex VII to Directive 2007/46/EC and Annex I to Regulation No 582/2011 regarding section 3 of the type approval number;
 - issue an EC type-approval certificate using model in Appendix 5, 6 and 7 to Annex I of Reg. 582/2011 (depending the subject of the type-approval);
 - ensure that each engine type receives a separate number. (Art. 6, 8, 10, 17)
- Manufacturers and the competent authority have to take the relevant measures to ensure conformity of production pursuant to Art. 12 of Directive 2007/46/EC and that the conformity of production is checked based on type-approval certificates (Appendices 5, 6 and 7 to Annex I) and assessed in accordance with the specific conditions and statistical methods referred to in Art. 11(3), Regulation No 582/2011. (Art. 11, Regulation No 582/2011).
- Ensure that all relevant measures are taken in regard to the in-service conformity of vehicles or engine systems type approved under Regulation No 582/2011 or Directive 2005/55/EC, having particular regard to Art. 12 of Directive 2007/46/EC, Annex II of Regulation No 582/2011 (if type approved under the Regulation) and Annex XII of Regulation No 582/2011 (where typed approved under Directive 2005/55/EC). Art. 12 and Annex II of Regulation No 582/2011 specifies technical measures, checks and reporting of in-service testing to be taken by the manufacturer. The approval authority may require confirmatory tests and reports and can request the manufacturer to submit a plan of remedial measures in case of unsatisfactory results of in-service tests. This procedure of testing, reporting and remedial measures involve the manufacturer, the Member State that reported non-conformity with Art. 12 and Annex II of Regulation No 582/2011, the approval authorities, the manufacturer and experts. (Article 12, Regulation No 582/2011)
- Where in-service testing and conformity testing is unsatisfactory, the manufacturer has to submit a plan of remedial measures. These are the main steps of this procedure:

- manufacturer submits plan within 60 days upon receipt of the notification from the approval authority;
 - manufacturer assesses the need to amend the type-approval documents and reports findings to the approval authority;
 - the approval authority approves or rejects the plan of measures within one month and notifies the manufacturer about this Decision;
 - manufacturer executes the plan and keeps a record of engine system or vehicle recalled, repaired or modified and keeps this record available to the approval authority for a period of five years. Repairs and modifications have to be recorded in a certificate supplied by the manufacturer to the owner of the engine/vehicle (Art. 13, Regulation No 582/2011).
- The manufacturers must take technical measures to ensure that the tailpipe emissions are effectively limited throughout the normal life of the vehicles under normal conditions of use (e.g. the mileage and period of time by reference to which the tests for durability of pollution control devices undertaken for type-approval and testing of conformity of in-service vehicles or engines (depending on category and class of vehicle) are to be carried out according to the provisions of Art. 4(2) of Regulation No 595/2009 and annexes of Regulation No 582/2011.
 - Manufacturers must ensure compliance with the emission limits set out in Annex I as revised by Regulation 582/2011. (Art. 5(1), Regulation No 595/2009)
 - Manufacturers must equip vehicles and engines so that the components that may affect emissions are designed, constructed and assembled to, in normal use, comply with Regulation 595/2009 and its implementing measures. (Art. 5(2), Regulation No 595/2009)
 - Member States and manufacturers must ensure that the use of defeat strategies that reduce the effectiveness of emission control equipment is not allowed. (Art. 5(3), Regulation No 595/2009)
 - The manufacturer must take measures to ensure that the tailpipe emissions are effectively limited throughout the normal life of the vehicle and under all normal conditions of use, taking into account the conditions of Art. 14, Regulation No 582/2011 (e.g. performance requirements, the ban on defeat strategies, requirements related to off-cycle in-use vehicle testing) and also fulfil the specific requirements and test procedures set out in Annex VI. Additional requirements with respect to off-cycle-in use vehicle testing is expected in 2015. (Art. 14, Regulation No 582/2011).
 - Manufacturers must ensure that all engine systems and vehicles are equipped with an OBD system designed, constructed and installed in accordance with Annex X also ensuring compliance with the in-use performance requirements, testing conditions, storage of data set out in the same annex. Article 4(7 and 8) allows for temporary alternative provisions for monitoring of the DPF (1 September 2014 and 1 September 2015 respectively). (Art. 4, Regulation No 582/2011)
 - Manufacturers must ensure unrestricted and standardised access to vehicle OBD information, diagnostic and other equipment, tools including any relevant software and vehicle repair and maintenance information to independent operators. Ensure that this information duty is shared between the manufacturer responsible for the relevant type-approval and the final manufacturer, with the latter responsible for communicating information about the whole vehicle to independent operators. This information duty has to take into account the provisions of Articles 6 and 7 of Regulation (EC) No 715/2007. This information must:

- include a standardised, secure and remote facility to enable independent repairers to complete operations which involve access to the vehicle security system (Art. 6, Regulation No 595/2009);
- be presented in an easily accessible, non-discriminatory manner and where relevant in compliance with CEN standards;
- be made available on the manufacturers' websites or in another appropriate format.
- Manufacturers, repairers and operators of the vehicles may not tamper with systems which use a consumable reagent and operators may not drive a vehicle without a consumable reagent. (Art. 7, Regulation No 595/2009)

2.3. Monitoring and Enforcement

- Monitor that the emission control monitoring system for use in vehicles is in conformity with Regulation No 595/2009 and 582/2011.
- Member States have to introduce national provisions on effective, proportionate and dissuasive penalties applicable for infringement of the provisions of this Regulation and its implementing measures and shall take all measures necessary to ensure that they are implemented. The infringements which are subject to penalty for manufacturers are:
 - making false declarations during the approval procedures or procedures leading to a recall;
 - falsifying test results for type-approval or in-service conformity;
 - withholding data or technical specifications which could lead to recall or withdrawal of type-approval;
 - use of defeat strategies;
 - refusal to provide access to information.
- Manufacturers, repairers and operators of the vehicles tampering with systems, which control NO_x emissions must also be subject to penalties.
- Operators of the vehicles are subject to a penalty where driving a vehicle without a consumable reagent. (Art. 11, Regulation No 595/2009)
- It should be noted that this legislation is covered by the Environmental Crimes Directive (2008/99/EC).

2.4. Reporting

Inform the Commission about:

- plans to institute or change the financial incentives referred to in paragraphs 1 and 2. (Art. 10, Regulation No 595/2009);

- the provisions on penalties for non-compliance of manufacturers with Regulation No 595/2009 and its implementation measures to the Commission by 7 February 2011 and immediately notify any subsequent amendment to these penalties (Art. 11, Regulation No 595/2009);
- of each type-approval granted to small volume manufacturers (Art. 2d, Regulation 2011/582);
- of the circumstances of each type-approval granted under Sections 2.4.1 and 2.4.2. (Annex X, Regulation (EU) 2011/582);
- of circumstances of each type-approval granted under Section 2.8. (Annex XVII, Regulation (EU) 2011/582).

Specific reporting obligations of the manufacturers are determined in Annex VIII (section 6. Report to the approval authority and the Commission).

2.5. Additional Legal Instruments

- Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe amended by Commission Directive (EU) 2015/1480
- Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air, amended by Regulation (EC) 219/2009 and Commission Directive (EU) 2015/1480;
- Council Directive 2001/81/EC on national emission ceilings for certain atmospheric pollutants, as amended by Council Directives 2006/105 and 2013/17/EU and Regulation (EC) 219/2009;
- Directive (EU) 2016/802 of the European Parliament and of the Council of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels
- Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions
- Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law
- Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC, as amended by Commission Directives 2000/71/EC, 2011/63/EU, 2014/77/EU, Directives 2003/17/EC, 2009/30/EC, (EU) 2015/1513 and Regulation (EC) 1882/2003;
- Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information, amended by Commission Regulations (EC) 692/2008, (EU) 566/2011, (EU) 459/2012 and Regulation (EC) 595/2009;

- Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, as amended by Commission Directives 2001/63/EC, 2010/26/EC, 2012/46/EU, Directives 2002/88/EC, 2004/26/EC, 2011/88/EU, Council Directive 2006/105/EC and Regulation (EC) 596/2009;
- Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (repealing Directive 77/537/EEC on smoke emissions from diesel engines for use in agricultural or forestry tractors as of 31 December 2015)
- Directive 2009/40/EC of the European Parliament and of the Council of 6 May 2009 on roadworthiness tests for motor vehicles and their trailers (*to be repealed by Directive 2014/45/EU of the European Parliament and of the Council of 3 April 2014 on periodic roadworthiness tests for motor vehicles and their trailers and repealing Directive 2009/40/EC as of 19 May 2018*)
- Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive), as amended
- Directive 2005/64/EC of the European Parliament and of the Council of 26 October 2005 on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability and amending Council Directive 70/156/EEC, as amended by Commission Directive 2009/1/EC.

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing the Regulation No 595/2009 as amended, are summarised in the checklist below.

Table 21. Regulation on Emissions from Heavy Duty Vehicles (Euro VI) - Key Implementation Tasks

DIRECTIVE ON EMISSIONS FROM ENGINES TO BE INSTALLED IN NON-ROAD MOBILE MACHINERY - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate the competent authority or authorities responsible for implementing and supervising compliance with the relevant legislation. Responsibilities would include: <ul style="list-style-type: none"> • issuing and/or withdrawing type-approval certificates; • registering and permitting the placing on the market of new engines; • testing and inspecting engines; • serving as contact point with the approval authorities of other Member States; • supervising correct implementation by the manufacturer.
1.2	Consider introducing financial incentives for retrofitting in order to meet the emission limit values set out in Annex I of in-use vehicles and for scrapping vehicles not complying with Reg. 595/2009.
1.3	Consider whether to integrate the emissions of pollutants as an additional cost for road traffic taxes on motor vehicles.
1.4	Introduce the laws, Regulations and administrative provisions necessary to implement Regulation No 595/2009 and Regulation No 582/2011 and any subsequent amendment thereto.
2	Regulation
2.1	Adopt the systems and procedures <ul style="list-style-type: none"> • to ensure that certificates of conformity which accompany new vehicles or new engines pursuant to Regulation No 595/2009 and 582/2011 after the relevant dates are no longer valid, and prohibit the registration, sale and entry into service or use of new vehicles unless they comply with the requirements set out in the annexes; • a system only to allow the registration, sale and putting into use of vehicles and replacement pollution control devices that have been type-approved and conform with the requirements set out in Annexes I to VIII; • a national database of certificates; • after granting type-approval, take the necessary measures to ensure that it is informed of any change in the particulars appearing in the information package.
2.2	Manufacturers must demonstrate that engines type-approved in accordance with the emission limit values for limits of: <ul style="list-style-type: none"> • 160 000 km or five years, whichever is the sooner, in the case of engines fitted to vehicles (category M 1 , N 1 and M 2); • 300 000 km or six years, whichever is the sooner (category N 2 , N 3 with a maximum technically permissible mass not exceeding 16 tonnes and M 3 Class I, Class II and Class A, and Class B with a maximum technically permissible mass not exceeding 7,5 tonnes); • 700 000 km or seven years, whichever is the sooner (category N 3 with a maximum technically permissible mass exceeding 16 tonnes and M 3 , Class III and Class B with a maximum technically permissible mass exceeding 7,5 tonnes). <p>Consider the changes to the emission limit values for Euro VI engines set out in annex to Regulation 582/2011 as amended.</p>

2.3	<p>Manufacturers shall demonstrate that all new vehicles sold, registered or put into service within the EU, all new engines sold or put into service within the EU and all new replacement pollution control devices requiring type-approval, which are sold or put into service within the EU, are type-approved in accordance with Regulation 595/2009 and Article 3 of Regulation No 582/2011 (Article 4(1), Regulation No 595/2009). With regard to the requirements for obtaining and EC type approval of a vehicle with an improved system with regard to emissions and vehicle repair and maintenance information, manufacturers must ensure compliance with Art. 3 of Regulation No 582/2011 regarding specifications of reference fuels (Annex IX), installations requirements (Annex I), conditions for receiving extension of EC type-approvals (Annex VIII), type approvals for engine system or engine family, design, construction, assembling and installations requirements for engine systems or other design elements affecting emissions (Annex VI), requirements on fuel range (Annex I), requirements for petrol or E85 fuelled engines (Annex I), requirements regarding electronic system security (Annex X), technical measures to limit tailpipe emissions, procedures and test conditions to demonstrate conformity with emission limits (Annex VII), maximum levels of carbon monoxide content and on information to be submitted to the approval authority regarding deNox system and EGR system.</p>
2.4	<p>Manufacturers shall apply for type-approval with regard to emissions and access to vehicle repair and maintenance information and for this purpose comply with the type-approval procedures for verifying conformity of production, durability of pollution control devices and in-service conformity pursuant to the specifications laid down by Articles. 5, 6, 7, 8, 9 and 10 of Regulation (No) 582/2011. (Article 4(2), Regulation No 595/2009). This applies to vehicle with an approved engine system with regard to emissions and access to vehicle repair and maintenance information (Art. 7), a vehicle with regard to emissions and access to vehicle repair and maintenance information (Art. 9), replacement pollution control devices (catalytic converters, deNO_x devices and particulate filters) intended to be fitted to EC type-approved engine systems or vehicles (Art. 15), replacement pollution control device as a separate technical unit (Art. 16) and pollution control devices (Art. 17). The documentation package should:</p> <ul style="list-style-type: none"> • Contain all the specifics listed in the relevant annexes (e.g. manufacturer declaration, documentation of OBD system, statement of emissions, plans for testing); • Be retained at the approval authority, available also for interested parties; • The full documentation package that may contain confidential information may be retained by the manufacturer under certain circumstances.
2.5	<p>Manufacturers and the competent authority have to take the relevant measures to ensure conformity of production pursuant to Art. 12 of Directive 2007/46/EC and that the conformity of production is checked based on type-approval certificates (Appendices 5, 6 and 7 to Annex I) and assessed in accordance with the specific conditions and statistical methods referred to in Art. 11(3), Regulation No 582/2011. Where in-service testing and conformity testing is unsatisfactory, the applicable procedure is complied with regarding submitting a plan of remedial measures, assessing the need to amend the type approval documents, implementation of the plan and record keeping of repair and modifications.</p>
2.6	<ul style="list-style-type: none"> • National authorities have to refuse to grant EC type-approval or national type-approval in respect of new types of vehicles or engines not compliant with Regulation 595/2009 and 582/2011 as amended. • Type-approval technical certificates corresponding to the emission stages prior to Euro VI may be granted to vehicles and engines intended for export to third countries, where certificates state that the vehicles/engines cannot be marketed in the EU • As from 31 December 2013, national authorities shall, in the case of new vehicles, which do not comply with this Regulation and its implementing measures, consider certificates of conformity no longer valid (referring to Article 26 of Directive 2007/46/EC) and thus, prohibit the registration, sale and entry into service of such vehicles. • As from 31 December 2013, national authorities must prohibit the sale or use of new engines which do not comply with Regulation No 595/2009 (exception for replacement engines for in-service vehicles) • Even prior to the above-mentioned dates, national authorities may (if a manufacturer so requests) not refuse to grant EC type approval or national type approval for a new type of

	<p>vehicle or engine or prohibit the registration or sale of such vehicles and engines where they comply with Regulation No 595/2009 (Article 8, Regulation No 595/2009).</p> <ul style="list-style-type: none"> Prohibit the sale or installation on a vehicle of new replacement pollution control devices intended to be fitted on vehicles type approved under Regulation No 595/2009 where they are not of a type in respect of which a type-approval has been granted (Art. 9, Regulation No 595/2009).
2.7	Manufacturers must ensure that all engine systems and vehicles are equipped with an OBD system designed, constructed and installed in accordance with Annex X also ensuring compliance with the in-use performance requirements, testing conditions, storage of data set out in the same annex. Article 4(7 and 8) allows for temporary alternative provisions for monitoring of the DPF (1 September 2014 and 1 September 2015 respectively)
2.8	The manufacturer must take measures to ensure that the tailpipe emissions are effectively limited throughout the normal life of the vehicle and under all normal conditions of use, taking into account the conditions of Art. 14, Regulation No 582/2011 and also fulfil the specific requirements and test procedures set out in Annex VI.
2.9	Ensure that all relevant measures are taken in regard to the in-service conformity of vehicles or engine systems type approved under Regulation No 582/2011, having particular regard to Art. 12 of Directive 2007/46/EC and Annex II of Regulation No 582/2011.
2.10	Manufacturers (manufacturers for each type approval and the final manufacturers) must ensure full and non-discriminatory access to OBD information for the purposes of testing, diagnosis, servicing and repair ensuring information provision to independent operators, and easy information provision in conformity with Directive 2005/55/EC and in conformity with Regulation No (EC) 595/2009 4(4)). Manufacturers must comply with any kind of CEN standards regarding this information where relevant.
3	Monitoring
3.1	Adopt a testing/inspection system to control the quality of engine types or families. The system should: <ul style="list-style-type: none"> control the quality of engine production; ensure the conformity of production; ensure and enforce compliance with type-approval; ensure compliance with emission standards.
3.2	In cases of non-conformity with the approved type or family that it has previously granted, take measures to ensure that the engines in production again conform to the approved type or family.
3.3	Co-operate with other Member States over disputes relating to non-conformity.
3.4	Monitor that the emission control monitoring system for use in vehicles is in conformity with Regulation No 595/2009 as amended by Regulation No 582/2011.
4	Enforcement
4.1	Introduce national provisions on effective, proportionate and dissuasive penalties applicable for infringement of the provisions of this Regulation and its implementing measures and shall take all measures necessary to ensure that they are implemented. The infringements which are subject to penalty for manufacturers are: <ul style="list-style-type: none"> making false declarations during the approval procedures or procedures leading to a recall; falsifying test results for type-approval or in-service conformity; withholding data or technical specifications which could lead to recall or withdrawal of type-approval; use of defeat strategies; refusal to provide access to information. <p>Ensure penalties for manufacturers, repairers and operators of the vehicles tampering with systems which control NO_x emissions.</p> <p>Ensure penalties for operators of the vehicles driving a vehicle without a consumable reagent.</p>
5	Reporting
5.1	Inform the Commission about: <ul style="list-style-type: none"> plans to institute or change the financial incentives referred to in paragraphs 1 and 2. (Art. 11, Regulation No 595/2009);

	<ul style="list-style-type: none"> • the provisions on penalties for non-compliance of manufacturers with Regulation No 595/2009 and its implementation measures to the Commission and immediately notify any subsequent amendment to these penalties (Art. 11, Regulation No 595/2009). <p>Ensure that approval authority informs the Commission in accordance with the Regulation (EU) 2011/582.</p>
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3.2. Phasing Considerations

The most demanding and time-consuming tasks associated with implementing Regulation (EC) No 595/2009 and Regulation (EC) No 582/2011 are deemed to be establishing and developing the institutional structure responsible for the type-approval and monitoring regime, in particular the acquisition and training of sufficient personnel, and the development of systems and procedures for all aspects of type-approval and monitoring. Given that the type approval system for these types of vehicles and engines were first introduced in 1988 by Directive 88/77/EEC, it is a well-established scheme at EU level in which the existing Member States have extensive experience. To the extent possible, candidate countries should try to take advantage of this experience and copy cost-efficient systems and solutions.

4. IMPLEMENTATION GUIDANCE

4.1. Regulation

- It is recommended that the competent authority responsible for road vehicle type- approval is also designated the competent authority responsible for all aspects of type- approval as regards engines to be installed in non-road mobile machinery. It is hence, recommended that the same competent authority is responsible for implementing Regulations (EC) No 595/2009 and (EU) No 582/2011 and for Regulation (EU) No 715/2007 and Directive 2007/46/EC.
- Technical service means a private sector organisation or a public body that has been appointed as a testing laboratory to carry out tests or inspections on behalf of the competent authority. The competent authority may itself carry out the tests and inspections. Each Member State does not need to have its own technical service, but can use services situated in another Member State. The designation of a technical service is, thus, optional. If technical services are appointed, they must be accredited to ensure their competence.
- The accredited organisations that act as technical services in type-approval matters may be research institutes established specifically to carry out certification and type-approvals, or organisations responsible for vehicle roadworthiness testing.
- For advice on how to establish effective administrative structures, type-approval authorities and technical services, authorities in candidate countries should consult Member States that have large national automotive industries.

4.2. Monitoring and Enforcement

- As there is an obligation to register these vehicles, this will be one of the main mechanisms to ensure compliance with its requirements. It is recommended that the authority granting type-approval for engines and vehicles regularly demands the manufacturer to provide a list containing information on the engines produced in accordance with the requirements of Regulations No 595/2009 and 582/2011. With help provided by the manufacturers, the authority must register and control the identification numbers of those engines produced in conformity with the granted approval. The competent authorities should be given powers to carry out spot checks.
- The delivery of information by the manufacturers to the competent authorities shall be enforced by effective administrative provisions, which should include penal sanctions. The new Regulations fall under the scope of the Environmental Crimes Directive (2008/99/EC) requiring introduction of effective, dissuasive and proportionate penal sanctions in case of non-compliance.
- Some degree of self-regulation can be expected, when competing manufacturers and dealers in engines and machinery act as watchdogs for the products of other manufacturers and provide the authorities with information on non-compliance.

- In case of non-conformity, the authority shall ensure (by means of guidance, administrative orders, and withdrawal of approval) that the vehicles or pollution control devices in production are brought into conformity with the specifications of Regulations No 595/2009 and 582/2011.
- Regulation No 595/2009 introduces direct obligation on part of candidate countries to ensure effective, proportionate and dissuasive penalties for manufacturers but also to a certain extent suppliers and vehicle operators for certain infringements. Given the application also of the Environmental Crimes Directive (2008/99/EC) it is important to oversee the national penalties system and ensure that the national legislation provide for such penalties and that these are really enforced.
- The enforcement requires increased staffing and the training of the bodies handling the vehicle approvals and registrations or governing the technical safety of machinery. The workload expected depends heavily on the number of vehicle types being offered on the market. Thus, it is very difficult to estimate costs.

5. COSTS

The main types of costs arising from the implementation of this Directive are given in the checklist below.

Table 22. Checklist of the Types of Cost Incurred to Implement the Regulations on emissions from heavy duty vehicles

Checklist of the Types of Cost Incurred to Implement the Regulations
Initial set-up: <ul style="list-style-type: none">• the establishment of competent authorities;• devising systems and procedures for conformity checking, type-approval, monitoring etc;• provisions for training;• the preparation of technical guidance.
Capital expenditure: <ul style="list-style-type: none">• test laboratory/installation for exhaust emissions measurements.
Ongoing running costs: <ul style="list-style-type: none">• labour costs for certification testing;• operating costs of the test laboratory;• costs relating to testing services;• labour costs for the processing of data and reporting to the Commission.
Cost sharing: <ul style="list-style-type: none">• Costs can partly be shared with other related EU legislation on type-approval including Regulation No. 715/2007 and Directives on non-road vehicles

If a candidate country chooses to use technical services in another Member State, capital expenditure will be minimal, although on-going costs would be higher since the acquisition of testing services would then include the cost of depreciation for the equipment at the agency providing the testing services.

REGULATION ON TYPE APPROVAL OF MOTOR VEHICLES REGARDING EMISSIONS FROM VEHICLES

Official Title: Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type-approval of vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information (OJ L 171/1, 29.6.2007),

as amended by:

Commission Regulation (EC) No 692/2008 of 18 July 2008 implementing and amending Regulation (EC) No 715/2007 of the European Parliament and of the Council on type-approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information (OJ L 199, 28.7.2008)

Regulation (EC) No 595/2009 of the European Parliament and of the Council of 18 June 2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC (OJ L 188, 18.7.2009)

Commission Regulation (EU) No 566/2011 of 8 June 2011 amending Regulation (EC) No 715/2007 of the European Parliament and of the Council and Commission Regulation (EC) No 692/2008 as regards access to vehicle repair and maintenance information (OJ L 158, 16.6.2011)

Commission Regulation (EU) No 459/2012 of 29 May 2012 amending Regulation (EC) No 715/2007 of the European Parliament and of the Council and Commission Regulation (EC) No 692/2008 as regards emissions from light passenger and commercial vehicles (Euro 6) (OJ L 142, 1.6.2012)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The main objectives of Regulation No. 715/2007 are:

- to contribute to the functioning of the internal market by establishing common technical requirements concerning emissions from motor vehicles, the type-approval of vehicles, and replacement parts including replacement pollution control devices;
- to guarantee equal access to vehicle repair and maintenance information for independent operators on the same basis as for authorised dealers and repair operators;
- to limit, to the extent possible, pollution caused by road vehicles and its adverse effects on human health and the environment.

In order to limit pollution caused by road vehicles, this Regulation introduces common requirements for emissions from motor vehicles and their specific replacement parts (Euro 5 and Euro 6 standards). It also lays down measures improving access to information on vehicle repairs and promoting the rapid production of vehicles in compliance with the provisions of the Regulation.

The Regulation also lays down rules for in-service conformity, the durability of pollution control devices, on-board diagnostic systems, and the measurement of fuel consumption. It also introduces new common requirements for emissions from motor vehicles and their specific replacement parts (Euro 5 — light-duty vehicles; and Euro 6 — heavy-duty vehicles). The Regulation attempts to strike a balance between a need to further improve emission limits and to mitigate the implications for the markets and the competitiveness of manufacturers, as well as the direct and indirect costs for businesses.

The Regulation covers a wide range of pollutant emissions: carbon monoxide (CO), non-methane hydrocarbons and total hydrocarbons, nitrogen oxides (NO_x) and particulates (PM) covering tailpipe emissions, evaporative emissions and crankcase emissions.

The Regulation sets out emission limits for Euro 5 and Euro 6 standards, set for each category of pollutant emissions and for the different types of vehicle listed above. The reductions for Euro 5 standard range from 20% to 80% compared to the Euro 4 standard.

The Regulation covers vehicles of categories M1, M2, N1 and N2, with a reference mass not exceeding 2 610 kg. This includes:

- Passenger vehicles, vans, and commercial vehicles intended for the transport of passengers or goods or certain other specific uses (for example ambulances), which have either positive-ignition engines (petrol, natural gas or liquefied petroleum gas (LPG) or compressed ignition (diesel engines) (mandatory coverage);
- Vehicles intended for the transport of passengers or goods with a reference mass of between 2 610 kg and 2 840 kg where requested by the vehicle manufacturers (facultative)
- Key obligations on part of the vehicle manufacturers:
- Comply with the emission limit values for a wide range of pollutant emissions: carbon monoxide (CO), non-methane hydrocarbons and total hydrocarbons, nitrogen oxides (NO_x) and particulates (PM), covering tailpipe emissions, evaporative emissions and crankcase emissions. The emission limits depends both on the category of pollutants and the type of vehicle.

- Ensure that devices fitted to control pollution are able to last for a distance of 160 000 km.
- Conformity must be checked for a period of 5 years or over a distance of 100 000 km.
- Provide easy and clear access to information on vehicle repair and maintenance:
 - ensure that independent operators have easy, restriction-free and standardised (particularly in terms of compliance with the OASIS standard) access via the internet to information on the repair and upkeep of vehicles, without discrimination in favour of dealerships and official repair workshops. This obligation covers on-board diagnostic systems and their components, diagnostic tools, testing equipment and standard working units or time periods required for repair and maintenance activities;
 - ensure that independent repairers have access to the registers of information free of charge and under the same conditions as authorised dealers and repairers;
 - make information available on vehicle repair and maintenance, as well as on the transactional services.

As soon as the Euro 5 and Euro 6 standards enter into force, Member States must refuse the approval, registration, sale and introduction of vehicles that do not comply with these emission limits. An additional delay of one year is allowed for goods transport vehicles (category N1, classes II and III, and category N2) and vehicles designed to fulfil specific social needs.

To ensure a smooth transition from the existing legal framework to this Regulation, a transitional period has been provided for. During this transitional period, manufacturers are allowed to choose to have vehicles approved under the existing Directives or this Regulation. To give incentives for an earlier phase-in of the new requirements, Member States are encouraged to provide financial incentives to use the stricter requirements and emission limits under the new Regulation. Such incentives may be approved if:

- they apply to all new vehicles available for sale on the market of a Member State, which meet the requirements of this Regulation before their entry into force;
- they end on the date the new limits come into force;
- are worth less than the cost, including fitting, of the devices used on any type of motor vehicle in order to guarantee that the values laid down are not exceeded.

Table 23. Key Deadlines (note that these include past deadlines, the main purpose to be illustrative for the candidate countries in terms of the sequence and timing of the obligations)

Key Deadlines	
2 July 2007	Member States had to ensure the granting of EC type-approval or national type-approval or the registration, sale or entry into service of a new vehicle complying with Regulation No 715/2007 and its implementing measures, especially regarding Euro 5 and Euro 6 limit values; Member States may introduce financial (tax) incentives for the production of vehicles complying with Euro 5 and Euro 6 standards. However, these incentives had to apply to all new vehicles available for sale on the market of a Member State that comply with the requirements of the Regulation and must be phased out by the date on which the new limits come into force.
2 July 2008	Member States had to introduce the implementing measures referred to in Articles 5(3) and 14(6)

3 January 2009	Regulation No 715/2007 entered into force
1 September 2009	Member States must refuse the approval, registration, sale and introduction of vehicles that do not comply with these emission limits; the Euro 5 standard will come into force for the approval of vehicles
1 September 2010	Member States must refuse the approval, registration, sale and introduction of category N1 classes II and II and category N2 vehicles that do not comply with these emission limits. An additional delay of one year is allowed for goods transport vehicles and vehicles designed to fulfil specific social needs (category N1, classes II and III, and category N2).
January 2011	The Euro 5 standards came into force for the registration and sale of new types of cars
1 September 2014	The Euro 6 standard applies to the type approval of vehicles
1 September 2015	The Euro 6 standard applies for the registration and sale of new types of cars

Table 24. Further key deadline for direct injection gasoline engines:

Particle number emission limits for spark ignition vehicles	Regulation (EC) No 715/2007 requires that a PN limit value for positive ignition cars is set at the latest by the Euro 6 stage. A number standard must be set before 1 September 2014. In June 2012 Regulation 459/2012 introduced a particle number limit for Euro 6 specification vehicles. This enters into force in two different steps: <ul style="list-style-type: none"> • step 1: $6 * 10^{12}$ particles/km in 2014 • step 2: $6 * 10^{11}$ particles/km in 2017 (aligning GDI with Diesel standards).
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The legislation on vehicle emissions and fuel consumption has evolved over 35 years and was spread over a great number of Directives, that are repealed by the Regulation¹³⁸. The main aim of the Regulation is to consolidate most of these EU measures within one instrument that is directly applicable to manufacturers, approval authorities and technical services, and a number of implementing EU measures. Updates of the measures and emission limits will be much easier and faster now as the Commission will mainly resort to a fast-track regulatory procedure involving technical committees. Based on this procedure, the Commission has adopted so far four new Regulations, i.e. Regulation (EC) No 692/2008, Regulation (EC) No 595/2009, Regulation (EU) No 566/2011 and (EU) No. 459/2012.

A summary of the new Regulations is given below:

- Commission Regulation (EC) No 692/2008 of 18 July 2008 implementing and amending Regulation (EC) No 715/2007 of the European Parliament and of the Council on type-approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information requires the Commission to introduce the new test procedure for particle mass and numbers emitted by light duty vehicles. This Regulation Implements Articles 4, 5 and 8 of Regulation (EC) No 715/2007 and introduces amendments to the existing provisions (set out in XVII). Firstly, it adds a paragraph 6 to Art. 10 relating to emission limits

¹³⁸ Regulation 715/2007 amended Directives 70/156/EEC and 2005/55/EC and it repealed, from 2 January 2013, the following Directives: 70/220/EEC, 72/306/EEC, 74/290/EEC, 77/102/EEC, 78/665/EEC, 80/1268/EEC, 83/351/EEC, 88/76/EEC, 88/436/EEC, 89/458/EEC, 91/441/EEC, 93/59/EEC, 94/12/EC, 96/44/EC, 96/69/EC, 98/69/EC, 98/77/EC, 99/100/EC, 99/102/EC, 2001/1/EC, 2001/100/EC, 2002/80/EC, 2003/76/EC and 2004/3/EC.

referring to the amended tables 1 and 2 of Annex regarding emission limits for Euro 5 and Euro 6 engines. For instance, a 4,5 mg/km emission limit for mass of particulate matter and the particle number limit referred to in Tables 1 and 2 of Annex I was effective from 1 September 2011 for the type-approval on new types of vehicles and from 1 January 2013 for all new vehicles sold, registered or put into service in the EU.

- Regulation No 595/2009: a new separate Regulation in the context of the EU type-approval procedure under Directive 2007/46/EC establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive). Regulation amends Annexes IV, VI and XI to that Directive accordingly. It introduces a few minor changes to Regulation (EC) No 715/2007 (adding a point to Art. 5(3) and deletion of Art. 14(6)). This Regulation came into force 7 August 2009 and will repeal Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC from 31 December 2013.
- Regulation No 566/2011 amending Regulations (EC) No 715/2007 and 692/2008 in several ways, e.g.
 - Article 6, Reg. 715/2007 on extended and more detailed list of information that manufacturers need to provide;
 - Art 6(8), Reg. 715/2007: new provision guaranteeing that independent, approved and authorised manufacturers or repairers have access to records in a central base free of charge;
 - Article 7(2), Reg. 715/2007: Manufacturers shall make available vehicle repair and maintenance information including transactional services such as reprogramming or technical assistance either time-based or transaction based (at a reasonable fee);
 - Article 2, Reg. 692/2008 - new point 33 is added defining cold start;
 - Article 6(1) and 10(1), Reg. 692/2008 – new points 4 and 5 regarding reference to Art. 13 and approval procedure according to UN/ECE Regulations No 83, series of amendments 06, No 101, series of amendments 01 and in the case of compression ignition vehicles No 24 Part III, series of amendments 03 and the replacement pollution control devices have been approved according to UN/ECE Regulation No 103;
 - Article 13(9), Reg. 692/2008 new text regarding the Forum on Access to Vehicle Information, which advises the Commission on issues of confidentiality and processes for approving and authorising independent operators by accredited organisation to access information on vehicle security;
 - Amendments to Annexes I, III, IV, VIII, IX, XI, XII, XIV, XVI and XVIII of Regulation 692/2008;
 - Replacement of Annex II, Regulation 692/2008.
- Commission Regulation (EU) 549/2012 amending Regulation (EC) No 715/2007 of the European Parliament and of the Council and Commission Regulation (EC) No 692/2008 as regards emissions from light passenger and commercial vehicles (Euro 6) defines particle number (PN) standard for vehicles equipped with a positive ignition engine to be approved according to Euro 6 standards. Hence, the Regulation (EU) 549/2012 amends Annex I of the Regulation (EC) No 715/2007 and Annexes I, XI and XVI of the Regulation (EC) No 692/2008.

In 2014, the European Commission issued a proposal for a regulation amending Regulations (EC) 715/2007 and (EC) 595/2009, which would give it extra powers to take measures to reduce polluting emissions (COM (2014) 28 final of 31 January 2014).

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Consider whether to introduce financial (tax) incentives for the production of vehicles complying with Euro 5 and Euro 6 standards. These incentives must apply to all new vehicles available for sale on the market of a Member State that comply, at least, with the emission limit values in table 1 of Annex I (Euro 5 limits) and had to be phased out by 1 January 2011 or 1 January 2012 in the case of category N1, classes II and III. The candidate countries can also consider only giving financial incentives for vehicles complying with the limit values set out in Table 2 of Annex I (the more stringent Euro 6 limits), but these need to be phased out by 1 September 2015 or 1 September 2016 (the latter date applying to category NI, classes II and III vehicles) (Art. 12(1)). The size of the financial incentives must be in accordance with Article 12(3) and these incentives must be announced in advance to the Commission.
- Consider whether to introduce financial incentives to upgrade the existing fleet of older non-conforming vehicles, such as subsidies for the retro-fitting of vehicles in use and for scrapping older non-complying vehicles (Art. 12(2), Regulation No 715/2007).

The light duty legislation (mainly Regulation (EC) No 715/2007, (EC) No 692/2008 and (EC) No 566/2011) has the following regulatory outlook:

Table 25. Regulatory Outlook of the Light Duty Legislation

OBD	The implementing legislation does not contain any OBD thresholds limits (OTL) for Euro 6 vehicles, apart from interim thresholds designed for the early introduction of Euro 6 diesel vehicles. Final Euro 6 OBD threshold limits will need to be confirmed by the date of entry into force of the Euro 6 standards.	Regulation (EU) 459/2012 lays down Euro 6 OTLs.
Reference fuels	Euro legislation contains a specification for the low-temperature reference for petrol (E5), but not for the low-temperature version for Ethanol (E75).	Reference fuel specifications for E75 introduced through REG 566/2011
Low temperature emissions testing on CO and HC	Regulation (EC) No 715/2007 contains a requirement for the Commission to review the emission limits set for petrol cars under the low temperature test at -7°C . The concern is that the limits (on CO and HC), carried over from Euro 3 and 4 are not applicable	Test procedures at low temperature introduced through amendment by REG 566/2011 (TBC ENTR) Brought in line with UNECE Regulation 83 (annex 8). January 2012: Adaptation to technical progress (Euro 5 and Euro 6) of 715/2007 through a mandate for the Commission is under impact assessment.

	anymore for Euro 5 and 6 vehicles.	
Low temperature emissions of NOx.	A review is needed due to the risk of elevated Diesel NOx emissions under Euro 6 at cold temperature with EGR (exhaust gas recuperation ¹³⁹) and NOx after treatment.	2s2014: Adaptation to technical progress (Euro 5 and Euro 6) of 715/2007 through a mandate for the Commission is under impact assessment. 2s2017 Application
Emissions of NO2	Euro 6 emission Regulation specifies a limit value for total NOx emissions, but not for NO2 emissions. Filter technology for diesels requires the need to balance NO2/NOx emissions	January 2012: the introduction of a mandate for the Commission to specify through a delegated act an additional NO2 value in REG 715/2007 is under impact assessment. 2s2014 Adoption 2s2017 Application
Emissions of methane	Include methane as a CO2 equivalent and remove it from the THC emission limit in order not to hinder entry into the market of CNG vehicles. Adapt HC limits	January 2012: the introduction of a mandate for the Commission to account for GH effects of methane emissions through a delegated act is under impact assessment. This act may also change the THC limits. 2s2014 Adoption and application
Emissions of ammonia	Concerns emissions of ammonia by NG drive vehicles Objective still undefined.	No planning known
Evaporative emissions	Due to the wider introduction of biofuels, the Commission intends to review test procedures for evaporative emissions. This review should consider whether greater global harmonisation is desirable through alignment of the European test procedure with that used in the United States. In-service conformity and durability must be taken into account.	Amendment of Reg 715/2007 2s2013 Adoption 2s2017 Application
H2 and H2NG vehicles requirements	Regulation (EC) No 715/2007 foresees that the Commission considers reviewing the approach to calculating CO2 emissions from vehicles to include other greenhouse gases such as methane emissions. Requirements for using H2 and variable mixtures of H2 and CNG. Certifying validity of NOx emissions and emission test procedures.	TCMV agreed in Nov 2011 on draft modifications of REG 692/2008. Adoption foreseen in 2012
Emissions test procedure	Regulation (EC) No 715/2007 requires that the Commission keep this under review, and propose changes if the	This is an ongoing process. Amendment of Reg 715/2007 is foreseen for 2013/2014. The Commission has taken the lead in a UNECE WG.

¹³⁹ This is the primary technique of reducing NO2 emissions from Diesels. Cooled exhaust gases are fed back to the cylinder, reducing the amount of O2 and thus lowering the temperature (and NO2 content) of exhaust gases

	procedures for assessing the emissions and fuel consumption of light duty vehicles (based on NEDC) are no longer adequate or do not reflect real world emissions.	2s2013 Adoption 2s2014 Application w/o not-to-exceed values 2s2017 Full application
Emissions test procedure for EV/HEV		2s2013 Adoption 2s2014 Partial application 2s2017 Full application
Vehicle Mass neutral emissions standards	Regulation (EC) No 715/2007 foresees that with future emission limits, consideration should be given to introducing mass neutral emissions standards (as in US legislation). It would cause the deletion of the current vehicle category N1, Class I, II and III distinction	No information on projects available
Reference mass limits for light duty vehicles	The reference mass for LD vehicles is limited to 2610/2840 kg which for certain vehicles is too low. This leads to type approval in the "wrong" category and to double type approval in some cases (variants of the vehicle).	January 2012: Measures are under impact assessment. Environmental impact must be assessed as vehicles shift from one type of testing to another.
Durability of pollution control devices	Durability of pollution control devices (new bench aging and durability factors).	2s2014 Adaption 2s2014 Partial application 2s2017 New bench aging procedure: adoption and full application
Type approval of replacement pollution control devices	The Commission intends to review requirements for the type approval of replacement pollution control devices to take account of the revised OBD requirements and also the introduction of new pollution control device tech.	No information on projects available

For Heavy Duty legislation the main lines of the legal outlook are as follows:

Table 26. Regulatory Outlook of the Heavy Duty Legislation

2013 Comitology Package	<ul style="list-style-type: none"> Aligning cross references Euro VI and UNECE Reg 49 PN limits for positive ignition engines Including monitoring requirements relative to OTL of Particle matter after treatment devices Including provisions on PM for PEMS 	Vote TCMV foreseen 2013
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	performance and PEMS assessment.	
Ammonia limit for positive ignition Euro VI vehicles	Small amounts of ammonia may originate from a (HD) CNG (or petrol) driven engines which would be complicated to remove. This puts cleaner CNG engines in disadvantage compared diesel engines	January 2012: under impact assessment (to be followed up closely)
Retrofit measures Euro VI	The Comm. must prepare a proposal to harmonise national legislation on retrofitting (as requested by REG 595/2009).	Requirements under elaboration by UNECE REG working group (mainly PM and NOx control devices). Draft proposal foreseen in 2013.
NO2 limit value		Remains to be confirmed

2.2. Regulation

Obligations for competent authorities:

- Ensure understanding of the definitions set out in Article 2 of Regulation 692/2008, as amended by Regulation No 566/2011.
- Amendments to the type-approval is done according to Articles 13, 14 and 16 of Directive 2007/46/EC. Manufacturers can request application of Section 3 of Annex 1. (Article 7, Regulation No 692/2008)
- Member States must not invalidate a type-approval in case of changes to the make of a system, component or separate technical unit that occur after a type-approval (only if the characteristics or technical parameters are changed so that the functionality of the engine or pollution control system is affected. (Art. 5(10), Regulation No 692/2008)
- Where the requirements are met, the approval authority must for vehicles, control devices and replacement pollution control device (as separate technical unit):
 - grant an EC type-approval and issue a type-approval number in accordance with the numbering system set out in Annex VII to Directive 2007/46/EC. Section 3 of the type-approval number shall be drawn up in accordance with Appendix 6 to Annex I to this Regulation;
 - issue an EC type-approval certificate using model in Appendix 4 to Annex I of Reg. 692/2008 for vehicles and Appendix 2 to Annex XIII for replacement control devices (Art. 6 and 12, Regulation No 692/2008);
 - ensure that each engine type receives a separate number (Art. 6 and 12, Regulation No 692/2008);
 - decide whether to grant, at the request of the manufacturer, type approval for a vehicle with an OBD system that does not fully meet the specific requirements of Annex XI (provided that Section 3 of Annex XI is complied with). The approval authority shall notify the Decision to grant such a type approval to all approval authorities in the other Member States in accordance with the requirements set out in Article 8 of Directive 2007/46/EC. (Art. 6, Regulation No 692/2008);

- not subject during the type-approval procedure, replacement pollution control devices covered by section 2,3 of the Addendum to Appendix 4 to Annex I, to the requirements in section 4 of Annex XIII. (Art. 12, Regulation No. 692/2008)
- The approval authority may check compliance with the provisions of Regulation No 715/2007 and the terms of the Certificate on Access to Vehicle OBD and Vehicle Repair and Maintenance Information on its own initiative, on the basis of a complaint, or on the basis of an assessment by a technical service.
 - in case of non-conformity, the authority must take the appropriate measures which include withdrawal or suspension of the type approval, fines;
 - the authority can request an audit to verify compliance in case of complaints of independent operator. (Art. 14, Regulation No 692/2008)
- Refuse to grant EC type-approval or national type-approval for new types of vehicles that do not comply with the Regulation and its implementing measures:
 - for meeting Euro 5 emission limit values, including the 5,0 mg/km emission limit for mass of particulate matter referred to in table 1 of Annex I to Regulation No 692/2008 (amending table 1 in Regulation No 715/2007) (Art. 10(2), Regulation No 715/2007 and Art. 10(6), Regulation No 692/2008);
 - as of 1 September 2014 (except for category N1, classes II and III and N2 vehicles, for which the applicable date is 1 September 2015) for meeting Euro 6 limit value, including the 5,0 mg/km emission limit for mass of particulate matter referred to in table 2 of Annex I to Regulation No 692/2008 (amending table 2 in Regulation No 715/2007) (Art. 10(4), Regulation No 715/2007 and Art. 10(6), Regulation No 692/2008));
 - regarding the 4,5 mg/km emission limit for mass of particulate matter and the particle number limit referred to in Tables 1 and 2 for the type-approval on new types of vehicles. (Art. 10(6), Regulation No 692/2008);
 - as from 1 January 2013 regarding the 4,5 mg/km emission limit for mass of particulate matter and the particle number limit referred to in Tables 1 and 2 for all new vehicles sold, registered or put into service in the EU. (Art. 10(6), Regulation No 692/2008)
- Must consider certificates of conformity to be no longer valid and prohibit the registration, sale or entry into service of new vehicles not complying with the Regulation and its implementing measures as follows:
 - for new vehicles not meeting the Euro 5 limit values set out in table I of Annex I to Regulation No 692/2008;
 - as of 1 September 2015 (except for category N1, classes II and III and N2 vehicles for which the applicable date is September 2016) for new vehicles not complying with the Euro 6 limit values set out in table II of Annex I to Regulation No 692/2008 (Art. 10 (3),(5), Regulation No 715/2007).
- Only allow the sale or installation of new replacement pollution control devices to be installed on Euro 5 and 6 conforming vehicles if they have been type-approved (Art. 11(1)).

- Ensure that the requirements set out in Annexes I, II, III, IV, VIII, IX, XI, XII, XIV, XVI and XVIII of Regulation 566/2011 are fully complied

Obligations relevant for the manufacturers:

- Provide sufficient demonstration that all new vehicles sold, registered or put into service in the EU as well as new replacement pollution control devices sold or put into service are type-approved in accordance with the Regulation and its implementing measures. (Art. 4(1), Regulation No 715/2007)
- Comply with the emission limits set out in Annex I (the Euro 5 and Euro 6 standards) (Art. 4(1), Regulation No 715/2007):
 - Emissions from diesel vehicles:
 - carbon monoxide: 500 mg/km;
 - particulates: 5 mg/km (80 % reduction of emissions in comparison to the Euro 4 standard);
 - nitrogen oxides (NO_x): 180 mg/km (20 % reduction of emissions in comparison to the Euro 4 standard);
 - combined emissions of hydrocarbons and nitrogen oxides: 230 mg/km.
 - Emissions from petrol vehicles or those running on natural gas or LPG:
 - carbon monoxide: 1 000 mg/km;
 - non-methane hydrocarbons: 68 mg/km;
 - total hydrocarbons: 100 mg/km;
 - nitrogen oxides (NO_x): 60 mg/km (25 % reduction of emissions in comparison to the Euro 4 standard);
 - particulates (solely for lean burn direct-injection petrol vehicles): 5 mg/km (introduction of a limit that did not exist for the Euro 4 standard).
- Comply with the Euro 5 standard and the three relevant categories of emission limits for vans and other light commercial vehicles intended for goods transport (i.e. under 1 305 kg, between 1 305 kg and 1 760 kg, and over 1 760 kg).
- Comply with the last category above of Euro 5 standard for goods transport vehicles (category N2).
 - in addition to the emission limit values indicated above for vehicles equipped with a diesel engine, these have to reduce their emissions of nitrogen oxides accordingly;
 - emissions from cars and other vehicles intended to be used for transport will be capped at 80 mg/km (an additional reduction of more than 50 % compared to the Euro 5 standard);
 - combined emissions of hydrocarbons and nitrogen oxides from diesel vehicles will also be reduced. These will be capped at, for example, 170 mg/km for cars and other vehicles intended to be used for transport.
- Put into place the necessary procedures and systems to be able to grant EC type- approval or national type-approval for a new type of vehicle complying with the Regulation and, in particular, with the emission limit values as of 2 July 2007. The registration, sale or entry into service of a new vehicle complying with these requirements must not be prohibited. (Art. 10(1), Regulation 715/2007)
- In order to receive an EC type-approval with regard to emissions and vehicle repair and maintenance information manufacturers have to prove:

- compliance with the specifications of reference fuels set out in Annex IX (Art. 3(1), Regulation No 692/2008);
- compliance with the specific requirements applying to small volume manufacturers that may request the granting of EC type-approval to a vehicle type which was approved by an authority of a third country or on the basis of the legislative acts set out in Section 2.1 of Annex I. Here it is sufficient to comply with emissions tests for roadworthiness (Annex IV) and tests for fuel consumption and CO₂ emissions (Annex XII) and the requirements for access to vehicle OBD and vehicle repair and maintenance information (Annex XIV);
- compliance with the various tests
 - those specified in Figure I.2.4 of Annex I. (Art. 3(2), Regulation No 692/2008);
 - emissions test results comply with the applicable limit value under the specified test conditions of this Regulation;
 - Type 2 test (Appendix 1 to Annex IV) for max. carbon monoxide content at normal and high engine idling;
 - Type 3 test (Annex V) regarding control of crankcase gases;
 - Type 6 test measuring emissions at low temperatures (Annex VIII), which does not apply to diesel vehicles. (Art. 3(6), (7), (8), Regulation No. 692/2008)
- compliance with the specific requirements for inlets to fuel tanks and electronic system security (Section 2.2 and 2.3 of Annex I) (Art. 3(4), Regulation No 692/2008).
- Manufacturers shall apply for type-approval of a vehicle with regard to emissions and access to vehicle repair and maintenance information (Art. 5, Regulation No 692/2008). The requirements include:
 - submit application to the designated approval authority;
 - application is in accordance with Appendix 3 to Annex I;
 - in the case of positive-ignition engines, a declaration by the manufacturer of the minimum percentage of misfires out of a total number of firing events that for instance, would result in emissions exceeding the limits set out in section 2.3 of Annex XI;
 - a description of the provisions taken to prevent tampering with and modification of the emission control computer(s);
 - OBD related information; i.e. description of the functional operation characteristics for the OBD system, the malfunction indicator to signal fault to the driver, a declaration by the manufacturer that the OBD system complies with the provisions of Section 3 of Appendix 1 to Annex XI (using the model in Appendix 7 of Annex I);
 - a plan describing the detailed technical criteria and justification for incrementing the numerator and denominator of each monitor that must fulfill the requirements of sections 3.2 and 3.3 of Appendix 1 to Annex XI. The approval authority shall make the information referred to in that point available to the approval authorities or the Commission upon request;
 - copies of other type-approvals with the relevant data to enable extension of approvals and establishment of deterioration factors;
 - demonstrate compliance for type-approval of mono fuel, bi-fuel and flex-fuel vehicles with Sections 1.1 and 1.2 of Annex I;

- submit to the technical service a vehicle representative of the type to be approved (Art. 5, Regulation No 692/2008);
- pollution control devices (catalytic converters and particulate filters), intended to be fitted to EC type-approved vehicles, have to be EC type-approved as separate technical units in accordance with Arts. 12-13 and Annex XIII of Regulation No 692/2011, with exception for certain replacement pollution control devices (covered by point 2,3 of the Addendum to Appendix 4 to Annex I). The devices have to carry identification markings (Art. 10, Regulation No 692/2011);
- replacement pollution control devices have to be EC type-approved as separate technical units in accordance with the model set out in Appendix 1 to Annex XIII. The manufacturer has to submit a vehicle equipped with a new original equipment pollution control device and one sample for the type of replacement pollution control device, which is clearly marked. Testing conditions have to comply with requirements of Section 3.1 of Annex to UN/ECE Regulation No 83 and comply with the requirements set out in Art. 11 of Reg. 692/2008).
- Manufacturers and the competent authority have to take the relevant measures to ensure conformity of production pursuant to Art. 12 of Directive 2007/46/EC and that the conformity of production is checked based on type-approval certificates (Appendix 4 to Annex I) and assessed in accordance with the specific conditions and statistical methods referred to in Section 4 of Annex I to Regulation No 592/2008 and Appendices 1-2 to the same annex. (Art. 8, Regulation No 592/2008)
- Ensure that all relevant measures, appropriate for confirming the functionality of the pollution control devices, are taken in regard to the in-service conformity of vehicles or engine systems type approved under Regulation No. 692/2008, having regard to Annex II and Annex XV, as well as Art. 12 of Directive 2007/46/EC for vehicles approved under Regulation No 692/2008 and Directive 70/220/EEC (to be repealed by Regulation 592/2009).
 - in service conformity measures shall be checked for a period of up to 5 years or 100,000, whichever is sooner;
 - audit is required unless annual sales are below 5000 across the EU (subject to more confined testing);
 - the approval authority may require confirmatory tests and reports and can request the manufacturer to submit a plan of remedial measures in case of unsatisfactory results of in-service tests in accordance with the criteria in Appendix 2 to Annex II;
 - where a vehicle type does not confirm to the conditions of Appendix, the approval authority has to notify the Member States which granted the original type-approval about the non-complying issues and request a plan of measures;
 - the manufacturer has two months to submit a plan of measures that needs to be agreed by the approval authority that issued the original type-approval;
 - the plan of remedial measures shall be in accordance with Appendix 1 of Annex II and approved by the approval authority, which has to announce its Decision to all Member States within 30 days. (Art. 9, Regulation No. 692/2008)
- The manufacturers must take technical measures to ensure that the tailpipe and evaporative emissions are effectively limited throughout the normal life of the vehicles under normal conditions of use. (Art. 3(5), Regulation 692/2008)

- Manufacturers must ensure that all engine systems and vehicles are equipped with an OBD system designed, constructed and installed so as to enable it to identify deterioration or malfunction over the entire life of the vehicle, ensuring compliance with Regulation No 692/2008 during conditions of normal use, testing conditions and in-use performance and that the in-use performance data is stored and reported by the OBD system and made available by the manufacturer to the national authorities and independent operators. Ensure that vehicles are not type-approved to Euro 6 class unless OBD thresholds have been introduced with exception of diesel vehicles to which other thresholds apply. (Article 4, Regulation No 692/2008)

2.3. Monitoring and Enforcement

Efficient, proportionate and dissuasive penalties for infringement of the provisions of the Regulation had to be put into place by manufacturers and corrective measures had to be ensured to bring them into compliance. The following infringements, at least, must be punished:

- making false declarations within the approval procedures;
- falsifying test results for type-approval or in-service conformity;
- withholding data or technical specifications that could lead to the recall or withdrawal of type-approval;
- use of defeat devices;
- refusal to provide access to information (Art. 13).

2.4. Information

- Manufacturers must ensure unrestricted and standardised access to vehicle OBD and vehicle repair and maintenance information. This has to take into account the provisions of Articles 6 and 7 of Regulation (EC) No 715/2007 and the provision for access to OBD information set out in Section 4 of Annex XI;
- Manufacturers have to submit a certificate on access to vehicle OBD and vehicle repair and maintenance information, in accordance with the model set out in Appendix 1 of Annex XIV;
- the approval authorities may not grant an EC type-approval prior to receiving the certificate;
- manufacturer shall make available to interested parties the following information: relevant information to enable the development of replacement components for functioning of the OBD system, information to enable the development of generic diagnostic tools;
- where manufacturers use diagnostic and test tools in accordance with ISO 22900 Modular Vehicle Communication Interface (MVCI) and ISO 22901 Open Diagnostic Data Exchange (ODX) in their franchised networks, the ODX files shall be accessible to independent operators via the web site;

- confirm with Art. 13, points 5, 6 and 7 of Regulation No 692/2008 regarding certain exceptions and dates if certain OBD and vehicle repair and maintenance information is not available or does not fully confirm to Article 6 and 7 or Regulation No 715/2007;
- charges for accessing such information are permitted if they are reasonable and proportionate (Arts. 6 and 7, Regulation No 715/2007).
 - Ensure that this information also includes the below items listed an unequivocal vehicle identification;
 - service handbooks, including repair and maintenance records;
 - technical manuals;
 - component and diagnosis information (such as minimum and maximum theoretical values for measurements);
 - wiring diagrams;
 - diagnostic trouble codes (including manufacturer specific codes);
 - the software calibration identification number applicable to a vehicle type;
 - information provided concerning, and delivered by means of, proprietary tools and equipment;
 - data record information and two-directional monitoring and test data; and
 - standard work units or time periods for repair and maintenance tasks if made available, either directly or through a third party, to manufacturers' authorised dealers and repairers. (Art. 6(2), Regulation (EC) No 566/2011)
- Where vehicle repair and maintenance records are kept in a central data base of the vehicle manufacturer, independent, approved and authorised repairers (pursuant to point 2.2 of Annex XIV to Commission Regulation (EC) No 692/2008) must have access to such records free of charge and under the same conditions as authorised dealers or repairers in order to record information on repair and maintenance performed. (Regulation (EC) No 566/2011)
- Manufacturers shall make available vehicle repair and maintenance information including transactional services such as reprogramming or technical assistance on an hourly, daily, monthly, and yearly basis, with fees for access to such information varying in accordance with the respective periods of time for which access is granted. In addition to time-based access, manufacturers may offer transaction-based access, for which fees are charged per transaction and not based on the time for which access is granted. Where both access systems are offered by manufacturers, independent repairers shall choose a preferred access system, either time-based or transaction-based. (Art. 7(2), Regulation (EC) No 566/2011)

2.5. Reporting

- Inform the Commission about the introduction of change to financial incentives to speed up the production of new vehicles complying with the terms of the Regulation as well as to retrofit or scrap vehicles that are not in compliance (Art. 12(4)); and the establishment and amendment of penalties for infringements of the Regulation.
- The approval authority granting an exception to the requirement that a vehicle with an OBD system has to fully meet the specific requirements of Annex XI to qualify for type-approval, has to notify the

Decision to all approval authorities in the other Member States in accordance with the requirements set out in Article 8 of Directive 2007/46/EC.

- The approval authority which has to announce its Decision regarding the plan of remedial measures, taken with in the in-service conformity procedures, to all Member States within 30 days (Art. 9(6), Regulation No 692/2008)
- For type 6 test measuring emissions at low temperatures, the approval authority, at the request of the Commission, shall provide information on the performance of NO_x after treatment devices and EGR system at low temperatures. (Art. 3(9), Regulation No 692/2008)
- The approval authority has to inform the Commission of the circumstance of each type approval granted under Art. 3(6) regarding small volume manufacturers that may request the granting of EC type-approval to a vehicle type which was approved by an authority of a third country or on the basis of the legislative acts set out in Section 2.1 of Annex I. (Art. 3(3), Regulation No 692/2008)

2.6. Additional Legal Instruments

2.6.1. Directly related acts:

- Regulation (EC) No 443/2009 setting emission performance standards for new passenger cars as part of the EU's integrated approach to reduce CO₂ emissions from light-duty vehicles
- Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe amended by Commission Directive (EU) 2015/1480
- Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive), as amended

2.6.2. Other relevant acts:

- Regulation (EC) No 595/2009 of the European Parliament and of the Council of 18 June 2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC, amended by Commission Regulations (EU) No 582/2011 and (EU) 133/2014
- Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air, amended by Regulation (EC) 219/2009 and Commission Directive (EU) 2015/1480;
- Council Directive 2001/81/EC on national emission ceilings for certain atmospheric pollutants, as amended by Council Directives 2006/105 and 2013/17/EU and Regulation (EC) 219/2009;

- Directive (EU) 2016/802 of the European Parliament and of the Council of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels
- Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions
- Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law
- Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC, as amended by Commission Directives 2000/71/EC, 2011/63/EU, 2014/77/EU, Directives 2003/17/EC, 2009/30/EC, (EU) 2015/1513 and Regulation (EC) 1882/2003;
- Directive 2009/40/EC of the European Parliament and of the Council of 6 May 2009 on roadworthiness tests for motor vehicles and their trailers *(to be repealed by Directive 2014/45/EU of the European Parliament and of the Council of 3 April 2014 on periodic roadworthiness tests for motor vehicles and their trailers and repealing Directive 2009/40/EC as of 19 May 2018)*
- Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (repealing Directive 77/537/EEC on smoke emissions from diesel engines for use in agricultural or forestry tractors as of 31 December 2015)
- Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, as amended by Commission Directives 2001/63/EC, 2010/26/EC, 2012/46/EU, Directives 2002/88/EC, 2004/26/EC, 2011/88/EU, Council Directive 2006/105/EC and Regulation (EC) 596/2009;
- Directive 2005/64/EC of the European Parliament and of the Council of 26 October 2005 on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability and amending Council Directive 70/156/EEC, as amended by Commission Directive 2009/1/EC.

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Regulation are summarised in the checklist below.

Table 27. Regulation On Type - Approval Of Motor Vehicles Regarding Emissions From Vehicles - Key Implementation Tasks

REGULATION ON TYPE-APPROVAL OF MOTOR VEHICLES REGARDING EMISSIONS FROM VEHICLES - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate the competent authority (or authorities) responsible for implementing and supervising compliance with the Regulation. Responsibilities would include: <ul style="list-style-type: none"> • issuing and/or withdrawing type-approval certificates; • registering and permitting the placing on the market of new engines; • regulating exemptions from the requirements of the Regulation; • testing and inspecting engines; • serving as contact point with the approval authorities of other Member States; • supervising correct implementation by the manufacturer.
1.2	Consider whether to introduce financial (tax) incentives for the production of vehicles complying with Euro 5 and Euro 6 standards. Candidate countries may also consider only giving financial incentives for vehicles complying with the limit values set out in Table 2 of Annex I (the more stringent Euro 6 limits), but these need to be phased out by 1 September 2015 and 1 September 2016. The size of the financial incentives must be in accordance with Article 12(3) and these incentives must be announced in advance to the Commission.
1.3	Consider whether to introduce financial incentives to upgrade the existing fleet of older non-conforming vehicles, such as subsidies for the retro-fitting of vehicles in use and for scrapping older non-complying vehicles. Where it is considered necessary, appoint an organisation or body to carry out technical services as required under the Regulation.
2	Regulation
2.1	Ensure compliance with Regulation No 692/2008 as from 31 July 2008 except for the obligations set out in Articles 4(5), 4(6), 5(3)(d) and 5(3)(e), which apply from 1 September 2011 for the type approval of new types of vehicles and from 1 January 2014 for all new vehicles sold, registered or put into service in the EU. Ensure compliance with Regulation No. 459/2012
2.2	Adopt the systems and procedures for type-approval of vehicles and certain new replacement pollution control devices within the given time-frames. This includes: <ul style="list-style-type: none"> • a system for initial type-approval; • procedures for amending type-approval certificates (including requirements relating to notification, revision of information packages, fresh tests or checks, and issuing revised type-approval certificates); • a system to allow the registration, sale and putting into use only of vehicles and replacement pollution control devices that have been type-approved; • a national database of certificates; and • a system for co-operation between the competent authorities of different Member States as well as the Commission, as required under the Regulation.
2.3	Have a type-approval procedure prepared for vehicles that meet the more stringent emission standards (Euro 5 and 6) ahead of the final deadline and to ensure that the approval and marketing of these vehicles is facilitated.

	After granting type-approval, take the necessary measures to ensure that it is kept informed of any change in the particulars appearing in the information package.
2.4	Put in place a system for the registration and placing on the market of new engines. The system should: <ul style="list-style-type: none"> • control identification numbers; and • compile information on purchasers and the identification number of the engine sold.
2.5	Adopt a system to regulate temporary derogations or less stringent conditions (i.e. category N1, classes II and II, and category N2 vehicles, vehicles designed to perform certain social needs and small scale vehicle producers).
2.6	Put into place a system to ensure and monitor that manufacturers: <ul style="list-style-type: none"> • provide sufficient demonstration that all new vehicles sold, registered or put into service in the EU as well as new replacement pollution control devices sold or • put into service are in compliance with the Regulation; comply with the emission limits set out in Annex I (the Euro 5 and Euro 6 standards) to Regulation No 692/2011; • comply with the type-approval procedures verifying the conformity of production, the durability of pollution control devices and in-service conformity; • carry out checks on in-service conformity measures for the minimum period specified as well as the durability testing of pollution control devices subject to type-approval; • provide the purchaser of the vehicle with a document setting out carbon dioxide emissions and fuel consumption figures; • design, construct and assemble vehicles and components in order to enable the • vehicle to comply with the Regulation; • fit vehicles with pollution control devices that can endure at least a distance of 160,000 km; • ensure that independent operators have easy, restriction-free and standardised (particularly in terms of compliance with the OASIS standard) access via the Internet to information on the repair and upkeep of vehicles, without discrimination in favour of dealerships and official repair workshops. This obligation covers on-board diagnostic systems and their components, diagnostic tools and testing equipment. Charges for accessing such information are permitted if they are reasonable and proportionate.
3	Monitoring
3.1	Adopt a testing/inspection system to control the quality of engine types or families. The system should: <ul style="list-style-type: none"> • control the quality of engine production; • ensure the conformity of production; • ensure and enforce compliance with the type-approval; • ensure compliance with the emission standards.
3.2	In cases of non-conformity with the approved type or family that has previously been granted, take measures to ensure that the engines in production again conform to the approved type or family.
3.3	Co-operate with other Member States over disputes relating to non-conformity.
3.4	Monitor the marketing of engines complying with the Euro 5 and Euro 6 standards to ensure that their marketing is not made more difficult than that of engines complying with the less strict standards. Such engines should bear a specific label informing consumers about the engine and its superior environmental performance.
3.5	If a private sector organisation is appointed as a technical service, establish a system for monitoring its activities.
3.6	Establish systems and procedures for requesting, receiving and handling information from engine manufacturers.
4	Reporting
4.1	Inform the Commission of: <ul style="list-style-type: none"> • the introduction of changes to financial incentives to speed up the production of new vehicles complying with the terms of the Regulation, as well as to retrofit or scrap vehicles that are not in compliance (Art. 12(4)); and

	<ul style="list-style-type: none"> the establishment and amendment of penalties for infringements of the Regulation (by 2 January 2009).
4.2	The approval authority granting an exception to the requirement that a vehicle with an OBD system has to fully meet the specific requirements of Annex XI to qualify for type-approval, has to notify the Decision to all approval authorities in the other Member States in accordance with the requirements set out in Article 8 of Directive 2007/46/EC.
4.3	<p>The approval authority has to inform the Commission about:</p> <ul style="list-style-type: none"> the introduction of change to financial incentives to speed up the production of new vehicles complying with the terms of the Regulation as well as to retrofit or scrap vehicles that are not in compliance; the establishment and amendment of penalties for infringements of the Regulation (by January 2009). for type 6 test measuring emissions at low temperatures, information on the performance of NO_x after treatment devices and EGR system at low temperatures if so requested by the Commission; the Commission of the circumstance of each type approval granted under Art. 3(6) regarding small volume manufacturers that may request the granting of EC type-approval
4.4	<p>The approval authority granting an exception to the requirement that a vehicle with an OBD system has to fully meet the specific requirements of Annex XI to qualify for type-approval, has to notify the Decision to all approval authorities in the other Member States in accordance with the requirements set out in Article 8 of Directive 2007/46/EC.</p> <p>The approval authority which has to announce its Decision regarding the plan of remedial measures, taken with in the in-service conformity procedures, to all Member States within 30 days (Art. 9(6), Regulation No 692/2008)</p>
5	Technical Advice and Guidance
5.1	Prepare and issue technical guidance to ensure full understanding of the technical requirements for testing set out in the Regulation.

3.2. Phasing Considerations

The most demanding and time-consuming tasks associated with applying this Regulation are deemed to be the establishment and development of the institutional structure for the type- approval and monitoring regime, in particular the acquisition and training of sufficient personnel and the development of systems and procedures for all aspects of type-approval and monitoring. Candidate countries should estimate whether these systems and procedures can be put into place earlier than the stated deadlines. If they can, the candidate countries can opt to phase in the new requirements earlier and provide financial incentives for manufacturers to design vehicles and pollution control equipment meeting the new, more stringent emission limit values.

4. IMPLEMENTATION GUIDANCE

4.1. Regulation

- It is recommended that the competent authority responsible for road vehicle type- approval is also designated the competent authority responsible for all aspects of type- approval as regards engines to be installed in non-road mobile machinery.
- "Technical service" means a private sector organisation or a public body that has been appointed as a testing laboratory to carry out tests or inspections on behalf of the competent authority. The competent authority may itself carry out the tests and inspections. Each Member State does not require its own technical service but can use services situated in another Member State. The designation of a technical service is, thus, optional. If technical services are appointed, they must be accredited to ensure their competence.
- The accredited organisations that act as technical services in type-approval matters may be research institutes established specifically to carry out certification and type-approvals, or organisations responsible for vehicle roadworthiness testing.
- For advice on how to establish effective administrative structures, type-approval authorities and technical services, authorities in candidate countries should consult Member States that have large national automotive industries.

Example of Practice in the United Kingdom

An assessment in the UK revealed that the main markets affected would be vehicle and engine manufacturers/suppliers, manufacturers and suppliers of exhaust after-treatment systems and owners/operators of vehicles. The Euro 5 and 6 standards were not expected to alter market structures in general, although if the standards necessitate particular technologies, those producing alternative abatement techniques may be excluded from the market.

In the UK, several options were considered regarding compliance with the new regulation, taking into account results and costs and benefits for society. One of the options — Option A — was based on the establishment of a programme of incentives for the early introduction of Euro 5/V/VI in order to help achieve EU limit values. This is similar to policies implemented in other EU countries, such as Germany and Austria.

The uptake rates of these incentives are:

- 2007 25% Euro 5 LDVs, 15% Euro V HDVs
- 2008 50% Euro 5 LDVs, 23% Euro V HDVs
- 2009 75% Euro 5 LDVs (Euro V now mandatory for HDVs)
- 2010 25% Euro VI HDVs (Euro 5 now mandatory for LDVs)
- 2011 50% Euro VI HDVs
- 2012 75% Euro VI HDVs
- 2013 (Euro VI now mandatory for HDVs)

- The registration duty is one of the main mechanisms under the new Regulation to ensure compliance with its requirements. The obligation of the manufacturers to supply information to the authorities is also important. It is recommended that the authority granting type-approval for engines regularly demands the manufacturer to provide a list of information on the engines produced in accordance with the requirements of the Regulation. With the help of the manufacturers, the authority must register and control the identification numbers of those engines produced in conformity with the granted approval. The competent authorities should be given powers to carry out spot checks.
- The delivery of information by the manufacturers to the competent authorities shall be forced by effective administrative provisions, which should include sanctions (also criminal penalties as pursuant to Directive 2008/99/EC on environmental crimes).
- Some degree of self-Regulation within the lighter-vehicle sector and new vehicle pollution control devices can be expected, when competing engine and machinery manufacturers and dealers act as watchdogs for the products of other manufacturers and provide authorities with information on non-compliance.
- In case of non-conformity, the authority shall ensure (by means of guidance, administrative orders, and the withdrawal of approval) that the vehicles or pollution control devices in production are brought into conformity with the specifications of the Regulation. Appropriate penalties for non-compliance should be established.
- Enforcement requires increased staffing and the training of bodies handling vehicle approvals and registrations, or governing the technical safety of machinery. The expected workload depends heavily on the number of vehicle types being offered on the market. It is thus very difficult to approximate costs.
- If a candidate country chooses not to use accredited technical organisations in other EU Member States to carry out testing for certificate and type-approvals, the competent national organisations responsible for testing and approvals need to also check that engine emissions conform to the standards set out in the Regulation. These new tasks are closely related to those required by Regulation 595/2009.

Examples from Member States of the Early Uptake of Euro 5 and 6 Standards

Several Member States, including Germany, Austria, the Netherlands, France and Sweden, are planning to introduce, or have already introduced, fiscal incentives for an early phase-in of the more stringent emission limit values. These incentives may be in the form of existing fiscal instruments (for example the company car tax), vehicle excise duty (VED), enhanced capital allowances or a grants scheme.

One of the disadvantages, as reported by the UK, is that manufacturers may have to produce a greater range of models to satisfy markets both with and without incentives for vehicles meeting the voluntary standards, which could potentially result in significant costs and higher unit costs due to smaller production runs.

5. COSTS

The main types of costs arising from the implementation of this Regulation are given in the checklist below.

Table 28. Checklist on costs

Checklist on costs
<p>Initial set-up costs:</p> <ul style="list-style-type: none"> • the establishment of competent authorities; • the devising of systems and procedures for conformity checking, type-approval, monitoring etc.; • provisions for training; • the preparation of technical guidance.
<p>Capital expenditure:</p> <ul style="list-style-type: none"> • test laboratory/installation for exhaust emissions measurements.
<p>On-going running costs:</p> <ul style="list-style-type: none"> • labour costs for certification testing; • operating costs for the test laboratory; • acquisition costs for testing services; • labour costs for the processing of data and reporting to the Commission.
<p>Cost sharing:</p> <ul style="list-style-type: none"> • these costs can partly be shared with those arising from Regulation (EC) 595/2009

If a candidate country chooses to use technical services in another Member State, capital expenditure will be minimal but ongoing costs will be higher since the acquisition of testing services will then include the cost of depreciation of the equipment at the agency providing the testing services.

Enforcement requires increased staffing and training in bodies handling vehicle approvals and registrations, or governing the technical safety of machinery. It is, in general, difficult to estimate the costs.

Candidate countries will also incur some costs with respect to the voluntary producer labelling of engines that are already in compliance with the emissions standards in advance of the mandatory deadlines. Ideally, the candidate country shall take measures to promote this labelling, emphasising the potential market advantage for producers from early compliance with the emissions standards.

THE DECISION ON THE PROTOCOL ON LONG-TERM FINANCING OF EMEP

Official Title: Council Decision 86/277/EEC on the conclusion of the protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on long-term financing of the co- operative programme for monitoring and evaluation of the long-range transmission of air pollutants in Europe (EMEP) (OJ 181, 4.7.86)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The Decision approves, on behalf of the EU, the EMEP Protocol, adopted under the 1979 Convention on Long-Range Transboundary Air Pollution. The protocol lays down the long-term financing arrangements for the co-operative programme for the monitoring and evaluation of the long-range transmission of air pollutants in Europe (EMEP). The Decision commits the European Union to paying its share of the costs of EMEP, which are allocated to the Member States in accordance with an agreed formula.

2. PRINCIPAL OBLIGATIONS

The Decision commits the EUEU to paying its share of the costs of EMEP, which are allocated to the EU and its Member States in accordance with an agreed formula (UN scale of financing).

3. IMPLEMENTATION

The protocol entered into force on 28 January 1988. For countries that have already ratified the protocol, all key tasks are complete other than to maintain annual payments.

4. IMPLEMENTATION GUIDANCE

The implementation of this Decision (i.e. paying the EU's share of the budget) is the responsibility of the Council. Implementation of the protocol by Member States is independent of the EU. There are no implementation costs, other than those already committed to. An indicative timetable is not applicable.

**WASTE
MANAGEMENT**

Section 4

1. INTRODUCTION AND OVERVIEW	446
1.1. EU Waste Policy.....	446
1.2. EU Legal Instruments.....	451
2. DEVELOPMENT OF A SECTORAL STRATEGY AND IMPLEMENTATION PLAN	457
2.1. Introduction.....	457
2.2. Possible Approaches	458
2.3. Strategy Development.....	459
2.3.1. Key stages	460
2.3.2. Definition of scope	460
2.3.3. Review and analysis of the existing situation	460
2.3.4. Problem identification, definition and analysis.....	462
2.3.5. Definition and analysis of strategic objectives.....	464
2.3.6. Identification and evaluation of options (for achieving the objectives)	465
2.3.7. Strategy formulation.....	466
2.3.8. Strategy implementation plan	466
3. INSTITUTIONS AND RELEVANT PARTIES	468
3.1. Stakeholders.....	468
3.2. National Government Institutions	468
3.3. Competent Authorities	469
3.4. Regional and Local Government.....	471
3.5. Private Sector Involvement.....	472
3.6. Communication and Consultation.....	472
4. TECHNICAL ISSUES	474
5. REGULATION AND ENFORCEMENT.....	476
5.1. Overview.....	476
5.2. Licensing/Permitting	476
5.3. Monitoring, Inspection and Enforcement.....	478
5.4. Data Collection and Reporting.....	480
6. PRIORITIES AND TIMING.....	483
6.1. Prioritising the Implementation Tasks	483
6.1.1. Legislative considerations.....	483
6.1.2. Environmental considerations	483
6.1.3. Prioritisation and cost-effectiveness.....	484

6.1.4.	Economic considerations	484
6.2.	Timescales.....	485
7.	ECONOMIC AND FINANCIAL ISSUES	486
7.1.	Introduction.....	486
7.2.	Institutional Development	486
7.3.	Facilities.....	487
7.4.	Cost Recovery	488
7.5.	Application of Other Economic Tools.....	489
8.	SUMMARY OF KEY ISSUES	492
	WASTE FRAMEWORK DIRECTIVE	495
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	496
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	500
2.1.	Planning.....	500
2.2.	Regulation	502
2.3.	Monitoring and enforcement.....	505
2.4.	Information and Reporting.....	505
2.5.	Additional Legal Instruments	507
3.	IMPLEMENTATION	509
3.1.	Key Tasks.....	509
3.2.	Phasing Considerations	513
4.	IMPLEMENTATION GUIDANCE	514
4.1.	Institutional Organisation	516
4.2.	Planning and Provision of Infrastructure and Facilities.....	518
4.3.	Waste Management Planning and Prevention	519
4.3.1.	Waste Management Plans	519
4.3.2.	Waste Prevention Programmes.....	520
4.4.	Regulation	523
4.5.	Reporting	527
4.6.	Technical Advice and Guidance.....	528
4.7.	Communications and Consultation	531
5.	COSTS.....	532
	THE DIRECTIVE ON THE DISPOSAL OF PCBS AND PCTS.....	534
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	535

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	536
2.1. Planning.....	536
2.2. Regulation	536
2.3. Communication and Reporting.....	537
2.4. Additional Legal Instruments	537
3. IMPLEMENTATION	539
3.1. Key Tasks.....	539
3.2. Phasing Considerations	540
4. IMPLEMENTATION GUIDANCE	541
4.1. Planning and Provision of Infrastructure	541
4.2. Regulation.....	542
5. COSTS.....	543
THE SEWAGE SLUDGE DIRECTIVE	544
1. SUMMARY OF MAIN AIMS AND PROVISIONS.....	545
2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	546
2.1. Regulation.....	546
2.2. Monitoring and Enforcement.....	546
2.3. Reporting	547
2.4. Additional Legal Instruments	547
3. IMPLEMENTATION	548
3.1. Key Tasks.....	548
3.2. Phasing Considerations	549
4. IMPLEMENTATION GUIDANCE	550
4.1. Planning.....	550
4.2. Regulation.....	551
4.3. Monitoring and Reporting	552
4.4. Technical Standards and Guidance.....	553
5. COSTS.....	554
THE BATTERIES DIRECTIVE	555
1. SUMMARY OF MAIN AIMS AND PROVISIONS.....	556
2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	560
2.1. Planning.....	560
2.2. Regulation	560

2.3.	Communication and Reporting.....	563
2.4.	Additional Legal Instruments	563
3.	IMPLEMENTATION	565
3.1.	Key Tasks.....	565
3.2.	Phasing Considerations	567
4.	IMPLEMENTATION GUIDANCE	568
4.1.	General Administrative Arrangements	568
4.2.	Standards of Manufacture	569
4.3.	Collection, Disposal and Recycling.....	570
4.4.	Communications.....	572
5.	COSTS.....	573
	THE PACKAGING AND PACKAGING WASTE DIRECTIVE.....	575
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	576
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	579
2.1.	Planning.....	579
2.2.	Regulation	580
2.3.	Communication and Reporting.....	581
2.4.	Additional Legal Instruments	582
3.	IMPLEMENTATION	583
3.1.	Key Tasks.....	583
3.2.	Phasing Considerations	584
4.	IMPLEMENTATION GUIDANCE	585
4.1.	Planning and Provision of Infrastructure	585
4.2.	Regulation	588
4.3.	Communication and Reporting.....	590
4.4.	Further information and studies	590
5.	COSTS.....	591
	THE REGULATIONS ON SHIPMENTS OF WASTE.....	592
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	594
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	597
2.1.	Planning.....	597
2.2.	Regulation	597
2.2.1.	Shipment procedures	598

2.3.	Additional Legal Instruments	600
3.	IMPLEMENTATION	601
3.1.	Key Tasks.....	601
4.	IMPLEMENTATION GUIDANCE	602
4.1.	Planning.....	602
4.2.	Regulation	605
4.3.	Reporting	605
5.	COSTS.....	606
DIRECTIVE ON THE LANDFILL OF WASTE.....		607
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	608
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	609
2.1.	Planning.....	609
2.2.	Regulation	610
2.3.	Monitoring and Enforcement.....	611
2.4.	Communication and Reporting.....	613
3.	IMPLEMENTATION	614
3.1.	Key Tasks.....	614
3.2.	Phasing Considerations	616
4.	IMPLEMENTATION GUIDANCE	618
4.1.	Planning and Provision of Infrastructure	618
4.2.	Regulation	620
4.3.	Monitoring.....	621
4.4.	Technical Competence	621
4.5.	Financial Aspects	622
4.6.	Reporting	623
5.	COSTS.....	624
THE DIRECTIVE ON END-OF-LIFE VEHICLES (ELVS)		626
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	628
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	631
2.1.	Planning.....	631
2.2.	Regulation	631
2.3.	Reporting and Information.....	634
2.4.	Additional Legal Instruments	634

3. IMPLEMENTATION	636
3.1. Key Tasks.....	636
3.2. Phasing Considerations	637
4. IMPLEMENTATION GUIDANCE	638
5. COSTS.....	642
DIRECTIVES ON ELECTRICAL AND ELECTRONIC EQUIPMENT & RESTRICTION OF HAZARDOUS SUBSTANCES (WEEE & ROHS)	643
1. SUMMARY OF MAIN AIMS AND PROVISIONS.....	645
1.1. WEEE Directive 2012/19/EU.....	645
1.2. RoHS Directive 2011/65/EU.....	646
1.3. Planning.....	651
1.4. Regulation.....	654
1.5. Monitoring and Enforcement.....	659
1.6. Reporting and information	660
1.7. Additional Legal Instruments	662
2. IMPLEMENTATION	664
2.1. Key Tasks.....	664
2.2. Phasing in Considerations.....	667
3. IMPLEMENTATION GUIDANCE	669
3.1. Planning and Institutional Procedures	669
3.2. B2C and B2B.....	670
3.3. Collection systems	670
3.4. Promotional measures for design change.....	670
3.5. Guidance documents	671
4. COSTS.....	672
THE EXTRACTING WASTE (MINING) DIRECTIVE.....	676
1. SUMMARY OF THE MAIN AIMS AND PROVISIONS.....	677
2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	679
2.1. Planning.....	679
2.2. Regulation.....	680
2.2.1. Basic regulatory obligations	680
2.2.2. Specific regulatory obligations for operators	681
2.2.3. Specific regulatory obligations on part of the competent authority.....	684
2.3. Monitoring and Enforcement.....	686
	443

2.4.	Reporting	688
2.5.	Additional Legal Requirements	689
3.	IMPLEMENTATION	691
3.1.	Key Tasks.....	691
3.2.	Phasing Considerations	693
4.	IMPLEMENTATION GUIDANCE	695
4.1.	General.....	695
4.2.	Regulation.....	698
4.3.	Monitoring.....	700
4.4.	Enforcement.....	701
5.	COSTS.....	703
	SHIP RECYCLING REGULATION	705
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	706
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	708
2.1.	Planning.....	708
2.2.	Regulation.....	708
2.3.	Monitoring and Reporting	709
2.4.	Additional Legal Instruments	710
3.	IMPLEMENTATION	711
3.1.	Key Tasks.....	711
4.	IMPLEMENTATION GUIDANCE	712
4.1.	Planning and Regulation.....	712
5.	COSTS.....	713

WASTE MANAGEMENT - OVERVIEW

1. INTRODUCTION AND OVERVIEW

This section of the Handbook deals with EU legislation in the waste management sector. It contains an introductory overview of the sector followed by individual fiches for selected pieces of legislation. For more information and the full scope of the waste management legislation, please consult the waste website of the European Commission at: <http://ec.europa.eu/environment/waste/index.htm>

1.1. EU Waste Policy

The European Union's environment policy is based on Article 191 of the Treaty on the Functioning of the European Union (TFEU). It aims to preserve, protect and improve the quality of the environment and to protect human health. It also focuses on the careful and rational use of natural resources and to tackle climate change. The EU waste policy has evolved significantly over the past 30 years through the series of environmental action plans and framework legislation.

In December 2005 the Commission published a Communication on the Thematic Strategy on the prevention and recycling of waste¹⁴⁰. Progress towards the objectives set out in the 2005 Strategy has been reviewed in a 2011 Commission Report¹⁴¹ on the Thematic Strategy on waste prevention and recycling by a Staff Working Document, which includes a summary of the main actions taken by the Commission, the main available statistics on waste generation and management, a summary of the main forthcoming challenges and recommendations for future actions. The report on the Thematic Strategy includes several recommendations including to take new initiatives to favour the use of economic instruments to implement the waste hierarchy.

On 4 December 2015 the European Commission adopted far-reaching Circular Economy Package, which includes revised legislative proposals on waste. This legislative proposals on waste amend six different waste directives and affects a significant number of legally binding obligations, including comprehensive revision of targets stipulated in Waste Framework Directive 2008/98/EC, Directive 1999/31/EC on landfill of waste, Directive 94/62/EC on packaging and packaging waste as well as simplification of Directive 2000/53/EC on end-of-life vehicles, Directive 2006/66/EC on batteries and accumulators and Directive 2012/19/EU on on waste electrical and electronic equipment.

The Circular Economy Package also includes an EU Action Plan for the Circular Economy, i.e. the Commission Communication 'Closing the loop – An EU action plan for the Circular Economy', establishing a concrete and ambitious programme of action, with measures covering the whole cycle: from production and consumption

¹⁴⁰ First published as a Commission Communication to Council SEC (89) 934 Final, and latest version as revised and endorsed under Council Resolution of 24 February 1997 on a Community Strategy for Waste Management (OJ C 76/1 of 11.3.1997)

¹⁴¹ Institute for European Environmental Policy, Ecologic, Arcadis, Umweltbundesamt, Bio Intelligence Services, Vito, Final report – supporting the thematic strategy on waste prevention and recycling service request under contract ENV.G.4/FRA/2008/0112, 25 October 2010

to waste management and the market for secondary raw materials. The annex to the action plan sets out the tentative schedule when the actions will be completed.

The revised legislative proposals on waste set clear targets for reduction of waste and establish an ambitious and credible long-term path for waste management and recycling. Key elements of the revised waste proposal include:

- A common EU **target for recycling 65% of municipal waste** by 2030;
- A common EU **target for recycling 75% of packaging waste** by 2030;
- A binding landfill target to **reduce landfill to maximum of 10%** of all waste by 2030;
- A ban on landfilling of separately collected waste;
- Promotion of economic instruments to discourage landfilling;
- Simplified and improved definitions and harmonised calculation methods for recycling rates throughout the EU;
- Concrete measures to **promote re-use and stimulate industrial symbiosis** –turning one industry's by-product into another industry's raw material;
- Economic incentives for producers to put **greener products on the market** and support recovery and recycling schemes (e.g. for packaging, batteries, electric and electronic equipment, vehicles).

The development and implementation of EU waste policy takes place in a context of much wider EU policies and programmes, which include: 7th Environment Action Programme¹⁴², the Resource Efficiency Roadmap¹⁴³ and the Raw Material Initiative¹⁴⁴. The 7th EAP puts a special focus on turning waste into a resource, which is one key to a circular economy. In this context the 7th EAP sets the following priority objectives for waste policy across the EU:

- reducing the amount of waste generated;
- maximising recycling and re-use;
- limiting incineration to non-recyclable materials;
- phasing out landfilling to non-recyclable and non-recoverable waste;
- ensuring full implementation of the waste policy targets in all Member States.

¹⁴² Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' Text with EEA relevance; link:<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013D1386>

¹⁴³ COM(2011) 571; link: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52011DC0571>

¹⁴⁴COM(2008) 699 and COM(2014)297; link: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2008:0699:FIN> and <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2014:0297:FIN>

The Roadmap to a Resource Efficient Europe outlines how can Europe's economy be transformed into a sustainable one by 2050. It proposes ways to increase resource productivity and decouple economic growth from resource use and its environmental impact. It illustrates how policies interrelate and build on each other. The Resource Efficiency Roadmap provides a framework in which future actions can be designed and implemented coherently. It sets out a vision for the structural and technological change needed up to 2050, with milestones to be reached by 2020. As regards waste, Resource Efficiency Roadmap sets the following milestone: 'By 2020, waste is managed as a resource. Waste generated per capita is in absolute decline. Recycling and re-use of waste are economically attractive options for public and private actors due to widespread separate collection and the development of functional markets for secondary raw materials. More materials, including materials having a significant impact on the environment and critical raw materials, are recycled. Waste legislation is fully implemented. Illegal shipments of waste have been eradicated. Energy recovery is limited to non-recyclable materials, landfilling is virtually eliminated and high quality recycling is ensured.'

The Raw Material Initiative sets out a strategy for tackling the issue of access to raw materials in the EU. Sustainable access to raw materials is considered crucial to the competitiveness and growth of the EU economy and to the objectives of the Europe 2020 Strategy. The Raw Material Initiative has three pillars, which aim to ensure:

- Fair and sustainable supply of raw materials from global market
- Sustainable supply of raw materials within the EU
- Resource efficiency and supply of 'secondary raw materials' through recycling.

Several studies were carried out in support of the waste policy review:

- [Support to the additional analysis to complement the impact assessment](#) (October 2015)
- [Final Report – Ex-post evaluation of certain waste stream Directives](#) (18 April 2014)
- [Support to the preparation of the impact assessment - final report](#) and [appendixes](#)
- [Development of a European waste generation and management model](#)
- [Development of Guidance on Extended Producer Responsibility \(EPR\)](#)

The EU policy is implemented through a number of waste legislation focusing on management, disposal options, separate waste streams, extended producer liability responsibility, control of waste shipments. The 2005 Thematic Strategy resulted in revision of the Waste Framework Directive, the backbone of the EU waste policy. The rationale behind the overhaul was an attempt to consolidate, streamline and simplify legislation facilitating an integrated approach to waste management. The revision, i.e. adoption of the Directive 2008/98/EC brought a modernised and more ambitious approach to waste management. The emphasis was placed on prevention and application of the waste hierarchy, where prevention is the best option, followed by the re-use, recycling and other forms of recovery with disposal via landfill as the last resort. The concept of a life-cycle thinking was introduced into the waste policy.

Table 1. Principles for waste management and priorities for implementing waste management

<p>Legislation Principles:</p> <ul style="list-style-type: none"> • Waste management hierarchy: Waste management strategies must aim primarily to prevent the generation of waste and to reduce its harmfulness. Where this is not possible, waste materials should be reused, recycled or recovered, or used as a source of energy. As a final resort, waste should be disposed of safely (e.g. by incineration or in landfill sites).

- Self-sufficiency at EU and, if possible, at Member State level. Member States need to establish, in co-operation with other Member States, an integrated and adequate network of waste disposal facilities.
- Best available technique) (BAT): European IPPC Bureau (EIPPCB) has issued a number of BREF documents describing BAT
- Proximity: Wastes should be disposed of as close to the source as possible.
- Precautionary principle: The lack of full scientific certainty should not be used as an excuse for failing to act. Where there is a credible risk to the environment or human health from acting or not acting with regard to waste, that which serves to provide a cost- effective response to the risk identified should be pursued.
- Producer responsibility: Economic operators, and particularly manufacturers of products, have to be involved in the objective to close the life cycle of substances, components and products from their production throughout their useful life until they become waste.
- Polluter pays: Those responsible for generating or for the generation of waste, and consequent adverse effects on the environment, should be required to pay the costs of avoiding or alleviating those adverse consequences. A clear example can be seen in the Landfill Directive 99/31/EC, Article 10.
- Life Cycle Thinking: Life Cycle Thinking and Assessment provide a scientifically sound approach to ensure that the best outcome for the environment can be identified and put in place. Life Cycle Thinking considers the range of impacts throughout the life of a product. Life Cycle Assessment quantifies this by assessing the emissions, resources consumed and pressures on health and the environment that can be attributed to a product. It takes the entire life cycle into account – from the extraction of natural resources through to material processing, manufacturing, distribution and use; and finally the re-use, recycling, energy recovery and the disposal of remaining waste.

Main priorities/challenges:

- Ensuring an adequate network of safe and legal waste disposal and recovery facilities. Matching the capacity of waste infrastructure to the volume of waste generated is fundamental to good waste management. Waste management plans can help ensure the necessary capacity, but only if they are effectively implemented.
- Reducing and better managing certain waste streams. The achievement of certain EU waste reduction and management goals, such as the diversion of biodegradable waste from landfills and the collection of end-of-life vehicles and waste electrical and electronic equipment (WEEE), also depends on adequate forward planning and the development of the necessary organisational arrangements and recovery facilities.
- Combating the illegal waste trade and illegal waste disposal. Tackling the use of thousands of illegal landfills in several Member States requires strategic action across several fronts to comply with the Waste Framework Directive and the Landfill Directive: investments in legal facilities; better systems of national detection, enforcement and deterrence; and adequate site clean-up. Adequate controls on trans-frontier waste shipments are also essential. The Commission has taken horizontal action for lack of controls on illegal landfills and there have been several important rulings by the Court of Justice of the European Union.
- Transition to a more circular economy, where the value of products, materials and resources is maintained in the economy for as long as possible. Minimising the generation of waste and providing essential contribution to the EU's efforts to develop a sustainable, low carbon, resource efficient and competitive economy.

In addition to these main principles and priorities/challenges, the EU's waste management policies also seek to achieve a number of other objectives, which are summarised below.

- A common definition of waste across Member States. Waste is defined by the Waste Directive as „any substance or object which the holder discards or intends or is required to discard; whereas ‘hazardous waste’ means waste which displays one or more of the hazardous properties listed in Annex III;“ (Art. 3(1), (2)). Also waste oils and bio-waste are defined at EU level. The definitions are broad in meaning

and the intention behind such an approach is to provide a definition of waste that is as inclusive as possible, not exclusive. This approach can also be seen reflected in the rulings in this area of the Court of Justice of the European Union (CJEU).

- The wording of the Directive is mandatory for all Member States and applies to all wastes irrespective of whether they are destined for disposal or recovery operations. In addition, there is the European Waste Catalogue, which was published in January 1994 with Commission Decision 2000/532/EC, last amended by Commission Decisions 2014/955/EU. In 2000, a replacement waste list and hazardous waste list was introduced, which came in to force on 1 January 2002 and has since been amended four times. The list, which provides a common terminology for various types of waste, is reviewed and revised where necessary, by the Commission. The inclusion in the list of a substance does not necessarily mean that it is waste in all circumstances; it must also satisfy the definition of waste in Article 3 of the Waste Directive regarding encouraging clean products. By encouraging the development, manufacturing and consumption of clean products, it should be possible to reduce the environmental impact of a product through its full life cycle. This can be done through improved use of resources, reduction of emissions from manufacturing, and waste management. Two possible tools for achieving this objective are to apply life-cycle assessment and environmental labelling schemes. The life-cycle assessment involves a study of the overall consumption of raw materials and emission of environmentally harmful materials to the environment for manufacture, distribution, use and disposal, providing manufacturers with information that can be used to plan the production of cleaner products. Environmental labelling schemes provide information to consumers on the efficient use of energy and raw materials in the full life cycle of the product. Consumers can then make a choice to purchase more "environmentally friendly" products and so influence manufacturing through market forces. Voluntary eco-labelling schemes are discussed further in the industrial pollution control and risk management sector. This "cradle-to-grave" approach can be seen further embodied and enhanced by European Parliament and Council Directive 2000/53/EC on end-of-life vehicles (see further below), Directive 2012/19/EU on waste electronic and electrical equipment, and, to a large extent, Directive 94/62/EC on packaging waste. These Directives also encourage Member States to use mechanisms such as life-cycle assessments and producer responsibility schemes whereby the producers are made physically and financially responsible for the collection, recycling and disposal of their products
- Encourage the use of economic instruments. This approach aims to influence environmental performance through market mechanisms. Various types of economic instruments are available such as taxes or fees on waste production, transport and disposal; tradeable permits on waste production; tradeable certificates on recycling; deposits on beverage containers; and import duties on waste that is difficult to dispose of. The European Environment Agency (EEA) has established together with the OECD a useful database on economic instruments in environmental policy, which can be located on the website <http://www2.oecd.org/ecoinst/queries/>. Further guidance and discussions on environment-related taxes and the economic impacts of their application can be found in another OECD publication: <http://www.oecd.org/env/tools-evaluation/env%20policy-natural%20resources%20brochure.pdf>
- Regulate the shipment of waste. Waste legislation seeks to regulate the shipment of waste between Member States, as well as to and from Member States to countries beyond the EU. For domestic waste shipments within one Member State, Member States are obliged to establish a supervision and control system that is coherent with the EU system. It is important to keep in mind that waste

shipment in general should only be allowed for non-hazardous waste and where the receiving country can guarantee recycling, treatment and disposal according to environmental requirements equivalent to those that apply in the EU. For instance, amounts of packaging waste, WEEE and end-of-life vehicles can only be counted against the mandatory recycling and energy recovery targets applicable where the requirements are at least as stringent as in the EU. These requirements help to prevent large volumes of waste being exported abroad in line with the proximity principle (e.g. waste should in general be treated and disposed of close to where it was produced).

- Environmental protection and the internal market. EU waste legislation seeks to strike a balance between the need for a high level of environmental protection and the need for an appropriate level of regulation to ensure the functioning of the internal market. This is to allow economic operators to act within the EU while creating a level playing field for waste by establishing common rules yet respecting the legitimate wish of Member States to define and implement waste policies and waste management measures at national level. This is seen particularly with regard to shipments of waste, which might affect the planning basis for waste management systems in the Member States (as illustrated by the common shipment of waste for recovery). Legislation on this matter is aimed at ensuring that waste is shipped to the closest possible disposal area and to ensure that countries do not export waste. In general, the Commission wants waste generated within the EU, and which cannot be recycled or used for energy recovery, to be disposed of within its borders. Another example of internal market protection is the maximum recycling and energy recovery targets under Directive 94/62/EC on packaging waste. These maximum targets are meant to prevent large discrepancies between countries with large capacities for recycling and those with lower capacities or less favourable economic conditions.

1.2. EU Legal Instruments

EU legislation on waste management can be divided into the following sub-areas:

Table 2. Useful links to other indirectly related legislation

1	Waste Framework Legislation
1.1	Waste Framework Directive (2008/98/EC), which repealed Directive 2006/12/EC on waste (the codified version of Directive 75/442/EEC as amended), hazardous waste Directive 91/689/EEC, and the Waste Oils Directive 75/439/EEC. It provides for a general framework of waste management requirements and sets the basic waste management definitions for the EU.
1.2	Decision 2000/532/EC establishing a list of wastes. This Decision establishes the classification system for wastes, including a distinction between hazardous and non-hazardous wastes. It is closely linked to the list of the main characteristics which render waste hazardous contained in Annex III to the Waste Framework Directive above.
1.3	Regulation (EC) No 1013/2006 on shipments of waste, which specifies under which conditions waste can be shipped between countries.
2	European Union legislation on waste management operations
2.1	Council Directive 1999/31/EC on the landfill of waste. This Decision concerns a questionnaire for Member States reports on the implementation of Directive 1999/31/EC on the landfill of waste

2.2	Directive 2010/75/EU on industrial emissions (Chapter IV related to incineration and co-incineration of waste)
2.3	Directive 2000/59/EC of the European Parliament and of the Council of 27 November 2000 on port reception facilities for ship-generated waste and cargo residues - Commission declaration
3	European Union legislation on specific waste streams
3.1	Batteries and accumulators containing certain dangerous substances (Council Directive 2006/66/EC).
3.2	Packaging and packaging waste (Council Directive 94/62/EC).
3.3	The disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT) (Council Directive 96/59/EC).
3.4	Protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture (Council Directive 86/278/EEC).
3.5	Electrical and electronic waste (WEEE Directive 2012/19/EU) and RoHS Directive (2011/65/EU)
3.6	End-of-Life Vehicles (European Parliament and Council Directive 2002/53/EC).
3.7	Mining Waste Directive (Directive 2006/21/EC of the European Parliament and of the Council)
3.8	Ship Recycling Regulation ((EU) No 1257/2013
4	Reporting and questionnaire legislation
4.1	Directive 91/692/EEC standardizing and rationalizing reports on the implementation of certain Directives relating to the environment
4.2	Commission Decision 94/741/EC concerning questionnaires for Member States reports on the implementation of certain Directives in the waste sector
4.3	Commission Decision 97/622/EC concerning questionnaires for Member States reports on the implementation of certain Directives in the waste sector
4.4	Commission Decision 2009/358/EC of 29 April 2009 on the harmonisation, the regular transmission of the information and the questionnaire referred to in Articles 22(1)(a) and 18 of Directive 2006/21/EC of the European Parliament and of the Council on the management of waste from extractive industries
4.5	Commission Decision 2000/738/EC concerning a questionnaire for Member States reports on the implementation of Directive 1999/31/EC on the landfill of waste
4.6	Commission Decision 2001/753/EC concerning a questionnaire for Member States reports on the implementation of Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles
4.7	Commission Decision 2007/151/EC, amending Decisions 94/741/EC and 97/622/EC as regards the questionnaires for the report on the implementation of Directive 2006/12/EC of the European Parliament and of the Council on waste and on the implementation of Council Directive 91/689/EEC on hazardous waste
4.8	Commission Decision 2011/753/EU of 18 November 2011 establishing rules and calculation methods for verifying compliance with the targets set in Article 11(2) of Directive 2008/98/EC of the European Parliament and of the Council
4.9	Commission Implementing Decision of 18 April 2012 establishing a questionnaire for Member States reports on the implementation of Directive 2008/98/EC of the European Parliament and of the Council (link: http://ec.europa.eu/environment/waste/reporting/pdf/C_2012_2384.pdf)

Specific Wastes

In addition, it is important to note the the Directive on Industrial Emissions 2010/75/EU (IED), fundamentally changed a number of waste-related Directives in the sense that it consolidates and brings these under one piece of legislation. The IED recasts seven existing Directives related to industrial emissions into a single clear and coherent legislative instrument. The recast includes the IPPC Directive 2008/1/EC, the Large Combustion Plants Directive 2001/80/EC, the Waste Incineration Directive 2000/76/EC, the Directive 1999/13/EC on activities using organic solvents and three Directives on Titanium Dioxide: 78/176/EEC, 82/883/EEC and 92/112/EEC. For more information in relation to the IED, consult the Europa website at: <http://ec.europa.eu/environment/industry/stationary/index.htm> .

There are links not only between the legislation within the waste sector, but also between this body of legislation and that in other sectors. The links between the Waste Directive and the other waste legislation have already been explained above. The most important links with legislation in other sectors are identified in the Table below. Implementation of waste legislation, without co-ordination with the implementation of other related legislation, could lead to duplication of resources and over-complex bureaucracy.

Table 3. Summary of Key Inter-relationships between Legislation in the Waste Management Sector and other EU Legislation in the Environmental Acquis

Related Sector Legislation	Relevance
Horizontal Sector	
Environmental Impact Assessment Directive (2011/92/EU)	Requires an EIA for new projects that are judged to have a significant impact on the environment. The results are to be made public and the views of the public taken into consideration in the consent procedure. Projects affected include waste disposal facilities.
SEA Directive 2001/42/EC on the assessment of certain plans and programmes.)	Requires an assessment procedure involving public participation in the context of certain public plans and programmes such as the waste management plans under Waste Directive (2008/98/EC).
Access to Environmental Information Directive (2003/4/EC)	Requires environmental information held by public bodies to be made available to the general public on request. Some of the waste Directives require Member States to collect information. Any such information held by public bodies would be covered by this Directive. Sets out provisions on the transmission of information and reports concerning certain EU Directives from Member States to the European Commission. Waste Directives comprise reporting requirements.
Public Participation Directive (2003/35/EC)	Member States shall ensure that the public is given early and effective opportunities to participate in the preparation and modification or review of the plans or programmes required to be drawn up under the provisions listed in Annex I (e.g. provisions in Waste Directive, Batteries Directive, Packaging Waste Directive and WEEE Directive).
Directive 2003/35/EC on public participation	Includes provision on the involvement of in respect of the drawing up of certain plans stakeholders in the planning of certain and programmes relating to the environment activities including IPPC activities such as large-scale waste management operation
Regulation on the European Pollutant Release and Transfer Register ((EC) 166/2006)	This Regulation sets up a pollutant release and transfer register (PRTR) at EU level in the form of a publicly accessible electronic database. The public will be able to access this register free of charge on the Internet and will be able to find a wide range of information (type of pollutant, geographical location, affected environment, source

	facility, etc.). The register will contain information on releases of pollutants to air, water and land, as well as transfers of waste and pollutants, where emissions exceed certain threshold values and derive from specific activities. The register will also cover releases of pollutants from diffuse sources (such as transport).
Environmental Liability Directive (2004/35/EC)	This Directive covers direct or indirect damage to the aquatic environment and to species and natural habitats, where protected at EU level. The principle of liability applies to environmental damage and imminent threat of damage resulting from occupational activities, where it is possible to establish a causal link between the damage and the activity in question. The first liability scheme applies to the dangerous or potentially dangerous occupational activities listed in Annex III to the Directive. These include those industrial activities that need an IPPC/IED licence, such as waste management activities (including landfills and incinerators). Under this first scheme, operators may be held responsible even if they are not at fault.
Environmental Crimes Directive (2008/99/EC)	Art. 3 (b) and (c) consider the following criminal offence demanding the imposition of effective, dissuasive and proportionate penal sanctions: <ul style="list-style-type: none"> the collection, transport, recovery or disposal of waste, including the supervision of such operations and the aftercare of disposal sites, and including action taken as a dealer or a broker (waste management), which causes or is likely to cause death or serious injury to any person or substantial damage to the quality of air, the quality of soil or the quality of water, or to animals or plants the shipment of waste, where this activity falls within the scope of Article 2(35) of Regulation (EC) No 1013/2006 on shipments of waste (1) and is undertaken in a non-negligible quantity, whether executed in a single shipment or in several shipments which appear to be linked.
INSPIRE Directive (2007/2/EC)	Among the spatial data themes referred to in Articles 6(B) AND 9(B) and set out in Annex III are: <ul style="list-style-type: none"> Utility and governmental services (e.g. sewage, waste management) Production and industrial facilities (e.g. installations covered by IPPC/IED, mining, storage sites.
Air Quality Sector	
Ambient Air Quality and Cleaner Air for Europe (2008/50/EC)	Sets out a framework for a common strategy to address air pollution, covering objectives for ambient air quality, assessment of air quality, publication of information, and maintaining air quality. These objectives could affect waste management options (e.g. incineration).
Heavy Metals Directive (2004/107/EC)	This Directive, amongst others, establish a target value for the concentration of arsenic, cadmium, nickel and benzo(a)pyrene in ambient air so as to avoid, prevent or reduce harmful effects of arsenic, cadmium, nickel and polycyclic aromatic hydrocarbons on human health and the environment as a whole. Such emissions can be the result of waste treatment or disposal activities.
Water Quality Sector	
Water Framework Directive 2000/60/EC	Aims to establish a framework for protecting the quality and quantity of surface water and groundwater resources. The development of waste management strategies and plans should take account of potential impacts of different options on water resources.
Urban Waste Water Directive (91/271/EEC)	Sets prescribed standards for wastewater nature of the receiving waters. This affects the volume and character of sludge produced and future waste management strategies.
Nitrates Directive (91/676/EEC)	Sets out measures to reduce the pollution by nitrates of receiving waters as a result of agricultural practices. This potentially affects the disposal of sewage sludge to land.

Directive 2008/105/EC on environmental quality standards in the field of water policy	Controls emissions of dangerous substances to receiving waters through permitting. This potentially affects the design, location and permitting of waste treatment and disposal facilities, for example on wastewater discharges and site drainage.
Nature Protection	
Habitats Directive (92/43/EEC)	Waste management operations can have a major impact on the conservation of natural habitats and of wild and thus such activities are not allowed on protected sites, including EMERALD sites, Natura 2000 etc.
Industrial Pollution Control and Risk Management Sector	
Industrial Emissions Directive 2010/75/EU	A recast of seven earlier pieces of legislation on industrial emissions, it lays down rules to prevent and control pollution into the air, water and land and to avoid generating waste from large industrial installations. Requires permits for prescribed activities (including waste treatment and disposal), which set conditions including emission limits. Requires application of BAT. This affects waste treatment and disposal facilities.
Seveso III Directive (2012/18/EU)	Aims to prevent major accidents involving dangerous substances and limiting impacts on people and the environment. Wastes can be dangerous substances, and accidents can potentially occur during the collection, treatment, transport and disposal of wastes.
EMAS Regulation ((EC) 1221/2009)	The objective of EMAS, as an important instrument of the Sustainable Consumption and Production and Sustainable Industrial Policy Action Plan, is to promote continuous improvements in the environmental performance of organisations by the establishment and implementation of environmental management systems by organisations, the systematic, objective and periodic evaluation of the performance of such systems, the provision of information on environmental performance.
Chemicals	
Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures	Set rules on classification, packaging and labelling of prescribed chemicals. Requires substances notification of the placement of these substances on the market in Member States. This potentially affects the transport of materials recovered or recycled from wastes.
REACH (Registration, Production, Marketing and Use of Chemicals) Regulation ((EC) 1907/2006)	Consolidates the chemical legislation and repeals a number of chemical laws. The REACH Regulation introduces a more evaluation, authorisation and restriction of systematic and stringent system of controls for chemicals (REACH), establishing a European agency, chemicals. The responsibilities on the part of chemical producers and importers have been and Commission extended, especially in terms of assessing the as well as risks of chemicals.
Asbestos Directive (87/217/EEC)	Measures have to be taken to ensure that the concentration of asbestos emitted through the discharge ducts into the air during use of asbestos does not exceed a limit value of 0,1 mg/m ³ (milligrams of asbestos per m ³ of air discharged). The Directive also refers to waste as covered by the Waste Directive applying to demolition of buildings with asbestos giving result to asbestos waste.
Regulation on export ban and safe storage of metallic mercury ((EC) No 1102/2008)	This Regulation governs the exports and the storage of metallic mercury an certain compounds and mixtures. It has implications for mineral extraction activities under the Mining Directive for instance but can also apply to mercury waste from certain other industrial facilities (IED/IPPC installations).

Import and Export of Dangerous Chemicals Regulation ((EU) No 649/2012)	It applies to industrial chemicals and pesticides (including biocides) that are banned or severely restricted for health or environmental reasons. The export of such chemicals is subject to two types of requirements: export notification and explicit consent.
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More information and guidance on categories of waste legislation and links with other sectoral legislation can be obtained at:

Website of DG ENV:

<http://ec.europa.eu/environment/waste/legislation/index.htm>

Website on summaries of EU legislation:

http://europa.eu/legislation_summaries/environment/waste_management/index_en.htm

2. DEVELOPMENT OF A SECTORAL STRATEGY AND IMPLEMENTATION PLAN

2.1. Introduction

EU legislation on waste management, in particular the Waste Framework Directive (2008/98/EC), requires the competent authority in Member States to draw up waste management plans and specifies, in very general terms, the scope of such plans. Similarly, other more specific waste legislation requires operators to draw up waste management plans and strategies focusing on a particular waste stream and waste management processes, e.g. under the Mining Waste Directive (2006/21/EC). Waste management plans in general, are an essential tool in ensuring that the capacity of the waste management infrastructure corresponds to the actual volume of waste — that is, that there is a sufficient network of safe and legal waste disposal and recovery facilities to deal with the waste generated and/or imported. However, in order to be consistent and cost-effective, a waste management plan of any kind (e.g. national, regional or local) needs to be based on a strategy for managing waste and must be implemented effectively. Thus, in practice, a waste management plan as required by EU legislation should consist of two principal components — a strategy for managing wastes (an overall framework or "blueprint" that stipulates what actions will be taken and by when); and a plan for implementing the strategy (containing details of how these actions will be undertaken and by whom). Although the two components may be produced as a single document, it is important to make some distinction as each component will need to be communicated to different audiences or target groups and require the involvement of different competent authorities, key actors, mechanisms and measures. Here, the Member States have certain discretion in choosing a method best suited to the overall national waste policy and local particularities. In any event, strategy development must, by definition, precede the preparation of an implementation plan. This process should necessarily be that adopted in order to ensure compliance with the above-mentioned SEA Directive 2001/42/EC on the assessment of the impact of certain plans and programmes on the environment (see Section 2), including as concerns waste management (see Article 3(2)).

The purpose of this section is therefore to outline the essential principles, steps and decisions which need to be addressed in order to develop and implement an effective strategy for managing wastes and achieving compliance with EU policies and legislation on waste management. It is written mainly from the perspective of the national government agency or public authority charged with responsibility for planning, overseeing and controlling the management of wastes. However, many of the principles and techniques described here would be equally applicable to others involved in managing wastes; e.g. municipalities and other service providers.

A key proposition of this section is that the development of a waste management strategy and implementation plan is most effective when carried out in an integrated, holistic manner whereby all facets (political, legal, organisational, environmental, technical, social [including consultation], economic, etc.) relevant to future arrangements for managing and controlling wastes within a country, region or locality are systematically addressed. The rest of this section therefore considers the selection of an overall approach to strategy development, and briefly describes the sequence of steps required to formulate and implement a cost-effective strategy for managing wastes.

2.2. Possible Approaches

There are two broad approaches possible for developing a strategy for managing wastes. These may generally be described as the "integrated" approach or the "traditional" approach. The difference between the two approaches lies in their scope and methodology — it does not relate to the level of government at which a strategy is developed. The main steps involved in each approach are summarised in the Box below.

Table 4. Box with approaches to developing a waste management strategy

"Integrated" Approach	"Traditional" Approach
Prepare a survey and analysis of existing conditions, arrangements and practices relating to waste management generally within a region or area.	Identify and characterise existing and future sources and volumes of specific waste streams.
Identify significant problems/deficiencies associated with existing systems.	Identify the functions and activities necessary to handle and dispose of these wastes.
Define the strategic objectives for the future management of all wastes.	Determine the facilities, systems and other physical resources required to perform these functions and activities.
Identify and assess the options available for achieving the strategic objectives. Select the preferred option(s) based on multi-criteria assessment.	Formulate a strategy for managing these wastes based on these elements.
Formulate an integrated waste management strategy.	Prepare a detailed strategy implementation plan.

An integrated approach investigates and systematically considers the entire spectrum of existing waste management policies, institutions, activities, practices and facilities within a country, region or area, and then endeavours to resolve comprehensively the strategic question: "What changes or improvements need to be made in order to be able to reach our overall goal for managing wastes?" This approach is wide ranging and holistic and aims ultimately to arrive at a fully integrated strategy for managing wastes.

The traditional approach begins by investigating the types and quantities of wastes which are (or will be) generated within a country, region or area, and then seeks to answer the specific question: "What facilities, systems and resources are needed to manage these wastes in the future?"

The traditional approach is used either because of resource constraints or because it is based on a political decision. This approach has a narrow focus, primarily on the nature of the waste streams, and therefore tends to lead to the adoption of "technical fixes" for handling and managing each type of waste. This has been the customary way of developing a waste management strategy, but can be subject to numerous practical limitations or drawbacks, for example:

- The resulting strategy/implementation plan may fail to identify and tackle the root causes of some of the existing problems and deficiencies concerning waste management.
- Not all of the multitude of factors which could determine the ultimate success or failure of the strategy, and their dynamic inter-relationships, may have been identified and properly considered.

- Not all of the underlying key assumptions and the various pre-conditions on which the strategy is founded may have been fully recognised or understood.
- Not all of the potential risks and consequences of the failure to fulfil the key assumptions or pre-conditions on which the success of the strategy depends may have been considered.
- In trying to solve or mitigate the environmental problems associated with a particular waste stream, a strategy may inadvertently create problems or adverse impacts in other environmental media.
- Weaknesses in the underlying logic, and a lack of transparency in the way in which the strategy has been formulated, may give rise to fundamental objections by those who will be affected by the strategy.

On the other hand, an integrated, objectives-oriented approach provides a broader, more logical and consistent framework for strategy development and subsequent implementation. It also reveals far more clearly the process by which the final strategy has been formulated and, accordingly, makes it less susceptible to misinterpretation or criticism. It is also more consistent with EU environmental policy, as well as with the EU's Seventh Environmental Action Programme.

The development of an integrated waste management strategy and implementation plan generally requires considerably more time and effort, and is therefore likely to cost significantly more to prepare and finalise, than the "traditional" approach. However, experience suggests that the resulting strategy and plan are likely to be much more robust, defensible and cost effective, and consequently have a much greater prospect of succeeding. Likewise, the time and money invested in preparing an integrated waste management strategy and plan will be well spent if this avoids potentially expensive mistakes and modifications later on, or delays due to strong resistance from the public and other affected interest groups. Further, as wastes are "goods" within the free movement of goods provisions under the Treaty on the Functioning of the European Union (TFEU, see Article 34), having an "integrated" approach involves making provision to ensure that the overall result intended in a waste management plan is the least disruptive to environmental and economic operations.

2.3. Strategy Development

In order to assist national, regional and local competent authorities in preparing waste management plans in line with the requirements of the Waste Framework Directive, the Commission has published in 2012 a methodological Guidance Note¹⁴⁵. The Guidelines contain a review of the overall policies and principles applying to planning in the field of waste management in the EU. This includes a review of legislation in force, and in some fields practical methods are indicated for filling in the framework set up by the EU and the various Member States for the contents of management plans. Furthermore, a framework – or a “step-by-step model” – is presented as a source of inspiration for drawing up an individual waste management plan. It also contains examples from waste management plans or from other guidelines, as well as a checklist with relevant items to consider in the planning process.

¹⁴⁵ http://ec.europa.eu/environment/waste/plans/pdf/2012_guidance_note.pdf

2.3.1. Key stages

The development of an integrated and cost-effective waste management strategy involves the following key stages:

- 1) Definition of scope and goal of strategy — for example, taking due account of the objective that the EU as a whole be self-sufficient in waste management terms, covering the whole country, set at municipality level.
- 2) Forecast of future amounts and composition of waste and socio-economic aspects.
- 3) Review and analysis of the existing situation.
- 4) Identification and definition of the problems and deficiencies associated with existing arrangements and systems for managing wastes.
- 5) Definition and analysis of strategic objectives.
- 6) Identification and evaluation of options for achieving the defined objectives.
- 7) Formulation of the strategy.
- 8) Preparation of a strategy implementation plan.
- 9) Provision for periodic review.

The main components for each of these stages are outlined below.

2.3.2. Definition of scope

The purpose of this initial step is to define the geographical areas and sectors as well as the time period for which the strategy will be developed. This would involve a clear definition of areas — e.g. municipalities and/or waste management districts that are included; which sectors — e.g. households, industry, agriculture etc.; and finally the time period over which the strategy will be implemented — e.g. five years, ten years or even longer. Please note that according to the Waste Framework Directive, waste management plans need to be evaluated at least every sixth year and revised as appropriate. Furthermore, it is important to identify which organisations are involved or have interests in waste management activities, thereby outlining which organisations should be involved in the further development of strategies in the field.

2.3.3. Review and analysis of the existing situation

The purpose of this initial step is to gather, review, analyse and document sufficiently comprehensive data and information on all the relevant aspects of the existing situation regarding wastes and waste management. The range of data required is illustrated in Table 5 below. One of the most important tasks which must be undertaken during this initial stage is to determine the sources, types and quantities of wastes generated in the strategy area, their present fate, and how these might change in the future. The definitions of waste types contained in the European Waste Catalogue, whilst essential for performing a range of functions such as the regulation and control of waste management, are too specific to be used directly for strategy development. For this purpose, a method of broadly grouping and categorising wastes needs to be adopted.

All of the categories of waste need to be investigated and considered in developing a comprehensive, integrated waste management strategy and implementation plan. A waste management system may be planned and

developed to address any one, or a combination of, waste streams. However, experience indicates that it is generally much more cost effective to plan and develop integrated systems for managing all of the waste streams that arise in a given region, community or organisation.

For strategic planning purposes, detailed data are not necessary, but it is important that the overall data are as reliable as possible. This can be done through cross-checking data from different areas and holding in-depth discussions with the people involved. Establishing a databank system at national level is an important step in order to put in place an effective strategy for reducing waste. If the strategy will require waste minimisation, basic data on industry and manufacturing processes will be needed.

Table 5. Box with scope of data required for a diagnostic study of existing conditions

Scope of Data Required for a Diagnostic Study of Existing Conditions
<p>Regional, demographic and socio-economic characteristics</p> <ul style="list-style-type: none"> • Land use and water resources • Environmental characteristics, quality and sensitivity • Existing transportation networks • Nature, distribution and stage of development of industry • Demographic data (number of inhabitants, demographic trends) • Niche of local industry • Particularly sensitive areas and population groups to be considered
<p>Nature and Scale of Waste-Related Problems</p> <ul style="list-style-type: none"> • Sources, types and quantities of wastes • Waste-stream analysis, including all stages from collection to landfill and including recycled materials • Current health risks/impacts from waste-related pollution • Current impacts of wastes on air and water quality • Status quo and efficacy of waste management system including technical, institutional and economic aspects • Extent of land contamination related to existing/past waste management practices • Occurrence of major incidents involving wastes • Efficacy of the existing organisational arrangements for managing wastes • Current level of activity directed towards waste minimisation and recycling • Standard/quality of existing waste storage and collection arrangements • Standard/quality of waste transport systems • Quality and adequacy of existing waste processing/treatment facilities • Standard/quality of existing landfill sites • Extent of uncontrolled dumping of wastes • Extent and nature of stockpiling of wastes • Existence and scale of mining activities • Current amounts of waste exported abroad for recycling, treatment or final disposal
<p>Legislation and Enforcement</p> <ul style="list-style-type: none"> • Requirements of existing EU and national waste-management policies and legislation • Status and anticipated requirements of pending, relevant EU and national policies and legislation • Adequacy of the existing regulatory regime (taking into account results, compliance levels and recognition of key stakeholders and general public) • Adequacy of existing monitoring arrangements • Efficacy of the existing arrangements and procedures for enforcement including imposition of penal sanctions • Current and proposed environmental quality objectives and emission standards and the evaluation of whether these are being reached

<p>Public Perceptions and Attitudes</p> <ul style="list-style-type: none"> • Public perceptions and attitudes towards waste management generally, e.g. existing public concerns and expectations • Whether the community willing and able to accept higher financial costs of improved waste management standards • Public attitudes to the selection and siting of new waste management facilities • Attitudes of industry to the goals of improved waste management performance and standards, and increased costs • Attitude of public to increased costs of improved waste-management system
<p>Financial Issues and Constraints</p> <ul style="list-style-type: none"> • Current arrangements for financing and recovering the costs of waste-management services and facilities • Current extent of private sector involvement in the provision of waste-management services and facilities • Whether waste producers can afford the short-run financial costs of meeting higher standards • Whether the government is able to finance the transition to higher standards and, if so, to what extent • Whether external sources of finance are available in the form of loans and grants (not constituting state aid) • Existing policies and attitudes regarding competition for the provision of waste management services and facilities
<p>Suggested Waste Categories for the Purposes of Strategy Development</p> <ul style="list-style-type: none"> • Municipal solid waste (MSW): includes household waste and wastes of a similar nature to household waste produced by commercial premises, institutional wastes (schools, government offices, etc.), market wastes and street/drain-cleaning wastes • Inert waste • Garden and bulky waste • Organic waste (suitable for composting or for anaerobic digestion) • Hazardous wastes: special wastes that, being toxic, infectious, irritant, explosive, flammable, or having carcinogenic, teratogenic or mutagenic effects, are or may be harmful to human health or the environment • Other industrial wastes: wastes of an industrial origin not requiring special methods of handling, treatment and disposal. Many industrial wastes fall under this category e.g. most construction wastes • "Special" wastes: wastes which, because of their nature or quantity, require special methods of handling, treatment and disposal (for economic and/or environmental reasons in particular) • Healthcare (hospital and clinical) wastes: a particular type of special waste, some of which must be considered as obnoxious or potentially hazardous • Ash and slag from combustion processes: typically relates to ash or slag from solid fuel-fired processes for steam-raising and/or power production, some of which (e.g. fly-ash from waste incineration plants) may be potentially hazardous • Agricultural wastes: in particular wastes from intensive cropping and livestock production • Sludge: in particular from water and wastewater treatment • Mining wastes • Construction waste • Waste streams covered by producer liability provisions (e.g. batteries, packaging, end-of- life vehicles, electronic and electrical waste)

2.3.4. Problem identification, definition and analysis

Having reviewed and analysed the existing situation regarding wastes and waste management, the next step is to identify and define clearly all of the significant problems or deficiencies associated with the existing and future (based on forecasts) waste management arrangements. The waste strategy and implementation plan will

need to address these problems and to establish a hierarchy of cause and effect relationships for each of the negative features of the existing arrangements. As expressed here, an effect means a logical consequence or impact (direct or indirect) of some failure, deficiency or other negative condition. In order to eliminate or mitigate an adverse effect, it is necessary to devise and implement measures that specifically address the underlying cause(s) of that effect — any other actions are likely to fail or, at best, result only in a temporary alleviation of the unwanted effect. Thus, by identifying and defining all of the specific problems to be addressed by the strategy, a fundamental logic is introduced into the strategy formulation process.

Problem identification and definition can be assisted by applying a variety of analytical techniques. For example, logical framework analysis can be used to identify (a) the principal areas of concern, (b) key problems for each area, (c) main causes of the problems, and (d) their significant effects. A simplified example is given in Table 6 below.

Table 6. Simplified Example of a Logical Framework Analysis

Simplified Example of a Logical Framework Analysis			
Area or Activity	Key Problems	Principal Causes	Principal Effects
Institutional framework	Insufficient capacity	Insufficient resources (technical, human and financial)	Inappropriate or ineffective waste management systems
Policy and legislation	National policy on waste management not sufficiently developed. Existing legislation governing waste management inadequate	Existing policy does not address all key areas of performance for waste management. Proposed new legislation not yet implemented.	No clear basis for determining priorities, performance requirements or targets. Required standards for waste Management difficult/impossible to implement and enforce
Waste arising	Data on sources, nature and quantities of wastes inaccurate and/or unreliable.	Regular monitoring of waste types and quantities not carried out effectively.	Planning, management and control of waste management services
Waste prevention	Waste producers not aware of potential opportunities for, and benefits of, preventing wastes.	Information on opportunities and techniques for waste prevention not generally available. The true costs of environmentally sound waste management are not perceived or met by waste producers.	Resources, including resources for waste management, are not used efficiently. Requirements for waste treatment and disposal are higher than need be.
Sorting and recycling	Limited or no demand for some recyclable materials.	Low quality and market value of some recyclable materials. Lack of local market outlets for some recyclable materials.	Without intervention, scope for further recovery and recycling of some materials severely constrained.
Waste treatment and disposal	Available facilities and capacities for treatment and disposal of wastes inadequate.	Legislation and standards not effectively enforced.	Waste of resources. Pollution of air, water resources and land

This technique can be extended to include all significant aspects or activities concerning waste management; e.g. financing of facilities and services. When endeavouring to identify, define and analyse the problems associated with existing arrangements and practices, it is important to try to be as specific as possible, and to articulate the true nature of their causes and effects. It is also important that definitions of problems and their underlying causes are expressed as a "negative state"; i.e. a condition that has, through various measures and actions, the potential to be transformed eventually into a positive state. It is usually advisable to involve the main stakeholders in this process. This not only normally provides useful input into developing the strategy itself, but can also help to gain broad acceptance of the final strategy. Consultations can take place through the circulation of briefing notes or the organisation of workshops, and involve interested ministries, local government planners, NGOs and principal waste producers.

2.3.5. Definition and analysis of strategic objectives

Once all of the problems to be addressed by the waste management strategy have been defined precisely as "negative conditions", the next step is to transpose these into specific strategic objectives (expressed as "positive conditions") that are either necessary or desirable, and that are realistically achievable. This is accomplished by reformulating each of the problems identified and defined in the problem analysis into a hierarchy of objectives and means-ends relationships. This will produce an „objectives tree” containing all of the objectives that will need to be achieved by the waste management strategy. The highest-level objective or goal represents the overall purpose of the strategy. If formulated correctly, the strategy goal and objectives will inversely reflect the existing problems associated with waste management in the specific country or region. These will therefore vary both from country to country, and from region to region within a country. However, as all Member States in the EU must achieve and maintain certain minimum standards and requirements laid down in EU policy and legislation, the overall goals and higher-level objectives of waste management strategies will (or should) be similar throughout the EU. It is with respect to the lower-level objectives, and the related means-ends relationships, where the main differences between strategies will occur.

The overall goal or purpose of an integrated waste management strategy might be expressed along the following lines: „to establish and maintain a system for managing wastes in the relevant country, region or area that meets the stipulated performance standards and requirements, and minimises the overall adverse impacts on the environment”. Some of the higher-level objectives of an integrated strategy could be, for example:

- To meet the policies and legislation of the EU within the designated time frames.
- To select and apply waste management practices, systems and technologies that are proven and appropriate to local cultural, environmental and economic conditions.
- To develop and progressively introduce a more comprehensive and effective regime for regulating and controlling waste producers, waste management practices and facilities.
- To adopt and apply progressively, to the extent that is possible in practice, equitable arrangements for recovering the full economic costs of waste management from waste producers (the polluter pays principle).

Whatever the objectives, it is important that they are capable of being (and are) translated into measurable indicators, e.g. performance criteria and target dates for completion. Otherwise, there is no clear basis for monitoring and evaluating progress towards fulfilling the overall goal and subsidiary objectives of the strategy.

2.3.6. Identification and evaluation of options (for achieving the objectives)

This step involves identifying, evaluating and comparing different options or alternatives (the potential "means") for achieving the various strategic objectives (the "ends"). Adopting and applying the concept of the "best practicable environmental option" (BPEO) provides a rigorous and systematic methodology for identifying and evaluating different options (technical, environmental, organisational, economic, etc.) for achieving the strategic objectives. In this context, the BPEO may be defined as "the option (or combination of options) which, in meeting the strategy objectives, minimises the overall adverse impacts on the environment at an acceptable cost". This methodology is particularly useful for addressing sensitive or contentious issues. The basic stages involved in a BPEO analysis are:

- identify the objectives and the constraints
- collect data and information
- generate the options
- screen options
- evaluate options
- identify the preferred option(s)
- implement and monitor the preferred option(s)

As a general rule, this sequence of activities should be adhered to, in order to avoid any pre-judgment or bias. For the purposes of strategy development, much of the information required to carry out a BPEO analysis should already have been obtained during the initial review of the existing situation. Likewise, the strategic objectives and related constraints should already have been established based on the results of the problem analysis. However, in order to evaluate options in sufficient detail, it may sometimes be necessary to gather further data and/or to elaborate the objectives specific to an option.

A full audit trail should be established, in order to monitor progress and to be able to explain and justify judgments and conclusions to others not immediately or directly involved in the analysis. Ideally, the analysis should also be subject to independent peer review in order to validate the methods used and confirm (or otherwise) the conclusions reached.

The screening process should be undertaken in several stages, progressively eliminating the less suitable or less appropriate options. This will ensure that time and effort is devoted primarily to the detailed evaluation of a small number of practicable options. It will be necessary to develop and agree upon a set of criteria for screening and evaluating all of the options identified. These criteria will need to establish the minimum requirements and relative weightings (importance) which should be assigned, for example, to considerations such as:

- technical suitability and performance
- operational reliability and security

- environmental performance and risk
- costs and cost-effectiveness
- social acceptability
- long-term sustainability.

2.3.7. Strategy formulation

Strategy formulation essentially involves consolidating and documenting the outputs and proposals from preceding steps into an overall framework and system for the future management of wastes, the setting of priorities, and the development of programmes for their realisation. Where the BPEO analysis enabled a preferred set of options for achieving the strategic objectives to be clearly identified, then it is usually a relatively straightforward task to configure a strategy around that set of options. However, in practice there may be several possible routes to achieving a specific strategic objective, each depending on certain assumptions and pre-conditions, and a decision to proceed along one route might preclude the possibility of proceeding along another. Accordingly, the aim should be to formulate a strategy based upon a set of options which has the greatest prospect of succeeding but which also preserves, as far as possible, the availability of alternatives in the event of any difficulties or failures. It is recommended that the document comprising the waste management strategy should generally contain, as a minimum, the elements presented in the Box below.

2.3.8. Strategy implementation plan

The final step in the strategy development and planning process is to prepare an implementation plan. Unlike the strategy itself, which is typically aimed at a very wide audience, the implementation plan is primarily intended for the use of those charged with executing the strategy. It therefore needs to elaborate in considerable detail all of the tasks and activities which must be undertaken in order to realise the various objectives, proposals and programmes contained in the strategy. It is recommended that the document comprising the strategy implementation plan should generally contain, as a minimum, the elements presented in the Table 7 below.

It should also be borne in mind that completion of a waste management strategy and implementation plan represents only the initial element of what should ultimately be an iterative process. Needs and circumstances relating to waste management can and often do change. It is therefore vital that both the strategy and implementation plan are continually monitored and regularly reviewed to ensure that the various objectives, measures and underlying assumptions are still valid/appropriate, and that the timescale for achieving the overall goal of the strategy is still realistic.

Table 7. Box with recommended minimum content of a waste management strategy

<p>Recommended Minimum Content of a Waste Management Strategy</p> <ul style="list-style-type: none"> • Policy statement incorporating the overall goal and strategic objectives — EU and national. • Statement of the key principles and criteria upon which the strategy is founded. • Summary of the key data and assumptions on which the strategy is based. • Description of the main elements/features of the strategy: <ul style="list-style-type: none"> – nature of wastes and waste arising, and related forecasts – key existing problems/deficiencies – applicable legislation, standards and regulations (EU and national level) – future institutional and organisational arrangements for managing wastes – measures for preventing, reducing, recovering, recycling or reusing wastes (including economic instruments and voluntary agreements) – standards, methods and technologies for storage, collection and transportation – technologies/techniques to be applied for treatment and final disposal – measures and procedures for clean-up and restoration of waste sites – methods and procedures for detailed planning, assessment, development and operation of waste management facilities – methods to be adopted for financing and recovering costs of waste management facilities and services – approach and methods for educating, informing and communicating with the public/key interest groups • A programme for implementing the required institutional and organisational changes. • Description of the main systems and procedures to be developed and applied for implementing the strategy. • A programme for developing the required physical facilities for waste management. • Estimates of the human resources required to implement the strategy. • Estimates of the magnitude and timing of the capital and operating expenditures required in order to provide and operate the physical facilities for waste management. • A programme for funding facilities, infrastructure or other types of project related to waste management, and for introducing or improving systems for cost recovery. • A programme for communicating the strategy to the public and other key interest groups. • Overall timetable for achieving the goals of the strategy and for reviewing the strategy.
<p>Recommended Minimum Content of a Strategy Implementation Plan</p> <ul style="list-style-type: none"> • Identification of the authorities/agencies responsible for strategy implementation. • Identification and definition of all the key tasks and activities required in order to implement the adopted strategy. Please note that Waste Framework Directive defines minimum content of the waste management plan. • The sequence, timing and linkages of key tasks and activities. • Key implementation decision points and milestones. • Detailed timetables for implementation. • Detailed estimates of the resources required and related costs. • Cash flow projections for the overall plan and for all plan sub-components. • A detailed financing plan. • Supporting data and explanatory text, as required; e.g. identifying and detailing the allocation of responsibilities for key implementation tasks; indicators of achievement to be used.

3. INSTITUTIONS AND RELEVANT PARTIES

3.1. Stakeholders

A large number of stakeholders have an interest in, or may be affected by, waste management. The principal stakeholders and their roles in the process of developing and implementing a sectoral strategy to achieve compliance with EU policies and legislation on waste management are identified in Table 8 below. The following subsections focus on the main groups of organisations that need to be involved in waste management, followed by issues on communications.

3.2. National Government Institutions

National governments are ultimately responsible for achieving and maintaining compliance with EU policies and legislation on waste management. They have a duty and obligation to secure compliance in a manner and within a programme either stipulated in the relevant EU instrument, or agreed with the responsible EU institution. They are also responsible for developing and implementing national waste management strategy. The national waste management strategy could be part of, or at least should comply with, the national environmental strategy. Typically, the primary responsibility for achieving and maintaining compliance is delegated to a single national institution, e.g. a ministry or department of environment. However, other ministries or departments in national government will inevitably need to be involved in some way at various stages in the planning and implementation process. For example, ministries with responsibilities for agriculture, economy, export/import, foreign affairs, local government, public health, trade and industry would all potentially be affected by the implementation of EU waste legislation. The lead ministry (presumably the environment ministry) should identify which other ministries (see above), national government agencies and bodies need to be involved and given competence in the process of planning and implementing EU waste legislation. For example, the development of the waste management strategy described in Section 2 is likely to require technical inputs from other government organisations such as specialised agencies, a national standards institute, a national statistics institute and existing public regulatory or waste service bodies. The role and input of each type of organisation to be involved must be carefully identified and agreed between the lead ministry and the organisation concerned.

Table 8. Box with principal stakeholders and their roles in waste management

Stakeholders	Roles
Central government (e.g. a ministry or department)	<ul style="list-style-type: none">– Implementation and maintenance of compliance with EU policies and legislation on waste.– Develop and implement national waste management strategy.
Environmental agencies working on behalf of central government (e.g. regulatory authority, national standards laboratory)	<ul style="list-style-type: none">– Provision of planning, regulation and technical assistance.

Regional and local government	– Provision of planning, regulation, and monitoring.
Municipalities	– Collection, treatment, recovery and disposal and some planning and regulation.
Waste management companies	– Provision of waste management, collection, recovery and disposal services.
Industrial/commercial waste producers	– Prevention, minimisation and recycling of waste. – Duty to ensure proper handling, recovery and disposal of waste. – Monitoring and reporting on waste production, recovery and disposal.
Public	– Separation at source, recycling and minimising and prevention of domestic waste. – Payment of waste collection, recovery and disposal services. – An interested and affected party within the proximity of waste management facilities.
NGOs	– Representing the public interest. – Lobbying on planning and environmental issues.
Research institutions (e.g universities)	– Technical research, inter alia, to develop new waste management technologies, or conduct environmental analysis.

The lead ministry should identify and appoint the competent authorities required to take responsibility for functions prescribed in the legislation. The lead ministry must ensure that the competent authorities have the required legal powers and resources (financial, technical, and logistical) to meet their obligations. Competent authorities are discussed further in Section 3.3 below.

3.3. Competent Authorities

The types of functions to be undertaken by competent authorities to implement EU waste management legislation are illustrated in Table 9 below. These range from legal and administrative functions to highly specialised, technical ones. Candidate countries may already have institutions which carry out some of the tasks indicated in this table, for example existing regulatory bodies. Alternatively, expertise may exist in a number of agencies, but may need to be brought together in a single organisation. Special consideration needs to be given to the requirements for specialist staff, as the expertise or sufficient staff resources needed may not be readily available within the country. Competent authorities can be appointed for one or more functions across several environmental sectors. For example, the drafting of legislation may be undertaken, or at least co-ordinated, by a single body. Again in the area of regulation, various Directives across the environmental sectors require permitting of installations and emissions. Therefore, consideration should be given to the interaction between the competent authorities appointed in the waste sector, and those operating in other sectors, particularly air, water and industrial pollution control.

Table 9. Examples of activities that are specifically required from a Competent Authority in respect to EU waste legislation. (Note that this list is indicative and not exhaustive)

<p>Planning and Implementation</p> <ul style="list-style-type: none"> • Preparation of waste management plans (Directive 2008/98/EC) incorporating hazardous waste streams, waste falling under producer responsibility legislation and waste oils • Classification of landfill sites (Directive 99/31/EC) • Mining (Directive 2006/21/EC requiring classification of waste facilities and approving waste management plans) • Incineration of waste • Waste shipments • Set up systems including institutional structures for collection, recycling and treatment of WEEE, batteries, ELV and packaging waste
<p>Technical Standards</p> <ul style="list-style-type: none"> • Set emission limit values for certain pollutants (normally these may be more stringent than those prescribed by EU legislation) • Prescribe rules for measuring/standardising measurements • Approve sampling and monitoring programmes • Set maximum permissible periods for stoppages affecting emission standards • Ensure stack height sufficient to safeguard human health and environment • Set standards for location, set up and running of landfill sites • Translate EU standards (e.g. on sampling protocols under the Mining Directive) into national standards (in local language) • Provide technical guidance providing best practice and reference to BAT
<p>Regulation</p> <ul style="list-style-type: none"> • General requirement to ensure and verify compliance with Directives and standards (2008/98/EC, 2010/75/EU, 94/62/EC, 99/31/EEC, 2011/65/EU, 2012/19/EU and 2006/66/EC) • Registration of establishments for which permits are not required (2008/98/EC, 99/31/EC) • Permitting of establishments e.g. waste recovery, waste disposal installations, landfill sites, mining sites (e.g. 2008/98/EC, 2010/75/EU, 99/31/EC, 2006/21/EC). There are general permitting requirements in Directive 2008/98/EC, whereas more specific requirements are laid down in specific pieces of legislation such as the Landfill Directive. In the case of larger establishments, permitting might fall under the Industrial Emissions Directive. • Authorisation of exemptions for conditions different to those stated in the Directives (e.g. Directives 2010/75/EU, 2006/21/EC, and 99/31/EC) • Inspection of sites (e.g. Directives 2008/98/EC; 99/31/EC, 2010/75/EU, Directive 2006/21/EC) • Request, receive or hold information (e.g. Directives 2008/98/EC, 94/62/EC, 2006/66/EC, 2006/21/EC, 2011/65/EU, 2012/19/EU, 96/59/EC, 99/31/EC and Regulation (EC) No 1013/2006 and 1418/2007(shipments)) • Examine trends in the state of technology development and/or the environment to revise, where necessary, permits granted to establishments (e.g. Directives 2008/98/EC, 99/31/EC; 2010/75/EU) • Ensure that plants and sites do not operate while failing to comply with emission standards (e.g. Directives 2010/75/EU, 99/31/EC) • Ensure that waste is only accepted at landfill sites if they comply with specified rules (99/31/EC on landfills and Council Decision 2003/33/EC establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive 1999/31/EC) • Monitor quantities of certain wastes (e.g, Directives 96/59/EC, 99/31/EC, 2006/66/EC, 2006/21/EC, 2012/19/EU)
<p>Reporting</p> <ul style="list-style-type: none"> • Determine appropriate procedures and forms for information (e.g. Directives 2010/75/EU, 94/62/EC, 99/31/EC, as amended. Also see INSPIRE Directive (2007/2/EC) setting out standardisation for spatial information) • Report to the Commission e.g. on decisions to delay implementation, permissions for conditions not given

The closest form of integration for cross-sectoral competent authorities would be provided either by a single national body, or by regional bodies operating under the same management system. This type of structure would help to avoid duplication in many areas and provide economies of scale through shared facilities and resources. Alternatively, a sectoral approach could be adopted, but mechanisms would be required to ensure close co-operation and co-ordination between the different sectoral authorities. Competent authorities with strategically important roles or requiring specialised technical expertise should be established at the national level in order to provide consistency of approach and make efficient use of scarce resources. Examples are functions for legal responsibilities and drafting of legislation, national planning, and setting technical standards. Where local experience or local accountability is important, competent authorities can be established at the regional or local level — for example in local planning, permitting and inspection of facilities.

3.4. Regional and Local Government

The role of regional and local government in the context of waste management is important for two reasons. Firstly, most countries have a tiered administrative structure in which certain powers are devolved to the regional (e.g. counties, department, Länder) or local level of government (local planning authority or municipality). This decentralisation is stronger in federal countries but exists elsewhere, and usually includes waste management services. Consequently, the implementation of central government functions would not in itself be sufficient to implement the waste directives. Secondly, waste generation and disposal occurs at the regional/local level, requiring tools for planning, regulation and monitoring.

Under the new waste management strategy, responsibilities for waste management may still continue to be devolved to the regional and local authorities. These responsibilities may include approval of sites for waste management facilities and the provision of services (collection, transportation, treatment, recovery and disposal) for municipal waste or regulatory functions. Local authorities would also be responsible for issuing bye-laws relating to waste management which support the implementation of national legislation — for example, rules relating to when and how waste is collected.

Where regional or local government takes on more than one role, there is a potential for conflicts of interest to arise. This has happened in some Member States where local government was given responsibilities for certain waste management services and regulation (see the Waste Framework Directive fiche).

The relative roles of regional and local government in waste management may also vary according to economies of scale and waste type. Some countries have a very large number of small municipalities with individual responsibility for managing municipal waste. These are frequently too small to be able to construct suitable disposal facilities to the high standards demanded by EU legislation at an affordable cost. In this case, inter-municipal co-operation can be very beneficial in achieving groupings with enough waste to make suitable facilities affordable. This regional approach can also be appropriate for hazardous waste disposal. However, the regions tend to be larger given the lower overall quantities and economies of scale imposed by the need for specialist staff and facilities. If the regional approach is to be promoted, the existing policy, legal and administrative framework governing local government bodies needs to be reviewed to ensure that there is an adequate basis for inter-municipal co-operation. In some countries there may actually be legal obstacles to such

co-operation. Where this is not the case, it is still necessary to examine carefully the nature of any forms of voluntary agreements, joint ventures or associations between local government bodies to ensure that issues such as resource sharing and liability are addressed appropriately.

3.5. Private Sector Involvement

The interests of private sector organisations in waste management may be manifested in a variety of ways, for example as producers of wastes, providers of waste management-related services, investors in waste management facilities, developers of new methods and technologies, and technical advisers. In all EU Member States, private sector organisations are major stakeholders in waste management to an extent which has yet to evolve in the candidate countries. In some Member States, the private sector has a major role in the management of most types of wastes, while in others the private sector focuses on the management of industrial wastes, with municipal wastes managed primarily by local government.

While the private sector can provide valuable finance and offer substantial improvements in efficiency, it is not a panacea for efficiency per se. If a public sector monopoly is simply transferred to the private sector, inefficiency may be replaced by profiteering. Any successful programme of privatisation will need to ensure a strong element of competition and regulation. Existing public sector bodies, which often have many years of experience, should also be allowed to compete on level terms. If privatisation is undertaken, the public service element should still be recognised, especially in the case of municipal waste. Municipalities should not simply abdicate responsibility for the quality of the service in favour of contractors, as they are ultimately accountable to the public for service provision.

3.6. Communication and Consultation

Planning and implementation of waste management legislation will require co-ordination between government, competent authorities and other stakeholders. Consequently, communication is important for effective implementation of the legislation. During the development of a waste management strategy, a communication programme should be conducted whereby the views and opinions of interested and affected parties are solicited by national government in order to assess the acceptability and practicability of all aspects of waste legislation and the proposals for its implementation (see Section 2). Parties which should be consulted include:

- other central government ministries
- regional and local government
- industrial waste producers
- private sector waste management companies
- the general public, as producers of household wastes
- environmental NGOs.

For example, it is common in the EU for national governments to consult industry on new standards or regulations. This provides industry with an opportunity to inform government about the potential impact of the proposals on the viability of their business; to provide technical advice which may not be available to government, for example on the practicalities of procedures or techniques; and to start planning for the introduction of the new regime. Once the waste management strategy has been determined, clear lines of communication are needed between the competent authorities to support the roles and activities of the various bodies involved. Government will also need to continue a dialogue with interested parties such as industry, NGOs and the public — for example to update guidance notes on BATNEEC, and BAT reference notes (BREF), to encourage producers to move up the waste management hierarchy, and to disseminate information on existing, revised or new government waste management policies and legislation. In the longer term, achieving compliance with the EU's principles of waste management will require a major change in values and attitudes to the environment by all levels of government, industry and consumers. A programme should be developed for education and awareness rising. As an example, NGOs can be expected to contribute positively to public debate on waste minimisation and the adoption of the waste management hierarchy, and should be encouraged to do so.

Public consultation forms another element of communication. Several Directives specifically require Member States to make information available to the public and consult them on certain issues (see Section 1 and the horizontal legislation sector, particularly with regard to EIA Directive (2011/92/EU), SEA Directive (2001/42/EC), Access to Environmental Information (Directive 2003/4/EC) and Public Participation Directive (2003/35/EC). Basically all newer EU environmental legislation provide separate provisions on the need for environmental information and public consultation, including the Mining Waste Directive (2006/21/EC) and Directives introducing producer responsibility for certain waste streams (e.g. WEEE Directive (2012/19/EU), Batteries Directive (2006/66/EC), etc.).

4. TECHNICAL ISSUES

The general purpose of technical standards is to establish minimum technical requirements for the quality of certain goods or resources, and/or the operation and performance of specified activities. Such standards can take many forms, for example:

- International; e.g. World Health Organisation (WHO) guidelines and standards;
- European; e.g. EN/CEN standards, energy performance standards, BAT standards, BREF and other EU guidelines and standards;
- National; e.g. technical instructions/regulations developed and introduced by government; formal standards issued by national standards bodies;
- Sectoral; e.g. technical guidelines or specifications developed by industrial or professional associations applicable to a particular sector or type of activity;
- Mandatory, e.g. EU standards relating to the incineration of hazardous wastes;
- Voluntary, e.g. EN ISO 14000 series, the international and European standard for the environmental management systems (EMAS) and relate to different targets, for example: products, such as batteries and waste storage containers;
- Activities, e.g. discharges or emissions of a pollutant;
- Operation of a waste treatment facility;
- Environmental media, e.g. air quality; water quality;
- Procedures, e.g. for acquiring, and providing access to environmental information.

Within the Member States, EU technical standards take precedence over all other standards and, accordingly, national standards need to reflect and complement any relevant EU standards. However, given that existing EU standards relating to waste management are still fairly limited in number and scope, there is likely to be a need for national governments or other institutions to develop additional technical guidelines and standards covering a range of issues and activities which are not presently covered by EU guidelines and standards. In this respect, the candidate countries should examine, and consider adapting for their own purposes, some of the extensive range of technical standards that have been developed and introduced in EU Member States.

Some of the EU standards relating to certain types of processes (e.g. emissions from waste incineration) and waste streams (e.g. waste oils, titanium dioxide, PCB, asbestos, scrap batteries, ELV and WEEE, mining waste) are clearly set out in Directives. Others, however, will be at the discretion of the Member State (such as additional requirements relating to the emission of dioxins and furans from incinerators, and the standards for storage of PCBs). In addition, there is likely to be a need for Member States to issue technical standards/guidelines on the operation of waste management facilities.

The definition of discretionary standards generally requires an iterative process based on the development of outline policies, leading to the preparation of outline plans, technical reviews and an assessment of the affordability of the options. At one or more stages, the competent authority responsible for developing a standard should consult with interested parties including regulatory bodies, waste producers and NGOs, in

order to obtain their views, and should revise the policies and plans accordingly.

Technical standards and related guidance should be developed centrally, under the auspices of an organisation with appropriate technical expertise. This could be undertaken at ministry level or, where extensive technical expertise is required, by a specialised standards institution or regulatory body. Standards should be clear and unambiguous, achievable by those to whom they apply and, in the case of mandatory standards, practicable to monitor and enforce. Within the field of technical standards, the BREF notes provide guidance on the best available techniques for industrial processes, including aspects of waste management.

5. REGULATION AND ENFORCEMENT

5.1. Overview

Legislation governing waste management is not in itself sufficient to ensure that its objectives are met in practice. In order to be effective, legal measures must be properly administered and enforced, which in turn requires that adequate systems, procedures and resources are deployed for this purpose.

The regulatory function at municipal/local government level consists of three primary tasks:

- issuing licences or permits for waste management facilities and activities;
- monitoring, supervision and inspection to ensure that licence or permit conditions are being adhered to;
- taking enforcement action in case of non-compliance with permit conditions or other provisions of EU waste legislation (as transposed into national system), which should entail effective, dissuasive and proportionate sanctions (normally fines).

A discussion on the competent authorities required to undertake these functions can be found in Section 3 above.

5.2. Licensing/Permitting

Waste management licences/permits are intended to control the facilities and activities authorised by the licence for the purposes of preventing the pollution of the environment, harm to human health and adverse effects upon the amenities of the community. In general, the Waste Directive contains general provisions on the licensing of waste management installations, which should be read in conjunction with the Industrial Emissions Directive. More specific requirements are laid down in the Directives dealing with certain waste management forms, e.g. Landfill Directive, or with certain waste streams. However, in some cases the overarching provisions in the Industrial Emissions Directive apply, which is often the case for larger incineration plants, and for industrial plants producing large quantities of hazardous and/or non-hazardous wastes.

The principal tasks relating to the issuing of licences or permits are:

- licensing of waste storage, treatment and disposal facilities;
- licensing of certain waste recovery facilities/operations;
- licensing/registration of waste collection services and waste brokers;
- registration of exempt facilities and activities;
- assessing and verifying the qualifications and suitability of licence applicants and holders;
- reviewing licences/registrations, and related conditions, on a regular basis; and
- varying, suspending or revoking licences where conditions are breached, or in other specified circumstances.

In general, the licensing of waste management facilities and the registration of related exemptions represents the most demanding task of the competent authority with respect to licensing. Technical judgments and decision making are important elements of the licensing process, which is therefore more than merely an administrative task. It will be necessary, for instance, to provide thorough technical training for waste regulators and inspectors. Environmental enforcement authorities (“environmental inspectorates”) need adequate human and material resources in order to effectively carry out their mandate and achieve their goals. Access to such resources will very much depend on government support, expressed mainly through institutional development and the allocation of finance. Where such support exists, at least partly, the individual competence of staff becomes one of the decisive factors not only for ensuring the effectiveness of current activities, but also for the long-term development needs of environmental compliance assurance systems.

The licensing system should include a tendering procedure which complies with the public procurement Directives. To be effective, licences need to have conditions attached specifying, for example, the types and quantities of wastes permitted to be handled, recycled, recovered, transported or disposed of as well as technical requirements, operating methods, and safety/security precautions. Such conditions should be justifiable, comprehensive in scope, unambiguous and enforceable. They also need to be applied consistently and, for this reason, a common framework for issuing and administering licences should be established through, for example, the development and use of guidelines for the determination of licence applications, and the supervision, revocation and surrender etc. of licences.

In drafting licence conditions, the regulator must endeavour to satisfy two basic objectives. Firstly, the operator should not be unduly constrained from being able to operate in a cost-effective manner. Secondly, the competent authority needs to retain the means of imposing controls which are (a) required by legislation and (b) necessary in the public interest. A good test for the validity of licence conditions is whether they are (i) unambiguous, (ii) necessary, (iii) lawful and (iv) enforceable. In this context, licence conditions are normally of three basic types:

- conditions which set absolute but relatively straightforward obligations and requirements;
- conditions which set absolute environmental performance standards, but which may give the operator some discretion as to how to meet the standards;
- conditions which require the operator to carry out an activity in accordance with an operating or working plan (prepared by the operator).

If a waste management facility or company is totally or partially owned by a local authority, the licensing and monitoring of facilities should be carried out by a separate regulatory authority.

In setting conditions, the competent authority should reflect the interests of other statutory bodies, the public and any other person or group that may be affected by the facility or activity by, for example, publishing details of licence applications and consulting with interested or affected parties. The competent authority should also establish and maintain a public register of waste management licences and related information.

Modifications to licences may take place at the initiative of the competent authority or the licence holder. (Where modifications are necessary to give effect to EU obligations there should be an effective legislative framework to provide for this.) Modification of licence conditions is usually required when changes in a facility or activity will affect the activities authorised by the licence. Where such changes demonstrably achieve or improve upon existing standards, and do not compromise the primary objectives of the licence, the competent authority should generally allow them without requiring modifications to the licence conditions. If changes are

so significant that they might prejudice the primary objectives of the licence, then these should be the subject of modified or new conditions.

Licensing procedures must incorporate minimum requirements regarding the suitability of licence holders, in terms of their technical competence, financial capacity and past record of compliance with environmental legislation. This is a particularly important requirement of the Landfil Directive.

Competent authorities involved in permitting and inspection should consult guidance documents and a manual for permitting and inspections (including monitoring) of waste management operations developed in 2012 within a project “Services to support Member States' enforcement actions and inspections concerning the application of EU waste legislation”. The guidance document is divided into different sections/chapters, especially distinguishing between the level of permitting and the level of inspections. The guidance document is accompanied by a manual. The purpose of the manual is to provide information on a more practical level. The key element of the manual is the provision of 20 best practice examples, elaborated on the basis of existing permitting and inspection practice applied within the EU Member States. Further tools were elaborated to enhance the process of permitting and inspection, i.e. permitting and inspection checklists, Frequently Asked Questions, overview table for legal obligation, letter to advice to announce inspections. Set of guidance and best practice documents which are presented on the following link: <http://ec.europa.eu/environment/waste/framework/inspections.htm>

5.3. Monitoring, Inspection and Enforcement

Monitoring, inspection and enforcement are intended to ensure that those who require a waste licence hold one, and that any conditions attached to the licence are complied with, as well as to ensure that other legal requirements and mandatory standards are being met.

The principal tasks relating to monitoring, inspection and enforcement are:

- monitoring and inspection of licensed waste management facilities;
- monitoring and inspection of waste carriers and brokers;
- monitoring and inspection of exempt facilities and activities;
- monitoring and control of movements of certain types of waste;
- monitoring and control of trans-frontier shipments of waste;
- identification of unlicensed/illegal facilities or activities;
- taking enforcement action in respect of breaches of waste licences and related conditions, and/or other legal requirements/mandatory standards.

The essential features of an effective monitoring, inspection and enforcement regime are:

- legally well-defined inspection and enforcement powers;
- suitably stringent sanctions to encourage compliance;
- sufficient, appropriately qualified and motivated human resources;

- sufficient and appropriate technical resources (equipment, etc.);
- clear, properly documented operational systems and procedures;
- comprehensive systems for storing, recording and retrieving data and information (and also one which provides for public access, with due regard to commercial confidentiality (see here the Access to Environmental Information Directive)).

Without these elements, it is difficult, if not impossible, to give effect to establish policies, legislation and standards governing waste management. As such, this aspect of the regulatory function should be seen as crucial to the achievement of compliance with EU Directives on waste management.

Routine monitoring and inspection of licensed operations should include regular visits by competent authority staff in order, for example, to examine records, take samples of wastes and assess operational performance. In addition to such formal visits, the competent authority should have the right to conduct unannounced inspections. The findings of such inspections should be communicated to the operator in writing as soon as possible. Any breach of licence conditions or other offences should be acted upon immediately, especially if these may give rise to significant pollution or risks to public health. The competent authority should have the requisite powers to amend or revoke licences (with a right of appeal for the licence holder) and, if circumstances demand, to initiate remedial actions. In addition, consideration should be given to granting the competent authority powers to take civil or criminal action for serious infringements of licence conditions or other legal requirements. Penalties should be sufficiently severe to act as a deterrent to the infringement of laws or licence conditions.

In EU Member States, monitoring and inspection of waste management facilities is normally undertaken by the same organisation which is responsible for issuing permits. However, some countries have favoured an independent inspectorate to provide impartiality. In all EU countries, some or all of the costs of inspection and enforcement are recovered through licensing fees and other charges, and revenues generated from the imposition of financial penalties. Furthermore, the permitting, monitoring and inspection functions should be carried out by an authority at a higher level.

The introduction and application of formal environmental management and audit systems to waste-related activities and facilities can help to reduce the overall burden of monitoring and enforcement, for example the EU Eco-Management and Audit Scheme (EMAS) and the EN ISO 14000 series. Such systems and standards are being increasingly applied in the waste management sector throughout the EU.

Guidance on best practices for training and qualifications for environmental inspectors has been developed by IMPEL and OECD for instance:

- IMPEL at: <http://inece.org/resource/best-practices-concerning-training-for-environmental-inspectors/>
- Guidance on individual competence development within environmental inspectorates of Eastern Europe, Caucasus and Central Asia (2011): <http://www.oecd.org/env/outreach/49036523.pdf>

In addition, Candidate Countries can consult the information in INECE Environmental Compliance Inspections Forum available at: <http://inece.org/2010/04/09/updated-resource-page-on-environmental-compliance-inspections/>

5.4. Data Collection and Reporting

A summary of the type of data collection and reporting required under EU waste legislation is provided in the Table below. Procedures and methods for reporting are given in the Reporting Directive (91/692/EEC) and Commission Decision 2000/532/EC, as amended, on the waste catalogue. Further details are also provided in the specific waste acts.

All organisations with responsibilities for reporting should be made aware of their responsibility during the implementation phase. For example, competent authorities should be made aware of their reporting duties while they are being established, and operators of facilities should be made aware of their obligations when they apply for licences/permits.

A large amount of data and information on the quantities and types of waste produced, and facilities for their recovery, treatment and disposal, needs to be collected. The competent authority with responsibility for regulation will generally be best placed to collect this information. Consideration should be given to setting up a suitable database for storing and retrieving such data, which could then be used as a basis for reporting both to the national government and to the Commission. Most EU Member States have opted for the regulatory authority to be the body with responsibility for reporting to the Commission. Other options that could be considered include the ministry, if this is not the regulatory authority, or a central statistical office.

The Commission has issued several Decisions and one Regulation ((EC) 1013/2006) on shipment of waste) concerning the use of questionnaires by Member States to report information:

- Commission Implementing Decision of 18 April 2012 establishing a questionnaire for Member States reports on the implementation of Directive 2008/98/EC of the European Parliament and of the Council on waste
- Commission Decision 2007/151/EC amending Decisions 94/741/EC and 97/622/EC as regards the questionnaires for the report on the implementation of Directive 2006/12/EC of the European Parliament and of the Council on waste and on the implementation of Council Directive 91/689/EEC on hazardous waste;
- Commission Decision 97/622 relates to Directive 2008/98/EC and 94/62/EC (packaging and packaging waste);
- Regulation (EC) No 1013/2006 on shipment of waste: setting out requirements on questionnaire;
- Decision 2000/738/EC: questionnaire for landfills under Directive 1999/31/EC and 2001/753/EC require questionnaires to be used for Directive on ELV (2000/53/EC). The need for questionnaires has arisen due to the significant differences in the format and content of previous reports from the Member States
- Commission Decision 2009/358/EC of 29 April 2009 on the harmonisation, the regular transmission of the information and the questionnaire referred to in Articles 22(1)(a) and 18 of Directive 2006/21/EC of the European Parliament and of the Council on the management of waste from extractive industries
- Commission Decision 2004/249/EC of 11 March 2004 concerning a questionnaire for Member States reports on the implementation of Directive 2002/96/EC of the European Parliament and of the Council on waste electrical and electronic equipment (WEEE) and Commission Decision of 3 May

2005 laying down rules for monitoring compliance of Member States and establishing data formats for the purposes of Directive 2002/96/EC of the European Parliament and of the Council on waste electrical and electronic equipment

- Commission Decision 94/741/EC of 24 October 1994 concerning questionnaires for Member States reports on the implementation of certain Directives in the waste sector

The collection of data will also require inputs from local authorities and waste management operators, as they will be the basic providers of reliable waste data. Therefore, in preparing the waste management strategy, resources should be allocated for this.

Table 10. Examples of reporting requirements in the EU waste legislation

Body Responsible	Receiver of Information	Type of Information
International (EU level)		
European Commission	European Parliament European Council	Report on the implementation of Directives (e.g. 2008/98/EC) Art. 11(4): By 31 December 2014 at the latest, the Commission shall examine the measures and the targets referred to in paragraph 2 with a view to, if necessary, reinforcing the targets and considering the setting of targets for other waste streams. The report of the Commission, accompanied by a proposal if appropriate, shall be sent to the European Parliament and the Council
European Commission	Member States	Report on implementation of Directives across Member States (e.g. 2008/98/EC)
Member States	European Commission	Notification of transposition of legislation and submission of main text of national law (all Directives) Plans and programmes e.g. waste management plans, plans to reduce certain pollutants (e.g. Directives 2008/98/EC, 2006/66/EC, 2006/21/EC) Reports at set intervals e.g. 3 or 5 years, on implementation of Directives (e.g. Directives 2008/98/EC, 86/278/EEC, 2012/19/EU) Reports at set intervals (e.g. 3 years) to prevent and programme reduction in waste (e.g. 78/176/EEC) Information on technical expertise and experience gained in implementing the Directive (e.g. 2008/98//EC) Derogations or delays in implementation (e.g. 2008/98/EC) Information on establishments, waste materials, processes etc (e.g. 2008/98/EC) Decisions to regard certain waste to be waste in accordance with national criteria in the absence of EU level standards (2008/98/EC)
Member States	Member States	Competent authorities have to provide information to competent authorities of other Member States (e.g. 2006/21/EC)
Within Member States		
Member	Public	Public information on storage and collection of wastes (e.g. 2008/98/EC,)

State		Permits (e.g. 94/67/EC)
Competent authority	Public	Information on obligations of Directive, emission limit values (e.g. 2010/75/EU)
Producer and transporter of wastes, operators of waste treatment and disposal facilities	Competent authority	Data on the quantity, quality, nature, origin, destination, frequency of collection, mode of transport, and treatment of wastes (e.g. 2008/98//EC, 86/278/EEC) Exceedances of emission limit values (e.g. 2010/75/EU)
Sewage sludge producers	Users of sewage sludge	Data on sludge (86/278/EEC)

6. PRIORITIES AND TIMING

6.1. Prioritising the Implementation Tasks

5.1.1. Legislative considerations

In preparing their strategies and implementation plans, the candidate countries will need to prioritise the various major tasks to be undertaken. The process of preparing a waste management strategy (Section 3) should determine the existing environmental problems and options for resolving them, the relative costs and benefits of these options, the financial investments and other resources required to implement the selected options, programmes for their implementation, the effects of their implementation on the economy, etc. The priorities and timescales for implementation will therefore need to be established by the candidate countries during this process, and formalised in the implementation plan. The following section identifies some of the issues to be considered in setting key priorities and the factors that will influence the implementation timetable.

Candidate countries must transpose all of the European Directives into national legislation by the date of accession. However, consideration should be given to the order in which the various items of legislation are transposed. Implementation of the Waste Framework Directive must be given a high priority, as these provide the structure and foundation for the specific legislation focusing on specific waste streams or waste processes. Furthermore, the Waste Framework Directive should be prioritised and programmed in conjunction with key legislation in other sectors e.g. Industrial Emissions Directive (2010/75/EU), Water Framework Directive (2000/60/EC), Air Quality Framework Directive (2008/50/EC), and Reporting Directives. Also, the implementation of the Urban Waste Water Treatment Directive (91/271/EEC) needs to be programmed in conjunction with legislation governing waste management so that acceptable disposal routes for sludge are available prior to the commissioning of new (or upgraded) wastewater treatment plants. Legislation implementing international treaties should be given a higher priority where applicable, e.g. the legislation on transboundary movement of wastes. Consideration should also be given to providing a robust legal framework allowing for amendments to legislation and, where necessary, to environmental permits, in order to ensure the easier and swifter implementation into national law of EU law obligations, and compliance thereafter with such obligations.

5.1.2. Environmental considerations

As landfilling is the most commonly used and widespread method of waste disposal in the candidate countries, and poorly designed and managed and/or inadequately controlled landfill sites can cause significant pollution and other environmental hazards, it may be considered more appropriate to concentrate initially on implementing policies and legislation aimed at improving and controlling the standards and practices for landfilling in preference to other methods of waste treatment and disposal. Measures to mitigate the impacts of existing and old landfills and those to establish new landfills are both very expensive. Candidate countries will need to determine which option would be the most effective and efficient.

As regards incineration, a number of long-term effects of incineration should be taken into consideration: effects on waste minimisation (incinerators should operate at full capacity to make the investment feasible); and effects on landfill planning (incineration reduces the volume of solid waste but creates toxic residues that need

safe disposal). Planning has to ensure that prevention (minimisation of the generation of waste) and recycling (including composting) are given priority over other options.

5.1.3. Prioritisation and cost-effectiveness

Legislation intended to implement measures which have the ability or potential to achieve the greatest environmental benefits per unit of cost or expenditure should usually be given a higher priority than legislation with lower anticipated cost-benefit ratios. However, legislation which is likely to require major investments in new facilities should not be ignored or postponed, as the candidate countries will need to plan for their development, financing and construction, and prepare the public and industry for their eventual introduction. The new generation of EU environmental law from 2000 onwards increasingly focus on cost-effectiveness issues and for instance the Industrial Emissions Directive and the Waste Framework Directive merge existing, individual pieces of EU legislation into the framework of one piece. This increases cost-effectiveness as well as transparency.

Study published by the Commission shows that full implementation of EU waste legislation would save €72 billion a year, increase the annual turnover of the EU waste management and recycling sector by €42 billion and create over 400,000 jobs by 2020. Illegal waste operations or missing infrastructure in Member States are causing missed opportunities for economic growth, which we cannot afford, and leading to environmental threats. It is therefore paramount to take decisive steps to bridge the implementation gap in waste management and move towards a resource efficient society¹⁴⁶.

5.1.4. Economic considerations

The candidate countries need to consider which items or aspects of legislation are likely to have significant consequences for their economies. Legislative requirements affecting commercial and industrial sectors that make a major contribution to the economy should be addressed before those relating to small or non-existent industries. For example, all of the candidate countries will need to address the disposal of waste batteries and accumulators, packaging, waste electrical and electronic equipment, discarded vehicles, PCBs and PCTs, asbestos waste and sewage sludge. However, not all candidate countries have a significant titanium dioxide industry, a mining industry or generate large quantities of waste oils or metallic waste. Legislation introducing producer responsibility for certain waste streams such as packaging and packaging waste, end-of-life vehicles, electronic and electrical equipment in particular requires major changes in approach to the manufacture, distribution and consumption of packaging materials across all economic sectors, and the achievement of quantified targets for recycling and reduction of packaging waste. Producer responsibility legislation shifts the responsibility and burden of costs for waste management from municipalities to producers (e.g. manufacturers, retailers and suppliers). By facing this additional financial burden, producers tend to take a more cost-efficient approach, which makes economic sense but does not always guarantee the best environmental results.

The European Union and various national governments provide financial assistance for waste management projects in candidate countries -- for example, the EU's IPA instrument. In developing their waste management

¹⁴⁶ Source: "Implementing EU legislation for green growth", final report of 29 November 2011, available at: <http://ec.europa.eu/environment/waste/studies/pdf/study%2012%20FINAL%20REPORT.pdf>.

strategies, candidate countries should investigate these sources of finance as well as look to positive, cost-efficient examples from the current Member States.

5.2. Timescales

In principle, candidate countries must implement and comply with waste management legislation. Possible transitional periods will be subject to the enlargement negotiations between each candidate country and the EU. Implementation tasks that will tend to be especially time-consuming are:

- Developing and approving waste management strategies and implementation plans;
- Developing appropriate institutional arrangements, with competent authorities, adequate human and financial resources and coordination mechanisms;
- Developing tools for regulation, monitoring, and enforcement, which might require changes to the sanctioning system;
- Planning, designing and constructing new infrastructure and facilities, including waste management collection, recycling and disposal facilities. These include cost-intensive installations such as landfills and incineration plants;
- Providing permits for new infrastructure and facilities, and inspection and supervision of all existing ones.

There may be instances where implementation of a specific requirement cannot be achieved by the date of accession, for example due to the long lead times associated with planning, financing and constructing certain types of waste treatment or disposal facility. The negotiation of appropriate transitional arrangements with the Commission, such as extended periods for implementing and achieving compliance with specific requirements of EU legislation has to be based on well-defined and justified requests and detailed, tight, economically feasible and legally binding implementation plans, the putting into effect of which already has to start during the pre-accession period. New investments in waste management infrastructure and facilities in candidate countries should be in line with the environmental acquis upon accession, particularly those investments receiving funding from the EU.

6. ECONOMIC AND FINANCIAL ISSUES

6.1. Introduction

This section provides guidance on economic and financial issues relating to the implementation of legislation on waste. The first two subsections indicate the types of costs that will be incurred during implementation, while the last two subsections discuss cost recovery and the use of economic tools. Examples of unit costs related to specific items of legislation are provided in the fiches where appropriate.

6.2. Institutional Development

Implementation of the waste Directives will require the training of staff. Without sufficient and suitably trained staff, systems for waste management planning, regulation and enforcement cannot be effectively implemented. It is therefore important to ensure that adequate budgets are provided to enable the responsible institutions to perform their functions effectively. Salaries need to be set at levels that enable staff with the necessary experience and training to be attracted and retained. A training needs assessment should be carried out to ensure that, once staff are recruited and working, any skills deficiencies can be remedied within a reasonable period of time.

Human resources are required for:

- developing and setting environmental/technical standards and guidelines;
- waste management strategy development and implementation planning at central and local levels;
- issuing licences/permits;
- supervision, monitoring and inspection of waste management facilities and activities;
- initiating and pursuing enforcement actions; and
- data collection, analysis and reporting.

It is not possible to generalise on the costs of establishing the institutional structure, which will depend on the size of country, the degree of industrialisation, the choice of organisational structure and local salary levels. The aspects that are likely to incur the greatest incremental costs, to the extent that they are not already available, are:

- additional professional and technical staff (and their training/development);
- acquisition of the necessary sampling and monitoring equipment;
- laboratory testing and analytical services; and
- data collection, storage, analysis and reporting.

6.3. Facilities

It will be necessary to upgrade the quality and environmental performance of existing facilities and ensure that new facilities are provided to the environmental standards that have been set as part of the national policy and strategy. Finance needs to be raised for capital investment expenditures and the recurrent costs incurred during operations. Ultimately, the full costs of facility provision and operation should be recovered from waste producers. Finance should preferably derive from the private sector, normally in the context of producer liability legislation. However, neither industry nor the public sector can be expected to provide such finance without having first established an adequate cost-recovery system based upon sound legislation (see Section 7.4 below), and a fool proof regulatory system which does not permit competitors, from the public or private sectors, to operate at lower standards. The capital for facilities for municipal waste management may initially need to be financed (or co-financed) by the municipalities themselves, especially for "historic" waste (e.g. where producers marketed products prior to the date of entry into force of producer responsibility legislation). However, it is expected that municipalities will bear the main financial burden for specific waste streams such as organic waste, household chemicals and medical waste for a considerable time to come.

The costs incurred in establishing new facilities will depend on the number, type and capacities of the additional facilities required. Indications of approximate unit costs for new waste management facilities of different types in existing Member States are given in the appropriate fiches. The actual costs will depend, inter alia, on the technologies selected, local conditions and economies of scale and, especially for landfill, on the costs of acquiring suitably located land for which the necessary permits can be obtained.

A study prepared on behalf of DG ENV¹⁴⁷ has identified that the capital investment required for the ten Member States in order to comply with EU waste management legislation for their accession in 2004 was between EUR 9.7 and 22.7 billion. The lower estimate is based on a scenario with extensive landfilling while the higher estimate is based on optimum re-use and recycling. A number of more detailed studies have also been produced, although they may not be directly comparable. A study on the costs of implementing EU waste management legislation in Slovakia¹⁴⁸ estimated the total capital costs (net present value in 1999 at 5%) to be EUR 1.17 billion. A study on the costs of environmental approximation in Poland¹⁴⁹ shows a total investment requirement for waste management of EUR 3.695 billion. A similar study for Latvia¹⁵⁰ shows capital costs of EUR 237.9 million. The last two studies only estimate the impact of the hazardous waste and landfill Directives, which have the greatest cost impact. Also, the 2001 report¹⁵¹ from the Danish Environmental Protection Agency gives good examples of the costs that the new Member States faced in their transposition and implementation of the EU waste management legislation. During the negotiations Croatian authorities estimated the costs of compliance with the waste management legislation to be EUR 982 mil. (estimated costs refer to restoration of existing landfills and construction of waste management facilities). The EU and various national governments provide financial assistance for waste management projects, including the development

¹⁴⁷ Compliance Costing for Approximation of EU Environmental Legislation in the CEEC, EDC Limited, May 1997

¹⁴⁸ Provision of Technical Assistance in the Approximation of Waste Management legislation in the Slovak Republic

¹⁴⁹ DISAE project SR-104. Halcrow Group Limited, February 1999.

¹⁵⁰ Costing and Financial Analysis of Approximation, DISAE project POL-101. AgriConsulting Europe, June 1998 103
Development of the Latvian Approximation Strategy and Programme, DISAE Project LAT-103. Halcrow Group Limited, July 1998

¹⁵¹ "The Environmental Challenge of EU Enlargement in Central and Eastern Europe", report obtainable on the web at http://www.mst.dk/udgiv/Publications/2001/87-7972-044-7/html/default_eng.htm

of appropriate institutional frameworks, e.g. Regional Development Operational Programme (IPA) and European Regional Development Fund (ERDF). In developing their waste management strategies, candidate countries must investigate these sources of finance. However, candidate countries should strengthen their organisational structures, especially at local level, in order to be able to use available EU funds. Experience has shown that organisational weakness, bureaucracy, lack of expertise may impede use of financial sources reserved for these countries.

6.4. Cost Recovery

There are two important aspects of financing to be considered with any waste management strategy and implementation plan. These are:

- how to finance capital investment expenditure for the provision of waste management facilities and equipment; and
- how to finance the recurrent costs incurred during operation.

Accordingly, a policy for recovering the costs of waste management needs to determine the total amount of recurrent funding needed each year and how this will be provided.

The minimum amount of recurrent funding required will be that which is necessary to finance the direct operating expenditures and any debt service obligations incurred in providing a facility or service — i.e. sufficient revenues must somehow be generated to cover annual cash outflows. If the objective is for the facility or service to become self-financing, then it will also be necessary to generate and set aside funds sufficient to maintain asset values, finance long-term liabilities and provide a return on investment.

The full costs of providing waste management services are substantial and rising in real terms.

As these costs have risen, so governments in Member States have become increasingly reluctant to allow these costs to be met from central or local government taxation. In line with the polluter pays principle, most Member States have already reduced or eliminated any subsidies for waste management, whilst the remainder are in the process of doing so. This has meant that organisations directly responsible for the provision of waste management facilities and services have been obliged to move towards a position where their service charges recover the full costs of the services provided.

There are two broad ways of recovering the costs of waste management:

- user charges, where a charge is paid (directly or indirectly) by the users of a specific service, e.g. waste collection, treatment or disposal; and
- earmarked charges, levied, for example, on a specific product or activity, and where the resulting revenues are earmarked for expenditure on waste management-related purposes such as to finance the provision of waste recycling facilities (see Section 7.5 below).

Charging waste producers for the management of their wastes, at a fixed rate and/or at a variable rate related to the quantity or quality of wastes produced, is now almost universal throughout the EU. Typically, householders are charged a fixed rate for their waste management services, while commercial and industrial waste charges are usually weight or volume related. However, EU municipalities are increasingly turning to

variable rate charging (or a combination of fixed and variable rate charging) for the management of domestic and similar wastes. Methods of variable charging range from simply setting a price for refuse sacks or labels, to sophisticated systems where waste containers incorporating micro-chips are able to relate the container to its owner (allowing the producer of the waste to be billed accordingly). Most of these financial mechanisms aim at creating incentives for waste minimisation and at municipal waste separation and recycling, such as "pay per garbage bag" or more favourable waste management charges for less frequent waste collection (e.g. every two weeks).

Whichever charging methods are used, progressively raising user charges for waste management to levels which reflect the true long-term costs of managing wastes in a legally compliant and environmentally safe manner (known as long-run marginal costs — LRMC) is potentially the single, most effective policy measure open to the candidate countries for encouraging the reduction of wastes requiring disposal and for ensuring that the necessary facilities and services are provided.

It should be appreciated that LRMC pricing implies not just aiming to recover the full costs of current waste management facilities and services, but setting charges at levels which reflect the full costs of providing future facilities and services that comply with current and impending EU environmental legislation. Currently, certain waste management activities and services in the candidate countries, particularly for the management of municipal solid wastes, are effectively subsidised. This tends to create distortions in the market for waste management services and to discourage the development of environmentally desirable attitudes and patterns of behaviour amongst waste producers.

Although desirable, applying such a policy is not simple in practice and would need to consider, inter alia, such factors as:

- the state of the economy;
- public acceptability;
- affordability, particularly for the poorer members of society; and
- the enforcement capacities and capabilities of the regulatory authorities.

Nevertheless, a policy of progressively increasing prices for waste management services and facilities in real terms (i.e. over and above the general rate of inflation) and removing market distortions is probably unavoidable if the candidate countries are eventually to achieve full compliance with EU waste legislation.

6.5. Application of Other Economic Tools

The use of economic tools or instruments in environmental policy has long been promoted by economists as a (potentially) more efficient way of achieving environmental goals. Environmental costs are usually underestimated and often not internalised and therefore constitute external costs to society as such. It is essential to take into account environmental concerns when calculating the costs of implementing waste management strategies. For example, the costs of establishing new landfill sites would need to include the costs of mitigating measures to protect the environment. The major advantage of economic tools is that, in theory, they incorporate environmental concerns and costs directly into the market price mechanism and therefore possess all the efficiency properties of competitive market pricing. The efficiency properties of economic tools,

however, depend crucially on (a) the flexibility and effectiveness of other related environmental policy instruments, and (b) marginal cost differentials for different waste management/pollution abatement options.

The implementation phase of new economic tools can often bring surprises. The need to carry out detailed research and assessment studies in order to understand complex economic and business linkages is sometimes recognised only after the first phase of implementation. This underlines the importance of proper preparation, even if the political climate seems to offer the opportunity for the rapid introduction of a new economic tool. Ideally, the design and application of such tools should satisfy the following criteria:

- Economically efficient — it should interfere as little as possible with well-informed resource allocation decisions in competitive markets, and provide a continuous incentive for seeking least-cost solutions;
- Environmentally effective — it should be aimed at mitigating specific pollution or resource usage problems;
- Fair — it should not be significantly regressive, i.e. it should not impose a disproportionate cost burden on the least-well-off members of society;
- Administratively cost-effective — it should involve low administrative and compliance costs;
- Compatible — it should be compatible with other European and national legislation and policies;
- Financially effective — it should be able to generate appropriate amounts of revenue for financing necessary expenditures.

Some examples of economic tools applied within the EU are given below.

Examples from a Member State

Waste disposal taxes/levies have been introduced in several EU Member States, most commonly for the landfilling of wastes. The basic aim of such taxes/levies is to discourage the disposal of wastes and thus promote waste management options that are higher up the waste management hierarchy, such as waste reduction and recycling. The revenues from such taxes are frequently earmarked for specific related purposes. A potential concern associated with such taxes is that they may have the unwanted effect of increasing the incidence of illegal disposal practices. Note that under Article 10 of the Landfill Directive, a duty is imposed on Member States to ensure that the operator of a landfill site charges "full costs" for setting up, running, closing and aftercare related to that landfill site.

Product charges (or input charges) are added to the price of certain products that are considered to cause adverse environmental effects during their manufacture, use or disposal. Such charges can be found in most EU countries. Examples include disposable razors, disposable cameras, batteries, beverage packaging, paper and plastic bags, virgin construction materials, disposable plates and cutlery, and plastic window and door frames.

Deposit refund schemes entail the application of a surcharge or deposit on certain products, where a partial or total refund may be made when specified conditions are met. These schemes have been used for many years and are widely applied in EU Member States, particularly for beverage containers and, more recently, packaging waste. Some are mandatory whilst others involve voluntary producer responsibility schemes — an example is the German "green dot" scheme for packaging wastes, where the manufacturers of packaging products have established a nationwide system for collecting and recovering packaging wastes bearing a green dot. A tax may be levied on drinks containers if they are not part of a deposit refund system, if they are not reusable, or if a minimum percentage is not recycled. This has resulted in a significant increase in the use of deposit refund systems during the last decade. These schemes are generally very effective and may achieve as

much as an 80 to 100% return of waste packaging and used containers. An example of quite a radical solution in this regard is to be seen in the End-of-Life Vehicles Directive 2000/53/EC. Tradeable permits could be used for waste generation but there are currently no such schemes operating across the EU. However, the UK has introduced a system of tradeable certificates for packaging recycling/recovery, which serve to confirm the achievement of recycling and recovery targets for packaging wastes. The UK is also in the process of launching a system for landfills with the main aim of bolstering the implementation of the Landfill Directive (1999/31/EC), which may be of interest to candidate countries.

The UK's Waste and Emissions Trading Act, adopted in 2003, requires local authorities to progressively reduce the amount of biodegradable waste going to landfill. This will be achieved by setting tradeable landfill allowances so that councils with low landfill rates can sell their unused landfill allowances to councils with high landfill rates.

The new legislation requires each of the territories of the UK to produce a strategy to reduce the amount of biodegradable waste which may be sent to landfill. Tying in with the Landfill Directive, the new law will see each of the four UK nations setting their own annual targets for the amount of biodegradable material going to landfill. The allowances that will be given to waste disposal authorities will be calculated so that the system will be able to reach the directive's targets in 2010, 2013 and 2020. Those unable to get away from high landfill rates need to buy landfill allowances from authorities with low landfill rates.

It is envisaged that this system will enable authorities in cheap landfill areas to make reductions in their own landfilling while selling permits to areas where landfill may be more expensive. There is also a certain scope in the bill for landfill allowances from one year to be used in a different year. Landfill allowances will not be tradeable by anyone other than waste disposal authorities. The Environment Agency will monitor the system throughout the UK.

It remains to be seen whether such trading schemes might hinder the development of efficient waste management in the relevant areas by providing an easy way out for local communities willing to pay the price for extra capacity. If such a system were compatible with EU waste management law and the TFEU as a whole, it might prove of interest for a EU-wide scheme.

7. SUMMARY OF KEY ISSUES

Achieving and maintaining compliance with EU policies and legislation on waste management presents a major challenge for the candidate countries. In order to minimise the associated administrative burden and costs, this challenge needs to be managed in a systematic and cost-effective manner. With this in mind, the governments of the candidate countries should endeavour to focus their efforts and actions on addressing those issues and requirements that are fundamental to EU approximation in this sector, in particular by ensuring that:

- the totality of policies, legislation, legal mechanisms and standards adopted at the national level achieve the objectives and results aimed at by EU policies and legislation;
- a single national government agency is given the overall responsibility and requisite authority for planning and managing the process of achieving compliance with EU policies and legislation;
- a strategy and detailed plan for the future management of wastes is prepared and implemented;
- arrangements are put in place for the effective involvement and participation of all other bodies or interest groups that have a significant role or function to perform in relation to waste management;
- appropriate competent authorities are designated or established, and their respective duties, functions and powers are clearly defined;
- sufficient human and technical resources are allocated to allow all key functions and tasks to be performed properly, especially those relating to regulation and enforcement;
- the resources and expertise of the private sector are mobilised and utilised in appropriate ways.

A well-prepared, integrated strategy provides the means by which these and all other significant issues relating to waste management can be systematically identified and addressed. A checklist of the key questions that should be considered in preparing and implementing such a strategy is presented in Table 11 below.

Table 11. Checklist with key questions to be considered in preparing and implementing a waste management strategy

<p>Is there sufficient, comprehensive knowledge and understanding of the existing arrangements, methods and practices for managing wastes, in particular concerning:</p> <ul style="list-style-type: none"> • sources, types, and quantities of wastes now and in the future? • existing waste management systems and facilities? • existing health risks/environmental impacts of waste management? • existing legislative, institutional and regulatory requirements/arrangements?
<p>Have all the significant problems/deficiencies associated with the existing arrangements and practices for managing wastes, and their underlying causes and effects, been identified, defined and systematically analysed, in particular problems or deficiencies in:</p> <ul style="list-style-type: none"> • the legislative/institutional/regulatory framework? • available data on the origins and fate of wastes? • waste management practices and facilities? • communications with key stakeholders?
<p>Do the strategic policies and objectives for the future management of wastes address each of the problems or deficiencies identified, and have these objectives been translated into measurable and verifiable indicators?</p>
<p>Have the measures/actions selected for achieving the strategic objectives been arrived at after a thorough assessment of all available options against clearly stated criteria, in particular:</p> <ul style="list-style-type: none"> • legislative/institutional/organisational options?

<ul style="list-style-type: none"> • environmental/technical options? • economic/financial options? • social/communicative options?
<p>Does the resulting strategy contain all of the elements and requirements for accomplishing the overall goal (i.e. compliance with EU policies and legislation) and subordinate objectives for waste management, in particular?</p> <ul style="list-style-type: none"> • a policy statement? • strategic principles and criteria? • key data and underlying assumptions? • a description of the main elements/features of the strategy? • specific measures and programmes for achieving the overall goal and objectives? • estimates of the human, financial and other resources required to implement the strategy?
<p>Is there a comprehensive and detailed plan for implementing the final strategy, providing, in particular?</p> <ul style="list-style-type: none"> • definitions of all key tasks necessary for implementing the adopted strategy? • allocation of responsibilities for key implementation tasks? • key implementation decision points and milestones? • detailed timetables for implementation? • detailed resource/cost estimates? • cash flow projections and a detailed financing plan?
<p>Have arrangements and supporting systems been established for monitoring and periodically reviewing progress in implementing the strategy, and rectifying any shortcomings or difficulties?</p>

The candidate countries should benefit from the experience gained within a compliance-promotion exercise launched by the Commission in 2013. It aimed at assessing and monitoring the implementation of EU waste legislation as well as providing technical guidance and recommendations to support Member States. So far 17 Member States, starting with the less performing countries, were covered by the exercise. The key recommendations discussed with Member States within the 2013-2015 compliance promotion exercise is given in the box below.

Table 12 Experience gained within a compliance-promotion exercise (2013-2015)

<p>Key recommendations discussed with Member States during the 2013-2015 compliance promotion exercise include:</p> <ul style="list-style-type: none"> - Introduce and gradually increase charges on landfill/MBT/incineration. Revenues from these charges should be used to support separate collection, awareness raising and the creation of modern infrastructure, focusing on prevention, re-use and recycling. - Establish/improve and control separate collection systems. - Expand systems for door-to-door separate collection schemes as soon as possible and undertake pilot projects on separate collection to develop solutions for local circumstances. - Initiate/intensify awareness-raising and information designed for different target groups. - Reform administrative structures and procedures to simplify administration of waste management, e.g. bundle capacities via inter-municipal associations and harmonise systems in place by providing guidelines on administrative and practical approaches. - Support local authorities in setting up separate collection schemes (by incentives and/or penalties) and other central tasks (e.g. tendering procedures).
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- Extend and improve the monitoring and transparency of existing EPR schemes via better inspection and enforcement activities, accompanied by guidance.
- Update national and regional WMPs including measures on how to achieve legally binding targets and objectives.
- Enforce national strategies on bio-waste management.
- Revise statistics by aligning reporting to EUROSTAT guidelines.
- Use EU funding to finance infrastructure and initiatives related to the first steps of the waste hierarchy.

Source: COMMISSION STAFF WORKING DOCUMENT Implementation Plan Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2008/98/EC on waste Proposal for a Directive of the European Parliament and of the Council amending Directive 94/62/EC on packaging and packaging waste Proposal for a Directive of the European Parliament and of the Council amending Directive 1999/31/EC on the landfill of waste Proposal for a Directive of the European Parliament and of the Council amending Directives 2000/53/EC on end-of-life vehicles, 2006/66/EC on batteries and accumulators and waste batteries and accumulators, and 2012/19/EC on waste electrical and electronic equipment SWD/2015/0260 final - 2015/0275 (COD)

WASTE FRAMEWORK DIRECTIVE

Official Title: Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008)

Amended by:

Commission Regulation (EU) No 1357/2014 of 18 December 2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives (OJ L 365, 19.12.2014)

Commission Directive (EU) 2015/1127 of 10 July 2015 amending Annex II to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives (OJ L 184, 11.7.2015)

2000/532/EC: Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (OJ L 226, 6.9.2000) as last amended by:

Commission Decision 2014/955/EU of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council Text with EEA relevance (OJ L 370, 30.12.2014)

Commission Decision 2007/151/EC amending Decisions 94/741/EC and 97/622/EC as regards the questionnaires for the report on the implementation of Directive 2006/12/EC of the European Parliament and of the Council on waste and on the implementation of Council Directive 91/689/EEC on hazardous waste (OJ L 67, 7.3.2007)

Commission Implementing Decision of 18.4.2012 C(2012) 2384 final establishing a questionnaire for Member States reports on the implementation of Directive 2008/98/EC of the European Parliament and of the Council on waste

Repealed: Council Directive 75/439/EEC of 16 June 1975 on the disposal of waste oils, Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste and Council Directive 91/689/EEC on hazardous waste

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Directive 2008/98/EC, which was adopted on 19 November 2008, entered into force on 12 December 2008 and repealed three main waste Directives as from 12 December 2010; i.e. Directive 2006/12/EC on waste, Directive 91/689/EEC on hazardous waste and Directive 87/101/EEC on waste oils. The Waste Directive, which stems back to 1975 (Directive 75/442/EEC) established a framework for the management of waste across the EU. The Directive is closely linked to the objectives of the EU Waste Strategy, which have as its main objectives:

- decoupling economic growth from environmental impacts;
- waste prevention;
- moving towards a recycling society;
- promoting the use of waste to produce energy;
- better implementation of waste legislation.

Directive 2008/98/EC sets the basic concepts and definitions related to waste management, such as definitions of waste, recycling, and recovery. It explains when waste ceases to be waste and becomes a secondary raw material (so called end-of-waste criteria), and how to distinguish between waste and by-products. The Directive establishes basic waste management principles: it requires that waste be managed without endangering human health and harming the environment, without risk to water, air, soil, plants or animals, without causing a nuisance through noise or odours, and without adversely affecting the countryside or places of special interest. Waste legislation and policy of the EU Member States shall apply as a priority order the following waste management hierarchy:



Some main elements of the new Directive, which largely aims at simplifying and consolidating existing legislation:

- Introduces a new approach to waste management which focuses on prevention, where Member States have to establish waste prevention programmes no later than 12 December 2013;
- Lays down a five-step hierarchy of waste management options which must be applied by countries when developing their national waste policies. It further clarifies the notions of recovery, disposal, end of waste status and by-product. In this respect, the new legislation considers energy-efficient waste

incineration a recovery operation, provided that it complies with certain energy-efficiency criteria. Also the Directive introduces an approach in considering the waste hierarchy that takes into account the whole life cycle of products and materials and not only the waste phase;

- Ensures that the development of waste legislation and policy is a fully transparent process, observing existing national rules about the consultation and involvement of citizens and stakeholders;
- Take into account the general environmental protection principles of precaution and sustainability, technical feasibility and economic viability, protection of resources as well as the overall environmental, human health, economic and social impacts;
- Defines the conditions for mixing hazardous waste;
- Provides for measures to encourage the separate collection of bio-waste with a view to the composting and digestion of bio-waste;
- Requires EU countries to take measures in terms of control of hazardous waste;
- Strengthens the measures that must be taken in regard to waste prevention;
- Strengthens the promotion of introducing producer responsibility for new waste streams (e.g. waste oils) to strengthen the re-use and the prevention, recycling and other recovery of waste, countries. Such responsibility will cover any natural or legal person who professionally develops, manufactures, processes, treats, sells or imports products (producer of the product);
- Emphasizes the importance of reducing the environmental impacts of waste generation and waste management, thereby strengthening the economic value of waste;
- More precisely delimits the scope of application for specific waste streams such as animal waste, as well as in distinguishing between the preliminary storage of waste pending its collection, the collection of waste and the storage of waste pending treatment;
- More precise in relation to long-term storage covered by Directive 1999/31/EC on the landfill of waste.

Excluded waste streams include gaseous effluents, radioactive waste, mineral waste, animal carcasses and agricultural waste, wastewater, mining wastes, and decommissioned explosives subject to specific acts.

The abandonment, dumping or uncontrolled disposal of waste is prohibited. Waste prevention, recycling and processing for re-use must be promoted. Member States shall inform the Commission of any draft rules on the use of products giving rise to technical difficulties and excessive disposal costs and encouraging a reduction in the quantities of certain wastes; the treatment of wastes for recycling or re-use; the use of energy from certain waste; and the use of natural resources that may be replaced by recovered materials.

Any undertakings or establishments treating, storing or tipping waste on behalf of third parties must obtain a permit from the competent authority relating, in particular, to the types and quantities of waste to be treated, the general technical requirements and the precautions to be taken.

The competent authority periodically checks that the conditions of the permit are being complied with and monitors undertakings that transport, collect, store, tip or treat their own waste or third parties' waste. Permits are also required for any recovery centre and undertaking disposing of its own waste.

Member States have to designate competent authorities. These authorities have to carry out several measures including:

- Draw up one or more management plans relating, in particular, to the types, quantities and origins of the wastes to be recovered or disposed of, the general technical requirements, any special arrangements for particular wastes, and suitable disposal sites and installations;
- Establish an integrated and adequate network of disposal installations;
- Co-operate with competent authorities in other Member States with a view to establishing an integrated and adequate network of disposal installations (taking account of the best available technologies), enabling the EU and each individual Member State to become self-sufficient in waste disposal. This network should enable waste to be disposed of in one of the nearest appropriate installations, so as to guarantee a high level of environmental protection.

Directive 2008/98/EC had to be transposed by 12 December 2010. However, it sets some targets for the future:

- By 2015, separate collection shall be set up for at least the following: paper, metal, plastic and glass;
- By 2020, the preparing for re-use and the recycling of waste materials such as at least paper, metal, plastic and glass from households and possibly from other origins as far as these waste streams are similar to waste from households, shall be increased to a minimum of overall 50% by weight;
- By 2020, the preparing for re-use, recycling and other material recovery, including backfilling operations using waste to substitute other materials, of non-hazardous construction and demolition waste excluding naturally occurring material defined in category 17 in the list of waste shall be increased to a minimum of 70% by weight;
- By 31 December 2014 the European Commission shall examine the measures and the targets referred to in the Directive with a view to, if necessary, reinforcing the targets and considering the setting of targets for other waste streams.

The Waste Directive should also be read in conjunction with Decision 2000/532/EC establishing a list of wastes (the so-called waste catalogue). This Decision establishes the classification system for wastes, including a distinction between hazardous and non-hazardous wastes. It is closely linked to the list of the main characteristics which render waste hazardous contained in Annex III to the Waste Framework Directive above. From 1 June 2015, waste classification is based on:

- Commission Decision 2014/955/EU of 18 December 2014, amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European parliament and of the Council
- Commission Regulation (EU) No 1357/2014 of 18 December 2014, replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives.

In addition, Commission Decision 2007/151/EC, amending Decisions 94/741/EC and 97/622/EC as regards the questionnaires for the report on the implementation of Directive 2006/12/EC of the European Parliament and of the Council on waste and on the implementation of Council Directive 91/689/EEC on hazardous waste sets out the questionnaires for the report on the implementation of the Directive. In 2012, the Commission adopted Commission Implementing Decision of 18 April 2012 establishing a questionnaire for Member States reports on the implementation of Directive 2008/98/EC of the European Parliament and of the Council on

waste. First implementation report covers the period from the date of transposition of Directive 2008/98/EC, i.e. from 12 December 2010, until the end of the three-year reporting period, i.e. until 31 December 2012.

The European Commission adopted in 2015 Circular Economy Package, which includes revised legislative proposals on waste to stimulate Europe's transition towards circular economy. The legislative proposals on waste include proposal to amend the Waste Framework Directive 2008/98/EC. The main elements of the proposals are alignment of definitions, new targets for preparing for recycling and re-use, strengthened requirements for extended producer responsibility schemes, new measures to promote prevention, simplified reporting provisions, introduction of the early warning systems for monitoring compliance with the recycling targets.

More information on the proposed amendments can be found at:

http://ec.europa.eu/environment/waste/target_review.htm.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Establish, or designate, competent authorities responsible for the implementation of the Directive.
- Ensure that competent authorities draw up waste management plans, also comprising the management of hazardous waste, and make these plans public. (Waste Framework Directive, Art. 28)
- Member States must establish a date by which hazardous waste operators and other facilities generating qualifying quantities of hazardous waste must report on the quantities, pollutants, monitoring data, emission factors and other methods etc. For the first reporting year (2007), the Member States should have the information in sufficient time to be able to submit a full report to the Commission by 31 June 2009 (Art. 7(1), Regulation (EC) 166/2006 on the European Pollutant Release and Transfer Register).
- Draw up waste prevention programmes by 12 December 2013 and further:
 - introduce a mechanism to ensure that they are evaluated at least every six years and evaluated as appropriate;
 - decide whether it is more effective to integrate these programmes into the waste management plans and general environmental policies or to treat them as separate programmes;
 - clearly describe the waste prevention objectives and measures;
 - describe existing measures and evaluate these against the measures set out in Annex IV of the Directive or other relevant measures. (Waste Framework Directive, Art. 29)
- Plan measures to:
 - prevent and reduce the amount of waste produced and its harmfulness;
 - ensure that waste is managed without endangering human health and harming the environment, and in particular without risk to water, air, soil, plants or animals, without causing a nuisance through noise or odours, and without adversely affecting the countryside or places of special interest;
 - take into account the general environmental protection principles of precaution and sustainability, technical feasibility and economic viability, protection of resources as well as the overall environmental, human health, economic and social impacts;
 - adhere to the waste management hierarchy and encourage the recovery of waste, including recycling, re-use or reclamation, and the use of waste as a source of energy;
 - take measures to encourage the options that deliver the best overall environmental outcome, which may lead to specific waste streams departing from the hierarchy where this is justified by life-cycle thinking. (Art. 4, Waste Framework Directive)

- Ensure transparency in developing waste legislation and policy involving citizens and stakeholders. (Art. 4(2), Waste Framework Directive)
- Take a comprehensive approach to implementation of the Waste Framework Directive, ensuring that also waste oils and hazardous waste are dealt with in the same policy and legal framework.
- Consider whether to introduce additional measures to promote separate collection of waste oils and their proper treatment in the form of technical requirements, producer responsibility, economic instruments or voluntary agreements. (Art. 21(3), Waste Directive). In case these measures call for regeneration of waste oils where technically feasible, Member States may restrict transboundary shipment of waste oils from their territory to incineration facilities to give priority to regeneration. (Art. 21(2), (3), Waste Framework Directive)
- Plan measures to ensure that the recycling and recovery targets are met including the new targets to be achieved by 2020 (i.e. 50% preparing for re-use and recycling of certain waste materials from households and other origins similar to households, and 70% preparing for re-use, recycling and other recovery of construction and demolition waste). (Art. 11(2), Waste Framework Directive)
- Plan measures to promote separation collection of bio-wastes.
- Develop qualitative and quantitative benchmarks for waste prevention measures adopted to facilitate their monitoring and evaluation. Such benchmarks can be in the form of targets and indicators. (Art. 29(3), Waste Framework Directive)
- Ensure that any original waste producer or other holder carries out the treatment of waste himself or has the treatment handled by a dealer or an establishment or undertaking which carries out waste treatment operations or arranged by a private or public waste collector in accordance with Articles 4 and 13. (Art. 15, Waste Framework Directive)
- Consider whether to make producers responsible for their products as waste for categories additional to those where producer responsibility already exists (e.g. WEEE, ELV, packaging). (Art. 15(3), Waste Framework Directive)
- Establish an integrated and adequate network of disposal installations, taking account of the best available technology, in accordance with specific objectives and principles (such as self-sufficiency and proximity in waste disposal). (Art. 16(1)), Waste Framework Directive).
- Determine whether, for reasons of protecting the waste network and for environmental grounds to limit incoming and outgoing shipments of waste (in line with derogation allowed also in Regulation (EC) No 1013/2006) and inform Commission of such decisions. (Art. 16(2), Waste Framework Directive)
- Establish the necessary adequate and appropriate system for the permitting of the establishments or undertakings carrying out operations specified by the annexes. (Arts. 23, 24, 25, 26, Waste Framework Directive).
- Establish an inspection system, or appropriately adapt the existing inspection system, in order to make it able to carry out the prescribed periodic inspections of the establishments or undertakings by the competent authority.
- Apply the polluter pays principle to the disposal of waste, to ensure that the cost of disposing of waste is borne by the producer of the waste or by the holder who has it handled by a waste collector or

undertaking and/or the previous holders or the producers of the product that generated the waste. (Art. 14, Waste Framework Directive).

- Ensure that undertaking referred to in Article 23(1), the producers of hazardous waste and the establishments and undertakings which collect or transport hazardous waste on a professional basis, or act as dealers and brokers of hazardous waste, keep a chronological record of the quantity, nature and origin of the waste, and, where relevant, the destination, frequency of collection, mode of transport and treatment method foreseen and make that information available, on request, to the competent authorities.
 - for hazardous waste keep the records for at least three years, except for waste transporters which have to keep the records for at least one year;
 - documentary evidence that the management operations have been carried out shall be supplied at the request of the competent authorities or of a previous holder. (Art. 35(1), (2), Waste Framework Directive)
- Plan and create a reporting system (Arts. 37 and 38, Waste Framework Directive)
- If exemptions from the permit requirements are to be granted, adopt general rules governing those exemptions and provide for the registration of exempt operations. Those rules shall be designed to ensure that waste is treated in accordance with Article 13. In the case of disposal operations referred to in point (a) of Article 24 those rules should consider best available techniques. (Arts. 24 and 25, Waste Framework Directive)

2.2. Regulation

- Effectively implement the "polluter pays principle" and the principle of "extended producer responsibility" in regard to covering the cost of waste management and disposal. (Art. 14, Waste Framework Directive)
- Meet the recycling and recovery targets to be achieved by 2020:
 - 50% preparing for re-use and recycling of certain waste materials from households and other origins similar to households, and
 - 70% preparing for re-use, recycling and other recovery of construction and demolition waste. (Art. 11(2), Waste Framework Directive)
- Ensure application of rules and calculation methods for verifying compliance with the targets set in Article 11(2) laid down in Commission Decision 2011/753/EU establishing rules and calculation methods for verifying compliance with the targets set in Article 11(2) of Directive 2008/98/EC.
- Ensure effective implementation and evaluation of the waste management plans and waste prevention programmes.
- Ensure that waste is recovered or disposed of without endangering human health, and without using processes or methods that could harm the environment (e.g. without risk to water, air, soil, plants or

animals; without causing a nuisance through noise or odours; and without adversely affecting the countryside or places of special interest. (Art. 13, Waste Framework Directive)

- Take measures to prohibit the abandonment, dumping or uncontrolled disposal of waste, which should be coupled with penalties. (Art. 36, Waste Framework Directive)
- Ensure that holders of waste either have the waste handled by a waste collector or an undertaking that carries out disposal or recovery operations listed in Annex I and II or that they recover or dispose of the waste themselves in accordance with the Directive. (Art. 15, Waste Framework Directive)
- Require establishments and undertakings that carry out waste disposal operations (listed in Annex I) or recovery operations (listed in Annex II) to obtain a permit, in the required form, from the competent authority. (Art. 23, Waste Framework Directive)
- Ensure that exemptions from the permit requirements are only granted in respect of waste recovery or the disposal of waste at the place of production subject to general rules and subject to compliance with the conditions relating to environmental protection set out in Article 13. (Art. 25(2), Waste Framework Directive)
- Ensure that establishments or undertakings (for both hazardous and non-hazardous waste) are registered with the competent authority if:
 - they are exempt from the permitting requirements (Arts. 24 and 25); or
 - they collect or transport waste on a professional basis, or they arrange for the disposal or recovery of waste on behalf of others, but are not subject to authorisation (Art. 26, Waste Framework Directive)
- Take measures to ensure that hazardous waste is not mixed, either with other categories of hazardous waste or with other waste, substances or materials including mixing for the purpose of dilution of hazardous substances unless:
 - mixing operation is carried out by an establishment holding permit under Art. 23;
 - the effect on human health and the environment is not adversely affected;
 - mixing is carried out according to BAT. (Art. 18(1) and (2), Waste Framework Directive)
- Where hazardous waste is already mixed with other waste, substances or materials, ensure that the waste is separated, where this is technically and economically feasible and necessary to comply with Article 13 of the Directive. (Art. 18(3), Waste Framework Directive)
- Whenever hazardous waste is transferred within a Member State, it shall be accompanied by an identification document, which may be in electronic format, containing the appropriate data specified in Annex IB to Regulation (EC) No 1013/2006. This waste also is subject to inspection provision set out in Article 34(2) of the Waste Directive. (Art. 19(2), Waste Framework Directive)
- Ensure that, in the course of collection, transport and temporary storage, hazardous waste is packaged and labelled in accordance with the international and EU standards in force. (Art. 19(1), Waste directive)
- Ensure that waste oils are collected and disposed of (within the wider meaning of the term "disposal" as defined in the Directive) without causing avoidable damage to human health and the environment. (Art. 13, Waste Framework Directive)

- In managing waste oils, give priority to processing by regeneration, then to combustion, and finally to safe destruction, controlled storage or (final) disposal. (Art. 21, Waste Framework Directive)
- Prohibit:
 - the discharge of waste oils into waters or onto soil;
 - the uncontrolled discharge of waste oil residues; and
 - emissions to air, as a result of processing, in excess of permitted levels. (Arts. 13 and 36, Waste Framework Directive)
- Require any undertaking that collects waste oils to be subject to registration and supervision. (Art. 26 and 34, Waste Framework Directive)
- Require any undertaking that disposes of waste oils to be subject to prior authorisation (through permitting). (Art. 23, Waste Framework Directive)
- Subject the authorisation of undertakings that regenerate or use waste oil as fuel to the fulfilment of appropriate environmental and health protection measures including BAT. (Art. 23, Waste Framework Directive)
- Take measures to ensure that:
 - waste oils are collected separately, where this is technically feasible;
 - respect the waste hierarchy (Art. 4, Waste Framework Directive);
 - waste oils are treated in a way that is not endangering human health or harming the environment (e.g. without risk to water, air soil, plants or animals, without causing noise or odours) (Art. 13, Waste Framework Directive);
 - where this is technically feasible and economically viable, waste oils of different characteristics are not mixed and waste oils are not mixed with other kinds of waste or substances, if such mixing impedes their treatment;
 - risks associated with the quantity and toxic and dangerous characteristics of residues are reduced to a minimum and that the residues are disposed of in accordance with the provisions in the Waste Framework Directive on hazardous waste.
- Where the public authorities have entered into voluntary agreements with producers of waste oils or has introduced producer responsibility (either individual responsibility or in the form of collective schemes), as additional measures supplementing the mandatory provisions in the Directive, the competent authorities have to ensure supervision and compliance with these mechanisms. (Art. 21, Waste Framework Directive)
- Ensure that undertakings covered by Article 23(1), the producers of hazardous waste (including waste oils) and the establishments and undertakings which collect or transport hazardous waste on a professional basis, or act as dealers and brokers of hazardous waste, keep a chronological record of the quantity, nature and origin of the waste, and, where relevant, the destination, frequency of collection, mode of transport and treatment method foreseen in respect of the waste, and shall make that information available, on request, to the competent authorities. (Art. 35, Waste Framework Directive)

- Ensure that competent authorities carry out periodic inspections of establishments and undertakings that carry out the disposal, recovery, collection and transportation of waste, or are dealers and brokers in waste. (Art. 34, Waste Framework Directive).
- Require establishments and undertakings that carry out disposal or recovery operations to keep specified information and to make it available to the competent authority. For hazardous waste, the records shall be preserved for at least three years except in the case of establishments and undertakings transporting hazardous waste which must keep such records for at least 12 months. (Art.35, Waste Framework Directive)
- Ensure that operators of activities listed in Annex I, and meeting the threshold values in Annex II, keep a record of reported data for at least five years, including data on chosen methodology for data gathering. (Art. 5(5), Regulation (EC) 166/2006).
- Take measures to encourage the separate collection of bio-waste:
 - giving priority to composting and digestion;
 - promote treatment which fulfils a high level of environmental protection;
 - encourage the use of environmentally safe materials produced from bio-waste. (Art. 22, Waste Directive)

2.3. **Monitoring and enforcement**

- Carry out inspections of undertakings to ensure compliance with permits. The intensity and frequency of these inspections could partly be dependent upon whether the operator is affiliated to EMAS. (Art.34, Waste Framework Directive)
- Establish effective, proportionate and dissuasive penalties applicable to infringements of the provisions of this Directive and shall take all measures necessary to ensure that they are implemented. (Art. 36(2), Waste Framework Directive)

2.4. **Information and Reporting**

- Every three years (nine months after each three-year period), inform the Commission about the implementation of this Directive in the form of a sectoral report in an electronic form. This report must also comprise information on the management of waste oil and on the progress achieved in the implementation of the waste prevention programmes and, as appropriate, information on measures as foreseen by Article 8 on extended producer responsibility. This report is drawn up on the basis of a questionnaire established on the basis of Directive 91/692/EEC. (Art. 37(1), Waste Directive)
- Also report to the Commission on:

- general rules relating to exemptions from the permit requirements (Art. 25(3), Waste Framework Directive);
 - measures limiting incoming and outgoing shipments of waste (in line with derogation allowed also in Regulation (EC) No 1013/2006) for grounds of protecting the domestic waste network or for environmental grounds. (Art. 16(2), Waste Framework Directive);
 - transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 40, Waste Framework Directive).
- Submit the data in the questionnaire set out in Commission Implementing Decision of 18 April 2012 establishing a questionnaire for Member States reports on the implementation of Directive 2008/98/EC of the European Parliament and of the Council on waste, Decisions 94/741/EC and 97/622/EC, as amended by Decision 2007/151/EC.
 - Ensure that waste management operators as well as other industrial facilities carrying out activities listed in Annex I to Regulation (EC) No 166/2006 on the European Pollution Release and Transfer Register, including public or private establishments and undertakings, comply with the reporting and information requirements set out in the Regulation. For instance, such enterprises include those involved in the transportation, disposal and/or recovery or processing of hazardous waste, as well as activities that produce hazardous waste streams such as the mineral industry, chemical industry, and paper and wood production/processing. These undertakings must comply with their reporting obligations under Regulation (EC) No 166/2006. These operators must annually inform the competent authority about the amounts of releases to air, water and land of Annex II pollutants exceeding applicable threshold values, off-site transfers (e.g. shipments) of hazardous waste exceeding two tonnes a year, and off-site transfers of Annex II pollutants in wastewater discharged for wastewater treatment where Annex II threshold values are exceeded. The facility must submit information according to the format referred to in Annex III, e.g.:
 - information on all deliberate, accidental, routine and non-routine activities;
 - reference year;
 - identification of the facility (ID number, address, operating hours a year, number of employees);
 - list of all Annex I activities of the facility;
 - data on releases to air, water or land (naming the pollutants, quantities, and methods used for assessment);
 - off-site transfers of pollutants destined for wastewater treatment where quantities exceed values laid down in Annex II;
 - off-site transfers of hazardous waste exceeding threshold values set out in Annex II — within the country for recovery or disposal (measured in tonnes/year, referring to analytical and calculation methods used); or exported to other countries for recovery or disposal (measured in tonnes/year, referring to analytical and calculation methods used) (Art. 5, Regulation (EC) No. 166/2006);

2.5. Additional Legal Instruments

All the legislation in the waste sector should be borne in mind when implementing the Waste Directive. Consideration should also be given to legislation in other sectors (and note that EU Decisions have also been adopted further to these legislative acts to supplement their operation), particularly:

- Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste. This Regulation specifies under which conditions waste can be shipped between countries
- Packaging and Packaging Waste Directive (94/62/EC)
- Electronic and Electrical Waste Directive (2012/19/EU)
- Restriction of Hazardous Substances in Electronic and Electrical Directive (RoHS Directive) (2011/65/EU)
- End-of-Life Vehicle Directive (2000/53/EC)
- Mining Waste Directive (2006/21/EC)
- Landfill Directive (99/31/EC)
- Asbestos Directive (87/217/EEC)
- Sewage Sludge Directive (86/278/EEC)
- Directive 96/59/EC on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT)
- Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy
- Urban Waste Water Treatment Directive (91/271/EEC)
- Water Framework Directive (2000/60/EC)
- Nitrates Directive (91/676/EEC)
- Industrial Emissions Directive (2010/75/EU)
- Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (SEVESO III)
- Regulation (EC) No. 166/2006 on the European Pollutant Release and Transfer Register
- Regulation (EC) No 1221/2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS),
- Regulation (EU) No 649/2012 concerning the export and import of dangerous chemicals
- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
- Regulation (EC) No 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury
- Environmental Impact Assessment Directive (2011/92/EU)

- SEA Directive (2001/42/EC) on the assessment of the impact of certain plans and programmes)
- Environmental Liability Directive (2004/35/EC)
- Directive on Access to Environmental Information (Directive 2003/4/EC)
- Directive 2007/2/EC establishing an Infrastructure for Spatial Information in the European Community (INSPIRE)
- Environmental Crimes Directive (2008/99/EC)
- Reporting Directive (91/692/EEC)
- Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the Table 12, organised in chronological order (where possible) within each subheading.

Table 13. Checklist with key implementation tasks

THE FRAMEWORK DIRECTIVE ON WASTE - KEY IMPLEMENTATION TASKS	
1	Institutional Organisation
1.1	<p>Appoint competent authority/authorities. Responsibilities would include:</p> <ul style="list-style-type: none"> • establishing a list of wastes in line with Commission Decision 2000/532/EC; • drawing up a national waste management plan including a section focusing on hazardous waste; • issuing permits for disposal and recovery operations; • registering collectors, transporters and dealers of waste; • ensuring compliance and enforcing regulations prohibiting the uncontrolled disposal of waste; • carrying out inspections of waste management facilities; • enforcement action.
2	Planning and Implementation of Plans
2.1	<p>Establish an integrated waste management strategy at central government level, incorporating the principles stated in the Directive, with timescales and responsibilities clearly defined also connecting with the waste prevention programmes where appropriate (see below).</p> <p>Devise the measures to ensure that waste is managed without endangering human health and harming the environment, and in particular without risk to water, air, soil, plants or animals, without causing a nuisance through noise or odours, and without adversely affecting the countryside or places of special interest.</p>
2.2	Ensure a comprehensive approach to implementation of the Waste Directive, ensuring that also waste oils and hazardous waste are dealt with in the same policy and legal framework.
2.3	Carry out an assessment of existing disposal installations to determine what additional infrastructure is needed to establish an integrated and adequate network of disposal installations
2.4	<p>Develop a national waste management plan that identifies, inter alia,</p> <ul style="list-style-type: none"> • the type, quantity and origin of waste to be recovered and disposed of; • steps to ensure adherence to the waste management hierarchy general technical requirements; • any special arrangements for particular wastes; • suitable disposal sites and installations.
2.5	<p>Draw up waste prevention programmes, which has to be evaluated every 6 years and revised as appropriate. These programmes can be integrated into waste management plans and/or policies or be separate programmes. The waste prevention objectives and measures have to be clearly described and existing measures compared against Annex IV of the Directive that sets out examples of waste prevention measures that candidate countries should consider implementing. These instruments could be:</p> <ul style="list-style-type: none"> • Economic instruments for sustainable resource use; • Promotion of eco-design for products; • Campaigns to change consumer behaviour;

	<ul style="list-style-type: none"> Supporting the reduction of industrial waste (EMAS, ISO 14001); Green public procurement
2.6	<p>Introduce the prevention targets and indicators, i.e. appropriate specific qualitative or quantitative benchmarks for waste prevention measures adopted, in order to monitor and assess their progress.</p> <p>In doing this take into account the system to be established by the Commission for sharing information on best practice regarding waste prevention and developed guidelines in order to assist the Member States in the preparation of the programmes.</p>
2.7	<p>Make a decision as to whether to exempt from permit requirements establishments carrying out their own disposal operations at their place of production or carrying out waste recovery operations. Compile a register of exempted establishments.</p>
2.8	<p>Identify undertakings that collect or transport waste on a professional basis or that arrange for the disposal or recovery of waste on behalf of others but that will not be subject to authorisation.</p>
2.9	<p>Consider whether to make producers responsible for their products as waste for categories additional to those where producer responsibility already exists</p>
2.10	<p>Put in place measures to encourage the prevention or reduction of waste production, the recovery of waste and its use as an energy source. This should include measures to encourage:</p> <ul style="list-style-type: none"> the development of clean technologies that are sparing in their use of natural resources; the technical development and marketing of products designed to limit the harmful impacts of waste and pollution hazards; the development of techniques for the final disposal of dangerous substances contained in waste destined for recovery; the recovery of waste; the use of waste as an energy resource.
2.11	<p>Gather information on waste quantities/types and on existing waste management facilities.</p>
2.12	<p>Assess the financial implications of implementing the Directive, in particular the costs of developing an integrated and adequate network of disposal installations and of other measures included in the waste management plan.</p>
2.13	<p>Identify the roles of the public and private sectors. Introduce full cost recovery to ensure the implementation of the polluter pays principle.</p>
2.14	<p>Introduce appropriate economic tools to encourage the implementation of plans. These may include: landfill/incineration charges, extended producer responsibility schemes, pay-as-you-throw schemes, subsidies/penalties for local authorities to ensure development of separate collection.</p>
2.15	<p>Ensure the provision of an adequate network of waste disposal installations.</p>
2.16	<p>As part of measures to ensure separate collection of waste oils and encourage regeneration of waste oils</p>
2.17	<p>Plan measures to encourage separate collection of bio-waste, focusing on composting and digestion of bio-waste, which also comprises measures to promote the marketing and use of products developed from bio-waste</p>
3	<p>Regulation and Monitoring</p>
3.1	<p>Establish measures to ensure compliance with:</p> <ul style="list-style-type: none"> requirements to recover or dispose of waste without endangering human health or causing harm to the environment; and the prohibition against the abandoning, dumping and uncontrolled disposal of waste.
3.2	<p>Establish measures to ensure that holders of waste:</p> <ul style="list-style-type: none"> have waste handled by private or public waste collectors or undertakings that carry out operations listed in Annex I and II; recover or dispose of waste themselves in accordance with the requirements of the Directive.
3.3	<p>Establish and implement systems and procedures for issuing permits to waste management facilities carrying out disposal and recovery operations listed in Annex I and II of the Directive. Permits for Annex II operations should specify the types and quantities of waste; the technical requirements; the security precautions to be taken; the disposal site; and the treatment method. The permitting system should also cover requirements relating to record keeping and reporting, together with procedures for registrations of exempt facilities.</p>

3.4	Establish a system for issuing permits for: <ul style="list-style-type: none"> • allowing hazardous waste to be mixed with other wastes; • if required, the recovery of hazardous wastes; • operations of hazardous waste management facilities according to the Waste Directive.
3.5	Establish and implement systems and procedures to register waste carriers and brokers.
3.6	Ensure that the recycling and recovery targets are met including the new targets to be achieved by 2020 (i.e. 50% preparing for re-use and recycling of certain waste materials from households and other origins similar to households, and 70% preparing for re-use, recycling and other recovery of construction and demolition waste)
3.7	Establish systems and procedures for identifying and inspecting producers of hazardous waste. Require these producers to keep records of the quantity, nature, and origins of hazardous wastes and make these available to the competent authority.
3.8	Identify establishments that carry out their own disposal of hazardous waste and require them to obtain permits in accordance with the Directive. Ensure that unsuitable facilities are in any event prevented from accepting hazardous waste.
3.9	Establish a procedure to ensure that wastes are not mixed where this is not allowed. The procedure needs to ensure that the permitting systems for transport and treatment or disposal explicitly prevent mixing where necessary. Establish criteria for the circumstances under which the mixing of wastes will be allowed if it does not harm human health and/or the environment.
3.10	Design and enforce a consignment note system in accordance with Regulation (EC) 1013/2006 on shipments of waste for recording the collection, transportation and delivery of hazardous wastes.
3.11	Carry out inspections of hazardous waste producers, transporters and waste management facilities to ensure compliance with permits and with requirements for keeping records. Require these producers to keep records of the quantity, nature, and origins of hazardous wastes and make these available to the competent authority.
3.12	Establish a system for keeping records in accordance with the Waste Directive.
3.13	Establish rules for packaging and labelling hazardous wastes, in accordance with international and EU standards.
3.14	Have producers of electrical and electronic equipment and passenger vehicles establish one or several collection and recycling schemes for waste electronic and electrical equipment (WEEE) and end-of-life vehicles (ELVs). This is often done through associations of producers, retailers and importers and is often commonly financed. Municipalities normally finance historic waste, e.g. products put on the market prior to the entry into force of WEEE and ELV legislation, and thus have to ensure systems for the collection, receiving, storing, recycling and disposal of this waste.
3.15	Establish and implement a system to inspect waste management facilities.
3.16	Adopt rules for the types and quantities of waste and the conditions under which exempted activities may be carried out, including rules to ensure that requirements relating to the safe recovery and disposal of waste are complied with.
3.17	Compile a register of undertakings exempted from permitting requirements and of undertakings that, although not subject to authorisation requirements, collect or transport waste on a professional basis or arrange for the disposal or recovery of waste on behalf of others.
3.18	Provide training for waste regulators and inspectors.
3.29	Ensure that non-compliance is sanctioned with efficient, dissuasive and proportionate sanctions, which also is a requirement under the Environmental Crimes Directive (2008/99/EC).
4	Reporting
4.1	Establish reporting and data recording systems to ensure that the data required (see below) are collected.
4.2	Notify the Commission of rules adopted for the exemption of certain waste management facilities from permitting.
4.3	Establish procedures to ensure periodic submission of a sectoral report to the Commission about the implementation of this Directive This report must also comprise information on the management of waste oil and on the progress achieved in the implementation of the waste prevention programmes

	and, as appropriate, information on measures as foreseen by Article 8 on extended producer responsibility. This report is drawn up on the basis of a questionnaire established on the basis of Directive 91/692/EEC
4.4	Report to the Commission on: <ul style="list-style-type: none"> • measures taken to implement the waste hierarchy; • national waste management plans; • measures taken to prevent movements of waste not in accordance with waste management plans; • measures taken to implement the Directive; • the name and address of each hazardous waste disposal establishment and the type and quantities of waste handled.
4.5	Ensure that hazardous waste operators, including facilities producing larger quantities of hazardous waste (e.g. the mining and paper/pulp industries), submit all requested information to the competent authorities annually, pursuant to Regulation 166/2006 on the European Pollutant Release and Transfer Register.
4.6	Make reported information available to the public.
4.7	Submit the questionnaire set out in Commission Implementing Decision of 18 April 2012 establishing a questionnaire for Member States reports on the implementation of Directive 2008/98/EC of the European Parliament and of the Council on waste, Decision 2007/151/EC, providing statistical data to the Commission and the EU Member States.
4.8	Ensure that waste management operators as well as other industrial facilities carrying out activities listed in Annex I to Regulation No. 166/2006 on the European Pollution Release and Transfer Register, including public or private establishments and undertakings, comply with the reporting and information requirements set out in the Regulation.
5	Technical Advice and Guidance
5.1	Provide technical guidance on: <ul style="list-style-type: none"> • clean technologies; • the identification of wastes other than those on the list of hazardous wastes that display hazardous properties; • the segregation and separation of wastes; • on packaging and labelling, which should take into consideration Directive 2008/68/EC and the UN publication on recommendations for the transport of dangerous goods
5.2	Provide technical guidance on opportunities for waste minimisation, re-use, and recovery and recycling.
5.3	Provide technical guidance on methods of waste recovery, treatment and disposal, based on BAT.
5.4	Provide technical guidance on the procedures to be followed for issuing waste management permits.
5.5	Provide guidance to establishments and undertakings and producers on keeping specific records and information, available to the competent authority upon request and used for reporting purposes.
5.6	Prepare and issue detailed guidance to ensure a full understanding of the list of hazardous wastes given in the Wastes List Decision (2000/532/EC). Candidate countries are advised to consult the guidance document available at: http://ec.europa.eu/environment/waste/hazardous_index.htm
5.7	Test methods should also be specified for identification of wastes
6	Communications and Consultation
6.1	The lead ministry/agency should raise awareness and consult with stakeholders before introducing the new waste regulation procedures and during the development stages of the waste management plan and waste prevention programmes. Ensure coordination and synergies with consultation and information provision requirements under EIA, SEA, Access to Environmental Information and the Public Participation Directives. Also take into account the relevant provisions in the SEVESO III Directive and the Industrial Emissions Directive on stakeholder involvement.
6.2	Design and implement a communications programme to encourage waste producers to minimise waste and to make use of processes further up the waste management hierarchy.

3.2. Phasing Considerations

Experience within Member States suggests that the most demanding and time-consuming tasks associated with implementing this Directive are the following:

- Transposing the requirements of the Directive into national legislation and policy;
- Initial consultations with key stakeholders, information campaign and setting up institutional structures for ensuring public access to certain waste information;
- Establishing and developing the institutional structure for controlling waste management, in particular the acquisition and training of sufficient personnel, and the development of systems and procedures for permitting, monitoring and enforcement and for the collection/reporting of information. This should also comprise a coordination mechanism for work related to other sectors and for international efforts of waste management (e.g. Basel Convention);
- Preparation of an integrated waste management strategy and the waste prevention programmes, including an implementation plan, with indicators, timelines and division of responsibilities clearly identified;
- Detailed planning, design, permitting and construction of new or upgraded facilities for waste treatment and disposal.

These tasks should therefore be planned to commence during the initial phase of implementation.

Depending on the existing institutional structure, the transposition of legislation may be required before a new structure can be introduced. A data collection system should be established to ensure that the information is readily available for reporting.

4. IMPLEMENTATION GUIDANCE

Implementation of this Directive will be influenced by the present status, needs and conditions concerning waste management in each candidate country. Drawing on the experience of selected Member States, a number of general observations and suggestions for implementing the Directive are presented below. Much of the philosophy and methodology for these tasks, however, particularly in relation to institutional organisation, planning and regulation, has been discussed at some length in the sector overview.

The implementation of the Waste Framework Directive should be closely linked with the objectives of the objectives of the Resource Efficiency Roadmap¹⁵² and the 7th Environment Action Programme¹⁵³, which calls for a resource-efficient economy. In this context, there is a special focus on turning waste into a resource.

The Waste Framework Directive introduced a new approach to waste management that encourages the prevention of waste. While Member States must design and implement waste prevention programmes, the Commission will report periodically on progress concerning waste prevention.

In addition, the Directive lays down a five-step hierarchy of waste management options that must be applied by Member States when developing their national waste policies:

- waste prevention (preferred option);
- reuse;
- recycling;
- recovery (including energy recovery); and
- safe disposal, as a last resort.

In this respect, the new legislation considers energy-efficient waste incineration to be a recovery operation — a provision that promotes resource efficiency, thus reducing the consumption of fossil fuels. The Directive also sets the recycling targets. By 2020, Member States must recycle 50% of their household and similar waste; and 70% of their construction and demolition waste.

Five overarching principles for waste management drive the EU approach to this sector. These are:

- The waste management hierarchy, which defines the waste management strategy to be employed. In descending order of preference, these are to prevent the production of waste, to re-use, recover and recycle waste, to use waste as a source of energy, and, as a final resort, to dispose of waste safely by incineration or in landfill.
- The principles of self-sufficiency and proximity, whereby Member States are required to move towards developing their own waste disposal facilities wherever practical, while respecting the objective of allowing the EU as a whole to become self-sufficient from the waste management perspective; and the principle that wastes should be disposed of as close to the source of waste as possible. Materials that can be reclaimed or recycled are not included under this principle.

¹⁵² COM(2011) 571

¹⁵³ Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 ‘Living well, within the limits of our planet’ (OJ L 354, 28.12.2013, p. 171).

- The principle of best available techniques (BAT), which relates to integrated pollution prevention and control (IPPC) (see also BAT requirements in BAT briefing notes — or BREFs — to be established for landfilling) and requires the incorporation of BAT to minimise the environmental impacts associated with any process.
- The polluter pays principle, whereby the polluter should bear the costs of pollution prevention and control.
- Waste management without endangering human health or the environment, and in accordance with the precautionary principle.

In all of the above, it is essential that the definition of waste, as set out in the Waste Directive, is mandatory for all Member States. Any substance or object in the categories set out in Annex I that the holder discards, intends to discard, or is required to discard falls within that definition of waste. Assistance is to be gained from rulings from the Court of Justice of the European Union in this area, which has proved at times to be somewhat problematic.

The Commission has produced a guidance document on implementation of the Waste Framework Directive: Guidance on the interpretation of key provisions of Directive 2008/98/EC on waste:

http://ec.europa.eu/environment/waste/framework/pdf/guidance_doc.pdf

Examples from a Member State: Recycling Practice

Spain: Spain has successfully implemented a project to recycle tyres. The two-year project was supported by the government and the European Commission's LIFE programme. The province in which the project was undertaken has a serious problem with dumped tyres, which was exacerbated by a concentration of local transport operators. The project has developed a new mechanical separation and granulation process for the tyres. Previous projects have encountered problems in fully separating the three components —steel, fabric and rubber. However, this was overcome in the current project.

One of the biggest problems with any recycling process is finding markets for the recycled material. In an attempt to overcome this problem, the project has worked with partners to devise new solutions. These partners include the local university and private sector companies that use the recycled materials to produce tool handles, street furniture, road surfacing materials and noise barriers. The local development agency is now looking for partners throughout Europe to develop the inventions through technology transfer.

Useful background information, reference to legal sources and studies on waste management can be obtained at:

- Summary of EU waste management legislation: Website of DG ENV: <http://ec.europa.eu/environment/waste/framework/index.htm>
- Information on new waste management programmes: <http://ec.europa.eu/environment/waste/plans/index.htm>
- Best practices on waste prevention: <http://ec.europa.eu/environment/waste/prevention/practices.htm>
- European Platform on Life Cycle Assessment Life Cycle guidance for waste management: <http://eplca.jrc.ec.europa.eu>

- Review of waste policy and legislation: http://ec.europa.eu/environment/waste/target_review.htm
- Information on permitting and inspection of waste management operations, including guidance and best practices: <http://ec.europa.eu/environment/waste/framework/inspections.htm>

4.1. Institutional Organisation

- Ensure a strong and independent specialist competent authority, which is a prerequisite for the successful control of waste management.
- The Directive requires an organisational structure to be developed for three main functions: waste management planning; waste regulation (including enforcement) and permitting; and data collection and reporting.
- A broad waste management strategy needs to be established at the central level. The development of detailed plans may be undertaken at a lower administrative level.
- Where institutional responsibility is decentralised, it will be necessary for a clearly defined co-ordination system to be put in place.
- Competent authorities, whether centralised or decentralised, should have no other responsibilities that may lead to a conflict of interest.
- In most Member States the private sector has a major role in the management of industrial wastes. Municipal wastes are managed by the municipalities or the service may be contracted out to the private sector.
- If privatisation is undertaken, the public service element should still be recognised, especially in the case of municipal waste. Municipalities should not simply abdicate responsibility for the quality of the service in favour of contractors, as they are ultimately accountable to the public for service provision.
- In many Member States, municipalities that have privatised the municipal waste service demonstrate their commitment to the provision of a public service by operating a telephone hotline to handle complaints from the public about the quality of the service. These complaints are then passed on to the contractor, whose contract frequently contains penalty clauses in the event that it fails to provide an adequate service level.
- Some Member States also consider that the provision of a hazardous waste management service is also a public service, so as to ensure adequate environmental standards and treatment. Plants are operated either by groups of municipalities or by chambers of commerce on a co-operative basis.
- The strategy should address the issue of cost recovery in order to implement the polluter pays principle. Also, private sector companies will not be prepared to invest in facilities unless waste producers bear the full cost of service provision.
- Where services are provided by municipalities, particular attention is required to ensure that the accounting systems used to record costs cover the repayment of capital and also provisions for future liabilities, such as landfill aftercare.

Examples from a Member State: institutional arrangements

Portugal: waste management authorisation is granted by the Ministry of Environment, through the Institute of Wastes (INR) or regional directorates of the environment (DRAs), depending on the type of waste and waste management operations. The INR is the competent authority to deal with the management of hazardous waste, the incineration of non-hazardous waste and the management of a network of municipalities, whereas the DRAs are in charge of the municipal management of non-hazardous waste. The management of hospital waste is carried out by the General Directorate of Health (DGS), subject to binding advice from the INR. Co-ordination is arranged through periodic meetings between the DRAs and the INR in which practical procedures for waste management are discussed and assessed.

United Kingdom: waste regulation used to be carried out by regional authorities, which also had an executive responsibility for the management of municipal solid waste. This led to a conflict of interest, even though the departments were nominally separate. Following an intermediate period when the functions were separated more clearly within the regional authorities, the regulatory authority was organised on a national basis, reporting to a ministry, but established as a separate accountable body. The regulatory authority has responsibility for ensuring the implementation of strategy, waste management planning, issuing permits, registration, inspection, enforcement and other regulatory functions and also for providing advice to the bodies responsible for delivering waste management services. The advantage of this new approach is a clear separation of regulation and operation, which allows for easier enforcement action and prevents any conflict of interest between regulators and service providers. From the waste management planning viewpoint, the regulatory authority is the only one in a position to develop such plans, since the service providers are mainly from the private sector. From its centralised standpoint, the regulatory authority has unique access to a national waste management database, derived through its regulatory function, from which to develop such plans. In the past, waste management plans were drawn up on a regional basis at county level. The new system will ensure that a national strategy is applied which can take account of the EU strategy.

Portugal: the Institute of Wastes (INR) performs an advisory role in the process of providing authorisations for waste treatment facilities. For industrial waste facilities, authorisation is needed from the Ministry of Environment as well as from the Ministry of the Economy. Due to the national importance of commercial issues, other waste treatment facilities are authorised only by the Ministry of Environment. The ministerial procedures are due to be rationalised into a single procedure in the near future, though both the ministries will still be involved. For incineration facilities, the advisory role of the INR includes undertaking environmental impact assessments. Once waste facilities are authorised, they are regulated by their regional directorate of the environment, except for dangerous waste treatment facilities, which are regulated by the INR. The fundamental feature of the implementation of waste management policy has been the separation of responsibility between public companies for waste collection and the operation of waste management facilities, and government institutions for the regulation of these waste management companies.

Examples from a Member States - private sector involvement

United Kingdom: virtually all waste management services are provided by the private sector. A national strategy is prepared by the centralised competent authority, while detailed local plans are prepared by the regional land-use planners, who identify the facilities required and locate suitable sites for them. The private sector then complies with the local plans when applying for permits. The private sector invested in hazardous waste incinerators some years ago on the basis of a market survey that identified significant volumes of wastes suitable for incineration. Unfortunately, the permitting system

continued to allow combustible wastes to be landfilled and the incinerator companies operated at a loss for several years until landfills were no longer permitted to accept these wastes.

France: municipalities may contract a private company to collect and/or dispose of household waste. The Ministry of the Interior has issued a model contract for this, which can be modified by the municipality to suit local circumstances.

Denmark: an association of municipalities, providing an incineration, treatment and landfill service to nationwide industry, owns the hazardous waste management facilities.

Germany: regional chambers of commerce own some facilities, while regional state government owns others. In two smaller Member States (IE, PT) there are no hazardous waste incineration facilities because the small volumes of waste would render them uneconomic. These states make use of facilities in other Member States and export their wastes using the procedures contained in Regulation (EC) No. 1013/2006 on shipments of waste.

Examples from a Member State: Technical Qualifications for Permit Holders

United Kingdom: UK has specified technical qualifications for permit holders, according to the type of waste management facility. It also requires, for example, landfill operators to provide sufficient financial security (by means of bonds, guarantees, sinking funds or escrow accounts) to cover the costs of restoration and aftercare. Permits may be refused to applicants who have been convicted of environmental offences. Note that such financial security is a requirement under the Landfill Directive (99/31/EC).

Portugal: the civil servants responsible for waste management in the Institute of Wastes (INR) are required to have a degree in chemical or environmental engineering. Also, the INR has a training centre for waste management and recovery and recycling, which, in collaboration with the Institute of Environmental Promotion (IPAMB) and the Institute of Employment and Professional Training, promotes training programmes for people responsible for waste management at different levels. The national waste law also requires the developers and operators of any project in this sector to demonstrate their economic capacity and, particularly for landfill projects, a bank guarantee is required to cover future restoration of the landscape and any aftercare measures.

4.2. Planning and Provision of Infrastructure and Facilities

- Hazardous waste management cannot be tackled cost-effectively at a local level. It should be approached at a regional or national level. In all Member States, facilities are provided on a regional or national basis. Indeed, some of the smaller states rely on neighbouring states for the more capital intensive facilities, such as incineration.
- There are two basic options for the provision of facilities: by the private sector (individually or in co-operatives) or by the public sector (sometimes in partnership with the private sector). The former requires substantially more control over the activities of waste producers to ensure that market conditions are such that the initiative is taken to provide the necessary facilities. The latter will ensure that adequate facilities are provided in a timely manner, but may involve government financing.
- In order to minimise the costs and risks of transporting relatively small quantities of hazardous wastes over long distances, consideration should be given to the development and operation of suitably

located reception centres for the secure interim storage of wastes prior to their final treatment/disposal at a centralised facility. Such reception centres should also incorporate pre-treatment processes in order to reduce the volume and/or hazard.

4.3. Waste Management Planning and Prevention

4.3.1. Waste Management Plans

- Before detailed plans for implementation can be prepared, it is necessary to establish an integrated waste management strategy. It will need to take account of the principles incorporated in the Directive, which have been identified in Section 2.1 above, and in the overview chapter of this section of the Handbook. An integrated national strategy and plan for managing hazardous wastes is essential, forming part of an overall strategy and implementation plan for wastes management. This is all the more important in the light of the prohibition on the co-disposal of hazardous waste. It is necessary to start planning for solely hazardous waste sites, where required, as soon as possible. In at least one Member State (UK), the risk of a shortage of viable hazardous waste disposal capacity has already been highlighted.
- Consider whether to integrate the Waste Prevention Programmes into these plans or to have them operate as separate programmes but with clear links and synergies to the plans.
- The preparation of plans will require the collection of accurate data on waste quantities and types and on existing waste management facilities. This will require the establishment of effective data gathering and processing systems.
- The strategy will involve the setting of waste prevention indicators as well as technical standards for those issues that are not prescribed in EU legislation. The strategy may be implemented through two routes: through the plans and through the regulatory system.

Take measures on work to establish end-of-waste criteria to support recycling markets and improve the implementation of waste management law. Such criteria is being developed by the Commission together with Member States and JRC working groups. Such criteria have to consider: 1), product quality (e.g. compliance with European or customer specification), 2) Input material-treatment (e.g. are their hazardous compounds to be decontaminated) 3) Quality management.

So far, the criteria have been laid down for: iron, steel and aluminium scrap (Council Regulation (EU) 333/2011), glass cullet (Commission Regulation (EU) No 1179/2012) and copper scrap (Commission Regulation (EU) No 715/2013).

- A number of technical issues will need to be addressed during the development of the strategy and technical standards, some of which will result from specific waste Directives. Some examples are:
 - the specific measures required for hazardous waste and waste oils, which now are dealt with under the Waste Framework Directive;
 - the need for long-term leachate management and aftercare at landfills;
 - the consequences of a reduction in organic waste being landfilled as a result of the Landfill Directive;

- the specific requirements needed for dealing with WEEE and ELVs, including more complex waste streams such as LCD screens and components containing heavy metals, which are to be recycled/processed using more advanced and complex methods;
- the impact of waste reduction and recycling on future waste quantities; and
- the impact of recycling on the calorific value of residual waste and its effect on a waste-to-energy strategy.

4.3.2. Waste Prevention Programmes

- Candidate countries should when designing the objective, approach and content of their prevention programmes consider the waste prevention measures/initiatives set out in Annex IV of the Directive. Several EU Member States already operate effective strategies to promote public awareness of waste prevention and to reduce the generation of specific types of waste. In the table below, waste prevention measures set out in Annex IV and also highlighted by the Commission are listed (see: <http://ec.europa.eu/environment/waste/prevention/examples.htm>).
- European Commission prepared a guidance document¹⁵⁴ to support Member States when developing Waste Prevention Programmes. The handbook clarifies the main concepts related to waste prevention, suggesting a framework to develop Waste Prevention Programmes and providing best practices and examples of national and regional programmes employing an effective mix of measures. It also includes a list of further resources on waste prevention theory and practice. The Guidance can be obtained at: <http://ec.europa.eu/environment/waste/prevention/pdf/Waste%20prevention%20guidelines.pdf>
- A separate guidance,, accompanied by a number of best practice examples, has been prepared to address a specific problem of food waste prevention¹⁵⁵ which has been identified as one of the major priorities in the Resource Efficiency Roadmap, due to its relevance and its impacts on the environment, greenhouse gas emissions and global food security. The guidance is available at: <http://ec.europa.eu/environment/waste/prevention/guidelines.htm>

Table 14. Box with examples of waste prevention measures

1	Measures that can affect the framework conditions related to the generation of waste
1.1	The use of planning measures, or other economic instruments promoting the efficient use of resources.
1.2	The promotion of research and development into the area of achieving cleaner and less wasteful products and technologies and the dissemination and use of the results of such research and development.
1.3	The development of effective and meaningful indicators of the environmental pressures associated with the generation of waste aimed at contributing to the prevention of waste generation at all levels, from product comparisons at EU level through action by local authorities to national measures.
2	Measures that can affect the framework conditions related to the generation of waste
2.1	The promotion of eco-design (the systematic integration of environmental aspects into product design with the aim to improve the environmental performance of the product throughout its whole life cycle).
2.2	The provision of information on waste prevention techniques with a view to facilitating the implementation of the best available techniques by industry.
2.3	Organise training of competent authorities in regards to the insertion of waste prevention requirements in

¹⁵⁴ Waste Prevention – Handbook: Guidelines on waste prevention programmes (2012)

¹⁵⁵ For more information see: http://ec.europa.eu/food/safety/food_waste/index_en.htm

	permits under the Waste Framework Directive and Directive 96/61/EC.
2.4	The inclusion of measures to prevent waste production at installations not included in Directive 2010/75/EU. Where appropriate, such measures could include waste prevention assessments or plans.
2.5	The use of awareness campaigns or the provision of financial, decision making or other support to businesses. Such measures are likely to be particularly effective where they are aimed at, and adapted to, small and medium sized enterprises and work through established business networks.
2.6	The use of voluntary agreements, consumer/producer panels or sectoral negotiations so that relevant businesses or industrial sectors are able to set their own waste prevention plans or objectives or correct wasteful products or packaging.
2.7	The promotion of credible environmental management systems, including EMAS and ISO 14001.
3	Measures that can affect the consumption and use phase
3.1	Economic instruments such as incentives for clean purchases or the institution of an obligatory payment by consumers for a given article or element of packaging that would otherwise be provided free of charge.
3.2	The use of awareness campaigns and information provision directed at the general public or a specific set of consumers.
3.3	The promotion of credible eco-labels.
3.4	Agreements with industry, such as the use of product panels, which is being carried out within the framework of Integrated Product Policies or with retailers on the availability of waste prevention information and products with a lower environmental impact.
3.5	In the context of public and corporate procurement, the integration of environmental and waste prevention criteria into calls for tenders and contracts that are in line with the <i>Buying green handbook</i> (available at: http://ec.europa.eu/environment/gpp/buying_handbook_en.htm)
3.6	The promotion of the reuse and/or repair of appropriate discarded products or of their components, notably through the use of educational, economic, logistic or other measures such as support to or establishment of accredited repair and reuse-centres and networks especially in densely populated regions.

- When considering waste prevention measures and the use of good practices, also take into account the following criteria:
 - Targeted: Practices have a strong waste prevention focus, clearly distinct from other waste management strategies or broad environmental goals;
 - Innovative: Practices use original or resourceful techniques for waste prevention;
 - Replicable: Practices can be easily reproduced and are similarly relevant in regions across Europe;
 - Representative: Practices originate from a wide range of countries, operate at national, regional and local level, and target a variety of waste streams;
 - Effective: Practices have clearly defined objectives and measurable results.

Table 15. Box with examples of best practices in EU

<p>Examples of best practices in EU Member States but also outside the EU as identified by the European Commission (http://ec.europa.eu/environment/waste/prevention/practices.htm). These practices demonstrate excellent examples of informational, promotional and regulatory measures to stimulate the prevention of waste.</p> <ul style="list-style-type: none"> • The Courtauld Commitment (UK) • Eco-Emballages Packaging Advisory (France) • Eco-Point Initiative (Italy)
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- [Flanders Waste Prevention Plan \(Belgium\)](#)
- [The Green Business Initiative \(Ireland\)](#)
- [Halving Waste to Landfill \(UK\)](#)
- [It's Smart with Less Waste' Helsinki \(Finland\)](#)
- [Love Food Hate Waste \(UK\)](#)
- [Clever Akafen Ecolabel \(Luxembourg\)](#)
- [Menu Dose Certa \(Portugal\)](#)
- [Nemsitt.hu Construction Material Exchange \(Hungary\)](#)
- [Carbon Tax on Packaging \(Netherlands\)](#)
- [Stop Pub \(France\)](#)
- [Vienna Waste Prevention Programme \(Austria\)](#)
- [Zero Waste Manual \(Croatia\)](#)
- [Bricolage Design Prize \(Australia\)](#)
- [California Waste Prevention World \(USA\)](#)
- [Local Authority Prevention Demonstration Programme \(Ireland\)](#)
- [National Industry Symbiosis Programme \(UK\)](#)
- [The Real Nappy Campaign \(UK\)](#)
- ['Sustainable Concordia' Campus Waste Prevention Strategy \(Canada\)](#)
- [EMAS Poland](#)
- [Eu Nao Faça Lixo \(Portugal\)](#)
- [European Week for Waste Reduction](#)
- [Piedmont Home Composting Campaign \(Italy\)](#)
- [Kringloop Reuse Centres \(Flanders\)](#)
- [No Disposables Campaign \(Korea\)](#)
- [Swap-O-rama-rama \(USA\)](#)
- [Waste Cap \(USA\)](#)
- [WasteWise \(USA\)](#)
- [SuperDrecksKesch \(LUX\)](#)
- [Reusable Shopping Bag "Eco-Sac" \(LUX\)](#)

Examples from a Member State: waste prevention programmes

Ireland: The Minister for the Environment, Heritage and Local Government launched the National Waste Prevention Programme (NWPP) in April 2004. The programme is led by the Environmental Protection Agency (EPA). A National Waste Prevention Committee was also set up, which includes a broad stakeholder group who meet periodically to provide strategic direction for the EPA in implementing the National Waste Prevention Programme.

The main aim of the national programme is to deliver substantive results on waste prevention and minimisation and to integrate a range of initiatives addressing awareness-raising, technical and financial assistance, training and incentive mechanisms.

Among the various initiatives undertaken under the NWPP, one is specifically aimed at empowering Local Authorities. This is the Local Authority Prevention Demonstration Programme (LAPD) in effect between 2006 and 2009. The LAPD led to the ongoing Local Authority Prevention Network (LAPN).

More information:

Text of national waste prevention programme: www.nwpp.ie

Local Authority Prevention Demonstration Programme <http://localprevention.ie>

4.4. Regulation

- Effective waste regulation is critical for raising the environmental standard of waste management facilities, especially if the private sector is to be involved in the provision of finance. No private company can operate successfully to high environmental standards if its competitors are able to avoid operating to similar standards due to ineffective waste regulation.
- The permitting process is undertaken in Member States either in a centralised fashion by a national environmental agency or by regional competent authorities, which, in at least one Member State, are audited by a central body. The competent authority should ensure that the appropriate conditions, particularly those relating to potential pollution of the environment, are incorporated into permits. This will require a technical and environmental assessment of the facility and the consideration of other issues such as water and air quality.
- National laws in many Member States extend the directive's polluter pays principle, which is fundamental to all projects, by making the producer of the waste liable and responsible for environmentally sound waste management if a subsequent holder of the waste disposes of it improperly. This is sometimes called the "duty of care".
- Consideration should also be given to requiring, as part of the permitting process for waste management facilities, that operators can demonstrate some or all of the following:
 - a specified level of technical competence;
 - sufficient financial resources to comply with long-term obligations; and
 - no previous record of convictions for serious environmental offences.
- Systems and procedures for permitting and inspection should be well designed and carefully documented to ensure a standardised approach and consistency in application. Without consistency, there is a danger that operators will favour areas where procedures are least rigid.
- The European Commission has prepared Guidance on permitting and inspection of waste management operations and the Practical manual on permitting and inspection of waste management operations accompanying guidance document providing a practical advice to improve permitting and inspection of waste management operations. Both documents are available at: <http://ec.europa.eu/environment/waste/framework/inspections.htm>.
- When setting standards for the technical conditions to be applied to individual permits, there are two possible approaches: the conditions may be standardised regardless of location; or they may be site specific, based on a detailed risk assessment. The former achieves a level playing field so that no facility has any commercial advantage by virtue of its location. The latter achieves the lowest-cost approach but requires a deeper technical knowledge and understanding by regulators.
- In many instances, it will be necessary to provide training for waste regulators and inspectors in the monitoring and enforcement of technical issues. For instance, training may be required for regulators in the environmentally sound management of waste oils. Technical guidance notes may also be needed. This could be achieved by using external consultants (e.g. from existing EU Member States).
- Waste management facility operators may be charged for the issuing of permits, to cover the administrative costs of permitting, inspection and enforcement.

- The management of waste oils should be conducted in accordance with the priority order of the waste hierarchy, and preference should be given to options that deliver the best overall environmental outcome. The separate collection of waste oils remains crucial to their proper management and the prevention of damage to the environment from their improper disposal.
- Facilities unsuitable for accepting waste oils should be expressly prohibited. This should be recorded and regular audits should be undertaken at the facility to ensure compliance with this decision.
- Waste producers and others in the waste handling chain should be made legally liable for any environmental or health damage caused by the handling, treatment and disposal of hazardous wastes. This means, *inter alia*, that producers should not be able to discharge their liability merely by transferring the waste to another party. In such circumstances they must also show that they have carried out their duty of care by ensuring that the third parties are able to, and will handle the waste in a safe manner and in accordance with the relevant legal requirements.
- Consideration should be given to requiring that establishments or undertakings that produce significant quantities of hazardous waste nominate (to the regulatory agency) a person who has the legal responsibility for waste management within the concern. This person should not have any other responsibilities that may conflict with his/her duties and responsibilities relating to the management of wastes. This ensures that responsibility is allocated to a natural as well as a legal person (which might be a company with limited liability).
- Consignment notes for waste shipments (see Waste Shipment Regulations) vary in complexity among Member States — from a simple one-page form (UK) to some 15 pages (DE), requiring detailed explanations of the steps taken to reuse or recycle the wastes. The more complex the consignment note procedure, the more substantial the resources that would be required to administer it.
- The costs of managing hazardous wastes in an environmentally sound manner are high, which may tempt waste producers to make use of questionable practices. Strict regulatory controls are therefore required, which might include:
 - evaluation of consignment notes before waste movements take place;
 - waste producer registration — identifying waste types, quantities and the disposal methods to be used; and
 - availability of sufficient trained human resources to investigate every reported incident of suspected illegal practices.
- Developments in technology and knowledge of the health risks and environmental impacts associated with hazardous wastes mean that standards are continually evolving. Permits should therefore be subject to regular review and revision in the light of current knowledge.

Examples from a Member State: regulatory controls

France: a financial guarantee must be provided as part of obtaining authorisation for waste disposal or storage at a site. The guarantee is in the form of a written commitment from a credit or insurance company. It must cover the cost of intervention on site in case of pollution, whether before or after cessation of operations, as well as post-operation monitoring and the cost of restoration and aftercare. Negotiations with industry are currently taking place to establish a take-back agreement for waste consisting of electrical and electronic equipment.

The Agency for Environment and Energy (ADEME) produces studies on waste and guides on good management

practices. These include:

- "The Guide to Financing the Collection and Treatment of Municipal Waste." This explains financing mechanisms at the European, national, regional and department levels.
- "Management of Industrial Waste within a Company." This is designed particularly for small companies. It explains how to organise waste management within a company based on ISO 14001.

United Kingdom: UK takes a site-specific risk analysis approach to the permitting of waste management facilities. Emission limit values may be set, but some may be advisory rather than completely mandatory, and are provided in guidance notes. For instance, the Guidance Note on Waste Incineration contains some recommended emission limit values and others that are mandatory. Mandatory values are introduced to ensure conformity with EU Directives, whilst recommended values may include other matters not covered by them.

Germany: introduced detailed and comprehensive legally binding technical guidelines that are applied to all permits regardless of location, in order to ensure that no location experiences a competitive disadvantage by being obliged to adopt higher standards.

Example from a Member State: regulatory controls

United Kingdom: Producers of hazardous waste are placed by law under a mandatory duty of care to ensure that all wastes, including hazardous wastes, are handled without harm to the environment. This requires waste to be transferred to a licensed person. The discharge of the duty of care is governed by a code of practice, which requires producers of hazardous wastes to take reasonable care that systems are in place to ensure that the wastes are not subsequently transferred to an unlicensed operator. This requires a careful audit trail by means of consignment notes. There is no system of registration for waste producers.

This same Member State requires all hazardous waste management facilities, including those performing recovery operations, to be permitted in the same manner as provided for under the Waste Directive. Facility operators are subject to the duty of care, and failure to comply is a criminal offence. The competent authority undertakes enforcement.

Furthermore, UK has specified technical qualifications for permit holders, according to the type of waste management facility. It also requires, for example, landfill operators to provide sufficient financial security (by means of bonds, guarantees, sinking funds or escrow accounts) to cover the costs of restoration and aftercare. Permits may be refused to applicants who have been convicted of environmental offences.

Examples from a Member State: transpositional measures

United Kingdom: The Waste (England and Wales) Regulations 2011 (S. I. 2011/988) came into force on 29 March 2011. These Regulations affect all companies within the waste chain including waste carriers and brokers. Under these Regulations businesses have to apply the waste management hierarchy when transferring waste, and to include a declaration on their waste transfer note that this has been done. The Regulations have excluded some new categories of waste from control and the controls on hazardous wastes have been amended.

The application of the waste hierarchy will become a standard condition of an environmental permit for an operation which generates waste, and will be added to existing permits at time of review. The waste hierarchy is also set to apply to waste collections with a requirement of separate collections of waste paper, metal, plastic and glass from 1 January 2015.

The Regulations introduces a two-tier system for waste carrier, broker and dealer registration.

- 1) Upper tier: Companies which carry, broker or deal in controlled waste produced from another source need to register as an upper tier carrier or broker. Companies carrying construction and demolition waste will also need to register in this upper tier, even if carrying their own waste.
- 2) Lower tier: Persons who only carry, broker or otherwise deal in the following categories of waste:
 - Animal by-products;
 - Waste from mines and quarries; and
 - Waste from agricultural premises

Also, certain groups will need to register in this lower tier if they are carrying, brokering or dealing in other people's waste (i.e. a waste collection, disposal or regulation authority; and a charity or voluntary organisation)

From the end of December 2013 companies will be required to register as a lower tier carrier where they normally and regularly carry their own controlled waste (other than construction or demolition waste, which falls into the higher tier, as discussed above). This change was brought in to rectify a gap identified by the ***Court of Justice of the European Union ruling in European Commission v Italy (Case C-270/03)***.

Source: <http://www.stjohnsbuildings.com/>

Examples from a Member State: legal transposition

Malta: Following a public consultation on the transposition and implementation of this Directive carried out in collaboration with the Malta-EU Steering and Action Committee (MEUSAC) in July 2009, Malta transposed this Directive through Legal Notice 184 of 2011, the Waste Regulations 2011.

The overarching objective of these Regulations, in line with Directive 2008/98/EC, is to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving the efficiency of such use.

The main obligations emerging from the Regulations include the following:

1. Local councils must set up separate collection for at least paper, metal, plastic and glass by 2013.
2. Any person who collects and/or transports waste on a professional basis, dealers, brokers and waste treatment operators is required to possess the minimum qualification requirements as defined by the competent authority.
3. The competent authority may introduce legislative measures for specific products, such as oils and tyres, so that producers of such products use existing systems or set up systems, individually or collectively, or both, in accordance with any existing laws and regulations, to provide for:
 - the return and, or collection of waste from the consumer, other final user, or from the waste stream in order to channel it to the most appropriate waste management alternatives;
 - the recovery, including regeneration in the case of waste oils, where technically feasible and economically viable of the waste collected.
4. Review of the national waste management plan and the setting up of national waste prevention programmes by 2013. The objectives and provisions that are to be included in the plan and waste prevention programme are laid down in Schedule 5 of the Regulations. These include:
 - the organisational aspects related to waste management, such as collection frequency and collection times, including a description of the allocation of responsibilities between public and private actors carrying out waste management;
 - an evaluation of the usefulness and suitability of the use of economic and other instruments in tackling various waste problems, taking into account the need to maintain the smooth functioning of the internal market;
 - the use of awareness campaigns and information provision directed at the general public or at a specific set of consumers;
 - historical contaminated waste disposal sites and measures for their rehabilitation.
5. Producers of hazardous waste and establishments and undertakings which collect hazardous waste must trace, from production to final destination, and control hazardous waste.

4.5. Reporting

- Government will need to decide which agency has responsibility for reporting to the Commission. Most existing EU Member States choose a central government ministry for this function, although some data need to be provided by the competent authorities.
- A system will be required to collect and process data for reporting. The importance of this should not be underestimated.

- Facility operators must be made aware of their reporting obligations at the permitting stage.

4.6. Technical Advice and Guidance

Technical guidance is an important feature. As technology and procedures are complex and constantly developing, it is not practical to incorporate every requirement into legislation. Waste regulators, waste producers and waste managers therefore need reference documents that explain the procedures they should follow and some of the options with which they are faced. This can best be done by means of official technical guidance documents, which can readily be revised. For instance, competent authorities need to prepare the necessary guidance for the establishments or undertakings as well as the producers to make clear all details of their obligation to keep specific records and information and to make it available to the competent authority upon request

Examples from a Member State: guidance on waste input and outputs:

Ireland: The Irish Environmental Agency has produced the following guidance:

Waste input	Valuable outputs
Biodegradable waste (segregated at source)	Compost; products of anaerobic digestion (biogas and fertilisers)
Blast furnace slag (BFS)	Aggregate
Construction, demolition and excavation waste (inert)	Aggregates
Cooking oil and rendered animal fat	Biodiesel
Glass – cathode ray tube (CRT)	Aggregate; CRT glass manufacture; X-ray shielded glass
Glass – flat	Processed cullet (various uses)
Incinerator bottom ash (IBA)	Aggregate
Lubricating oil	Processed fuel oil
Marine-dredged materials (MDM)	Aggregates
Paper sludge ash (PSA)	Agricultural liming agent; cement and block manufacture; sewage sludge stabiliser; desiccant for cattle bedding
Plasterboard	Gypsum for plasterboard and cement manufacture; soil improver
Plastics (non packaging)	Raw material for various uses
Poultry litter ash (PLA)	Agricultural fertiliser
Pulverised fuel ash (PFA) and furnace bottom ash (FBA)	Aggregate
Soil – contaminated	Can be selectively used as soil but end-of-waste criteria to be decided on a case-by-case basis
Soil – uncontaminated topsoil	Can be used as topsoil but end-of-waste criteria to be decided on a case-by-case basis
Steel slag	Aggregate and soil modifier
Tyres	Tyre crumb (various uses); tyre bales for civil and construction works
Wood – non-virgin, from post-industrial and post-consumer sources	Chipboard; animal bedding; horticultural mulch; biomass fuel

Examples from a Member State: calculating BMW content of municipal waste

Ireland: The below table lists the current factors to calculate the BMW content of municipal waste streams, as approved by Irish EPA (published in June 2011).

Municipal Waste Stream	BMW factor
Untreated 1-bin household waste Note 1	0.65
2-bin residual household waste	0.63
3-bin residual household waste	0.47
Untreated 1-bin commercial waste Note 1	0.77
2-bin residual commercial waste	0.75
3-bin residual commercial waste	0.68
Untreated MSW skip waste Note 1	0.35
Bulky waste from sorting of MSW skips	0.50
Oversize residues from MSW skips	0.43
Fines residues from MSW skips	0.40
Oversize residues from MSW bin collections (“wet waste”)	0.41
Fines residues from MSW bin collections (“wet waste”)	0.95
Residues from source separated recyclable waste (“clean MRF”)	0.47
Bio-stabilised residual waste	0
Untreated cleansing waste (fly-tipping, street bins, road sweepings etc.) Note 1	0.65
Residual MSW from civic amenity facility	0.63
Ash residue from MSW incineration	0

Source:

http://www.epa.ie/downloads/advice/waste/municipalwaste/Table_of_Approved_EPA_Factors.pdf

Examples from a Member State: Guidance materials

United Kingdom: the Department for Environment Food and Rural Affairs (DEFRA) adopted guidance to accompany the transposing Regulations in England. Guidance for businesses and organisations on how waste disposal is regulated and what they need to do to comply is available at: <https://www.gov.uk/guidance/waste-legislation-and-regulations>

4.7. Communications and Consultation

- The permitting process requires extensive consultations to be conducted with other regulatory bodies, both those involved in environmental sectors (this will be achieved through the IED and those involved in other sectors such as health and safety, fire prevention, road traffic etc.
- Public consultation on key components of this Directive is an important feature. This is often undertaken through the land-use permitting system, which is a required precursor to application for a permit and where public consultation is mandatory. An environmental impact assessment, if required, is applied at this stage, providing further procedures to ensure the involvement of stakeholders and the public. Through this procedure, the public has an opportunity to express its opinion on the siting of facilities. Also stakeholders (e.g. waste producers, waste managers, NGOs) and the public should have be consulted during the development of the integrated waste management plan, comprising section on hazardous waste, and the waste prevention programmes and the final documents be made publicly available.
- To avoid that the consultation process lead to extensive delays in granting permits it is crucial that the national regulations introduce clear time limitations on the consultation procedure.

Examples from a Member State: waste management plans

Slovakia: Waste management plans are subject to mandatory impact assessment of strategic documents under the Act on the environmental impact assessment. Also Regional Environmental Office is obliged to publish a draft of the plan as usual at least for 30 days to take enable to inform the public of the affected area. Public (including municipalities) have the right to make written comments within this period. Regional Environmental Office is obliged to hold a public hearing draft of the program and take into account written comments submitted to the processing of the plan. Waste management plans approved for the Slovak Republic are available on the Internet.

5. COSTS

Meeting the requirements laid down in both the Waste Directive, which now incorporates provisions of the former Hazardous Waste Directive (91/689/EEC) and the Waste Oils Directive (75/439/EEC), together with the provisions set out in the Landfill Directive (99/31/EC), is likely to be very costly. The provision of higher-standard facilities together with the creation of an adequate institutional structure providing for waste permitting and drafting and implementation of waste management plans and waste prevention programmes will constitute the largest elements of the overall costs of achieving compliance.

It should be appreciated that the provision of facilities will incur not only initial capital costs but also significant recurring annual costs for operation and maintenance, together, in the case of landfill, with long-term costs for restoration and aftercare. Most facilities are also subject to very substantial economies of scale, with the unit costs of larger plants being much lower than those of smaller ones. Another factor that has an impact on costs is land. In most Member States the cost of land for hazardous waste treatment processes is very high, because of the scarcity of suitable sites that are acceptable in land-use planning terms. Further costs will be incurred in providing the additional human resources required within the competent authority(ies).

The main types of costs arising during the implementation of the Waste Directive are illustrated in the checklist below.

Table 16. Checklist with examples of implementation cost

<p>Initial set-up costs:</p> <ul style="list-style-type: none"> • establishing the competent authority(ies); • devising systems and procedures; • providing training; • preparing technical guidance notes; • preparing a waste management strategy and detailed plans.
<p>Capital expenditures:</p> <ul style="list-style-type: none"> • waste oils regeneration and disposal facilities; • new and upgraded storage, disposal and treatment facilities for municipal waste, hazardous waste and special waste streams (including medical, foodstuff); • hazardous waste incinerators; • adaptation of co-incineration plants, such as cement kilns, to accept certain hazardous wastes for incineration; • physico-chemical treatment plants; • solidification plants for certain wastes before landfilling, to ensure acceptable leaching and other applicable criteria (see further under the Landfill Directive (99/31/EC)); • secure landfills solely for hazardous wastes; • transfer stations for the sorting and accumulation of small quantities of hazardous wastes for further treatment; • collection and transport systems for both liquid and solid hazardous wastes; • storage facilities at waste producers premises — especially tanks for liquid wastes.
<p>Ongoing running costs:</p> <ul style="list-style-type: none"> • regeneration and disposal of waste oils; • collecting of waste oils; • issuing of permits and registrations;

- annual operating costs of hazardous waste management facilities;
- periodic inspections of waste producers and carriers, and taking enforcement action;
- processing of consignment notes;
- collecting data for reporting to the Commission;
- reporting requirements pursuant to the EPRTR Regulation (EC) No. 166/2006);
- inspections of waste management facilities, and taking requisite enforcement action;
- collecting data for reporting to the Commission;
- consultation procedures;
- implementation of a communications programme;
- reporting to the Commission.

THE DIRECTIVE ON THE DISPOSAL OF PCBS AND PCTS

Official Title: Council Directive 96/59/EC on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT) (OJ L 243, 24.9.96), as amended by Regulation (EC) No 596/2009¹⁵⁶ (OJ L 188, 18.7.2009)

¹⁵⁶ Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Directive 96/59/EC on the disposal of PCBs and PCTs aims at disposing completely of PCBs and equipment containing PCBs as soon as possible. This Directive sets the requirements for an environmentally sound disposal of PCBs. Member States have to make an inventory of larger equipment containing PCBs, have to adopt a plan for disposal of inventoried equipment, and outlines for collection and disposal of non-inventoried equipment (small electrical equipment very often present in household appliances manufactured before the ban on marketing of PCBs). Also the Member States had to dispose of big equipment (equipment with PCB volumes of more than 5 litres) by the end of 2010 at the latest.

Inventories must be compiled of equipment with PCB volumes of more than 5 dm³, which Member States must send to the Commission by September 1999 at the latest. These inventories must supply certain data; e.g. the names and addresses of the holders; the location and description of the equipment; the quantity of PCBs contained in the equipment; the date and types of treatment planned; and the date of the declaration.

Any equipment which is subject to inventory must be labelled.

Member States must prohibit the separation of PCBs from other substances for the purposes of reusing the PCBs and the topping-up of transformers with PCBs.

Member States must take the necessary measures to ensure that:

- PCBs, used PCBs and equipment containing PCBs which is subject to inventory are transferred to licensed undertakings, at the same time ensuring that all necessary precautions are taken to avoid the risk of fire;
- any incineration of PCBs or used PCBs on ships is prohibited;
- all undertakings engaged in the decontamination and/or the disposal of PCBs, used PCBs and/or equipment containing PCBs obtain permits;
- transformers containing more than 0.05% by weight of PCBs are decontaminated under the conditions specified by the Directive.

Regulation No 596/2009 amended the Directive to allow for the regulatory (committee) legislative procedure for producing a list of the production names of capacitors, resistors and inductance coils containing PCBs, fix reference methods of measurement to determine the PCB content of contaminated materials, fix technical standards for the other methods of disposing of PCBs.

Furthermore, the Commission has adopted an EU Strategy¹⁵⁷ on Dioxins, Furans and PCBs aimed at reducing as far as possible the release of these substances in the environment and their introduction in the food chains.

In addition, Regulation (EC) No 850/2004 on persistent organic pollutants covers PCB.

More information about PCBs and the EU legislative framework is accessible on DG ENV website: <http://ec.europa.eu/environment/waste/pcbs/index.htm>

¹⁵⁷ Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee Community - Strategy for Dioxins, Furans and Polychlorinated Biphenyls (COM/2001/0593 final). Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52001DC0593:EN:NOT>

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Compile and regularly update inventories of equipment containing PCBs. (Arts. 3 and 4)
- Draw up plans for the decontamination and/or disposal of PCBs and of equipment containing PCBs which is notified and inventoried in accordance with Article 4 ("inventoried equipment"). (Art. 11)
- Draw up plans for the collection and disposal of non-inventoried equipment. (Art. 11)
- Develop installations for the disposal, decontamination and safe storage of PCBs. (Art. 8)
- Ensure that PCBs and equipment containing PCBs are decontaminated or disposed of within specified deadlines. (Art. 3)

2.2. Regulation

- Require holders of equipment containing PCBs to notify the competent authorities. (Art. 4)
- Ensure that inventoried equipment is labelled. (Art. 4)
- Ensure that operators who dispose of PCBs comply with certain procedural requirements, including keeping registers of information and making information available to competent authorities and the public (Art. 4)
- Prohibit:
 - the separation of PCBs from other substances for the purpose of the re-use of PCBs (Art. 5);
 - the filling of transformers with PCBs;
 - the maintenance of transformers containing PCBs except subject to specified conditions (Art. 5); and
 - the incineration of PCBs on ships (Art. 7).
- Where PCBs are incinerated, ensure compliance with the requirements on waste incineration set by the Industrial Emissions Directive 2010/75/EU¹⁵⁸ and where other disposal methods are used, ensure that equivalent environmental safety standards and best available techniques are applied. (Art. 8)
- Ensure that decontamination and disposal of PCBs, or equipment containing PCBs, is carried out subject to a permit in accordance with the Waste Directive and subject to specified conditions. (Arts. 8 and 9)

¹⁵⁸ Committee Community - Strategy for Dioxins, Furans and Polychlorinated Biphenyls (COM/2001/0593 final). Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52001DC0593:EN:NOT>

- Ensure that used PCBs and equipment containing PCBs are transferred, removed or collected in accordance with specified requirements. (Art. 6)

2.3. Communication and Reporting

- Report to the Commission on:
 - inventories of equipment containing PCBs (Art. 4);
 - plans for the decontamination and/or disposal of equipment containing PCBs (Art. 11);
 - the implementation of the Directive (Art. 10 and Council Directive 91/692/EEC);
 - measures taken to comply with the Directive (Art. 12); and
 - transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 12).

2.4. Additional Legal Instruments

A number of other legislative instruments may have relevance to the management of PCBs and PCTs and must also be borne in mind during the implementation of this Directive. These include:

- Commission Decision 2001/68/EC on reference methods for the measurement of PCBs
- Waste Framework Directive (2008/98/EC)
- RoHS Directive (2011/65/EC)
- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) 1907/2006
- Regulation (EC) No. 1907/2006 on the registration, evaluation and assessment of chemicals (REACH)
- Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants
- Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals
- Regulation on supervision and control of shipments of waste (EC) No. 1013/2006
- Commission Regulation (EC) No. 1418/2007 concerning the export and recovery of certain waste listed in Annex III or IIIA to Regulation (EC) No. 1013/2006 to certain countries to which the OECD Decision on the control of transboundary movements of waste does not apply
- Commission Decision 96/302/EC establishing a format in which information is to be provided pursuant to Article 8(3) of Council Directive 91/689/EEC

- Industrial Emissions Directive (2010/75/EU)
- Environmental Impact Assessment Directive (2011/92/EU)

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the following checklist, organised in chronological order (where possible) within each subheading.

Table 17. Checklist with implementation tasks

DIRECTIVE ON THE DISPOSAL OF PCBs AND PCTs - KEY IMPLEMENTATION TASKS	
1	Planning and Provision of Infrastructure
1.1	Designate a competent authority responsible for performing duties arising from the Directive. The authority's responsibilities would include: <ul style="list-style-type: none"> • compiling an inventory of equipment containing PCBs; • developing a programme for the disposal and decontamination of all equipment containing PCBs; • ensuring that equipment containing PCBs is properly labelled; • providing guidance to PCB disposal undertakings; • assessing PCB disposal, contamination and storage facilities.
1.2	Produce a national plan to eliminate PCBs in accordance with the requirements of the Directive.
1.3	Carry out an assessment of the number and capacity of PCB disposal, decontamination and safe storage facilities.
1.4	Put in place a programme for the disposal and decontamination of all equipment containing PCBs.
1.5	Set up a system for compiling and updating the inventory of equipment containing PCBs. The procedure for compiling the inventory should include details of information that should be gathered from PCB disposal undertakings.
1.6	Establish a labelling system for PCBs.
1.7	Ensure the timely provision of the necessary facilities identified in the national plan.
1.8	Consider extending the phase-out period beyond the 31 December 2010 deadline long enough to allow owners to dispose of PCB contaminated waste.
2	Regulation
2.1	Determine conditions under which stocks of PCBs are to be maintained before disposal in accordance with the Directive.
2.2	Make mandatory the notification of PCB stocks and the conditions under which they are maintained.
2.3	Provide guidance for holders of PCBs on their identification and procedures to be followed.
2.4	Establish an inspection system to cover inspections of holders of PCB equipment and PCB disposal undertakings and undertakings that carry out maintenance of transformers. Inspect equipment containing PCBs and ensure it complies with the conditions.
2.5	Ensure that the decontamination of equipment containing PCBs is a process that has to be permitted under waste management legislation in accordance with the Waste Directive and issue permits for decontamination that comply with the conditions in the Directive.
2.6	Issue permits for disposal facilities that need to comply with the provisions of Industrial Emissions Directive 2010/75/EU and otherwise comply with BAT, and ensure continuing effective enforcement.
3	Reporting
3.1	Establish reporting systems to ensure that the data required (see below) are collected.
3.2	Report to the Commission on:

	<ul style="list-style-type: none"> • inventories; • plans for the decontamination and/or disposal of inventoried equipment; • transposition and implementation.
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3.2. Phasing Considerations

Experience within Member States suggests that priority should be given to the following tasks:

- Inventory (necessary for establishing planning on the basis of an idea of the magnitude of the problem).
- Preparation of a plan for the elimination of PCBs, with timescales and responsibilities clearly allocated.
- Transposing the requirements of the Directive into national legislation and policy.
- Establishing and developing the institutional structure for controlling PCBs and the training of sufficient personnel.
- The detailed planning, design, permitting, procurement and construction of new or upgraded facilities for treating and disposing of PCBs.

These tasks should therefore be planned to commence during the initial phase of implementation. The reporting requirements will necessitate the establishment of a data collection system, to ensure that the information is readily available for reporting.

First ex-post evaluation of the implementation of the PCB Directive¹⁵⁹ has found that most Member States have not been able to comply with the obligation “to eliminate all PCB equipment with size > 5 dm³ and concentration > 500 ppm” by 31 December 2010. For newer Member States e.g. Bulgaria, Croatia, not benefiting from transition provisions in its accession treaty, it was even harder to meet the PCB disposal deadline. The drawbacks in meeting the deadline could be explained by economic problems, legal problems, lack of communication and information, illegal handling and robbery of PCB equipment, discovery after 2010 of privately owned PCB equipment and lack of incineration facilities. Hence, candidate countries should try to eliminate or mitigate the obstacles hampering effective implementation of this Directive.

¹⁵⁹ Ex-post evaluation of certain waste stream Directives, Final report, European Commission – DG Environment 18 April 2014

4. IMPLEMENTATION GUIDANCE

Drawing upon the experience of selected Member States, a number of general observations and suggestions for implementing this Directive are presented below.

4.1. Planning and Provision of Infrastructure

- Ensure the elimination of PCBs.
- Plans setting out the procedures and facilities necessary to eliminate PCBs will be required, with timescales and responsibilities clearly identified.
- When planning for the elimination of PCBs, account must be taken of the availability of environmentally appropriate disposal routes. It may be that principles of self-sufficiency and proximity need to be set aside for economic reasons. Planning should also take into account how long it will take to provide viable alternatives to PCB-filled equipment when setting the deadlines for elimination.
- Ensure that disposal facilities complying with the requirements of the Directive are available or are constructed, as identified in the elimination plan.
- High temperature incineration is the only practical solution at the present time for the disposal of PCBs, and this is very costly. In the short term, it may be possible for some Member States who do not yet have suitable incineration capability to make use of the facilities available in existing Member States, some of which have excess capacity. This is contrary to the proximity principle but in certain circumstances may be acceptable on economic grounds. (Article 6 (3) recognises this problem and provides for co-operation between Member States.)

Examples from a Member State: Regulatory controls

Sweden: national legislation concerning PCBs was introduced in 1972; requiring permits to be obtained for the new use of PCBs. Permits were subsequently issued only for certain types of heavy electrical equipment. No permits for the new use of PCBs have been issued since 1978. This Member State has a ban on the on-going use of transformers and power capacitors (> 2kVAr) containing PCBs and these were due to be phased out by 1995.

Attention then focused on buildings, small capacitors and the "open" uses of PCB in sealants, glazing units and flooring. Leakage from flooring is known to occur and there is a voluntary agreement in the building trade (consultants, owners, builders and material suppliers) to maintain an inventory of material containing PCBs.

4.2. Regulation

- A competent authority to control PCBs and their elimination will need to be appointed. It is most likely that this will be the authority appointed to issue permits for waste management facilities under the Waste Framework Directive, as is the case in most, if not all, Member States. Specialised training is likely to be required.
- In order to prepare inventories, it will be necessary to require holders of PCBs to report the quantities held.
- It will be necessary to ensure that unsuitable facilities are expressly prohibited from accepting PCBs. Such controls can be implemented through permitting procedures. The competent authorities would then only authorise facilities that they were convinced were suitable.
- The conditions for the maintenance of PCBs are at the discretion of Member States. These should be established with due regard for health, safety and the environment. There is no specific legislation controlling the way in which PCBs are marked or stored in some Member States, although others have introduced strict regulations. In these cases, they are often classified as dangerous substances and therefore subject to the extensive legislation on this subject and on health and safety.
- Technical guidance notes for industry and regulators will be required to explain how to identify whether PCBs are being held, and the procedures necessary for their safe storage and elimination.

Examples from a Member State: Eliminating PCB containing equipment

Germany: Equipment with PCB volumes of more than 5 litres was disposed of before the deadline stipulated by the PCB Directive. Inventories were established in 2000 and 2010. The last inventory in 2010 revealed few cases where small electrical equipment was discovered coming mostly from private households. In addition, few publicly owned electrical transformers were discovered and disposal plans have been established.

Netherlands: two main actions were undertaken, first in the 1980s and then during 2000-2004, which collected many transformers. Today around 0.1% of the original amount is still being removed each year.

France: In 2009, the French utility company organised a national inventory of over 70 000 transformers containing PCBs, followed by a large clean-up operation in 2010. Finally, in France, authorities started a reflection on actions to implement after the PCB Directive's 2010 deadline. A decree was issued in April 2013 that requires the decontamination of equipment containing PCBs at a level between 50 and 500 ppm by 2025. The decontamination process will happen in three phases depending on the manufacturing date of devices. For holders that own more than 150 pieces equipment, "special phase-out plans" can be submitted, stipulating that at least 50% of their equipment must be decontaminated by 2020 and the rest by 2025.

Source: Ex-post evaluation of certain waste stream Directives, Final report, European Commission – DG Environment 18 April 2014

5. COSTS

The main types of costs arising during the implementation of this Directive are illustrated, as far as possible, in the checklist below.

The additional costs of administering this Directive, over and above the introduction of the Waste Framework and Hazardous Waste Directives, are relatively small. The major cost item may be the provision of suitable facilities for the destruction of PCBs if these are not already available. A modern waste incinerator capable of incinerating a wide range of wastes, including PCBs, may cost as much as EUR 60 million or more. This figure is for a 50,000 tonne p.a. plant with capacity to incinerate other materials as well. Please note that if larger quantities of PCBs are detected at the initial phase of implementing the PCB Directive, which exceed the domestic incineration capacities, the candidate country may have to consider exporting the exceeding quantities to other EU Member States with sufficient incineration capacity. Such exports are subject to the provision of the Waste Shipment Regulation ((EC) No 1013/2006).

Table 18. Checklist with examples of implementation costs

Initial set-up costs: <ul style="list-style-type: none">• preparing a plan for elimination of PCBs;• preparing an inventory of PCBs;• devising systems and procedures;• provision of training;• preparing technical guidance notes.
Capital expenditure: <ul style="list-style-type: none">• hazardous waste incinerators;• storage facilities at waste producers' premises.
Ongoing costs: <ul style="list-style-type: none">• costs of disposal of PCBs;• costs of storage of PCBs;• periodic inspections of stocks of PCBs;• continuing regulatory and requisite enforcement action;• collecting data for reporting to the Commission.

THE SEWAGE SLUDGE DIRECTIVE

Official Title: Council Directive 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture, as amended by Directive 91/692/EEC (OJ L 181, 04.07.86) and Regulation (EC) No. 807/2003 (OJ L 122, 16.5.2003) and Regulation (EC) No 219/2009 (OJ L 87, 31.3.2009)¹⁶⁰

¹⁶⁰ Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Two

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The main aims of the Directive are to regulate the use of sewage sludge in agriculture in order to prevent harmful effects on soil, vegetation, animals and humans, and to encourage the correct use of sewage sludge. To achieve these aims, the Directive requires Member States to apply maximum limit values for certain heavy metals, both in the sewage sludge and in the soil to which it is applied, to pre-treat sludge, and to restrict its use on certain soils. Regulation No. 807/2003 and Regulation No 219/2009 modify the Directive only in terms of the procedure for updating the annexes. The main aim of the Regulation is to ensure a faster procedure for amending annexes to reflect scientific and technical progress. A substantial improvement has been achieved by the introduction of a committee procedure.

The European Commission is currently assessing whether the current Directive should be reviewed – and if so, the extent of this review. For example, the Directive may have to be adapted to match the developments in several Member States where stricter limit values for heavy metals also covering a wider scope of contaminants have been introduced. This review so far has involved public consultations in 2010, a study¹⁶¹ on the environmental, economic, and social as well as health impacts of present practices of sewage sludge use on land. More information about the review and the study and public consultations can be obtained from DG ENV website: <http://ec.europa.eu/environment/waste/sludge/index.htm>

¹⁶¹ This study identified possible options for European policy and estimated their costs and benefits and has been commissioned to the consultancy team of Milieu Ltd, WRc PLC and RPA Ltd

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Regulation

- Ensure that the use of sewage sludge in agriculture is regulated and complies with the conditions laid down in the Directive relating to:
 - pre-treatment (Arts. 3 and 6);
 - the nutrient needs of plants (Art. 8);
 - the quality of soil (Art. 8);
 - the protection of surface waters and groundwaters (Art. 8);
 - complying with limit values for the concentration of heavy metals in soil (Art.5).
- Prohibit the use of sewage sludge:
 - on specified categories of land within defined periods prior to harvesting (Art. 7);
 - where the concentration of heavy metals in the soil exceeds specified limit values (Art. 5 and Annex IA).
- Ensure that records containing the following information are kept and made available to the competent authorities:
 - the quantities, composition, use, treatment, and results of analysis of sewage sludge;
 - the names and addresses of recipients of sewage sludge;
 - places where sewage sludge is to be used (Art. 10).
- Require producers of sewage sludge to provide users with specified information relating to the composition of the sludge (Arts. 6 and 11 and Annex IIA).

2.2. Monitoring and Enforcement

- Analyse sewage sludge, and the soil on which it is used, to ensure that concentrations of heavy metals in the sludge and soil do not exceed specified limit values. (Art. 9 and Annexes IIA, B and C)
- Ensure that effective, dissuasive and proportionate (criminal) sanctions are introduced for non-compliance as the Sewage Sludge Directive is listed as one of the Directives for which Member States have to ensure criminal sanctions under the Environmental Crimes Directive (2008/99/EC).

2.3. Reporting

- Report to the Commission on:
 - the use of sewage sludge in agriculture (Art. 17 and Council Directive 91/692/EEC);
 - measures taken to comply with the Directive, including circumstances where more stringent measures than required under the Directive are adopted (Art. 16);
 - transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 16).

2.4. Additional Legal Instruments

A number of other legislative instruments have relevance to the incineration of sewage sludge and must also be borne in mind during the implementation of this Directive. These include:

- Waste Framework Directive (2008/98/EC)
- Environmental Impact Assessment Directive (2011/92/EU)
- SEA Directive 2001/42/EC
- Access to Environmental Information Directive (2003/4/EC)
- Urban Waste Water Treatment Directive (91/271/EEC, as amended)
- Water Framework Directive (2000/60/EC) also covering surface water protection
- Directive 2008/105/EC on environmental quality standards in the field of water policy
- Landfill Directive (1999/31/EC)
- Mining Waste Directive (2006/21/EC)
- Regulation on export and recovery of certain wastes ((EC) No. 1418/2007)
- Environmental Crimes Directive (2008/99/EC)
- Directive on Industrial Emissions (2010/75/EU)
- The European Pollutant Release and Transfer Register (PRTR) (Regulation ((EC) No. 166/2006) in case of large applications (10 tonnes per day)
- Heavy Metals in Air Directive (2004/107/EC)

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the following checklist, organised in chronological order (where possible) within each sub-heading.

Table 19. Checklist with key implementation tasks

THE SEWAGE SLUDGE DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate a competent authority to regulate the spreading of sludge on agricultural land.
1.2	Establish a prior authorisation procedure requiring a permit to spread sludge on farmland.
1.3	Engage in dialogue with stakeholders and major producers of sewage sludge to identify possibilities and problems relating to using sewage sludge. Identify the most acceptable user applications of sludge.
1.4	General public consultation and awareness raising about the possibilities for sewage sludge and the controls to regulate the content of dangerous substances.
1.5	Integrate the provisions on sewage sludge in the overall national and local waste management plans assessing the role of sewage sludge to reduce the reliance on landfilling and incineration (without energy recovery).
1.6	Produce guidance on acceptable methods of sewage sludge treatment and spreading on farmland.
1.7	Specify limits for heavy metals in soil and consider introducing stricter limit values for heavy metals as being done in several Member States.
1.8	Adaptations to the regulatory and sanctioning system to ensure that non-compliance is sanctioned.
1.9	Ensure efficient supervision and monitoring of competent authority and self-regulation of industrial and other commercial operators producing significant amounts of sewage sludge.
1.10	Select method of applying heavy metal limits (according to Art 5.2).
2	Regulation
2.1	Ensure that sludge producers are required to make the required information available to the competent authority.
2.2	Ensure restrictions on cropping and sludge use in accordance with the Directive.
3	Reporting
3.1	Establish reporting and data recording systems to ensure that data are collected on transposition and implementation and reported to the Commission.
4	Monitoring and enforcement
4.1	Establish a soil sampling programme.
4.2	Monitor to ensure that restrictions on cropping are complied with.
4.3	Ensure that effective, dissuasive and proportionate (criminal) sanctions are introduced for non-compliance as the Sewage Sludge Directive is listed as one of the Directives for which Member States have to ensure criminal sanctions under the Environmental Crimes Directive (2008/99/EC).

3.2. Phasing Considerations

Experience within Member States suggests that priority should be given to establishing and developing the institutional and regulatory structure for controlling the spreading of sludge on farmland and the training of sufficient personnel. Priority should also be given to awareness rising among the public and key stakeholders to enhance the knowledge of the potentials for controlled use of sewage sludge in applications such as agriculture and as construction material or using sludge in anaerobic processes to produce biogas. Ensuring that limit values are met and possibly introducing stricter limit values for heavy metals than those prescribed by the Directive will result in greater public support for extended use of sewage sludge. Also close attention should be given to the overall waste management and disposal policy and the preferred waste disposal options given the existing waste management infrastructure, investments and local peculiarities and needs. Using sewage sludge will contribute to reduced amounts of sludge ending up in landfills or in incineration.

4. IMPLEMENTATION GUIDANCE

Sewage sludge from domestic sewage treatment works is a useful source of nitrogen, phosphorus and organic matter and is therefore generally beneficial if applied to agricultural land. Spreading on land is often the most economical way of disposing of sludge and provides a source of cheap nutrients. Sludge may, however, contain significant levels of heavy metals due to industrial discharges to sewer, surface water run-off into combined sewer networks, and from domestic sources.

Drawing upon the experience of selected Member States, a number of general observations and suggestions for implementing this Directive are presented below.

4.1. Planning

- It will be necessary to designate a competent authority to regulate the spreading of sludge on agricultural land. The same competent authority as that created for the Waste Directive would be the most likely choice. However, in some countries, the competent authority for the implementation of this Directive is the one responsible for agriculture.
- The areas where sewage sludge is spread or could be spread should be identified and soil content analysed for pH and metals. Limits for heavy metals in soil can be established using these results but they must not be higher than the limit values prescribed by the Directive (taking into account that these values are likely to become more stringent as a result of the current review of the Directive).
- The Directive provides for two alternative methods of specifying limits for the application of sludge in Article 5.2 in order to ensure that heavy metal concentrations do not exceed the limits set out in Annex 1A. It may be done either by means of specifying the maximum quantities of sludge which may be applied to soil over a unit area annually while observing the limits on maximum concentrations as set out in Annex 1B (Art 5.2a); or require compliance with limit values for the quantities of metals introduced into a unit of soil over a particular time period (Art. 5.2b and Annex 1C). The second method provides greater flexibility, especially if heavy metal concentrations are typically lower than the maximum shown in Annex 1B.
- In certain EU Member States (Denmark, Finland, Sweden, Netherlands) provisions are more stringent than those set out in the Directive. This may mean that these states allow lower concentrations of particular parameters specified, or that they include a wider range of parameters such as pathogens, nitrates, phosphates or organic contaminant

Examples from Member States

Sweden: One of the main elements of the monitoring is to appreciate the actual use of sewage sludge and identify the application areas. It will be important to sample the soil to measure concentrations of heavy metals.

During 2010 some 203 520 tons of sewage sludge was produced in Sweden, whereof 50,460 was used on agricultural land (approx. 25% of total amount). The remaining amounts were used as construction soil (fillers for parks and golf courses).

Source: Swedish EPA

4.2. Regulation

- Producers of sludge should be obliged to identify themselves to the competent authority and apply for authorisation to spread sludge. This should be through a system of permitting, in which application should be made in advance of the operation and conditions applied to the methods and types of sludge spreading. This permitting has to be fully consistent with permitting under the IED (2010/75/EU) and under Waste Framework Directive (2008/98/EC) and also take into account specific restrictions concerning the location of the sludge use, respecting certain nature protection areas.
- In issuing permits, consideration should be given to the linkages between sludge disposal and the potential for transmission of pathogens to the human food chain, and into watercourses or supplies through nutrient leaching. For instance, sewage sludge is not recommended in areas in close vicinity to major water bodies, statuaries and coastal areas, unless rigorous control and monitoring is ensured.
- Sludge producers must be obliged to provide the owners of land where sludge will be applied with details of sludge composition.

Examples of Member States (Regulatory Controls)

United Kingdom: The UK operates a pre-notification system through its competent authority.

This is designed to ensure that sewage sludge is given suitable treatment before spreading on agricultural land, and has led to the setting of legal limits for metals in soil according to the requirements of the Directive. In addition, this Member State has set limits for 10-year average rates of application for metals in sludge and requires that producers must identify suitable sites. A code of practice for the agricultural use of sewage sludge in agriculture has been issued, and there is a separate code dealing with the agricultural use of sludge in forests. The responsibility for undertaking sampling and analysis lies with the sludge producers, who must support their activities by maintaining records and supplying data to the Environment Ministry. Sampling and analytical procedures are in accordance with the code of practice, which incorporates the directive's requirements, and specifies restrictions to minimise risks to health.

Water UK has published a detailed briefing note entitled 'The Beneficial Use of Sewage Sludge in Land Reclamation' prepared on our behalf by Enviro.

More information on: <http://www.water.org.uk/home/policy/positions/sewage-sludge>

4.3. Monitoring and Reporting

- A sampling and analysis laboratory should be appointed. Analytical methods used by the laboratory for heavy metals must conform to those in Annex II C.
- Soil in each proposed spreading area should be sampled at a frequency determined by the competent authority. Sludge from small plants that are exempted from treatment requirements, and from keeping records of composition or spreading location, should be tested according to Annex IIA.
- Monitoring should also be undertaken by the competent authority to ensure that restrictions on cropping are complied with.
- Information should be recorded on amounts and types of sludge used in agriculture and its sources and destinations. Records in some Member States indicate the quantities of sludge produced and supplied for use in agriculture, sludge analyses, types of sludge treatment, soil analyses, and estimates of soil metal concentrations where samples have not yet been taken. They also state the names and addresses of recipients of sludge, locations of application sites, quantities and quality of sludge applied (and details of any other sludge applied), and details of any written advice issued by the national authorities in respect of the sludge or site. In some cases, the producers must give farmers sludge analyses of nutrient content, so they can use the sludge properly. In certain Member States these records must be kept for at least 10 years, and the operator of a sewage plant must submit annual environmental reports to the permitting authority.

Examples from a Member State: monitoring procedures

United Kingdom: Monitoring is undertaken in accordance with the Directive, whereby soil is analysed on first application and at least every twentieth year during which sludge is spread to determine its pH and metals levels. Sludge is analysed at least every six months and every time significant changes occur in the quality of the sewage treated at the works. Analysis is the responsibility of the sludge producer but records must be kept and made available to the Environment Ministry. The analytical methods used are in accordance with the Directive. The parameters analysed conform to the Directive and there are a number of additional ones.

Portugal: The national law requires sampling of both the sludge and the soil. The sludge is analysed by the user, who has the burden of proof that it complies with the legally established limits. The results are then made available to the Institute of Wastes (INR), regional directorates of the environment (DRAs) or General Inspectorate of Environment (IGA), who give the final approval. The analyses of the soil are to be undertaken before sludge is applied, although there is no specification of sampling frequency after the sludge is spread. The results must be kept for five years.

Sweden: The producer of sludge is responsible for carrying out sampling and analysis of sludge in respect of dry matter and loss on ignition; pH; total phosphorus; total nitrogen; ammonium nitrogen; lead, cadmium, copper, chromium, mercury, nickel and zinc. The order that requires this also lays down detailed rules on sampling and analysis methods. The frequency of sampling and analysis is determined according to the treatment capacity of the plant. As a minimum, the sampling and analysis must be done on an annual basis. Permitting authorities are responsible for supervision and inspection.

4.4. Technical Standards and Guidance

- Guidance notes or a code of practice should be provided on acceptable methods of sewage sludge treatment and on use of land, grazing or cropping and spreading of sludge and the types of sludge permitted on certain crops.

5. COSTS

The main types of costs arising during the implementation of the Sewage Sludge Directive are illustrated, as far as possible, in the checklist below.

A major cost item will be establishing the pre-notification and permitting system. This will require additional resources at the competent authority established under the Waste Framework Directive. Costs will also include sampling and analysis of soil and sludge. It may be necessary to change methods of analysis if sewage laboratories are used for this purpose, and this could involve costs for additional equipment and training. Where no treatment is currently given to raw sludge it will be necessary to construct suitable treatment plants, if it is intended to apply the sludge to farmland. Additional costs of sludge treatment are high.

In some cases, existing spreading arrangements may be too intensive to comply with the Directive. In this case, additional transport costs may be incurred to ensure less intensive spreading. Where metal levels in sludge are found to be very high, or where the soil is very acidic or high in metal content, it may not be possible to use the spreading route for disposal of sludge. In these cases, alternative ways of dealing with sludge will have to be found, including landfill or incineration. This may lead to further high additional costs. Metal levels may be reduced by better control of industrial effluents discharged to sewer, but additional costs will be incurred in the increased requirements for treatment by industry and by the inspection and enforcement regime controlling these effluents.

Table 20. Checklist with types of implementation costs

Initial set-up costs: <ul style="list-style-type: none">• initial soil sampling programme;• establishing testing laboratories and procedures;• establishment of permitting systems and procedures;• provision of training;• preparing technical guidance notes.
Capital expenditure: <ul style="list-style-type: none">• sewage treatment plants where raw sludge is currently disposed of to land;• alternative disposal facilities for contaminated sludge.
Ongoing running costs: <ul style="list-style-type: none">• operation of acceptable spreading techniques;• additional transport costs;• inspections of spreading operations, and any requisite enforcement action.

THE BATTERIES DIRECTIVE

Official Title: Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC, as amended by Directive 2008/12/EC¹⁶² (OJ L 76, 19.3.2008) and Directive 2008/103/EC¹⁶³ (OJ L 327, 5.12.2008) and Directive 2013/56/EU¹⁶⁴ (OJ L 329, 10.12.2013)

Implementing legislation:

Commission Decisions 2008/763/EC¹⁶⁵ (OJ L 262, 1.10.2008), 2009/851/EC¹⁶⁶ (OJ L 312, 27.11.2009) and Commission Regulations (EU) No 1103/2010¹⁶⁷ (OJ L 313, 30.11.2010) and (EU) 493/2012¹⁶⁸ (OJ L 151, 12.6.2012)

¹⁶² Directive 2008/12/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators, as regards the implementing powers conferred on the Commission

¹⁶³ Directive 2008/103/EC of the European Parliament and of the Council of 19 November 2008 amending Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators as regards placing batteries and accumulators on the market

¹⁶⁴ Directive 2013/56/EU of the European Parliament and of the Council of 20 November 2013 amending Directive 2006/66/EC of the European Parliament and of the Council on batteries and accumulators and waste batteries and accumulators as regards the placing on the market of portable batteries and accumulators containing cadmium intended for use in cordless power tools, and of button cells with low mercury content, and repealing Commission Decision 2009/603/EC

¹⁶⁵ 2008/763/EC: Commission Decision of 29 September 2008 establishing, pursuant to Directive 2006/66/EC of the European Parliament and of the Council, a common methodology for the calculation of annual sales of portable batteries and accumulators to end-users (notified under document number C(2008) 5339) (Text with EEA relevance)

¹⁶⁶ 2009/851/EC: Commission Decision of 25 November 2009 establishing a questionnaire for Member States reports on the implementation of Directive 2006/66/EC of the European Parliament and of the Council on batteries and accumulators and waste batteries and accumulators (notified under document C(2009) 9105)

¹⁶⁷ Commission Regulation (EU) No 1103/2010 of 29 November 2010 establishing, pursuant to Directive 2006/66/EC of the European Parliament and of the Council, rules as regards capacity labelling of portable secondary (rechargeable) and automotive batteries and accumulators

¹⁶⁸ Commission Regulation (EU) No 493/2012 of 11 June 2012 laying down, pursuant to Directive 2006/66/EC of the European Parliament and of the Council, detailed rules regarding the calculation of recycling efficiencies of the recycling processes of waste batteries and accumulators

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The Batteries Directive seeks to improve the environmental performance of batteries and accumulators as well as the environmental performance of the activities of economic operators involved in the life cycle of batteries and accumulators, e.g. producers, distributors and end users and, in particular, those operators directly involved in the treatment and recycling of waste batteries.

The Directive prohibits the placing on the market of certain batteries and accumulators with a proportional mercury or cadmium content above a fixed threshold. In addition, it promotes a high rate of collection and recycling of waste batteries and accumulators and improvement in the environmental performance of all involved in the life-cycle of batteries and accumulators, including their recycling and disposal.

The aim is to cut the amount of hazardous substances - in particular, mercury, cadmium and lead - dumped in the environment; this should be done by reducing the use of these substances in batteries and accumulators and by treating and re-using the amounts that are used. Thus, as regards the presence of mercury, the Directive prohibits batteries and accumulators, whether or not incorporated in appliances, containing more than 0,0005 % by weight of mercury. Button cells with a mercury content of no more than 2 % by weight are exempted from this prohibition until October 2015. In the case of button cells for hearing aids, this exemption remains under review by the Commission. Concerning cadmium, portable batteries and accumulators, including those incorporated in appliances, with a cadmium content by weight of more than 0,002 % are prohibited (except for portable batteries and accumulators for use in emergency and alarm systems or medical equipment). An exemption from this prohibition is established for portable batteries and accumulators for cordless power tools until 31 December 2016, enabling the recycling industry and consumers along the whole value chain to further adapt to the relevant substitute technologies.

The Directive applies to all types of batteries and accumulators, apart from those used in equipment to protect Member States' security or for military purposes, or in equipment designed to be sent into space.

To ensure that a high proportion of spent batteries and accumulators are recycled, Member States must take the necessary measures (including economic instruments) to promote and maximise separate waste collections and prevent batteries and accumulators being thrown away as unsorted municipal waste. They have to make arrangements enabling end-users to discard spent batteries and accumulators at collection points in their vicinity and have them taken back at no charge by the producers. Collection rates of at least 25% had to be reached by 26 September 2012 and 45% by 26 September 2016. The latest amendments to the Batteries Directive requires that appliances incorporating batteries and accumulators are accompanied by instructions on how these can be safely removed by either the end-user or by independent qualified professionals.

Directive requires that batteries and accumulators that have been collected are treated and recycled using best available techniques. As a minimum, treatment must include removal of all fluids and acids. The Directive also establishes obligations in relation to the efficiencies of the recycling processes to which batteries are subject to, depending on their chemical composition.

Battery recycling processes must meet the following levels of efficiency since September 2011 (Article 12(4) and Annex III, Part B):

- Lead-acid batteries: recycle lead as far as technically feasible, and recycle a minimum of 65 % of batteries by average weight;

- Nickel-cadmium batteries: recycle cadmium as far as technically feasible, and recycle a minimum of 75 % of batteries by average weight;
- Other batteries: recycle a minimum of 50 % of batteries by average weight.

Batteries and accumulators containing cadmium, mercury or lead may be disposed of in landfills or underground storage if there is no viable end-market for the recycling products, or if a detailed assessment of environmental, economic and social impact concludes that recycling is not the best solution. Otherwise, it is prohibited to put waste from industrial and automotive batteries and accumulators into landfill, or to incinerate it. Only residues from treating and recycling them may be disposed of in these ways.

In addition, consumers must be informed about the dangers of uncontrolled disposal, the marking system and how to remove batteries from appliances.

This Directive repeals and replaces Directive 91/157/EEC as from 26 September 2008.

The Directive has been amended several times in the past 6-7 years.

Below a summary of the amendments:

1. Directive 2008/12/EC

This Directive ensures that the certain technical and non-essential elements of the Batteries Directive can be modified using the regulatory (fast-track legislative) procedures. The following articles will be concerned with this legislative procedure:

- 10(4) relating to transitional arrangements that may be laid down in accordance with the regulatory procedure in case of specific national circumstances and regarding the common methodology that was established for the calculation of annual sales of portable batteries and accumulators to end-users;
- Art. 12(6), stating that non-essential elements will be adapted on the basis of this fast-track procedure;
- Art. 17 on measures for harmonizing the procedural requirements for the registration of battery producers;
- Art. 21(2) regarding implementing measures to ensure that the capacity of all portable and automotive batteries and accumulators is adequately indicated in a visible, legible and indelible form;
- Art. 21(7) regarding exemptions to the labelling requirements

This Directive entered into force on 20 March 2008 and all of the measures referred to above have been adopted (i.e. Decision 2008/763).

2. Directive 2008/103/EC

This Directive clarifies that Article 6(2) of Directive 2006/66/EC means that batteries and accumulators which were legally placed on the market anywhere in the EU before 26 September 2008 and which do not comply with that Directive can remain on the market in the EU after this date. This Directive aimed at strengthening the legal certainty for such batteries.

3. Directive 2013/56/EU

The Directive removes exemptions regarding the use of cadmium in portable batteries used in cordless power tools (Article 4(3)) and with respect to the use of mercury in button cells (Article 4(2)). Changes were made to some other provisions of the Directive, in particular placing on the market (Article 6(2)) and the removability

of batteries (article 11). Furthermore, the procedural requirements for the registration of producers (previously laid down in Commission Decision 2009/603/EC) were incorporated in a new Annex IV of the Directive and Decision 2009/603/EC was repealed with effect from 1 July 2015.

4. Decision 2008/763

This Decision establishes a common methodology for the calculation of annual sales of portable batteries and accumulators to end-users. Member States should base the calculation of annual sales of portable batteries and accumulators to end-users on collected data. Statistically significant estimates based on the collected data may also be used for the calculation.

5. Commission Decision 2009/851/EC

This Decision Implements Article 22(1) of the Batteries Directive concerning the duty to report regularly on implementation to the Commission. The Decision sets out a list of information which this reporting duty should be limited to.

6. Regulation (EC) No 1103/2010

This Regulation introduces harmonised rules on the existing capacity labelling rules for portable secondary (rechargeable) and automotive batteries and accumulators. The Regulation allows for a transitional period. This Regulation entered into force on 30 November 2010 although it allows for an 18-month transitional period before producers of batteries and accumulators have to adapt their technological process to the new capacity labelling requirements.

7. Regulation (EU) 493/2012

This Regulation lays down detailed rules regarding the calculation of recycling efficiencies of the recycling processes of waste batteries and accumulators.

In addition to the above and especially in relation to the capacity label, the Commission has mandated the standardisation bodies; CEN/CENELEC/ETSI to elaborate a capacity label for portable primary (non-rechargeable) batteries by means of standardization. The Commission has mandated them to amongst others: 1) review the current methods of measuring battery capacity and the standards relating to these methods, taking into account different and typical applications at national, European and international level, 2) identify the availability of stakeholders in this standardization process, 3) study the appropriateness of formal standard(s) for the capacity labelling of portable primary (non-rechargeable) batteries, 4) review existing standards/provisions applicable to similar labelling schemes for consumer information, 5) provide recommendations on the further priorities for European and international standardisation in view of the European contribution to the European and international standardisation¹⁶⁹. More information can be obtained at:

Summary of Batteries Directive: <http://ec.europa.eu/environment/waste/batteries/index.htm>

Questions and Answers: <http://ec.europa.eu/environment/waste/batteries/pdf/faq.pdf>

¹⁶⁹ M/494 „Feasibility Study on Labelling and Efficiency of Primary Batteries“ can be obtained at: <http://ec.europa.eu/environment/waste/batteries/pdf/CENELEC%20feasibility%20study.pdf>

In December 2015, the Commission has adopted the proposal to amend Directive 2006/66/EC on on batteries and accumulators and waste batteries and accumulators as a part of the within the a Circular Economy Package which also includes a Commission Communication "Closing the loop – An EU action plan for the Circular Economy".

More information on the new legislative proposal can be obtained at:
<http://ec.europa.eu/environment/circular-economy/>

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Ensure efficient organisation of separate collection systems; and, where appropriate, consider the use of economic instruments to encourage recycling (Art. 7). This system should ensure the maximisation of separate waste collection and the minimisation of disposal. (Art. 7)
- Promote research and encourage the increased environmental performance of batteries and accumulators throughout their life cycle (Art. 5), and encourage the development of new recycling and treatment technologies and the introduction of EMAS. (Art. 13)
- Decide on the specifics regarding the registration system for producers of batteries and accumulators (Art. 17 and Annex IV), e.g.
 - whether this registration should take place with the designated national registration authority or through authorised national producer responsibility organisations;
 - whether this registration should be in paper form or electronically or a combination thereof;
 - whether this registration system should form part of another producer registration procedure (cost-effective and transparency are pros for this option) or be a separate procedure;
 - produce technical guidance regarding the registration system targeting the applying registration authority or producer responsibility organisation on one hand and the producers on the other;
 - ensure that the competent authority and the national registration authority has sufficient knowledge, competence and resources for operating the registration system.
- Establish the national reporting system ensuring that the data set out in Annex to Decision 2009/85EC is submitted from the competent authority to the Commission. The reporting should cover all the items laid out in the annex to the Decision.
- Plan the full implementation of Regulation (EC) No 1103/2010 considering the capacity of portable secondary (rechargeable) batteries and accumulators as well as automotive batteries and accumulators to ensure that they are determined under the basis of the established IEC-EN standards (depending on the chemical substances contained therein, expressed as unit of capacity measurement (Art. 3 of the Regulation) and labelled adequately. (Arts 2-5, Regulation (EC) No 1103/2010)

2.2. Regulation

- Prohibit the marketing of all batteries and accumulators containing more than 0.0005% by weight of mercury, subject to an exemption for button cells which must have a mercury content of less than 2% by weight, and the marketing of portable batteries and accumulators with a cadmium content by

weight of more than 0.002%, except for portable batteries and accumulators for use in emergency and alarm systems, medical equipment or cordless power tools. (Art. 4)

- Ensure that batteries and accumulators that do not meet the requirements of the Directive are not placed on the market, and that those in compliance can be marketed on the territory of the Member States (applicable as from 26 September 2008), however, batteries which were lawfully placed on the market prior to the date of application of the respective prohibitions in Article 4, may continue to be marketed until stocks are exhausted (Art. 6)
- Establish a system of separate collection of batteries and accumulators, with a view to their recovery or disposal. (Art. 8)
- Ensure that spent batteries and accumulators can be readily and safely removed from appliances. Appliances in which batteries and accumulators are incorporated must be accompanied by instructions on how those batteries and accumulators can be safely removed by either the end-user or by independent qualified professionals. (Art. 11)
- Ensure that batteries and accumulators that have been collected are treated and recycled using BAT.
- Prohibit the disposal in landfills or by incineration of waste industrial and automotive batteries and accumulators, except for residues from treating and recycling them. (Art. 14)
- Ensure that spent batteries and accumulators are taken back free of charge by the producers, and that the costs arising from waste collection, recycling and treatment do not result in double charging. (Arts. 8 and 16)
- Ensure that labelling requirements for batteries and battery packs are complied with (Art. 21). Symbol for separate collection (the roll-out container crossed through) must appear on all batteries and battery packs. Capacity of battery must appear on all portable and automotive batteries. Presence of heavy metals must be indicated on all batteries and button cells containing more than 0.0005% mercury by weight, 0.002% cadmium, and/or 0.004% lead.
- Establish penalties for non-compliance with the national provisions adopted pursuant to the Directive, also taking into account that non-compliance with the provisions of the Battery Directive is considered a criminal environmental offence subject to criminal sanctions under the Environmental Crimes Directive (2008/99/EC).
- Ensure that the annual sales of portable batteries and accumulators to end-users in a given year, is calculated as the weight of portable batteries and accumulators placed on the market in the territory of the Member State in the year concerned, excluding any portable batteries and accumulators that have left the territory of that Member State in that year before being sold to the end-users. (Art. 1(1), Decision 2008/763/EC)
- Ensure that the placing on the market of each battery is only counted once and that is based on collected data or in alternative statistically significant estimates based on collected data. (Art. 1(2) and Art. 2, Decision 2008/763/EC)
- Ensure a registration system in accordance with Article 17 and Annex IV for producers of batteries and accumulators, which are operated by the designated national authority or authorised national producer responsibility organisation. This registration can take place either on paper or electronically:

13. this registration has only to take place once in a Member State – at the first time that they, on a professional basis, put batteries and accumulators on the market
14. each producer receives a registration number upon registration;
15. registration is subject to a reasonable fee provided that these are cost-based and proportionate. For this reason, registration bodies taking out fees must inform the competent national authorities of the methodology to calculate the fees.
 - Producers must ensure that they register before placing batteries or accumulators on the EU market, on a professional basis. To this end producers have to:
16. Submit the requested information for the registration set out in Annex IV to the Directive:
 - name of the producer and brand names (if available) under which they operate in the Member State;
 - address(es) of the producer: postal code and location, street name and number, country, URL, telephone number, as well as a contact person, fax number and e-mail address of the producer, if available;
 - indication on the type of batteries and accumulators placed on the market by the producer: portable batteries and accumulators, industrial batteries and accumulators, or automotive batteries and accumulators;
 - information on how the producer meets its responsibilities: by individual or collective scheme;
 - date of the application for registration;
 - national identification code of the producer, including European tax number or national tax number of the producer (optional);
 - declaration stating that the information provided is true.
 - Ensure that in the event of the data set out in Annex to Decision 2009/603/EC being changed, this change is notified to the competent authority, no later than one month after changes (Annex IV);
 - Ensure that if the producers no longer put batteries or producers on the market, they are deregistered from the registration system (Annex IV).
 - Ensure that for the portable secondary (rechargeable) batteries and accumulators as well as automotive batteries and accumulators (exempting those secondary batteries and accumulators listed in Annex I to the Regulation):
 - the capacity is determined on the basis of the established IEC-EN standards (depending on the chemical substances contained therein, expressed as unit of capacity measurement; for secondary batteries: IEC/EN 61951-1, IEC/EN 61951-2, IEC/EN 60622, IEC/EN 61960 and IEC/EN 61056-1 standards specified in Annex II, Part A and for automotive batteries: IEC 60095-1/EN 50342-1 specified in Annex II, Part B. (Art. 2, Regulation No 1103/2010);
 - the unit of capacity measurement should be expressed in "milliampere-hour(s)" or "ampere-hour(s)", using the abbreviations mAh or Ah respectively (Art. 3, Regulation No 1103/2010);
 - marked with the label containing the information set out in Annex III, Part A for secondary batteries of the minimum size of the label specified in Annex IV, Part A and for automotive

batteries the label should comply with Annex III, Part B and Annex IV, Part B concerning information and the size of the label (Art. 4, Regulation No 1103/2010).

2.3. Communication and Reporting

- Ensure that consumers are provided with specified information about batteries and accumulators, including information about potential effects on the environment and on human health of substances contained in such products, and the collection and recycling arrangements when discarded. (Art. 20)
- Require that users of appliances in which batteries and accumulators are incorporated are provided with instructions on their type and on how the batteries and accumulators can safely be removed.
- Report to the Commission on:
 - collection rates, including information on how the information for calculating the rates was obtained (Art. 10);
 - levels of recycling achieved and compliance with minimum recycling efficiency rates set out in Annex III, Part B (Art. 12);
 - the implementation of the Directive and measures taken to encourage developments affecting the impact of batteries and accumulators on the environment (including new recycling and treatment techniques).
- Producers should report to the national registration authority or the authorised producer responsibility organisation about changes to their registration data. (Annex IV)
- Establish the national reporting system ensuring that the data set out in Annex to Decision 2009/851 is submitted from the competent authority to the Commission. The reporting should cover all the items laid out in the annex to the Decision.
 - this information basically covers all the main provisions of the Battery Directive in terms of details about measures taken to improve the environmental performance of batteries and accumulators, details about the collection schemes, collection targets and treatment and recycling targets;
 - ensure that the producers submit sufficient information to be able to fulfill this reporting duty towards the Commission.

2.4. Additional Legal Instruments

A number of other legislative instruments may have relevance to the management of batteries and battery wastes and must also be borne in mind during the implementation of this Directive. These include:

- Waste Framework Directive (2008/98/EC)

- Waste Electrical and Electronic Equipment Directive (2012/19/EU). Batteries incorporated in WEEE can be collected on the basis of the WEEE Directive. However, after collection, they will be removed from the appliance and they will count for the collection targets of the Batteries Directive. They also have to be recycled as required by the Batteries Directive. A producer of electrical and electronic equipment is also regarded as a battery producer in a Member State under the Batteries Directive, if the appliance producer places the battery (inside an appliance) for the first time on the market in that Member State on a professional basis. This is to ensure that there will be a producer responsible for all batteries placed on the market. However, Member States should avoid any double charging of producers when batteries are collected with appliances under the WEEE Directive.
- Restrictions of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive 2011/65/EC). The Batteries Directive and the RoHS Directive have similar substance restrictions. The RoHS Directive restricts the use of heavy metals, such as mercury and cadmium in electrical and electronic equipment, but does not apply to batteries. The Batteries Directive restricts the use of mercury and cadmium in batteries.
- Regulation on shipments of waste (EC) No. 1013/2006
- Commission Regulation (EC) No. 1418/2007 of 29 November 2007 concerning the export and recovery of certain waste listed in Annex III or IIIA to Regulation (EC) No. 1013/2006
- End-of-Life Vehicles Directive (2000/53/EC) ELV Directive covers vehicles and end-of-life vehicles (categories M1 and N1 as defined in Annex IIA to Directive 2007/46/EC and three-wheeled motor vehicles as defined in Directive 2002/24/EC) including their components, such as batteries. The Batteries Directive applies to all batteries, including automotive batteries, placed on the EU market. The ELV Directive restricts the use of mercury, cadmium and lead in cars, although it allows a maximum concentration of mercury of up to 0.1% by weight and per homogenous material. There was an exemption for the use of cadmium in batteries for electric vehicles which expired on the 31 December 2008, and an exemption for lead in batteries without expiry date. The Batteries Directive and the ELV Directive both establish the principle of producer responsibility. A car producer is also regarded as a battery producer in a Member State under the Batteries Directive if it places the battery on the market (inside the car) for the first time in that Member State on a professional basis. This is to ensure that there is a producer responsible for all batteries placed on the market. However, the Batteries Directive states that Member States should avoid any double charging of producers when car batteries are collected under the ELV Directive.
- Regulation concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) (EC) No. 1907/2006
- Industrial Emissions Directive (2010/75/EU)
- Commission Communication on Integrated Product Policy (COM (2003)302) In line with IPP, the Directive requires Member States to promote research into and encourage improvements in the environmental performance of batteries throughout their life-cycle. In addition to this, Member States shall encourage treatment facilities to introduce EMAS, which contributes to the reduction of life-cycle environmental impacts of batteries.
- Regulation on the classification, packaging and labelling of substances and mixtures ((EC) 1272/2008)

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the following checklist, organised in chronological order (where appropriate) within each subheading.

Table 21. Checklist with key implementation tasks

THE BATTERIES DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate a competent authority to perform duties arising under this Directive. Responsibilities will include: <ul style="list-style-type: none"> • checking that those batteries prohibited by the Directive are not placed on the Market after 26 September 2008 (however, batteries and accumulators that do not meet the requirements of Directive 2013/56/EU, but which were lawfully placed on the market prior to the date of application of the respective prohibitions set out by the directive, may continue to be marketed until stocks are exhausted); • establishing and operating a scheme for the collection of spent batteries and accumulators; • ensuring the recycling and treatment of collected batteries and accumulators; • ensuring that batteries are properly labelled; • ensuring duly registration of producers at the time of the first placement of batteries or accumulators on the market of an EU Member State and developing campaigns to provide the general public with information.
1.2	Put into place the procedures and the systems to ensure that the calculation of the annual sales of portable batteries and accumulators to end-users in a given year is in accordance with Decision 2008/763/EC (e.g. the placing of the market of each battery is counted only once and based on collected data or statistically significant estimates).
1.3	Determine the registration system and procedures for producers of batteries and accumulators, which involves designating a national registration authority or an authorised national producer responsibility organisation, ensuring the appropriate software applications and possibly integrating the registration system with another producer registration system.
1.4	Decide what economic instruments are appropriate to encourage recycling. Introduce legislation to impose economic instruments, if appropriate.
1.5	Ensure that the competent authorities and designated public bodies have sufficient resources, competencies and staff to ensure efficient implementation of the provisions including monitoring, supervision and enforcement in case of non-compliance. For this reason, technical guidance should be produced targeting both the involved authorities but also the producers themselves.
1.6	Establish the national reporting system ensuring that the data set out in Annex to Decision 2009/851 is submitted from the competent authority to the Commission. The reporting should cover all the items laid out in the annex to the Decision.
1.7	Plan the full implementation of Regulation (EC) No 1103/2010 considering the capacity of portable secondary (rechargeable) batteries and accumulators as well as automotive batteries and accumulators to ensure that they are determined under the basis of the established IEC-EN standards (depending on the chemical substances contained therein, expressed as unit of capacity measurement (Art. 3 of the Regulation) and labelled adequately.
2	Regulation
2.1	Ensure that the annual sales of portable batteries and accumulators to end-users in a given year, is

	calculated as the weight of portable batteries and accumulators placed on the market in the territory of the Member State in the year concerned, excluding any portable batteries and accumulators that have left the territory of that Member State in that year before being sold to the end-users.
2.2	Ensure that the placing on the market of each battery is only counted once and that is based on collected data or in alternative statistically significant estimates based on collected data. (Art. 1(2) and Art. 2, Decision 2008/763/EC)
2.3	Producers must ensure that they register before placing batteries or accumulators on the EU market, on a professional basis. To this end producers have to: <ul style="list-style-type: none"> • submit the requested information for the registration set out in Annex IV; • ensure that in the event of the data set out in Annex IV being changed, this change is notified to the competent authority, no later than one month after changes; • ensure that if the producers no longer put batteries or producers on the market, they are deregistered from the registration system.
2.4	Ensure that for the portable secondary (rechargeable) batteries and accumulators as well as automotive batteries and accumulators (excepting those secondary batteries and accumulators listed in Annex I to the Regulation) as from 30 May 2012: <ul style="list-style-type: none"> • the capacity is determined on the basis of the established IEC-EN standards (depending on the chemical substances contained therein, expressed as unit of capacity measurement; for secondary batteries: IEC/EN 61951-1, IEC/EN 61951-2, IEC/EN 60622, IEC/EN 61960 and IEC/EN 61056-1 standards specified in Annex II, Part A and for automotive batteries: IEC 60095-1/EN 50342-1 specified in Annex II, Part B. (Art. 2, Regulation No 1103/2010); • the unit of capacity measurement should be expressed in "milliampere-hour(s)" or "ampere-hour(s)", using the abbreviations mAh or Ah respectively (Art. 3, Regulation No 1103/2010); • marked with the label containing the information set out in Annex III, Part A for secondary batteries of the minimum size of the label specified in Annex IV, Part A and for automotive batteries the label should comply with Annex III, Part B and Annex IV, Part B concerning information and the size of the label (Art. 4, Regulation No 1103/2010).
3	Collection, Disposal and Recycling
3.1	Establish a system for the collection of spent batteries and accumulators.
3.2	Identify institutions to be responsible for the provision of separate collection services.
3.3	Prepare guidance notes for the efficient provision of collection services.
4	Monitoring
4.1	Establish a system to ensure that batteries are not placed on the market unless they comply with the requirements of the Directive. The system should specify at which point batteries will be checked (manufacture, point of import, point of sale). It must ensure that specified types of batteries are not placed on the market that batteries and accumulators cannot be used in specified appliances unless they can easily be removed by the consumer; and that batteries are labelled as required under the Directive.
4.2	Monitor collection rates on a yearly basis.
5	Information and Reporting
5.1	Design and implement a communications strategy providing information on safe methods for the disposal of spent batteries for manufacturers, importers, distributors and consumers.
5.2	Establish reporting and data recording systems to ensure that the data required (see below) are collected.
5.3	Report to the Commission as required on: <ul style="list-style-type: none"> • measures employed to ensure efficient collection and to encourage recycling; • progress in transposition and implementation.
5.4	The producers have to submit to the designated national authority or organisation certain information at the time of registration and in case of changes to this data. Producers also have to report on the quantities

	of batteries and accumulators sold taking into account the calculation methods laid down.
5.5	Producers should report to the national registration authority or the authorised producer responsibility organisation about changes to their registration data (Annex IV)
5.6	<p>Establish the national reporting system ensuring that the data set out in Annex to Decision 2009/851 is submitted from the competent authority to the Commission. The reporting should cover all the items laid out in the annex to the Decision.</p> <ul style="list-style-type: none"> • This information basically covers all the main provisions of the Battery Directive in terms of details about measures taken to improve the environmental performance of batteries and accumulators, details about the collection schemes, collection targets and treatment and recycling targets. • Ensure that the producers submit sufficient information to be able to fulfil this reporting duty towards the Commission

3.2. Phasing Considerations

Experience within Member States suggests that the most demanding and time-consuming tasks associated with implementing this Directive are the following:

- Establishing and developing the institutional structure and the various procedures (registration procedure, monitoring system) to achieve the various objectives of the Directive, some of which do not relate to waste management but more to market surveillance and ensure efficient functioning of the EU internal market.
- Identify how the various requirements of the Directive are to be met, including timescales and clearly allocated responsibilities and the concerned authorities.
- Ensure efficient supervision and sanctioning in case of non-compliance

These tasks should therefore be planned to commence during the initial phase of implementation.

4. IMPLEMENTATION GUIDANCE

Drawing upon the experience of selected Member States, a number of general observations and suggestions for implementing this Directive are presented below.

4.1. General Administrative Arrangements

This Directive involves not only aspects of waste management but also concerns many other aspects. Hence, implementation could, therefore, involve more than one competent authority. If this is the case, a single authority should be given the role of co-ordinating the implementation of the Directive and clear channels of communication between the competent authorities should be established. Also sufficient resources have to be furnished to ensure that this authority can effectively carry out all its tasks, including registration, data collection, controlling the labelling requirements, reporting towards the Commission, monitoring and enforcement. Hence, given the range of tasks, it can be advisable to delegate the registration duty to a producer responsibility organisation, which also increases the amount of self-regulation of the industry and also contribute to allow the producers greater insight into the implementation of the Directive and its objectives.

- Consider to mainly rely on (binding) environmental agreements with the battery industry to transpose the Battery Directive. On the basis of these agreements the economic operators are even more directly involved in the collection of waste batteries, export of waste batteries and information for end-users.
- As a minimum 25% collection rate for waste portable batteries had to be achieved by 2012, rising to 45% by 2016, and as a 100% collection and recycling target is in effect set for waste industrial and automotive batteries and accumulators, Member States should consider the institutional structure and facilities necessary to achieve these objectives as well as national targets voluntarily defined for recovery and recycling.
- Ensure that the implementation strategy for the Battery Directive is harmonised with the overall national recycling strategy, ensuring synergies and strong cooperation with competent authorities involved in the implementation of the End-of-Life Vehicle Directive (2000/53/EC) and WEEE Directive (2012/19/EU).
- Also measures must be taken to ensure adequate and reliable systems for collected data or statistical estimates regarding annual sales and amounts put on the market.

Examples from a Member State: transpositional measures and guidance

United Kingdom:

UK Regulations the Waste Batteries and accumulators Regulations 2009 (SI 2009 No. 890) implementing the waste provisions of the Batteries Directive were laid in Parliament on 14 April 2009. A Government guidance document intended to give advice on the Waste Battery and Accumulator Regulations 2009 (SI 2009/890) was also issued: „The Waste Batteries and Accumulators Regulations 2009: Government guidance notes”

Source: <https://www.gov.uk/guidance/waste-batteries-producer-responsibility>

Example from a Member State: Institutional Arrangements

United Kingdom: The implementation of the Batteries Directive is shared between Defra and the Department for Business, Enterprise and Regulatory Reform (BERR, formerly DTI). Defra is responsible for provisions on portable/household batteries (including portable batteries used in business and industry) and on treatment provisions for all batteries, while BERR is responsible for automotive/industrial batteries and single-market provisions.

As part of the BREW (Business Resource Efficiency and Waste) programme being run by Defra, the Waste and Resources Action Programme (WRAP) is to develop options for a cost-effective UK battery collection infrastructure. In terms of household batteries, Defra has also requested WRAP to pilot collection schemes by working in partnership with a range of local authorities and not-for-profit organisations that already run recycling collection services. BIS has appointed the National Measurement office (NMO) as the enforcement body responsible for enforcing the Batteries and Accumulators (Placing on the Market) Regulations 2008. More information on the enforcement action in the UK can be found at: <http://www.bis.gov.uk/nmo/enforcement/batteries-home>

Portugal: AGEFE is the Portuguese association of importers and wholesalers of electrical and electronic equipment (including consumer electronics), household appliances, photographic equipment and watches.

AGEFE covers more than 85% of the national battery market and has strong cooperation with the national government (Ministério das Cicadas, do Ambiente e do Ordenamento do Território; INR – Instituto dos Resíduos), other sectoral trade associations, consumer groups and leaders of industry. Moreover, AGEFE is one of the founding members of ECOPIILHAS, the Portuguese entity licenced by the Portuguese government for the management of an integrated system of collection and recycling used portable batteries in Portugal (according with the Decree-Law 62/2001).

Example from a Member State: Information Campaigns

Denmark: On 1 January 2009 a new act on producer responsibility for batteries and accumulators entered into force. In this context a national information campaign was launched. The aim of the campaign was partly to highlight the responsibility of producers and importers of batteries and electrical equipment have and that all battery producers have to register to the Danish Producer Register (DPA-System), regardless of the number of batteries produced or imported. With this campaign the Danish EPA (Miljøstyrelsen) wanted to provide sufficient information to prevent a situation where so called free-riders can blame their non-registration on insufficient knowledge. Access to lists of affected activities and names of battery producers/importers can be obtained from the Battery Association (BatteriForeningen)

Information on the Danish producer register: www.dpa-system.dk

4.2. Standards of Manufacture

- The imposition of standards of manufacture — involving mercury content and also labelling — will need to be imposed by means of legislation controlling both indigenous manufacture and imports. This can best be done by controlling the sale and distribution of batteries and accumulators. It is also important to note the duty of the competent authorities to report to the Commission about measures

to improve the environmental performance of batteries and accumulators. Hence, the candidate countries are advised to take active measures to try to influence standards of manufacture and product design, especially since a revised Batteries Directive to includes more stringent requirements on this.

- The need for inspection will depend on the degree to which the battery industry can be relied upon for self-regulation. Self-regulation presumes good cooperation and regular communication between the national competent authority and the national producer responsibility organisations and major producers.

4.3. Collection, Disposal and Recycling

- Some Member States have introduced voluntary or mandatory producer responsibility schemes to ensure the recovery and recycling of batteries. These schemes also range from single national schemes to a network of multiple schemes.
- Care should be taken that outlets for recycling are assured for the separate collected batteries. Storage of batteries awaiting an outlet could exacerbate environmental problems.
- Commission has issued non-binding Guidelines on the application of Commission Regulation (EU) 493/2012 laying down detailed rules regarding the calculation of recycling efficiencies of the recycling processes of waste batteries and accumulators available at: <http://ec.europa.eu/environment/waste/batteries/pdf/Guidelines%20on%20RE.pdf>

Various studies on the topic of batteries are available at: <http://ec.europa.eu/environment/waste/batteries/studies.htm>

Examples from a Member State: Regulatory Controls

Germany: The German Batteries Act entered into force on 1 December 2009, revising the law of waste-related product responsibility for batteries and accumulators. For the first time, the Act specifies binding collection targets for portable batteries. It extends the restrictions on the use of mercury to a ban on selling portable batteries containing cadmium. A notification register has been set up at the Federal Environment Agency, where manufacturers and importers of batteries and accumulators must provide notice of their market participation.

WFZ Ruhr is a voluntary initiative of public and private companies working in the area of closed substance cycle waste management in the German Ruhr region. More than 101 members specialising in a number of activities are involved in this expert group, including waste collection and sorting, production of secondary raw materials and energy, and supporting services. The network supports the sharing and development of knowledge and business opportunities, particularly with regard to improving resource efficiency.

Source: http://www.ecopol-project.eu/en/waste_recycling/good_practices/germany)

Portugal: The management of waste batteries is undertaken through a mandatory scheme for both retailers/distributors and importers of batteries. They are obliged to keep a record of all the transactions (number of batteries sold, distributed and returned). These records are to be made available to the Institute of Waste (INR). A protocol on the selective collection and recycling of used car batteries has been adopted between the Car Industry Association (ACAP) and Sonalur, a national company in charge of collecting and recycling the used lead batteries from ACAP associates. A national NGO (Quercus) and the INR undertook a campaign for the collection of used batteries.

Under Portuguese law, all economic operators are co-responsible for the management of used batteries, but producers and importers must pay to the municipalities the collection service. Producers and importers are also responsible for valorization or disposal of used batteries. Visible fee is mandatory. Distributors are obliged to accept free of charge, from end consumers, the used batteries (of the type they commercialize). For the producer responsibility AGEFE adheres to the principle of producer responsibility as established in the WEEE Directive, based on the principles of shared responsibility between all stakeholders of the collection and recycling chain. But the principles of sharing responsibility must mean sharing the costs and avoid the free-riders. Municipalities and retailers, who have a direct link to the consumer at end of life battery stage, must be responsible for collection.

Source: <http://ec.europa.eu/environment/waste/batteries/pdf/batteryassoc.pdf>

Austria: Collections of batteries were started at national level in 1992 and led to a recycling rate across the country of 40%. Battery recycling operations are overseen by the independent organisation "Umweltforum Batterien", founded in 2001, which comprises all Austrian importers and producers. Members are charged a fee dependent on battery type and weight, which is used to fund the collection and recycling system within the country. A comprehensive collection network has been developed and the system is well known and well supported.

Source: <http://www.batteriensammeln.at/>)

Examples from Member States

Belgium: A tax on batteries was agreed by the Belgian Government in 1993 as part of the eco-tax legislation. However, a voluntary agreement was signed with industry in 1997, which provided for the exemption of batteries from the eco-tax in the event that a voluntary collection and recycling scheme for used batteries is set up. Today, the Bebat Association, a non-profit organisation founded by the battery industry, collects used batteries and accumulators.

More information can be obtained from: www.environment.fgov.be, www.bebat.be, www.ebra.org and <http://www.economicinstruments.com/index.php/solid-waste/article/153->

Denmark: Applies eco-taxes on nickel-cadmium batteries and uses the proceeds to pay collectors who deliver these batteries for recycling. A recovery rate of more than 50% has been achieved.

Sweden: Anyone commercially manufacturing or importing hazardous batteries is required to supply the Environmental Protection Agency (EPA) with information on the quantity of batteries transferred or imported for use in the importer's own commercial operations. This information must be supplied through the EPA electronic register „the Battery Register Anyone under a duty to supply information shall pay a charge to cover the cost of:

- disposal or recovery of hazardous batteries;
- information which must be distributed to achieve the purposes specified in the ordinance;
- municipal sorting of hazardous batteries;
- collection of lead batteries weighing over three kilograms; and
- the EPA's administration of the information to be supplied concerning hazardous batteries.

The collection of lead-acid batteries is very successful, with a collection rate of nearly 100%, whilst progress is being made on other types of batteries. More information about the battery registry, the Battery Collection and the 2010 EPA regulations on compensation through the Battery Fond can be obtained at: <http://www.swedishepa.se/Start/Produkter-och-avfall/Avfall/Producentansvar/Batterier/>

4.4. Communications

- A communications strategy should be designed and implemented for manufacturers, importers, distributors and consumers of batteries and accumulators. Such information should be tailored as required to the recipient group, and should inform them of the dangers, responsibilities and options for purchase and disposal.

5. COSTS

The costs for relevant policies, legislative framework and various procedures for registration, data collection and reporting towards the Commission as well as costs for devising and undertaking public campaigns are mainly attributed to the national government and the competent authorities. However, the heaviest costs for implementing the Directive; i.e. expenses related to the separate collection, sorting, recycling and treatment of batteries are borne by the producers themselves. When recycling rates are high, it is unlikely that the costs associated with the collection and recycling of batteries and accumulators will be significant. In most cases, collection and transportation costs make up the majority of the costs of recycling. The profit from re-selling recycled batteries can partly off-set these costs. Furthermore, it is an increasing trend to have some of these costs added to the sales price (green charge) or covered by eco-taxes.

Table 21. Portable Batteries - Collection and Recycling Costs in EU Member States Collecting All Portable Batteries

	Austria	Belgium	France	Germany	Netherlands
	UBF	BEBAT	SCRELEC	GRS	STIBAT
Main Characteristics					
Financial Responsibility	Shared	Consumers (via producers)	Partial shared	Producers	Producers
Mandatory collection targets	Only quite recently	Yes	From 2003	No	Yes
Starting date	1991	1996	2001	1998	1995
Collection system		Bring back to different types of collection points	Bring back to sale and municipal collection points	Bring back system mainly to sale points	Bring back system with small chemical waste
No. of inhabitants / collection point	1100	500	2000-2500	410	1500
Main general purpose batteries recycling		Dedicated plants of all Zinc and Alk batteries	Dedicated plants	Mostly metal plants (except high Hg-content batteries which are disposed of)	Metal Plants and dedicated plants
Results					
Quantities collected kt/yr	1440t	2368t	4139t	11256t	1876t
Collection rates:					
% of sales	44%	60%	16%	38%	32%
% of spent batteries	45%	63%	17%	39%	33%

% of spent batteries available for collection	80%	90%	45%	64%	82%
G/inhab/yr	179	228	69	137	116
Recycling plant input % of collected	100%	100%	96%	67%	100%

Source: Impact Assessment on Selected Policy Options for Revision of the Battery Directive, Final Report July 2003, European Commission, DG Environment, BIO intelligence service. Table: Portable Batteries- Collection and Recycling Costs in EU Member States collecting all portable batteries.

THE PACKAGING AND PACKAGING WASTE DIRECTIVE

Official Title: European Parliament and Council Directive 94/62/EC on packaging and packaging waste (OJ L 365 31.12.94)

Amended by:

Directive 2004/12/EC of the European Parliament and of the Council of 11 February 2004 amending Directive 94/62/EC on packaging and packaging waste, (OJ L 47, 18.2.2004)

Directive 2005/20/EC of the European Parliament and of the Council of 9 March 2005 amending Directive 94/62/EC on packaging and packaging waste (OJ L 70, 16.3.2005)

Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 (OJ L 87, 31.3. 2009)

Commission Directive 2013/2/EU of 7 February 2013 (OJ L 37, 8.2.2013)

Directive (EU) 2015/720 of the European Parliament and of the Council of 29 April 2015 (OJ L 115, 6.5.2015)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The aim of this Directive is to harmonise national measures on the management of packaging and packaging waste, in order to prevent or minimise any environmental impacts of packaging and packaging waste and to avoid distortions of competition within the internal market. The Directive lays down measures aimed, firstly, at preventing the production of packaging waste and, additionally, at increasing the reuse, recovery and recycling of such waste. These measures include minimum standards and criteria for packaging materials as well as minimum and maximum targets for the recovery and recycling of packaging waste. The rationale behind having maximum targets is to avoid the distortion of the internal market and to allow less-advanced countries to catch up with Member States that have a greater capacity for recycling and recovery. The Directive also includes provisions encouraging the prevention of packaging waste and awareness campaigns to increase recovery and recycling rates.

The Packaging and Packaging Waste Directive requires Member States to establish collection schemes and lays down the following mandatory quantitative recycling and recovery targets:

- By no later than 30 June 2001, between 50 and 65% by weight of packaging waste to be recovered or incinerated at waste incineration plants with energy recovery;
- By no later than 31 December 2008, at least 60% by weight of packaging waste to be recovered or incinerated at waste incineration plants with energy recovery;
- By no later than 30 June 2001, between 25 and 45% by weight of the totality of packaging materials contained in packaging waste to be recycled (with a minimum of 15% by weight for each packaging material);
- By no later than 31 December 2008, between 55 and 80% by weight of packaging waste to be recycled;
- No later than 31 December 2008 the following recycling targets for materials contained in packaging waste must be attained:
 - 60% for glass, paper and board;
 - 50% for metals;
 - 22.5% for plastics;
 - 15% for wood.

Directive 94/62/EC has been amended several times, first by Directive 2004/12/EC and later by Directive 2005/20/EC. Directive 2004/12/EC introduces substantial amendments to Directive 94/62. The main elements of this Directive, with which Member States had to comply by 18 August 2005, include:

- the introduction of more specific criteria for defining packaging, including illustrative examples of such items in Annex I. This definition is wide and includes packaging components and ancillary elements unless they are an integral part of the product and/or intended to be consumed;
- the introduction of additional measures to prevent the production of packaging waste, including national programmes and producer responsibility schemes;
- a call for the Commission to develop appropriate European standards aiming at minimising the environmental impact of packaging (similar to eco-label standards) and to adopt proposals for

complementary measures aimed at ensuring that the environmental impact of packaging is minimised (e.g. life-cycle assessments);

- revised recovery and recycling targets to be attained by 30 June and 31 December 2008;
- conditions for allowing exported packaging waste to be counted against targets;
- an obligation on the Member States to publish the implementing measures and targets and to carry out information campaigns for the general public and economic operators (e.g. participatory approach);
- a provision obliging the Commission, by 30 June 2005 at the latest, to present a report on the progress of the implementation along with proposals for further amendments;
- explicit permission for Member States with greater capacities for recycling and recovery to set national programmes that go beyond the minimum targets, as long as these measures do not distort the internal market and hinder compliance by other Member States (e.g. importing large amounts of packaging waste from other Member States). Such measures must be notified and approved by the Commission prior to introduction;
- further provision calling for the promotion of consumer information dissemination and awareness campaigns;
- procedures for adapting the identification system (Art.8) and the illustrative examples of packaging to technical progress as well as a committee procedure;
- specific requirements applying to agreements between the competent authorities and the relevant economic sectors for attaining the recycling and recovery rates to ensure their enforceability and results;
- a call on the Council and the European Parliament to fix targets for the period 2009 to 2014 based on an analysis of practical experience gained in the Member States and on the findings of scientific research and evaluation techniques.

Directive 2005/20/EC amends Article 6 of Directive 94/62/EC by adding a paragraph allowing the new Member States transitional periods for attaining the energy recovery and recycling targets for 31 December 2008. The transitional periods range from 31 December 2012 to 2015. In 2013 Annex I of the Directive containing the list of illustrative examples of items that are or are not to be considered as packaging was revised in order to provide more clarity by adding a number of examples to the list and to avoid doubts as to what is packaging and what is not.

The latest revision of Packaging and Packaging Waste Directive, i.e. Directive (EU) 2015/720, which entered into force on May 2015, concerns consumption of lightweight plastic carrier bags. The Directive requires Member States to reduce the use of plastic carrier bags with a thickness of below 50 microns by either:

- taking measures to reduce annual average consumption of lightweight plastic carrier bags to 90 per person by the end of 2019, and 40 by 2025
- or by ensuring that by the end of 2018, no more lightweight plastic carrier bags are handed over free of charge to shoppers.

Member states have an 18-month limit to transpose it into their national law.

In December 2015, the Commission has adopted the proposal to amend Directive 94/62/EC on packaging and packaging waste as a part of the Circular Economy Package which also includes a Commission

Communication "Closing the loop – An EU action plan for the Circular Economy". Key element of the proposal is increase of the preparing for reuse and recycling targets for packaging waste and the simplification of the set of targets.

More information on the new legislative proposal can be obtained at:
<http://ec.europa.eu/environment/circular-economy/>

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Include a chapter on the management of packaging and packaging waste in the waste management plans required by the Waste Framework Directive (Art. 14).
- Set up systems for the return and collection of used packaging and packaging waste and their reuse or recovery; and ensure that systems are open to economic operators of all relevant sectors and competent public authorities, and apply to imported products (Art. 7).
- Adopt a national programme for the recovery and recycling of packaging waste. It should be decided to what extent to encourage recovery or recycling or whether there are environmental and cost-related reasons for preferring incineration with energy recovery to material recycling (Arts. 4 and 6(3), Directive 94/62/EC as amended by Directive 2004/12/EC).
- Encourage the use of materials obtained from recycled packaging waste for the manufacturing of packaging and other products, especially by improving the market conditions for such materials (e.g. creating economic stimulants for recycled materials) and by reviewing national rules preventing the use of recycled materials (Art. 6, Directive 94/62/EC as amended by Directive 2004/12/EC).
- Consider how economic instruments could be used to implement the objectives of the Directive (Art. 15).
- Establish databases on packaging and packaging waste (Art. 12) (to include information on the volume and characteristics of packaging and packaging waste) in accordance with the formats laid down in Commission Decision 2005/270/EC.
- Organise an information campaign for the general public and economic operators regarding the recycling and recovery targets and the national measures adopted. Member States shall, in general, promote enhanced consumer information and awareness campaigns with a view to attaining high recovery and recycling rates (Arts. 6(6) 13, Directive 94/62/EC as amended by Directive 2004/12/EC).
- Decide on the extent to which regulatory measures (laws and administrative provisions) and producer responsibility schemes should be introduced, and on the extent of agreements between the competent authorities and the economic sectors concerned.
- Decide on waste prevention measures, ensuring that all possible steps are taken to reduce the environmental impact of packaging. The most important component of this strategy will be the national programme as well as other administrative and financial measures shifting the main burden of costs for recycling, recovery and disposal to producers instead of local authorities. The national programme should make it clear whether the aim is to attain the mandatory targets in Article 6 or whether it goes beyond these targets. If the aim is to go beyond them, it must be ensured that these more stringent requirements do not lead to the distortion of the internal market. Preventive instruments should include studies and pilot projects, especially concerning packaging waste prevention plans, cost-benefit studies of reuse versus recycling, life-cycle assessments, and producer

responsibility schemes (Arts. 4(1) and 6(9) Directive 94/62/EC as amended by Directive 2004/12/EC).

- Address to the Commission requests for transitional periods, granting temporary derogations from attaining the recovery and recycling targets. For instance, the new Member States (Czech Republic, Estonia, Cyprus, Lithuania, Hungary, Slovenia and Slovakia) had until 31 December 2012 to comply with the energy recovery targets and recycling targets that have to be met by 31 December 2008. Malta, Poland and Latvia negotiated even longer transitional periods (2013, 2014 and 2015).
- Aim at attaining the recycling and recovery targets mainly by dealing with the packaging waste produced within the territory of a given Member State, and avoid relying either on exports or imports of packaging waste. Ensure that, for the export of packaging material, the receiving recycler or waste processor provides sound documentation that the recovery or recycling has taken place in line with the requirements prescribed by EU legislation.
- Consider introducing measures to promote the reuse of packaging. These measures should be adopted in cases when it would be beneficial for the environment and where no distortions are imposed on the free movement of goods. (Art. 5)

2.2. Regulation

- Ensure that the recovery and recycling targets cover all possible packaging, packaging components and ancillary items in line with the criteria set out in Article 3, taking into consideration the illustrative examples set out in Annex I to amending Directive 2013/2/EU. This wide definition includes packaging that also has other functions, items designed to be filled at the point of sale, packaging components and ancillary elements integrated into packaging such as sweet boxes, film overwrap around a CD case, paper and plastic carrier bags, disposable plates and cups, cling film, sandwich bags, aluminium foil, labelling hung directly on or attached to a product that forms part of the packaging, sticky labels attached to a packaging item, staples, and devices for measuring dosages.
- Take appropriate measures to prevent the production of packaging waste, including the measures set out in Article 9, including national programmes and producer responsibility schemes on a larger or more restricted scale. Such measures should preferably be developed in co-operation and consultation with economic operators and draw on the experience of other Member States (Art. 4 of Directive 94/62, as amended by Directive 2004/12).
- Ensure that the following minimum targets for recovering and recycling packaging waste are being met covering the whole territory of the Member State.
- The following are the minimum recycling targets for materials contained in packaging waste:
 - 60% by weight for glass;
 - 60% by weight for paper and board;
 - 50% by weight for metals;
 - 22.5% by weight for plastics;

- 15% by weight for wood.
- Ensure that no packaging is marketed unless it complies with certain compulsory requirements relating to safety, consumer acceptance and other specified requirements (Art. 9 and Annex II).
- Ensure that packaging may only be identified in accordance with the identification system provided for in Commission Decision 97/129/EC. However, note that that system is voluntary and applies to the plastic materials mentioned in Annex I, the paper and fibreboard materials mentioned in Annex II, the metals mentioned in Annex III, the wood materials mentioned in Annex IV, the textile materials mentioned in Annex V, the glass materials mentioned in Annex VI, and the composites mentioned in Annex VII.N. There is no marking system, however, pursuant to Article 8.
- Ensure that the concentration of heavy metals in packaging does not exceed specified limits (Art. 11). Derogations concerning glass packaging and plastic crates/pallets are laid down in Commission Decisions 2001/171/EC and 2009/292/EC respectively.
- Ensure that there are no obstacles that impede the placing on the market of packaging that complies with the Directive (Art. 18).
- Ensure that packaging is labelled indicating the nature of the packaging materials used on the basis of Commission Decision 97/129/EC to facilitate its identification and classification and its subsequent collection, reuse and recovery (Art. 8(2), Directive 94/62/EC as amended by Directive 2004/12/EC).
- Take the necessary measures to ensure that, where agreements are entered into between the competent authorities and the economic sectors concerned (e.g. the packaging industry) with a view to transposing Article 7, these agreements comply with the requirements in Article 22, ensuring that they are enforceable, have specific objectives and time-frames, that they are made available to the public (by publication in official journals), that the results are monitored regularly by the economic sectors and reported to the competent authorities and the Commission, that the competent authorities examine the progress achieved and, where an agreement is not abided by, other implementing measures are introduced (Art. 22, Directive 94/62/EC as amended by Directive 2004/12/EC).

2.3. Communication and Reporting

- Require all economic operators involved in the packaging sector to provide the competent authority with data on their relevant sector (Art. 12).
- Organise an information campaign for the general public and economic operators, including the publication of measures and targets for recovery and recycling (Art. 6).
- Take measures to ensure that users of packaging, particularly consumers, obtain information about packaging and packaging waste, including information about how they can contribute to its re-use, recovery and recycling (Art. 13).
- Report to the Commission on:
 - data on packaging and packaging waste, in the formats laid down in Commission Decision 2005/270/EC (Art. 12);

- proposed measures to implement the requirements of the Directive according to the procedure of Directive 98/34/EC (Art. 16);
 - texts of national standards complying with the directive's essential requirements (Art. 9);
 - programmes going beyond the targets laid down in the Directive (Art. 6);
 - implementation of the Directive (Art. 17, Directive 91/692/EEC and Commission Decision 97/622/EC);
 - measures taken to comply with the Directive (Art. 22); and
 - transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 22).
- Inform the Commission of the laws, administrative provisions and other measures adopted to comply with Directive 2004/12/EC (Art. 2, Directive 2004/12/EC).
 - Inform the Commission of national measures that aim at going beyond the highest recycling and recovery targets (Art. 6(10), Directive 2004/12/EC).
 - Where a Member State chooses to transpose Article 7 by entering into agreements between national authorities and economic operators, the Commission must be informed of such agreements and the results achieved (Art. 22 (3a), Directive 94/62/EC as amended by Directive 2004/12/EC.)

2.4. Additional Legal Instruments

A number of other legislative instruments have relevance to packaging waste and must also be borne in mind during the implementation of this Directive. These include:

- Waste Directive (2008/98/EC)
- 2005/270/EC: Commission Decision establishing the formats relating to the database system pursuant to Directive 94/62/EC of the European Parliament and of the Council on packaging and packaging waste
- Commission Decision 97/129/EC establishing the identification system for packaging materials pursuant to European Parliament and Council Directive 94/62/EC on packaging and packaging waste
- Commission Decision 97/622/EC concerning questionnaires for Member States' reports on the implementation of certain Directives in the waste sector, as amended by Decision 2007/151/EC
- Commission Decision 2009/292/EC on derogations for plastic crates and pallets
- Commission Decision 2001/171/EC on derogations for glass packaging, as amended by Decision 2006/340/EC
- Commission Decision 2001/524/EC on references for standards regarding packaging
- Regulation on the European Pollutant Release and Transfer Register Council Directive 1999/31/EC on the landfill of waste as amended by Regulations (EC) 1882/2003 and (EC) 1137/2008 and Council Directive 2011/97/EU

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the following checklist, organised in chronological order (where possible) within each subheading.

Table 22. Checklist with key implementation tasks

THE PACKAGING WASTE DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Administration, Planning and Provision of Infrastructure
1.1	Appoint a competent authority with powers to oversee the implementation of this Directive.
1.2	Set practically achievable targets for the recovery and recycling of packaging wastes that at least meet the requirements of the Directive.
1.3	Produce a national strategy for the management of packaging and packaging wastes in accordance with the Directive and incorporate into the national waste management plan. The strategy should include measures to attain the national recovery and recycling targets.
1.4	Identify the industries on which the obligation to recovery and recycle will fall.
1.5	Organise an information campaign for the public and for economic operators concerning national measures and targets.
1.6	Make a Decision on whether to use economic instruments to promote the objectives set out in the Waste Directive and the Packaging Waste Directive (94/62/EC) with regard to packaging waste.
1.7	Develop a mechanism for ensuring the co-operation of relevant sectors in achieving recovery and recycling targets.
1.8	Organise an information campaign for the general public and economic operators regarding the recycling and recovery targets and the national measures adopted.
1.9	Decide on waste prevention measures, including a national programme and producer responsibility schemes to ensure that all possible steps are taken to reduce the environmental impact of packaging.
1.10	Negotiate potential temporary transitional periods with the Commission to attain the recycling and recovery targets.
2	Regulation
2.1	Set up systems for the necessary return/collection and recycling/recovery of used packaging and packaging waste as identified in the national strategy.
2.2	Adopt appropriate measures to prevent the production of packaging waste and for encouraging packaging reuse systems and the use of recycled packaging materials (attention should be given to the obligation to respect internal market rules).
2.3	Transpose and implement the voluntary system for identifying packaging to indicate the nature of packaging material.
2.4	Develop and implement a system for measuring and reporting the amount of packaging waste produced and the proportion that is recovered and recycled.
2.5	Establish the mechanisms for ensuring that packaging waste is recovered and recycled.
2.6	Develop and implement rules and a system to ensure that only packaging that complies with all essential requirements of the Directive is placed on the market.
2.7	Set/transpose standards for the content of certain heavy metals in packaging materials and for the requirements of Annex II relating to the design and characteristics of packaging.
2.8	Develop and implement an inspection and testing regime to ensure that packaging standards are met.
2.9	Ensure that the minimum targets for the recovery and recycling of packaging waste are being met, covering the whole territory of the Member State.

2.10	Ensure that the recovery and recycling targets cover all possible packaging, packaging components and ancillary items in line with the criteria set out in Article 3, taking into consideration the illustrative examples set out in Annex I to amending Directive 2013/2/EU.
2.11	Ensure that packaging is labelled, indicating the nature of the packaging materials used on the basis of Commission Decision 97/129/EC, in order to facilitate its identification and classification and its subsequent collection, reuse and recovery.
2.12	Ensure that, where agreements are entered into between the competent authorities and the economic sectors concerned (e.g. the packaging industry) with a view to transposing Article 7, these agreements comply with the requirements in Article 22 of Directive 2004/12/EC.
3	Communication and Reporting
3.1	Ensure that obligated enterprises are informed of their obligations.
3.2	Implement a communications programme to make information available to consumers and other packaging waste producers about their role in the implementation of the Directive, including the schemes and facilities available to them.
3.3	Establish databases in accordance with the Directive to enable reports to be made to the Commission in the format identified in Commission Decision 2005/270/EC.
3.4	Establish reporting and data recording systems to ensure that the data required (see below) are collected.
3.5	Inform the Commission of: <ul style="list-style-type: none"> • texts of national standards which comply with the Directive; • transposition and implementation of the Directive; • data in the form of databases; • formats and information; • drafts of economic measures; and • programmes going beyond targets.
3.6	Inform the Commission of the laws, administrative provisions and other measures adopted to comply with Directive 2004/12/EC amending Directive 94/62/EC.
3.7	Inform the Commission of national measures that aim to go beyond the highest recycling and recovery targets (Art. 6(10), Directive 2004/12/EC).
3.8	Inform the Commission of agreements between national authorities and economic operators.

3.2. Phasing Considerations

The most demanding and time-consuming tasks associated with implementing this Directive are likely to be the following:

- Preparing the strategy for meeting the recovery and recycling targets, including an implementation plan, with timescales and responsibilities clearly allocated.
- Developing a mechanism to ensure that packaging waste is recovered or recycled.
- Ensuring the provision of the necessary collection systems and recycling and recovery facilities.
- Establishing the necessary data recording and processing systems to ensure that the required information can be provided to the Commission.
- Developing the various measures for the prevention of the production of packaging waste, including a national programme and measures such as producer responsibility schemes and life-cycle assessment requirements.
- These tasks should therefore be planned to commence during the initial phase of implementation.

4. IMPLEMENTATION GUIDANCE

In implementing this Directive, candidate countries must take into account requirements relating to product quality, the protection of health, transportation and the regulation of hazardous waste. They should also consider the financial implications and the possibilities of introducing nation- wide producer responsibility schemes covering all or most types of packaging. For certain waste categories, producers have greater incentives to take over and control the costs of collection, recycling, recovery, transportation and disposal than for others. In general, for instance, producers of paper and cardboard, packaging made of aluminium or other metals and glass containers are more ready actively to participate in producer responsibility schemes than producers of PET bottles or other plastic packaging. The systems and measures opted for should preferably be in line with the general waste management plans and strategies, priorities and problem areas.

In 2011, the Commission published a report¹⁷⁰ with best practices in implementing the Packaging Waste Directive accessible at:

http://ec.europa.eu/environment/waste/packaging/pdf/packaging_final_report.pdf

Drawing upon the experience of selected Member States, a number of general observations and suggestions for implementing this Directive are presented below.

4.1. Planning and Provision of Infrastructure

- The implementation of this Directive requires the development of a strategy that covers, on the one hand, the management of packaging wastes and, on the other, the design, manufacture and marketing of packaging itself. For instance, improving the environmental performance and composition of the material at the design and use phase can have positive implications for its handling at the end-of-life stage. It might be far cheaper and easier to recycle and recover packaging composed of fewer composite materials and with fewer components (e.g. labels, ancillary components).
- It is likely that more than one institution will be involved in implementing the requirements of the Directive, since the responsibilities for environmental protection and for standards of manufacture usually lie in different ministries. A national standards institution may also be involved in providing advice on manufacturing standards. It is important to ensure good communication and co-operation between all the relevant parties.
- The national targets for recovery and recycling must be at least in accordance with those in the Directive, but may be higher. Targets should, however, be practically achievable and must be designed to avoid distortions of competition and barriers in trade, or discrimination against products. There are some practical issues associated with imposing the targets — in particular, on whom and how to place statutory obligations. This topic is addressed under "Regulation and Implementation" below.

¹⁷⁰ BIO Intelligence Service (Véronique Monier, Mathieu Hestin, Rita Schuster), and Arcadis (Mike Van Acoleyen, Ilse Lauyrensens), „*Awareness and Exchange of Best Practices on the Implementation and Enforcement of the Essential Requirements for Packaging and Packaging Waste*”, FINAL REPORT, European Commission, DG ENV, 3 August 2011

- In setting targets, it is important to recognise that the collection of recyclable material alone is insufficient. Facilities must be provided to reprocess the recovered materials, which, in turn, requires that markets exist for the products of these processes. Although the Directive allows the use of recycling facilities abroad to fulfil targets (but not the use of imported material to count towards Member States' targets), it may be necessary to take measures to develop markets for recycled materials. The following actions may assist in this development (it should be ensured that these actions are in line with EU state aid and public procurement legislation):
 - ensuring that government departments use recycled materials (e.g. through integrating environmental requirements into public procurement notices);
 - establishing communications programmes, including public awareness campaigns and consultations with the packaging sectors to generate interest in recycling, developing new markets for recycled materials etc.
 - encouraging manufacturers to adapt their processes to make use of recycled feedstock;
 - ensuring that national standards and norms do not unnecessarily preclude the use of recycled materials;
 - developing new uses for recycled materials;
 - government action to ensure price stability, such as price guarantees.
- The practicalities of undertaking separation at the point of use, at the collection point or the delivery point for collected wastes should be considered.
- The Directive requires that the waste management hierarchy is applied in respect of packaging waste, but it is recognised that life-cycle analysis may alter the hierarchy in individual cases. In particular, the environmental cost of collection, transport and processing should be taken into account when developing the strategy for packaging waste.
- It is also necessary to adopt measures to prevent the production of packaging waste, which should be addressed in the waste management strategy and the national programme, required under Directive 2004/12/EC. This could involve specific measures aimed at particular industries, such as the imposition of charges or taxes on particular types of packaging that lead to the production of wastes that are difficult to recycle. An example is a tax on plastic bags, such as is imposed in one Member State (IT). Another is the use of mandatory deposits for beverage containers, as required in another Member State (DK). Other examples are refundable deposit systems for glass containers.
- Facilities will need to be provided for the collection, recovery and recycling of packaging wastes. These may include:
 - separate collection schemes for household wastes;
 - separate collection of schemes for wastes from industry and distributors (e.g. retailers);
 - energy recovery plants (note that incineration of packaging in mixed municipal waste in waste incinerators cannot be counted for the recovery targets of the Directive);
 - composting plants;
 - materials recovery facilities;

- processing facilities at manufacturers (e.g. of glass, paper and plastics) which are adapted to accept recycled wastes.
- The strategy must address not only the need for particular facilities and systems, but also systems and mechanisms to ensure that these wastes are actually collected, recovered and recycled. Since the private sector is the main producer and distributor of packaging and is also heavily involved in recovery and recycling, it will be necessary to establish systems and mechanisms that ensure the participation and co-operation of private sector companies. This may be achieved by means of a communications programme, or by the provision of financial incentives, such as favourable tax rates or loans for the construction of facilities.
- Consider to implement option provided in Article 5 and to encourage reuse systems of packaging, which can be reused in an environmentally sound manner. Such measures may include the following:
 - Taxes (e.g. taxation that is applied on reusable packaging only when put on the market for the first time)
 - Exemptions on reusable packaging from requirements (e.g. exceptions of reusable packaging from take-back obligations or exception of reusable packaging from extended producer responsibility fees)
 - Deposit systems for household packaging, particularly for beverage packaging
 - Administrative simplifications (e.g. simplifications on the recording and notification procedures)
 - Introducing requirements to sell products in reusable packaging
 - Promotion of reuse through waste management plans
 - Awareness raising.

Examples from a Member State: Arrangements for developing and implementing waste strategy

Portugal: An integrated waste management system was implemented, based on the principle of the common responsibility of all the economic operators (manufacturers, packers and importers, households and municipalities) involved in the management of packaging waste and of packaging itself. Ponto Verde, a public company that undertakes the recycling of waste, is in charge of adopting measures to prevent the production of packaging waste through education and raising awareness, targeting the public and industry. Through the accreditation of packaging manufacturers, Ponto Verde acquires the financial resources required to grant economic incentives to urban waste treatment facilities, thus ensuring that a selective collection of packaging waste is undertaken.

Examples from a Member State: Deposit scheme for reusable packaging

Germany: The deposit scheme in Germany is regulated by the German Packaging Ordinance. The Ordinance sets a minimum packaging quota for reusable drinks packaging and one-way “ecological advantageous” packaging containers, namely 80%. The labelling of packaging as “ecological advantageous” is based on life-cycle analysis criteria that were carried out prior to the regulatory definition. In December 2004, the European Court of Justice confirmed that a compulsory deposit scheme is, in principle, compatible with EU law. In 2009, the market share for

reusable drink containers in Germany was 45% for water and carbonated drinks and 89% for beer, with an overall market share of 50%. The share of one-way packaging is continuously increasing comparing to the share of reusable packaging.

Source: Ex-post evaluation of certain waste stream Directives, Final report, European Commission – DG Environment 18 April 2014

4.2. Regulation

- Although not explicitly stated in the Directive, it will be necessary to designate competent authorities, with powers of enforcement, to ensure that recovery and recycling targets are met. The authority responsible for waste regulation under the Waste Directive is likely to be the best choice to undertake this task, although the ministry responsible for industry will also play an important role.
- Measures must be adopted to minimise the production of packaging waste. This may partly be achieved through the measures set out in Annex II. In addition, however, guidance should be prepared on possible approaches to the minimisation of packaging.
- It will be necessary to identify the amounts of packaging materials used in order to calculate the national targets to meet the directive's requirements. This will require an obligation on industry to report to the competent authority on the amounts of material produced.
- The systems introduced in most Member States have resulted in the development of specialist organisations to ensure that packaging wastes are recovered and recycled.
- The obligations to achieve recovery and recycling targets could be placed on the packaging industry rather than the waste producer itself, who has little control over the nature of the packaging to be discarded. This is known as producer responsibility. The mechanisms may involve economic tools such as voluntary or compulsory product charges, product taxes or tradeable permits.
- In addition, there are other methods to encourage the recovery and recycling of packaging wastes. One Member State (NL) has banned the disposal of packaging wastes to landfill altogether from 1999. Another (IT) will impose fines on those not achieving recycling and recovery targets and will use the funds received to finance recycling infrastructure. A third (DK) imposes a mandatory refundable deposit system for beverage containers.
- The mechanism may be mandatory or voluntary. In a mandatory scheme, specific obligations are placed on the packaging industry, whereas a voluntary scheme allows the industry to devise its own methods of compliance.
- In a mandatory scheme, targets are usually set on individual enterprises, by the competent authority. In one Member State (UK), individual targets are set according to annual financial turnover and the quantity of packaging handled per year.
- Return, collection and recovery systems must take into account requirements relating to environmental and consumer health protection; the quality, authenticity and technical characteristics of packaged goods and packaging material; and the protection of industrial and commercial property rights.

- Essential requirements for packaging are set out in Annex II of the Directive. These will need to be transposed into legislation. A choice exists as to whether to place the obligation to conform to these requirements on the packaging manufacturers/importers or on the packer/fillers. The latter option may be more practical, because of the number of potential stages in the manufacturing process and the problem of determining which party has responsibility for the packaging.
- A competent authority is also required to enforce these essential requirements, and the competent authority responsible for trading standards may be the most appropriate body to fulfil this task.
- A national standards institution could have a part to play in providing a standard that conforms to the requirements of the Directive.
- Effective enforcement of standards for the manufacture of packaging will involve auditing and sampling by the selected competent authority, which may require training.
- Research into materials used in the packaging industry will need to be carried out by an appropriate research institution to ensure that health and safety issues raised by the use of materials containing, for instance, heavy metals, are reduced to a minimum over time. The main aim of reducing concentrations of harmful materials will be to minimise emissions from energy recovery processes. Mandatory standards of packaging manufacture can then be introduced.

Examples from a Member State: Institutional Arrangements

United Kingdom: The competent authority for waste management has the practical responsibility of ensuring that recovery and recycling targets are met. The competent authority consults closely with the Department of Trade and Industry (DTI), which is involved in evaluating and allocating the cost burden on industry. DEFRA produced a user's guide to the The Producer Responsibility Obligations (Packaging Waste) accessible at <https://www.gov.uk/guidance/packaging-producer-responsibilities>

Portugal: The Institute of Wastes (INR) is responsible for the regulation and enforcement of waste legislation through the co-ordination, control and inspection of all the different operators involved in the management of packaging waste, and the packaging itself. The Regulating Commission for Packaging and Packaging Waste Management (CAGERE), the technical body responsible for advising government members in charge of granting licences to packaging manufacturers, was established through an INR regulation. Ponto Verde must present an annual report to the INR.

France: Responsibility for packaging waste falls on the consumer. A company has a choice either to deal with the waste itself or to contract one of three authorised agencies to deal with it. The consumer is responsible for segregating the waste at the point of production, to facilitate recovery. The recycling process itself is monitored by DRIRE.

Sweden: The Swedish EPA, together with local supervisory authorities, is mainly responsible for supervising and monitoring the Swedish producer responsibility system for packaging materials. It has issued a handbook providing guidance for local authorities as well as the packaging sectors.

4.3. Communication and Reporting

- This Directive places strong emphasis on the role of communications. Clearly, it is necessary to inform consumers and the packaging industry about their role in the national packaging obligations and the schemes and facilities available to them. This may be achieved by means of national and local advertising, leaflets and education programmes in schools.
- To achieve the objectives, it is also important to produce and disseminate information for industry about the minimisation of packaging and packaging waste.
- Obligated industries will need to be informed of their specific responsibilities and the targets set for recycling and recovery.
- It will be necessary to establish databases in accordance with the Directive to enable reports to be made to the Commission in the format identified in Commission Decision 2005/270/EC. This may be the duty of the competent authority. It should be noted that the reporting requirements of this Directive are extensive and will require significant resources to ensure that they can be complied with.

4.4. Further information and studies

More information and studies on packaging and packaging waste can be found on the following web pages:

General introduction: http://ec.europa.eu/environment/waste/packaging_index.htm

Annual data on packaging waste generation, recovery and incineration at waste incineration plants with energy recovery and recycling provided annually:

<http://ec.europa.eu/environment/waste/packaging/data.htm>.

Reports on the implementation of the Directive:

<http://ec.europa.eu/environment/waste/reporting/index.htm>

Studies on packaging waste and best practices in Member States:

<http://ec.europa.eu/environment/waste/packaging/studies.htm>

5. COSTS

The main types of costs arising during the implementation of the packaging Directive are illustrated, as far as possible, in the checklist below. Naturally, the relative size of the costs of the individual items will vary from country to country, especially where countries decide to introduce financial instruments (e.g. taxes, refundable deposit systems), which reduce the costs of collection and recycling for the concerned categories of waste borne by the competent authorities and municipal waste operators.

Meeting the requirements of the Directive is likely to be relatively costly. The provision of systems and facilities for the collection and recovery/recycling of packaging wastes, together with the creation of an adequate implementation mechanism and regulatory structure will constitute the largest elements of the overall costs of achieving compliance. Charges for registration and certification may be made to cover the cost of the regulatory system, thus ensuring the implementation of the polluter pays principle.

Table 23. Checklist with types of implementation costs

Initial set-up costs: <ul style="list-style-type: none">• preparation of a strategy to achieve the objectives of the Directive;• developing and introducing a mechanism to achieve compliance;• preparing procedures for registration and verification;• preparing technical guidance notes.
Capital expenditure: <ul style="list-style-type: none">• provision of systems for the collection of packaging waste;• provision of facilities for recovering and recycling packaging waste.
Ongoing costs: <ul style="list-style-type: none">• annual operating costs of collection, recovery and recycling systems/facilities;• registration and verification, and enforcement;• collecting data for reporting to the Commission.

THE REGULATIONS ON SHIPMENTS OF WASTE

Official Titles:

Regulation (EC) No. 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste, as amended by Commission Regulation (EC) No 1379/2007 (OJ L 190, 12.7.2006), as amended by:

- Commission Regulation (EC) No. 1379/2007 of 26 November 2007 amending Annexes IA, IB, VII and VIII of Regulation (EC) No. 1013/2006 of the European Parliament and of the Council on shipments of waste, for the purposes of taking account of technical progress and changes agreed under the Basel Convention (OJ L 309, 27.11.2007)
- Commission Regulation (EC) No. 669/2008 of 15 July 2008 on completing Annex IC of Regulation (EC) No. 1013/2006 of the European Parliament and of the Council on shipments of waste (OJ L 188, 16.7.2008)
- Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Two (OJ L 87, 31.3.2009)
- Directive 2009/31/EC of the European Parliament and of the Council of 23 April 2009 on the geological storage of carbon dioxide and amending Council Directive 85/337/EEC, European Parliament and Council Directives 2000/60/EC, 2001/80/EC, 2004/35/EC, 2006/12/EC, 2008/1/EC and Regulation (EC) No 1013/2006 (OJ L 140, 5.6.2009)
- Commission Regulation (EU) No 413/2010 of 12 May 2010 amending Annexes III, IV and V to Regulation (EC) No 1013/2006 of the European Parliament and of the Council on shipments of waste so as to take account of changes adopted by OECD Council Decision C(2008) 156 (OJ L 119, 13.5.2010)
- Commission Regulation (EU) No 664/2011 of 11 July 2011 amending Regulation (EC) No 1013/2006 of the European Parliament and of the Council on shipments of waste to include certain mixtures of wastes in Annex IIIA thereto (OJ L 182, 12.7.2011)
- Commission Regulation (EU) No 135/2012 of 16 February 2012 amending Regulation (EC) No 1013/2006 of the European Parliament and of the Council on shipments of waste to include certain unclassified wastes in Annex IIIB thereto (OJ L 46, 17.2.2012)
- Commission Regulation (EU) No 255/2013 of 20 March 2013 amending, for the purposes of adaptation to scientific and technical progress, Annexes IC, VII and VIII to Regulation (EC) No 1013/2006 of the European Parliament and of the Council on shipments of waste Text with EEA relevance (OJ L 79, 21.3.2013)
- Regulation (EU) No 1257/2013 of the European Parliament and of the Council of 20 November 2013 on ship recycling and amending Regulation (EC) No 1013/2006 and Directive 2009/16/EC (OJ L 330, 10.12.2013)
- Regulation (EU) No 660/2014 of the European Parliament and of the Council of 15 May 2014 amending Regulation (EC) No 1013/2006 on shipments of waste (OJ L 189, 27.6.2014)

- Commission Regulation (EU) No 1234/2014 of 18 November 2014 amending Annexes IIIB, V and VIII to Regulation (EC) No 1013/2006 of the European Parliament and of the Council on shipments of waste (OJ L 332, 19.11.2014)
- Commission Regulation (EU) 2015/2002 of 10 November 2015 amending Annexes IC and V to Regulation (EC) No 1013/2006 of the European Parliament and of the Council on shipments of waste (OJ L 294, 11.11.2015)

Commission Regulation (EC) No 1418/2007 of 29 November 2007 concerning the export for recovery of certain waste listed in Annex III or IIIA to Regulation (EC) No 1013/2006 of the European Parliament and of the Council to certain countries to which the OECD Decision on the control of transboundary movements of wastes does not apply (OJ L 316, 4.12.2007), as amended by:

- Commission Regulation (EC) No 740/2008 of 29 July 2008 amending Regulation (EC) No 1418/2007 as regards the procedures to be followed for export of waste to certain countries (OJ L 201, 30.7.2008)
- Commission Regulation (EC) No 967/2009 of 15 October 2009 amending Regulation (EC) No 1418/2007 concerning the export for recovery of certain waste to certain non-OECD countries (OJ L 271, 16.10.2009)
- Commission Regulation (EU) No 837/2010 of 23 September 2010 amending Regulation (EC) No 1418/2007 concerning the export for recovery of certain waste to certain non-OECD countries (OJ L 250, 24.9.2010)
- Commission Regulation (EU) No 661/2011 of 8 July 2011 amending Regulation (EC) No 1418/2007 concerning the export for recovery of certain waste to certain non-OECD countries Text with EEA relevance (OJ L 181, 9.7.2011)
- Commission Regulation (EU) No 674/2012 of 23 July 2012 amending Regulation (EC) No 1418/2007 concerning the export for recovery of certain waste to certain non-OECD countries Text with EEA relevance (OJ L 196, 24.7.2012)
- Commission Regulation (EU) No 57/2013 of 23 January 2013 amending Regulation (EC) No 1418/2007 concerning the export for recovery of certain waste to certain non-OECD countries (OJ L 21, 24.1.2013)
- Commission Regulation (EU) No 519/2013 of 21 February 2013 adapting certain regulations and decisions in the fields of free movement of goods, freedom of movement for persons, right of establishment and freedom to provide services, company law, competition policy, agriculture, food safety, veterinary and phytosanitary policy, fisheries, transport policy, energy, taxation, statistics, social policy and employment, environment, customs union, external relations, and foreign, security and defence policy, by reason of the accession of Croatia (OJ L 158, 10.6.2013)
- Commission Regulation (EU) No 733/2014 of 24 June 2014 amending Regulation (EC) No 1418/2007 concerning the export for recovery of certain waste to certain non-OECD countries (OJ L 197, 4.7.2014)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Regulation (EC) No 1013/2006/EC establishes a system for controlling the movement of waste, to implement the Basel Convention on the control of transboundary movement of hazardous wastes and their disposal, and the OECD Council Decision C(2001)107/Final concerning the revision of Decision C(92)39/Final on the control of transboundary movements of wastes destined for recovery operations (OECD Decision). It sets up separate regimes governing shipments within the EU, imports to and exports from the EU, and transit shipments through the EU. Different requirements are laid down depending on the destination of the waste shipment, on whether the waste is destined for recovery or disposal, and, in the case of shipments for recovery, whether the waste is listed in Annexes III, IIIA or IIIB.

Regulation (EC) No 1013/2006 replaced Regulation (EEC) No. 259/93 with effect from 12 July 2007¹⁷¹.

The aim of Regulation (EC) No 1013/2006 is to reinforce, simplify and make specific the existing procedures for controlling waste shipments. It thus reduces the risk of waste shipments not being controlled and seeks to incorporate into EU legislation the amendments to the lists of waste annexed to the Basel Convention as well as the revision adopted by the OECD in 2001. Regulation (EC) No 1013/2006 comprises two main waste shipment control procedures:

- the procedure of prior written notification and consent — the procedure applicable to all shipments of waste destined for disposal, as well as to the shipments for recovery of hazardous and non-hazardous waste not listed in Annexes III, IIIA or IIIB of the Regulation;
- the procedure in which shipments are accompanied by certain information, applicable to certain non-hazardous waste destined for recovery that exceed 20 kg in weight, as well as to waste under 25 kg sent for laboratory analysis.

The Regulation states that waste shipments must be subject to a contract between the person responsible for shipping the waste, or having it shipped, and the consignee of such waste. In cases of a notification requirement applicable to the waste in question, the contract must include financial guarantees.

It is envisaged in the notification procedure that the notification shall be submitted by the notifier only to the competent authority of dispatch, which, in turn, is responsible for passing it on to the competent authority of destination and transit. The consent of the competent authority is to be given (with or without conditions) or objections expressed within 30 days. Any changes involving the main aspects of the shipment (quantity, itinerary, etc.) must be the subject of a new notification, with the exception of cases where all the competent authorities grant the notifier an exemption from this obligation.

The Regulation stipulates that interim recovery and disposal facilities are bound by the same obligations as final recovery and disposal facilities. Thus, the authorisation of a shipment involving interim operations can only be sanctioned if the shipment of the waste in question has also been authorised.

In the event that a shipment cannot be completed (including recovery or disposal), the notifier must take the waste back, normally at their own expense. This shall apply to all types of waste, subject to certain exceptions: if there is another way of recovering or disposing of this waste or if the waste has been irretrievably mixed with other types of waste. In the case of an illicit shipment, the notifier or the consignee must, to the extent that

¹⁷¹ Council Regulation (EEC) No. 259/93, Commission Regulation (EC) No. 801/2007, Council Regulation (EC) No. 1420/1999, Commission Regulation (EC) No. 1547/1999, Commission Decision 94/774/EC, Commission Decision 1999/412/EC

responsibility for the illegal shipment is attributable to one or other of them, take back, recover or dispose of the waste.

The Regulation includes other general provisions, such as a ban on the mixing of waste during shipment, the making available to the general public of appropriate information, and the obligation on the part of the notifier, the competent authority, the consignee and the facilities concerned to keep documents and information.

The Regulation prohibits exports to third countries of waste intended for disposal, except to EFTA (European Free Trade Association) countries that are party to the Basel Convention. Also prohibited are exports of hazardous waste destined for recovery to countries where the OECD Decision does not apply.

Regular checks must be organised according to the necessary provisions made by the Member States. Checks should take place throughout the entire waste shipment and waste recovery/waste disposal process.

Article 63 of the Regulation lays down transitional arrangements for new Member States.¹⁷²

Regulation No. 1013/2006 has been amended several times.

- Commission Regulation (EC) No. 669/2008: completes Annex IC of Regulation (EC) No. 1013/2006 and includes specific instructions for completing the notification and movement documents (Annex IA and Annex IB of Regulation (EC) No. 1013/2006).
- Directive 2009/31/EC amends the scope of the Regulation by excluding CO₂ captured and transported for the purposes of geological storage from the scope of application of the Waste Shipment Regulation.
- Commission Regulation (EU) No 660/2014 aims to strengthen EU countries' inspection and enforcement systems. The Regulation sets minimum requirements for inspectional supervision with a focus on problematic waste streams (hazardous waste and waste sent illegally for dumping or sub-standard treatment).

Amendments to the Annexes were introduced by:

- Commission Regulation (EC) No. 1379/2007: amends Annexes IA, IB, VII and VIII of Regulation (EC) No. 1013/2006 for the purposes of taking account of technical progress and changes agreed under the Basel Convention. This Regulation revises the forms for notification and movement documents and for the information to accompany shipments of green-listed waste.
- Commission Regulation (EC) No. 669/2008: completes Annex IC of Regulation (EC) No. 1013/2006.
- Commission Regulation (EC) No 308/2009: adapted to scientific and technical progress, Annexes IIIA and VI to Regulation (EC) No 1013/2006.
- Commission Regulation (EU) No 413/2010: amended Annexes III, IV and V to Regulation (EC) No 1013/2006 to take account of changes adopted by OECD Council Decision C(2008) 156.

¹⁷² On the basis of this provision, temporary derogations were granted to Latvia (Annex VIII to the Act of Accession of 2003, chapter 10(B)), Hungary (Annex X to the Act of Accession of 2003, chapter 8(A) - obsolete since 2005), Malta (Annex XI to the Act of Accession of 2003, chapter 10(B) - obsolete since 2006), Poland (Annex XII to the Act of Accession of 2003, chapter 13(B)), Slovakia (Annex XIV to the Act of Accession of 2003, chapter 9(B)), Bulgaria (Annex VI to the Act of Accession of 2005, chapter 9(B) (at p. 16)) and Romania (Annex VII to the Act of Accession of 2005, chapter 9(B) (at p. 21)).

- Commission Regulation (EU) No 664/2011: amended Regulation (EC) No 1013/2006 to include certain mixtures of wastes in Annex IIIA thereto.
- Commission Regulation (EU) No 135/2012: amended Regulation (EC) No 1013/2006 to include certain unclassified wastes in Annex IIIB thereto.
- Commission Regulation (EU) No 255/2013: adapted to scientific and technical progress, Annexes IC, VII and VIII to Regulation (EC) No 1013/2006.
- Commission Regulation (EU) 1234/2014: amended Annexes IIIB, V and VIII to Regulation (EC) No 1013/2006

Commission Regulation (EC) No. 1418/2007, as amended by Regulation (EC) No 740/2008, (EC) No 967/2009, (EU) No 837/2010, (EU) No 661/2011, (EU) No 674/2012, (EU) No 57/2013, (EU) No 519/2013 and (EU) No 733/2014: concerns the export for recovery of certain waste listed in Annex III or IIIA to Regulation (EC) No. 1013/2006 to certain countries to which the OECD decision on the control of transboundary movements of wastes does not apply. It concerns Article 37(1) of Regulation (EC) No. 1013/2006, whereby the Commission sent a written request to each country to which Decision C(2001)107/Final of the OECD Council concerning the revision of Decision C(92)39/Final on the control of transboundary movements of wastes destined for recovery operations does not apply, seeking confirmation in writing that waste which is listed in Annex III or IIIA to that Regulation and the export of which is not prohibited under its Article 36 may be exported from the EU for recovery in that country and requesting an indication as to which control procedure, if any, would be followed in the country of destination. Its annex sets out the preferred options of control of the various countries in regard to trade in wastes listed in Annex III and Annex IIIA for recovery and trade of wastes that is not prohibited under Article 36 of Regulation 1013/2006 to countries to which the OECD Decision does not apply.

Finally, it is important to note that there are a few types of wastes or situations that are governed by specific legislation. These include:

- Directive 2000/59/EC of the European Parliament and of the Council of 27 November 2000 on port reception facilities for ship-generated waste and cargo residues
- Council Directive 2006/117/EURATOM of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel
- Regulation (EC) No. 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules concerning animal by-products not intended for human consumption and repealing Regulation (EC) No 1774/2002.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Designate competent authorities responsible for the implementation of the Regulation, correspondents responsible for informing or advising or making enquiries, and specific customs offices of entry into and exit from the EU (Arts. 53, 54 and 55, Regulation 1013/2006).
- Establish the overall procedural framework as regarding the shipments and covering the requirements for written notification and consent, contracts between the notifier and the consignee, information to the public, competent authorities, parties involved and needed for procedural reasons, as well as the financial guarantees or equivalent insurance covering the costs of transport, costs of recovery or disposal and any necessary interim operation and the costs of storage for 90 days (Arts. 4, 5, 6, Regulation 1013/2006).
- Ensure there are the necessary facilities and appropriate means, such as Internet, making the information on notifications publicly available (Art. 21, Regulation 1013/2006).
- Establish a system for the supervision and control, inspections and spot checks of shipments of waste within the national jurisdiction, coherent with the system established under the Regulation and establish rules on penalties, applicable for infringements of the provisions of the Regulation (Art. 50, Regulation 1013/2006). In this context, prepare inspection plans covering the entire geographical territory by 1 January 2017 (Art. 1, Regulation (EU) No 660/2014 (amending Art. 50)).
- Ensure that any bilateral agreements and arrangements for the import of waste for recovery are concluded in accordance with specified conditions.
- Ensure the appropriate additional measure related to the implementation of the Regulation and adopted by the Commission (such as the calculating method for the financial guarantee, guidelines for application and co-operation, technical and organisational requirements as well as any further guidance and clarifications) are followed, implemented and passed to the interested parties.

2.2. Regulation

- Lay down the rules on penalties for the cases of illegal shipments (Art. 50, Regulation 1013/2006).
- Designate permanent staff for the cooperation among Member States as regards the prevention and detection of illegal shipments; as well as focal points responsible for the physical checks on shipments.
- Ensure compliance with the procedures set out in the Annex to Regulation (EC) No 1418/2007 (as amended) for the export for recovery of waste listed in Annex III or IIIA to Regulation (EC) No 1013/2006, which is not prohibited under Article 36 of that Regulation, to certain countries to which the OECD Decision does not apply. (Art. 1, Regulation 1418/2007)

- Provide that shipments of waste are subject to the provision of a financial guarantee or equivalent insurance (Art. 6, Regulation 1013/2006).
- Ensure that waste is shipped in accordance with specified requirements, which may include inspections and spot checks (Art. 50, Regulation 1013/2006).
- Ensure that notifiers or persons arranging the shipment of waste take responsibility for its safe disposal or recovery.
- Possibly designate customs offices of entry into, and departure from, the EU (Art. 50(6), Regulation 1013/2006).
- Ensure that the competent authorities, the notifier and the consignee keep documents sent to or by the competent authorities for at least three years (Art. 20, Regulation 1013/2006).
- Ensure that in case of an illegal shipment the waste is taken back taking into account whether the responsibility is attributed either to the notifier or to the consignee (Arts. 22 and 23, 24, 25, Regulation 1013/2006).

2.2.1. Shipment procedures

- Ensure that authorities, notifiers and producers of waste understand and comply with their obligations regarding shipments of waste. For ease of reference, the principal obligations of the key parties are set out below.
- Where a country to which the OECD Decision does not apply, in its reply to a written request sent by the Commission in accordance with the first subparagraph of Article 37(1) of Regulation (EC) No 1013/2006 indicates that, with regard to certain shipments of waste, it will not prohibit them nor apply the procedure of prior written notification and consent as described in Article 35 of that Regulation, Article 18 of that Regulation shall apply mutatis mutandis to such shipments. (Art. 1a, Regulation No. 1418/2007 as amended by Regulation (EC) No 740/2008)
- Notifiers must:
 - send the notification of the shipment to the competent authorities in the country of dispatch (Arts. 3, 4, 7, Regulation No. 1313/2006);
 - have a contract with the consignee of the waste for its disposal (Art. 5, Regulation No. 1013/2006);
 - establish a financial guarantee or equivalent insurance (Art. 6, Regulation No. 1013/2006);
 - provide additional information and documentation to the competent authorities, as required (article 4, para. 2 and 3);
 - inform the relevant competent authorities if the usual route of shipment is modified (Art. 17, Regulation No. 1013/2006).
- Competent authorities of dispatch must:
 - issue an acknowledgement of receipt of a notification;

- inform the notifier and the other competent authorities of any objections, and of any conditions attached, to the shipment and refuse to allow a shipment if a conflict arises (Arts. 10, 11, and 12, Regulation No. 1013/2006);
- ensure that the notifier takes back the waste in case the shipment cannot be completed as intended (Art. 22);
- where illegal traffic in waste is the responsibility of the notifier, ensure that the waste is taken back or suitably disposed of or recovered (Art. 24, Regulation No. 1013/2006).
- Competent authorities of destination must:
 - acknowledge receipt of a notification for a shipment, authorise or object to the shipment, and notify the notifier, the competent authorities and the consignee of their decisions (Arts. 8, 9, 10, 11, Regulation No. 1013/2006);
 - follow up on the receipt/disposal/recovery of the waste in the country of destination (illegal traffic). In case an illegal traffic of waste is the responsibility of the consignee, ensure that the waste is suitably disposed of (Art. 24, Regulation No. 1013/2006).
- Competent authorities of transit must:
 - consent or object to the shipment and inform the notifier and the other competent authorities of their decisions (Art. 31, Regulation No. 1013/2006);
 - if they are the last competent authority of transit within the EU, inform the notifier of receipt of notification, authorise or refuse the shipment, notify competent authorities of their decision, and issue a consignment note (Art. 31, Regulation No. 1013/2006).
- Reporting

Member States shall report to the Commission on:

- measures to prohibit or object to shipments (Arts. 11, 12, Regulation No. 1013/2006);
- decisions to issue pre-consents to specific recovery facilities (Art. 14, Regulation No. 1013/2006);
- systems for the supervision and control of shipments of waste within a Member State (Art. 50, Regulation No. 1013/2006);
- bilateral agreements and arrangements (Art. 41, Regulation No. 1013/2006);
- provisions on financial guarantees (Art. 6, Regulation No. 1013/2006);
- designation and details of competent authorities and correspondents (Art. 53 and 54, Regulation No. 1013/2006);
- the customs office, if it is decided to designate a customs office of entry into and departure from the EU for shipments of waste entering and leaving the EU (Art. 55, Regulation No. 1013/2006); and
- reporting according to Article 51 — i.e. sending a copy of the yearly report to the Basel Convention, and a report based on the questionnaire in Annex IX to the Regulation.

2.3. Additional Legal Instruments

The most relevant legislation that directly or indirectly concerns waste, exports and imports of dangerous chemicals:

- Directive 2008/98/EC on waste
- Batteries Directive (2006/66/EC)
- End-of-Life-Vehicles (2000/53/EC)
- WEEE Directive (2012/19/EU)
- Environmental Crimes Directive (2008/99/EC)
- Regulation (EC) No 850/2004 on persistent organic pollutants
- Regulation (EU) No 649/2012 concerning the export and import of dangerous chemicals
- Regulation (EC) No 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury

3. IMPLEMENTATION

3.1. Key Tasks

The regulations implement the Basel Convention. However, in addition to the provisions of the Basel Convention, these:

- prohibit exports of waste for disposal except to other Member States or EFTA states that are parties to the Basel Convention;
- implement Decision III/1 of the Basel Convention Conference of the Parties, by prohibiting the export of Annex V wastes for recovery to countries to which the OECD Decision not apply;
- cover all wastes, not simply hazardous wastes;
- cover shipments between Member States, imports into and exports out of the European Union from and to third states;
- require a system for the supervision and control of waste shipments within each Member State.

The key tasks involved in the implementation of the Regulation are summarised in the following checklist, organised in chronological order (where possible) within each subheading.

Table 24. Checklist with the regulations on shipments of waste key implementation tasks

THE REGULATIONS ON SHIPMENTS OF WASTE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate a competent authority(ies) responsible for performing duties arising under the Basel Convention and these Regulations.
2	Regulation
2.1	Identify the differences between the detailed procedures in the Regulations and those of the Basel Convention, and revise existing procedures accordingly.
2.2	Put in place procedures, as specified in the Regulations, to be used for the supervision and control of waste.
2.3	Provide guidance and training to implementing officers, including customs officers.
2.4	Ensure that all actors understand their duties, for example by disseminating information on the effects of the regulations.
2.5	Establish a system for handling cases of illegal traffic of waste and for taking action when a shipment cannot be completed in accordance with terms of the consignment note or the contract between the notifier and the consignee.
2.6	Establish a monitoring system to ensure that the provisions of the regulations are complied with. The system would include inspections of establishments and undertaking spot checks of shipments, measures to ensure that documents relating to the shipment are kept for three years and measures to ensure fulfilment of reporting obligations.
3	Reporting
3.1	Establish reporting and data recording and processing systems to ensure that the required data are collected.
3.2	Notify the Commission as per requirements in the Regulations.

4. IMPLEMENTATION GUIDANCE

The candidate countries might want to explore the possibility for certain time-limited derogations, as granted to the new Member States according to Article 63 of Regulation 1013/2006¹⁷³.

Drawing upon the experience of selected Member States, a number of general observations and suggestions for implementing these Regulations are presented below.

Various guidance documents and studies are available at:

http://ec.europa.eu/environment/waste/shipments/other_documents.htm and
<http://ec.europa.eu/environment/waste/shipments/guidance.htm>

4.1. Planning

- The Regulations refer to the principles of proximity and self-sufficiency and provide powers for Member States to take measures to prohibit or object to shipments of waste for disposal. The policy will need to take this into account. Member States can establish measures to object to shipments of wastes for disposal. However, with regard to shipments of waste for recovery, they are confined to the limited reasons for objection under Regulation 1013/2006 (see Art. 12). Furthermore, the export prohibitions apply directly and leave no margin of discretion to Member States. These provisions shall be read in conjunction with information listed in the annex to Regulation (EC) 1418/2007.
- The policy will also need to take into account cases where quantities of hazardous waste are small and render specialised treatment plants uneconomic. Some Member States do not produce sufficient quantities of hazardous waste that would justify the existence of specialised installations and therefore rely on the facilities of other Member States.
- Designate competent authorities responsible for the implementation of the Regulations, correspondents responsible for informing or advising or making enquiries, and specific customs offices at points of entry into and exit from the EU (Arts. 53, 54 and 55, Regulation 1013/2006).
- Establish the overall procedural framework regarding shipments and covering the requirements for written notification and consent; contracts between the notifier and the consignee; information to the public, competent authorities, parties involved and information necessary for procedural reasons; as well as financial guarantees or equivalent insurance, covering the costs of transport, costs of recovery or disposal and any necessary interim operations and the costs of storage for 90 days (Arts. 4, 5 and 6, Regulation 1013/2006).
- Ensure there are the necessary facilities and appropriate means, such as Internet, to make the information on notifications publicly available (Art. 21, Regulation 1013/2006).

¹⁷³ For more information regarding the transitional arrangements for the new Member States, consult Europa site: <http://ec.europa.eu/environment/waste/shipments/legis.htm>.

- Establish a system for the supervision and control, inspections and spot checks of shipments of waste within the national jurisdiction, consistent with the system established under the Regulation and establish rules on penalties applicable for infringements of the provisions of the Regulation (Art. 50, Regulation (EC) 1013/2006 as amended by Regulation (EU) 660/2014).
- Ensure that any bilateral agreements and arrangements for the import of waste for recovery are concluded in accordance with specified conditions.
- Ensure the appropriate additional measures related to the implementation of the Regulation and adopted by the Commission (such as the calculating method for the financial guarantee; guidelines for application and co-operation; technical and organisational requirements; as well as any further guidance and clarifications) are followed, implemented and passed to the interested parties.

Examples from a Member States

United Kingdom:

In May 2012 DEFRA prepared an amended version of „UK Plan for Shipments of Waste”, which entered into force on 9 August 2007 (which replaced earlier plan of 1996). This Plan sets out Government policy on shipments of waste for disposal to and from the United Kingdom. The Plan applies to any shipment of waste for which notification is required under Regulation (EC) No. 1013/2006 on shipments of waste (the EU Regulation) is subject to this Plan.

The Plan takes into account the UK’s obligations under international, EU and national law, particularly under the UN Basel Convention on the Control of Transboundary Movements of Hazardous Waste and their Disposal (the Basel Convention) and the EU Regulation, which implements the Basel Convention within the EU. The Plan is in line with the requirement of regulation 11 of the Transfrontier Shipments of Waste Regulations 2007 as amended (the TFS SI) which requires the Secretary of State to prepare a waste management plan containing his policies in relation to the shipment of waste for disposal into and out of the UK.

Anyone shipping waste should ensure that they are doing so in compliance with the EU Regulation, the TFS SI and this Plan. All shipments for disposal to and from the UK are subject to the procedure of prior written notification and consent.

Shipments of waste to and from the UK for disposal are prohibited except for:

- emergency situations that may require the shipment of hazardous waste to the UK from any country;
- emergency situations that may require shipment of hazardous waste from the UK to other Member States and EFTA countries;
- trial runs to the UK from any country in order to test a specific specialised treatment technology which results in the disposal of waste, except where the technology to be tested exists in the country of dispatch;
- trial runs from the UK to other Member States or EFTA countries in order to test a specific specialised treatment technology which results in the disposal of waste, except where the technology exists in the UK;
- shipments of hazardous waste between Northern Ireland and the Republic of Ireland, in either direction, for disposal operations specified in this Plan and where the waste is generated and disposed of within Northern Ireland or the Republic of Ireland;
- shipments of hazardous waste, or contaminated river sediments that are classified as non-hazardous waste, produced in such a small quantity overall per year in the UK, another Member State or an EFTA country that the provision of new specialised disposal installations in the country of dispatch would be uneconomic;
- shipments of waste into the UK from a Party to the Basel Convention outside the EU where a UK competent authority has acceded to a duly reasoned request;
- shipments of waste into the UK from a non-Party to the Basel Convention with which the UK Government has concluded a bilateral agreement.

UK competent authorities responsible for the controls on shipments of waste:

- Competent Authority of Transit: Environment Agency (Transfrontier Shipments National Service)
- Competent Authorities of dispatch and destination:
- For England and Wales: Environment Agency (Transfrontier Shipments National Service)
- For Scotland: The Scottish Environment Protection Agency
- For Northern Ireland: The Environment and Heritage Service

Source: <http://www.defra.gov.uk/publications/files/pb13770-waste-shipments.pdf>

4.2. Regulation

- It should not be necessary to change the existing organisation for the supervision of waste imports and exports as required by the Basel Convention. The need is to adapt the procedures to cover an additional range of shipments. Also, for shipments for recovery between Member States, the principle of free circulation prevails, so there are limited possibilities to object to such shipments.
- The essence of the Regulations is to develop a supervision and control system for shipments of waste, normally by means of a notification and consignment note system. This system must record, supervise and control all waste shipments, whether for export or not, and also whether hazardous or non-hazardous.
- Additional requirements are imposed for transboundary shipments in order to give effect to the Basel Convention, which, as with Regulation 1013/2006, includes such matters as the provision of financial guarantees.
- A procedure will need to be developed for the supervision and control of waste shipments within the candidate country. Whilst the procedures may be somewhat simpler, especially regarding notification, some form of consignment note system may be advisable.
- In practical terms, the shipment of waste involves five separate possible scenarios. First, waste may be moved between EU Member States; secondly, it may be exported from the EU; thirdly, it may be imported into the EU; fourthly, it may also pass through the EU from countries outside the EU for disposal or recovery also outside the EU; fifthly, waste may also be moved within individual Member States. Also, an important distinction is made between countries applying the OECD Decision and those not applying it. The competent authorities must set up a system that is capable of identifying which of these cases applies to a particular consignment of waste, and must follow the relevant and applicable requirements.
- The competent authorities and correspondents should be responsible for informing and guiding persons (including other Member States' correspondents) making inquiries; training implementing officers, including customs officers; and disseminating information to ensure that all actors understand their responsibilities. It may also be responsible for reporting. The focal point should ensure that all actors understand their obligations as detailed in the Regulation. This can be achieved through training programmes, through seminars and through inspections of records, premises and shipments.

4.3. Reporting

- A system will be required to collect and process data for reporting. The importance of this should not be underestimated. Refer to reporting under the Basel Convention to which Regulation (EC) 1013/2006 refers and to the questionnaire in Annex IX to the Regulation.

5. COSTS

The implementation costs of administering these Regulations should not be significantly greater than those for implementing the Basel Convention. While on the one hand, the cost of implementation is lowered by simplifying and reducing the number of procedures as compared to the old Regulation, the procedures have now become more specific, leading to an increase in the administrative implementation costs. As Member States are obliged to introduce a system for regular checks throughout the whole shipment and waste recovery/waste disposal process, this will also require some input in terms of administrative costs, as well as the cost of training inspectors. The obligation on the notifier, the consignee, the facilities and the competent authority to keep documents and information contributes to the implementation costs. In addition, the introduction of an electronic system for the paperless transfer of documents is expected to have an appreciable effect in the long-term reduction of costs for the national authorities.

DIRECTIVE ON THE LANDFILL OF WASTE

Official Title: Council Directive on the landfill of waste (99/31/EC) (OJ 182, 16.7.99), as amended by Regulation (EC) No. 1882/2003 and (EC) 1137/2008¹⁷⁴ and Council Directive 2011/97/EU¹⁷⁵ (OJ L 328 10.12.2011)

Council Decision 2003/33/EC of 19 December 2002 establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to the Directive 1999/31/EC

¹⁷⁴ Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny.

¹⁷⁵ Council Directive 2011/97/EU of 5 December 2011 amending Directive 1999/31/EC as regards specific criteria for the storage of metallic mercury considered as waste.

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The main substantive aim of this Directive is to provide for measures, procedures and guidance to prevent or reduce the negative effects on the environment, and the risks to human health, from the landfilling of waste. It requires Member States to take a number of measures to achieve this aim, including treating waste before landfilling it, phasing out co-disposal (the mixing of hazardous waste with non-hazardous waste) and exercising controls over site closure and aftercare. Importantly, the polluter pays principle is given effect in two significant ways: (i) by requiring the operator of the landfill to provide financial security for the lifetime of operations at and in relation to the landfill and (ii) by ensuring that the operator's charges cover full costs in relation to the setting up, running, closure and aftercare of the landfill site.

The main aims of this Directive are to seek to encourage Member States and operators (including the public) to push waste management higher up the waste hierarchy, so reducing the desire or need for final disposal, especially by landfill; and to have greater "true" costs applied in relation to the landfilling of waste, and with greater transparency (so perhaps aiding the achievement of the first policy aim mentioned).

The Directive was amended by:

1. Regulation (EC) No. 1882/2003 and Regulation (EC) No 1137/2008 only concern the internal procedures of the Commission, in which it is assisted by certain committees for amendment of non-essential elements
2. Directive 2011/97/EU introducing specific criteria for the storage of metallic mercury considered as waste referred to in Art. 16 of the Landfill Directive. This Directive should also be seen in the light of Regulation (EC) No 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury (in particular Article 4(3) thereof).

In addition, Council Decision 2003/33/EC establishes criteria and methods for accepting waste at landfills, pursuant to the principles set out in the Landfill Directive and in particular in its Annex II. Member States are obliged to apply the producers set out in Section 1 of the Annex to Decision 2003/33/EC to determine the accessibility of waste at landfills, ensure that the waste accepted fulfils the acceptance criteria set out in Section 2 of the Annex and the sampling and testing methods have to be in compliance with those listed in Section 3 of the Annex. These criteria and procedures, however, do not apply to mining waste.

In December 2015, the Commission adopted a proposal to amend Directive 1999/31/EC on the landfill of waste as a part of the Circular Economy Package. The main element of the proposal to amend the Landfill Directive is to gradually limit the landfilling of municipal waste to 10% by 2030.

More information on the new legislative proposal can be obtained at: <http://ec.europa.eu/environment/circular-economy/>

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Prepare and implement a national strategy for reducing the amount of biodegradable municipal waste going to landfill to meet specified targets (Art. 5).
- Classify landfill sites according to the type of waste to be disposed of at the site (Art. 4).
- Review existing landfill sites and consider new landfill sites anticipated to be required in relation to hazardous and non-hazardous waste disposal by landfill, and plan for anticipated increased need for specific hazardous waste disposal capacity (Arts. 4, 5 and 6).
- Identify landfill sites on islands and in isolated settlements that qualify for exemption from certain provisions of the Directive (Art. 3).
- Provide for the preparation of conditioning plans for existing landfill sites (Art. 8 and 14), their review and the application of new regulatory controls.
- Plan the introduction of procedures and systems to ensure compliance with the procedures, criteria and sampling and testing methods for accepting waste at landfills set out in Annex to Council Decision 2003/33/EC.
- Decide whether to make use of the possibility to derogate from the ban in Art. 5(3)(a) and allow (on the basis of Regulation (EC) No 1102/2008) the temporary storage, not exceeding one year, or for permanent storage in certain types of landfills metallic mercury being contained in appropriate containment. If yes take the necessary preparatory measures for:
 - permitting procedures pursuant to Article 23 of Directive 2008/98/EC on waste and Arts. 7-9 of Landfill Directive where storage is for more than one year;
 - efficient control and monitoring pursuant to Art. 12 of the Landfill Directive and amended Annexes I-III;
 - safety assessment pursuant to Appendix A of Decision 2003/33/EC in case of underground storage;
 - record keeping procedures pursuant to amended Annex III of the Landfill Directive and pursuant to general requirements set out in the Waste Directive;
 - ensure coordination with measures required under SEVESO Directive (2012/18/EU) applying to temporary over-ground storage;
 - as from 15 March 2013, ensure compliance with detailed requirements on storage, monitoring, assessments, reporting as set out in the amended Annex I, II and III taking into account the specific characteristics of metallic mercury (see Annex, Directive 2011/97/EU);
 - take into account latest research on safe disposal options, including the solidification of metallic mercury and if need be carry out additional assessments of the long-term behaviour of metallic mercury in underground storage.

2.2. Regulation

- Ensure that landfill sites are located, constructed and operated in accordance with specified standards (Arts. 8, 14 and Annex I).
- Ensure that certain types of waste are not accepted at landfill sites, and that waste is accepted only in accordance with specified criteria and procedures, which include inspection and documentation procedures (Arts. 5, 6, 11 and Annex II). For this purpose, Council Decision 2003/33/EC lays down the procedures for accepting waste at landfills, the acceptance criteria for different types of landfills and the sampling/testing methods to be used.
- Prohibit the dilution of waste simply to satisfy waste acceptance criteria (Art 5).
- Ensure that applications for landfill permits contain specified minimum information (Art. 7).
- Ensure that landfill permits are not issued unless specified conditions are met. Conditions should include requirements that:
 - landfills are managed by technically competent persons;
 - adequate financial security is provided for the management and aftercare of the site;
 - the landfill project is compatible with relevant national waste management plans,
 - developed to implement the requirements of the Waste Directive. (Arts. 8 and 9)
- Require operators of existing landfill sites to prepare conditional plans for the sites.
- On the basis of the conditioning plans submitted, decide whether existing landfill sites may continue to operate, and close down sites that have not been granted a permit to continue to operate (Art. 14).
- In the case of sites permitted to remain open, provide for them to meet the requirements of the Directive as soon as possible but not later than the stipulated deadline (Art. 14).
- Ensure that permits contain at least the information specified in the Directive.
- Ensure that the minimum price charged by landfill operators for the disposal of waste in landfills covers all the costs involved in setting up and operating the site, including, as far as possible, the costs of providing financial security, and the estimated costs of closure and aftercare (Art. 10).
- Require operators of landfill sites to notify the competent authority of any waste that was not accepted for disposal at the site (Art. 11).
- Ensure that landfill sites are only closed in accordance with the specified closure procedure, which includes inspection and control by the competent authority (Art. 13).
- Ensure that the storage of metallic mercury, which is considered as waste, for up to 1 year is subject to the permit requirements according to Article 23 of Directive 2008/98/EC on waste.
- Ensure that the requirements, set out in amended Annex I regarding temporary storage of metallic mercury for more than one year, are fully complied with as from 15 March 2013:
 - metallic mercury is stored separately from other waste;

- containers are stored in collecting basins suitably coated so as to be free of cracks and gaps and impervious to metallic mercury with a containment volume adequate for the quantity of mercury stored and in a way to make containers easily retrievable;
- the storage site has engineered or natural barriers to effectively to protect the environment against mercury emissions and be of a containment volume adequate for the total quantity of mercury stored.;
- the storage site floors are covered with mercury-resistant sealants and have a slope with a collection sump;
- the storage site shall be equipped with a fire protection system. (Directive 2011/97/EU)
- Ensure that waste in landfills is only accepted if it complies with the Annex to Council Decision 2003/33/EC:
 - complies with the producers set out in Section 1 of the Annex to Decision 2003/33/EC to determine the acceptability of waste at landfills,
 - complies with Section 2 of the Annex regarding the acceptance criteria of the relevant landfill class;
 - complies with sampling and testing methods listed in Section 3 of the Annex.
- Ensure that the requirements, set out in amended Annex II regarding temporary storage of metallic mercury for more than one year, are fully complied with as from 15 March 2013:
 - ensure that containers are only accepted if they have a certificate in accordance with Section D of Annex II also complying with the acceptance procedures in Section C of Annex II;
 - ensure that the composition of mercury is in accordance with Section A of Annex II;
 - ensure that the mercury is being contained in accordance with Section B of Annex II, e.g. that storage containers are corrosion and shock resistant and comply with specifications:
 - container material: carbon steel (ASTM A36 minimum) or stainless steel (AISI 304, 316L);
 - containers shall be gas and liquid tight;
 - the outer side of the container shall be resistant against the storage conditions;
 - the design type of the container shall successfully pass the drop test and the leakproofness tests as described in Chapters 6.1.5.3 and 6.1.5.4 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria;
 - the maximum filling ratio of the container shall be 80 % by volume;
 - ensure conformity with the acceptance procedures set out in Section C of Annex II.

2.3. Monitoring and Enforcement

- Establish systems for monitoring the amount of municipal waste going to landfill sites and the proportion of that waste which is biodegradable (Art. 5).
- Carry out inspections of:

- new landfill sites prior to the commencement of disposal operations to ensure compliance with permit conditions (Art. 8);
 - exempted landfill sites on islands and in isolated settlements to ensure acceptance of only local non-hazardous waste (Art. 11);
 - existing landfill sites to ensure compliance with relevant provisions of the Directive, and thereafter compliance with conditions for ongoing operations in accordance with the landfill permit.
- Require holders of landfill permits to report at least annually on the types and quantities of waste disposed of and the results of monitoring programmes (Art. 9).
 - Require a register to be kept on the quantities and characteristics of waste deposited at landfill sites including exempted sites (Art. 11).
 - Ensure that minimum control and monitoring procedures are followed during the operational phase of landfill sites, that the results of monitoring are reported to the competent authority, and that corrective measures are taken if required by the competent authority (Art. 12 and Annex III).
 - Ensure that after closure of a landfill site (in accordance with the specified procedures) the operator remains responsible for the maintenance, monitoring and control of the site for as long as is required by the competent authority (Art. 13 and Annex III).
 - Ensure that the analysis of the results of control and monitoring procedures is subject to quality control by competent laboratories (Art. 12).
 - Ensure that waste in landfills is only accepted if it complies with the Annex to Council Decision 2003/33/EC and Section 3 of the Annex regarding the sampling and testing methods.
 - All landfilling facilities for the temporary storage of metallic mercury for more than 1 year are subject to the control and monitoring requirements laid down in Article 12 of the Waste Directive (2008/98/EC) and the following requirements set out in amended Annex III to the Landfill Directive:
 - a continuous mercury vapour monitoring system with a sensitivity of at least 0,02 mg mercury/m³ shall be installed in the storage site. Sensors shall be positioned at ground level and head level. This shall include a visual and acoustic alert system. The system shall be maintained annually;
 - the storage site and containers shall be visually inspected by an authorised person at least once a month;
 - where leaks are detected, the operator shall immediately take all necessary action to avoid any emission of mercury to the environment and restore the safety of the storage of the mercury;
 - emergency plans and adequate protective equipment suitable for handling metallic mercury shall be available on site;
 - for storage of metallic mercury exceeding one year, ensure that all documents containing the information referred to in Section 6 of Annex II, including the certificate accompanying the container, as well as records concerning the destocking and dispatch of the metallic mercury after its temporary storage and the destination and intended treatment shall be kept for at least 3 years after the termination of the storage of metallic mercury. (Directive 2011/97/EU)

2.4. Communication and Reporting

A number of other legislative instruments are relevant to the Waste Landfill Directive and must also be borne in mind during the implementation of this Directive. These include:

- Waste Directive (2008/98/EC) (especially in regard to permitting and monitoring requirements)
- Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury
- Packaging Waste Directive (94/62/EC)
- Batteries Directive (2006/66/EC)
- End-of-Life Vehicles Directive (2000/53/EC, as amended)
- Waste Electronic and Electrical Equipment Directive (2012/19/EU)
- RoHS Directive (2011/65/EU)
- Industrial Emissions Directive (2010/75/EU)
- Environmental Impact Assessment Directive (2011/92/EU)
- SEA Directive (2001/42/EC)
- Environmental Liability Directive (2004/35/EC)
- Environmental Crimes Directive (2008/99/EC)
- Water Framework Directive (2000/60/EC)
- Regulation on the Shipment of Waste (EC) No. 1013/2006
- Commission Regulation (EC) No. 1418/2007 of 29 November 2007 concerning the export and recovery of certain waste listed in Annex III or IIIA to Regulation (EC) No. 1013/2006 to certain countries to which the OECD Decision on the control of transboundary movements of waste does not apply
- Mining Waste Directive (2006/21/EC)
- Access to Environmental Information Directive (2003/4/EC)
- Public Participation Directive (2003/35/EC)
- SEVESO III Directive (2012/18/EU) (the provisions of the Directive on the control of major-accident hazards involving dangerous substances apply to facilities for the temporary above-ground storage according to Article 3(2) of Regulation (EC) No 1102/2008)
- Council Decision 2003/33/EC establishing criteria and procedures for accepting waste at landfills
- Commission Decision 2000/738/EC of 17 November 2000 concerning a questionnaire for Member States reports on the implementation of Directive 1999/31/EC on the landfill of waste
- Regulation establishing a European Pollutant Release and Transfer Register (EC) No 166/2006

3. IMPLEMENTATION

3.1. Key Tasks

This Directive places substantial restrictions on the way in which landfills may be used for the disposal of waste, including technical conditions for their design and operation as well as monitoring and closure, and restrictions on the types of wastes that may be landfilled. The administrative systems for achieving this will be established through the institutions that are required to be set up under the Waste Framework Directive (2008/98/EC).

The key tasks involved in implementing this Directive are summarised in the following checklist, organised in chronological order (where possible) within each subheading.

Table 25. Checklist with key implementation tasks

THE LANDFILL DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Administration, Planning and Provision of Infrastructure
1.1	Designate a competent authority responsible for control of the disposal of waste to landfill sites. The authority should have responsibility for authorising landfills, implementing control and monitoring procedures, deciding when landfills should be closed, and overseeing the monitoring and aftercare of closed landfills.
1.2	Produce a national strategy for the reduction of biodegradable waste going to landfill, to take into account the end of co-disposal and the possible early closure of existing landfill sites, and incorporate the requisite strategies into the national waste management plan.
1.3	Update the national waste management plan to incorporate the requirements of the Directive and to provide for its consequences.
1.4	Establish procedures to identify and classify landfills to which the Directive would apply. As a result of this procedure, determine which landfill sites are to be exempted from permitting requirements and which are to be classified as sites for hazardous waste, for non-hazardous waste, and for inert waste.
1.5	Ensure the timely provision of the necessary facilities identified in the national strategy.
1.6	Put into place the measures and systems to ensure compliance with the acceptability procedures and criteria laid down in Annex II to the Landfill Directive and in Decision 2003/33/EC and also ensure that the staff are sufficiently trained to apply these procedures and methods.
1.7	Decide whether to make use of the possibility to derogate from the ban in Art. 5(3)(a) and allow (on the basis of Regulation (EC) No 1102/2008) the temporary storage, not exceeding one year, or for permanent storage in certain types of landfills metallic mercury being contained in appropriate containment. If yes take the necessary preparatory measures for: <ul style="list-style-type: none"> • Permitting procedures pursuant to Article 23 of Directive 2008/98/EC on waste and Arts. 7-9 of Landfill Directive where storage is for more than one year • Efficient control and monitoring pursuant to Art. 12 of the Landfill Directive • Safety assessment pursuant to Appendix A of Decision 2003/33/EC in case of underground storage • Record keeping procedures pursuant to the Waste Directive • Ensure coordination with measures required under SEVESO III Directive applying to temporary over-ground storage • As from 15 March 2013, ensure compliance with amended Annex I, II and III taking into account the specific characteristics of metallic mercury (see Annex, Directive 2011/97/EU) • Take into account latest research on safe disposal options, including the solidification of

	metallic mercury and if need be carry out additional assessments of the long-term behaviour of metallic mercury in underground storage.
2	Regulation
2.1	Ensure that the competent authorities with responsibility for permitting waste management facilities under the Waste Directive have the necessary technical expertise to implement the technical requirements of this Directive, and therefore ensure that permits are granted only to those sites and to those operators demonstrably able to comply with the requirements of the Directive.
2.2	Establish a permitting system that sets out conditions of permits and the content of permits for landfill sites. Applicants should be required to provide adequate information for setting permit conditions.
2.3	Establish a monitoring, inspection and enforcement system to ensure that: <ul style="list-style-type: none"> • all landfills that cannot comply with permitting requirements are closed; • appropriate procedures for the acceptance of waste are applied.
2.4	Establish closure and aftercare rules and procedures which should cover, inter alia, conditions under which a landfill operator may start closure operations, setting out who is responsible for the maintenance, monitoring and control of the landfill after closure, and the period of time for which the operator is responsible for monitoring the landfill site after closure.
2.5	Ensure that inspectors are adequately trained in the technical aspects of landfill design and management.
2.6	Ensure that the storage of metallic mercury, which is considered as waste, for up to 1 year is subject to the permit requirements according to Article 23 of Directive 2008/98/EC on waste.
2.7	Ensure that waste in landfills is only accepted if it complies with the Annex to Council Decision 2003/33/EC: <ul style="list-style-type: none"> • complies with the producers set out in Section 1 of the Annex to Decision 2003/33/EC to determine the accessibility of waste at landfills, • complies with Section 2 of the Annex regarding the acceptance criteria; • complies with sampling and testing methods listed in Section 3 of the Annex
2.8	Ensure that the requirements, set out in amended Annex I regarding temporary storage of metallic mercury for more than one year, are fully complied with as from 15 March 2013 regarding ensuring separate storage of metallic mercury, compliance with technical requirements on the engineering of the storage site, the storage technique, the containers and storage site floors including equipping the site with a fire protection system.
2.9	Ensure that the requirements, set out in amended Annex II regarding temporary storage of metallic mercury for more than one year, are fully complied with as from 15 March 2013, which comprise a valid certificate, compliance with acceptance procedures, ensuring meeting the criteria for composition of mercury and requirements on the storage containers and the type approvals (e.g. (ASTM A36 minimum) or stainless steel (AISI 304, 316L).
3	Technical Competence
3.1	Establish a system of formal qualifications to demonstrate the technical competence of landfill operators, ensuring their understanding of the acceptance procedures, criteria and sampling and testing methods set out in the Annex to Decision 2003/33/EC and also the specific safety measures needed for temporary storage of metallic mercury.
3.2	Ensure the provision of the necessary training courses for landfill operators ensuring full understanding of all the steps of landfilling including initial assessments, monitoring and sampling during landfilling and measures taken upon closure of a landfill.
3.3	Develop a system of examination and certification of landfill operators.
4	Financial Aspects
4.1	Determine the method by which financial security can be demonstrated, having regard to the financial instruments that are available.
4.2	Issue guidance to waste regulators on how to interpret the financial requirements of landfill permit applications.
4.3	Develop and implement a system to ensure that landfill prices reflect at least the full costs involved

	in establishing and operating landfill sites.
5	Monitoring
5.1	Ensure compliance with the sampling and testing methods set out in Decision 2003/33/EC on acceptability of waste at landfills.
5.2	Ensure that all facilities storing metallic mercury for more than 1 year have to be controlled and monitored pursuant to Article 12 of the Waste Directive (2008/98/EC)
5.3	Ensure that all facilities for the temporary storage of metallic mercury for more than 1 year are subject to the monitoring and record keeping requirements set out in amended Annex III, e.g.: <ul style="list-style-type: none"> • installing a continuous mercury vapour monitoring in the storage site, with a visual and acoustic alert system that has to be maintained annually. • the storage site and containers shall be visually inspected by an authorised person at least once a month and where leaks are detected all steps should be immediately taken to avoid emission of mercury to the environment. • keeping available emergency plans and adequate protective equipment on site. • ensure that all documents containing the information referred to in Section 6 of Annex II, including the certificate accompanying the container, as well as records concerning the destocking and dispatch of the metallic mercury after its temporary storage and the destination and intended treatment are kept for at least 3 years after the termination of the storage. (Directive 2011/97/EU)
6	Reporting
6.1	Establish reporting and data recording systems to ensure that the required data (see below) are collected.
6.2	Make information available to national and EU statistical authorities: <ul style="list-style-type: none"> • data on amounts and types of wastes in landfills; • the proportion that is biodegradable; • particulars of permits.
6.3	Inform the Commission of: <ul style="list-style-type: none"> • the list of exempted islands and isolated settlements; • the reduction strategy to minimise the amount of biodegradable waste in landfills; and • transposition and implementation of the Directive.
6.4	By 15 March 2013 notify the Commission the text of the national provisions transposing the requirements set out in amending Directive 2011/97/EU regarding temporary and long-term storage of metallic mercury.

3.2. Phasing Considerations

The most demanding and time-consuming tasks associated with implementing this Directive are likely to be the following:

- Preparation of the strategy for reducing the amount of biodegradable waste landfilled, including an implementation plan, with timescales and responsibilities clearly allocated.
- The detailed planning, design, permitting, and construction (i) of new or existing landfills, taking into account the prospects that some existing sites may need to be closed early, and new facilities may be required as a result of the end of co-disposal; and (ii) of other facilities to accept wastes no longer permitted to be landfilled.
- The introduction of systems to ensure the technical competence and financial security of landfill operators, and for the charging of at least the full costs of and associated with landfill site operations.

- Specific consideration should also be given to temporary storage of certain toxic materials such as metallic mercury ensuring safe storage in approved containers, appropriate surveillance and monitoring systems

These tasks should therefore be planned to commence during the initial phase of implementation.

4. IMPLEMENTATION GUIDANCE

A number of general observations and suggestions for implementing this Directive are presented below.

4.1. Planning and Provision of Infrastructure

- An institution must be appointed to prepare the national strategy for the reduction of biodegradable waste going to landfill. This is likely to be the institution charged with preparing the national waste management plan. However, the plan would require inputs from municipal authorities with responsibility for providing services for and/or regulating the disposal of biodegradable municipal waste.
- The national strategy for reducing the amount of biodegradable municipal waste going to landfill is fundamental, and its preparation requires an assessment of the costs and practicality of providing the necessary alternative facilities, which may be recycling, incineration or composting plants. Separate collection of municipal waste may also be required, to make recycling or composting practical and economically viable.
- As part of the strategy and plan, candidate countries must decide whether to exempt landfill sites situated on islands or isolated settlements from certain requirements of the Directive. The strategy should contain criteria on which such decisions would be based; and the plan could contain the details of exactly which sites would be exempted. Since these sites would not be controlled through the permitting system, specific rules would need to be put in place for regulating and monitoring these sites.
- Whilst the Directive will lead to a reduction in the amount of waste going to landfill, landfills will continue to be an important part of the waste management infrastructure, especially in countries where incineration with energy recovery is not feasible due to various reasons (infrastructural, economic, community resistance). Hence, existing landfills may need to be upgraded or closed and replaced with new ones. The latter may be necessary by virtue of the quality of construction and/or of the location of the landfill. Requirements include the following:
 - in addition to a geological barrier, provision, where appropriate, must be made for a leachate sealing and collection system in accordance with Annex I of the Directive. Requirements will vary depending on the risk posed by leachate to the environment and groundwater resources.
 - landfill gas must be collected from all sites receiving biodegradable waste. Gas must be flared if it cannot produce energy.
 - measures must be taken to minimise impacts from odour and dust, noise and traffic, birds, vermin and insects, and the formation of fires.
 - measures must be taken to ensure the stability of the mass of waste and associated structures, and to secure the site with fencing.

- Facilities will be required for wastes that may no longer be accepted in landfills, e.g. tyres and healthcare, flammable and liquid wastes.
- Co-disposal will no longer be permitted and special landfills will be required for hazardous wastes.
- The strategy should set out how waste will be treated before landfilling and provide for the necessary facilities. Indications are that simple compaction may be considered as "treatment".
- The national waste management strategy should be revised to take account of the new installations required as a result of the Directive. These would include both landfills and other facilities needed to accept wastes that may no longer be landfilled, such as recycling and composting facilities.
- In order to meet the target for reduction in biodegradable municipal waste on a national basis, there are two options. The first is to require the target reduction figure to be achieved equally by all municipalities. The second is to allocate quotas to each municipality so that the national target is reached. The latter approach is likely to be the least-cost solution, since some municipalities will have greater potential for the provision of alternative facilities than others.
- If a quota system is used, the way in which quotas are allocated will require careful consideration. One approach is to seek proposals from each municipality on their plans to reduce biodegradable municipal waste landfilled and to calculate whether these plans will achieve the targets. If there is a shortfall, a practical approach will be necessary to identify the necessary additional facilities needed and to impose quotas on the municipalities falling short of the national target by taking a least-cost approach.

Example from a Member State: Regulatory Control

United Kingdom: Landfill has been the major disposal method for most non-hazardous and some hazardous wastes. Achieving a reduction in the amount of biodegradable municipal waste landfilled will require a substantial programme for the construction of alternative facilities. A system of landfill permitting with comprehensive technical conditions has been in place for more than 20 years. Since landfill has been the major disposal method, the UK has built up a strong technical base in landfill design and operation. The UK has also relied on the co-disposal of hazardous and non-hazardous wastes and the prohibition of this will also require changes to current procedures.

Germany: This country has introduced legislation to prevent the landfill of biodegradable waste by imposing a limit on total organic carbon (TOC) for three classes of landfill. This stipulation exceeds the requirements of the Directive

4.2. Regulation

- Permitting and inspection of landfills is likely to be carried out by the competent authorities appointed under the Waste Directive (2008/98EC).
- Other EU legislation has an impact on the permitting process for waste management facilities. For example, an environmental impact assessment (EIA) is normally required and most landfills will also be regulated under the IED Directive (2010/75/EU) and covered by certain provisions of the SEVESO III Directive (2012/18/EU). See also, the SEA Directive 2001/42/EC on the assessment of certain plans and programmes. Attention also has to be given the links with legislation on transport of dangerous substances such as Regulation (EC) No 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury
- Locations where landfills may be allowed to be developed must take into account a number of factors, including the distance from residential and recreational areas, the existence of groundwater, coastal water and nature protection zones, geological and hydrogeological conditions, risk of flooding, subsidence, landslides or avalanches and the protection of heritage sites. Member States will need to set their own standards for these factors, in order to determine whether permits should be granted.
- It is important to ensure that the competent authority has the necessary technical expertise to implement the technical conditions of this Directive. This may require additional training and capacity building, especially regarding the supervision and monitoring of storage of toxic substances such as metallic mercury.
- For existing landfills, operators must provide a plan for the long-term care of the site (the conditioning plan) that specifies any corrective measures required to conform with the technical standards of the Directive and that will also require a new permit. The competent authority, in issuing the new permit, should make an evaluation of the effects of the landfill on the environment, as well as taking account of the other factors listed in the Directive.
- A permitting procedure will need to be developed incorporating the requirements of the Directive in relation to:
 - classification of landfills;
 - wastes not acceptable in landfills;
 - information contained in applications;
 - permit conditions;
 - content of the permit;
 - waste acceptance procedures;
 - location;
 - design and construction;
 - operating procedures;
 - control and monitoring procedures;
 - closure and aftercare procedures;

- condition procedures for existing landfills.
- The competent authority should develop detailed standard conditions for new landfill permits based on the technical requirements of the Directive and should ensure that inspectors are adequately trained in the technical aspects of landfill design and management.

4.3. Monitoring

- For each landfill, the monitoring of a range of parameters is required, to ensure that processes within the landfill proceed as desired, that environmental protection systems are functioning as intended, and that permit conditions are fulfilled. The competent authority should ensure that the operator implements an appropriate programme of monitoring, using a competent laboratory for analysis.
- Post-closure (aftercare) monitoring forms an integral part of these requirements.
- The competent authority must inspect the site prior to the commencement of operations to ensure compliance with the conditions of the permit.
- For as long as the competent authority considers that a landfill is likely to cause environmental hazards, the operator will be responsible for monitoring gas emissions, leachate generation and the groundwater regime in the vicinity of the site.

4.4. Technical Competence

- A system of formal qualifications to demonstrate the technical competence of landfill operators must be established and will need to be incorporated into legislation. It would be advisable to extend such a system to cover other aspects of waste management (see the Waste Framework Directive fiche), such as the operation of treatment plants and other waste management facilities.
- It will be necessary to ensure the provision of training courses and mechanisms for the dissemination of information.
- A system of examination and certification for landfill managers and technicians will need to be established.

Commission has prepared non-binding Guidance on landfill gas control (2013) in order to:

- help competent authorities improve methane collection through the enforcement of the Landfill Directive requirements;
- provide clarity on landfill gas control requirements within the context of the technical and regulatory requirements of the Landfill Directive;
- set out the most important criteria in ensuring effective collection, treatment and use of landfill gas.

Examples from a Member State: Requirements relating to Technical Competence

United Kingdom: The Environmental Permitting (England and Wales) Regulations 2010 (the ‘Regulations’) and section 9 of the Government’s core permitting guidance (‘core guidance’) set out requirements for the competence of operators holding environmental permits including waste landfill operators. The EPA has issued a guidance document (Regulatory Guidance Series, No RGN 5, “Operators’ Competence”, March 2011). This guidance sets out key elements of a management system which also cover waste management operators. For instance, operators of relevant waste operations will explain in their management system how they intend to demonstrate technical competence and they must satisfy one of the following:

- compliance with an approved industry scheme (currently there are two);
- holding an appropriate Certificate of Technical Competence (CoTC) – this can be checked on the WAMITAB CoTC database;
- holding registered and validated deemed competence status;
- has previously completed an Environment Agency assessment for non-CoTC activities

Appendix 1 to the Operators manual details requirements for waste competence also stipulating how often the certified staff needs to be at the site.

Along with this guidance on technical competence for landfill (and other waste management facility) the Waste Management Industry Training and Advisory Board issues certificates of technical competence according to a clearly specified curriculum. Legislation has been introduced stipulating the minimum qualifications to be held by operators of various types of waste management facility. Universities and professional bodies, such as an institute of waste management, provide many training courses in the country.

More information:

http://www.environmentagency.gov.uk/static/documents/Business/RGN_5_Operator_Competence.pdf

4.5. Financial Aspects

- The method by which financial security can be demonstrated should be determined, having regard to the financial instruments that are available within the country.
- The competent authority should issue guidance to waste regulators on how to interpret the financial requirements, bearing in mind that they will typically have little financial training.
- A requirement for the provision of financial security to ensure adherence to all waste management permit conditions was introduced into legislation in one Member State (UK) in 1990. Guidance notes have been provided for waste regulators and facility operators on how to interpret the provisions and select the most appropriate security according to the nature of the permit. The security is designed to suit each particular situation and risk, i.e. the possible need for corrective action, the need for restoration and aftercare etc. A combination of insurance, bankers' bonds, financial provisions where funds are placed in accounts reserved for the purpose and other instruments may be used.
- A requirement exists to ensure that prices for landfilling reflect the full costs, including establishing, constructing and operating the site, together with monitoring, closure and aftercare measures for up

to 30 years. This will require a system of accrual accounting. The private sector can be expected to use such a costing approach in order to ensure its financial viability. A problem may exist, however, with the public sector, notably municipalities, many of which use cash accounting techniques that provide neither the amortisation of capital costs nor accruals for future liabilities, such as restoration and aftercare. It will be necessary to ensure that municipalities use such systems for measuring the cost of landfilling.

4.6. Reporting

- The reporting requirements of this Directive are relatively complex, involving, inter alia, the gathering of data on:
 - the proportion of biodegradable municipal waste going to landfill;
 - the origins and producers of waste going to landfill;
 - the location of hazardous waste in landfills;
 - data collected where an environmental impact assessment has been conducted;
 - environmental monitoring data.

This will require the establishment of systems and databases for recording the data and systems to ensure that landfill operators report it.

- Regulation (EC) No. 166/2006 on the European Pollutant Release and Transfer Register imposes certain reporting obligations on operators of landfills (excluding landfills of inert waste or those that were definitely closed by 16 July 2001) receiving at least 10 tonnes per day or having a total capacity of 25,000 tonnes. The reporting requirements concern both the operators and the Member States. Article 5 of the Regulation sets out all the information and the method for measurements that need to be submitted by the operators, including site-related operational, accidental, routine and non-routine activities and off-site transfers of pollutants set out in Annex III. Operators must collect and report information and need to keep available for the competent authorities records of the data for a period of five years. The frequency of reporting is to be determined by the Member State. The Member State, in turn, must submit a report to the European Commission containing all this data 18 months after the end of the first reporting year (2007) and thereafter within 15 months of the end of the reporting year.

5. COSTS

The main types of costs arising during the implementation of this Directive are illustrated, as far as possible, in Table 25 below. Naturally, the relative size of the costs of the individual items will vary from country to country.

The provision of alternative facilities to enable the reduction of the quantities of biodegradable municipal waste being landfilled, together with facilities for wastes that are no longer allowed to be landfilled and the replacement of non-conforming landfills, will constitute the largest elements of the overall costs of achieving compliance.

It should be appreciated that the provision of facilities will incur not only initial capital costs but also recurring annual costs for operation and maintenance together with long-term costs for restoration and aftercare. Another factor that has an impact on costs is that of land. In most Member States, the cost of land for landfills is very high, because of the scarcity of suitable sites that are acceptable in land-use planning terms.

Indicative estimates have been made of the cost of implementing this Directive in Poland¹⁷⁶ in a study prepared on behalf of DG ENV. The total cumulative investments for the collection, recycling and landfill of domestic urban and rural waste and industrial waste amounted to EUR 2,780 million. Additional sundry costs for the approximation of this Directive were also calculated, bringing the total investments needed to comply with the Directive to approximately EUR 3.5 billion. Almost 60% of this investment would be required for the aftercare of existing landfills and those due to be closed. Additional investment needs for controlled landfills are relatively small, since the amount of waste to be landfilled will decrease due to higher recycling rates (as required by this Directive and, for example, by the Packaging and Packaging Waste Directive (94/62/EC)).

Similar investment estimates have been made for the implementation of this Directive in Latvia¹⁷⁷. The total investment required is estimated to be EUR 154 million.

Table 26. Checklist with the types of implementation costs

<p>Initial set-up costs:</p> <ul style="list-style-type: none"> • preparation of a strategy to achieve the objectives of the Directive; • preparing procedures for permitting and inspection; • developing criteria for technical competence and financial security; • issuing new permits for all existing landfills; • preparing technical guidance notes; • developing training courses to establish technical competence.
<p>Capital expenditure:</p> <ul style="list-style-type: none"> • provision of alternative facilities to reduce biodegradable waste being landfilled, including: <ul style="list-style-type: none"> – recycling facilities; – composting plants; – separate collection systems; • provision of facilities for materials no longer permitted to be landfilled, including: <ul style="list-style-type: none"> – tyres; – healthcare wastes; – flammable wastes; – liquid waste; • new landfills.

¹⁷⁶ DISAE Project POL-101. Costing and Financial Analysis of Approximation, Agriconsulting Europe, June 1998 DISAE

¹⁷⁷ Project LAT-103. Development of the Latvian Approximation Strategy and Programme, Halcrow Group

Ongoing costs:

- annual operating costs of new landfills and other facilities;
- training of landfill operators and technicians;
- issuing of permits for landfills;
- inspections of landfills to verify compliance, and taking enforcement action.

THE DIRECTIVE ON END-OF-LIFE VEHICLES (ELVs)

Official Title: Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of-life vehicles (OJ L 269, 21.10.2000), as amended by Directives 2008/33/EC [OJ L 81, 20.3.2008]¹⁷⁸ and 2008/112/EC [OJ L 345, 23.12.2008]¹⁷⁹

Implementing legislation:

Legislation amending or replacing Annex II:

Commission Directive (EU) 2016/774 of 18 May 2016 amending Annex II to Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles (OJ L 128, 19.5.2016)

Commission Directive 2013/28/EU of 17 May 2013 amending Annex II to Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles (OJ L 135, 22.5.2013)

Commission Directive 2011/37/EU of 30 March 2011 amending Annex II to Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles (OJ L 85, 31.3.2011)

Commission Decision 2010/115/EC of 23 February 2010 amending Annex I to Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles [OJ L 48, 25.2.2010]

Commission Decision 2008/689/EC of 1 August 2008 amending Annex II to Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles [OJ L 225, 23.8.2008]

Council Decision 2005/673/EC of 20 September 2005 amending Annex II of Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles [OJ L 254, 30.9.2005]

Commission Decision 2005/438/EC of 10 June 2005 amending Annex II to Directive 2000/53/EC of the European Parliament and of the Council on end-of life vehicles [OJ L 152, 15.6.2005]

Commission Decision 2005/437/EC of 10 June 2005 repealing Decision 2005/63/EC amending Annex II to Directive 2000/53/EC of the European Parliament and of the Council on end-of life vehicles [OJ L 152, 15.6.2005]

Commission Decision 2002/525/EC of 27 June 2002 amending Annex II of Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles [OJ L 170, 29.6.2002]

Legislation on compliance with reuse, recycling and recovery targets – annual data:

¹⁷⁸ Directive 2008/33/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2000/53/EC on end-of-life vehicles, as regards the implementing powers conferred on the Commission

¹⁷⁹ Directive 2008/112/EC of the European Parliament and of the Council of 16 December 2008 amending Council Directives 76/768/EEC, 88/378/EEC, 1999/13/EC and Directives 2000/53/EC, 2002/96/EC and 2004/42/EC of the European Parliament and of the Council in order to adapt them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

Decision 2005/293/EC of 1 April 2005 laying down detailed rules on the monitoring of the re-use/recovery and re-use/recycling targets set out in Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles [OJ L 94 of 13.4.2005]

Component and material coding standards:

Decision 2003/138/EC of 27 February 2003 establishing component and material coding standards for vehicles pursuant to Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles [OJ L 53 of 28.2.2003]

Minimum requirements for Certificates of Destruction:

Decision 2002/151/EC of 19 February 2002 on minimum requirements for the certificate of destruction issued in accordance with Article 5(3) of Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles [OJ L 50 of 21.2.2002]

Reporting:

Decision 2001/753/EC of 17 October 2001, concerning a questionnaire for Member States' reports on the implementation of Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles [OJ L 282 of 26.10.2001]

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The ELV Directive aims to prevent the production of waste from vehicles and to encourage reuse, recycling and recovery from end-of-life vehicles (ELVs) as well as reduce the random disposal of ELVs and used parts. In terms of prevention, the Directive restricts, in the short-term, the use of certain heavy metals. In the longer perspective the aim is to change the way that cars are designed and produced in the first place.

The Directive sets reuse/recovery/recycling targets and requires Member States to ensure that end-of-life vehicles can only be treated by specifically authorised undertakings/treatment centres and that certificates of destruction issued by such undertakings are mutually recognised throughout the EU. This is combined with an obligation on the relevant economic operators to establish collection and treatment systems at no expense to the last owner.

The ELV Directive covers any end-of-life vehicle that constitutes waste within the meaning of the Waste Directive (2008/98/EC), being:

- any end-of-life vehicle designated as a category M1 or N1 vehicle (as defined in Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles);
- two-wheel or three-wheel motor vehicles and their components.

The primary objective of the Directive is waste prevention. To this end, vehicle manufacturers and material and equipment manufacturers have to:

- reduce the use of hazardous substances when designing vehicles and ensure that components of vehicles placed on the market after 1 July 2003 do not contain mercury, hexavalent chromium, cadmium or lead, except in the applications listed in Annex II (see latest amending acts: Directive (EU) 2016/774, 2013/28/EU, Directive 2011/137/EC and implementing Decisions 2002/525/EC, 2005/437/EC, 2005/438/EC, 2005/673/EC, 2008/689/EC and 2010/115/EC);
- design and produce vehicles that facilitate the dismantling, re-use, recovery and recycling of end-of-life vehicles;
- provide dismantling information for each type of car;
- increase the use of recycled materials in vehicle manufacture.

The Directive contains provisions on the collection of all end-of-life vehicles (Art. 5). To this end, Member States have to set up collection systems for end-of-life vehicles, ensure that all vehicles are transferred to authorised treatment facilities, and establish a system for the deregistration of discarded vehicles. The storage and treatment of end-of-life vehicles is also subject to strict control, in accordance with the requirements of the Directive and of Annex I to the Directive.

The aim of this Directive is to increase the rate of re-use and recovery in terms of average weight per vehicle/year to 95% by 2015, and to increase the rate of re-use and recycling over the same period to at least 80% and 85% respectively in terms of average weight per vehicle/year. Less stringent objectives may be set for vehicles produced before 1980. Member States may incorporate some of the directive's provisions into national law by means of agreements with the economic sectors concerned.

The ELV Directive was implemented in two phases: In the first phase, only vehicles registered after 1 July 2002 fell under the extended producer responsibility obligations in the Directive, whereas in the second phase, starting at 1 January 2007, all vehicles a given producer had ever introduced into the market fell under the extended producer responsibility obligations.

The ELV Directive is adopted on the basis of Article 192 of TFEU (former Article 175(1) of EC Treaty). This provision concerns the strengthening of environmental protection exclusively. There are no elements of market integration, save for the interest in establishing uniform operating conditions in order to prevent distortions of competition. This also means that Member States are not excluded from setting or maintaining rules that are stricter than the ones in the Directive, provided that such measures are otherwise compatible with the TFEU. The ELV Directive is a so-called minimum harmonisation Directive. The deadline for transposition was 21 April 2002. The ELV Directive was amended several times. Below is the summary of the relevant amendments.

- Directive 2008/33/EC: introduces the regulatory procedure for certain non-essential requirements of the ELV Directive
- Directive 2008/112/EC: This Directive adapts the ELV Directive to the provisions of Regulation (EC) No 1272/2008. As from 1 December 2010, Art. 2(11) is amended to refer to hazardous substances that fulfils the criteria for any of the following hazard classes or categories set out in Annex I of this Regulation and hazard classes listed in Art. 4 to the Directive.
- Commission Decision 2002/525/EC, Decision 2005/437/EC, Decision 2005/438/EC, Decision 2008/689/EC, Decision 2010/115/EC and Directives 2011/37/EU, 2013/28/EU, (EU) 2016/774: amend Annex II on an earlier exemption to the ban on the use of lead, cadmium or hexavalent chromium in materials in Article 4(2)(a). More information can be obtained at: <http://elv.exemptions.oeko.info/index.php?id=58>. Latest review covers the renewal of three exemptions: Exemption 2(c): 'Aluminum with a lead content up to 0.4 % by weight'; Exemption 3: 'Copper alloy containing up to 4 % lead by weight' and Exemption 5: Lead and lead compounds in 'Batteries'¹⁸⁰.

Several Directives and Decisions have been adopted to detail the implementation and the various measures to be taken. These are being updated continuously to reflect technical and scientific process. These Decisions are:

- Decision 2001/753/EC: concerning a questionnaire for Member States' reports on the implementation of Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles. Member States must complete the questionnaire in the annex to Decision 2001/753/EC concerning the transposition and implementation of the ELV Directive.
- Commission Decision 2002/151/EC: sets minimum requirements for the certificate of destruction issued in accordance with Article 5(3) of Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles. This Decision further implements Articles 5(5) and 11(4) of Directive 2000/53/EC regarding specific requirements applying to the certificate of destruction. The setting out of minimum requirements for the certificate of destruction, which is mandatory for deregistering vehicles, will make it easier for competent authorities to mutually recognise and accept certificates of destruction issued in other Member States. The minimum requirements concern the

¹⁸⁰ For more information on the upcoming events please visit DG ENV website: http://ec.europa.eu/environment/waste/elv/events_en.htm

identity and details of the treatment facility, competent authority and vehicle holder, and important information relating to the vehicle.

- Decision 2003/138/EC: establishing component and material coding standards for vehicles pursuant to Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles. This Decision sets out requirements for the use and labelling of component and material coding standards to facilitate the identification of components and materials that are suitable for reuse and recovery. This Decision entered into force on 1 July 2003 and mainly applies to producers and manufacturers of material and equipment.
- Commission Decision 2005/293/EC: laying down detailed rules on the monitoring of the reuse/recovery and re-use/recycling targets set out in Directive 2000/53/EC on end-of-life vehicles. This Decision implements, in particular, Article 7(2) of Directive 2000/53/EC setting out recycling/reuse targets for ELVs to ensure that the Member States can demonstrate that these targets are being met. Decision 2005/293/EC facilitates and harmonises the calculation of the targets so as to make the data comparable between the Member States. It aims both at guaranteeing reliable data and at facilitating the task of assessing the reaching of the targets. For instance, although it obliges Member States to base the denominator for the calculation of the targets on the number of ELVs entering the treatment system of a particular Member State, it allows the use of a metal content assumption for the determination of the amount of metals recoverable from ELVs. It also calls for the use of standardised available vehicle data for the determination of the individual vehicle weight and for calculating the fuel removed during dismantling based on an EU average amount. It also clarifies that recycling and recovery rates from exported vehicle parts are credited to the exporting Member State and not to the Member States of destination. The Decision also imposes reporting requirements regarding the quantity of materials from de-pollution and dismantling, the shredding of ELVs, as well as the monitoring of ELVs arising in a Member State and exported for further treatment.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Encourage vehicle manufacturers to make vehicles more suitable for recycling, to increase the use of recycled material and to make the dismantling of vehicles easy (Art. 4, Directive 2000/53/EC).
- Ensure the existence of an adequate amount of facilities for the collection and treatment of ELVs (Art. 5, Directive 2000/53/EC).
- Ensure that certificates of destruction issued in other Member States are recognised (Art. 5, Directive 2000/53/EC). For this purpose, Commission Decision 2002/151/EC lays down the minimum requirements for the content of such a certificate.
- Introduce a permit system for undertakings treating ELVs and encourage the introduction of certified environmental management systems in such undertakings (Art. 6, Directive 2000/53/EC).
- Ensure that the degree of reuse/recycling/recovery of ELVs reaches a minimum of 85% of reuse/recovery and a minimum of 80% reuse/recycling in terms of average weight by 1 January 2006 and a minimum of 95% of reuse/recovery and a minimum of 85% reuse/recycling in terms of average weight per vehicle/year to be attained by 2015 (Art. 7, Directive 2000/53/EC).
- Ensure that the monitoring and reporting of the quantity of ELVs de-polluted, dismantled, shredded, treated and exported for further treatment is adequately planned and carried out in accordance with Articles 1 to 3 and the annex to Decision 2005/293/EC.
- Ensure that the calculation of the reuse/recovery and reuse/recycling targets referred to in Article 7(2) of Directive 2000/53 is based on reused, recycled and recovered materials from de-pollution, dismantling and post-shredding operations. It is important that the actually achieved recovery is taken into account and in accordance with the annex to Decision 2005/293/EC (Art. 1 of the same Decision).
- Ensure that there is a reliable system/procedure in place to track and collect sufficient evidence about the quantity and quality of the recycling and recovery of ELV materials or parts thereof that were exported to other Member States or third countries for further treatment. The importing countries should be requested to submit reliable information about the actual recycling and recovery that took place there (Art. 2, Decision 2005/293/EC).
- Ensure that the certificate of destruction issued by the competent authority in the Member State is in accordance with the requirements set out in Decision 2002/151/EC and that certificates of destruction issued by other Member States are fully recognised and accepted.

2.2. Regulation

- Prohibit the marketing of vehicles in which there are certain heavy metal components (Art. 4, Directive 2000/53/EC). Heavy metals should only be used in components or for processes listed in Annex II to the ELV Directive as last amended by Directive (EU) 2016/744. In this regard, Member States and vehicle manufacturers must ensure compliance with the restrictions or the regulation of some of these applications with several applications already phased out, e.g.
 - ban the use of lead as an alloying element in aluminium for machining purposes with a lead content of up to 0.4% by weight and lead-bearing shells and bushes;
 - ban the use of lead and lead components in vulcanising agents and stabilisers for elastomers in fluid-handling and power-train applications, copper in the friction materials of brake linings containing more than 0.4% lead by weight, and valve seats (for engines developed before 1 July 2003);
 - ban the use of hexavalent chromium in corrosion preventive coatings and corrosion preventive coatings related to bolt and nut assemblies for chassis applications;
 - ban the marketing of thick film pastes containing cadmium;
 - ban the use of cadmium in batteries for electrical vehicles, except as replacement parts for vehicles put on the market before this date.
- Ensure labelling, according to Article 4(2)(b)(iv) of Directive 2000/53/EC, of the following components containing heavy metals that are still provisionally allowed (see amending Directive 2013/28/EU):
- Ensure that spare parts for the repair of vehicles put on the market later than 1 July 2003 do not contain components of lead, mercury, cadmium and hexavalent chromium. However, exemptions are allowed for spare parts using lead, mercury or hexavalent chromium in spare parts for the repair of vehicles already put on the market before 1 July 2003 (Art. 4, Directive 2000/53/EC and Annex II, as last amended by Directive 2013/28/EU).
- Require that car producers/distributors set up systems for the collection and treatment of ELVs (Art. 5, Directive 2000/53/EC).
- Ensure that the last owner of an ELV can only have it deregistered upon presentation of a certificate of destruction and that such certificates can only be issued if the ELV has been transferred to an authorised collection/treatment facility (Art. 5, Directive 2000/53/EC).
- Ensure that the certificate of destruction contains at least the information set out in the annex to Decision 2002/151/EC:
 - the name, address, signature and registration or ID number of the establishment issuing the certificate;
 - the name and address of the competent authority that issued the permit for the establishment issuing the certificate of destruction;
 - the date of issue of the certificate of destruction;
 - vehicle nationality mark and registration number;
 - class of vehicle, brand and model;

- vehicle identification number;
- name, address, nationality and signature of the holder or owner of the vehicle delivered.
- Ensure that the delivery of ELVs to such facilities does not entail any cost for the last owner (Art. 5) (Art. 12, Directive 2000/53/EC).
- Ensure that the general requirements of the Waste Framework Directive (2008/98/EC) are observed as regards the storage and treatment of ELVs (Art. 6 and Annex I, Directive 2000/53/EC).
- Make certain that undertakings carrying out the treatment of ELVs obtain permits in accordance with Directive 2008/98/EC (Art. 6, Directive 2000/53/EC).
- Ensure that such undertakings use certain procedures in order to reduce environmental impact and improve possibilities for reuse, recycling and recovery (Art. 6, Directive 2000/53/EC).
- Require that producers of cars and spare parts provide dismantling information about components and materials as well as the location of hazardous substances in order to facilitate the treatment of ELVs. In this connection, the Commission has in its Decision 2003/138/EC issued component and material coding standards (Art.8, Directive 2000/53/EC).
- In the case of ELVs, or materials or parts thereof for which a certificate of destruction has been issued by a national authorised treatment facility and which have been exported to other Member States or third countries for further treatment, any recycling or recovery taking place in the importing country can only be attributed to the exporting Member State and included in the calculation of the recycling/recovery targets if there is sound evidence that such recycling/recovery took place under conditions equivalent to the requirements prescribed under EU law (Art. 2(1), Decision 2005/293/EC).
- Where ELVs, materials or parts thereof are imported into a Member State for recovery and/or recycling and the Member State or a third country exporting it has also issued a certificate of destruction, it is not possible to count this as recycled or recovered in the importing Member State (Art. 2, Decision 2005/293/EC).
- Ensure that, in terms of exports to third countries, sufficient evidence is provided by those countries that the exported materials are actually recycled or recovered. It may be necessary to request specific documentation from the importing third countries (Art. 2(2), Decision 2005/293/EC).
- Ensure that the component and material coding standards (i.e. the nomenclature of ISO standards) set out in the annex to Decision 2003/138/EC are used by producers and material and equipment manufacturers for the labelling and identification of those components and materials suitable for reuse and recovery (Art. 1, Decision 2003/138/EC).
- Ensure compliance with amended Article 2(11) in regard to provisions of Regulation (EC) No 1272/2008 regarding hazardous substances that fulfil the criteria for any of the following hazard classes or categories set out in Annex I of this Regulation and hazard classes listed in Art. 4 to amending Directive 2008/112/EC.

2.3. Reporting and Information

- Report at three-year intervals to the Commission on the implementation of the Directive using the questionnaire format laid down in Decision 2001/753/EC (Art. 9, Directive 2000/53/EC)¹⁸¹.
- Ensure that car producers and distributors etc. provide information on various aspects of the recovery and recyclability qualities of their cars and that such information is included in marketing material etc. (Art. 9, Directive 2000/53/EC).
- Complete Tables 1 to 4 in the annex to Decision 2005/293/EC along with a description of the data used for the calculation of the reuse/recovery and reuse/recycling targets. In filling out these tables, Member States are allowed to use an assumption concerning the average percentage of reused, recycled and recovered materials from ELVs (metal content assumption), supported by detailed data for the assumed percentage of metal content, metal reuse, recovery and recycling. This data must be valid for at least 95% of the ELVs originating from the Member State in question. The Member State must present the data according to the breakdown referred to in Article 1(3) of Decision 2005/293/EC. (Art. 1 of the same Decision). These tables need to be:
 - completed on an annual basis;
 - sent to the Commission within 18 months of the end of the relevant year (Art. 3(1), Decision 2005/293/EC);

2.4. Additional Legal Instruments

- Directive 2005/64/EC (as amended by Commission Directive 2009/1/EC) as it lays down minimum thresholds for the re-use, recycling and recovery of the component parts and materials of new vehicles with the aim of facilitating the re-use, recycling and recovery of parts in order to meet the 2015 objectives for the recycling and recovering of end-of-life vehicles. It provides for a preliminary assessment of manufacturers before Member States grant EC type-approval or national type-approval. Vehicles that do not comply with the requirements of this Directive may not be granted EC type-approval or national type-approval. From 15 July 2010, the marketing of new vehicles that do not comply with the requirements of this Directive are prohibited (for more details see separate fiche below).
- Directive 2007/46/EC establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles
- Directive 2008/98/EC on waste
- Landfill Directive (1999/31/EC)

¹⁸¹ The Commission has proposed to abolish the obligation for the MS to submit a tri-annual report on the implementation of the ELV, Packaging, WEEE, WFD, Batteries and Landfill Directives in the waste review, part of the Circular Economy Package, currently in discussion with the Council and the E.P.

- WEEE Directive (2012/19/EU)
- RoHS Directive (2011/65/EU)
- Batteries Directive (2006/66/EC)
- Regulation (EC) No 1013/2006 on shipments of waste
- Commission Regulation (EC) No. 1418/2007 concerning the export and recovery of certain waste listed in Annex III or IIIA to Regulation (EC) No. 1013/2006 to certain countries to which the OECD Decision on the control of transboundary movements of waste does not apply
- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
- REACH Regulation (1907/2006)
- POPs Regulation (EC) 850/2004
- Regulation (EC) No 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury
- Regulation (EC) No 1221/2009 on the Community eco-management and audit scheme (EMAS)
- Industrial Emissions Directive (2010/75/EU)
- Regulation (EC) No. 166/2006 on the European Pollutant Release and Transfer Register
- Environmental Crimes Directive (2008/99/EC)

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised below, organised in chronological order (where possible) within each subheading.

Table 27. Checklist with key implementation tasks

THE END-OF-LIFE VEHICLE DIRECTIVE-KEY IMPLEMENTATION TASKS	
1	Institutional Organisation
1.1	Appoint competent authority/authorities responsible for implementation, notably the issuing of permits to the relevant undertakings (mainly dismantlers, motor salvagers, shredders and scrap yards) and for the monitoring of these undertakings as well as the supervision of the system for certificates of destruction (CoD) and for taking enforcement actions in case of non-compliance. The authorities in question can be existing bodies already in charge of environmental issues, which actually can provide several advantages in terms of cost-efficiency, transparency, a more holistic organisation. To ensure the proper follow-up of de-registered vehicles for which a CoD has been issued and in order to reduce the number of "ELVs of unknown whereabouts", a close cooperation with the registration authorities is important. The competent authorities should also ensure coordination and consistency with implementation of relevant legislation (e.g. Waste Directive, Waste Shipment Regulation, Industrial Emissions Directive, WEEE and RoHS Directives, Batteries Directive, Landfill Directive and chemical legislation). The use of the Waste Shipment Correspondents Guidelines on waste vehicles No 9 agreed in July 2011 by the Waste Shipment Correspondents and in use as from 1 September 2011 is important.
2	Planning and implementation of plans
2.1	Establish an overview of existing problems and resources, i.e. the amount of end-of-life vehicles and used spare parts being sporadically disposed of, the amount of existing treatment undertakings, such as dismantlers, shredders, motor salvagers etc.existing authorisation schemes applicable, as well as producers/distributors of vehicles and their respective market shares.
2.2	Adjust existing waste planning on central and regional/local level.
2.3	Develop a short- and long-term strategy for the financing of costs in connection with the take-back and treatment of ELVs.
2.4	Initiate public campaigns to introduce the ELV system to the general public.
2.5	Establish a format for the certificate of destruction, and procedures for the issuing of such certificates as well as the integration of the certificate system with existing car registers.
2.6	Establish structured contacts with other Member States to ensure the smooth running of the arrangements for the mutual recognition of certificates.
2.7	Co-operate with other Member States on developing a common understanding of calculation and measures to ensure that the reuse/recycling and reuse/recovery targets for 2015 are being met.
2.8	Establish a system for reporting between undertakings handling ELVs and the relevant authorities, including a uniform method for calculating reuse/recycling/recovery percentages for each ELV, which is currently being developed by the European Commission.
3	Regulation
3.1	Determine the extent to which transposition of the Directive should take place by means of agreements with the relevant enterprises and organisations for those articles as allowed in Article 10 of the Directive.
3.2	Determine who should carry the direct responsibility for <ul style="list-style-type: none"> • establishing collection systems; • ensuring treatment facilities corresponding to the technical requirements of the Directive;

	<ul style="list-style-type: none"> making sure that the targets for reuse/recycling and reuse/recovery are being met.
3.3	Prohibit the charging of last owners as from 1 July 2002 and after 2007 for vehicles put on the market before 1 July 2002 or introduce other measures to ensure that vehicle producers bear the costs connected with the take-back, collection and treatment of ELVs.
3.4	Establish a system for the authorisation and control of collection/treatment undertakings. This includes, notably, requirements as regards both collection/treatment sites and operational and procedural aspects.
4	Reporting and monitoring
4.1	Procedures, formats and addressees for the information on the reuse/recovery/recycling properties of their cars that manufacturers/distributors are obliged to produce. This includes requirements concerning marketing material for consumers.

3.2. Phasing Considerations

The Directive allows Member States quite a degree of discretion as to how national regulation should look — or whether there should be any national regulation at all to the extent that agreements permitted by the Directive with interested parties will suffice. At any rate it is important to ensure sufficient procedures for supervision, enforcement and data collection and reporting. One of the main challenges would be combating illegal treatment facilities and illegal shipments of ELVs. Thus, it is particularly important to devote sufficient time to examining existing structures for the treatment of ELVs that involve different types and sizes of enterprises, and to have in-depth consultations with the various stakeholders.

Otherwise, the major tasks will be the setting up of systems for issuing permits for treatment and certificates of destruction. It will also be a substantial task to develop a structure for bringing together the reporting on reuse/recycling/recovery to present national progress towards the targets established in the Directive.

However, the main challenges remain with the undertakings, car producers and distributors, as well as existing undertakings dealing with the collection and treatment of ELVs. They will have to take major measures to ensure compliance also entailing capital investments and efforts relating to product design and choice of materials. For this reason, as well, it is important to allow sufficient time for consultations.

4. IMPLEMENTATION GUIDANCE

The Commission services have developed a Guidance Document, which aims at facilitating the implementation of the ELV Directive and the secondary legislation at national level. The document provide guidance in interpretation of the Directive's key concepts and may be obtained at: http://ec.europa.eu/environment/waste/pdf/guidance_doc.pdf

Furthermore, a Guidance Document, which aims at facilitating the annual reporting on targets has been developed and available at: <http://ec.europa.eu/eurostat/web/waste/reporting/2015>.

Drawing on the experience of some Member States, a number of general observations and suggestions for implementing the Directive are presented below.

- The Directive allows several possibilities for assigning responsibility for collecting and treating ELVs and for meeting the overall reuse/recycling and reuse/recovery targets. In UK, for example, several options were considered, the most simple being that car producers/importers are responsible for their respective models. This may result in a corresponding fragmentation of collection and treatment facilities, where some collectors accept certain brands of cars and not others. An alternative option — which would be most convenient for the last owner — would be a system in which a car can be handed in anywhere and where the car producers/importers share costs according to, for example, their respective market share.

Examples from Member States

Sweden: Sweden was the first country in Europe to introduce producer responsibility for cars, which was introduced in 1998. Since 1 June 2007, the producer responsibility is laid down in Ordinance (SFS 2007:185). There are also a number of other laws that are directly or indirectly linked to producer responsibility, including:

- Regulations by the Road Authority (Vägverket)
- Environmental Code, Chapter 29 Ordinance 2007:185 (<http://www.notisum.se/rnp/sls/lag/20070185.htm>)
- Ordinance 1998:950, which contains provisions on sanctions, including the Environmental Sanction Fee (an administrative charge to confiscate the potential advantages of not complying with reporting obligations etc.) (<http://www.notisum.se/rnp/sls/lag/19980950.htm>)
- Handbook (2001:8) with general guidance, although this does not contain the provisions
- of Ordinance 2007:186 on car scrapping (<http://www.naturvardsverket.se/Documents/publikationer/620-6263-8.pdf>)
- Ordinance 1998:900 on supervision according to the Environmental Code (<http://www.notisum.se/rnp/sls/lag/19980900.htm>)

In Sweden, car owners can hand in their car to one of the collection points of the car producers, which are normally linked to the network of car producers. This handover is free of charge unless the car lacks significant parts (e.g. motor, gear box or emission control device) or contains other waste fractions. It is also possible to hand over the car to an accredited car recycler, although such recyclers sometimes charge for this disposal. The Road Authority has published detailed instructions on how to de-register and scrap cars.

Source: Handbook with general guidance to the EPA regarding regulations on car scrapping (Bilskrotning: Handbok med allmänna råd till Naturvårdsverket föreskrifter om bilskrotning), December 2001

- Among the responsibilities of car producers facilitating the environmentally sound disposal of cars are:
 - To facilitate the collection of discarded cars and refer the car owner to suitable collection points;
 - To ensure that collected cars are handled and treated by an accredited car scrapper/recycler;
 - To accept not only cars but also buses and lorries that do not exceed 3,500 kg.
- The nature of the collection system will also depend on who will be entitled to issue certificates of destruction. A system where such certificates can be issued by facilities other than the treatment undertakings would be flexible and can work provided that there is ample guarantee that the ELVs in question actually end up in an appropriate treatment facility.
- With respect to permits for treatment undertakings, it is appropriate to co-ordinate this system with the other permit schemes required under the IED or the Waste Directive. The reason is that ELVs that have not had pollutants removed are categorised as hazardous waste in Commission Decision 2000/532/EC, and many, but not necessarily all, treatment undertakings would require a waste permit according to the Waste Directive.
- Introducing incentive policies, such as premiums for bringing back the ELV have proven effective in increasing collection rates of ELVs in several countries (Germany, Finland, Netherlands, Italy). High landfill taxes may result in higher amount of collected ELVs to get recycled instead of landfilled.
- Frequent inspections of treatment facilities also ensure legality of the facilities. Inspections also of the shipments of waste vehicle following the Waste Shipment Correspondents' Guidelines No 9 ensure legality of shipments.

Various studies on the implementation of the ELV Directive are available at:
http://ec.europa.eu/environment/waste/elv/events_en.htm

Examples from a Member States: Supervisory Tasks

Sweden: Municipalities are supervisory authorities and one of their main responsibilities is to monitor how car producers comply with the provisions of Ordinance 2007:186 on car producer responsibility.

In addition, the county boards (Länsstyrelserna) also have supervisory duties according to Ordinance 1998:900 on supervision according to the Environmental Code.

If two authorities have so-called operative responsibility, they enter into an agreement on how the responsibility will be shared.

The Swedish Environmental Protection Agency (Naturvårdsverket) has central responsibility for the supervision and monitoring/evaluation of the system of producer responsibility for cars. Tasks involve providing guidance to the other supervisory authorities and submitting reports of car producers' data to the European Commission.

Some of the main obligations for car scrappers/recyclers mainly set out in Ordinance 2007:186 on car scrapping include:

- the requirement for accreditation by the county board (länsstyrelsen);
- notification (so-called C application) as environmentally hazardous activities according to the Environmental Code, Chapter 9 (6) and Article 21 of Ordinance 1998:899 on environmentally hazardous activities and health protection in the municipality;
- the requirement for some car scrappers/recyclers, e.g. those handling lorries, to obtain a permit from the county board
- a reporting obligation according to Ordinance 2007:186, with duties to submit data to the relevant car producers that are needed to be able to comply with their reporting obligations. Such reports should be submitted to the official representative of the car producers — Bil Sweden — also submitting a copy to the municipalities where the car scrapper/recycler carries out its activities;
- self-regulation pursuant to the Environmental Code, Chapter 26, Article 19, and Ordinance 1998:901 on operators' self-regulation (förordningen om verksamhetsutövarens egenkontroll).

Case C-64/09: Judgment of the Court (First Chamber) of 15 April 2010.

Concerns: Commission requested the Court to declare that, France has failed to fulfil its obligations under Directive 2000/53/EC on end-of-life vehicles, i.e. Article 2.13, Article 4(2)(a), Article 5(3) and (4), Article 6(3), Article 7(1) and Article 8(3)

Summary of Court of Justice of the European Union ruling:

It is clear from the actual wording of Article 5(4) of Directive 2000/53 that the delivery of an end-of-life vehicle to an authorised treatment facility must be free of charge, the related costs being borne by the manufacturers.

For any demolisher accepting voluntarily an end-of-life vehicle for destruction, the national system must make provision for a system of compensation for the costs of treatment, in this case the same as that provided for treatment facilities which are obliged under the national system to accept such vehicles.

By excluding from the system of compensation provided for in Article 6 of Decree No 2003-727 those demolishers who have accepted a vehicle for destruction, the French Republic has failed to fulfil its obligations under Article 5(4) of Directive 2000/53.

The Directive does not prevent certain treatment facilities from opting whether or not to accept, provided that the number of treatment facilities obliged to accept end-of-life vehicles delivered is sufficient to allow, in practice, for a transfer to such a facility. Thus, by providing for the obligation for shredders and collection centres to accept end-of-life vehicles, on the one hand, and for severe sanctions incurred in the case of abandonment of such a vehicle, referred to in paragraph 65 of the French Republic's statement in defence, on the other, French law has introduced a system for the acceptance of end-of-life vehicles which cannot be regarded as being incompatible with Article 5(4) of Directive 2000/53.

5. COSTS

The main share of costs will be incurred by the private undertakings that need to make investments to meet requirements in connection with the prevention, collection and treatment. There are also costs associated with the provision of adequate administrative structures regarding, for example, the issuing of certificates of destruction and monitoring compliance with the collection and recycling system and reporting on targets. It is possible to make use of financial instruments to minimise these costs, including insurance that may cover some of the costs for administering the ELV system. Most of the costs associated with the above Decisions implementing Directive 2000/53/EC are related to administrative tasks, including:

- making changes to the current certificate of destruction to ensure that it meets the minimum requirements in Decision 2002/151/EC and to ensure mutual recognition of certificates issued in other Member States;
- improving the documentation of ELVs, materials and components thereof exported to other Member States or third countries for recycling and recovery to ensure that this treatment is actually carried out in accordance with EC legal standards;
- collecting information regarding recycling/reuse and recovery/reuse targets and ensuring annual reporting to the Commission as well as compliance with the reporting requirements set out in Decision 2001/753/EC concerning a questionnaire for Member States' reports on the implementation of Directive 2000/53/EC of the European Parliament and of the Council on end-of-life vehicles.

The costs of implementing Decision 2003/138/EC establishing component and material coding standards for ELVs will mainly be borne by producers and material and equipment manufacturers since they have to ensure the use and labelling of these ISO standards. The cost for providing dismantling information for each type of new vehicle will also be mainly borne by producers who have already put in place a system for this purpose.¹⁸²

¹⁸² International Dismantling Information System (IDIS) at: <http://www.idis2.com/>

DIRECTIVES ON ELECTRICAL AND ELECTRONIC EQUIPMENT & RESTRICTION OF HAZARDOUS SUBSTANCES (WEEE & ROHS)

Official Title: Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) Text with EEA relevance (OJ L 197, 24.7.2012)

Implementing legislation:

Commission Decision 2004/249/EC of 11 March 2004 concerning a questionnaire for Member States reports on the implementation of Directive 2002/96/EC of the European Parliament and of the Council on waste electrical and electronic equipment (WEEE) (notified under document number C(2004) 714) (OJ L 78, 16.3.2004)

Commission Decision 2005/369/EC of 3 May 2005 laying down rules for monitoring compliance of Member States and establishing data formats for the purposes of Directive 2002/96/EC of the European Parliament and of the Council on waste electrical and electronic equipment (notified under document number C(2005) 1355) (OJ L 119, 11.5.2005)

Official title: Directive 2011/65/EC of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011)

As amended by:

Commission Delegated Directive (EU) 2016/585 of 12 February 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes

Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances (OJ L 137, 4.6.2015)

Two Commission Delegated Directives (EU) 2015/573 and (EU) 2015/574 amending for the purposes of adapting to technical progress Annex IV, as regards an exemption for lead in polyvinyl chloride sensors in in-vitro diagnostic medical devices and for mercury in intravascular ultrasound imaging systems respectively.

Eight Commission Delegated Directives 2014/69/EU to 2014/76/EU amending for the purposes of adapting to technical progress, Annexes III and IV to Directive 2011/65/EU, respectively.

Sixteen Commission Delegated Directives 2014/1/EU to 2014/16/EU amending for the purposes of adapting to technical progress, Annexes III and IV to Directive 2011/65/EU, respectively.

Two Commission Delegated Directives 2012/50/EU and 2012/51/EU amending for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU.

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The WEEE and ROHS Directives are complementary measures aimed at addressing the rapidly increasing amounts of (hazardous) waste from electrical and electronic equipment. The main categories are mobile smartphones and tablets, household and office equipment and various audio/video machines. The amount of waste is increasing because of sharply falling consumer prices. In addition, treatment of this type of waste is made difficult because of the content of hazardous components.

1.1. WEEE Directive 2012/19/EU

The Directive 2012/19/EU on waste electrical and electronic equipment entered into force on 13 August 2012 and had to be transposed by the Member States by 14 February 2014. It is a recast of the original WEEE Directive 2002/96/EC, which set a minimum target for public waste collection of 4kg per inhabitant per year from private households for a wide range of electrical and electronic goods. In addition, the original Directive made the producer responsible for their product in the end-of-life phase, which means that producers have to make a financial contribution to cover the costs of collecting, treating and sustainably disposing of both non-household and household electrical and electronic waste deposited at dedicated collection points.

The Directive aims to prevent or reduce the negative environmental effects resulting from the generation and management of WEEE and from resource use. Its key purpose is to contribute to sustainable production and consumption by, as a first priority, the prevention of WEEE and, in addition, by the re-use, recycling and other forms of recovery of such wastes.

Recast of the original WEEE Directive has introduced following main changes:

- clarifies the distinction between electrical and electronic waste (WEEE) from households and non-household waste, so that it is easier to determine which products fall under the Directive and to establish the obligations applying to equipment producers;
- the period between 13 August 2012 and 14 August 2018 is set as a transitional period. During this period the scope of the Directive is identical to the scope of the old Directive (10 categories of electrical and electronic equipment (EEE)) with the exception of photovoltaic panels (PV panels) that have been added to the scope of the Directive with immediate effect. From 15 August 2018 onwards the scope of the Directive is widened to include all EEE. All EEE shall then be classified within 6 categories instead of the existing 10 categories;
- sets an annual WEEE collection rate at 45 % per Member State as from 2016, according to the average quantity of equipment placed on the market in the three preceding years;
- sets from 2019, the collection rate at 65% of EEE placed on the market of a Member State in the three preceding years or 85% of WEEE generated on the territory of a Member State. Member States have to demonstrate achievement of either one of the collection rates;
- simplifies reporting obligations on producers;

- sets minimum inspection requirements for Member States;
- gives Member States the tools to fight the illegal export of WEEE more effectively by oblige exporters to test whether equipment works or not, and provide documents on the nature of shipments that could be thought illegal;
- requires Member States to determine effective, proportionate and dissuasive penalties to be applied in case of infringements.

The WEEE Directive was adopted on the basis of Article 192(1) of the TFEU. This provision concerns the strengthening of environmental protection exclusively. There are no elements of market integration, save for the interest in establishing uniform operating conditions in order to prevent distortions of competition. This also means that Member States are not excluded from setting or maintaining rules that are stricter than the ones in the Directive, provided those measures are otherwise compatible with the TFEU. The WEEE Directive is a so-called minimum harmonisation Directive.

The WEEE Directive was supplemented by a number of implementing Decisions:

- Commission Decision 2004/249: Lay down the questionnaire for the report of the Member States on the transposition and implementation of the WEEE Directive.
- Commission Decision 2005/369/EC: laid down requirements for monitoring compliance of Member States and establishing data formats under the WEEE Directive. It implements Art. 7(2) of WEEE I Directive. Member States have to demonstrate compliance with the recovery, reuse and recycling rates set out in Article 7(2) of Directive 2002/96/EC by completing Table 2 set out in the Annex to this Decision. Also, Member States have to report the information set out in Table 1 of the Annex. Finally, the Decision clarifies that where WEEE is collected and exported for treatment in a third country, or is sent for treatment in another Member State in accordance with Article 6(5) of Directive 2002/96/EC, that only the Member State that have collected and exported this WEEE can count it towards the targets set out in Article 7(2) of that Directive (e.g. cannot be counted twice).
- In addition, EN 50419 is the applicable European standard on marking of electrical and electronic equipment in accordance with Article 14(4) of the WEEE Directive

1.2. RoHS Directive 2011/65/EU

The RoHS Directive concerns the reduction of the content of certain hazardous substances in electrical and electronic equipment (EEE). Even when EEE is collected separately according to the WEEE Directive, the content of hazardous substances will still pose a risk. The substances in question are heavy metals, PBB and PBDE. Hence, the RoHS Directive lays down restrictions as to the composition of products, particularly in terms of the use of hazardous substances. The Directive is thus relevant to harmonise the requirements for the free movement of such products. For the functioning of the internal market it is vital that such restrictions are applied uniformly in all Member States. The legal basis is therefore Article 114 of the TFEU, which limits Member States from introducing more stringent measures than legislation based on Article 192.

The RoHS Directive 2011/65/EU entered into force on 21 July 2011 and had to be transposed by Member States by 2 January 2013. It recasted original RoHS Directive 2002/95/EC, which set strict limit values for lead,

mercury, cadmium, hexavalent chromium, polybrominated biphenyls or polybrominated diphenyl ethers in specified types of electrical and electronic equipment. Based on the revision of the original RoHS Directive 2002/95/EC launched in 2008, the legislation has prevented thousands of tonnes of banned substances from being used in EEE, disposed of and potentially released into the environment. The new Directive was adopted with the main aim of improving its implementation, its coherence with other pieces of EU legislation and adapting it to technical and scientific progress. The key elements of the revised Directive are as follows:

- more clarified scope extending to medical devices, monitoring and control instruments, and all other products that meet the EEE definition in RoHS, with a transition period until 22 July 2019;
- clarification of important definitions;
- setting out a mechanism to allow for new bans to be introduced in coherence with the REACH Regulation (EC) 1907/2006;
- clearer and more transparent rules for granting exemptions from the substance ban;
- sets a maximum validity period of five years for exemptions for the majority of products and seven years for medical devices and monitoring and control instruments, so as to stimulate efforts to find substitute products;
- introduces requirements for product conformity assessment, as well as mechanisms for monitoring the market, consistent with the common framework for the marketing of products.

In view of the significant extension of the scope, the new Directive introduces transition periods of up to 8 years for the new products affected by the rules. Photovoltaic panels are exempted from the Directive 2011/65/EU in an effort to help the EU reach its objectives for renewable energy and energy efficiency. Implementation and compliance are now important aspects of the new rules, which include a mechanism to make it easier for the Commission to monitor compliance.

RoHS Directive will be subject to review by the Commission, which will examine the need to modify the scope in respect of the EEE referred to in Article 2, which will result in a report thereon to the European Parliament and the Council accompanied by a legislative proposal, if appropriate, with respect to any additional exclusions related to that EEE. A general overhaul of the entire RoHS II Directive is furthermore scheduled for no later than 22 July 2021.

The RoHS Directive should be seen in connection with Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products aimed at products in general and where the purpose is to establish common environmental standards and obligations in respect of eco-labelling and documentation for environmental qualities. This so-called EEE will, like the ROHS Directive, be aimed at development of EEE which are eco-friendly but in a way that will not provide obstacles to the Internal Market and the free movement of goods.

The RoHS Directive has been amended by Commission Delegated Directive (EU) 2015/863 of 31 March 2015. This Directive Amends Annex II setting restricted substances referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials; the enforcement of the four phthalates restriction will begin on the 22 July 2019.

There are also exemptions for a number of applications, listed in the Annex III and IV to the Directive. Any amendments to this list of exemptions resulting from new scientific or technical progress are adopted and published as Commission Delegated Directives. A list of the Directives amending the relevant Annexes is presented below.

- Commission Delegated Directive (EU) 2016/585 of 12 February 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes
- Commission Delegated Directive (EU) 2015/574 of 30 January 2015 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for mercury in intravascular ultrasound imaging systems
- Commission Delegated Directive (EU) 2015/573 of 30 January 2015 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in polyvinyl chloride sensors in in-vitro diagnostic medical devices
- Commission Delegated Directive 2014/76/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for Mercury in hand crafted luminous discharge tubes (HLDTs) used for signs, decorative or architectural and specialist lighting and light-artwork
- Commission Delegated Directive 2014/75/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for mercury in cold cathode fluorescent lamps (CCFLs) for back-lighting liquid crystal displays, not exceeding 5 mg per lamp, used in industrial monitoring and control instruments placed on the market before 22 July 2017
- Commission Delegated Directive 2014/74/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead used in other than C-press compliant pin connector systems for industrial monitoring and control instruments
- Commission Delegated Directive 2014/73/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in platinized platinum electrodes used for conductivity measurements
- Commission Delegated Directive 2014/72/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems
- Commission Delegated Directive 2014/71/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solder in one interface of large area stacked die elements
- Commission Delegated Directive 2014/70/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in micro-channel plates (MCPs)
- Commission Delegated Directive 2014/69/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC for industrial monitoring and control instruments

- Commission Delegated Directive 2014/16/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi 2 O 5 :Pb) phosphors
- Commission Delegated Directive 2014/15/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead, cadmium and hexavalent chromium in reused spare parts, recovered from medical devices placed on the market before 22 July 2014 and used in category 8 equipment placed on the market before 22 July 2021, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer
- Commission Delegated Directive 2014/14/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for 3,5 mg mercury per lamp in single capped compact fluorescent lamps for general lighting purposes < 30 W with a lifetime equal to or above 20000 h
- Commission Delegated Directive 2014/13/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators
- Commission Delegated Directive 2014/12/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment
- Commission Delegated Directive 2014/11/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for hexavalent chromium in alkali dispensers used to create photocathodes in X-ray image intensifiers until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 January 2020
- Commission Delegated Directive 2014/10/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in alloys, as a superconductor or thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems, in medical devices (category 8) and/or in industrial monitoring and control instruments
- Commission Delegated Directive 2014/9/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors
- Commission Delegated Directive 2014/8/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards

- Commission Delegated Directive 2014/7/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors which are used (a) in magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or (b) in magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy
- Commission Delegated Directive 2014/6/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in the surface coatings of pin connector systems requiring nonmagnetic connectors which are used durably at a temperature below – 20 °C under normal operating and storage conditions
- Commission Delegated Directive 2014/5/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on printed circuit boards, termination coatings of electrical and electronic components and coatings of printed circuit boards, solders for connecting wires and cables, solders connecting transducers and sensors that are used durably at a temperature below – 20 °C under normal operating and storage conditions
- Commission Delegated Directive 2014/4/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers
- Commission Delegated Directive 2014/3/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead acetate marker for use in stereotactic head frames for use with CT (Computed Tomography) and MRI and in positioning systems for gamma beam and particle therapy equipment
- Commission Delegated Directive 2014/2/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in phosphor coatings in image intensifiers for X-ray images until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 January 2020
- Commission Delegated Directive 2014/1/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation
- Commission Delegated Directive 2012/51/EU of 10 October 2012 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for applications containing cadmium
- Commission Delegated Directive 2012/50/EU of 10 October 2012 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for applications containing lead

1.3. Planning

- Take measures to promote the designing of electrical/electronic products and to promote cooperation between producers and recyclers with a view to facilitate dismantling, recovery and recycling. These measures should take into account Directive 2009/125/EC so that the ecodesign requirements facilitating re-use and treatment of WEEE established in the framework of Directive 2009/125/EC are applied and producers do not prevent, through specific design features or manufacturing processes, WEEE from being re-used, unless such specific design features or manufacturing processes present overriding advantages, for example, with regard to the protection of the environment and/or safety requirements (Art. 4)
- Ensure phasing in the application of WEEE Directive in two phases:
 - 13 August 2012 to 14 August 2018 (transitional period) WEEE Directive applies to the electrical and electronic equipment (EEE) categories listed in Annex I (indicative list of EEE in Annex II), except for those listed in Article 2(3) (e.g. equipment for security purposes, certain equipment which is installed in other equipment; filament bulbs,) In summary, during this period the scope of the Directive is identical to the scope of the old WEEE Directive 2002/96/EC (10 categories of EEE with the exception of photovoltaic panels, that have been added to the scope of the Directive with immediate effect).
 - From 15 August 2018 WEEE Directive applies to all EEE except for those listed in Article 2, paragraphs (3) and (4). From this date all EEE shall be classified within six categories instead of the existing ten categories. Categories are set out in Annex III. As the list leaves an open scope, Member States are free to widen the scope and use additional sub-categories (except for those EEE listed in Article 2, paragraphs (3) and (4), e.g. equipment for security purposes, certain equipment which is installed in other equipment; filament bulbs, space equipment, large-scale stationary industrial tools, large-scale fixed installations, transportation vehicles, non-road mobile machinery for professional use, equipment exclusively designed for research and development purposes not for private uses, certain medical devices).
- Plan the phasing in of new WEEE and RoHS multiple provisions at Member States level, which introduce an extended scope and new mechanisms but also changes to the numbering of articles in the Directives which have to be carefully checked. This Member State planning should cover:
 - informing the producers, distributors and other involved actors regarding their responsibilities under the Directives
 - general information campaign for the public and consumers of EEE
 - ensure transposition of RoHS and WEEE Directive into national provisions, and related delegated/implementing acts. The transposition deadlines were set at 2 January 2013 and 14 February 2014, respectively and report these provisions to the Commission
 - the introduction of the new mechanism in RoHS Directive allowing new bans to be introduced in line with the REACH Regulation

- the introduction of the new requirements for product conformity assessments and the mechanisms for market monitoring, which has to be consistent with the common legislative framework for the marketing of products
 - set an annual WEEE collection rate at 45 % per Member State as from 2016, according to the average quantity of equipment placed on the market in the three preceding years;
 - include the re-use of whole appliances in the increased target for recycling combined with re-use;
 - set a new target for the recycling of medical devices;
 - harmonise the requirements for registration and reporting falling upon producers;
 - set minimum inspection requirements in accordance with Article 23 of the WEEE Directive,
 - set market surveillance in accordance with the Regulation (EC) 765/2008 to ensure that EEE complies with the requirements set out in the RoHS Directive
 - ensure that manufacturers have the possibility to appoint an authorised representative functioning on the basis of a clear mandate from the manufacturer being responsible for certain tasks
 - introduce the new requirements for product conformity assessments and the mechanisms for market monitoring
 - ensure a clear distinction between electrical and electronic waste from households and non-household waste to more easily determine which products fall under the Directive and to establish the obligations applying to equipment producers
 - ensure effective market surveillance system with trained staff and adequate resources, including for laboratory analysis
 - put into place mechanisms to ensure correct application of the regime for CE marking and issuing of declaration of conformity
 - ensure that the necessary measures, mechanisms and procedures are in place to identify non-compliance with RoHS and ensure imposition of effective, dissuasive and proportionate sanctions
- Put into place the mechanisms to ensure cooperation and exchange of information with competent authorities from other Member States to facilitate the implementation of the WEEE Directive, including results of inspections. (Art. 18, WEEE Directive)
 - Determine whether to conclude agreement between the competent authorities and the EEE sectors concerned to comply with the obligations set out in Article 8(6), Article 14(2) and Article 15 under WEEE Directive, provided that they are enforceable, contain objectives and deadlines, officially published and made available to the public, the results are monitored and reported to the competent authorities and the Commission, progress is being evaluated and non-compliance lead to cancelling the agreement and adopting regulatory provisions in its place. (Art. 24(1), (2), (3), WEEE Directive)
 - Introduce mechanisms and procedures to ensure a coordinated approach to the implementation of the RoHS and WEEE Directive also taking into account obligations under other waste legislation and chemical legislation (e.g. REACH Regulation, Waste Framework Directive)

- Decide whether to derogate from the obligation of distributors to taken back WEEE at the time of purchasing new equipment, free of charge, and duly inform the Commission about it (Art. 5(2), WEEE Directive)
- Designate the operators that are allowed to collect WEEE from private households and decide whether to require that the household WEEE deposited at collection facilities is handed over to producers or third parties acting on their behalf or is handed over, for purposes of preparing for re-use, to designated establishments or undertakings. (Art. 5, paragraphs (3) and (4), WEEE Directive)
- Decide whether to set up minimum quality standards for the treatment of the WEEE that has been collected and inform the Commission thereof. (Art. 8(5), WEEE Directive)
- Take the measures required to ensure that appropriate mechanisms or refund procedures are developed for the reimbursement of contributions to the producers where EEE is transferred for placing on the market outside the territory of the Member State concerned. Member States can adopt such procedures themselves or delegate this to the producers or their representation organisations (Art. 12(5), WEEE Directive).
- Determine whether to charge the costs of appropriate analyses and inspections, including storage costs, of used EEE suspected to be WEEE to the producers or to third parties acting on their behalf or to other persons arranging the shipment of used EEE suspected to be WEEE. (WEEE Directive Art. 23(3))
- Decide whether to make specific arrangements for the return of WEEE from private households either at collection points, at the time of purchasing new equipment or at the distributors' retail areas in cases where the equipment does not contain its essential components or if the equipment contains waste other than WEEE. (Art. 5(2), WEEE Directive)
- Determine the measures to encourage producers or other understating carrying out treatment operations to introduce EMAS. (Art. 8(6), WEEE Directive)
- Encourage consumers to participate in the collection of WEEE and facilitate the process of re-use, treatment and recovery, which may include information campaigns through various media, information at the place of collection points. The information obligation can be delegated to producers and/or distributors. (Art. 14, paragraphs (3) and (5), WEEE Directive)
- Put into place arrangements and systems to ensure full compliance with monitoring and reporting obligations set out in WEEE Directive and in Decision 2005/36/EC which demonstrates compliance with the recovery, reuse and recycling rates.
 - Determine whether for completing Table 2 of Annex to Decision 2005/36/EC to use an estimate as to the average percentage of reused, recycled and recovered materials, such as metals, glass and plastics, and components of waste electrical and electronic equipment,
 - Set up procedures to ensure that WEEE which is collected and exported for treatment in another Member State or in a third country is counted towards the targets set out in Art. 7(1) of WEEE Directive
 - Determine the estimations and methodology used for ensuring compliance with Tables 1 and 2 of the Annex to Decision 2005/36/EC.

1.4. Regulation

- Ensure that any establishment or undertaking carrying out treatment operations obtains a permit from the competent authorities in compliance with Article 23 of the Waste Directive (2008/98/EC) ensuring necessary detail to ensure compliance with recovery targets and treatment requirements. (Art. 9, paragraphs (1), (2) and (3), WEEE Directive)
- Ensure compliance with the restrictions on materials and hazardous substances set out in RoHS Directive (2011/65/EU) by ensuring that these restrictions cover all the EEE falling within the categories set out in Annex I, exempting the equipment indicated in Art. 2(4) of RoHS Directive (Art. 2-4, RoHS Directive (2011/65/EU).
- Ensure compliance with the phase in of the provisions of WEEE Directive:
 - 13 August 2012 to 14 August 2018 (transitional period) WEEE Directive applies to the EEE categories listed in Annex I (indicative list of EEE in Annex II), except for those listed in Article 2(3);
 - from 15 August 2018 WEEE Directive applies to all EEE except for those listed in Article 2, paragraphs (3) and (4). From this date all EEE shall be classified within the categories set out in Annex III.
- Take measures to minimise the disposal of WEEE in the form of unsorted municipal waste, to ensure the correct treatment of all collected WEEE and to achieve a high level of separate collection of WEEE, particularly focusing on temperature exchange equipment containing ozone-depleting substances and fluorinated greenhouse gases, fluorescent lamps containing mercury, photovoltaic panels and small equipment (categories 5 and 6 of Annex III). (Art. 5(1), WEEE Directive)
- Ensure that collection systems for WEEE from private households are set up where final holders and distributors can return such waste free of charge, including necessary collection points where such waste can be deposited/handed in. Member States have to ensure adequate availability and accessibility, taking into account especially population density. (Art. 5(2), WEEE Directive)
- Distributors have to ensure the following arrangements for collection of household WEEE:
 - that at the time of supplying a new product, they must return such waste, free of charge, at a one-to-one basis if it is of an equivalent type (unless Member States have derogated away from this duty and made another equivalent solution for bringing back WEEE free of charge);
 - at retail shops with sales areas relating to EEE of at least 400 m², or in collection areas in their immediate proximity, of very small WEEE (max 25 cm external dimension). This collection is free of charge to end-users and with no obligation to buy new equivalent EEE. (Article 5(2), WEEE Directive)
- Ensure that all collected WEEE is treated (other than preparing for re-use, recovery or recycling operations) properly in line with the conditions of an Article 8 of the WEEE Directive. This must at least comprise the removal of all fluids and a selective treatment in accordance with Annex VII. They must make specific arrangement for collection of WEEE that may cause contamination.

- Allow producers to set up and to operate individual and/or collective take-back systems for WEEE from private households meeting the requirements in the WEEE Directive (with exception for WEEE that could present a health and safety risk to personnel) (Art. 5(2), WEEE Directive)
- Ensure compliance with the minimum annual collection rates:
 - From 2016 (until 2019): minimum collection rate shall be 45% calculated on the basis of the total weight of WEEE collected (expressed as a percentage of the average weight of EEE placed on the market in the 3 proceeding years). The volume of WEEE collected must evolve gradually between 2016-2019. (Art. 7(1), WEEE Directive). There is for newer Member States possibility to derogate, for reasons of lack of the necessary infrastructure and low level of EEE consumption and thus it is sufficient to achieve a collection rate higher than 40% but lower than 45% of the average weight of EEE placed on the market in the 3 proceeding years (Article 7, paragraphs (1) and (3.a) WEEE Directive).
 - From 2019 onwards: minimum collection rate to be achieved annually shall be 65 % of the average weight of EEE placed on the market in the three preceding years in the Member State concerned, or alternatively 85 % of WEEE generated on the territory of that Member State. There is a possibility for newer Member States to derogate, for reasons of lack of the necessary infrastructure and low level of EEE consumption to postpone attainment until 14 August 2021 (Article 7, paragraphs (1) and (3.b) WEEE Directive)
- Take measures to ensure that recovery rates must be attained. The rates range from 75% to 85%, and a certain amount must be achieved through recycling and reuse, as opposed to, for example, incineration with energy recovery (Art. 11, WEEE and Annex V) These requirements include:
 - Minimum recovery targets in Annex V of WEEE Directive for all WEEE separately collected and sent for treatment:
 - 15 August 2015 - 14 August 2018 with reference to certain categories listed in Annex I of WEEE Directive: 55-80% recycled and reused, 75-85% recovery
 - From 15 August 2018 with reference to certain categories listed in Annex III of WEEE II Directive: 55-80% recycling and reuse, 75-85% recovery
 - The achievement of the targets shall be calculated, for each category, by dividing the weight of the WEEE that enters the recovery or recycling/preparing for re-use facility, after proper treatment with regard to recovery or recycling, by the weight of all separately collected WEEE for each category, expressed as a percentage. (Art. 11(2), WEEE Directive)
- Ensure that new electrical and electronic equipment sold to any other EU Member State does not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls or polybrominated diphenyl ethers unless contained in the list of exempted applications set out in Article 4 and Annex II of Directive 2011/65/EU, Art. 4(1), (3) and (4).
- Prohibit disposal of separately collected WEEE unless it has undergone the treatment specified in Article 8 of WEEE Directive. (Art. 6(1) WEEE Directive,)
- Ensure that the collection and transport of separately collected WEEE is carried out in a way which allows optimal conditions for preparing for re-use, recycling and the confinement of hazardous substances. (Art. 6(2), WEEE Directive)

- Ensure that producers provide for separate collection of non-household WEEE. (Art. 5(5), WEEE Directive).
- Ensure that all separately collected WEEE undergoes proper treatment and that producers or third parties acting on their behalf set up systems to provide for the recovery of WEEE using best available techniques. The systems may be set up by producers individually or collectively. (Art. 8 paragraphs (1) and (3), WEEE Directive).
- Ensure that any establishment or undertaking carrying out collection or treatment operations stores and treats WEEE in compliance with the technical requirements set out in Annex VIII of WEEE II Directive (Art. 8(3), WEEE Directive). In this framework, ensure that any establishment or undertaking carrying out treatment operations obtains a permit from the competent authority in compliance with Article 23 of Directive 2008/98/EC (Art. 9(1), WEEE Directive).
- Ensure that waste shipments of WEEE to other Member States or outside the EU comply with the Waste Shipment Regulations (EC) No 1013/2006 and Regulation (EC) No 1418/2007. Such waste can only be counted towards fulfilling targets if it complies with conditions of Waste Shipment Regulations and the exporter proves that the treatment is equivalent to what is required under WEEE Directive. (Art. 10(1) and (2), WEEE Directive)
- Ensure that producers provide at least for the financing of the collection, treatment, recovery and environmentally sound disposal of WEEE from private household that has been deposited at collection facilities (Art. 12(1), WEEE Directive)
 - producers may also be encouraged to cover costs for collection of WEEE from private households to the collection facilities. (Art. 12(2), WEEE Directive)
 - For new household WEEE (placed on the market on or before 13 August 2005) each producer have to finance the waste operations relating to his own products either individually or in a collective scheme. (Art. 12(3), WEEE Directive)
 - Producers shall finance costs of historical WEEE (put on the market before 13 August 2005) in a collective system in which producers cover their costs proportionally (share of market by type of EEE). (Art. 12(4), WEEE Directive)
 - Ensure that each producer provide a financial guarantee (e.g. participation in collective scheme, recycling insurance or a blocked bank account) when placing a EEE on the market indicating how WEEE management will be financed and that the EEE is duly marked in accordance with Art. 15(2) of WEEE Directive (Art. 12(3), WEEE II Directive).
 - Ensure that producers or the collective scheme to which they belong establish refund or reimbursement procedures (Art. 12(5), WEEE Directive)
- Ensure that for non-household WEEE, producers are responsible for financing collection, treatment, recovery and environmentally sound disposal of WEEE accordingly:
 - For WEEE being replaced by new equivalent products or by new products fulfilling the same function. (Member States may opt for an arrangement whereby the costs are distributed over users other than private households). (Art. 13(1), WEEE Directive)
- Ensure that producers and users other than private households cover the costs for collection, treatment and recovery/recycling of non-household WEEE, which are handed in at the time of

purchasing a new, equivalent EEE. Producers and users may conclude agreements laying down the terms of the financing methods. (Art. 13(2), WEEE Directive)

- Ensure that producers are allowed to appoint a legal or natural person as authorised representative fulfilling the obligations of the producer. This appointment must be made by written mandate (Art. 17, paragraphs (1) and (3), WEEE Directive)
- Member States (competent authorities) have to comply with its main tasks under the RoHS II Directive:
 - Allow EEE that was outside the scope of RoHS I Directive (2002/95/EC), but which would not comply with new RoHS Directive (2011/65/EU), on the market until 22 July 2019, having regard to provisions of Article 4(3) and 4(4) which set different deadlines for medical devices and monitoring and control instruments. (Art. 2(2), RoHS Directive)
 - Ensure that EEE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II of RoHS Directive. This applies to:
 - medical devices and monitoring and control instruments, which are placed on the market from 22 July 2014 (Art. 4(3), RoHS Directive);
 - in vitro diagnostic medical devices which are placed on the market from 22 July 2016;
 - industrial monitoring and control instruments which are placed on the market from 22 July 2017 (Art. 4(3), RoHS Directive).
 - Ensure that the above does not apply to:
 - cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity for EEE placed on the market before 1 July 2006;
 - EEE which benefited from an exemption and which was placed on the market before the exemption expired (i.e. historic EEE);
 - reused spare parts, recovered from EEE placed on the market before 1 July 2006 and used in equipment placed on the market before 1 July 2016, where reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer;
 - applications listed in Annex III and IV
 - Ensure that in EEE the maximum concentration value by weight in homogeneous materials as specified in Annex II is not exceeded. (Art. 6(1), (2), RoHS Directive).
 - Allow the appointment of an authorized representative for the manufacturer complying with conditions of Art. 8, RoHS Directive,
 - Ensure and monitor that EEE placed on the market bear CE marking in compliance with provisions of Art. 15 and that the correct use of the CE marking is being adhered to and that in the case of non-compliance this is subject to penal sanctions. It must be presumed that such EEE are compliant in the absence of contrary evidence (Arts. 15, and 16 RoHS Directive)
 - Take the necessary steps to ensure efficient market surveillance and functioning of the market surveillance authorities, which include identification of economic operators and carrying out market surveillance in accordance with Articles 15 to 29 of Regulation (EC) No 765/2008 (Arts. 12, and 18 RoHS Directive)

- Ensure that manufacturers carry out their main tasks under the RoHS Directive (especially requirements set out in Art. 4 and 7). This comprise
 - Ensure that the EEE placed on the market comply the requirements of Art. 4 regarding design and manufacturing;
 - Ensure that the technical documentation has been drawn up and that there is a procedure for internal production control, corresponding to Annex II to Decision No 768/2008/EC, which demonstrates compliance with RoHS requirements;
 - That an EU declaration of conformity is drawn up and is kept by the manufacturer for 10 years upon having been placed on the market and the finished EEE bears CE marking. The declaration of conformity may be integrated also covering requirements stemming from other EU legislation;
 - That procedures are in place for series production and that these procedures take into account changes in product design or changes or updated harmonized standards and technical specifications;
 - That there is a register for non-conforming EEE and product recalls and that there are procedures for keeping distributors informed of this;
 - That the EEE can be easily identified through a type, batch or serial number or for larger or where more practical through information on packaging or accompanying document;
 - That the EEE or its packaging or accompanying document (where more practical) bears information on manufacturer's name or registered trademark and contact details;
 - Ensure that all corrective measures are taken in case of non-conforming EEE, which may include market withdrawal or recall and that immediately inform the competent authorities of the Member States where the EEE has been placed on the market;
 - Cooperate with a competent national authority and upon request supply information and documentation demonstrating conformity of the EEE in a language understood and to take further action to ensure compliance with the RoHS II Directive. (Art. 7, RoHS Directive);
 - Decide whether to appoint an authorized representative for a part of the responsibilities but not for fulfilling the obligations laid down in point (a) of Art. 7 and for drawing up technical documentation (certificate of conformity, CE marking etc.). Such a representative has to be appointed through written mandate and only performs the tasks in this mandate, which should at least comprise providing a service to store and supply national authority with technical documentation and to overall cooperate with the competent national authorities and take action to ensure compliance within the written mandate. (Art. 8, RoHS Directive)
- Ensure that importers comply with the requirements of RoHS Directive. This includes following tasks:
 - Before they place EEE on the market in an EU Member State ensure it is compliant with RoHS Directive and that manufacturer has carried out the conformity assessment procedure with the resulting technical documentation,
 - When the importer suspects that an EEE is not in conformity ensure that EEE is not placed on the market, until it is compliant. Importer must inform the manufacturer and the market surveillance authorities thereof;

- Ensure that the EEE is easily identified also indicating the importer’s name and contact details;
- Importers document and keep on file a copy of the declaration of conformity for 10 years, along with other technical documentation (Art. 9, RoHS Directive)
- Importers and distributors have shared responsibility – also subject to verification of the Member States - to:
 - Ensure that the EEE put on the market is CE marked, accompanied with the required technical documents in a language easily understood by consumers and other end-users and that the manufacturer has complied with his responsibilities under Art. 7 (f), (g), RoHS Directive);
 - Keep a register of non-compliant EEE and EEE recalls, and keep distributors informed thereof;
 - Where there are reasons to believe that it is non-conforming ensure that corrective measures to ensure compliance or to withdraw/recall the product and inform competent authorities and the market surveillance authorities about this
 - Cooperate and provide information and documentation to a national competent authority (Art. 9 and 10, RoHS Directive)
 - Take on obligations of manufacturer in certain cases (e.g. where traded under the name of importer or distributor or modifies the EEE already placed on the market (Art. 11, RoHS Directive)
- Lay down effective, dissuasive and proportionate penalties for non-compliance with RoHS and WEEE Directives.

1.5. Monitoring and Enforcement

- Ensure monitoring demonstrating compliance with recovery, reuse and recycling rates set out in Article 7(1) of Directive 2012/19/EU taking place in the data formats set out in Table 2 of Annex to Decision 2005/369/EC (Art. 2(1), Decision 2005/369/EC).
- Carry out the necessary inspections and monitoring to verify proper implementation of the WEEE Directive. Some of these costs for analyses and inspections may be charged to the producers or to third parties acting on their behalf. The inspections shall at least cover: (Art. 23(1), WEEE Directive)
 - information reported into the producers’ register;
 - shipments, in particular exports of WEEE outside the EU to verify compliance with Waste Shipment Regulations. Ensure that shipments of used EEE suspected to be WEEE are carried out in accordance with the minimum requirements in Annex VI and shall monitor such shipments accordingly (Art. 23(2) WEEE Directive);
 - and operations at treatment facilities also taking into account Waste Framework Directive.
- Monitor manufacturers’ compliance with requirements of RoHS Directive regarding design and manufacturing specifics, internal production control, the requirement to hold the necessary technical documentation (e.g. EU declaration of conformity), ensuring that finished EEE bear CE marking,

that there are procedures in place for series production and that they keep a register of non-conforming EEE and product recalls. Penalties for infringements, which may include criminal sanctions for serious infringements, especially for incorrect use or non-use of CE marking should be effective, dissuasive and proportionate. (Art. 7 and Art. 15(3), RoHS Directive)

- Monitor that where WEEE is collected and exported for treatment in a third country, or is sent for treatment in another Member State in accordance with Article 10(1) of WEEE Directive, that these quantities count towards the targets set out in Article 11(1) of WEEE Directive (e.g. cannot be counted twice).
- Take all measures to ensure the effective enforcement of the Directives. (Art. 23, RoHS Directive and Art. 22, WEEE Directive)

1.6. Reporting and information

- Draw up a register of producers of electrical and electronic equipment (EEE), including producers supplying EEE by means of distance communication (Art. 16(1), WEEE Directive).
- Ensure that each producer, or each authorised representative, is registered and has the possibility to enter online in the national register all relevant information reflecting that producer's activities in that Member State (distant producers have to be registered in the Member State to which they sell).
 - ensure that the registration contains the minimum information set out in Annex X of WEEE Directive;
 - ensure that the national register provides links to other national registers;
 - collect information, on an annual basis, on the quantities and categories of EEE placed on the market, prepared for re-use, recycled and recovered within the Member State, and on separately collected WEEE exported. (Art. 16 paragraph (1), (2), (3) and (4), WEEE Directive)
- Ensure that producers or third parties acting on their behalf have to keep records on the weight of WEEE, its components, materials or substances when leaving (output) the collection facility, entering (input) and leaving (output) the treatment facilities and when entering (input) the recovery or recycling/ preparing for re-use facility. (Art. 11(4), WEEE Directive)
- Ensure that the EEE is duly marked in accordance with Article 14 of WEEE Directive.
 - this marking shall include a separate collection symbol (crossed-out wheeled bin) of European standard EN 50419 referred to in Annex IX of WEEE Directive (14(4) and Annex IX WEEE Directive);
 - the mark must specify that the EEE was placed on the market after 13 August 2005, preferably by using the EN 50419. (Art. 15(2), WEEE Directive);
 - the marking may exceptionally be placed on the packaging. (Art. 14(4) WEEE Directive)
- Ensure that users are informed about their role in contributing to the collection of WEEE, available collection/return facilities, the health and environmental hazards from hazardous substances used in electrical and electronic equipment and the meaning of the crossed-out wheeled bin symbol.

- Producers may be required to show purchasers, at the time of sale of new products, the costs of collection, treatment and disposal. All or some of these obligations may be put on producers and/or distributors. (Art. 14(1), WEEE Directive)
- Ensure that producers provide information, free of charge, about preparation for re-use and treatment for each type of EEE placed on the market for the first time. This information must be transmitted at the latest one year after the placement on the market and describe the different EEE components and materials, the location of dangerous substances and mixtures in EEE and made available to centres which prepare for re-use and treatment and recycling. This information can be in the form of manuals or electronic media. must provide treatment facilities with all appropriate information to identify components, materials and the location of hazardous substances in products (Art. 15(1), WEEE Directive).
- Ensure that information concerning the collected WEEE, in accordance with Article 5, is transmitted to the Member States free of charge, including at least information on WEEE that has been:
 - received by collection and treatment facilities;
 - received by distributors;
 - separately collected by producers or third parties acting on their behalf. (Art. 7(2), WEEE Directive)

According to Art. 16(4) of WEEE Directive, information concerning the collected WEEE, including substantiated estimates shall cover WEEE collected through all routes.

- Report to the Commission as required on:
 - measures employed to ensure efficient collection and to encourage recycling; about the national legal measures to transpose WEEE and RoHS Directives, including their subsequent modifications, into the national legal system. (Art. 25, RoHS Directive, Art. 24(1), WEEE Directive);
 - rules on penalties applicable to infringements of the national provisions adopted to transpose RoHS and WEEE Directives.
- Report to the Commission on the implementation of Directive on the basis of Article 16. The report should cover in detail both the incorporation of the Directive into national law and its implementation. It should be drawn up on the basis of the questionnaire set out in Decision 2004/249/EC and the information and data format set out in Decision 2005/369/EC, e.g.
 - report on the information required in Article 16(4) of Directive 2012/19/EU using the data formats set out in Table 1 of the Annex to this Decision. (Art. 1, Decision 2005/369/EC);
 - the information submitted should sufficiently demonstrate compliance with the recovery, reuse and recycling rates set out in Article 7(1) of WEEE Directive by completing Table 2 set out in the Annex to Decision 2005/369/EC (Art. 2(1), Decision 2005/369/EC), for which Member States may use an estimate as to the average percentage of reused, recycled and recovered materials, such as metals, glass and plastics, and components of WEEE;
 - if need be supply additional documents to those required under the Article 10(2) of Directive 2012/19/EU (Art. 2(3), Decision 2005/369/EC);

- provide the Commission with detailed description how the data have been compiled and the estimates and methodology used in complying with Tables 1-2 of Annex to Decision 2005/36/EC (Article 3, Decision 2005/36/EC);
- for the report under WEEE Directive, this should be drawn up at three-year intervals on the basis of a questionnaire laid down in Commission Decisions 2004/249/EC and 2005/369/EC and be made available by September of the following year. However, the first report shall cover the period from 14 February 2014 to 31 December 2015. (Art. 16(5). WEEE Directive)

1.7. Additional Legal Instruments

- Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products
- Directive 2008/98/EC on waste
- Directive 2006/66/EC on batteries and accumulators
- EMAS Regulation (EC) No 1221/2009 (establishments responsible for treatment operations must obtain a permit from the competent authorities. They are encouraged to participate in EMAS)
- Landfill Directive (1999/31/EC)
- EIA Directive (2011/92/EU): assessment required for public or private projects concerning waste management facilities (e.g. treatment, recovery, recycling and disposal of WEEE)
- SEA Directive (2001/42/EC)
- Access to Information Directive (2003/4/EC)
- Public Participation Directive (2003/35/EC)
- Environmental Crimes Directive (2008/99/EC)
- Directive 2004/107/EC relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air: WEEE management operations may give rise to ambient air pollutants
- Industrial Emissions Directive 2010/75/EU
- Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) 1907/2006
- Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury
- REACH Regulation (EC) No 1907/2006: RoHS Directive II introduces a mechanism allowing new bans to be introduced in line with the REACH Regulation

- Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC: New RoHS II Directive introduce requirements for product conformity assessment, as well as mechanisms for monitoring the market, consistent with the common framework for the marketing of products

2. IMPLEMENTATION

2.1. Key Tasks

The key tasks involved in implementing these Directives are summarised in the following checklist, organised in chronological order (where appropriate) within each subheading.

Table 28. Checklist with key implementation tasks

THE RoHS and WEEE DIRECTIVES - KEY IMPLEMENTATION TASKS	
1	Planning and Institutional Organisation
1.1	Identification of a suitable competent authority to carry responsibility for the implementation. This includes not only the various tasks connected to waste collection and treatment (WEEE) but also co-ordination with other authorities responsible for market surveillance (RoHS) in order to enforce the restrictions of the RoHS Directive as well as marketing and labelling of EEE products.
1.2	Engage in wide consultation with the stakeholders which should include general and targeted information campaigns and consult economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations, especially in regard to the type of collection schemes and the financial mechanisms used.
1.3	Ensure that sufficient institutional structures and resources (e.g. financial, human and technical resources) have been provided for the competent authorities, the market surveillance authorities and other involved public bodies involved in the planning of WEEE structures, carrying out of certain organisational tasks, monitoring, supervision and enforcement.
1.4	Plan the smooth phase-in compliance with the phase in of the provisions of WEEE Directive: <ul style="list-style-type: none"> • 3 August 2012 to 14 August 2018 (transitional period) WEEE Directive applies to the EEE categories listed in Annex I; • from 15 August 2018 WEEE Directive applies to all EEE except for those listed in Article 2, par. (3) and (4).
1.5	Plan the measures to encourage eco-design, strong cooperation between producers and recyclers, also taking into account Directive 2009/125/EC.
1.6	Determine who should carry the direct responsibility for <ul style="list-style-type: none"> • establishing collection systems; • ensuring treatment facilities corresponding to the technical requirements of the Directives; • making sure that the targets for recovery are being met.
1.7	Decide whether to make use of specific arrangements for household wastes due to their content and whether to designate operators entitled to collect WEEE from private households and whether to all household WEEE collected be handed over to EEE producers or their representatives for preparing for re-use (partly applicable from 14 February 2014).
1.8	Consider the possibility of having treatment and information issues regulated by private agreements as an alternative to regulation.
1.9	Set up permit and inspection schemes for waste treatment plants. Ensure co-ordination with other permit arrangements (IED and Waste Framework Directives) and consider ways to encourage EMAS.
1.10	Establish guidelines and regulations concerning producer-initiated take-back systems for

	household as well as non-household waste.
1.11	Develop strategies and measures to encourage eco-design and production for the purpose of preventing waste accumulation and to encourage research and development to develop new recovery, recycling and treatment technologies.
1.12	Implement various types of measures (for example monitoring and information activities) to ensure the separation of electrical/electronic waste and thus avoid it being mixed with normal municipal waste.
1.13	Consider whether national minimum quality standards for electrical/electronic waste treatment should be developed.
1.14	Development of systems for the producer financing of the handling of household waste and requirements concerning the producer guarantee as a condition for marketing, eventually by setting up a common insurance scheme.
1.15	Consider, in the case of non-household waste, the possibility of having part of the costs borne by commercial users.
1.16	Plan the phasing in of WEEE and RoHS, which introduces an extended scope and new mechanisms etc. For instance, this planning should cover: <ul style="list-style-type: none"> • the introduction of the new mechanism in RoHS Directive allowing new bans to be introduced in line with the REACH Regulation; • the introduction of the new requirements for product conformity assessments and the mechanisms for market monitoring, which has to be consistent with the common legislative framework for the marketing of products; • clarifies the distinction between electrical and electronic waste (WEEE) from households and non-household waste, so that it is easier to determine which products fall under the Directive and to establish the obligations applying to equipment producers; • set an annual WEEE collection rate at 45% per Member State as from 2016, according to the average quantity of equipment placed on the market in the three preceding years; • include the re-use of whole appliances in the increased target for recycling combined with re-use; • set a new target for the recycling of medical devices; • harmonise the requirements for registration and reporting falling upon producers; • set minimum inspection requirements to enable that proper implementation of the WEEE Directive is verified; • set up market surveillance to ensure compliance with the RoHS Directive • the introduction of the new mechanism in RoHS Directive allowing new bans to be introduced in line with the REACH Regulation.
1.17	Put into place arrangements and systems to ensure full compliance with monitoring and reporting obligations set out in WEEE Directive (2012/19/EU), and in Decision 2005/36/EC which demonstrates compliance with the recovery, reuse and recycling rates.
1.18	Allow EEE that was outside the scope of the repealed RoHS Directive 2002/95/EC, but which would not comply with the RoHS Directive 2011/65/EU, on the market until 22 July 2019 (Art. 2(2), RoHS II Directive
2	Regulation
2.1	Ensure that any establishment or undertaking carrying out treatment operations obtains a permit from the competent authorities in compliance with the Waste Directive (2008/98/EC) and that this is sufficiently detailed.
2.2	Ensure compliance with the phase in of the provisions of WEEE Directive: <ul style="list-style-type: none"> • 13 August 2012 to 14 August 2018 (transitional period) WEEE II Directive applies to the EEE categories listed in Annex I (indicative list of EEE in Annex II), except for those listed in Article 2(3) • from 15 August 2018 WEEE II Directive applies to all EEE except for those listed in Article 2 par. (3) and (4). From this date all EEE shall be classified within the categories set out in Annex III (Annex IV contains a non-exhaustive list of EEE which falls within

	the categories set out in Annex III)
2.3	Prohibit any charges or other measures that entail expenses for households in connection with the collection or treatment of electrical/electronic waste.
2.4	Ensure that all collected WEEE is treated properly which at least must comprise the removal of all fluids and a selective treatment in accordance with Annex VII.
2.5	Ensure that waste shipments are compliant with Waste Shipment Regulations and amounts exported are only counted towards meeting the targets if the treatment is equivalent in quality to what is required under WEEE Directive.
2.6	Lay down requirements regarding the manner in which producers must keep records for the purposes of calculating recovery targets.
2.7	Ensure compliance with European Standard EN 50419 on marking of electrical and electronic equipment in accordance with Article 11(2) of the WEEE Directive.
2.8	Ensure compliance with the annual WEEE collection rate at 45% per Member State as from 2016, according to the average quantity of equipment placed on the market in the three preceding years.
2.9	Ensure that the increased target for recycling combined with re-use include whole appliances
2.10	Ensure compliance with the new target for the recycling of medical devices
2.11	Ensure that distributors take the required measures to enable collection of household WEEE
2.12	Ensure that the manufacturers fulfil their obligations under RoHS Directive regarding e.g. design and manufacturing requirements, the duty to draw up certain technical documentation verifying EEE compliance with RoHS Directive (e.g. EU declaration of conformity), that the EEE is adequately CE marked and that the labelling easily identifies the manufacturer and that there are procedures in place for series production, internal production control and that they keep a register of non-complying and/or recalled EEE and that they comply with information duty towards distributors and the competent national authorities (covering all Member States where the EEE is being placed on the market)
2.13	Manufacturers should consider whether to appoint an authorized representative for a part of the responsibilities but not for fulfilling the obligations laid down in point (a) of Art. 7 and for drawing up technical documentation (certificate of conformity, CE marking etc.).
2.14	Ensure that importers and distributors comply their obligations under the RoHS Directive which comprises surveillance/monitoring duties (check compliance), taking corrective measures in terms of having non-conforming EEE come into compliance or ensure that such EEE are withdrawn or recalled from the market and that the manufacturer and competent authorities comprising the market surveillance authorities are duly informed. Importers and distributors also have to safeguard that the EEE holds the CE marking and contain the information necessary for consumers or end-users to identify the manufacturer and/or importer. Also they have to keep certain files on record and cooperate and supply information to competent national authorities.
2.15	Ensure compliance with the restrictions on materials and hazardous substances set out in the RoHS Directive (2011/65/EU) as applicable to all Member States as from 3 January 2013 ensuring that these restrictions cover all the EEE falling within the categories set out in Annex I,
2.16	Ensure compliance with recovery targets, comprising the modifications made by WEEE II Directive, e.g. include the re-use of whole appliances in the increased target for recycling combined with re-use and the new target for the recycling of medical devices
2.17	Producers must ensure that they register before placing EEE (note also the registration obligation for accompanying batteries or accumulators under Directive 2006/66/EC), on a professional basis.
2.18	Establish a system for the collection of WEEE but also spent batteries and accumulators (ensuring coordination with obligations under the Batteries Directive).
2.19	Prepare guidance notes for the efficient provision of collection services.
2.20	Lay down effective, dissuasive and proportionate penalties for non-compliance with RoHS and WEEE Directives.
3	Monitoring and Enforcement

3.1	Establish a system to ensure that EEE (as well as the supplied batteries) are not placed on the market unless they comply with the requirements of the WEEE and RoHS Directives.
3.2	Monitor collection rates on a yearly basis.
3.3	Ensure compliance with the new requirements in WEEE Directive for product conformity assessments and the mechanisms for market monitoring, which has to be consistent with the common legislative framework for the marketing of products.
3.4	Comply with the minimum inspection requirements set out in WEEE and RoHS Directives.
3.5	Ensure monitoring demonstrating compliance with the compliance with recovery, reuse and recycling rates set out in Article 7(1) of Directive 2012/19/EU taking place in the specific data formats.
3.6	Monitor manufacturers' compliance with requirements of RoHS Directive regarding design and manufacturing specifics, internal production control, the requirement to hold the necessary technical documentation (e.g. EU declaration of conformity), ensuring that finished EEE bear CE marking, that there are procedures in place for series production and that they keep a register of non-conforming EEE and product recalls.
3.7	Monitor that where WEEE is collected and exported for treatment in a third country, or is sent for treatment in another Member State in accordance with Article 6(5) of Directive 2002/96/EC, that these quantities count towards the targets set out in Article 7(2) of that Directive (e.g. cannot be counted twice).
3.8	Take all measures to ensure the effective enforcement of the Directives. These Directives are also listed as legislation for which Member States have to ensure penal sanctions pursuant to the Environmental Crimes Directive (2008/99/EC).
4	Information and Reporting
4.1	Develop an information strategy composed of general campaigns in the media as well as more targeted communications and guidelines. This information campaign should provide information on safe methods for the disposal of WEEE (and batteries) for manufacturers, importers, distributors and consumers.
4.2	Determine the format and content of the product information to be provided to treatment plants.
4.3	Ensure compliance with the harmonised requirements for registration and reporting falling upon producers set out in WEEE Directive.
4.4	Inform the Commission about the national legal measures to transpose WEEE and RoHS Directives into the national legal system.
4.5	Ensure free of charge information exchange with Member States regarding separately collected WEEE.
4.6	Establish reporting and data recording systems to ensure that the data required (see below) are collected.
4.7	Report to the Commission as required on: <ul style="list-style-type: none"> • measures employed to ensure efficient collection and to encourage recycling; • transpositional measures; • rules on penalties applicable to infringements of the national provisions adopted to transpose RoHS and WEEE Directives
4.8	At three-year interval send to the Commission a report on the implementation of Directive 2012/19/EU. The first report covered the period from 14 February 2014 to 31 December 2015.

2.2. Phasing in Considerations

Experience within Member States suggests that the most demanding and time-consuming tasks associated with implementing the WEEE Directive are the following:

- Establishing and developing the institutional structure and the various procedures (registration procedure, monitoring system) to achieve the various objectives of the Directive, some of which do not relate to waste management but more to market surveillance and ensure efficient functioning of the EU internal market;
- Setting up the waste management infrastructure;
- Information provisions, including marking, information campaigns;
- Identify how the various requirements of the Directive are to be met, including timescales and clearly allocated responsibilities and the concerned authorities;
- Ensure efficient supervision and sanctioning in case of non-compliance.

These tasks should therefore be planned to commence during the initial phase of implementation.

The recast of WEEE and RoHS Directives aim at improving their effectiveness and implementation. Candidate countries are, hence, strongly advised to start to phase in the requirements and approach of WEEE and RoHS as soon as possible with a view to reducing the administrative costs related to their application. Also the competent authority involved should be strongly coordinated with the competent authority for market surveillance and conformity assessments as well as for those supervising restrictions on the use of dangerous substances and mixtures.

As can be seen from the previous points, the Directives allow Member States quite a degree of discretion as to how national regulation should look — or in fact whether, in certain areas, there should be any national regulation at all to the extent that agreements permitted and implemented with interested parties in accordance with the Directive will suffice.

Otherwise, the major tasks will be the setting up of collection systems, and financing schemes and systems for issuing permits for treatment. Because of the broad nature of this type of waste, it will also be a substantial task to develop a comprehensive information strategy in relation to the public at large.

For all these issues, it is important to devote sufficient time for the examination of existing structures and to have in-depth consultations with the various stakeholders.

3. IMPLEMENTATION GUIDANCE

3.1. Planning and Institutional Procedures

- WEEE is implemented nationally within EU Member States each of which has its own system and rules. The new WEEE Directive and forthcoming implementing rules will reduce the negative impacts of versatile systems (e.g. by streamlining reporting, registration and date collection requirements).
- Implementation of WEEE and RoHS Directives may involve more than one competent authority — for example, the ministry/department responsible for trade, and the bodies responsible for developing and implementing standards. If this is the case, it could be advisable to establish a single authority, with the appropriate resources and procedures, to ensure efficient co-ordination of the implementation of the Directive and clear channels of communication between all relevant authorities and with the key players of the Directives.
- Candidate countries have to ensure efficient, continuous cooperation between producers and recyclers both for monitoring purposes but also for encouraging innovation into eco-design. Given the minimum nature of the Directive rules, there is the possibility to have a system with the mandatory separation of electrical/electronic waste for private households as well as enterprises. This option must be considered. Such a system will only function in a reasonable manner when a generous amount of collection points and other facilities are available and when the launch has been prepared by means of considerable information campaigns.
- There are an increasing number of WEEE regulations in place outside of the EU, for example in Japan, many US States, Korea and China, with which certain coordination is needed.

Examples of Member States:

Member States have some flexibility to decide on the scope of EEE covered, WEEE providing the minimum scope. WEEE II Directive clarified the scope to some extent. Some examples of varying approaches below:

- Some States such as the UK include only products that are clearly within Annex IA (WEEE I Directive)
- Some States exclude large machine tools and some types of “fixed installations” from scope, whereas many States include these types of products
- A few States such as Finland endeavor to include as many types of electrical equipment as possible

Source:

<http://ecsnuk.org/Legislation/WEEE/2WEEE%20directive%20&%20implementation%20in%20EU%20sept09v2.pdf>

3.2. B2C and B2B

- Candidate countries must grasp the important difference between products sold to “households” – so-called B2C and products sold to businesses – B2B. This is because the obligations for B2C and B2B are different. To ensure a correct interpretation, consult good practices of Member States and the data collected by the Commission. This will ensure a more uniform application of the definition of B2C and B2B and the scope of EEE covered. Some Member States have produced lists of products that are regarded as being B2C whereas anything not listed are assumed to be B2B. Some States allow producers to decide and there are several other different definitions that are used.
- Regarding B2C, some Member States use the “Clearing House” approach (e.g. in Germany). Other countries do not have Clearing Houses and so trading of evidence is carried out to ensure that each system has financed the correct quantity of WEEE collection and recycling.
- For B2B a common approach used is for businesses that have WEEE for disposal and recycling to contact either the individual producer that sold them the product or their compliance system who arranges for the equipment to be collected. Producers and their customers may make alternative arrangements so that the user is responsible for disposal but the default situation is that the producer is responsible. Older equipment sold to businesses before WEEE legislation was adopted is “historical waste” and producers are obliged to collect one equivalent product when they supply one new product. Any other historical waste is the responsibility of the user.

3.3. Collection systems

- All Member States have one or more national Producer Compliance Systems (PCS), which producers can join and who meet all of the obligations of their members for a fee.
- Most systems operate only in single Member States although there are a few that operate in several States. It is possible for producers to meet their obligations individually but very few find that this is feasible. Some States such as the UK and Germany have multiple PCS, whereas many other States have very few systems and in some of these (e.g. Holland) there is only one system for each type of product. A few States including Belgium have only one national PCS although producers can “go it alone” if they wish.
- The situation with distance sellers, i.e. companies that export equipment directly to users in other countries, is complex and treated differently in the Member States. These sellers are required by some Member States to join the compliance system in the country in which they put EEE on the market.

3.4. Promotional measures for design change

- The aim of the financial mechanisms of the Directive is clearly to encourage preventive measures at the design/production stage. During recent years, methods have been established to integrate the

problem of waste and other environmental aspects in the product development process. In the field of electronics, recent years have, for example, seen the creation of a PC-based tool for the "eco-conscious design of electrical and electronic equipment".

- In addition to improvement of design, a review of the production process as such can improve the resource efficiency of the products and thus reduce waste creation. The tools for increasing the efficiency of production processes are internal and external quality and eco-management (such as ISO 9000, the ISO 1400 series, EMAS and supply chain management). The LIFE+ Programme can provide some financial resources for innovative investments in this field.
- WEEE Directive reinforces the main idea of individual producer responsibility to spur design changes for easier recycling. Financing models should promote better design for the environment (and human health) and be able to make cost savings by designing products that have less environmental impact and are simpler to recycle.

3.5. Guidance documents

When planning implementation of the WEEE and RoHS Directives candidate countries should consult various studies facilitating interpretation of the relevant Directives but also providing examples of practices and different approaches to implementation. Studies concerning WEEE Directive implementation are available at: http://ec.europa.eu/environment/waste/weee/events_weee_en.htm

Recent studies relevant for WEEE implementation include:

‘Study on harmonisation of the format for registration and reporting of producers of electrical and electronic equipment (EEE) to the national register and on the frequency of reporting’ (2016)

‘Study on WEEE recovery targets, preparation for re-use targets and on the method for calculation of the recovery targets’ (2015)

‘Study on collection rates of waste electrical and electronic equipment (WEEE)’ (2014)

‘Study on the review of the scope of Directive 2012/19/EU on WEEE’ (2013)

‘Study on equivalent conditions for WEEE recycling operations taking place outside the European Union’ (2013)

In addition, the Commission developed two documents, the so-called Frequently Asked Questions (FAQ) documents, with an aim to clarify certain aspects of Directives 2012/19/EU and 2011/65/EU. FAQ document for WEEE Directive (2014) can be obtained at: <http://ec.europa.eu/environment/waste/weee/pdf/faq.pdf>, whereas RoHS FAQ guidance document (2012) is available at: http://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf.

4. COSTS

Overall, the costs for implementing the WEEE and RoHS Directives will be shared between the public and private sector but with the private sector being expected to take on the largest share for collecting, treating, recycling/recovering, transport and final disposal of WEEE as well as for making the necessary adaptations to materials, product design and production processes to ensure compliance with the restrictions on using certain substances, materials listed in the RoHS Directive. WEEE falls in the group of EU legislation laying down producer responsibility implying that most of the responsibilities and costs are to be taken on by industry. In this regard, EEE producers are likely to bear the majority of the costs of treating and recovering. Distributors and business users are likely to bear costs in relation to free take-back. Local authorities may bear some costs as a result of increased separate collection, but they will benefit from avoiding the costs associated with the current landfilling or incineration.

The financial burden for local authorities is mainly relating to market surveillance, monitoring, supervision, data collection and reporting systems to ensure compliance with the obligations in the WEEE and RoHS legislation. Costs for the public sector regarding the actual collection, recycling, recovery, treatment and disposal of WEEE largely depends upon whether the WEEE is from products put on the market prior to 13 August 2005 (historic waste) or after this date (new WEEE), and on whether the waste is from private household users or from users other than private households (e.g. industrial users, business sector). For instance, the financial burden for local authorities is greater for historic waste, and in particular for WEEE deriving from users other than private households (e.g. professional users such as the business sector, industry etc.), since Article 13 established a provision to mitigate the economic burden on EEE producers by limiting the mandatory financial responsibility for the collection, treatment, recovery and disposal of WEEE from professional users with respect to products put on the market prior to 13 August 2005. For such historic WEEE from professional users, EEE producers are only obliged to cover the costs of waste management when WEEE is replaced by a new equivalent product fulfilling the same function, i.e. on the basis of the old-for-new rule. Member States can also provide that other users are made totally or partly responsible for the financing of the waste management costs.

Hence, Member States have some flexibility in deciding how to allocate the financial liability for historic waste. Where historic waste is taken back by producers or retailers upon the purchase of new EEE, Member States can choose whether to make producers completely liable or to have the costs for collecting, storing, disassembling, recycling and disposal shared between the producers, municipalities and other users (other than private households), such as retailers and importers, amongst others. Producers and users can enter into agreements on how to share the financial burden. Where WEEE is discarded without the purchase of a new equivalent product fulfilling the same function, the financing of the collection, recovery and disposal should be provided by users other than private households.

For new WEEE, there is less flexibility and producers should, in principle, be fully responsible for all the waste management, although some Member States still share some of the financial burden for this waste management. Additional cost factors are:

- the costs of covering the management of WEEE from free-riders, e.g. producers that are not part of well-established WEEE collection and recovery schemes and that state that they will establish individual schemes but do not fulfil these tasks properly;
- the management of WEEE dumped in nature or otherwise not properly disposed of.

In as far as the costs borne by producers and/or distributors are passed on to consumers, it is expected that consumers will also bear some costs. Some Member States choose to impose a mandatory environmental fee on WEEE, mainly to provide consumer information about the environmental costs involved in the disposal and recovery of certain WEEE. The European Commission estimates that the WEEE Directive will result in average price increases of 1% for most products, and 2 to 3% for some products, such as refrigerators and televisions. However, with falling prices for a large range of EEE, the additional costs passed on to consumers are likely to have no more than a negligible impact on their purchasing power and on the market overall.

The costs for implementing and complying with the RoHS Directive differ slightly from those related to the WEEE Directive, as RoHS restricts the use of certain substances and components. By imposing such restrictions, it obliges, in absence of exemptions, EEE producers to make design changes to ensure compliance with the Directive and to cater to changing consumer preferences.

The main costs here are borne by the EEE industry, rather than local authorities. The actual distribution of the costs of the RoHS Directive depends on the market structure of the particular sector concerned. The extent to which costs are passed on to consumers also depends on how easy it is to make the design changes (e.g. whether it is cumbersome and expensive to substitute materials, substances etc.). In the short term, component suppliers are likely to be substantially affected and to bear a large share of the costs. For instance, a supplier of components or materials not meeting the requirements in the RoHS Directive will not be able to supply their products and it is expected that some of these operators will disappear from the market. On the other hand, RoHS provides economic opportunities for producers and suppliers of more environmentally friendly components. However, in the medium to long term they are likely to pass these additional costs on to product assemblers and/or manufacturers. The magnitude of this pass-on will again depend on the relevant market structure.

Table 29. Types of implementation costs

Planning and organisational
<ul style="list-style-type: none"> • Costs for establishing competent authorities and ensure coordination with authorities responsible for other producer responsibility waste streams (batteries, ELVs and packaging) and for shipment of waste (costs for public sector) • Costs for transpositional measures and policy documents (mainly costs for public sector) • Costs for information campaigns and awareness raising (shared between public and private sector) • Costs for setting up producer responsibility organisations responsible for the collection, recycling, recovery, treatment, transport) (costs mainly for the private sector) • Costs for setting up a producer registry (costs for the public sector) • Setting up inspection and enforcement mechanisms (mainly for the public sector) • Procedures for certificate of conformity, verification, market surveillance • Technical guidance, transposing EN standards
Capital investments
<ul style="list-style-type: none"> • Costs for setting up the necessary facilities, e.g. temporary storage, collection stations, transport system, recovery and recycling facilities, including pre-treatment (mainly for producers regarding new EEE and partly shared for historical waste) • Costs for possible adaptations to concerned facilities to ensure compliance with the Directives • Investments into IT' equipment and software for collecting, processing and sharing data (both for the public and private sector) • Investments into the research for design changes to develop EEE with less complex and dangerous components and substances, which are easier to dismantle, re-cover and recycle (mainly for the private sector)
Operational
<ul style="list-style-type: none"> • Costs for running the collection, pre-treatment centers and facilities for recover and recycling (mainly for the private sector, apart from non-household WEEE and WEEE which is dangerous to handle, which partially can be financed by the public sector) • Costs for the supervision of producer responsibility organisations/producer compliance systems and their collection and recovery schemes (mainly for the public sector except for systems of self-compliance) • Costs for the transport of WEEE within the Member State or to be exported to another Member State or third country for recycling or recovery (mainly for the private sector) • Costs for the market surveillance with procedures for product withdrawal and information to suppliers (divided between public and private sector)
Monitoring and enforcement
<ul style="list-style-type: none"> • Costs for monitoring compliance with collection, recovery and recycling targets (also for the private sector in case of privately financed and administered collection and recycling schemes) • Costs for monitoring compliance with private agreements between competent authority and private sector (shared between public and private sector) • Adapt sanctioning system to provide for penal sanctions in case of non-compliance (mainly for the public sector)
Information and reporting

- Costs regarding data collection and statistics (both for the public and private sector)
- Reporting to the Commission (mainly for public sector)
- Reporting to the competent authority and information sharing (for the private sector)
- Information sharing regarding withdrawn EEE, properties of EEE to pre-treatment centres, to private and professional users (shared between public and private sector)

THE EXTRACTING WASTE (MINING) DIRECTIVE

Official Title: Directive 2006/21/EC of the European Parliament and of the Council of 15 March 2006 on the management of waste from extractive industries and amending Directive 2004/35/EC (OJ L 102, 11.04.2006), as amended by Regulation (EC) 596/2009¹⁸³ (OJ L 188, 18.7.2009),

Implementing legislation:

Commission Decision 2009/337/EC of 20 April 2009 on the definition of the criteria for the classification of waste facilities in accordance with Annex III of Directive 2006/21/EC of the European Parliament and of the Council concerning the management of waste from extractive industries (OJ L 102, 22.4.2009)

Commission Decision 2009/335/EC of 20 April 2009 on technical guidelines for the establishment of the financial guarantee in accordance with Directive 2006/21/EC of the European Parliament and of the Council concerning the management of waste from extractive industries (OJ L 101, 21.4.2009)

Commission Decision 2009/360/EC of 30 April 2009 completing the technical requirements for waste characterisation laid down by Directive 2006/21/EC of the European Parliament and of the Council on the management of waste from extractive industries (OJ L 110, 1.5.2009)

Commission Decision 2009/359/EC of 30 April 2009 completing the definition of inert waste in implementation of Article 22(1)(f) of Directive 2006/21/EC of the European Parliament and the Council concerning the management of waste from extractive industries (OJ L 110, 1.5.2009)

Commission Decision 2009/358/EC of 29 April 2009 on the harmonisation, the regular transmission of the information and the questionnaire referred to in Articles 22(1)(a) and 18 of Directive 2006/21/EC of the European Parliament and of the Council on the management of waste from extractive industries (OJ L 110, 1.5.2009)

¹⁸³ Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four

1. SUMMARY OF THE MAIN AIMS AND PROVISIONS

This Directive, which entered into force on 1 May 2008, addresses the management of waste resulting from the prospecting, extraction, treatment and storage of mineral resources and the working of quarries, which is referred to in the Directive as "extractive waste". It provides for measures, procedures and guidance to prevent or reduce as far as possible any adverse effects on the environment and any resultant risks to human health brought about as a result of waste generated from the extractive industries. The objective of the Directive expressed in Article 4 is to ensure that extractive waste is managed without using processes that could harm human health or pose environmental risks. In this regard it targets, in particular, adverse effects on water, air, soil, fauna, flora, the landscape and places of interest, as well as the curbing of noise and odours. The Directive imposes the following measures to meet its objective:

- A waste management plan for extractive waste;
- Major accident prevention measures and the provision of information to that effect;
- Rules for applications and permits for extractive waste facilities;
- Classification of extractive waste facilities;
- Measures addressing excavation voids;
- Rules on the construction and management of extractive waste facilities;
- Rules on the closure and after-closure procedures for extractive waste facilities;
- Inspections of extractive waste facilities by the competent authority;
- Inventory of closed extractive waste facilities;
- Prevention of air and soil pollution as well as water status deterioration;
- Controls to prevent transboundary harm;
- Financial guarantee provisions;
- Applicability of the Environmental Liability Directive;
- Rules for public participation;
- Exchange of information with the Commission and other Member States;
- Penalties.

The Directive has three annexes. Annex I lists the major-accident prevention policy and information that is to be communicated to the public concerned. Annex II lists waste characterisation criteria; and Annex III lists criteria for determining the classification of waste facilities, establishing when a waste facility is to be classified as belonging to Category A.

Category A waste facilities are those posing a higher risk to the environment and human health.

The Directive excludes from its scope extractive waste resulting from:

- offshore activities;
- the injection of water or re-injection of pumped groundwater;

- the extraction, treatment and storage of peat, unless deposited in a Category A waste facility.

It also excludes inert waste and unpolluted soil resulting from the prospecting, extraction, treatment and storage of mineral resources and the working of quarries, unless such waste is deposited in a Category A waste facility.

The Mining Directive has been amended and several implementing measures have been adopted:

- Regulation (EC) No 596/2009: this Regulation introduces the regulatory procedure for the amendment of non-essential elements of the Directive.
- Commission Decision 2009/335/EC: This Decision aims at establishing a common approach between the Member States regarding the financial guarantee referred in Article 14 of the Directive (e.g. the relevant information and method of calculation of guarantee applied)
- Commission Decision 2009/337/EC: this Decision defines the criteria for the classification of waste facilities in accordance with Annex III of the Mining Directive, defines the meaning of loss of structural integrity or incorrect operation of a waste facility, which is crucial for determining whether a waste facility should be classified under Category A in accordance with the first indent of Annex III of the Mining Directive.
- Commission Decision 2009/358/EC: this Decision aims to establish minimum requirements for ensuring an harmonized, timely and appropriate gathering and transmission of the information referred to in Article 7(5), 11(3) and 12(6) of the Mining Directive and to set the basis for the questionnaire referred to in Article 18(1) of the same Directive (which had to cover, for the first time, the period from 1 May 2008 to 30 April 2011 – had to be transmitted to the Commission by 1 February 2012).
- Commission Decision 2009/359/EC: this Decision clarifies the definition of inert waste.
- Commission Decision 2009/360/EC: this Decision establishes requirements concerning the operator's obligation to characterise waste in terms of procedures to be adhered, information to be obtained but also regarding the obligation to collect and evaluate certain information and to draw up a sampling plan.
- Also CEN is developing harmonised EU-level standards In accordance with Article 22 (1) (b and f), the Commission has also given a mandate to CEN in order to develop the required standardised sampling and analysing methods. These standards are expected to be finalised in 2013.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Identify operators generating extractive waste and waste facilities that manage extractive waste, assessing the classification of waste in accordance with Annex II and facilities in accordance with Annex III of the Directive. Ensure that this assessment takes into account the criteria and methodology to interpret the notions of loss of structural integrity, or due to incorrect operation of a waste facility could lead to:
 - non-negligible potential for loss of life;
 - serious danger to human health;
 - serious danger to the environment, which are laid down in Decision 2009/337/EC and its two annexes.
- Plan the permitting procedure as all operators must first obtain a permit pursuant to Article 7. Ensure that the permit application contains the elements specified in Art. 7(2), e.g. the identity of the operator; the proposed location of the waste facility, the waste management plan pursuant to Article 5; a financial guarantee or equivalent, information provided by the operator in accordance with the EIA Directive if an EIA will be required. The permit must also clearly indicate the category of the waste facility in accordance with the criteria referred to in Article 9.
- Identify which are the best disposal options in the short and long term for inclusion in waste management plans in accordance with Article 5.
- Identify the responsibilities of the competent authorities that will be responsible for fulfilling the different obligations of the Directive, namely regulation, compliance monitoring, enforcement, co-ordination with the public and the stakeholders, and reporting to the Commission, to other Member States, to the competent authorities and to the general public. Identify any additional capacity-building needs to implement the Directive.
- Identify the stakeholders that are involved in order to facilitate co-ordination and to ensure that there is no duplication of roles or uncertainties regarding responsibilities.
- Identify any extractive waste facilities that are likely to cause transboundary harm and, in consultation with stakeholders, discuss best-practice methodologies and procedures to implement the obligations under Article 16 of the Directive.
- Provide information and promote the use of the Reference Document on Best Available Techniques for the management of tailings and waste-rock in mining activities covers activities related to tailings and waste-rock management of ores that have the potential for a significant environmental impact. These techniques are so-called „good practices” for mining techniques and mineral processing relevant to tailings and waste-rock management. (Refer to DG ENV: <http://ec.europa.eu/environment/waste/mining/bat.htm>)

- Assess existing waste management application and permit systems to ensure conformity with Article 13 of the Directive and to determine whether any further legal, administrative and logistical measures are required.
- Identify monitoring procedures for extractive waste management facilities to ensure compliance with the Directive from construction to operation, as well as closure, after closure and rehabilitation.
- Ensure that for Category A waste facilities, pursuant to Article 6, except for waste facilities which instead are covered by Seveso III Directive 2012/18/EU, the operator (prior to starting operations) draw up a major-accident prevention policy for the management of extractive waste and put into effect a safety management system and a safety manager to implement it. The operator must also put into operation an internal emergency, specifying the measures to be taken in case of accidents. These measures include proper identification of major-accident hazards and that the necessary features are incorporated into the design, construction, operation and maintenance, closure and after-closure of the waste facility in order to prevent such accidents and to limit their adverse consequences for human health and/or the environment, including any transboundary impacts.
- The competent authority must draw up external emergency plan specifying the measures to be taken off site in the event of an accident. This plan is mainly based on the information submitted by the operator when applying for the permit.
- Ensure procedures for the proper assessment of waste characteristics to be able to define them as inert waste, taking into account the criteria set out in Decisions 2009/359 and 2009/360 and determine whether, with the view to facilitate the correct interpretation of the Mining Directive and its scope, to draw up lists of waste materials to be regarded as inert in accordance with the criteria defined in Decision 2009/359/EC.
- Ensure procedures for the annual submission of information and the report referred to in Article 7(5), 11(3) and 12(6) of the Mining Directive (annual information covering the period between 1 May and 30 April of the following year; first report was due in 2012), which should take into account the requirements and information listed in Decision 2009/358/EC. This information should also comprise elements relevant to the external emergency plans under Article 6 of the Directive. For instance, pursuant to Art. 6(5) Member States must inform the public concerned about external emergency plans to be drafted and ensure that the relevant information is made available, including, inter alia, information about the right to participate in the decision-making process.

2.2. Regulation

2.2.1. Basic regulatory obligations

- Article 4 of the Directive provides the ultimate objective of the legislation transposing the Directive. The general regulatory requirements are:
 - to ensure that extractive waste is managed without endangering human health and without using processes or methods that could harm the environment, and in particular without risk to water, air, soil and fauna and flora, without causing a nuisance through noise or odours, and without adversely affecting the landscape or places of special interest;

- to prohibit the abandonment, dumping or uncontrolled depositing of extractive waste.
- The obligation to prevent or reduce adverse effects on the environment and human health is to be imposed upon the operator managing the extractive waste, who is to be made legally responsible for:
 - managing the waste facility from construction to closure and post-closure;
 - the prevention of major accidents involving the facility; and
 - taking measures to limit the consequences of major accidents for the environment and human health. (Art. 4, Mining Directive)
- The establishment of competent authority/ies responsible for the regulation of extractive waste management operations, compliance monitoring, enforcement, co-ordination with stakeholders including transboundary dealings with the competent authorities of other Member States, and the carrying out of reporting requirements towards the public and the Commission.
- Effective, proportionate and dissuasive penalties should be included in national legislation transposing this Directive for infringement of the obligations imposed thereunder. Measures must be included in national legislation to ensure that these penalties are implemented. (Art. 19, Mining Directive, see also Environmental Crimes Directive (2008/99/EC))

2.2.2. Specific regulatory obligations for operators

- Ensure a correct characterisation of waste, in compliance with Decision 2009/360/EC, ensuring that this characterisation:
 - cover the categories of information as specified in the Annex to the Decision (i.e. background information; geological background of deposit to be exploited; nature of the waste and its intended handling; geotechnical behaviour of the waste; and geochemical characteristics and behaviour of the waste;
 - take into account the criteria for defining inert waste as laid down in Decision 2009/359/EC where assessing the geochemical behaviour of waste (inert waste is only subject to the relevant part of geochemical testing referred to in point 5 of the Annex). (Art. 1, Decision 2009/360/EC)
- Ensure in determining what waste is inert the operator assesses it against the criteria both in the short and the long-term as set out in Decision 2009/359/EC and the assessment of the inert property of waste must be carried out in the framework of the waste characterisation referred in Decision 2009/360/EC. It must be ascertained that:
 - waste will not undergo any significant disintegration or dissolution or other significant change likely to cause any adverse environmental effect or harm human health;
 - waste has a maximum content of sulphide sulphur of 0,1 %, or the waste has a maximum content of sulphide sulphur of 1 % and the neutralising potential ratio, defined as the ratio between the neutralising potential and the acid potential, and determined on the basis of a static test prEN 15875 is greater than 3;
 - waste may be considered as inert waste without specific testing if it can be demonstrated, to the satisfaction of the competent authority, that the criteria set out in Art. 1(1) of this Decision,

supported by existing information or valid procedures or schemes. (Art. 1 and 2, Decision 2009/359/EC)

- The drawing up of a waste management plan with the same objectives as those listed in Article 5, which entails:
 - the prevention and minimisation of waste by taking the necessary measures at the design phase and through the choice of extracting methods:
 - assessing which type of treatment is required to prevent impacts on the environment following extraction;
 - reusing the extractive waste on site, for example by placing it in excavation voids and encouraging recovery, in accordance with the Directive
 - the prevention and reduction of the harmful effects of the management of extractive waste:
 - using less dangerous substances for the treatment of mineral resources;
 - ensuring the safe long-term and short-term disposal of extractive waste during design and operation and after the closure of the waste facility;
 - the classification of the waste facility in accordance with Annex III, which should take into account the specifics of Decision 2009/337/EC regarding criteria to take into account when classifying a waste facility as a Category A facility pursuant to the first indent of Annex III to the Mining Directive;
 - Category A waste facilities must provide, in their waste management plan:
 - a major-accident prevention policy;
 - a safety management system for implementation; and
 - an internal emergency plan
 - non-Category A waste management facilities must provide in their waste management plan:
 - justification for their non-Category A classification; and
 - identification of possible accident hazards
 - the waste management plan must also provide details of:
 - the amount of waste to be generated during operations;
 - the characteristics of the extractive waste;
 - the adverse effects on the environment and on human health resulting from the deposit of such waste;
 - the preventive measures that will be taken during operation and after closure in accordance with Article 11 (2);
 - a closure plan, including after-closure procedures;
 - measures for the prevention of water status deterioration in accordance with the Water Framework Directive (2000/60/EC), and for the prevention of air and soil pollution in accordance with Article 13;
 - a survey of the condition of the land that will be affected by the waste facility;
 - the best-practice tools that will be adopted to deliver appropriate safe management of the waste;
 - any information proving the operator's ability to meet the objectives of the waste management plan for evaluation by the competent authorities.

- demonstration that the management methods are tailored to the particular characteristics of the waste; the long-term stability of the waste; and that the stockpiling or permanent storage of large amounts of waste is avoided.
- A review of the waste management plan every five years and the effecting of the necessary amendments if there are any changes in operations and in the waste deposited by the facility. The operator is to notify the competent authorities accordingly. (Art. 5(4), Mining Directive)
- Take the measures to ensure the safety of waste management facilities referred to above, similar to those contained in the Seveso II and III Directives and including the appointment of a safety manager responsible for implementation. Such measures would apply to waste management facilities that are included as Category A waste facilities and that are not already included in the scope of the revised Seveso II Directive. (Art. 6, Mining Directive)
- Set up the infrastructure to communicate the necessary information to the public and the relevant services or authorities in the area in the event of a major accident. (Art. 6, Mining Directive)
- Provide for rehabilitation, restoration and clean-up following a major accident. Legislation should provide for the right of the competent authority to carry out such responsibilities at the operator's expense if necessary. (Art. 6, Mining Directive)
- Take adequate measures to reduce any dust or gas emissions. (Art. 13, Mining Directive)
- Take necessary measures when placing extractive waste back in excavation voids to prevent or minimise water status deterioration, and water and soil pollution. (Article 13, Mining Directive)
- Provide the necessary information to the competent authorities to ensure compliance with the Water Framework Directive and any other applicable EU legislation. (Article 13, Mining Directive)
- Comply with the discharge limits within the specified time frames provided in Article 13 (6), in the case of extractive operations resulting in a pond (defined in the Directive as a natural or engineered facility for disposing of fine-grained waste with varying amounts of water) involving cyanide. Provide, at the request of the competent authority, a risk assessment showing that concentration limits need not be further lowered.
- Provide information immediately, and not later than 48 hours after any event likely to affect the stability of the waste facility and any significant adverse effects this may cause to the environment and human health. The operator must implement an internal emergency plan and follow the instructions of the competent authority.
- Provide, prior to the commencement of operations, a financial guarantee to ensure an appropriate level of financial security such that sufficient funds are available to leave waste sites in a satisfactory state after closure, after becoming insolvent or even engaging in asset-stripping practices, and to rehabilitate land affected by a waste facility to a satisfactory state in the event that an operator defaults on their closure obligations. This is in line with a similar requirement in Article 8(a) (iv) of the Landfill Directive. (Article 14, Mining Directive)
- Comply with the permit conditions at all times, and keep up-to-date-records and make them available for inspection by the competent authorities.
- Ensure that there is an appropriate transfer of information, and update the records of the waste facility in the case of a transfer of ownership. Responsibility should rest with the first owner until the transfer

obligations are complied with and the necessary information has been submitted to the competent authorities.

2.2.3. Specific regulatory obligations on part of the competent authority

- The competent authority shall issue a permit for all extractive waste management operations and stipulate conditions that are to be imposed when issuing operating permits and authorising extractive waste management facilities, to ensure that the operator allows for sufficient environmental and safety measures. The permitting should be carried out in parallel with Article 4 on the application of the prevention principle, the necessity to take the necessary measures to ensure that extractive waste is managed without endangering human health and without using processes or methods which could harm the environment and applying the best available techniques as set out in the BREFs (see: <http://eippcb.jrc.ec.europa.eu/reference/>)
- The competent authority shall only issue a permit for an extractive waste management facility if the permit is accompanied by the following details, as a minimum:
 - identification of the operator;
 - location of the facility and any alternative locations;
 - a waste management plan in accordance with Article 5 - the competent authority must ensure that the operator prepares the waste management plan before it issues a permit- and any information related to Article 5 of the EIA Directive, where applicable;
 - the waste characterisation details and the collected information thereof that will feed into the waste management plan (see Decision 2009/360/EC);
 - detailed information that the operator is capable of managing the extractive waste in accordance with the waste management plan referred to in Article 28 of the Waste Framework Directive.
 - a financial guarantee that all obligations under the permit issued, including for closure and after closure of the facility, can be executed by the operator and that there is sufficient funding at any time for the rehabilitation of the land where the facility is located. The competent authority shall calculate the guarantee on the basis of Article 14 (2) (a) and (b) and take into account the information and method of calculation of the guarantee set out in Decision (e.g. the likely impacts on the environment and on human health of the waste facility; the definition of the rehabilitation including the after use of the waste facility; applicable environmental standards and objectives, the technical measures needed to achieve environmental objectives; measures required to achieve objectives during and after closure, including land rehabilitation, after closure treatment and monitoring if required; the estimated time scale of impacts and required mitigation measures; and an assessment of the costs necessary to ensure land rehabilitation, closure and after closure including possible after closure monitoring or treatment of contaminants, which has been performed by independent and suitably qualified third parties. (Decision 2009/335/EC)
- Set up the necessary arrangements to provide information to the public, at the earliest stages in the procedure of granting a permit (or whenever the information becomes available). The infrastructure

must be able to function on a national level and, where applicable, for transboundary consultations in accordance with Article 16.

- The information to the public, which should be provided by the competent authority, should include:
 - the application for the permit/details of amendments to a permit, where applicable;
 - whether transboundary consultations are required;
 - details regarding the competent authorities responsible for taking the decision and regarding which authorities can provide the relevant information;
 - details of the time frames that the public has for submitting questions and comments and for the competent authority to provide replies;
 - the nature of possible decisions that will be taken by competent authorities;
 - details on public participation arrangements. (Arts. 7 and 8, Mining Directive)
- The competent authority cannot take a final decision unless it provides the necessary procedures for the public to express comments and opinions to it beforehand. (Art. 8, Mining Directive)
- The competent authority is responsible for classifying the waste facility in accordance with the provisions of the Mining Directive, its Annex III and implementing Decisions. The competent authority determines whether it should be classified as Category A facility pursuant to the first indent of Annex III to the Mining Directive on the basis of the provisions and criteria set out in the Mining Directive and the implementing Decision 2009/337/EC (providing for detailed description of the notions of loss of structural integrity, incorrect operation, non-negligible potential for loss of life; serious danger to human health; and serious danger to the environment) either confirm or reject the operator's classification of the facility, which it submits together with the waste plan and the application for the permit. Articles 2-8 and Annex I and II to Decision 2009/337/EC provides detailed description of the elements of the classification comprising for instance:
 - a facility should always be considered Category A facility if the predicted consequences in the short or the long term of a failure due to loss of structural integrity, or due to incorrect operation of this facility could lead to: (a) non-negligible potential for loss of life; (b) serious danger to human health; and (c) serious danger to the environment (Art. 1(1), Decision 2009/337/EC);
 - a facility does not have to be classified as Category A where criteria in Article 7 of Decision 2009/337/EC are met (e.g. a site specific risk assessment, focusing on the effects of the hazardous waste was carried out as part of the classification based on the consequences of failure due to loss of integrity or incorrect operation, which demonstrated that it should not be classified as Category A);
 - the obligation to consider the entire life-cycle of the facility, including the after-closure phase, in the evaluation of the hazard potential of the facility (Art.1(2), Decision 2009/337/EC);
 - ensure that the structural integrity of a waste facility is defined as its ability to contain the waste within the boundaries of the facility, that the evaluation of loss of structural integrity covers all possible failure mechanisms relevant to the structures of the waste facility and that the evaluated consequences comprise the immediate impact of any material transported from the facility and the resulting short and long term effects (Art. 2, Decision 2009/337/EC);

- assess an incorrect operation of the waste facility and the resulting release of contaminants in accordance with Article 3 of Decision 2009/337/EC. This assessment should consider whether the incorrect operation may result in a major accident, should cover design issues and the possible malfunction of environmental protection measures and assess short-term and long-term effects and evaluate potential hazards;
 - assess the consequences of a failure due to loss of structural integrity or incorrect operation of a waste facility in accordance with Article 4 of Decision 2009/337/EC, taking into account the definition of potential for loss of life or danger to human health and the potential danger for the environment, determining whether the threat is serious or not;
 - determining whether human lives shall be deemed to be threatened due to loss of structural integrity for tailings dams, waste heap slides or waste-mass movements shall take into account the criteria and factors set out in Articles 5 and 6 of Decision 2009/337/EC (Article 9, Mining Directive and Decision 2009/337/EC).
- The competent authority shall instruct the operator to implement any other measures it deems necessary (apart from the measures in the internal emergency plan), if any events affect the stability of the waste facility and significant adverse effects on the environment and human health ensue. (Art. 12(5), Mining Directive)
 - The competent authority has the right to appoint an independent expert to verify the information that the operator may provide it with in order to prove its compliance with the permit conditions. (Art. 11, Mining Directive)
 - The competent authority may authorise the closure of an extractive waste management facility only after it has carried out an on-site inspection, assessed the reports submitted by the operator and certified the land affected as rehabilitated and reports to the operator accordingly. (Art. 12, Mining Directive)
 - The competent authority shall take over the operator's tasks for the closure of the facility to minimise or eliminate any environmental and health risks and may do so at the expense of the operator.
 - The competent authority shall ensure that the owner of every closed-down facility draws up an inventory. It shall make such inventory available to the public. (Art. 20, Mining Directive)
 - Ensure application of the Environmental Liability Directive in case of damage.

2.3. Monitoring and Enforcement

- Competent authorities have to monitor and supervise that extractive waste management facilities operate with a permit obtained after the operator:
 - has fulfilled all the requirements in accordance with Article 7;
 - has submitted a waste management plan in accordance with Article 5;
 - has had the classification of the waste management facility endorsed by it taking into account the specific provisions and criteria set out in Decision 2009/337/EC;

- has adopted all the necessary plans for major-accident prevention and handling in case of an occurrence;
 - has shown that the design, management of operations and closure will be carried out in accordance with the Directive;
 - has an adequate financial guarantee approved by it that is monitored regularly for any necessary readjustments;
 - has shown that it has the capacity to ensure stability as well as to prevent or minimise as far as possible adverse impacts on the environment and on human health in accordance with the Directive.
- The operator ensures that within the process of waste characterisation and drawing up a waste management plan, the operator has collected and evaluated all the information set out in Article 2 of Decision 2009/360/EC (comprising existing investigations and studies, existing permits, geological surveys, lists of inert waste, certification schemes, standards), ensuring that the quality is carefully evaluated and gaps in information filled and where need be that a sampling plan is drawn up in accordance with standard EN 14899 and that the full characterisation process is evaluated.
 - Operators of extractive waste management facilities strictly comply with the conditions stipulated in the permit from the design stage to the operations stage and up to the closure and post-closure phase.
 - Whether, in view of any changes undertaken by the facility or the availability of new techniques, more conditions need to be stipulated in the permit and/or whether existing conditions should be revised.
 - Operators of extractive waste management facilities strictly comply with the waste management plan in accordance with Article 5 and that operators review it regularly every five years.
 - Operators comply with the Landfill Directive (1999/31/EC) when using excavation waste to fill excavation voids and that they ensure stability, including after closure, in accordance with Article 10 of this Directive.
 - Operators manage the waste facility in a competent manner and that technical development and the training of staff are regular activities.
 - Operators keep their records up to date and that records are made available to the competent authority upon demand.
 - The construction or modification of existing facilities, as well as their management and maintenance, meet the necessary conditions to prevent pollution from point and diffuse sources in accordance with the Water Framework Directive (2000/60/EC), the Groundwater Directive (2006/118/EC), Directive 2008/105/EC on environmental quality standards in the field of water policy, and the provisions of Article 13 of this Directive.
 - Operators have the waste facility monitored and inspected by competent persons to ensure stability and take the necessary action if environmental harm or hazards to human health arise.
 - Operators who apply for their waste facilities to be declared closed must satisfy the conditions stipulated in Article 12 before and after it declares the facility to be closed.
 - A final on-site inspection has been carried out by it in order to declare the facility to be closed.
 - The inventory of closed-down facilities is regularly updated.

- Penal sanction is introduced for non-compliance with the provisions of the Mining Directive, also required by the Environmental Crimes Directive.

Operators have to ensure the following monitoring and data collection duties

- Ensure that within the process of waste characterisation and drawing up a waste management plan, all the information set out in Article 2 of Decision 2009/360/EC has been collected, assessed and evaluated comprising:
 - existing investigations and studies, existing permits, geological surveys, lists of inert waste, certification schemes, standards);
 - that the information satisfies the technical requirements set out in the Annex to Decision 2009/360/EC;
 - where information necessary for the characterisation of waste is missing, a sampling plan is drawn up in accordance with standard EN 14899 and Art. 2(4) of Decision 2009/360/EC;
 - that the full characterisation process is evaluated and information gaps filled;
 - that the final result of this information gathering and evaluation process is feeding into the waste management plan. (Article 2, Decision 2009/360/EC).

2.4. Reporting

- Member States must endow their competent authorities with the necessary capacity to fulfil, within the appropriate time frames and on a permanent basis, reporting requirements to the Commission under Article 7, 11 and 18 of the Directive. This is a legal obligation that is binding upon the competent authorities of candidate countries but need not be included in a national legal instrument. To this end:
 - the annual transmission of the information covering the period between 1 May and 30 April, to be submitted before 1 July of each year and comprise the information set out in Annex II to Decision 2009/358/EC in case there is an event referred to in Article 11(3) and Article 12(6) (Art 18(2) of the Directive);
 - the reporting on the implementation of the Mining Directive referred to in Article 18(1) of the Mining Directive should include the items in Annex III to Decision 2009/358/EC;
 - the information to be submitted to the Commission, upon request, under Art. 7 of the Mining Directive should include the items set out in Annex I to Decision 2009/358/EC.
- Candidate countries must, however, provide for legal instruments that render obligatory reporting/providing information to the public both upon request and also at regular intervals such as, for example, in state of the environment reports.
- The competent authority must be in a position to provide upon request information to the public, even in the case of transboundary consultations, and to the Commission on the implementation rules adopted. The exchange of information with other Member States is also obligatory.

- The operator has reporting obligations towards the competent authority, which must be provided for in the national legislation transposing the Directive. These obligations include:
 - the operator must report, on the basis of aggregated data, all monitoring results to the competent authorities to demonstrate compliance with permit conditions and increasing knowledge about waste and facility conditions. (Art. 11(3) and Art. 12(6));
 - notification to the competent authority in case of any events likely to affect the stability of the waste facility and any significant adverse environmental effects revealed by the control and monitoring procedures of the waste facility. This notification has to be done immediately and not later than 48 hours after the incident. (Art. 11(3), Mining Directive);
 - following closure of a waste facility, immediate notification of any events or developments likely to affect the stability of the waste facility, and any significant adverse environmental effects revealed by the relevant control and monitoring procedures. (Art. 12(6), Mining Directive)

2.5. Additional Legal Requirements

- Directive on Waste (2008/98/EC) lays down general provisions and principles for the handling of waste, but excludes waste resulting from prospecting for, extracting, treating and storing mineral resources and the working of quarries where they are already covered by other legislation.
- The Landfill Directive (1999/31/EC): as this Directive does not cover waste from the extractive industries, it is important to ensure that waste generated from mineral extraction operations are exclusively subject to the provisions of the Mining Directive.
- Industrial Emissions Directive (2010/75/EU) provides that all installations covered by its Annexes are required to obtain an operating permit from the competent authorities in the Member States. Although extraction activities as such are not specifically addressed by the IED/IPPC, certain metallurgical activities, mineral processing activities, chemicals production activities and landfill activities (involving waste other than inert waste) fall within the scope of the Directive. Thus, if extraction is carried out as a "directly associated activity" to any of the activities listed in the IED/IPPC Directive, it must be covered by an IED/IPPC permit.
- SEVESO III Directive (2012/18/EU) aim to contribute to the prevention of major accidents that involve dangerous substances. In addition, it seeks to limit the adverse consequences of such accidents for human health and the environment. The Mining Directive complements the Seveso III Directive because Article 2(2)(e) of the latter Directive excludes from its scope the main activities of the extractive industries, namely exploration, extraction and processing, of minerals in mines and quarries, including by means of boreholes. Moreover, Article 2(2)(h) excludes "waste landfill sites".
- Water Framework Directive (2000/60/EC) establishes a general framework for the protection of all waters. It aims to prevent pollution at source and sets out control mechanisms to ensure the sustainable management of all pollution sources. The Water Framework Directive also has the potential to ensure that pollution originating from abandoned waste management facilities of extractive industries is properly addressed. It is referred to in the Mining Directive as a legal standard to prevent water status deterioration by extractive waste management.

- Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy
- Environmental Liability Directive (2004/35/EC): extractive waste management facilities are now included as one of those operative industries that are bound by strict environmental liability under this Directive.
- Environmental Crimes Directive (2008/99/EC) covers the Mining Directive and requires Member States to ensure a national legal framework is in place to impose penal sanctions in case of non-compliance.
- EIA Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment, . This Directive provides that projects that are likely to have significant effects on the environment are made subject to an environmental impact assessment (EIA) prior to development consent being given. The annexes to the Directive, which list those activities that are likely to have significant environmental impacts and that are to be subject to an EIA, include the extractive industry, particularly quarries and open-cast and underground mining and drillings.
- Commission Regulation (EC) No. 1418/2007 concerning the export and recovery of certain waste listed in Annex III or IIIA to Regulation (EC) No. 1013/2006 to certain countries to which the OECD Decision on the control of transboundary movements of waste does not apply, as amended by Regulation (EC) 740/2008 and (EC) 967/2008
- Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the checklist below. The tasks are arranged under subheadings and organised in chronological order of implementation wherever possible.

Table 30. Checklist with key implementation tasks

THE MINING DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Identify existing extractive waste facilities in accordance with Annex III of the Directive and Decision 2009/337/EC, including those that are likely to cause risks to the environment and to human health at a transboundary level. Identify streams of extractive wastes in accordance with Annex II of the Directive.
1.2	Identify the competent authority/ies that should act as regulators and the stakeholders involved in the extractive waste management processes. Ensure a proper delineation of roles and duties to avoid gaps and the duplication of work.
1.3	Hold discussions with stakeholders to identify the best disposal options and best available techniques to implement the obligations of the Directive in order to estimate their soundness, efficiency, feasibility and cost-effectiveness.
1.4	Organise meetings to determine how to co-ordinate the implementation of the Directive with competent authorities in other Member States likely to be affected at a transboundary level.
1.5	Assess capacity-building requirements to process applications and issue permits, review the classifications, waste plans submitted by the waste facility operators, issue technical guidance and other support to the operators, provide information to the public in accordance with the Directive, and ensure regular monitoring, enforcement and sanctioning in case of non-compliance.
1.6	Ensure adequate monitoring procedures comprising ensuring that the operators collect and evaluates all relevant information (see Decision 2009/360/EC) necessary for waste characterisation and that in case of information gaps the sampling plan adhere to EN 14899.
1.7	Set up procedures, coordination measures and instructions for ensuring timely and adequate reporting covering the annual submission of the information referred to in Arts. 7, 5, 11 and the report referred to in Art. 18 of the Mining Directive ensuring that the items set out in Decision 2009/369/EC.
1.8	Determine the measures to ensure a correct interpretation of inert waste. For this the competent authorities may decide to draw up list of such wastes.
2	Regulation
2.1	Operators must address, prior to the commencement of operations, the category of the waste facility, the amount of waste likely to be generated and its characteristics, and the method of management, including monitoring and closure procedures, by producing a waste management plan.
2.2	Operators must in the process of drawing up a waste management plan characterise waste in accordance with Decision 2009/360/EC, ensuring that this characterisation covers the categories of information as specified in the Annex to the Decision and takes into account the criteria for defining inert waste as laid down in Decision 2009/359/EC where assessing the geochemical behaviour of waste (inert waste is only subject to the relevant part of geochemical testing referred to in point 5 of the Annex).
2.2	Operators must only operate waste facilities if they hold a valid permit and if they comply with the conditions stipulated therein to secure environmental and safety measures to protect the environment and prevent accidents.
2.3	Operators of Category A waste facilities, because they present a significant accident hazard, must develop a major-accident prevention policy (similar to the provisions in the Seveso II Directive) to minimise the risk of accidents and to plan for clean-up in the event that an accident occurs.

2.4	Operators must draw up closure plans to ensure that the land affected by the waste facility is restored to a satisfactory state.
2.5	Operators must provide a financial guarantee, prior to the commencement of operations involving the deposit/accumulation of waste in a waste facility. The guarantee, the value of which will be assessed by the competent authority, needs to be able to cover the costs of carrying out all obligations under the permit and of rehabilitating the land affected to a satisfactory state, and to cover any rehabilitation costs in the case of an accident or in the event that an operator defaults on their closure obligations. This financial guarantee must take into account the requirements regarding the elements, information and method of calculation set out in Decision 2009/335/EC which involves the engagement of independent and suitably qualified third parties.
2.6	Operators must ensure the prevention of pollution or its reduction to a minimum. Discharges from point and diffuse sources occurring at the facility and/or as a result of extractive waste management at the facility must comply with all the applicable EU environmental legislation. Operators must ensure long-term stability at the waste facility.
2.7	Operators must have the necessary capacity to provide information on a regular basis to the competent authority and must keep up-to-date records, showing compliance with the permit conditions. Operators must also be in a position to inform, with immediate effect, the competent authority and the public in case of an accident.
2.8	The competent authority must provide information to the public on a regular basis and cannot take any decisions on the issuing of a permit for an extractive waste facility to start operating unless it has consulted the public first and considered any comments and suggestions made. It must ensure that operators are in full compliance with permit conditions once they start operations.
2.9	The competent authority is responsible for the classification of waste facilities and ensure that the determining of whether the facility is Category A facility all the criteria and factors considering the assessment of structural integrity, incorrect operation and the assessment of long-term and short-term consequences and effects are in line with Decision 2009/337/EC
2.10	The competent reviews the waste characterisation carried out by the operator ensuring compliance with Decision 3009/360/EC
2.11	The competent authority can only allow an operator to close down a facility if it is satisfied, after an inspection, that the permit conditions were and are being complied with.
2.12	The competent authority shall take the necessary legal measures to include extractive waste management as an activity that falls within the scope of activities listed in Annex III to the Environmental Liability Directive (2004/35/EC).
2.13	The competent authority should ensure the correct interpretation and scope of inert waste taking into account the assessment criteria laid down in Decision 2009/359/EC and may decide to establish lists of inert waste.
2.14	Draw up an inventory of closed waste facilities, having regard to available guidance documents and best practices
3	Training and Capacity Building
3.1	Prepare and publish guidelines on the role of the competent authority/ies, explaining operators' duties and the rights of members of the public to be kept informed and to participate in the decision-making process with respect to the permitting and management of extractive waste facilities. This technical guidance should in line with the implementing decisions highlight factors to be considered when classifying Category A waste facilities, determining whether waste is inert or not. Technical guidance should be developed both for the competent authorities including enforcement and sanctioning authorities and the waste facility operators themselves. Guidance may also be produced for the third sector to assist them in their role as watch dogs and in better exercising their information and consultation rights pursuant to EIA Directive, Public Participation Directive and the Access to Environmental Information Directive.
3.2	Provide technical training to officers in public authorities involved in monitoring compliance and to waste facilities operators, addressing small and medium-sized industries in particular so as to facilitate compliance and organisational set-up. Train a selected group to ensure the quality control of data submitted from operators and monitoring exercises. Also, provide training in communication skills for officers who will handle public requests and queries.
3.3	Provide information to stakeholders, including those representing the relevant competent

	authorities. The technical training should also assist trainees in internal management processes.
4	Monitoring, Information Collection and Reporting
4.1	Provide information at regular intervals at a national level and set up an infrastructure to handle demands upon request by the public or public authorities, whether national or from other Member States.
4.2	Ensure that the operators, particularly for the waste characterisation process, prior to the drawing up of a waste management plan and the permit, ensure that all relevant information is gathered, collated and evaluated with information gaps addressed and if need be adhere to the EN 14899 standard sampling plan
4.3	Set up the necessary infrastructure to report to the Commission any information in accordance with the Directive, including: <ul style="list-style-type: none"> • experience gained in implementing the Directive; • measures taken to comply with the Directive; • transposition; • obstacles encountered in implementing the Directive.
4.4	Given the importance of good co-ordination amongst public authorities for the implementation of this Directive, consider the appointment of one contact point responsible for co-ordination supported by a co-ordination structure.

3.2. Phasing Considerations

Candidate countries are likely already to have formulated and started implementing a national waste management plan, which includes the extractive waste stream and extractive waste management facilities. Some national authorities may already be carrying out monitoring and supervisory exercises to ensure that extractive waste facilities comply with environmental legislation, but the Directive will help to ensure better synergy and integrated compliance. The competent authority/ies may not need much time to transpose the Directive, but before it can be transposed the national authorities need to ensure the necessary capacity building, both logistically and in terms of human resources. Considerable time needs to be spent to determine the best disposal options and best available techniques to implement the obligations of the Directive. This entails discussions with stakeholders in order to estimate the soundness, feasibility and cost- effectiveness of the available options.

Furthermore, candidate countries need to acquire expertise in developing a major-accident prevention policy (similar to the provisions in the Seveso III Directives) and plans for rehabilitation and damage containment in the event that an accident occurs. Competent authorities must train experts to assess whether preventive measures taken at the facilities are appropriate to eliminate as far as possible or prevent risks to the environment and human health. Similarly, the examination of closure plans submitted by the operator and data submitted by the operator as a result of compliance monitoring requires experts to assess quality control. Another time-intensive and challenging task is the estimation of the financial guarantees required by operators under the Directive. Other major tasks that are also likely to be time-consuming involve vetting waste management plans submitted by operators and setting up co-ordinating services to facilitate reporting, the exchange of information and data sharing at national and EU level.

The nature of the Directive also involves the need to assess the socio-economic impacts that the obligations upon operators of extractive waste facilities may have at a national level. It is recommended that, although there may be various competent authorities at the regional and local level, there should be one authority responsible for co-ordination and reporting to the Commission.

The Directive provided for specific time frames for compliance by Member States, which depend on whether the facilities are new or existing facilities. The major timelines and phasing conditions that apply to Member States:

- 1 May 2006, extractive waste had to be managed in compliance with Article 4(1) on the general requirement to prevent harm to the environment and to human health) and any other applicable EU legislation.
- 1 May 2012: existing facilities (those that have been granted a permit by 1 May 2008) had to comply with the Directive, with the exception of Art. 14(1)
- 1 May 2014: the requirement of a financial guarantee prior to the commencement of operations and the measures
- Article 13(6) (measures for ponds containing cyanide) come into force in accordance with the timetable set out in this article.
- Facilities that stopped accepting waste before 1 May 2006, that are completing closing procedures, or that will be effectively closed by 31 December 2010 will not be subject to Articles 5, 6(3)-(5), 7, 8, 12(1) and (2) and 14 (1)-(3) of the Directive.
- Waste facilities closed by 1 May 2008 are not bound by Article 24(1).

4. IMPLEMENTATION GUIDANCE

4.1. General

During the transposition phase, careful consideration must be given to a number of legal and organisational issues to ensure compliance and better co-ordination. Legal issues that need to be addressed, given the nature of the obligations of the Directive, include: principles of confidentiality, conditions under which to allow a request for information to be refused, the legal duties and responsibilities of competent authorities involved when carrying out compliance monitoring, managing data or exchanging such data. Training officers in all authorities that will be involved in the implementation of the Directive is essential, both for compliance purposes and good governance. The permitting requirements laid down should strike an appropriate balance between, on the one hand, the extent of the administrative burden falling on operators or competent authorities when applying for or delivering a comprehensive waste management permit and, on the other hand, the benefits arising in terms of environmental protection and accident prevention. The vetting of waste management plans and emergency plans as well as the drawing up of financial guarantees requires specific expertise.

Member States were required to transpose this Directive into national law by 1 May 2008, except for some transitional periods granted to existing waste facilities (see above under phasing conditions). It is to be noted that the mining waste previously was covered by the Waste Directive (2008/98/EC) and the Landfill Directive. The transposition of the Directive may in fact make use of existing legislation although the Mining Directive introduces specific requirements for the extractive industries and their management of waste. As a result, care should be taken to avoid duplication in permitting requirements.

Example from a Member State:

Hungary: The risk-based inventory of the mine waste facilities had to be made public by 1 May 2012. In Hungary, the relevant transposing legislative framework is Decree of 14/2008 (IV. 3) GKM adopting the Directive's provisions on the inventory, environmental risk assessment and ranking to the competence of the mining authority. The Eötvös Loránd Geophysical Institute (ELGI), in co-operation with the Geological Institute of Hungary (MAFI), delivered the inventory of mine waste facilities in Hungary, as contracted out by the Hungarian Bureau of Mining and Geology (MBFH).

The first step taken in implementing the inventory was the acquisition of the necessary archive data. This means in addition to the review of all closed mine waste facilities and visualization in maps, the basic spatial, environmental and demographic acquisition, data on the facilities. The data had to be armonized in a database system.

The pre-screening method used in the first phase of the risk assessment is based on the known environmental impacts and on the study of the source-pathway-receptor chain. The 'precautionary principle' is the most important aspect of risk assessment. Accordingly, if uncertainty emerges in data or in the risk ranking of the facility, the facility should be regarded risky and classified for further examination.

Facilities not passing the preliminary risk screening (pre-selection) and classified for further analysis were processed in next step for risk-based ranking (selection). There is no standard method available in the EU for risk-based ranking currently, and it relies on the Member States. In the present approach, the character of the facility (tailings or waste heap), the status of remediation, the size of the facility and the slope of the underlying topographic terrain is used to develop risk classes defining the risk rank of the facility.

In order to improve the presentation efficiency, ranking was simplified to the status of remediation and the facility size for visualization. Classes were developed both for tailings and waste heaps, emphasised by colour coding. The rest of preliminary screening (pre-selection) and ranking parameters can be inquired as facility attributes in the internet application provided.

Source: The report providing more detail on the inventory and environmental risk assessment of the closed mine wastes facilities is available at: <http://elginfo.elgi.hu/mwf/mwf2012E.pdf>

Example from a Member State

United Kingdom: as a general approach, the UK Government is seeking to ensure that the outcome is based on a proportionate and risk-based approach to the management of extractive waste. The Scottish Government's intention is to transpose the directive by modifying existing planning application procedures so that they explicitly incorporate most of the requirements of the Extractive Waste Directive. This option was preferred because in this manner, applications for the management of extractive waste would be considered as an integral part of the whole mineral extraction process, lessening the impact of development on local communities and ensuring that negative effects on the environment can be fully addressed. Pre-application discussions are already an integral part of the planning application preparation process and, in the case of the transposition of this Directive, would serve to manage the interface between planning, pollution and health and safety controls under this Directive.

Operators would need to assess whether their extractive waste facility falls within the scope of the Directive and, if so, whether an Article 7 permit is required to operate that facility. If such is the case, it is being proposed that operators must submit a planning application by 1 May 2010. This is considered to be the most appropriate way of ensuring that the directive's requirements, particularly those relating to public participation, are met. The application should include all the information, including the proposed waste management plan, to ensure compliance with the relevant requirements of the Directive. The application would address only those aspects of the operation involving the management of extractive waste. The planning authority would then determine the application and subject it to consultation within the relevant competent authorities and among the public. The planning authority would only grant planning permission if it were satisfied that the operation complied with all the relevant requirements of the Directive. Planning permission would supersede any other existing permits.

The consultation process referred to is particularly valid for compliance with the requirements of the Directive. As a result, the Scottish Government is proposing that the competent authorities involved be established by law as consultees on all new planning applications involving extractive waste. This will help ensure that all proposals satisfy the requirements of the Directive prior to the commencement of work. It is also envisaged that the transposing regulations will include an amendment to the definition of "development" in Section 26 of the Town and Country Planning (Scotland) Act 1997 to make explicit that "development" includes the "management of extractive waste". Furthermore, existing legislation permitting development rights relating to waste tipping at mines will be amended to ensure that planning permission would be required to undertake these activities.

In addition to a waste management plan, operators of waste facilities will be required to obtain a permit that complies with Article 7 of the Directive. Permits are subject to the further requirements of public participation and requirements relating to the construction and management of waste facilities, closure and after-closure procedures, the prevention of water status deterioration and air and soil pollution, financial guarantees and inspections by the competent authority.

Enforcement will continue to be complemented by existing environmental and health and safety legislation but it is envisaged that the transposition of the Directive would still need to include specific provisions to ensure compliance with the directive's requirements in Article 6 relating to major-accident prevention, which applies only to extractive industries listed in Category A of Annex III. These provisions would render it compulsory for industries falling within the scope of Category A, Annex III, to have a safety management system and emergency plans, as well as to provide the dissemination of information to people likely to be affected. Additionally, the new legislation would ensure that these industries would be legally bound to have the required capacity to provide competent authorities with the relevant information to address actual or potential environmental damage in case of an accident.

Closure procedures will be governed by existing planning conditions dealing with the restoration and aftercare of mineral sites, and existing health and safety and environmental legislation. However, to ensure that the relevant requirements of the Directive are met, the Scottish Government proposes to provide planning authorities with the power to impose additional planning conditions where necessary.

Source: The information is based on the "Mining Waste Directive: Consultation Paper" dated April 2008, published by the Scottish Government.)

4.2. Regulation

The definitions of the Directive must be carefully transposed and abided by, to ensure compliance with the Directive. Apart from the specific obligations in the substantive text of the Directive, special attention must be given to the annexes, which set out the legal obligations upon Member States with respect to the contents of major-accident policies, the information that must be communicated to the public concerned, the conditions for waste characterisation, and the criteria for classifying waste facilities. Article 2 sets the scope of the Directive, also listing which type of extractive waste is excluded from the Directive, and Article 4 sets the general requirements. Candidate countries must draw up parameters to determine criteria that would regulate the licensing of applicants who wish to initiate extractive waste management operations. However, the Directive sets out specific conditions according to which competent authorities may proceed with issuing a permit. The Directive requires competent authorities to ensure that the public is involved in the decision-making process (Art. 8), and that a waste management plan (Art. 5) that includes emergency plans for major-accident prevention and information (Art. 6), as well as closure plans (Art. 12) and a financial guarantee (Art. 14) are submitted and endorsed by it. The Directive sets out specific obligations that national authorities in candidate countries must require operators to comply with, both in the construction and the management of waste facilities (Art. 11).

National legislation should leave as little discretion as possible to the operators to ensure smooth implementation and uniform application. Provision should also be made in legal instruments to establish how requests for information may be made. In case it is considered inappropriate to include certain measures in a legal instrument because of their predominantly administrative nature, it is recommended that memoranda of understanding be drawn up to ensure smooth and uniform implementation. Transparency is of vital importance and the competent authority/ies, as the regulator, must keep the public informed on a regular basis. Any limitations to access and any derogations, on any grounds, must be interpreted in a very strict manner.

Examples from a Member State

Malta: The Directive is transposed through the Waste Management (Management of Waste from Extractive Industries) Regulations (2008), amended in 2011.

At the transposition planning stage, the Malta Environment and Planning Authority has been considering which is the best regulatory regime, particularly in the context of better regulation.

The policy objective is to prevent or reduce harm to the environment and resultant risks to human health, whilst minimising the regulatory burden on the quarrying industry, by the effective and timely transposition of Directive 2006/21/EC in Malta.

The intention is that regulations implementing the Directive's requirements, making use of all derogations and transitional provisions available, should come into force as soon as possible. The Malta Environment and Planning Authority has considered two main options for transposing the Directive:

- the planning and existing consents option;
- the environmental permitting option, with the competent authority being the Malta Environment and Planning Authority.

The authority's preferred option is transposition through environmental permitting.

Indeed, should option 1 be adopted, there would be an added burden on the Planning Directorate of the Malta Environment and Planning Authority, given that its main role is the planning and regulation of the use of land, whereas the Directive is concerned with the management of waste. However, the environmental permitting option has been specifically designed as a platform to deliver environmental permitting Directives at lower cost and in a more efficient way than would be the case should a stand-alone system be designed to deliver the directive's requirements.

Past evidence indicates that the environmental permitting option implemented by the Malta Environment and Planning Authority will be the least costly option overall, with slightly lower direct costs for industry and significantly lower costs for the Government.

4.3. Monitoring

The primary competent authority for implementing this Directive is usually the ministry of environment, or an agency for environmental protection, which shall be the regulator responsible for monitoring compliance and enforcement. Sub-national competent authority participation, however, will often be vital as accountability and everyday communications with stakeholders will also almost inevitably take place at the sub-national level. Extractive industries may also be regulated by other public bodies within a state. At the central government level, these may include government ministries for spatial planning, trade, statistics, resources, industry and enterprise. Other types of national bodies that may have regulatory powers and provide related services include environmental protection agencies, federations of industries, and trading and commercial bodies. At the regional and local level, monitoring may be carried out by sub-national or local environmental inspectorates or environment agency offices, local government offices, local planning authorities, and municipalities. Although the lead ministry or the focal point for the purposes of the Directive may be the environment ministry or the environment agency that would have the necessary regulatory and monitoring powers, other public authorities may also be involved to avoid duplication and to ensure a one-stop shop. However, ultimately there needs to be one authority that has overall responsibility.

Competent authorities are responsible for determining:

- compliance with the legal requirements for the granting of permits;
- the contents of waste management plans, including the construction and maintenance, as well as the closure and post-closure plans of waste facilities;
- waste characterisation;
- a hierarchy of preferred disposal options and techniques to be used, including reuse and recovery options;
- criteria for waste facility classification;
- the contents of emergency plans;
- assessment tools for quality control to ensure operators' compliance with permit conditions;
- public participation;
- the calculation of the financial guarantee cover;
- co-ordination of compliance with environmental legislation by the waste facilities;
- regular inspections and final inspections for closure permitting and the compilation of inventories for closed facilities;
- transboundary consultations;
- reporting to the Commission.

4.4. Enforcement

The Directive obligates Member States to include effective, proportionate and dissuasive penalties under national legislation for the infringement of obligations specified in the Directive. The Directive also imposes strict liability for extractive waste management facilities in case of environmental harm resulting from their operations as one of the activities listed in Annex III of the Environment Liability Directive (2004/35/EC).

There are a number of further information sources providing background information to the Mining Directive. These include:

- Summary of EU legislation on mining waste: http://europa.eu/legislation_summaries/environment/waste_management/l28134_en.htm
- Reference document on the best available techniques on the management of waste from extractive industries: <http://eippcb.jrc.ec.europa.eu/reference/>
- Guidance document for pre-selection methodology for developing an inventory required by Art. 20 of the Mining Waste Directive¹⁸⁴: http://www.geology.cz/extranet/sgs/ulozna-mista-tezebnihodpadu/registr-rizikovych-uloznych-mist/2011_GUIDANCE_DOCUMENT_PRE_SELECTION.pdf
- Reports:
 - Commission report (2007) on classification of mining facilities European Commission¹⁸⁵: http://ec.europa.eu/environment/waste/mining/pdf/mwfs_report_dec_07.pdf
- Studies:
 - Study on Establishment of guidelines for the inspection of mining waste facilities, inventory and rehabilitation of abandoned facilities and review of the BREF document - DHI (April 2012)
 - Final Report including Annexes are available at: <http://ec.europa.eu/environment/waste/mining/legis.htm>
 - Study on the impact of gold extraction in the EU- Bio Intelligence Service (April 2010)
 - http://ec.europa.eu/environment/waste/mining/pdf/IH_2010-001.pdf
 - Management of mining, quarrying and ore-processing waste in the European Union: <http://ec.europa.eu/environment/waste/studies/mining/0204finalreportbrgm.pdf>
 - A study on the costs of improving the management of mining waste: http://ec.europa.eu/environment/waste/studies/mining/mining_cost.pdf

¹⁸⁴ Guidance document for risk-based pre-selection protocol for the inventory of closed waste facilities as required by Article 20 of the Mining Waste Directive. Developed by Gerry Stanley, Gyozo Jordan and Tamas Hamor with the support of Michel Sponar.

¹⁸⁵ Classification of mining waste facilities (No. 07010401/2006/443229/MAR/G4), Final Report, prepared by DHI Water·Environment·Health in cooperation with the Swedish Geotechnical Institute and AGH, University of Science and Technology, Krakow for the European Commission, DG Environment, December 2007,

- Study on the "Classification of mining waste facilities"
http://ec.europa.eu/environment/waste/mining/pdf/mwfs_report_dec_07.pdf
- Study on Financial Guarantees and Inspections - Monte April 2008
http://ec.europa.eu/environment/waste/mining/pdf/EU_Final_Report_30.04.08.pdf

In accordance with Article 22 (2) (a, b and e), the Commission has given a mandate to CEN in order to develop the required standardised sampling and analysing methods. CEN has also been mandated for the interpretation of the definition of inert waste, pursuant to article 22 (2) c).

The Final Report, available at:

http://ec.europa.eu/environment/waste/mining/pdf/Final%20report_SA_CEN_395_2007_08.pdf, was published end of 2012. For more details on the standards, please check:
<http://www.cencenelec.eu/standards/ENpurchase/Pages/default.aspx>

5. COSTS

Table 31. Checklist with examples of implementation costs

<p>Planning and organisational costs (mainly for national government and competent authorities)</p> <ul style="list-style-type: none"> • Establish competent authorities and ensure sufficient resources and training of staff (if need be engage external experts) • Legislative drafting • Initial consultation • Institutional procedures for permitting, monitoring, supervision, information share and consultation with stakeholders and the public • Establish an adequate inspection framework • Establish information collection and reporting systems with associated software • Set up coordination mechanisms between national competent authorities in other Member States regarding transitional issues as well as coordination mechanisms between competent authorities responsible for implementation of other relevant legislation (e.g. Waste Directive, Water Framework Directive, the Landfill Directive, the IED Directive and the SEVESO Directive) • Establish a procedure and conditions for financial guarantee • Preparatory work for characterisation of waste, drafting a waste management plan and gathering and evaluating certain technical documentation • Issue technical guidance addressed to competent authorities and involved bodies, on the one hand, and operators, on the other
<p>Capital investments</p> <ul style="list-style-type: none"> • Certain hardware and software applications for permitting, monitoring, data collection and reporting streams • Investments into the waste facilities to ensure compliance (e.g. preventive measures, safety protocols, certain equipment, building/construction structures, pollution control devices) (mainly for the operator) • Ensuring a financial guarantee (for the operator) • After closure arrangements (mainly for operator)
<p>Ongoing expenses</p> <ul style="list-style-type: none"> • Safety and precautionary measures (mainly for the operator) • Sampling according to approved sampling methods (for operator) • Review of waste management plans (for operator) • Collect and report certain data (shared between competent authority and operator)

The Directive requires a financial guarantee, or equivalent, before the commencement of operations that involve the accumulation or deposit of extractive waste in a waste facility. A financial guarantee is only required if the waste is to be deposited in a Category A waste facility. This may not be considered as an added cost, since it is already required and may already have been deemed necessary before a planning application to extract minerals is approved. The Commission's upcoming guidelines will be used as a basis for quantifying the financial guarantees.

Existing and new sites that require an Article 7 permit may be subject to planning fees for the processing of applications. However, it may be the case that, since operators already pay for such planning fees in applications for a development permit, no additional fees will be necessary. Facilities coming under Category A in Annex II would also be subject to additional costs to fulfil the extra requirements imposed upon such facilities by the Directive.

Administrative costs for the authorities would depend upon the extent to which the transposition of the Directive would be integrated in the existing administrative structure. The Directive introduces specific requirements that would require Member States to invest in new personnel and to carry out additional permitting, application processing, monitoring and consultation.

For more information on financial aspects, the study on costs of improving the management of mining waste can be consulted at: http://ec.europa.eu/environment/waste/studies/mining/mining_cost.pdf

SHIP RECYCLING REGULATION

Official Title: Regulation (EU) No 1257/2013 of the European Parliament and of the Council of 20 November 2013 on ship recycling and amending Regulation (EC) No 1013/2006 and Directive 2009/16/EC (OJ L 330, 10.12.2013)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Regulation (EU) No 1257/2013 of the European Parliament and of the Council aims, amongst other things, to minimise and, to the extent practicable, eliminate adverse effects on human health and the environment caused by ship recycling and to facilitate the ratification of the 2009 Hong Kong International Convention for the Safe and Environmentally Sound Recycling of Ships. The Convention will enter into force 24 months after ratification by 15 States, representing 40 per cent of world merchant shipping by gross tonnage, combined maximum annual ship recycling volume not less than 3 per cent of their combined tonnage.

The Hong Kong Convention intends to address all the issues around ship recycling, including the fact that ships sold for scrapping may contain environmentally hazardous substances such as asbestos, heavy metals, hydrocarbons, ozone-depleting substances and others. It will address concerns raised about the working and environmental conditions at many of the world's ship recycling locations. Regulations in the Convention cover: the design, construction, operation and preparation of ships so as to facilitate safe and environmentally sound recycling, without compromising the safety and operational efficiency of ships; the operation of ship recycling facilities in a safe and environmentally sound manner; and the establishment of an appropriate enforcement mechanism for ship recycling, incorporating certification and reporting requirements. Ships to be sent for recycling will be required to carry an inventory of hazardous materials, which will be specific to each ship. An appendix to the Convention provides a list of hazardous materials, the installation or use of which is prohibited or restricted in shipyards, ship repair yards, and ships of Parties to the Convention. Ships will be required to have an initial survey to verify the inventory of hazardous materials, renewal surveys during the life of the ship, and a final survey prior to recycling. Ship recycling yards will be required to provide a Ship Recycling Plan, to specify the manner in which each individual ship will be recycled, depending on its particulars and its inventory. Parties will be required to take effective measures to ensure that ship recycling facilities under their jurisdiction comply with the Convention.

The EU Ship Recycling Regulation brings into force an early implementation of certain requirements addressed above. In particular, Articles 5(9), 7(2), 10(1), 10(2), 12(1) and 12(3) of that Regulation provide for the alignment of Union law with the Convention.

The EU Regulation (EU) 1257/2013 apply to large commercial seagoing vessels (ships of 500 gross tonnes and above) flying the flag of an EU Member State and to ships flying the flag of the third country calling at EU ports or anchorages. Warships, naval auxiliary or other ships owned or operated by a state and used on government non-commercial service are excluded from the scope of the Regulation.

The Regulation sets out a number of requirements for European ships, European ship owners, ship recycling facilities wishing to recycle European ships and the relevant competent authorities and administrations. It also requires the Commission to adopt a number of acts to implement the Regulation. One of the key acts to be adopted by the Commission is the European List of ship recycling facilities authorized to recycle ships flying the flag of an EU Member State, i.e. the Regulation's practical application depends on the issuance of the European List of ship recycling facilities. It should be noted that the European List will be published in the Official Journal of the European Union and on the website of the Commission by the end of 2016.

According to the new rules, the installation or use of certain hazardous materials listed in Annex I on ships will be prohibited or restricted. Each new European ship or a ship flying the flag of a third country calling at an EU

port or anchorage will be required to have on board an inventory of hazardous materials verified by the relevant administration or authority and specifying the location and approximate quantities of those materials.

Owners of ships flying the flags of EU Member States will have to ensure that their ships are only recycled in ship recycling facilities included in the European List. They will have to ensure that each end-of-life ship is prepared for recycling.

EU Member States' port authorities will be authorised to control European ships to verify whether they have on board a ready-for-recycling certificate or a valid inventory of hazardous materials.

To be included in the European List, any ship recycling facility irrespective of its location will have to comply with a number of requirements. The Commission will assess the applications received from the ship recycling facilities located in third countries. For facilities located in the EU Member States, it is the national authorities, which will indicate to the Commission, which facilities located on their territory are compliant.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Designate competent authorities responsible for implementing and enforcing the relevant provisions of the EU Ship Recycling Regulation with regard to authorisation of ship recycling facilities (Art. 18)
- Designate one or more contact persons responsible for informing or advising natural or legal persons making enquiries. (Art. 19)
- Establish the overall procedural framework as regards ship recycling authorisation procedure (Art. 14)
- Consider derogation stipulated in Article 32(4). The abovementioned provision refers to the situation of Member States which have no ships flying their flag or registered under their flag or have closed their national ship registers. Those Member States may derogate from certain provisions of the Regulation as long as no ship is registered under their flag.

2.2. Regulation

- Establish measures for ensuring compliance with the relevant obligations in the EU Ship Recycling Regulation relating to the authorisation of ship recycling facilities (Art. 14(1)). These measures should enable competent authorities to differ existing permits and approvals so that they also provide authorisation for the purposes of the EU Ship Recycling Regulation in order to avoid unnecessary duplication of information and work by operators of ship recycling facilities.
- Establish and update a list of the authorized ship recycling facilities in the country. (Art. 14(2))
- Ensure that ships maintain an inventory of hazardous materials in accordance with the relevant International Maritime Organisation (IMO) guidelines, which must be periodically verified by a recognised organisation. (Arts. 4 and 8)
- Ensure that ships are subject to:
 - an initial survey to be conducted before the ship is put in service or before an inventory certificate is issued. For existing ships, an initial survey must be completed by 31 December 2020;
 - renewal surveys conducted at intervals of no longer than five years;
 - additional surveys following any modifications or repairs that affect an inventory of hazardous materials; and
 - a final survey conducted prior to the ship being taken out of service in preparation for recycling. (Art. 8)

The surveys should be carried out by recognised organisations according to the relevant IMO guidelines and resolutions. After successful completion of an initial, renewal or additional survey, a recognised organisation must issue an inventory certificate, which is valid for up to five years. (Art. 9)

- Ensure that operator of the ship recycling facility develops ship-specific ship recycling plan prior to any recycling of a ship. (Art. 7)
- Ensure that ship owners comply with the general requirements stipulated in Article 6 of the Regulation, i.e. that their ships are only recycled in ship recycling facilities included in the European List. These include:
 - providing the necessary information about the ship to the ship recycling facility via a ship recycling plan,
 - notifying the intention to recycle the ship to the relevant administration,
 - providing an updated inventory of hazardous materials,
 - minimising the amount of cargo residues, remaining fuel oil and ship generated wastes remaining on board,
 - providing a ready-for-recycling certificate to the ship recycling facility.
- Lay down provisions on effective, proportionate and dissuasive penalties applicable to infringements of this Regulation and take all the measures necessary to ensure that they are applied. (Art. 22(1))
- Ensure cooperation, with other MSs in order to facilitate the prevention and detection of potential circumvention and breach of this Regulation. (Art. 22(2))

2.3. **Monitoring and Reporting**

- All foreign-flagged ships are subject to state control inspections and may be warned, detained, dismissed or excluded from ports or offshore terminals under jurisdiction of the Member State in the event of failure to comply with the requirements of the Regulation. (Art. 11 and 12)
- Every three years, Member States should report to the Commission on the following: (Art. 21)
 - a list of the ships flying its flag to which a ready for recycling certificate has been issued, and the name of the ship recycling company and the location of the ship recycling facility as shown in the ready for recycling certificate;
 - a list of the ships flying its flag for which a statement of completion has been received;
 - information regarding illegal ship recycling, penalties and follow-up actions undertaken by the Member State.

2.4. Additional Legal Instruments

The most relevant legislation that directly or indirectly concerns ship recycling:

- Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste: To ensure legal clarity and avoid administrative burden, ships covered by the Ship Recycling Regulation will be excluded from the scope of the Regulation (EC) 1013/2006
- Directive 2009/16/EC of the European Parliament and of the Council of 23 April 2009 on port State control
- Regulation (EC) No 391/2009 of the European Parliament and of the Council of 23 April 2009 on common rules and standards for ship inspection and survey organisations
- Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives
- Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in the implementation of the Regulation are summarised in the following checklist, organised in chronological order (where possible) within each subheading.

Table 32. Checklist with the regulations on shipments of waste key implementation tasks

THE SHIP RECYCLING REGULATION - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate a competent authority(ies) responsible for performing duties arising under the this Regulation.
2	Regulation
2.1	Establish measures for ensuring compliance with the relevant obligations relating to the authorisation of ship recycling facilities
2.2	Put in place procedures, as specified in the Regulation, to be used for the surveys and issuing certificates.
2.3	Provide guidance and training to implementing officers.
2.4	Ensure that all actors understand their duties, for example by disseminating information on the effects of the Regulation.
2.5	Establish a system for handling cases of illegal export.
2.6	Establish a monitoring system to ensure that the provisions of the Regulation are complied with. The system would include state port inspections.
2.7	Establish an effective enforcement system. Penalties applicable to infringements of this Regulation must be effective, proportionate and dissuasive. Procedures for ensuring cooperation with other Member States in order to facilitate the prevention and detection of potential circumvention and breach of this Regulation should be established. In this context, Member States must designate members of their permanent staff that will be responsible for the cooperation.
3	Reporting
3.1	Establish reporting and data recording and processing systems to ensure that the required data are collected.
3.2	Notify the Commission as per requirements in the Regulation.

4. IMPLEMENTATION GUIDANCE

The Ship Recycling Regulation entered into force on 30 December 2013. However, the Regulation's practical application depends on the issuance of the European List of Ship Recycling Facilities. Article 16(2) of the Regulation requires the List to be published by no later than 31 December 2016, while Article 32 provides that the Regulation applies from six months after the date on which the combined, maximum annual ship recycling output of ship recycling facilities on the list amounts to at least 2.5 million light displacement tonnes or from 31 December 2018, whichever occurs first. That means that effective application date could take place any time between mid-2016 and the end of 2018.

Various guidance documents and studies are available at:

http://ec.europa.eu/environment/waste/ships/studies_projects.htm and
http://ec.europa.eu/environment/waste/ships/global_policy.htm

4.1. Planning and Regulation

- Candidate countries should focus on implementation of Article 13 and 14 of the EU Ship Recycling Regulation due to the fact that the other Articles in the EU Regulation do not enter into force until a later date. The procedure for authorisation of ship recycling facilities should not impose unnecessary burdens on business. It should also implement a consistent method for authorising facilities, fully considering and integrating existing permitting, licensing and authorisation processes.
- Candidate countries should consider developing guidance documents providing practical information on application procedure, charging schemes, developing ship recycling facility plans, inspection manuals, etc.

5. COSTS

The implementation costs of administering this Regulation should not be significant. Most of the costs shall be borne by the operators. As Member States are obliged to introduce a system for authorisation of ship recycling facilities this will require some input in terms of administrative costs, as well as the cost of training. Charging schemes (fees for the application) should also be developed.

WATER PROTECTION

Section 5

1. INTRODUCTION AND OVERVIEW	722
1.1. EU Policy on Water Protection	722
1.2. EU Legal Instruments.....	727
2. DEVELOPMENT OF A SECTORAL STRATEGY AND IMPLEMENTATION PLAN	732
2.1. River Basin Management.....	732
2.2. Programme of Measures.....	734
2.2.1. Programme of measures under the WFD	734
2.2.2. Programme of measures under the MSFD	734
2.3. Combined Approach.....	735
2.3.1. Combined approach under the WFD.....	735
2.3.2. Combined approach under the MSFD.....	737
2.4. Cost Recovery	737
2.5. Public Consultation	739
3. INSTITUTIONS AND RELEVANT PARTIES.....	740
3.1. Stakeholders.....	740
3.2. Central Government Institutions.....	740
3.3. Competent Authorities	743
3.4. Regional and Local Government	746
3.5. Private Sector Involvement.....	746
3.6. Environmental Inspectorate	747
3.7. Communication and Consultation.....	748
4. TECHNICAL ISSUES	750
5. REGULATION AND ENFORCEMENT.....	751
5.1. Overview	751
5.2. Authorisations and Permitting	751
5.3. Monitoring, Inspection and Enforcement.....	752
5.4. Data Collection and Reporting.....	754
6. PRIORITIES AND TIMING.....	758
6.1. Prioritising the Implementation Tasks	758
6.1.1. General Considerations	758
6.1.2. Legislative Considerations.....	758
6.1.3. Cost-effectiveness.....	759
6.1.4. Economic Considerations.....	759

6.1.5.	Timescales.....	760
7.	ECONOMIC AND FINANCIAL ISSUES	762
7.1.	Introduction.....	762
7.2.	Institutional Development.....	762
7.3.	Water Facilities.....	763
7.4.	Cost Recovery.....	765
7.4.1.	Pricing.....	765
7.4.2.	Pollution and use charges.....	766
7.4.3.	Tradable permits.....	767
7.4.4.	Subsidies.....	767
7.4.5.	Deposit-refund systems.....	767
7.4.6.	Enforcement incentives.....	767
8.	SUMMARY OF KEY ISSUES	769
	THE URBAN WASTE WATER TREATMENT DIRECTIVE	771
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	772
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	774
2.1.	Planning.....	774
2.2.	Regulation.....	774
2.3.	Monitoring.....	775
2.4.	Information and Reporting.....	776
2.5.	Additional Legal Instruments	776
3.	IMPLEMENTATION	778
3.1.	Key Tasks.....	778
3.2.	Phasing Considerations	781
4.	IMPLEMENTATION GUIDANCE	783
4.1.	Planning and Regulation.....	783
4.2.	Information and Reporting.....	784
5.	COSTS.....	786
	THE NITRATES DIRECTIVE	788
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	789
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	790
2.1.	Planning and Regulation.....	790
2.2.	Monitoring.....	790

2.3.	Notifications/Reporting.....	791
2.4.	Additional Legal Instruments	791
3.	IMPLEMENTATION	793
3.1.	Key Tasks.....	793
3.2.	Phasing Considerations	795
4.	IMPLEMENTATION GUIDANCE	797
4.1.	Planning.....	797
4.2.	Technical Advice and Guidance.....	798
4.3.	Regulation	798
4.4.	Monitoring.....	799
4.5.	Consultation and Reporting.....	799
5.	COSTS.....	801
	THE DRINKING WATER DIRECTIVE.....	802
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	803
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	805
2.1.	Planning.....	805
2.2.	Regulation	805
2.3.	Monitoring.....	806
2.4.	Information and Reporting.....	807
2.5.	Additional Legal Requirements	807
3.	IMPLEMENTATION	809
3.1.	Key Tasks.....	809
3.2.	Phasing Considerations	810
4.	IMPLEMENTATION GUIDANCE	812
4.1.	Planning.....	812
4.2.	Standards and Reporting	813
5.	COSTS.....	814
	THE WATER FRAMEWORK DIRECTIVE.....	815
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	817
1.1.	Planning.....	821
1.2.	Regulation.....	823
1.3.	Monitoring.....	826
1.4.	Consultation and Reporting.....	829

1.5.	Additional Legal Instruments	831
2.	IMPLEMENTATION	833
2.1.	Key Tasks.....	833
2.1.1.	Obligations related to international river basin districts	834
2.1.2.	Tasks entailing co-ordination requirements between Member States.....	835
2.2.	Key implementation tasks	836
2.3.	Phasing Considerations	840
3.	TIMETABLE FOR ACTION	845
4.	COSTS.....	849
	THE GROUNDWATER DIRECTIVE.....	852
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	853
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	855
2.1.	Planning.....	855
2.2.	Regulation	855
2.3.	Monitoring.....	856
2.4.	Consultation and Reporting.....	856
2.5.	Additional Legal Instruments	857
3.	IMPLEMENTATION	859
4.	COSTS.....	860
	ENVIRONMENTAL QUALITY STANDARDS DIRECTIVE	861
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	862
2.	PRINCIPAL OBLIGATIONS ON MEMBER STATES	864
2.1.	Planning and Regulation.....	864
2.2.	Monitoring and Enforcement.....	865
2.3.	Consultation and Reporting.....	866
2.4.	Additional Legal Instruments	867
3.	IMPLEMENTATION	869
3.1.	Key Tasks.....	869
3.2.	Phasing Considerations and Priority Setting.....	872
4.	IMPLEMENTATION GUIDANCE	874
4.1.	Administrative Arrangements.....	874
4.2.	Regulation	875
4.3.	Technical Guidance.....	876

5. COSTS.....	878
THE BATHING WATER DIRECTIVE.....	880
1. SUMMARY OF MAIN AIMS AND PROVISIONS.....	881
2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	883
2.1. Planning.....	883
2.2. Regulation	884
2.3. Monitoring.....	885
2.4. Reporting	885
2.5. Additional Legal Instruments	886
3. IMPLEMENTATION	887
3.1. Key Tasks.....	887
3.2. Phasing Considerations	889
4. IMPLEMENTATION GUIDANCE	891
4.1. Planning.....	891
4.2. Monitoring.....	891
4.3. Preparation of Bathing Water Profile.....	893
5. COSTS.....	894
FLOODS DIRECTIVE	895
1. SUMMARY OF MAIN AIMS AND PROVISIONS.....	896
2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	898
2.1. Planning and Regulation.....	898
2.2. Consultation	899
2.3. Reporting	899
2.4. Additional Legal Instruments	899
3. IMPLEMENTATION GUIDANCE	901
3.1. Key Tasks.....	901
3.2. Co-ordination in International River Basins	903
3.3. Co-ordination with the WFD	903
3.4. Guidance Documents	904
3.5. Timetable for Action.....	905
4. COSTS.....	908
THE MARINE STRATEGY FRAMEWORK DIRECTIVE.....	909
1. SUMMARY OF MAIN AIMS AND PROVISIONS.....	910

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	912
2.1. Planning.....	912
2.2. Regulation	914
2.3. Monitoring.....	915
2.4. Consultation and Reporting.....	916
2.4.1. Reporting	916
2.5. Additional Legal Instruments	917
3. IMPLEMENTATION	920
3.1. Key Tasks.....	921
3.1.1. Planning	921
3.1.2. Coordination and Consultation.....	924
3.2. Key implementation tasks	926
3.3. Phasing Considerations	928
4. TIMETABLE FOR ACTION	930
5. COSTS.....	932

WATER PROTECTION – OVERVIEW

1. INTRODUCTION AND OVERVIEW

This section of the Handbook deals with EU legislation in the water protection sector. It contains an introductory overview of the sector followed by individual fiches for selected pieces of legislation.

1.1. EU Policy on Water Protection

Water is perhaps together with waste management, one of the most comprehensively regulated areas of EU environmental legislation. Early European water policy began already from the 1970s with the adoption of political programmes as well as legally binding legislation. Today, two of the perhaps most essential programmes guiding the EU water policy and legislation are:

- Blueprint to Safeguard Europe's Water Resources¹⁸⁶, a strategy for ensuring that enough good quality water is available to meet the needs of people, the economy and the environment. The Water Blueprint sets out a three-tier strategic approach:
 - Improving implementation of current EU water policy by making full use of the opportunities provided by the current laws. For example, increasing the take-up of natural water retention measures such as the restoration of wetlands and floodplains or improving implementation of the "polluter pays" principle through metering, water-pricing and better economic analysis.
 - Increasing the integration of water policy objectives into other relevant policy areas such as agriculture, fisheries, renewable energy, transport and the Cohesion and Structural Funds.
 - Filling the gaps of the current framework, particularly in relation to the tools needed to increase water efficiency. In this regard, the Water Blueprint envisages water accounts and water efficiency targets to be set by Member States and the development of EU standards for water re-use.

The Water Blueprint's time horizon is closely related to the EU's 2020 Strategy¹⁸⁷ and, in particular, to the 2011 Resource Efficiency Roadmap¹⁸⁸, of which the Blueprint is the water milestone.

- The Environmental Action Programmes. The first programme covered the period 1973 to 1976, and the latest is the 7th Environmental Action Programme (7th EAP¹⁸⁹ – Living well, within the limits of our planet) adopted for the period up to 2020 and develops a vision for 2050.

It sets forth a general European Union action programme in the field of the environment for the period up to 31 December 2020. This programme is based on the precautionary principle, the principles of preventive action and of rectification of pollution at source and the polluter-pays principle. It has the following priority objectives:

186 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions A Blueprint to Safeguard Europe's Water Resources, (COM 2012/0673 final)

¹⁸⁷http://ec.europa.eu/europe2020/index_en.htm

¹⁸⁸http://ec.europa.eu/environment/resource_efficiency/about/roadmap/index_en.htm

¹⁸⁹<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013D1386>

- (a) to protect, conserve and enhance the European European Union’s natural capital;
- (b) to turn the European Union into a resource-efficient, green and competitive low-carbon economy;
- (c) to safeguard the European Union’s citizens from environment-related pressures and risks to health and well-being;
- (d) to maximise the benefits of European Union environment legislation by improving implementation;
- (e) to improve the knowledge and evidence base for European Union environment policy;
- (f) to secure investment for environment and climate policy and address environmental externalities;
- (g) to improve environmental integration and policy coherence;
- (h) to enhance the sustainability of the European Union’s cities; and
- (i) to increase the European Union’s effectiveness in addressing international environmental and climate-related challenges.

Water protection is in the focus of the policy objectives: Protection of natural capital, Resource Efficiency and Safeguarding EU’s citizens from environment-related pressures and risks to health and well-being. Thus, the 7th EAP calls for full implementation of the Blueprint to Safeguard Europe’s Water Resources by introducing measures that would reduce the impact of pressures to transitional, coastal and fresh waters as well as on marine waters in order to achieve, maintain or enhance good status as defined by the Water Framework Directive (2000/60/EC) and good environmental status under the Marine Strategy Framework Directive (2008/56/EC). It also requires resource efficiency in the water sector by setting and monitoring targets at river basin level on the basis of a common methodology for water efficiency targets to be developed under the Common Implementation Strategy process, and using market mechanisms, such as water pricing, as provided for in Article 9 of the Water Framework Directive and, where appropriate, other market measures, but also by developing approaches to manage the use of treated wastewater. Finally, the 7th EAP expresses the commitment of the EU, national authorities and stakeholders to achieve good status for Europe’s waters and marine environment, and to speed up the delivery of the objectives of the Blueprint to Safeguard Europe’s Water Resources

The Treaty on the Functioning of the European Union provides for a set of principles for EU environmental policy which are also relevant for the water policy as set out in the list below.

- High level of water protection – through achieving WFD goals of “good water status”
- Precautionary principle, preventive action, rectification of pollution at the sources and polluter pays principle as requirements of the river basin management planning, in line with the WFD
- Integration of environmental protection requirements into the definition and implementation of other EU policies — e.g. industry, agriculture, transport and energy
- The promotion of sustainable development (environmental, economic and social) as embodied by the WFD.

The “first wave” of legislation was adopted by the Community, starting with the 1975 Surface Water Directive and culminating in the 1980 Drinking Water Directive (80/778/EEC). This first wave of water legislation included water quality standard legislation on fish waters (78/659/EEC), shellfish waters (79/923/EEC), bathing waters (76/160/EEC) and groundwaters (80/68/EEC). In the field of emission limit values legislation, the Dangerous Substances Directive (76/464/EEC) and its Daughter Directives (82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, and 86/280/EEC) on various individual substances were adopted.

In the 1990s a “second wave” of water legislation followed a review of existing legislation and an identification of necessary improvements and gaps to be filled. This phase of water legislation included the Urban Waste Water Treatment Directive (91/271/EEC) and the Nitrates Directive (91/676/EEC). Other elements identified were revisions of the Drinking Water and Bathing Water Directives to bring them up to date (revisions being adopted in 1998 and 2006 respectively), the development of a Groundwater Action Programme and a 1994 proposal for an Ecological Quality of Water Directive.

A third wave of water legislation comprised the ground-breaking WFD (2000/60/EC). The WFD sets out requirements for the European Commission to propose further laws to protect against water pollution, which resulted in two 'daughter' Directives, the Groundwater Directive (2006/118/EC) aimed at protecting groundwater, and the Directive 2008/105/EC on environmental quality standards in the field of water policy (hereinafter referred to as the EQS Directive) also known as the Priority Substances Directive.

The WFD (2000/60/EC) reflects a new way of thinking and has the following particularly key objectives:

- the development of an integrated EU policy on and for the long-term sustainable use of water, and its application in accordance with the principle of subsidiarity;
- expanding the scope of water protection to all waters: surface waters, including coastal waters, and groundwater;
- achieving "good status" for all waters by a certain deadline, and preserving such status where it already exists;
- water management based on river basins, with a "combined approach" of emission limit values and quality standards, with appropriate co-ordination provisions for international river basin districts where river basins are located in more than one Member State and/or also involve territory of non-Member States;
- setting prices for water use taking into account the principle of cost recovery and in accordance with the polluter pays principle;
- getting citizens involved more closely;
- streamlining legislation.

The Groundwater Directive (2006/118/EC) relates to assessments on chemical status of groundwater, establishes a regime, which sets groundwater quality standards and introduces measures to prevent or limit inputs of pollutants into groundwater. The directive establishes quality criteria that takes account local characteristics and allows for further improvements to be made based on monitoring data and new scientific knowledge.

The Directive 2008/105/EC on environmental quality standards in the field of water policy (EQSD) is directly related to the WFD, as it lays down environmental quality standards (EQS) for priority substances and certain other pollutants as provided for in Article 16 of the WFD, with the aim of achieving good surface water chemical status. Directive 2008/105/EC repeals the Directives on individual substances (82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC and 86/280/EEC) to consolidate all these quality standards in one and the same Directive.

The WFD was supplemented with Decision No 2455/2001/EC establishing the list of priority substances in the field of water policy to become Annex X of the WFD. This first list was replaced by Annex II of the EQSD.

The third wave of water legislation also comprised the Floods Directive (2007/60/EC), introducing key principles in flood risk management.

Also part of this newer tranche of water legislation is Directive 2008/56/EC establishing a framework for Community action in the field of marine environmental policy (Marine Strategy Framework Directive - MSFD). This meant that the EU legislation was further extended to cover EU marine waters. EU provisions govern basically every kind of water body both in terms of maintaining sufficiently good water status quality and in terms of restricting and controlling activities, which can adversely affect water bodies.

There have been, at Member State as well as at European Union level, two different approaches tackling water pollution:

- The water quality objective approach (WQO) defines the minimum quality requirements of water to limit the cumulative impact of emissions, both from point sources and diffuse sources. This approach therefore focuses on a certain quality level of water which, in the prescribed condition and use, is not harmful for the environment or human health. This approach was mainly used in the first wave of water Directives (1975 to 1980) such as the Surface Water Directive (75/440/EEC, now replaced by WFD) or the Bathing Water Quality Directive (76/160/EEC).
- The emission limit value approach (ELV) focuses on the maximum allowed quantities of pollutants that may be discharged from a particular source into the aquatic environment. This approach in fact looks at the end product of a process (wastewater treatment, discharges from industry, effect of agriculture on water quality) or what quantities of pollutants may go into the water, and was mainly used in the second wave of water legislation during the 1990s: The Urban Waste Water Treatment Directive (91/271/EEC) and the Nitrates Directive (91/676/EEC).

Since then, the question of which approach was the most appropriate has been the subject of long scientific and political debate. Subsequently, more recent legislation both at European and Member State levels has been based on a combined approach, where ELVs and WQOs are used to mutually reinforce each other. In any particular situation, the more rigorous approach will apply. The new European water policy, and its operative tool the WFD (2000/60/EC) are based on this combined approach (see, in particular, Article 10 of the Directive). This combined approach is also in accordance with principles established in the Treaty on the Functioning of the European Union — the precautionary principle, the preventive principle and the principle that environmental damage should, as a priority, be rectified at source, as well as the principle that environmental conditions in the various regions shall be taken into consideration. It may also be considered that at heart such an approach reflects the further stipulation in the Treaty that environmental protection requirements be integrated into the definition and implementation of other EU policies.

Overall, with the adoption of the WFD, the EU water policy made a milestone step in water management by taking an integrated approach on the basis of the concept of river basin management aimed at achieving good ecological status by 2015.

The Communication and reports adopted by the Commission, alongside a variety of supporting background documents can be found at: http://ec.europa.eu/environment/water/water-framework/impl_reports.htm.

- 4th implementation report – assessment of the Water Framework Directive Programmes of Measures and the Flood Directive (2015)¹⁹⁰
- 3rd Implementation report of the Water Framework Directive (2012): River Basin Management Plans 2009-2015¹⁹¹
- Synthesis Report on the Quality of Drinking Water in the EU examining the Member States' reports for the period 2008-2010 - the report COM(2014) 363 final summarises the information provided by 27 Member States (16 June 2014)
- The Report on European bathing water quality in 2015 prepared by the European Environment Agency and the European Commission (25 May 2016), containing a compilation of data gathered in summer of 2015, indicating the quality of 21,000 bathing water expected in 2016.
- 8th Report on the Implementation Status and the Programmes for Implementation (as required by Article 17) of Council Directive 91/271/EEC concerning urban waste water treatment (SWD(2016) 45 final)
- Report from the Commission to the Council and the European Parliament The first phase of implementation of the Marine Strategy Framework Directive (2008/56/EC) The European Commission's assessment and guidance (COM/2014/097 final)
- Review of the EU policy on water scarcity and droughts - Communication “Addressing the challenge of water scarcity and droughts”¹⁹²
- Knowledge base and supporting background documents. This comprises several underlying EEA reports¹⁹³, the Fitness Check¹⁹⁴ and Impact Assessments and support studies for the Blueprint to safeguard Europe's water resources.
- The overall objective of the Blueprint to Safeguard Europe's Water Resources (2012) is to improve EU water policy in order to ensure good quality water, in adequate quantities, for all authorized uses. The Blueprint aims at improving the implementation of current EU water policy, fostering the integration of water and other policies, and when necessary, seeking the completion of the current policy framework. It is closely linked to EU 2020 Strategy and Resource Efficiency Roadmap.
- Regarding the EEA reports these demonstrate that water quality and quantity of European waters remain a cause for concern. The Fitness Check is a building block of the Blueprint and relates to both the “Smart Regulation” policy and the Commission’s Work Programme for 2010. The Fitness Check

¹⁹⁰http://ec.europa.eu/environment/water/water-framework/impl_reports.htm#fourth

¹⁹¹ Report from the Commission to the European Parliament and the Council on the Implementation of the Water Framework Directive (2000/60/EC) River Basin Management Plans, {SWD(2012) 379 final}, Brussels, 14.11.2012. Available at: http://ec.europa.eu/environment/water/water-framework/pdf/COM-2012-670_EN.pdf<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0670:FIN:EN:PDF>

¹⁹² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Report on the Review of the European Water Scarcity and Droughts Policy (COM/2012/0672 final). Available at:

<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52012DC0672:EN:NOT>

¹⁹³These reports can be obtained at the website of the EEA: <http://www.eea.europa.eu/themes/water/water-assessments-2012>

¹⁹⁴ The Fitness Check of EU Freshwater Policy (Staff Working Document) – SWD(2012) 393. Available at: <http://ec.europa.eu/environment/water/blueprint/pdf/SWD-2012-393.pdf>

involved an extensive review of the entire body of legislation in selected policy fields with the view to identify excessive burdens, overlaps, gaps, inconsistencies and/or obsolete measures. It investigates strengths and weaknesses in the implementation of current water legislation and coherence with other EU policy objectives.

More information can be obtained at: http://ec.europa.eu/environment/water/blueprint/index_en.htm

1.2. EU Legal Instruments

The water sector contains a range of directives and several decisions. The WFD provides a managerial framework for the whole range of water protection policy and legislation. It also repealed and replaced many of the "first-wave" legislation as of December 2013. The legislation affected includes: Directive 75/440/EEC on Surface Water for Drinking Water Abstraction, the Dangerous Substances Directive 76/464/EEC and its daughter directives, Council Decision of Exchange of Information 77/795/EEC, the Fish water Directive 78/659/EEC, the Shellfish Water Directive 79/869/EEC, the Directive of Measurement and Sampling of Surface Waters 79/869/EEC, and the Groundwater Directive 80/68/EEC.

In addition, the former Bathing Water Directive (76/160/EEC) was replaced by Directive 2006/7/EC concerning the management of bathing water quality, which Member States had to transpose by 24 March 2008.

More recent pieces of legislation comprise the Groundwater Directive (2006/118/EC), Directive 2007/60/EC on the assessment and management of flood risks, Directive 2008/105/EC on environmental quality standards, as amended by Directive 2013/39/EC and Directive 2008/56/EC establishing a framework for Community action in the field of marine environmental policy.

With regard to the Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council, and in particular Article 8b(5), the Commission Implementing Decision (EU) 2015/495 of 20 March 2015 is establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council.

With reference to the Article 8(3) of the Water Framework Directive 2000/60/EC of the European Parliament and of the Council, the Commission Directive 2009/90/EC of 31 July 2009 is establishing the technical specifications for chemical analysis and monitoring of water status. It establishes minimum performance criteria for methods of analysis to be applied by Member States when monitoring water status, sediment and biota, as well as rules for demonstrating the quality of analytical results.

Legislation in the Water Protection Sector Covered in Separate Fiches in this Chapter

Directive 2000/60/EC of the European Parliament and the Council establishing a framework for community action in the field of water policy, as amended

Council Directive 91/271/EEC concerning urban waste water treatment

Council Directive 91/676/EEC on the protection of waters against pollution caused by nitrates from agricultural sources

Council Directive 98/83/EC on the quality of water intended for human consumption

Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration

Directive 2007/60/EC of the European Parliament and of the Council of 23 October 2007 on the assessment and management of flood risks

Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for Community action in the field of marine environmental policy

Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, as amended.

There are also international conventions, which are not dealt with directly in this chapter but should be mentioned:

- Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (the Aarhus Convention), 1998
- United Nations Convention on the Law of the Sea (UNCLOS III), Part XI and the 1994 Agreement
- Convention for the Protection of the Marine Environment in the North-East Atlantic of 1992 (further to earlier versions of 1972 and 1974) – the OSPAR Convention (OSPAR)
- Convention on the Protection of the Marine Environment in the Baltic Sea Area of 1992 (further to the earlier version of 1974) – the Helsinki Convention (HELCOM),
- Convention for the Protection of Marine Environment and the Coastal Region of the Mediterranean of 1995 (further to the earlier version of 1976) – the Barcelona Convention (UNEP-MAP),
- Convention for the Protection of the Black Sea of 1992 – the Bucharest Convention.
- The Convention on the Protection and Use of Transboundary Watercourses and International Lakes (Water Convention), 1992
- Convention on Environmental Impact Assessment in a Transboundary Context (the Espoo Convention), 1991

Stockholm Convention on Protecting Human Health and the Environment from Persistent Organic Pollutants („the POPs Convention”), 2001

As can be seen from the above, the EU had established a set of legislation in the water sector also having important links with legislation in other sectors. The Water Framework Directive provides for the operation of much of this other legislation in a coherent and comprehensive manner. It is, however, also useful to consider the most important links with the relevant legislation in other sectors.

Table 1. Summary of key inter-relationships between EU water legislation and other EU environmental legislation (note the important role of the WFD in providing exactly for such a network of inter-linking legislation)

Related sector legislation	Relevance
Horizontal legislation	
Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment	Requires an EIA for new projects, which are judged to have a significant impact on the environment. The results must be made public and the views of the public taken into account in decisions. The impact on water quality is an important and relevant issue to consider in an EIA.
Directive 2003/4/EC of 28 January 2003 on public access to environmental information	Requires environmental information held by public bodies to be made available to the general public on request. Most of the water Directives specifies the collection of water quality information or information concerning permits. As a rule, any such information held by public bodies would be covered by this Directive. Directive 2003/4/EC would expand the scope of "public authorities" for this purpose. Note, however, the extensive rights of access to documentation under the WFD as regards designs, drafts and final versions of river basin management plans. The SEA itself requires plans and programmes for water use to be subject to strategic environmental assessment.
Reporting Directive (91/692/EEC)	Sets out provisions on the transmission of information and reports concerning certain EU Directives from Member States to the Commission. The reporting requirements specified in many water protection Directives are modified by this Directive.
Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage	This Directive also covers water damage, which is any damage that significantly adversely affects the ecological, chemical and/or quantitative status and/or ecological potential, as defined in Directive 2000/60/EC, of the waters concerned, with the exception of adverse effects where Article 4(7) of that Directive applies (Art. 2). Annex II provides the requirements and criteria for remediation of water damage.
Directive 2008/99/EC on the protection of the environment through criminal law	Member States shall ensure that certain conduct constitutes a criminal offence, when unlawful and committed intentionally or with at least serious negligence, set out in Article 3. Such offences include discharges, emissions of materials or ionising radiation into water, where these activities cause or are likely to cause death or serious injury to any person or substantial damage to the quality of air, the quality of water. Member States shall take the necessary measures to ensure that the offences referred to in the Directive are punishable by effective, proportionate and dissuasive criminal charges.
Directive 2007/2/EC establishing an Infrastructure for Spatial Information in the European Community (Inspire)	Provision should be made for the adoption of methodological standards for the assessment of the status of the marine environment, monitoring, environmental target sand the adoption of technical formats for the purposes of transmission and processing of data in line with Directive 2007/2/EC
Waste management	
Directive 2008/98/EC on waste	Requires the adoption of waste management plans. Within the plans, the siting and operation of waste sites must be such as to avoid water pollution, and the possibility of water pollution occurring must be an issue to be taken into account in the plan. Such installations are material considerations as regards the classification of the status of waters and as regards the creation of programmes of measures for river basin districts under the WFD.

Directive 86/278/EEC on sewage sludge	Regulates the use of sewage sludge in agriculture in such a way that contamination of soil and pollution of water does not occur from metal contaminants, nitrates and phosphates. Appropriate use of sludge is an important factor in the definition of programmes of measures for river basin districts under the WFD.
Nature protection	
Directive 2009/147/EC on the conservation of wild birds Council Directive 92/43/EEC on the conservation of natural habitats and of wild fauna and flora	<p>Aim to protect a network of habitats and wild bird species throughout Europe. Satisfactory water quality is an essential factor in such areas. Both are specifically pertinent to identification of protected areas for inclusion in river basin management plans under the WFD, and are material to measures to be adopted in programmes of measures for river basin districts under the WFD.</p> <p>The aim of widespread improvement in aquatic ecosystems under the Water Framework Directive contributes positively to the wider objectives of these Directives and to the EU Biodiversity Strategy goal of halting the loss of biodiversity and the degradation of ecosystem services in the EU by 2020, and restoring them in so far as feasible. Measures taken for the effective management and restoration of Natura 2000 sites, especially protected wetlands, will also contribute positively to water quality objectives.</p>
Industrial pollution control	
Directive 2010/75/EU on industrial emissions	<p>IED plays an important role in controlling pollutant discharges to water (so contributing to water policy objectives) and in enhancing the efficiency of water use in industrial activities. IPPC permits' emission limit values are to be based on the application of Best Available Techniques (BAT), but stricter emission limit values are required if these are necessary to meet an environmental quality standard in EU law, such as good status under the Water Framework Directive. The Directive is an important tool in controlling pressures on water bodies and contributing to achieving EU water policy objectives.</p> <p>The WFD specifically requires that measures in river basin management plans must include those which give full effect to the provision of the IED/IPPC Directive in relation to industries and activities specified in Annex I to the Directive. The Directive itself is specifically material to the measures to be adopted under programmes of measures for river basin districts under the WFD.</p>
Seveso III Directive (2012/18/EU)	<p>This Directive aims to prevent major accidents that involve dangerous substances. It requires operators to develop major-accident prevention policies and to provide safety reports outlining how they intend to manage and handle dangerous substances.</p> <p>The WFD also provides for Member States to adopt plans to deal with significant discharges of pollutants from technical installations as part of the programme of measures for river basin districts, and this Directive is specifically referred to for the latter purpose.</p>
Chemical management	
Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	This Regulation applies to existing substances and places related obligations on manufacturers and importers to provide data and requires Member States to carry out risk assessments. The WFD specifically requires that in drawing up strategies to deal with water pollution, the Commission must take into account risk assessments of pollutants carried out under the Regulation.
Regulation (EC) No 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury	Permitting, information and safety measures linked to storage of metallic mercury, which for instance aims at preventing leakage can also affect water bodies.
Biocides and plant protection	

<p>Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market</p>	<p>Art. 21: refers to the obligation to achieve the objectives of the WFD set out in Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3). Non-compliance will be taken into account in the approval of an active substance.</p> <p>Article 44 prescribes that a Member State shall review an authorisation where it concludes that the objectives of Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC may not be achieved.</p>
<p>Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides</p>	<p>Article 12: Member States shall ensure that the use of pesticides is minimised or prohibited in certain specific areas, which includes protected areas as defined in Directive 2000/60/EC</p> <p>Art. 4: the National Action Plans referred to must take into account plans under other Community legislation on the use of pesticides, such as planned measures under Directive 2000/60/EC</p>
<p>Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products</p>	<p>WFD obligations referred to in the Annexes to the Regulation, e.g. Annex II on information requirements for active substances.</p> <p>The compliance with the WFD is also required in applying Annex VI on common principles for the evaluation of dossiers for biocidal products. Here, reference is made to certain emission values fixed by the WFD in terms of concentrations of biocides in surface water intended for the abstraction of drinking water</p>

2. DEVELOPMENT OF A SECTORAL STRATEGY AND IMPLEMENTATION PLAN

The implementation management checklist, presented in Section 2.4 of the introductory chapter provides an overall framework for preparing a strategy to implement the legislation contained within this sector. The following text focuses on key issues pertinent to this environmental sector, which are developed in the remainder of this section. Further guidance on implementation is provided in the fiches for individual legal acts.

The water sector consists of a large body of legislation relating to different uses, polluting processes and pollutants. The tasks involved in implementing the legislation require actions by government, through competent authorities and interministerial mechanisms/structures to deal with interlinkages between different sectors and water, such as agriculture and water. The government will also need to set overall policy within the context of the EU Directives, for example establishing the role that taxation or other fiscal measures will have in implementing water quality objectives. In addition, the Urban Waste Water Treatment Directive (91/271/EEC) and the Directives concerned with use-related water quality (for example the Bathing Water Directive (2006/7/EC) and Drinking Water Directive (98/83/EC) require actions from water and sewerage services providers.

The Nitrates Directive (91/676/EEC) requires action from agricultural undertakings, and Directives addressing various industrial pollutants (included among the "priority substances" under Article 16 of the WFD) will also require action from industry. Further, the Floods Directive (2007/60/EC) requires action on the part of various authorities, ranging from planning authorities to civil protection bodies. Both the Floods Directive and the Marine Strategy Framework Directive target competent authorities similar to those involved in implementing the WFD, with several inter-linkages and overlaps. For these two Directives, very limited action would be expected from the private sector, mainly since the requirements largely focus on sectoral planning and risk assessments. The private sector will be mainly involved when their activities cause damage to river basins or coastal or other relevant marine water management areas. The costs of implementing these Directives are likely to have been very substantial overall, and the costs of any future implementation are also likely to be substantial, thus careful planning is necessary at the strategy formulation stage.

A number of new strategies will result from the implementation of the WFD. Specific issues that are important in formulating a sectoral strategy include the following.

2.1. River Basin Management

The new approach to water management set out in the WFD and in the Floods Directive requires water to be assessed and managed on the basis of river basins, rather than according to geographical or political boundaries (the competent authorities should however, not be the same for implementation of the WFD and the Floods Directive). Specific provision is made in the WFD for obligatory co-ordination between Member States sharing a river basin district, and for Member States to endeavour to co-ordinate responses for international river basins that are shared between Member States and non-Member States. This enables assessment of all activities that may affect all the water bodies in question, and their eventual control by measures that may be specific to the conditions affecting the river basin. The WFD and the Floods Directive therefore require river basin

management plans and the flood risk assessment, flood risk and hazard maps and flood management plans, respectively, to be drawn up on a river basin level. It may be necessary or desirable to sub-divide a large river basin into smaller units, and sometimes a particular water type may justify its own "sub-" or supplementary plan.

Fundamental to this approach, and in the interests of effective and appropriate administration, is the identification of river basins of a sufficient size to ensure the viability of an organisational framework set up to administer them. Prior to decisions being taken on the type and constitution of any new organisation, or on whether to use existing ones, the government will need to establish river basin boundaries. The adoption of suitable institutional structures to enable this to be achieved is one of the challenges for Member States in implementing the Directive. No general guidance can be provided from experience gained in the past, as indeed there are successful examples both for centralised and for decentralised administrations achieving the objectives of water protection. The WFD requires Member States to ensure appropriate administrative arrangements including the designation of a competent authority for each of the river basin districts that would be responsible for the WFD implementation.

It should be borne in mind that the river basin approach applies equally to river basins that cross national borders: the WFD, as indicated above, makes co-ordination across national boundaries mandatory between Member States, and recommends co-ordination with third countries. Considerable experience has been gained in international co-operation along rivers such as the Rhine and the Elbe. Also the international cooperation work along international rivers has progressed significantly over the years. A number of international River Basin Districts have also published River Basin Management Plans, i.e. Danube, Rhine, Elbe, Ems, Meuse, Scheldt/l'Escaut, Sava Commission (ISRBC) and Odra.

Most Member States, in line with the time frame indicated in the WFD, published the River Basin Management Plans by end of December 2009 but there have been several court cases against certain Member States for non-compliance. The national plans have been subject to an assessment by the Commission (based on requirement set out in Art. 18 of the WFD), resulting in the „3rd Implementation report of the Water Framework Directive: River Basin Management Plans 2009-2015”, available at: http://ec.europa.eu/environment/water/blueprint/index_en.htm. The assessment of the RBMPs is based on the reporting by Member States, consisting of the published plans and accompanying documentation and the electronic reporting through the Water Information System for Europe (WISE). At the time of the publication of the report in November 2012, 23 Member States had adopted and reported all their plans. Four Member States (BE, EL, ES and PT) have either not adopted Plans or only adopted and reported some plans (which resulted in infringement proceedings in the CJEU (Court of Justice of the European Union¹⁹⁵)). In total, the Commission had received 124 RBMPs (out of expected 174). 75% of them concern transboundary river basins.

The report is accompanied by Commission Staff Working Documents that include a detailed assessment of the RBMPs. It is one of the basis of the Commission Communication on the 'Blueprint to Safeguard Europe's Water Resources' (See above). The finalised plans can be accessed at:

http://ec.europa.eu/environment/water/participation/map_mc/map.htm

and the Member State specific assessments are available at:

http://ec.europa.eu/environment/water/water-framework/impl_reports.htm

¹⁹⁵ The Court has ruled against Belgium, Greece, Spain and Portugal for not having adopted and reported the plans. The cases are: Greece - C-297/11, Belgium - C-366/11, Portugal - C-223/11 and Spain – C-403/11.

Information about the River Basin Management Plans available in each River Basin District indicating status of adoption of the second River Basin Management Plans (in various stages of adoption) can be obtained at the following link: http://ec.europa.eu/environment/water/participation/map_mc/map.htm.

In terms of the MSFD, Member States have to adopt marine strategies, which include monitoring programmes and programme of measures, among other elements, while cooperating with other Member States sharing the same marine region or subregion.

2.2. Programme of Measures

2.2.1. Programme of measures under the WFD

Central to each river basin management plan will be a programme of measures to ensure that all waters in the river basin achieve good water status. There are also provisions for stand-still or "non-deterioration" obligations. The starting point for such programmes is the full implementation of any relevant national or local legislation as well as of a range of EU legislation on water and related issues. If this basic set of measures is not enough to ensure that the goal of good water status is reached, the programme must be supplemented with whatever further measures are necessary. These might include stricter controls on polluting emissions from industry or agriculture as well as from urban wastewater sources; land-use planning might, in this context, be a key issue to be taken into account. Measures in these river basins should also tackle flood risks, such as the flood risk assessment, which do not directly focus on achieving good water status but to mitigate the risk for floods and to define measures in cases a flood does happen.

The 4th WFD implementation report was adopted on 9 March 2015 and includes a review of progress in the implementation of the Programmes of Measures planned by Member States in their River Basin Management Plans. The interim report is based on the analysis of the reports submitted by Member States in accordance with Article 15(3) and it also provides suggestions for the improvement of future Programmes of Measures to be inserted in the update of the River Basin Management Plans, due at the latest by 22 December 2015. In order to identify and build on existing synergies with the Floods Directive it also includes a section on the assessment of that Directive's implementation. More information on the fourth implementation report can be obtained at the following link: http://ec.europa.eu/environment/water/water-framework/impl_reports.htm

The Water Framework Directive sets out clear deadlines for each of the requirements. The remaining deadlines refer to the second management cycle which will end by 2021 (Art. 4 & 13) and to the third management cycle to be finalized by 2027, which is also the final deadline for meeting objectives.

2.2.2. Programme of measures under the MSFD

The main goal of the Marine Directive is to achieve Good Environmental Status of EU marine waters by 2020. The Directive defines Good Environmental Status (GES) as: "The environmental status of marine waters where these provide ecologically diverse and dynamic oceans and seas which are clean, healthy and productive" (Article 3).

There are strong links between the Marine Strategy Framework Directive (MSFD) and the Water Framework Directive (WFD). WFD relates to improving and protecting the chemical and biological status of surface waters

throughout a river basin catchment from rivers, lakes and groundwaters through to estuaries (transitional) and coastal waters to one nautical mile out to sea and overlaps with MSFD in coastal waters

MSFD and WFD also have comparable objectives, with MSFD focussed on the achievement of Good Environmental Status in marine waters, and WFD aiming to achieve Good Ecological and Good Chemical Status.

MSFD explicitly recognises the overlaps with WFD and makes it clear that in coastal waters, MSFD is only intended to apply to those aspects of Good Environmental Status which are not already covered by WFD (e.g. noise, litter, aspects of biodiversity).

Article 6 of the MSFD addresses the cooperation and coordination arrangements that need to be in place in order to comply with the MSFD obligations. According to article 1, the purpose of the WFD is “to establish a framework for the protection of inland surface waters, transitional waters, coastal waters and groundwater” which contributes, inter alia, to “the protection of [...] marine waters” and aims “to prevent and eliminate pollution of the marine environment” and “to cease or phase out discharges, emissions and losses of priority hazardous substances, with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances”.

The WFD calls in article 3(4) on Member States to “ensure, that the requirements of this Directive for the achievement of the environmental objectives established under article 4, and in particular all programmes of measures are coordinated for the whole of the river basin district”.

In this perspective the cooperation structures implicated in the implementation of the WFD at river basin district level, especially the international river commissions, should play a crucial role in relation to achieve the common targets of both the MSFD and the WFD.

2.3. Combined Approach

2.3.1. Combined approach under the WFD

The WFD takes a "combined approach" to pollution control:

- limiting pollution at source by setting emission limit values or other emission controls;
- establishing water quality objectives for water bodies; or
- providing for control of certain diffuse impacts.

In each case, the approach that provides for setting the most stringent provisions will apply. Thus Member States will have to set down in their programmes of measures both limit values to control emissions from individual point sources and environmental quality standards (EQS) to limit the cumulative impact of such emissions as well as making provisions to take account of diffuse sources of pollution. The emissions limit values will have to be set in line with EU, national and regional legislation, inter alia with the Water Quality Standards Directive (2008/105/EC), the IED (2010/75/EU) and the Urban Waste Water Treatment Directive (91/271/EEC) for installations and discharges covered by these Directives, the Nitrates Directive (91/676/EC), the Directives adopted under Article 16 of the WFD, the Directives in Annex IX of that Directive and any other relevant EU legislation (see Article 10 of the WFD).

For relevant pollutants and pollution sources of priority concern ("priority substances" under Article 16) the WFD obliges the Council and the Parliament to establish EU emission controls and water quality objectives.

In addition to the list of Priority Substances laid down in Annex X of the WFD, which are regulated and monitored at EU level, the Member States need to identify pollutants of regional or local importance (WFD, Annex VIII) and provide environmental quality standards (EQS), monitoring schemes, and regulatory measures for them. The Member States need to decide which are the candidate substances for further investigation and which are the substances then to be declared as River Basin-Specific Pollutants (RBSP). This requires assessments of impacts as well as prioritisation efforts and strategic screening for substances possibly causing concern.

Decision 2455/2001/EC established the first list of priority substances, added to the WFD as Annex X. Directive 2008/105/EC on environmental quality standards in the field of water policy laid down environmental quality standards, in accordance with Directive 2000/60/EC, for the 33 priority substances identified in Decision No 2455/2001/EC. Directive 2008/105/EC also includes standards for eight "certain other pollutants" inherited from the earlier dangerous substances legislation. Annex X to the WFD has been recently amended by Directive 2013/39/EU, which has identified new substances for priority action at Union level and the EQS for those newly identified substances. The Directive 2013/39/EU revised the EQS for seven of the 33 original priority substances in line with the latest scientific and technical knowledge concerning the properties of the substances and set biota EQS for some existing and newly identified priority substances.

The revised EQS for those seven existing priority substances had to be taken into account for the first time in Member States' river basin management plans from 22 December 2015 with the aim of achieving good surface water chemical status in relation to those substances by 22 December 2021.

The 12 newly identified priority substances and their EQS should be taken into account in the establishment of supplementary monitoring programmes and in preliminary programmes of measures to be submitted by the end of 2018, with the aim of achieving good surface water chemical status in relation to those substances by 22 December 2027.

As waters used for drinking water abstraction are subject to particular protection, Member States are required to set EQS for certain bodies (defined in Art. 7(1) as "all bodies of water used for the abstraction of water intended for human consumption providing more than 10 m³ a day as an average or serving more than 50 persons, and — those bodies of water intended for such future use. These EQS should be designed to ensure that under the expected water treatment regime, the abstracted water will meet the requirements of the Drinking Water Directive (98/83/EC) (see Article 7 of the WFD).

The WFD also addresses water quantity in so far as it is relevant to water quality. Article 11 (3) of the WFD requires 'controls over the abstraction of fresh surface water and groundwater' (Article 11 (3e)). To that aim, any abstractions of groundwater or surface water have to be subject to a permitting procedure.

The same applies to impoundment measures affecting fresh surface water. Permits should only be granted for abstraction if they provide for compliance with the objective of a long-term balance between abstraction and recharge rates. In issuing permits, authorities will have to take into account the impact of abstractions on water quality, water availability, water status, and on other potential water users.

Assessment and control of water demand require significant forward planning by regional authorities, in conjunction with the authorities or companies that supply drinking water or otherwise abstract water for use or use water on any significant scale, to assess the future impact of population growth and industrial and other

development on the availability of water in the river basin. The potential impact on groundwater is particularly important in this respect.

The part of the combined approach focusing on setting environmental quality objectives for water bodies has been strengthened through the EQS Directive (2008/105/EC), which lays down environmental quality standards for priority substances, with the aim of achieving good surface water chemical status under the WFD. It streamlines and consolidates earlier legislation. Monitoring Programme is an essential element in the effective implementation of both the WFD and the MSFD. The systematic monitoring of surface water, groundwater and marine water quality and quantity required, particularly based on the requirements in Annex V of the WFD, falls under several categories:

- surveillance monitoring;
- operational monitoring;
- investigative monitoring.

Data on monitoring will be publicly available, and will also form the basis for the classification of status for water bodies within a river basin district and also for the designation of programmes of measures designed to achieve the objectives of the Directive for all water bodies within each river basin district. They should also be regularly reported to the Commission, as well as contributing to the monitoring network within the European Environment Agency.

2.3.2. Combined approach under the MSFD

Regarding the MSFD, to a larger extent, it gives Member States discretion in deciding upon the control measures to achieve GES of marine waters, i.e. to ensure that the different uses made of the marine resources are conducted at a sustainable level, ensuring their continuity for future generations. On the basis of the annexes to the MSFD, Member States have to, regarding each marine region or sub region, determine a set of characteristics for good environmental status and establish a comprehensive set of environmental targets and associated indicators for their marine waters so as to guide progress towards achieving good environmental status in the marine environment.

The MSFD requires Member States to determine GES for their waters by reference to a series of eleven indicators, and which range from the extent to which biodiversity and diverse marine habitats are maintained, to the sustainability of fish stocks, through to indicators of the levels of marine litter and noise. Further, the Member States must establish targets and indicators aimed at achieving or maintaining it by 2020, and subsequently devise and implement programmes of measures for this purpose.

2.4. Cost Recovery

Water is essential for a number of economic as well as environmental and health reasons, such as the maintenance of drinking water supplies, the irrigation of crops and use in many industries. It is therefore essential to the viability of the population. Waterbodies have traditionally been used for the carriage of effluents and wastes, both industrial and human. The application of economic instruments — such as charges for use of water as a resource or for the discharge of effluents into watercourses or as subsistence charges merely for

having a permit — is a policy explicitly endorsed in the WFD. Member States are to take account of the principle of recovering the costs of water services, including environmental and resource costs, having regard to an economic analysis specified under that Directive and in accordance, in particular, with the "polluter pays" principle. Economic assessment thus becomes an essential part of water management planning. The assessment of current levels of cost-recovery for water services is in accordance with Article 9 of the Water Framework Directive. Key elements to be investigated in the economic analysis include the status of water services, the institutional set-up for cost-recovery, the extent of the recovery of costs (financial, environmental and resource costs) of water services and the contribution of key water uses to the costs of these services, as well as the incidence of subsidies. Water pricing policies should have been applied by 2010, providing an adequate incentive for the efficient use of water and thereby contributing to the environmental objectives of the Water Framework Directive.

Many of the existing EU Member States have been incorporated the principle of the recovery of costs of water services in their national legislation fully or to a considerable extent for quite some time (Austria, Belgium, Denmark, Finland, France, Germany, Luxembourg, the Netherlands, Sweden, and United Kingdom). It should also be noted that a similar but not identical provision, requiring that the costs of landfilling be charged by the operator, has already been adopted by the EU (Landfill Directive 99/31/EC — see Section 4).

Financing programmes to improve water quality and to provide adequate water supply will be a major challenge for all candidate countries. The Blueprint to Safeguard Europe's Water Resources encourages continuing enforcement action to ensure compliance with Article 9, identification of water efficiency measures and also implementation of the polluter pays principle. Furthermore, the presence of a water pricing policy is envisaged as an ex ante condition to obtain financing for certain projects under the Commission's proposals for Rural Development and Cohesion funds.

The 3rd Implementation Report states that „Recovery of financial costs of water services, including capital costs, ensures the necessary long term sustainability of investments. Environmental and resource costs are also an essential part of the cost recovery to ensure that externalities generated by the use and disposal of water are adequately recovered. Moreover, the cost of water services should be recovered taking into account the polluter pays principle”¹⁹⁶. The report concludes that currently few Member States have implemented a transparent recovery of environmental and resource costs. Cost recovery has been focusing on households and industry. For agriculture, the biggest water user in many areas, water is charged only to a limited extent.

(See more under: http://ec.europa.eu/environment/water/blueprint/index_en.htm)

Charges reflecting the above-mentioned principle will contribute to the necessary investments; however, the introduction of such charges might also pose a significant problem if they entail considerable changes. The costs will have to be borne by the user/consumer whether domestic, industrial or agricultural, and will have to include the construction, financing and maintenance of measures such as the extraction, treatment and distribution of water for drinking or irrigation purposes or other uses, and the collection, treatment and discharge of wastewater.

In case of the MSFD, it explicitly provides that the implementation of this Directive shall be supported by existing EU financial instruments and programmes. It even goes further by stating that the programmes of measures to be drawn up shall be co-financed by EU financial instruments. This possibility should be fully utilised by the candidate

¹⁹⁶ Report on the Implementation of the Water Framework Directive (2000/60/EC), Brussels, 14.11.2012 COM(2012) 670 final, p. 11

countries. Market based instruments should also be considered such as water pricing for the consumption and use of water, whether for drinking water, or industrial use.

2.5. Public Consultation

There are detailed provisions related to the public consultation set out in the WFD, the Floods Directive and the MSFD. Information, consultation and active involvement of stakeholders are essential steps in the development of river basin management plans, flood risk assessments, maps and flood management plans as well as marine strategies. Much of what is to be decided will have a direct impact on peoples' lives, for example on the quality of waters in their neighbourhood and the fees for water use. The setting of emission limits also directly impacts industry and end-uses such as fishing and bathing. Hence, members of such a wider public have a legitimate interest in the setting of water quality objectives. Competent authorities need to make arrangements to facilitate the public access to the information, and to create the framework for participation and consultation.

As a further consequence, suitable consultation mechanisms have to be arranged in order for the public to have an opportunity to see and comment upon proposals for river basin management plans. It is important for citizens, consumer and environmental groups, local communities, and also relevant government departments, water utilities, industry and commerce to be fully involved in discussions on the design of river basin management plans, as these are likely to affect all these organisations and the plans will rely in large part upon actions by such organisations for the achievement of their objectives.

More in particular regarding the MSFD, Member States must ensure that all interested parties are given early and effective opportunities to participate in the implementation of this Directive, involving, where possible, existing management bodies or structures, including Regional Sea Conventions, Scientific Advisory Bodies and Regional Advisory Councils.

Some minimum information must be published and be made available to the public for comment, such as summaries of the different elements of their marine strategies.

Regarding information and consultation on key elements of the implementation of the Floods Directive, Member States shall aim at coordinating the application of this Directive with the WFD to achieve higher efficiency, strengthen the information exchange and attain other benefits relating to the environmental objectives laid down in the latter Directive.

3. INSTITUTIONS AND RELEVANT PARTIES

3.1. Stakeholders

There are a large number of stakeholders who have an interest in, or may be affected by, water management measures. The principal stakeholders, and their roles in the process of developing and implementing a sectoral strategy to achieve compliance with EU policies and legislation on water management, are identified in the Table below. The following subsections focus on the main groups of organisations that are involved in the water sector.

3.2. Central Government Institutions

In general, the WFD and the MSFD as well as the Floods Directive are neutral as regards specific organisational structures. This also applies to the type of competent authorities designated. Member States are only required to provide some information regarding these such as their competences; roles and network affiliation (for instance see Annex II to the MSFD). According to the WFD, "Competent Authority" means an authority or authorities identified under Article 3(2) or 3(3) stipulating obligations for the Member States to ensure the appropriate administrative arrangements, including the identification of the appropriate competent authority, for the application of the rules of the Directive within each river basin district lying within their territory. In addition, Member States shall ensure that a river basin covering the territory of more than one Member State is assigned to an international river basin district. At the request of the Member States involved, the Commission shall act to facilitate the assigning to such international river basin districts. Each Member State shall ensure the appropriate administrative arrangements, including the identification of the appropriate competent authority, for the application of the rules of this Directive within the portion of any international river basin district lying within its territory.

In the EU there are Member States with centralised as well as decentralised or federal constitutional structures, and it is the right of Member States to choose the approach they prefer for implementing Directives. Additionally, established practice and tradition might play a key role in the distribution of responsibilities between different national ministries and/or regional and local authorities.

However, certain key question should be addressed in any case:

- Decide on a responsible "lead" ministry for implementing the WFD, as well as ensuring that there is co-operation and involvement in the decision-making process where other ministries are to be involved. Coordinating framework between the institutions and responsibilities needs to be established in order to achieve effective coordination. In many cases the lead ministry is the ministry for the environment, but others are very likely to need to be active participants, such as those responsible for health or food issues (Drinking Water Directive), agriculture (Nitrates and Sewage Sludge Directives), industry (emission control for instance under IED), civil protection (Floods Directive) and foreign affairs (in the case of transboundary pollution in inland waterways and marine areas). Many Member States had traditionally a number of different institutions responsible for the

various issues addressed by EU water policy, which may present a challenge in terms of ensuring effective cooperation between the competent authorities. Administrative reorganisation at national, regional and local level is often required in order to fully implement integrated water management.

- Ensure an efficient coordination of administrative arrangements within river basin districts, with clear definition of responsibilities and institutional relationships. Member States shall ensure that the requirements of this Directive for the achievement of the environmental objectives established under Article 4, and in particular all programmes of measures are coordinated for the whole of the river basin district. For international river basin districts the Member States concerned shall together ensure this coordination and may, for this purpose, use existing structures stemming from international agreements. At the request of the Member States involved, the Commission shall act to facilitate the establishment of the programmes of measures. art 3(4). Member States shall ensure that a river basin management plan is produced for each river basin district lying entirely within their territory. In the case of an international river basin district falling entirely within the Community, Member States shall ensure coordination with the aim of producing a single international river basin management plan.
- Decide on the distribution of responsibilities (planning, legislation, monitoring, implementation, regulation, consultation and reporting) between national, regional and local bodies (it is possible that some of the monitoring may be done by water and sewerage utilities and others whose impact on water resources is controlled under EU legislation, but this will not be able to replace the overall coordinating, information gathering and collating required of governmental bodies).
- Arrange for the explicit involvement of other public bodies and agencies (e.g. national standardisation institute, environment agency, environmental inspectorate, enforcement authorities, including judiciary, civil protection bodies and institutes with coastal responsibilities).

Table 2. The principal stakeholders and their indicative roles in the water quality sector

Stakeholder	Roles/Responsibilities
Central government (e.g. a national or regional ministry or department)	Implementation and maintenance of compliance with EU policies and legislation in the water sector. Provision of guidance to affected sectors — farming, fishing, marine resource extraction, industry, the general public. Reporting to the Commission on compliance, extensions of time and derogations. Also, co-ordination in the case of international river basin districts and international catchment areas for the production of programme of measures, flood risk maps, flood management plans and marine strategies. Are likely to include the (key) body that sets and/or regulates the costs recovery obligation.
Environmental agencies working on planning, development of behalf of central government (e.g. regulatory accreditation agency for laboratories or industrial sectors), environmental inspectorate authority	Provision of environmental quality standards, application of standards, regulation, monitoring and compliance assessment and technical assistance. At least partially supervisory, monitoring and information giving responsibilities. Environmental inspectorate is mainly involved in ensuring compliance with environmental legislation and permit conditions.
Regional and local government/municipalities	Construction of publicly owned sewer networks, sewage treatment works, water treatment plants. Also likely to be the relevant authorities granting planning permission for such operations if these are to be completed by the private sector. They will thus need to ensure that their public powers are exercised in accordance with obligations under the EU law.
Water boards, judiciary branch	Investigate cases of non-compliance with water effluent limits, which also can constitute an environmental crime that have to be subject to criminal penalties pursuant to the Environmental Crime Directive (2008/99/EC).
Water and sewerage providers (public and/or private)	Construction and operation of privately owned water and wastewater treatment works. Likely to have key input on the costs recovery obligation.
Industrial companies and other commercial operators	Compliance with permits for water for water abstractions and effluent discharges. Also likely to have key input as to future water use and quality trends.
General public	Involvement in consultation processes for river basin management plans, marine strategy and flood management plans. Reporting pollution incidents, also calling on penalties under the Environmental Crimes Directive. Likely to be concerned with the costs recovery obligation and protection of those economically disadvantaged.
Environmental and consumer NGOs	Lobbying on behalf of the public with respect to water quality objectives, siting of treatment plants, pollution problems, and costs recovery issues. Monitoring implementation and put pressure on industrial actors to comply and to be held responsible for water damages under the Environmental Liability Directive and the Environmental Crimes Directive.
Research institutes (e.g. universities)	Technical research into monitoring equipment and standards, environmental quality standards, flood risk assessments, toxicity assessment, water analysis and various pressures on marine waters.

3.3. Competent Authorities

Examples of the duties that need to be carried out by the competent authorities in the water sector are illustrated in the Box below. In some countries, existing organisations — sometimes within central government, or regional or local bodies — already undertake similar work. There may be a need to expand their responsibilities or, if it is not already available, to consider a new organisation.

Competent authorities can be appointed for individual Directives, for environmental sectors or across environmental sectors. The last option allows the use of skills (such as permitting, inspection and compliance assessment), which are common across sectors, to be utilised efficiently, and also encourages cross-sector issues and the necessary links required by individual legislative instruments to be addressed with the minimum of administrative efforts. It should be noted that the competent authorities not always can be the same. For instance, the Floods Directive explicitly requires that the competent authorities be different from those designated under the WFD. Having said this, Member States still have to ensure that these authorities work closely together to achieve benefits, synergies to achieve the general environmental objectives and targets.

A cross-sectoral (i.e. across environmental sectors) competent authority, provided by a single national body or by regional bodies operating under the same management regime, covering the environment would result in economies of scale, synergies and better build-up of expertise through shared facilities and resources and would represent the closest form of integration on environmental issues. Alternatively, sectoral competent authorities would require close collaboration on those issues that are regarded as cross-sectoral, and their terms of reference should include the links between sectors.

Where issues of strategic importance to Member States arise, these should rather be dealt with by a national-level organisation. The need for specialised technical expertise supplied at a consistently high level also suggests the advantages to be gained by appointing national organisations, such as ministries, with the consequent efficient use of scarce resources.

As indicated above, the WFD requires decision making on a river basin district basis. A national competent authority will need institutional structures capable of operating in the geographical areas dictated by the limits of the river basin districts. The alternative of devolving responsibility to regional bodies that match, or that can accommodate, the boundaries of river basin districts might also be considered. However, in the latter event, it is important for the purposes of achieving the objectives of the Directive that such current administrative facility does not determine the identification and allocation of river basin districts.

As most elements of the legislation in this sector are linked through the river basin district approach and common methodologies, using either quality objectives that apply to waters and/or the application of limit values to effluents and/or controls on diffuse sources, it is advantageous for the competent body for all legislation concerning water quality and pollution control to be the same in each region of the country, if not across the country as a whole. Common methods of sampling and analysis are also required and it is possible in this way to avoid duplication of effort and to make savings by using samples for more than one purpose. This approach also has the advantage of allowing for standardised protocols for the taking and presentation of proof in enforcement actions. If individual regional or river basin organisations are appointed as competent authorities, they could share laboratory facilities. Close co-operation is required in this case, however, to avoid differences in testing procedures and in the interpretation of the results. A national competent authority could operate in river basin districts by setting up a managerial structure based on river basin districts.

Examples of Activities to Be Carried Out by a Competent Authority in the Water Sector

Planning and Implementation

- Identify river basins (2000/60/EC)
- Identify marine waters (2008/56/EC)
- Identify flood risk areas in river basins (2007/6/EC)
- Prepare river basin management plans (including investigations such as the pressures and impact assessment, economic analysis, programmes of measures (2000/60/EC).
- Make programmes of measures operational (2000/60/EC)
- Prepare preliminary flood risk assessments, flood risk maps, flood management plans (2007/6/EC)
- Perform the initial assessment of the current environmental status of national marine waters and the environmental impact and socio-economic analysis of human activities in these waters, determine the GES for national marine waters, establish the environmental targets and associated indicators to achieve GES by 2020, organize monitoring and develop programme of measures designed to achieve or maintain GES by 2020 (2008/56/EC)
- Identify bathing waters, shellfish waters, freshwater fish, marine regions or subregions (2006/7/EC, 2000/60/EC, 2008/56/EC)
- Identify agglomerations (point sources of pollution under the WFD) required under the Urban Wastewater Treatment Directive and as land based sources of pollution under the Initial Assessment of the MSFD 91/271/EEC, 2000/60/EC, 2007/60/EC, 2008/56/EC)
- Identify sensitive and less sensitive areas (91/271/EEC, 2000/60/EC)
- Identify nitrate vulnerable zones (91/676/EEC, 2000/60/EC)
- Identify water supply zones (98/83/EC)
- Apply exemptions and grant derogations (2000/60/EC; 98/83/EC)
- Identify the industries to which Directives apply (2000/60/EC, 2008/56/EC)
- Fix standards applicable to drinking water, bathing water, shellfish water, freshwater fish (98/83/EC, 2006/7/EC, 2000/60/EC)
- Set water quality objectives (2000/60/EC, 2008/105/EC)
- Set fixed emission limits (91/271/EEC; 2000/60/EC, 2010/75/EU, 2008/105/EC)
- Specify urban wastewater treatment requirements (size and type) and sewerage designs according to the identification of sensitive areas and the delineation of agglomerations (91/271/EEC)
- Decide whether to utilise the possibility in Directive 2008/105/EC on environmental quality objectives and instead of applying the EQS set out in Part A of Annex I apply EQS for sediment and/or biota in certain categories of surface water (2008/105/EC)
- Arrange for the long-term trend analysis of concentrations of those priority substances listed in Part A of Annex I that tend to accumulate in sediment and/or biota (2008/150/EC)

- Determine the frequency of monitoring in sediment and/or biota (2008/105/EC)
- Decide whether to designate mixing zones adjacent to points of discharge and make sure that these are described in the river basin management plans under the WFD
- Ensure that measures to provide the public with adequate and up-to-date information on the quality of water intended for human consumption are established
- Ensure information of the public about bathing water quality and beach management, through the so-called bathing water profiles (information on the kind of pollution and sources that affect the quality of the bathing water and pose a risk to bathers' health)
- Coordinate the timescale for compliance as resulting from the provisions of the Directives and the relevant treaties (Accession Treaty)
- Produce maps that identify areas prone to significant flood risks and indicate scenarios (based on high, medium or low probability) of a flood occurring there (2007/60/EC)
- Establish flood-risk management plans that are coordinated at the level of the river basin or coastal districts(2007/60/EC)

Technical Standards

- Develop a methodology for deciding water quality objectives (2008/105/EC, 2000/60/EC)
- Develop standards for intercalibration purposes (2000/60/EC).
- Develop a methodology for deciding emission limit values (2000/60/EC)
- Establish procedures for the issue of authorisations (2008/1/EC, 2001/75/EU)
- Ensure compliance with templates and standards set out by the Commission for the reporting and information exchange in line with the INSPIRE Directive
- Establish an inspectorate that is authorised to inspect installations, take samples, and take enforcement actions as stipulated by the Industrial Emissions Directive (2010/75/EU), UWWTD (91/271/EEC); BWD (2006/7/EC), DWD 98/83/EC, MSFD (2008/56/EC)
- Establish laboratories and associated technical facilities and equipment
- Set up monitoring programmes to determine compliance with directives (2000/60/EC, 2008/56, 98/83/EC, 91/271/EEC and 2006/7/EC)
- Establish databases and information systems to allow reports to be made to the Commission and to the general public (91/692/EEC, 2000/60/EC, 2010/75/EU,2008/56/EC, 98/83/EC, 91/271/EEC and 2006/7/EC).

Reporting

- Prepare reports on e.g. implementation, designations, authorisations, derogations etc. (91/692/EEC, 2000/60/EC, 2010/75/EU,2008/56/EC, 98/83/EC, 91/271/EEC and 2006/7/EC).

3.4. Regional and Local Government

The role of regional and local government in the water sector is important for two reasons:

First, most countries have a tiered administrative structure in which certain powers are devolved to the regional (county, department, Länder) or local level of government (e.g. planning authority, municipality, regional county boards). Such decentralisation is stronger in federal states but exists generally.

Second, the WFD and the Floods Directive are to a large extent based on a "decentralised" concept of river basin management and allows the involvement of local people as much as possible in the whole planning process provided that the WFD requirements are met. Also the MSFD is partly based on decentralised approach with measures and strategies developed for marine regions and sub regions, which to a large extent involves regional authorities and people from neighbouring countries.

The WFD and Floods Directive will require the co-operation of regional and local authorities in developing operational and strategic objectives that are to some extent also use-related (e.g. waters for drinking water abstraction, waters for bathing). Measures to meet prescribed water quality standards and abstraction limits will in any case require local action. A similar approach will be required for the implementation of the MSFD in defining and implementing programme of measures.

The provision of water, sewerage and waste water treatment may be the responsibility of the regional or local government. Such bodies will be involved in ensuring that drinking water is safe and that human waste products are disposed of in a satisfactory way so as to minimise public health risks and/or harm to water resources otherwise. Regional or local administrations may be responsible for, and be funded to construct, water and wastewater treatment plants, water mains, sewerage networks and waste management facilities. In such cases the regional authority may be an appropriate competent authority in the terms of the Drinking Water Directive (98/83/EC) or Urban Waste Water Treatment Directive (91/271/EEC). The role of the regional or local authority in implementing these Directives, and the possible conflict of interest, must be considered in such cases, since the authority could be in the position of both the regulator and the regulated.

The river basin district approach includes the catchments of cross-border rivers. If the competent authorities are based on regional or local authorities, provision must be made for inter-state co-operation and co-ordination to ensure that, at least as regards that part of the international river basin in their own territory, the requirements and objectives of the Directive are met. It may be necessary for the central government to reserve some powers for international co-operation on cross-border rivers. The same considerations apply to joint action required in the case of coastal and estuarine waters. In any case, it has to be ensured that the administrative boundaries within and between the countries do not hinder integrated water management.

3.5. Private Sector Involvement

EU legislation is neutral on the issue of ownership of water infrastructure and leaves this to Member States, following the principle of subsidiarity. Indeed, the Member States present a diverse picture:

- local communities or associations of such communities being the main owners and providers of services related to urban wastewater collection and treatment as well as drinking water supply in several Member States;
- large industries constructing and maintaining their own plants or having established partnerships with local communities;
- mixed public-private companies in others; and
- a completely privatised water industry, largely with some form of monopoly on water supply and wastewater disposal, in a major part of one Member State.

The Directive 2014/23/EU of the European Parliament and of the Council of 26 February 2014 on the award of concession contracts does not cover the water sector, considering that the concessions in the water sector are often subject to specific and complex arrangements which require a particular consideration given the importance of water as a public good of fundamental value to all Union citizens (Article 40).

Experience gained shows that all the approaches have certain merits in a particular context, but it is difficult to draw general conclusions since the historical development of the sector as well as the political and general economic situation have to be taken into account.

Whatever approach is to be taken, clearly defined mandate, competences and responsibilities will facilitate both the achievement of the environmental objectives and the best use of available resources.

3.6. Environmental Inspectorate

Water protection legislation contains monitoring and inspection requirements to check compliance.

One or more inspectorates may be needed to assess compliance with the requirements of the Directives and to take enforcement actions, although, as indicated above, advantages may be gained from having one inspectorate responsible for such matters across the country.

Details of how to organise all such inspectorates are left to the discretion of Member States. To encourage a more consistent and harmonious approach to environmental inspections in 2001, the Commission adopted a Recommendation 2001/331/EC providing for minimum criteria for environmental inspections in the Member States. The Recommendation contains non-binding criteria for the planning, carrying out, following up and reporting on environmental inspections. Its objective is to strengthen compliance with EU environmental law and to contribute to its more consistent implementation and enforcement in all Member States.

Many of the activities for the inspectorates are common to Directives in other sectors so there are advantages, in the event of more than one responsible inspectorate, in establishing inter-sectoral inspection and enforcement arrangements. Such inspectorate arrangements could be set up within the competent authorities. Any such inspectorate(s) requires specific terms of reference to undertake work within the remit of the Directives, and a clear reporting line, to enable enforcement procedures to be instigated. In the water sector, one such inspectorate could be located within the river basin management organisation, or inspectorate facilities could be attached to the local government. Any such organisation must be equipped with sampling and inspection facilities, vehicles, data processing systems and trained staff, and must have access to laboratory facilities that must use methods in accordance with those specified in the Directives.

The inspectorate(s) should take responsibility for monitoring adherence to all the Directives in the water sector. It is sometimes considered advantageous to use a separate organisation to monitor the Drinking Water Directive as there are health implications with respect to non-compliance and closer links with health authorities could be developed. Local municipalities or authorities could be used to monitor and report upon aspects of the water Directives, such as drinking water quality or effluent quality, but if this option is used the inspection role should be quite separate from other aspects of implementation such as the operation of works. IMPEL have recently completed a project on risk analysis criteria that should be used to select holdings/operators to be inspected. A targeted inspection process based on appropriate risk criteria will make efficient use of inspection resources.

The Environmental Inspectorate being an efficient body in ensuring supervision, monitoring and enforcement of water management and quality requirements, also plays an important role in ensuring that water damage caused by a private legal or natural person is being remedied and that the polluter is being subject to effective, proportionate and dissuasive penalties.

3.7. Communication and Consultation

The implementation of the WFD requires a review of the environmental impacts of human activity and an economic assessment of water use. This must be followed by the preparation of a river basin management plan and a programme of measures. In order to assess adequately activities within a river basin district, consultation with those who live and work there is essential. Similarly, as the management plan, flood risk maps, and programme of measures for the river basin districts, initial assessment, programme of measures, environmental targets and monitoring programmes of marine regions and subregions will affect residents and activities in these areas, consultation is necessary to ensure that the proposals are likely to be achievable and will not lead to an unacceptable burden on those who use that river basin district or marine region. These Directives require consultation to take place, and the competent authorities should arrange consultation mechanisms with interested parties. The parties to be consulted should include:

- other central government ministries;
- regional and local government;
- water and sewerage companies;
- industrial users of water;
- industrial wastewater producers;
- farmers;
- fishermen and other river users;
- fishermen, natural or legal persons carrying out extraction of minerals or other resources from marine regions;
- existing management bodies or structures for marine regions, including Regional Sea Conventions, Scientific Advisory Bodies and Regional Advisory Councils;
- tourist organisations and business (especially along river banks or coastal areas);

- the general public; and
- environmental NGOs.

Whilst EU water legislation is precise in its objectives, e.g. achieving a maximum elimination rate or minimum effluent concentrations for wastewater treatment plants or achieving good water status, it is not very prescriptive as to the means of achieving this objective. Consultation with all relevant parties might, in this context, also achieve a best-cost effectiveness and identify the best combination of measures on a proportionate level. Judgment on such measures is specifically required by Member States as regards consideration of the principle of costs recovery for water services. Therefore, preparation of measures to implement those parts of the WFD addressing information and consultation of all stakeholder groups and the public should be subject to serious efforts.

Where the achievement of environmental goals relies upon a change in public attitudes or methods, consultation and publicity is essential. This has proved to be effective in increasing awareness of the impact of activities on water quality, for example in farming practice, but also in measures to save water or limit pollution of wastewater from domestic sources.

Some Directives specify public consultation and the availability of information, e.g. the Environmental Impact Assessment Directive (2011/92/EU), Strategic Environmental Assessment (2001/42/EC) and the Directive on access to environmental information (2003/4/EC), the Reporting Directive (91/692/EEC) and the Public Participation Directive (2003/35/EC). The competent authorities dealing with the water sector must be aware of, and take action in accordance with, these Directives where information relating to the water environment is concerned.

4. TECHNICAL ISSUES

Examples of technical standards within the water sector include:

- Emission standards, which set maximum concentrations of a substance permissible in a discharge or the maximum quantity of a substance permissible in a discharge over a given period of time;
- Water quality objectives, which apply to bodies of water and relate to ambient conditions and are based on the toxicity, persistence and accumulative characteristics of substances. Quality objectives are used as a target standard to aim for in receiving waters;
- Environmental quality standards set out in Directive 2008/105/EC;
- Design, construction and maintenance of sewerage systems (as in the Urban Waste Water Treatment Directive);
- Develop technical formats for the purposes of transmission and processing of data, including statistical and cartographic data (for instance MSFD and Floods Directive, also taking into account the provisions of INSPIRE Directive);
- Methods of monitoring, sampling and analysis (in a range of Directives and 2009/90/EC).

The two prevailing approaches to technical issues is either for the EU legislation to define methods and format (now mainly through fast track regulatory procedure) or through providing references to CEN/ISO standards, at the same time making analytical quality assurance schemes and "best laboratory practice" mandatory.

Whilst EU water-related standards are clearly defined where mandatory, standards from other international or national bodies might take the character of recommendations. Alternative sources for technical or scientific standards might be WHO, national or international standardisation organisations (DIN, CEN ISO), but also internal industrial and/or accreditation bodies (e.g. OECD). As regards standardisation bodies, co-operation within ISO and CEN might facilitate access to information, data and resources.

5. REGULATION AND ENFORCEMENT

5.1. Overview

In order to achieve the objective of maintaining/achieving good status for waters, the measures put in place by the legislation in this sector and by legislation in other sectors such as the Industrial Emissions Directive (2010/75/EU), must be properly implemented and enforced. This can only be achieved by developing a suitable regulatory regime with adequate resources to implement and enforce the law. Regulation in the water sector involves:

- periodical review of permits and authorisations to identify measures contributing to WFD objectives;
- issuing authorisations or permits to abstract water from a water body or discharge wastewater;
- monitoring and inspection to ensure that authorisation or permit conditions are being observed;
- considering when and how to amend permit conditions in the light of new developments, further information and/or adverse effects on water bodies involved;
- taking enforcement and other suitable control action if they are not;
- the provision for and application of suitable dissuasive fines and penalties;
- reporting on implementation and enforcement measures and their success.

5.2. Authorisations and Permitting

The principal tasks related to authorisations or permitting in the water sector are:

- review of permits and authorisations to identify measures contributing to WFD objectives;
- issuing permits for discharges to water, including quantity and quality of the discharge, setting emission limit values according to European and national legislation and bearing in mind the combined approach, i.e. ensuring compliance with water quality objectives and environmental quality standards;
- issuing permits for the abstraction of water (from surface waters and groundwater), and for the impoundment of fresh surface water, bearing in mind the principle of a long-term balance between abstraction and natural recharge/low flow; and
- considering when and how to amend these permits.

Ensure that emissions from installations covered by the Industrial Emissions Directive (2010/75/EU) into water do not exceed the emission limit values set out in Part 1 of Annex VIII.

Common procedures for assessing applications from the discharger and for issuing permits should be established to ensure conformity throughout the country, to reduce administrative burden and to avoid problems of differing interpretations or unjustified different application being applied in various parts of the

country. There is a need to ensure that permit conditions reflect what is required by a Directive, by national legislation and by any other conditions that are necessary to achieve environmental targets. Transposing and implementing European legislation is mandatory; at the same time, Member States have the right to apply more stringent environmental objectives.

In setting conditions, the competent authority may have to take account of the interests of other statutory bodies and others who may be affected by the discharge or activity through consultation. The details of the permit must, as a rule, be available to the public in some readily accessible form under the Directive on access to environmental information (2003/4/EC).

5.3. Monitoring, Inspection and Enforcement

Monitoring is an essential part of the implementation of the whole range of EU water legislation, including, in particular, the WFD but also Floods Directive and MSFD. Systematic monitoring of surface water, groundwater and marine water quality and quantity will arise in several categories:

- surveillance monitoring;
- operational monitoring;
- technical monitoring;
- investigative monitoring.

This monitoring has to be in accordance with set standards, technical formats also corresponding to the requirements for exchange, collection of information established by the INSPIRE Directive (2007/2/EC)

The quality and comparability of analytical results generated by laboratories appointed by competent authorities of the Member States to perform water chemical monitoring for the purpose of assessing the ecological and chemical status pursuant to Article 8 of WFD should be ensured. Hence compliance with the Directive on technical specifications for chemical analysis and monitoring of water status (2009/90/EC) laying down, pursuant to WFD, technical specifications for chemical analysis and monitoring of water status must be ensured. The objective of this Directive is to establish common quality rules for chemical analysis and monitoring of water, sediment and biota carried out by Member States.

Proper co-ordination of monitoring will not only contribute to achieving environmental objectives, but also reduce the administrative and financial burden of monitoring.

Summarising the water legislation, monitoring must be established for:

- surface waters — for ecological, physico-chemical and morphological parameters and for the substances mentioned in points (a) and (b) of Article 3 of Directive 2008/105/EC;
- groundwater — for physico-chemical parameters;
- discharges of wastewater — parameters depending on the particular case;
- bathing waters during the bathing season — for bacteriological and chemical parameters;
- drinking water — for microbiological, chemical and indicator parameters;

- flood waters – description of the prioritisation and the way in which progress in implementing the plan will be monitored;
- marine waters – for the state of the marine waters and the progress in attaining good environmental status concerned to be evaluated on a regular basis of spatial protection measures such as special areas of conservation, special protection areas or marine protected areas.

Candidate countries should carefully plan the phasing in of provisions introduced by the WFD, the EQS Directive (2008/105/EC) and the MSFD. The Groundwater Directive (2006/118/EC) and the Environmental Quality Standards Directive (2008/105/EC) should be implemented in synergy with the WFD.

Providing for the establishment of an integrated, carefully coordinated monitoring scheme with shared resources, methods, structures, which is implemented in a step-by-step approach will have efficiency, cost-cutting and transparency benefits.

The relevant legislation here is:

- WFD (2000/60/EC)
- Groundwater Directive (2006/118/EC)
- Floods Directive (2007/60/EC)
- EQS Directive (2008/105/EC)
- MSFD (2008/56/EC)
- Directive on technical specifications for chemical analysis and monitoring of water status (2009/90/EC)

Monitoring required by Industrial Emissions Directive (2010/75/EU) may also be accommodated within these base programmes.

Other Directives will require a more targeted and in-depth monitoring in certain sectors:

- Bathing Water Directive (2006/7/EC) — monitoring of bathing areas during the bathing season
- Urban Waste Water Treatment Directive (91/271/EEC) — monitoring of discharges, as well as of affected bodies of water; in case of individually designated sensitive areas monitoring for a review of those areas
- Nitrates Directive (91/676/EEC) — monitoring of nitrates content in surface waters and groundwater; in case of individually designated vulnerable zones, monitoring for a review of those zones

To ensure appropriate implementation, the competent authority will require suitable powers to take enforcement action if, as a result of inspection or monitoring, the owner of a permit is found to be breaking the terms of the permit. The competent authority should also have appropriate powers to revoke or alter the terms of a permit, if for example pollution is found to be occurring despite compliance with its conditions, or in the event of other accidental or natural incidents.

The importance of environmental inspections should also be highlighted (also see above under section 3.6). The Candidate countries should take use of Recommendation 2001/331/EC providing for minimum criteria for environmental inspections in the Member States. The Recommendation contains non-binding criteria for the planning, carrying out, following up and reporting on environmental inspections. Its objective is to strengthen

compliance with EU environmental law and to contribute to its more consistent implementation and enforcement in all Member States. In 2007 the Commission adopted a Communication on the review of Recommendation 2001/331/EC outlining its initial views on how to further develop the Recommendation and a Report on the implementation of the Recommendation in Member States summarising the information received from Member States. This report concludes on the basis of the reports received from Member States that although the situation with inspections has been approved, the Recommendation has not been fully implemented in all Member States. The report formulates further suggestions how environmental inspections could be improved:

- modify the Recommendation to make it stronger and clearer, including a better reporting mechanism (providing simpler and more comparable data);
- where necessary, to complement the Recommendation with legally binding inspection requirements in individual Directives, and;
- continue supporting the exchange of information and best practice between inspectorates in the context of IMPEL.

IMPEL has contributed to the strengthening and further development of the Recommendations on Minimum Criteria for Environmental Inspections. The 7th Environmental Action Programme recognizes importance of strengthening the implementation and enforcement of EU environment law at all administrative levels has been. Extending binding criteria for effective Member State inspections to the wider body of the environment acquis and complementing these with support for networks of professionals, reinforcement of peer reviews and best practice sharing should be encouraged.

The monitoring and enforcement aspects have been strengthened through the Environmental Liability Directive (2004/35/EC) and the Environmental Crimes Directive (2008/99/EC). Under the Environmental Liability Directive, the polluter is responsible for certain damage and has to remediate and cover costs. Here the competent authority should ensure some kind of self-monitoring (as part of permit conditions for instance) in addition to the supervisory and monitoring activities normally undertaken by a central authority, such as the Environmental Inspectorate. This monitoring is also necessary to detect environmental crimes committed by natural or legal persons linked to activities which have damaged water bodies (e.g. transport, storage of waste or dangerous substances, industrial or other commercial activities resulting in polluting discharge to water bodies).

5.4. Data Collection and Reporting

Reporting is an important element of the water management legislation and policy. The WFD, the Floods Directive and the Marine Framework Strategy Directive, but also the UWWTD, the Drinking Water Directive, the Bathing Water Directive and EQSD, all contain provisions on both data collection and reporting. In this regard, the WISE reporting database fulfils a central role.

The Water Information System for Europe (WISE) is a partnership between the European Commission (DG Environment, Joint Research Centre and Eurostat) and the European Environment Agency. WISE was launched in 2007 providing a web-portal entry to water related information ranging from inland waters to marine. The web-portal is now grouped into sections for:

- EU water policies;
- Data and themes;
- Modelling;
- Projects and research
- WISE addresses several user groups:
 - EU institutions and the Member States (e.g. national, regional and local water policy or management administrations);
 - Professionals working in the water field from public or private organisations, with a technical interest on water;
 - Scientists working in the water field;
 - General public, including in this group those working in private or public entities not directly related to water policy.

WISE is accessed at: <http://water.europa.eu/>

A summary of the type of data collection and reporting required by EU legislation is given in the Table below.

Table 3. Examples of Reporting and Notification Requirements for the Water Sector

Body responsible	Receiver of the Information	Type of information
EU level (Commission)	European Parliament, Council and the general public	Periodic reports on implementation of Directives (e.g. Urban Waste Water Treatment Directive, Nitrates Directive, EQSDirective, WFD, MSFD, Floods Directive). For some Directives such as the MSFD, this report should include a review of the status of the EU marine environment, a survey of the marine strategies and a summary of data received from Member States.
European Environmental Agency	General public	Report on quality of bathing waters (under the Bathing Water Directive)
European Commission	General public	Synthesis report on the quality of drinking water in all Member States (under the Drinking Water Directive)
Member States	European Commission	<ul style="list-style-type: none"> • Notification of transposition of legislation and main texts (all Directives) • Implementation programmes and/or programmes of measures (e.g. WFD, Urban Waste Water Treatment Directive, Drinking Water Directive, MSFD). • Issue interim reports of implementation of the programme of measures such as required under WFD and the MSFD. Art. 15(3) of WFD stipulates that „Member States shall, within three years of the publication of each river basin management plan or update under Article 13, submit an interim report describing progress in the implementation of the planned programme of measures. • Floods hazard maps (2007/60/EC) • Issue reports in accordance with Article 15 of the WFD Member States, which shall include the inventories established pursuant to Article 5(1) of Directive 2008/105/EC, including the respective reference periods • Vulnerable zones; action programmes; codes of good practice (Nitrates Directive) • Sensitive areas (Urban Waste Water Treatment Directive)

		<ul style="list-style-type: none"> Prepare and make available the baseline report for IED sites, which is a practical tool for quantified comparison between the state of the IED site described in that report and the state of the site upon definitive cessation of activities, in order to ascertain whether a significant increase in pollution of groundwater has taken place (Industrial Emissions Directive (2010/75/EU))
Transboundary river basin commissions	General public and European Commission	River basin management plans (under the Water Framework Directive)
Member State	General public	Reports on state of urban waste water disposal and sewage sludge (Urban Waste Water Treatment Directive)
Member State	General public	Report on the quality of drinking water in the Member State (under the Drinking Water Directive)

Organisations with obligations to report should be made aware of their responsibilities. In particular, competent authorities must be given the powers to collect information and their duties should include the requirement to set up data collection and reporting systems, which should be in line with INSPIRE Directive¹⁹⁷ in terms of ensuring smooth information compilation, exchange and access for general public. Access to spatial data and services constitutes an important basis for environmental policies for all public authorities. This can be achieved through having access to the requirements for licensed wastewater dischargers and water abstraction or water users, as well as to those whose activities have a specific adverse impact on water resources and are requested to report information to the competent authority on the activities to which the licence permit or permission relates.

Reporting to the Commission is the responsibility of the government of the Member State.

In many cases this has been delegated to the competent authority, but in others a ministry retains the right to make the formal reports.

¹⁹⁷ The Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) was published in the official Journal on the 25th April 2007. The INSPIRE Directive entered into force on the 15th May 2007

6. PRIORITIES AND TIMING

6.1. Prioritising the Implementation Tasks

In preparing their implementation plans, the candidate countries will need to prioritise the major tasks to be undertaken. Note the detail in this regard in the fiches on water quality and management.

6.1.1. General Considerations

As a perhaps initial step in prioritising the policy and legislative measures to adopt the EU water management acquis, the candidate countries should consult the „Water Blueprint”¹⁹⁸, which sets out a number of actions for Member States. The Blueprint is based on various assessment, implementation reports and studies and reflect the current needs and objectives to improve overall water quality and water management practices and to achieve the overall objective set for 2015 in achieving good water status. The Communication: „A Blueprint to Safeguard Europe's Water Resources” not only focuses on protective measures but the need – also for the EU as whole - to focus on green growth and become more resource efficient (including water) to achieve a sustainable recovery from the current economic and environmental crisis, adapt to climate change and build resilience to disasters. Candidate countries should contribute to tackling these challenges by facilitating the boosting of green economic growth of the European water sector, with creation of more jobs in the water sector, e.g. in water utilities, water-using industries, water technology development etc.). The Communication sets out a table on page 6 with actions from both the Commission and the Member States, applying to the period 2013-2021. The actions proposed include 1) retention measures (green infrastructure) including better use of Structural and Cohesion Funds and EIB loans to support retention measures, 2) developing CIS Guidance for ecological flow and water accounts, 3) apply GMES services to detect illegal abstraction.

6.1.2. Legislative Considerations

Candidate countries must transpose all relevant elements of EU Directives into national legislation by the date of accession. However, consideration should be given to the order in which the various items are transposed.

Framework-type Directives are usefully transposed at an early stage as these will provide the outline for other related legislation, and usually the requirements for competent authorities and administrative infrastructure set up to meet the frameworks will suffice for the whole sector. In the water sector, the WFD will become the main lead Directive but the MSFD is also a key Directive in the protection of marine waters. However, as candidate countries have generally been involved in detailed implementation measures for the water sector for some time prior to adoption of the WFD, it may well be that some if not all their existing structures in this area of activity can be subsumed in re-organisational steps directed at the better implementation of the latter Directive. A Directive closely related to the WFD, is the Floods Directive (2007/60/EC) and candidate countries should implement these in close coordination and synergy although the competent authorities are not

¹⁹⁸ COM(2012)673 final

the same. The Floods Directive also has close links with civil protection and emergency measures as it not only deals with the protection against floods but also introduces measures in case of actual flooding situations.

In terms of restriction and control of the discharges of polluting substances to water bodies from industrial and other type of activities, the WFD supplemented with the Groundwater Directive (2006/118/EC) and the EQS Directive (2008/105/EC) setting out a solid framework for regulating the discharges of dangerous substances to water bodies. The Industrial Emissions Directive (2010/75/EU) also have an influence on the implementation of the WFD and EQS Directive as its provisions are a means to control pollution from large industrial installations, and it will be one of the foundations of the improvement programmes for river basin districts.

The Drinking Water Directive (98/83/EC) should be implemented early in the implementation plan as it is of great importance to public health and will continue to have some sort of "stand alone" function. The Urban Waste Water Treatment Directive (91/271/EEC) is an important Directive and, in areas with basic sewerage needs, requires lot of financial resources and technical infrastructures and, should be implemented at an early stage. At the same time, the issue of sewage sludge in the context of waste legislation has to be addressed, as appropriate ways for sewage sludge reuse and/or disposal will be required. The MSFD is less relevant for landlocked Member States. Countries with marine areas should preferably implement this Directive in close coordination with the WFD as these two Directives have several common elements and structures, such as preparing programmes of measures and the work towards reaching good environmental status entailing assessments, monitoring and reporting. Also both Directives require extensive cooperation with neighbouring countries.

6.1.3. Cost-effectiveness

In general, legislation which gives the greatest benefit to the cost of implementation should be given a higher priority than that producing lower cost/benefit ratios. However, legislation that will require major infrastructure renewal or capital spending on industrial improvements should also be given an early place in the phasing process. This is because in order to meet the deadlines in many of the Directives, new investments will be needed to be built and operating, and this takes time to plan and implement.

Furthermore, considering the approach, rationale, requirements of the provisions of the WFD, the Floods Directive and the MSFD for basic structural investments will ensure a cost-efficient and consolidated approach providing multiple benefits for the implementing authorities, the regulated sectors and the public in general. The EQS Directive (2008/105/EC) should be implemented in conjunction with both the WFD and the IED to ensure transparency and cost-efficiency.

6.1.4. Economic Considerations

The candidate countries should consider which legislation is likely to have significant consequences for their economies, which also depend on the structures and investments already made into the water quality sector. Legislation that affects industrial or commercial sectors that make a significant contribution to the economy should be addressed before legislation that relates to small or less significant industries. Also priority should be given to those industrial or commercial activities which may result in the highest pollution of water bodies. Where, the current status of water management is considerably lower than the measures prescribed by the EU water legislation and the institutional and technical structures are largely lacking, the candidate countries should make a financial assessment and carefully plan and priorities the financing of the implementation. For instance,

the WFD will result in considerably high costs only if measures under the river basin management plans have to go beyond those under existing legislation on urban wastewater treatment (Directive 91/271/EEC), EQS Directive (2008/105/EC) and IED (2010/75/EU). The Nitrates Directive (91/676/EEC) might, depending on the structure of agriculture and the state of surface and groundwater, affect the agricultural sector in terms of storage capacities for manure. In the longer term water treatment costs will be lessened through the reduced level of treatment needed to make water suitable for human consumption. On a shorter timescale, implementation of the EQS Directive, alongside the IED will more have an immediate effect on certain industries, due to the impact of the permitting, controlling and monitoring scheme and the application of best available technology. In the medium and long term, the measures for the "priority substances" (Article 16 of the WFD) will have an additional impact.

Candidate countries with marine areas will have a greater financial burden than land-locked countries due to the implementation of the MSFD. On the other hand, candidate countries can take use of a number of co-financing programmes for the implementation (see Article 22 of the Directive). In addition, these countries will enjoy benefits arising from the commercial activities in marine areas, which land-locked countries cannot.

6.1.5. Timescales

The dates by which the candidate countries must implement and comply with EU water Directives will be negotiated case by case during the accession negotiations. Experience from earlier enlargements of the EU shows that:

- Greece, Spain and Portugal received certain limited transition periods in the 1980s;
- Germany received transition periods of up to five years for its new Länder in 1990; and
- Austria, Finland and Sweden did not receive transition periods on accession in 1995.

The 10 CEE countries and Malta and Cyprus were granted several transition periods on accession in 2004 and 2007 regarding some of the old daughter Directives in the water sector (e.g. Council Directive 83/513/EEC of 26 September 1983 on limit values and quality objectives for cadmium discharges, as amended by Directive 91/692/EEC; Council Directive 84/156/EEC of 8 March 1984 on limit values and quality objectives for mercury discharges by sectors other than the chlor-alkali electrolysis industry, as amended by Directive 91/692/EEC; Council Directive 84/491/EEC of 9 October 1984 on limit values and quality objectives for discharges of hexachlorocyclohexane, as amended by Directive 91/692/EEC; and Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption). Croatia also negotiated transitional periods for compliance with the directives in the water sector. Thus, transitional period granted for compliance with the UWWT Directive expires on 1 January 2024, while for Drinking Water Directive transitional period is granted until 1 January 2019.

Implementation tasks may include:

- wastewater treatment — the planning, design and construction of sewerage and wastewater treatment plants;
- drinking water supply — the upgrading of distribution systems and, where necessary, drinking water treatment to meet quality standards;
- developing and implementing new managerial arrangements and institutional structures to implement the WFD, the Floods Directive and the MSFD;

- developing and implementing emission reduction programmes and monitoring for "priority substances" and selected dangerous substances;
- introduce a scheme for the efficient application of the EQS set out in Part A of Annex 1 to Directive 2008/105/EC including the requirements set out in Part B of the same Annex and deciding on the method and frequency of monitoring regarding biota and/or sediments;
- introduce the monitoring the control measures regarding selected dangerous substances set out in the Industrial Emissions Directive (2010/75/EU).

Careful technical and financial assessment will be an indispensable precondition for consideration of any requests for transition periods for implementing EU legislation.

7. ECONOMIC AND FINANCIAL ISSUES

7.1. Introduction

This section provides guidance on the economic and financial issues that will have to be considered in the implementation of the water legislation. The first two sections describe the types of costs likely to be incurred during implementation; the final sections discuss financial options.

7.2. Institutional Development

Although most candidate countries will have institutions devoted to the prevention of water pollution and the permitting of installations, they are unlikely to be developed everywhere to the extent required to implement the entire body of water legislation, particularly the WFD. The application of new types of standards — emission limits, EQS, quality objectives, best available techniques and the need for extensive monitoring together with facilities and data processing, with a focus on planning within river basin districts as well as marine regions and sub-regions — might sometimes require radical alterations in the method of working and in the institutional arrangements provided. It is therefore important to ensure that adequate budgets are provided for reorganisation, hiring the necessary human expertise, capacity building and training. Salaries need to be set at a level that enables staff with the necessary training and experience to be retained, and a significant capacity building and training budget is inevitable. Training needs should be assessed at an early stage and allowance made for any retraining which is necessary.

Human resources are required for:

- setting up an overall planning framework with clear objectives, priorities, division of responsibilities between the relevant competent authorities and other implementing bodies;
- financial and feasibility assessments which also can comprise cost-benefit analysis;
- ensuring consultation with directly and indirectly affected parties and the general public;
- legislative transposition, ensuring good legal drafters and a transparent legislative procedure;
- developing strategies, plans and programmes of measures directly relating to certain key Directives such as the WFD, the MSFD and the Floods Directive;
- developing water quality objectives, emission limit values and environmental quality standards;
- monitoring — sampling and analysing surface waters and groundwaters as well as discharges;
- issuing permits and authorisations, and providing for their periodic review;
- inspection and sampling of facilities;

- taking enforcement and other suitable control actions also taking into account the requirements under the Environmental Liability Directive (2004/35/EC) and the Environmental Crimes Directive (2008/99/EC);
- data collection, analysis and reporting;
- ongoing coordination within the water sector and across other sectors (e.g. industrial, foreign affairs, forestry, agriculture, fishing);
- dealing with transboundary issues, in terms of initial planning but also in the ongoing implementation which can involve transboundary pollution or flooding issues.
- it is not possible to generalise on the costs of providing the institutional structures because of the wide variety of organisational structures already in place and the variations in the size and complexity of the countries, but the aspects that are likely to be most costly are:
 - additional professional and technical staff and their training and development;
 - laboratory testing, analytical services and quality assurance;
 - sampling and monitoring equipment;
 - data collection, storage, analysis and reporting arrangements.

7.3. Water Facilities

It will be necessary to upgrade water facilities as a result of implementing the standards of the water Directives. Finance needs to be raised for capital investment expenditures and the recurrent costs incurred during operations. Ultimately, costs should be recovered from the users/polluters of waters, i.e. the consumers (domestic, industrial and agricultural sectors).

The costs incurred in establishing new facilities will depend on the standards that have to be adopted and the number, type and size of the facilities required conforming to these new standards. The final costs will also depend upon the current levels of treatment available for wastewaters, drinking waters, industrial discharges and agricultural practices. Such a wide variety of changes will be needed that it is impossible to give a precise figure of the costs of implementing water legislation.

Few studies are available on the costs of compliance with EU legislation. The Danish Environmental Protection Agency (DEPA¹⁹⁹) estimated the cost of complying with the Urban Waste Water Treatment Directive, the Drinking Water Directive and the Nitrates Directive for some of the earlier candidate countries. Assuming that wastewater treatment was carried out for agglomerations with a population equivalent (pe) of 2,000 and more, and that elimination of nitrogen and phosphorus was only carried out for settlements with 10,000 pe or more, DEPA estimated the total cost of compliance for the ten earlier candidate countries at DKK 100 billion (EUR 13.2 billion). However, this figure was an underestimate as it excluded sewerage works. Implementation of the Drinking Water Directive was estimated at DKK 140 billion (EUR 18.6), while agricultural works to comply with the Nitrate Directive were estimated at DKK 30 billion (EUR 4 billion). To counter balance these estimates cost-benefit analysis carried out for the purpose of the European Nitrogen

¹⁹⁹ DEPA, 1997. EU's udvidelse mod øst - miljømæssige perspektiver. Miljøstyrelsen.

Assessment highlights how the overall environmental costs of all reactive nitrogen losses in Europe are estimated at €70–€320 billion per year at current rates and outweigh the direct economic benefits of reactive nitrogen in agriculture.

A study²⁰⁰ prepared for DG ENV in 1997 indicated that, for the water sector, the total investment costs for the former ten candidate countries (CEE countries, Cyprus and Malta) would be EUR 3.5 billion per annum over five years with total short-term investment costs of EUR 17.5 billion. In the longer term, in order to achieve full compliance over a period of 20 years, the total cost would be of the order of EUR 50 billion and comes to about EUR 500 per capita.

A DISAE study in Latvia²⁰¹ estimated that capital costs to comply with the Urban Waste Water Treatment Directive (91/271/EEC), the Drinking Water Directive (80/778/EEC) and Nitrates Directive (91/67/EEC) would total EUR 810 million.

A 2002 study by the UK Department for the Environment, Food and Rural Affairs (Defra)²⁰² provides figures that can be used to identify estimated average capital costs for complying with the revision of the Bathing Water Directive in England and Wales. Estimated average capital costs are EUR 279 million without agricultural diffuse pollution costs and EUR 1,247 million with agricultural diffuse pollution costs.

Croatian Government estimated that costs to comply with the Urban Waste Water Treatment Directive (91/271/EEC) and the Drinking Water Directive (98/83/EC) would total EUR 4,5 billion.

Table 4: Implementation costs for "priority" water pollution Directives for Poland²⁰³.

Main Directives, investment outlays (million euro 2000)			
	Implementation year	Required outlays through 2006	Required outlays over the entire impl. period
Priority water, including:		7,419.1	10,912.4
91/271 (wastewater treatment) *	2015	4,112.3	6,882.8(1)
91/676 (agricultural nitrates)	2008	2,424.3	3,062.3
75/440 (drinking water quality)	2002	0	0
2006/11 (discharge of dangerous substances + 6 Directives)	2007	882.4	967.3
		2007 882.4	967.3

Source: K. Berbeka

²⁰⁰EDC Ltd., May 1997, "Compliance costing for approximation of EU environmental legislation in the CEEC."

²⁰¹Halcrow, 1998. Development of the Latvian Approximation Strategy and Programme.

²⁰² Cascade Consulting for Defra, May 2002, "Costing of the Revision to the Bathing Water Directive: Phase 3 Studies, Final Report."

²⁰³ Source: K. Berbeka, Kraków University of Economics, as published on the website of the Institute of Environmental Tax Reform (Instytut Ekologicznej Reformy Podatkowej), Kraków, Poland. <http://www.ierp.org.pl/wdrazanie/dyrektwy-eng.htm> (table indicating main Directives and investment outlays for Poland).

7.4. Cost Recovery

Part of the EU's environmental principles laid down in the Treaty on the Functioning of the European Union is the "polluter pays principle". This principle has further been strengthened through the Environmental Liability Directive and the Environmental Crimes Directive. This means that anyone whose actions pollute or adversely affect the environment should pay the costs of remedial action. Whilst there are considerable technical difficulties in assessing the value of environmental impacts, it is less difficult to calculate the economic costs of measures such as wastewater treatment plants. The polluter pays principle opens the way for the use of economics as an alternative to a regulatory approach for controlling pollution. To implement this, all actions that have a detrimental effect on soil, water or air should have an economic value attached to them that is related to the cost of the environmental damage. It follows those activities that are less damaging will incur a smaller cost and therefore be more economically justifiable. Whilst compliance with emission limit values and water quality standards has to be ensured, financial incentives such as environmental levies would additionally encourage environmentally more sound approaches. Such an "instrument mix" is also set out specifically in the WFD.

What is the attraction of economic instruments? Economic (or market-based) instruments rely on market forces to change the relative prices of goods and services, which in turn modifies the behaviour of public and private polluters such that environmental protection or improvements can take place. It is an alternative to regulatory control in that it has the potential to make pollution control economically advantageous to commercial organisations and the citizen.

The main instruments for recovering costs are:

- pricing;
- pollution charges;
- marketable permits;
- subsidies;
- deposit refund systems; and
- enforcement incentives.

In addition, some countries like Sweden, Denmark and the Netherlands have taken this one step further with something called the „confiscation fees”, which is an administrative fee which is imposed normally on a legal entity for more minor environmental offences to avoid that they gain an economic advantage in breaching the law.

The application of these tools in the water sector is discussed briefly below.

7.4.1. Pricing

Principle of recovery of the costs of water services, including environmental and resource costs, as described in the Annex III, and in accordance with the polluter pays principle must be taken into account. Resource costs represent the costs of foregone opportunities that other uses suffer due to the depletion of the resource beyond its natural rate of recharge or recovery (e.g. costs related to groundwater over-abstraction). These costs measure the value of lost opportunities, which are withheld from other users because a resource is being exploited to

excess (i.e. above the rate of regeneration). Cost Recovery can be as a source of funding for the Programme of Measures.

There are important differences, i.e. environmental costs are distinguished separately from the resource costs—differences exist in terms of water quantity and water quality management issues. The environmental costs refer to all damage costs related to the chemical and ecological status of a water body or river basin.

Water and wastewater tariffs or charges are set at levels that cover the costs for collection plus treatment or abstraction plus distribution, and this can induce organisations to use water-saving devices or bring in recycling or re-use.

The costs charged may be set to exceed the actual costs of treatment, for example. Marginal cost pricing can reduce water use (and consequent pollution). It is necessary to control the charges for effluent treatment at the same time, in some rational relationship to water-use charges. The use of dilution as a means of meeting effluent standards is largely prohibited by EU water legislation. In the water sector, the large increases in the price both of water supplies and of the collection and treatment of wastewater — inevitable in candidate countries as the standards of quality and environmental protection required in EU legislation are implemented — should encourage water saving and the re-use of wastewater. The economic value of environmental costs or benefits is often referred to as environmental values. It can be measured based on the identification of the goods and services (functions) affected by the pressure involved (e.g. water used for drinking water production, irrigation, food processing, recreation, wildlife habitat etc.).

7.4.2. Pollution and use charges

Pollution charges or "taxes" are defined as a price to be paid for the use of the environment.

There are four main types:

1. Effluent charges, based on actual quantities and/or pollution loads of effluents or on some surrogate (e.g. size of industrial installation), although they need to be set at a realistic level to encourage reduction in effluents produced. Such charges can be used to fund both the operating costs and loan charges for capital investment.
2. User charges, based on water consumption or on some surrogate (e.g. property values). High sewage treatment costs encourage in-house treatment by industry. The use of water meters will be encouraged as water charges rise.
3. Product charges, for example applied to the purchase of pesticides or fertilisers that will cause pollution before, during or after consumption. Their effectiveness will depend on the elasticity of demand for the product and whether there are less polluting substances available. This type of charge is useful for the control of non-point-source pollution, as rising charges will tend to cause a reduction in usage.
4. Administrative charges, which are used to cover the costs of operating the regulatory system. In some countries, the basic costs of administering the permitting and regulatory procedures, together with costs of monitoring, are paid for by an administrative charge that reflects the total costs of regulation. This is an example of applying the polluter pays principle. The charge does not raise sufficient funds for infrastructural improvement.

7.4.3. Tradable permits

The responsible authority sets a limit on the total allowable emissions of a pollutant and allocates this amongst the sources of pollution by issuing permits to emit a stipulated amount over a specified period of time. After the initial distribution, permits can be bought or sold. Trade can be external between different organisations or internal between different installations within the same organisation. Tradable permits work best where:

- the number of polluting sources is sufficient to establish a market;
- sources of pollution are well defined and easily measured;
- there are differences in the marginal costs of pollution control in the firms concerned;
- there is potential for technical innovation; and
- the environmental impact is not dependent on the location of the source or time of year.

It is possible to reduce the costs of regulation in this system, and the transfer of polluting loads between dischargers becomes a self-regulated issue within an overall permissible limit for the area.

7.4.4. Subsidies

Subsidies can include tax incentives, tax credits, grants and low-interest loans. The removal of subsidies can in itself act as an incentive to better environmental performance by forcing innovation and water-use reductions. However, it should be noted that the WFD expressly does not prevent funding of particular preventive or remedial measures in order to achieve the objectives of the Directive (see Article 9(3)).

7.4.5. Deposit-refund systems

Customers pay a surcharge when buying a potentially polluting product. On returning it to an approved centre for recycling or disposal, their deposit is refunded. This approach could be used for items such as pesticide containers, which would otherwise be dumped in the environment and lead to water pollution. The advantage of such a system is that it can be administered by the private sector. The costs of administration may be high.

7.4.6. Enforcement incentives

Environmental policies have been focusing on the use of economic and fiscal instruments and setting environmental standards for products, production, planning and management, described as horizontal environmental policy tools. Specific objectives and controls have been established, such as standards sector specific emission controls for water discharges. The most dominant horizontal tools are fiscal and subsidies policies, which could strengthen economic performance, societal welfare and environmental protection

Member States are obliged under the Article 9 of the WFD to develop water pricing policies for water uses in order to support the achievement of the environmental objectives and to implement a cost recovery for water services, taking environmental and resource costs into account.

The Article specifies that Member States had to ensure by 2010:

- that their water pricing policy is an incentive for efficient water use and thereby contributes to the environmental objectives;
- an adequate contribution for the different water uses to the recovery of the cost of water services.

The potential of using water pricing for improving enforcement and of moving towards sustainable water use is great if the Polluter Pays Principle is to be taken into account. Sectoral legislation and strategies against pollution from dangerous substances, river basin management and public participation are the main tools and objectives within which water pricing should be set.

In specific sectors, for example in agriculture, the Commission proposes to include water-related products in the Eco-design Working Plan, a cost-efficient solution that could have incentive role in water and energy reduction.

8. SUMMARY OF KEY ISSUES

In order to achieve a successful implementation of water legislation, the key points given in the checklist below may be considered.

Table 5. Illustrative checklist with key questions to be considered in implementing the EU water Directives

Checklist of Key Questions to Be Considered in Implementing EU Water Directives	
1	<p>Is there sufficient knowledge of the existing arrangements for managing water and effluents, including, in particular:</p> <ul style="list-style-type: none"> • existing water quality in surface waters (rivers, lakes, coastal waters), drinking water, groundwater and marine water? • identity of the substances of concern in the different river basins and marine regions? • introduce efficient programmes of measures for river basins and marine regions and subregions, along with monitoring of the water status? • identity of current point source discharges of wastewater? • effluent quality, treatment and management regimes? • the environmental impact of existing discharges and diffuse point sources? • existing drinking water quality and treatment? • existing legislative, institutional and regulatory arrangements?
2	<p>Have all significant problems associated with the existing arrangements been identified, in particular:</p> <ul style="list-style-type: none"> • the overall policy and planning framework? • the legislative/institutional/regulatory framework? • the shortfalls in infrastructure to meet the required standards? • the training/expertise shortfalls? • the consultation/communications requirements? • reporting and coordination requirements?
3	<ul style="list-style-type: none"> • Can the institutional framework be reorganised to operate on a river basin basis and a marine region and sub-region basis (for not land-locked countries), in particular? • are there organisations with expertise and resources to act as competent authorities? • can available data be assessed on a river basin or marine region basis? • are the organisations capable of undertaking sampling programmes? • are there laboratories that can analyse water and effluents in the prescribed manner? • do laboratories use accredited and standardised methods?
4	<ul style="list-style-type: none"> • Are clear links established between the competent authorities, central government and other organisations that have responsibilities for issues that affect the quality of water?
5	<ul style="list-style-type: none"> • Are the responsibilities for setting and meeting water quality objectives, limit values and issuing permits identified clearly?
6	<ul style="list-style-type: none"> • Does the legal/institutional framework give sufficient powers to: • enter premises? • inspect and sample? • authorise or otherwise control industrial effluent? • regulate urban wastewater discharges? • regulate the quality of drinking water?

	<ul style="list-style-type: none"> • regulate and monitoring bathing water quality • control activities within river catchments? • control activities within marine regions and sub-regions?
7	<ul style="list-style-type: none"> • Are arrangements in place for monitoring, surveillance and review of water and effluent quality? • Are arrangements in place to ensure that monitoring, surveillance and review of water and effluent quality are effective?
8	<ul style="list-style-type: none"> • Is a liability regime in place, ensuring application of the polluter pays principle, which also covers damages to water bodies corresponding to the definitions and requirements set out in the Environmental Liability Directive (2004/35/EC), also setting out clear lines of liability and accountability?
9	<ul style="list-style-type: none"> • Is an enforcement regime in place clearly setting out the activities and offences falling under the Environmental Crimes Directive, constituting an environmental crime for which it is mandatory to ensure efficient, dissuasive and proportionate penalties?
10	<ul style="list-style-type: none"> • Is an adequate data collection, processing and exchange system available, which also ensures formats in conformity with the INSPIRE Directive (2007/2/EC)?
11	<ul style="list-style-type: none"> • Are there adequate means of consultation/reporting with? • the Commission? • the public? • organisations affected by river basin action plans? • other countries where cross-border issues arise?
12	Are there means of undertaking economic assessments of requirements for the water sector?
13	Is there a means of obtaining adequate funding for the construction of new infrastructure?
14	Is an adequate training organisation in place?

THE URBAN WASTE WATER TREATMENT DIRECTIVE

Official Title: Council Directive 91/271/EEC concerning urban waste water treatment (OJ L 135, 30.5.91), as amended by Commission Directive 98/15/EC (OJ L 67, 7.3.98) and Regulation (EC) No. 1882/2003

Commission Implementing Decision 2014/431/EU of 26 June 2014 concerning formats for reporting on the national programmes for the implementation of Council Directive 91/271/EEC (OJ L 197, 4.7.2014)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The Urban Waste Water Treatment Directive is one of the key policy instruments under the EU water acquis.

The Directive establishes minimum requirements for:

- the collection, treatment and discharge of urban wastewater; and
- the treatment and discharge of wastewater from certain industrial sectors.

Its objective is to protect the environment from the adverse effects of such wastewater discharges. Member States must ensure that urban wastewater is collected and treated prior to discharge according to specific standards and deadlines.

The wastewater delivered by all collecting systems is subject to various standards of treatment, the minimum being 'appropriate treatment' as defined in Article 2(9) by 31 December 2005 for smaller agglomerations. According to Article 7, 'appropriate treatment' must be ensured when agglomerations with less than 2,000 p.e. which discharge to fresh-water and estuaries or agglomerations with less than 10,000 p.e. which discharge to coastal waters have a collecting system.

In terms of the treatment objectives, secondary (i.e. biological) treatment is the general rule, with more stringent treatment in so-called sensitive areas, for agglomerations with a p.e. above 10000. More stringent treatment can include nutrient removal in areas designated as sensitive because they are eutrophic.

The deadlines for implementing the Directive vary according to the size of the agglomeration and the characteristics of the receiving waters.

The implementation and operation of this Directive in candidate countries should be effected bearing in mind the extensive provisions of the WFD (2000/60/EC), which has influenced the legislative framework for EU water-related legislation and which has provided a modified structure for the practical application of this Directive. It is recommended that further implementation of this Directive take place after careful consideration of the WFD requirements (see separate fiche on it in this Handbook).

The Urban Waste Water Treatment Directive is specifically mentioned in the WFD for the purposes of the "combined approach" to water protection legislation (see Article 10 of the WFD). It is relevant to the designation of "protected areas" under Article 6 and Annex IV, and is also specifically required to be encompassed as a "basic measure" within programmes of measures for river basin management plans in order to achieve the objectives of the latter Directive (see also Annex VI of the same).

In 1998, the Commission adopted Directive 98/15/EC amending Table 2 of Annex I to the UWWTD clarifying some of the rules and requirements for discharges from urban waste water treatment plants to sensitive areas which are subject to eutrophication.

Methods and formats for reporting on the national implementation programmes are determined by Commission Implementing Decision 2014/413/EU adopted on 26 June 2014, which replaced Commission Decision 93/481/EEC of 28 July 1993. It defines the information that Member States should provide the Commission when reporting on the state of implementation of the Directive according to Article 17, and specifies the format in which the information should be provided. These formats adopted by the Commission in accordance with Article 18 of the Directive are set out in Tables 1-5 of Decision 2014/431/EU. These tables provide the necessary details for the Member States report of national implementing programmes relating to data for agglomerations, treatment plants, sludge and capital investments.

More information on the UWWT Directive can be obtained at:

http://ec.europa.eu/environment/water/water-urbanwaste/index_en.html

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Identify sensitive areas and less sensitive areas (if relevant), in accordance with specified criteria, and review the identification of these areas every four years (Arts. 5 and 6 and Annex II) (and see the requirements of the WFD as to the identification of such areas and as to the presentation of river basin management plans generally and also as to the timing of the latter to correlate the presentation of such identification and review reporting requirements).
- Identify the relevant hydraulic catchment areas of the sensitive areas and ensure that all discharges from agglomerations with more than 10000 p.e. located within the catchment area of the sensitive areas shall have treatment more stringent than secondary treatment.
- Establish a technical and financial programme for the implementation of the Directive for the construction of sewage collecting systems and waste water treatment plants addressing treatment objectives within the deadlines set by the Directive (and the Accession Treaties for new Member States) (Art. 17) (see also Article 9 of the WFD as to the application of the principle of costs recovery for water services, a term that includes the activities provided for under this Directive).

Member States shall plan how to ensure that the measures required under this Directive also reflect the measures devised pursuant to Art. 13(1) of MSFD

2.2. Regulation

- Provide for prior regulation or specific authorisation for all discharges of urban wastewater (Art.12, Annex IB) and of industrial wastewater from the agro-food sector (Art.13, Annex III), as well as for all discharges of industrial wastewater into urban sewage collecting systems and treatment plants (Art.11, Annex IC) (and see the WFD for the requirement to provide for a wider base for reviewing such permits and authorisations and for amending their operation in the event of, for example, emergencies affecting the water status of receiving water bodies).
- Ensure that systems for the collection of urban wastewater are provided for all agglomerations with a population equivalent of 2,000 or more (Art. 3 and Annex IA). Under Article 3, in certain conditions, individual and appropriate systems (IAS) can be used.
- Take measures to limit pollution of receiving waters from storm water overflows under unusual situations, such as heavy rain.
- Ensure that wastewater treatment is provided for urban wastewater entering collecting systems in all agglomerations above 2000 p.e., at the level of treatment specified and within the set deadline:

- The basic rule for the level of treatment is secondary, i.e. biological treatment (Art. 4 and Annex IB, Table 1). However, Article 7 stipulates that for discharges to fresh-water and estuaries from agglomerations of less than 2000 p.e., and for discharges to coastal waters from agglomerations of less than 10000 p.e, the urban waste water entering collecting systems shall before discharge be subject to appropriate treatment as defined in Article 2(9)—‘appropriate treatment’ means treatment of urban waste water by any process and/or disposal system which after discharge allows the receiving waters to meet the relevant quality objectives and the relevant provisions of this and other Community Directives. Further, the treatment has to be more stringent, i.e. tertiary, for discharges into so-called sensitive areas: in those cases, in addition to secondary treatment, the elimination of nitrogen and/or phosphorus and/or of any other pollutant affecting the quality or specific use of the water has to be provided (Art. 5 and Annex IB, Table 2) (see also Article 10 of the WFD for the role of this Directive within the "combined approach", and for the obligation to lay down more stringent conditions for permits and so forth as necessary).
 - For certain discharges to coastal waters, treatment might be less stringent, i.e. primary, under specific conditions and subject to the agreement of the Commission (Arts. 6 and 8) (see also Article 4(7) of the WFD, for example where derogations of a certain nature are provided for, including because of sustainable development measures).
 - The deadlines set for Member States were end-1998, end-2000 and end-2005 respectively, with the more ambitious deadlines for discharges into sensitive areas and for the larger agglomerations (population equivalent above 15,000).
- Ensure that environment is protected from adverse effects of the discharge of wastewater.
 - Ensure that the environmentally and technically sound reuse or disposal of sludge from urban waste water treatment plants is subject to general rules, registration or authorisation; and impose a ban on the disposal of sludge to surface waters (Art. 14) (see the reference to the WFD above in this regard). Ensure that specific inter-linked Directives on agricultural reuse (Sewage sludge Directive 86/278/EEC), incineration (IED 2010/75/EU) and landfill (Directive 1999/31/EC) are respected. Ensure that treatment plants are designed, constructed, operated and maintained to meet specified performance requirements. These requirements must ensure adequate capacity of the plant and treatment of urban waste water generated in agglomerations taking into account normal climatic conditions and seasonal variations. (Art. 10 and Art 4(4)).

2.3. Monitoring

- Ensure that monitoring programmes meet the requirements laid down in Annex ID of the Directive in terms of parameters monitored, analytical method and sampling frequency.
- Ensure appropriate monitoring capacity (bearing in mind the detailed provisions of the WFD as regards monitoring — see its Annexes II and V) for:
 - monitoring discharges from urban wastewater treatment plants; and
 - monitoring waters receiving discharges of wastewater covered by the Directive (Art. 15 and Annex ID).

- If considering applying for derogations (primary treatment for discharges into less sensitive areas), carry out comprehensive studies to determine the effect on the environment of discharges of urban wastewater in less sensitive areas (Arts. 6 and 8). Bear in mind that, inter alia, the Baltic Sea, the North Sea, the Black Sea and the Adriatic do not qualify as "less sensitive areas". (See, generally, the WFD as regards such matters, and see above for specific reference to derogations thereunder.)

2.4. Information and Reporting

- Ensure that the relevant authorities publish reports to the public every two years on the disposal of urban wastewater and sludge in their areas (Art. 16) (and see Article 14 of the WFD as to the more extensive provisions for public consultation and reporting).
- Ensure adequate mechanisms to allow the co-operation and exchange of information with other Member States in cases where discharges of waste water have a transboundary effect on water quality of shared waters.
- Report to the Commission on:
 - transposition of the Directive into national legislation, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 19);
 - implementation programmes (Art. 17 and Commission Decision 2014/431/EU). Commission Decision 2014/431/EU concerns formats for the presentation/report of national programmes as foreseen by Article 17 of the Urban Waste Water Treatment Directive. The information has to be in accordance with tables 1-5 regarding national implementing programmes relating to data for agglomerations, treatment plants, sludge and capital investments;
 - situation reports on the disposal and reuse of urban wastewater and sludge (Art. 16);
 - status of discharges from the food-processing industry to surface waters
 - comprehensive studies carried out in respect of discharges in less sensitive areas (in the case of applications for a derogation for less sensitive areas) (Arts. 6 and 8);
 - upon request by the Commission information collected through monitoring (Art. 15).

2.5. Additional Legal Instruments

There are several other legal instruments that should be borne in mind during the implementation of this Directive. These include:

- WFD (2000/60/EC);
- Floods Directive (2007/60/EC);

- Marine Strategy Framework Directive (2008/56/EC);
- Nitrates Directive (91/676/EEC);
- Landfill Directive (99/31/EC);
- EQS Directive (2008/105/EC);
- Sewage Sludge Directive (86/278/EEC);
- Industrial Emissions Directive (2010/75/EU),
- Reporting Directive (91/692/EEC) and the amending Decision 94/741/EEC concerning questionnaires for certain waste sector Directives, including sewage sludge;
- Directive on Access to Environmental Information (Directive 2003/4/EC);
- EIA Directive (2011/92/EU);
- E-PRTR Regulation (EC) No. 166/2006;
- INSPIRE Directive (2007/2/EC).
- Particularly relevant issues in these Directives concern:
 - the provisions under the Urban Waste Water Treatment Directive that are an integral part of the basic measures in the programmes of measures under the WFD, without any change to the deadlines set under the 1991 Directive;
 - the provision of adequate facilities for either incineration or landfill of sewage sludge;
 - the quality requirements for sewage sludge used in agriculture;
 - the environmental quality standards and the monitoring regime for biotas and/or sediments for EQS set out in Annex I to Directive 2008/105/EC;
 - the provisions on programmes of measures for marine waters to achieve good environmental status;
 - the Industrial Emissions Directive (2010/75/EU) covers certain industrial installations also covered by this Directive, setting more stringent objectives and using, as does the WFD, a "combined approach" of emission controls and water quality standards; in each particular case the more stringent approach applies.

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are set out in chronological order wherever possible in the checklist below.

Table 6. Illustrative checklist with the key implementation tasks

THE URBAN WASTE WATER TREATMENT DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning and Administrative Arrangements
1.1	Ensure a competent authority/competent authorities and institutional arrangements at national, regional and local levels for the implementation and enforcement of the Directive. These should include the authority or organisation responsible for developing programmes for the construction of new urban wastewater treatment infrastructure; providing public finance for construction (i.e. delivering the implementation programme under Article 17); and monitoring the progress during construction of infrastructure. (See, too, the WFD for the new arrangements to be put in place to address water protection issues on a river basin district basis, which may influence decisions for the allocation of competent authorities.)
1.2	Ensure adequate laboratory capacities either within the administration and/or commercial laboratories under contract. The laboratories must use the methods specified in Annex I of the Directive and be subject to regular quality control.
1.3	Decide whether to identify individual sensitive areas or to apply the more stringent tertiary treatment criteria to the whole territory. (See, too, Article 6 and Annex IV on the designation of "protected areas".)
1.4	Identify/delineate agglomerations of more than 2,000 population equivalents.
1.5	Determine, in co-operation with local and regional authorities, the current state of existing sewerage networks and wastewater treatment plants, and identify those which need a sewerage network to collect wastewater and the provision of a wastewater treatment plant.
1.6	Identify sensitive areas, i.e. those waters fitting into one or more of the criteria set in Annex II. Information may be obtained by carrying out studies and/or using available data. (See also point 1.2.)
1.7	Within sensitive areas, determine which of the parameters for more stringent treatment stipulated in Annex I.B have to apply in the particular situation. As a general rule, most marine waters have nitrogen as the limiting factor for eutrophication, whilst phosphorus is the limiting factor for most fresh waters. (See the WFD, Annex II, as to the approach to classification of the status of water bodies.) Identify the catchment limits of sensitive areas. Within the whole catchment of the sensitive area, all discharges from agglomerations of more than 10,000 will have to be provided with the more stringent treatment.
1.8	Establish an implementation programme for the construction of sewerage networks and wastewater treatment plants, based on the assessment needs, and addressing the treatment objectives, deadlines, and financing options.
1.9	As for the deadlines, there are three phased deadlines in the Directive: <ul style="list-style-type: none"> • by the end of 1998, sewerage systems and tertiary treatment for all agglomerations in sensitive areas with a population equivalent of more than 10,000;

	<ul style="list-style-type: none"> • by the end of 2000, sewerage systems and wastewater treatment for all agglomerations with a population equivalent of more than 15,000, plus appropriate treatment for discharges from the agro-food industry; • by the end of 2005, sewerage systems and wastewater treatment for all the other agglomerations covered by the Directive. <p>Derogations from these deadlines ("transition periods") might be part of the accession treaty. Careful technical and financial assessment will be an indispensable precondition for all consideration of transition periods. See, further, on derogations and extensions of time for complying with the obligations to meet the objectives of the WFD, Article 4(4)-(9), and also on suggestions for considering transitional periods for compliance with the WFD.</p> <p>As for the treatment objective:</p> <ul style="list-style-type: none"> • secondary (i.e. biological) treatment is the general rule; • additional nutrient removal or further measures are mandatory in so-called sensitive areas (tertiary treatment); • in certain marine areas, primary treatment (less sensitive areas) might be sufficient; less stringent objectives might also apply for agglomerations in high mountain areas, justified by thorough assessments. • For agglomerations with a population equivalent of less than 2,000, but equipped with a collecting system, 'appropriate treatment' has to be provided, i.e. a treatment that ensures good quality of the receiving water.
1.10	Assess whether there are marine waters in your territory that might qualify as less sensitive areas. (In this context, bear in mind that, inter alia, the Baltic Sea, the North Sea, the Black Sea and the Mediterranean Sea do not qualify as "less sensitive areas").
1.11	Impose a ban on any disposal of sewage sludge to surface waters.
1.12	Ensure an environmentally and technically sound reuse or disposal of sewage sludge. Options may be: <ul style="list-style-type: none"> • agricultural re-use, subject to the requirements of the Sewage Sludge Directive (86/278/EEC); • incineration, subject to the Waste Incineration Directive (2000/76/EC); and landfill, subject to the Directive on Landfill of Waste (99/31/EC).
1.13	Establish treatment and effluent standards for biodegradable wastewater from the industrial sectors listed in Annex III of the Directive where wastewaters do not enter sewerage networks for treatment at municipal plants. These may be on a nation-wide basis or specific to the local situation. The standards must be appropriate to the particular industries concerned and will involve consultation with the industry sectors. Bear in mind in this context that the IED covers certain industrial installations also covered by the Urban Waste Water Treatment Directive, setting more stringent objectives and using, as does the WFD, a "combined approach" of emission controls and water quality standards; in each particular case, the more stringent approach applies (see Article 10 of the latter).
1.14	Ensure that such industrial discharges are subject to a prior authorisation regime.
1.15	Specify requirements for industrial wastewaters discharging into the sewerage network. Such requirements have to comply with the provisions for pre-treatment according to Annex I C.
1.16	Ensure that such industrial discharges are subject to a prior authorisation regime.
1.17	Identify a means of recovering costs for the design, construction and maintenance of sewerage systems and wastewater treatment plants from the users and set up the charging system.
2	Regulation and Monitoring
2.1	Take measures to ensure consistency with monitoring and authorisation requirements under the WFD

2.2	Provide for a legally binding requirement that agglomerations in the size ranges set out in the Directive are provided with collecting systems by the dates specified, and the possibility to use IAS under certain conditions under Art 3 of the UWWTD
2.3	Provide for a legally binding requirement that discharges of urban wastewater are subject to secondary treatment or tertiary treatment (depending on the size of the agglomeration and the characteristics of the receiving water) before discharge.
2.4	Provide for a legally binding requirement that discharges of urban waste water entering collecting systems to fresh waters and estuaries from agglomerations with sewerage systems with less than 2,000 p.e., and from agglomerations of less than 10,000 p.e. to coastal waters are subject to appropriate treatment.
2.5	Establish a prior authorisation procedure for discharges of treated urban wastewater ensuring permission by the competent authority.
2.6	Establish a prior authorisation procedure for all relevant industrial wastewater discharges from the agro-food industry (Annex III) of more than 4,000 p.e. that are not connected to urban wastewater systems.
2.7	Establish a prior authorisation procedure for the disposal of sludge, under which general rules, registration or authorisation procedures are used to give the competent authority control of the disposal route.
2.8	Establish a monitoring and inspection programme for compliance assessment of discharges from urban wastewater treatment plants and for assessing the amounts and composition of sludge.
2.9	Ensure quality control with the laboratories involved. Sampling and analysis methods have to comply with the Directive. Accreditation schemes for laboratories are a means of constantly ensuring such quality control.
2.10	Re-assess sensitive and less-sensitive areas at four yearly intervals. Plan for follow-up surveys of all sensitive and less-sensitive areas during this period. Review the criteria to ensure that they remain valid.
3	Technical Standards (see also the WFD as to classification of water body status and standards)
3.1	The competent authority should develop and issue guidance on the precise definition of sensitive areas to be used in the territory, using the Directive standards as the basis. In particular, this should specify the scientific criteria by which the eutrophic state of waters is to be judged.
3.2	Prepare, in co-operation with experts as well as local and regional authorities, regulations for the design, construction and maintenance of sewerage networks, based at least on the provisions of the Directive (Annex I.A). Comparable technical guidance documents from other countries, prepared by national or regional authorities, technical associations or others, might be useful in this context.
3.3	Prepare, in co-operation with experts as well as local and regional authorities, regulations accompanied with guidance documents for the design, construction and maintenance of wastewater treatment plants, to ensure compliance with the provisions of the Directive (Annex IB, Table 2, "tertiary treatment" for sensitive areas and their catchments, Table 1 "secondary treatment" for other waters). Comparable technical guidance documents from other countries, prepared by national or regional authorities, technical associations or others, might be useful in this context.
3.4	Where appropriate, prepare guidance documents on suitable alternatives (Art. 3) to collecting systems, ensuring at least the same level of environmental protection.
3.5	Prepare a guidance document for 'appropriate treatment' for particular situations, giving examples, at the same time underlining that such treatment has to ensure the necessary good quality of the receiving water.
4	Consultation and Reporting

4.1	Ensure adequate co-operation and exchange of information with other Member States in cases where discharges of wastewater have a transboundary effect on the water quality of shared waters. (See, in particular, in this regard the provisions of the WFD as to international river basin districts and for management plans for the same — especially Articles 3 and 13.)
4.2	Set up an adequate reporting procedure and databases so that requests from the Commission for information on the efficiency of treatment plants and/or the water quality of receiving waters as well as national reports can be addressed, and the public has access to relevant information under the Directive on Access to Environmental Information (2003/4/EC). In the case of dealing with requests by the Commission on wastewater treatment plants, an electronic questionnaire on CD-ROM has been developed by the Commission and will be available free of charge.
4.3	<p>Report to the Commission (see the extensive reporting provisions under the WFD):</p> <ul style="list-style-type: none"> • on transposition of the Directive into national legislation, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 19); • on implementation programmes (Art. 17 and Commission Decision 2014/431/EU); • on situation reports on the disposal of urban wastewater and sludge (Art. 16); • in the case of applications for a derogation for less sensitive areas — on comprehensive studies carried out in respect of discharges in less sensitive areas (Arts. 6 and 8). (In this context, bear in mind that, inter alia, the Baltic Sea, the North Sea, the Black Sea and the Adriatic do not qualify as "less sensitive areas") • upon request by the Commission — on information collected through monitoring (Art. 15); see electronic questionnaire mentioned under 4.2); • on standards applicable to industrial discharges from the agro-food industry (Annex III) to surface waters; • in two-yearly reports to the public — on wastewater treatment and disposal of sludge (article 16); • all requests for derogations for using primary treatment only, or for delaying the completion of wastewater treatment plants due to technical problems, are subject to individual applications to the Commission.

3.2. Phasing Considerations

Implementation of the Urban Waste Water Treatment Directive ranked amongst the most challenging and expensive tasks throughout the range of EU legislation. Nevertheless, early and careful consideration of the environmental and technical aspects of the Directive remains significant to this end.

There are a number of tasks that must be carried out at a very early stage in order to be able to proceed. These relate primarily to the administration of the Directive and the collection of data to enable plans to be developed. The later stages involve the construction of sewers and wastewater treatment facilities, and the timescale will depend upon the availability of finance, and construction engineering resources in the candidate country. A key issue will be the phasing of programmes to enable the construction work to be accomplished at an achievable and affordable rate. Consideration of the requirements and deadlines in the WFD may influence any phasing considerations remaining for candidate countries in this regard.

The first phase of implementation should include:

- identifying the "agglomerations" in the country that are covered by the Directive;
- identifying sensitive areas in the country;

- identifying existing infrastructure (sewerage systems and wastewater treatment plants), and assessing where improvements are required;
- assessing existing monitoring and inspection systems, and providing for adaptation to the requirements of the Directive where necessary; and
- preparing the institutional and administrative structure (establishment of competent authorities, authorisation system) and other institutional structures.
- the second phase should involve:
 - establishing — based in particular on the findings of the first phase with respect to numbers/locations of "agglomerations", "sensitive areas" and "existing infrastructure", — an implementation programme for the construction of sewerage networks and wastewater treatment plants. Within such a programme, the issue of the re-use and/or disposal of sewage sludge will have to be addressed as well. Such an implementation programme will also be a major factor in all considerations as regards transition periods, i.e. derogations from compliance with certain obligations by the time of accession. Careful technical and financial assessment will be indispensable. The services of the European Commission (DG Environment) will be available for information, advice and interpretation;
 - preparing investment plans, based on the environmental and technical requirements established;
 - ensuring a system of cost recovery for sewerage and wastewater treatment, considering, inter alia, construction and maintenance costs;
 - making monitoring and inspection schemes operational, as well as enforcement of the standards laid down in national legislation (pursuant to the Directive);
 - reviewing sensitive and less sensitive areas every four years.

The third phase will involve completing the construction and upgrading of infrastructure (sewerage networks, wastewater treatment plants).

Time for putting in place the necessary infrastructure forms an important part of the accession negotiations. Careful technical and financial assessment will, in this context, be indispensable.

4. IMPLEMENTATION GUIDANCE

4.1. Planning and Regulation

Implementation of the UWWT Directive is challenging due to financial and planning aspects linked to the construction of waste water infrastructure.

There are several guidance documents and studies available at: http://ec.europa.eu/environment/water/water-urbanwaste/info/docs_en.htm providing support to the competent authorities in implementation of the UWWT Directive.

- Commission Implementing Decision of 26 June 2014 concerning formats for reporting on the national programmes for the implementation of Council Directive 91/271/EEC (notified under document C(2014) 4208)
- Guidance article 17 how to fill in the new tables for reporting under article 17 of the EU directive concerning the treatment of urban wastewaters (91/271/EEC, UWWTD) version 1.1 July 2014 addendum to the description of the data-blocks (reporting sheets)
- Guidance on practical arrangement for electronic reporting to the Water information system for Europe (WISE) “WISE reporting arrangements for uwwtd” final document (12/06/2009)
- The Report ‘Green Public Procurement: Criteria for Waste Water Infrastructure’ provides criteria recommended for the procurement of waste water infrastructure projects. The use of green public procurement criteria should be seen as an opportunity for waste water managing authorities to build and operate waste water infrastructures in an environmentally friendly manner.
- The Guidance document ‘Terms and Definition of the Urban Waste Water Treatment Directive’ provides guidance on key terms and concepts. It also aims to help those authorities responsible for implementing the Directive to better understand certain of its key provisions, but also to assist the reporting process.
- Extensive wastewater treatment processes guide - A guide to urban waste water treatment technologies that are appropriate for use in small (<5000 p.e.) agglomerations.
- Compliance Costs of the Urban Waste Water Treatment Directive (2010) The study provides an estimation of the costs of compliance with the Urban Waste Water Treatment Directive as based on data from 2005/2006, with a focus on identifying the financial gap which would have to be covered in order to reach compliance with the Directive, within the assumed timeframes. Cost estimates have been provided for EU27 and the candidate countries.
- Phosphates and Alternative Detergent Builders (2002) The study investigates the costs and benefits of substituting phosphorus in detergents with other appropriate builders and provide recommendations

on the most appropriate method of reducing phosphorus concentrations in surface waters, through either improving wastewater treatment, banning the use of phosphates as detergent builders, or a combination of the two approaches. The study covers EU15, Poland, Hungary and the Czech Republic.

- Mediterranean Waste Water Reuse Report (2007) The report assesses current knowledge and experience on treated waste water reuse in the EU and Mediterranean countries, recaps on key definitions and terminology, provides an overview of related benefits and risks (economic, social, health related and environmental), outlines applicable EU environmental legislation and legislative frameworks in several countries, highlights the importance of treated waste water reuse in the EU-Mediterranean region (with a set of 23 case studies) and provides a set of recommendations.

4.2. Information and Reporting

In order to streamline and facilitate the reporting and sharing of information on the water environment between the Member States, the European Commission, the European Environment Agency (EEA), EUROSTAT and the Joint Research Centre (JRC) agreed that a shared information system was required. Thus, the Water Information System for Europe (WISE) was launched for public use as a web-based service on 22 March 2007 providing a web-portal entry to water related information ranging from inland waters to marine. The web-portal is now grouped into sections for:

- EU water policies (directives, implementation reports and supporting activities)
- Data and themes (reported datasets, interactive maps, statistics, indicators,)
- Modelling (now - and forecasting services across Europe.)
- Projects and research (inventory for links to recently completed and ongoing water related projects and research activities.)
- WISE addresses several user groups:
- EU institutions as well as Member States national, regional and local administrations working in water policy development or implementation
- Professionals working in the water field from public or private organisations, with a technical interest on water
- Scientists working in the water field
- General public, including in this group those working in private or public entities not directly related to water policy but with an indirect interest in water (regular or sporadic)

For users from EU institutions or other environmental administrations WISE provides input to thematic assessments in the context of EU water related policies. For water professionals and scientists WISE facilitates access to reference documents and thematic data, which can be downloaded for further analyses. For the general public, WISE illustrates a wide span of water related information by visualisations on interactive maps, graphs and indicators.

WISE will be contributing as a building block to the Shared Environmental Information System (SEIS), which will cover data and information of all environmental themes. Furthermore, the geo-referenced information management within WISE will be consistent with, and build upon, INSPIRE.

5. COSTS

The main types of costs arising during the implementation of this Directive are given in the Box below.

Table 7: Examples of implementation costs incurred

<p>Initial set-up costs:</p> <ul style="list-style-type: none">• identifying agglomerations, sensitive areas, less sensitive areas;• establishing administrative structure and permitting system;• establishing implementation programme, including investment for new infrastructure.
<p>Capital investment:</p> <ul style="list-style-type: none">• construction of new, and upgrading of existing, sewerage networks;• construction of new, and upgrading of existing, wastewater treatment plants in accordance with the set secondary treatment;• construction of tertiary treatment plants in sensitive areas.
<p>On-going costs:</p> <ul style="list-style-type: none">• operation and maintenance of infrastructure (sewerage, treatment plants);• monitoring and any necessary ongoing regulatory action and also enforcement action;• administrative costs.

The major factors influencing the costs of investment have been found to be:

- the initial state of the infrastructure for the collection and treatment of urban wastewater before the implementation of the Directive;
- the improvements required in terms of collection of wastewater within the agglomerations addressed by the Directive, including those for prevention of leaks and for reduction of pollution from overflows in combined systems;
- improvements required to urban wastewater treatment plants to comply with the standards set by the Directive;
- constraints due to urban planning and site requirements, and climatic factors; and
- costs of labour and equipment.

There are also considerable preparatory costs due to the amount of assessment required to identify agglomerations and sensitive and less sensitive areas, and the introduction of an adequate sampling and monitoring system.

Costs can vary widely between Member States. The 1998 Commission Report "Implementation of Council Directive 91/271/EEC concerning Urban Waste Water Treatment, as amended by Commission Directive 98/15" provides figures both on the overall investment forecasts and on investment per population equivalent.

The EU dedicated a significant amount of funding under the EU Cohesion Policy funds (17.8 billion EUR in the 2007-2013 programming period have been allocated to construction of waste water collection and treatment infrastructure in 22 Member States)²⁰⁴. Investments in infrastructure lead, directly and indirectly, to economic growth and employment and therefore contribute to one of the key priorities of the current Commission to boost jobs, growth and investment.

²⁰⁴Source: Eighth Report on the Implementation Status and the Programmes for Implementation (as required by Article 17) of Council Directive 91/271/EEC concerning urban waste water treatment (COM/2016/0105 final); <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52016DC0105>

THE NITRATES DIRECTIVE

Official Title: Council Directive 91/676/EEC on the protection of waters against pollution caused by nitrates²⁰⁵ from agricultural sources (OJ L 375, 31.12.91), as amended by Regulation (EC) No. 1882/2003 (OJ L 284, 31.10.2003) and Regulation (EC) No. 1137/2008

²⁰⁵ Regulation (EC) No. 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty.

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The objectives of the Directive are twofold:

- to reduce water pollution caused or induced by nitrates from agricultural sources; and
- to prevent further pollution of this type.

To this aim, Member States must identify waters affected by such pollution and waters which could be affected by such pollution and designate all known areas draining into those waters as "vulnerable zones". For these zones, they must then establish and implement action programmes to prevent and reduce nitrates pollution. Such action programmes contain mandatory measures including, for instance, maximum amounts of manure that can be applied to land every year. For areas outside the vulnerable zones, prevention and reduction of pollution has to be promoted by (voluntary) codes of good agricultural practice. Member States are, in this context, obliged to monitor the nitrate concentrations in groundwater and surface waters as well as eutrophication in surface waters.

Note the encompassing nature of the WFD here, and the further specific reference therein to the Nitrates Directive for the purposes of applying the "combined approach" of water quality and emission limits control, together with control over diffuse sources (Article 10 of the former), and the inclusion of the Nitrates Directive further as a "basic" measure to be included in the required programmes of measures for river basin management plans.

Directive 91/676/EEC has been amended by Regulation (EC) No. 1882/2003 and Regulation No. 1137/2008, with provisions regarding the regulatory committee procedures of the Commission, ensuring that certain technical provisions can be reassessed and updated not having to go through lengthy legal procedure.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning and Regulation

- Identify, based on comprehensive monitoring, waters that are, or that could be, affected by pollution by nitrates from agricultural sources (Art. 3 and Annex I). Criteria under Annex I are:
 - surface freshwaters and groundwater that contain or could contain more than 50 mg/l of nitrates;
 - natural freshwater lakes, other freshwater bodies, estuaries, coastal waters and marine waters that are found to be eutrophic or in the near future may become eutrophic.
- Note that these criteria apply to all waters. Member States are therefore required to assess all waters, not just those currently used for the abstraction of drinking water.
- Designate as "vulnerable zones" all known areas of land that drain into the identified waters under the above criteria. Eutrophication caused by phosphorus as well as nitrogen must be taken into account when designating Nitrate Vulnerable Zones.
- Such a designation of vulnerable zones is not necessary if action programmes (under Article 5, below) are implemented throughout the whole territory of the Member State.
- Designations of vulnerable zones shall be reviewed and if necessary revised at least every four years (Art. 3).
- Establish a code (or codes) of good agricultural practice to be implemented by farmers outside vulnerable zones on a voluntary basis and by farmers within vulnerable zones on a obligatory basis, and, where necessary, establish a programme to promote the application of the codes (Art. 4 and Annex II). Note that codes of practice are designated as "supplementary" measures under the WFD for river basin management plans.
- Provide training and information for farmers, where appropriate.
- Establish and implement action programmes, either in respect of designated vulnerable zones or throughout the whole territory. These programmes must contain, as a minimum, the measures specified in the Directive (Art. 5, Annex II and Annex III).

2.2. Monitoring

The Directive distinguishes between two different kinds of monitoring rules. These are presented in Article 5 and Article 6:

- According to Art. 5(6), Member States should "draw up and implement suitable monitoring programmes to assess the effectiveness of action programmes established". Where a country opt for applying mandatory action programmes throughout the whole territory under Article 3(5): one is

required "to monitor the nitrate content of waters (surface waters and groundwater) at selected measuring points which make it possible to establish the extent of nitrate pollution in the waters from agricultural sources". At the same time, Member States applying action programmes throughout their whole territory are exempt from the monitoring requirements under Article 6.

- According to Article 6, in order to designate and revise designation of vulnerable zones, it is mandatory to monitor nitrate concentrations in surface freshwaters and groundwaters at least every four-year period, except those sampling stations where the nitrate concentration in all previous samples has been below 25 mg/l and no new factor likely to increase nitrate content has appeared, in which case, the monitoring programme need to be repeated only every eight years.
- Review the eutrophic state of fresh surface waters, estuarial and coastal waters every four years.

2.3. Notifications/Reporting

- Member States are required to notify to the Commission:
 - designation of vulnerable zones and changes made to it (Art. 3);
 - codes of good agricultural practice and changes made to it (Art. 4);
 - action programmes and changes made to it (Art. 5);
 - measures taken to comply with the Directive (Art. 12); and
 - transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 12).
- Member States are required to report to the Commission on the implementation of the Directive, every four years. (Art. 10 and Annex V)
- The Commission is obliged to provide a summary report to the European Parliament and to the Council, based on Member States' reports. (Art. 11)

2.4. Additional Legal Instruments

A number of other legal instruments should be borne in mind when implementing this Directive.

These include:

- WFD (2000/60/EC)
- Groundwater Directive (2006/118/EC)
- Urban Waste Water Treatment Directive (91/271/EEC)
- Sewage Sludge Directive (86/278/EEC)
- Drinking Water Directive (98/83/EC)

- Bathing Water Directive (2006/7/EC)
- Marine Strategy Framework Directive (2008/56/EC)
- Floods Directive (2007/60/EC)
- Industrial Emissions Directive (2010/75/EU)
- EQS Directive (2008/105/EC), implementing the WFD in regard to setting EQS

Particularly relevant provisions in these instruments include:

- River basin management plans and programmes of measures, ensuring "good status" for all surface waters and groundwaters under the WFD. The implementation of, inter alia, the Nitrates Directive, is, as indicated briefly above, part of the basic measures under the WFD, "vulnerable zones" being part of the "protected areas" under Annex IV of that Directive.
- Programmes of measures and strategies for the achievement of good environmental status for marine waters under the MSFD, also taking into account the EQS and the measures required set out in Annex I to the Directive.
- Identification of sensitive areas in the Urban Waste Water Treatment Directive (91/271/EEC). This identification should be seen in close context with the Nitrates Directive and its identification of vulnerable zones, as in many cases both Directives address the same phenomenon — pollution of waters by nitrates and eutrophication. The Urban Waste Water Treatment Directive sets the obligation for more ambitious treatment (nutrient removal) inter alia for wastewater discharges into waters and catchments subject to eutrophication (or in danger of become eutrophic) and/or subject to nitrate contents above 50 mg/l.

In order to increase efficiency and the wise use of resources, the implementation of the Nitrates Directive needs to be closely co-ordinated with other EU legislation on water, e.g. the Urban Waste Water Directive, the Bathing Water Directive, the WFD and the MSFD.

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks to implement the Nitrates Directive are summarised in the checklist below. The tasks are grouped under key headings and arranged in chronological order wherever possible. Some of the tasks might be found in parallel under more than one heading. Note, too, the WFD generally here, and the river basin district approach, and note the provision for international river basin districts.

Table 8. Illustrative checklist with key implementation tasks

THE NITRATES DIRECTIVE — KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Appoint a competent authority/competent authorities to implement the Directive
1.2	Ensure the necessary laboratory capacity for measuring nitrates in surface waters and groundwater, as well as for carrying out measurements to determine the degree of eutrophication of freshwater bodies, estuaries, coastal and marine waters.
1.3	Decide whether to: <ul style="list-style-type: none"> • identify nitrate vulnerable zones, for which one or more action programmes will be established; • establish action programmes for the whole territory. Member States have to monitor to assess the effectiveness of these programmes. .
1.4	Prepare criteria and issue guidance on how to identify the degree of eutrophication of freshwater bodies, estuaries, coastal and marine waters and the identification of waters affected by nitrate pollution. The criteria should include those set out in Annex 1 of the Directive. Scientific advice on what constitutes eutrophication, taking account of the natural physical and environmental conditions in the territory, should be considered in drawing up the criteria. Experience gained in the framework of international water protection conventions such as OSPAR (for the North-East Atlantic) and HELCOM (for the Baltic Sea) might be valuable in this context. Bear in mind that there is no choice between EU legislation and obligations under international conventions: EU Member States and signatory parties to conventions will have to comply with the rules under EU water legislation and those under international conventions such as HELCOM. Note, too, the objectives of the WFD include assisting in greater compliance with obligations of the EU and/or Member States in certain international conventions, including those mentioned above.
1.5	Identify sampling points for surface waters and groundwater. Surface waters should include estuaries and coastal and marine waters. As regards sampling stations, consider making use of already established ones (under national monitoring systems, the WFD), or other stations representative of surface and or groundwater conditions of the country. Set up a monitoring programme which would include sampling and testing over at least one year initially to obtain data on nitrate levels of groundwaters and surface waters and the degree of eutrophication of freshwater bodies, estuaries, coastal and marine waters, and which would be repeated at least every four years.
1.6	Set up a procedure to review the data obtained from the sampling programmes. The competent authority may undertake the review on a national or local scale.

1.7	Use the results of sampling, and information concerning agricultural activities to identify waters that are affected by nitrate pollution from agricultural sources (waters whose nitrates concentrations are above 50 mg/l or in danger of becoming so, and those which are subject to eutrophication, caused by nitrogen or phosphorus (or in danger of becoming eutrophic). If you have decided to identify nitrate vulnerable zones, identify land draining into these identified waters and designate them as vulnerable.
1.8	<p>Plan for the development of:</p> <ul style="list-style-type: none"> • voluntary code or several codes of good agricultural practice for reducing nitrate pollution from agricultural sources. The code should take account of the issues set out in Annex II of the Directive; • an action programme or several action programmes for the vulnerable zones. The action programme has to take account of the provisions set out in Annex II and III of the Directive and has to be based on available scientific and technical data and overall environmental conditions. <p>Prepare dissemination of information and training on those action programmes, including those measures that have to be mandatory (minimum storage capacities, restrictions to application fertilizers, etc.). Note that all measures in this action programme are mandatory.</p> <p>Plan for disseminating information on those codes and on the action programmes in co-operation with other interested and involved parties (brochures, information meetings, training, pilot projects).</p>
1.9	Ensure that the draft action programme for vulnerable zones is subject to a strategic environmental assessment prior to final adoption, where required. For instance, in certain situations, the Nitrates Action Programme may set the framework for future development consent of projects such as intensive livestock units. In such cases it could be considered a 'programme' within the meaning of the SEA Directive and could therefore require an 'environmental assessment'.
2	Regulation, Monitoring and Enforcement
2.1	<p>Prepare legislative acts for adopting the action programme(s). Examples of the measures to be included in the action programmes, listed in Annex III are:</p> <ul style="list-style-type: none"> • limitation of land application of fertilisers, to be based on a balance between nitrogen requirements of the crops and the nitrogen supply to the crops from the soil and from fertilisation (livestock manure and other nitrogen fertilisers); • periods when the land application of fertilisers is prohibited; • maximum of 170 kg of nitrogen per hectare per year from livestock manure to be applied to land²⁰⁶. There is an option for derogations, but only on condition that they are justified on the basis of objective criteria (e.g. long growing season and culture with high nitrogen absorption), do not prejudice the achievement of the objectives of the Directive, and are subject to a comitology procedure.
2.2	Establish an enforcement regime to ensure compliance with the regulations. This should use effective risk criteria, for instance in the selection of farms for inspection.
2.3	Identify other actions that will contribute to a reduction in nitrate levels in water bodies, e.g. from industrial and urban wastewater sources.
2.4	<p>Monitoring cycle and review of measures:</p> <ul style="list-style-type: none"> • Repeat the monitoring programme and assessment of designated waters, and all other waters, every four years²⁰⁷ in order to designate further zones if necessary

²⁰⁶ For the first four year action programme an amount of manure containing up to 210 kg N may be allowed.

²⁰⁷ Except where nitrate levels are less than 25 mg/l, where the monitoring can take place every eight years

	<ul style="list-style-type: none"> Set up a review process to check, at least every four years, the effectiveness of the measures, in the action programmes, as a basis for the necessary follow-up measures along the same lines, or along more stringent lines etc.
3	Communication and Consultation
3.1	Assess, with relevant ministries and other bodies at national, regional and local level, as well as farmers' organisations, the scope of options for awareness raising and training about the implications of the Directive, and decide on the necessary steps.
3.2	Arrange for information on the requirements (minimum storage capacities, restrictions to the application of fertilizers, etc.), in co-operation with other interested and involved parties (brochures, information meetings, training, pilot projects).
3.3	If you have chosen to designate individual vulnerable zones, take all the necessary steps, ensure compliance with the Nitrates Action Programme and arrange for information on codes of good agricultural practice in co-operation with other interested and involved parties (brochures, information meetings, training, pilot projects).
3.4	Arrange your government's representation at the management committee established under Articles 8 and 9 of the Directive.
4	Reporting
4.1	Establish a reporting system and databases to enable the recording and reporting of information gathered as a result of implementing the Directive's requirements.
4.2	Ensure the necessary reporting by a body within your administration on, <i>inter alia</i> : <ul style="list-style-type: none"> designation of nitrate vulnerable zones, including monitoring results; action programmes, including e.g. storage requirements and restrictions in fertilizers application; codes of good agricultural practice; review of designations of vulnerable zones; timescales for expected improvements.

3.2. Phasing Considerations

For guidance purposes, one can discern four main phases in the implementation of this Directive that require early involvement and careful consideration. However, it should be noted that these phases are meant as a facilitation in the transposition but are not per se mandated by the Directive.

Phase One:

- Establishing a measuring and monitoring programme to collect information from which it is possible to identify the waters that are, or could become, polluted by nitrates from agricultural sources or that are or could become eutrophic including where eutrophication is caused by phosphorus. This requires the establishment of an adequate monitoring network and the collection of data over a period of at least one year. Data need to include nitrates concentrations in groundwater and freshwaters, information on the trophic state of freshwater bodies as well as estuaries, coastal and marine waters,

information on land use, hydrogeological considerations, etc. The monitoring should also identify the main polluting sources, i.e. those releasing nitrates into land or water, such as larger or intensive agricultural activities and farmlands.

- Identifying the areas of land that should be classified as vulnerable zones in accordance with Article 3 and Annex I of the Directive, which include areas that drain into the identified waters. This requires, inter alia, a proper understanding of pollution sources, physical and environmental characteristics of the waters and land and the behaviour of nitrogen compounds in the environment, so as to differentiate waters polluted by agricultural and non-agricultural sources.

Phase Two:

- Preparing the codes of good agricultural practice and disseminate information and where relevant provide training on these codes.
- Preparing action programmes for vulnerable zones or for the whole territory, which contain mandatory measures. Different vulnerable zones may have one or more action programmes.

Phase Three:

- Implementing the code of good agricultural practices and undertaking training of farmers.
- Implementing the action programmes, undertaking training of farmers, Action programmes are to be established within a two-year period following the initial designation of a vulnerable zone or within one year of each additional designation (Art. 5(1)). They shall be implemented within four years of their establishment (Art. 5 (4)). Action programmes shall contain the measures listed in Annex III of the Directive and the measures which Member States have prescribed in the code(s) of good agricultural practice, except those which have been superseded by the measures in Annex III.

Phase Four:

- Establishing a monitoring programme in intervals of four years and undertaking a review of vulnerable zones.
- Establishing a monitoring programme to monitor and review the effectiveness of the measures taken to reduce nitrate pollution in intervals of four years and undertaking a review action programme and, if necessary, a revision every four years. If it becomes apparent that the measures in the action programme will not be sufficient to achieve the objectives of the Directive, additional measures or reinforced actions shall be taken.

4. IMPLEMENTATION GUIDANCE

4.1. Planning

- This Directive encourages ministries of the environment and of agriculture to collaborate in the identification of waters vulnerable to nitrate pollution and to reduce inputs of nitrates by requiring balanced fertilisation of crops and defining periods and conditions when fertilisers should not be applied. The ministry of health could also be involved relating to the pollution of drinking water. In deciding upon the most appropriate body to be appointed to the position of competent authority for the implementation of this Directive, the relationships between the proposed bodies should be examined to ensure that there are effective consultation arrangements and links between them, and also to ensure that the arrangements decided are compatible with the WFD core basis for water protection arrangements — the river basin district. The Directive requires action to be taken by the farming industry, and in most Member States a ministry of agriculture will have jurisdiction over farming issues. An effective code of good agricultural practice could be drawn up by the ministry of agriculture in consultation with the environment ministry or agency, or drawn up with the advice of specialists within the ministry of agriculture. As codes of conduct are supplementary measures, but otherwise also within programmes of measures for river basin management plans, the consultation provisions in the WFD will need to be complied with.
- The relationship with the Urban Waste Water Treatment Directive (91/271/EEC) is an important consideration as the designation of "sensitive areas" under that Directive uses similar criteria and requires action plans that may have an impact on action taken under this Directive.
- There are two options in the way this Directive may be implemented. The Directive requires the identification of land draining into waters that are affected by pollution by nitrates to be designated as "vulnerable zones", and the establishment of action plans to improve the situation in each zone. Under Article 3(5), however, a state may choose to apply an action programme to the whole of its territory. The first alternative requires extensive monitoring and investigation. The second option limits the amount of monitoring that must be undertaken in the first instance, but applies any agricultural changes that are required to the whole country.

As regards the designation of vulnerable zones, areas draining into surface waters and groundwater areas must be designated as vulnerable zones if the water contain or could contain more than 50mg/l of nitrates. Areas draining into natural freshwater lakes, other freshwater bodies, estuaries, coastal waters and marine waters areas must be designated if they are found to be eutrophic or could become eutrophic.

- In drawing up action plans, the possible role of non-agricultural sources of nitrates in causing an exceedance of the 50 mg/l limit for drinking waters or as a contribution to eutrophication must be taken into account. The most likely source of non-agricultural nitrate is from domestic sewage works. This is an important issue if the decision has been taken to implement the Directive through the identification of individual zones. The implementation of the Urban Waste Water Treatment Directive (91/271/EEC) may have a significant impact where nitrate removal is installed in wastewater treatment plants on the grounds that the sewage effluent discharges into a sensitive area under the

terms of that Directive. The relative contributions of nitrates from agriculture and sewage effluent are not always easy to determine. The competent authority should ensure that plans made under the Nitrates Directive take account of the plans to be implemented for the Urban Waste Water Treatment Directive (91/271/EEC).

The Nitrates Directive envisages the possibility to derogate from the maximum amount of 170 kg of nitrogen per hectare per year from livestock manure. This option may be considered on the basis of a solid action programme and after a comitology procedure. A derogation may be granted provided that objective criteria set in Annex III to the Directive are met and that the derogated amounts do not prejudice the achievement of the Directive objectives. Derogations are granted by means of a Commission Decision, following the opinion of the Nitrates Committee, which assists the Commission in the implementation of the Directive. The standards of management required of farmers in receipt of derogations need to be higher than those of the action programmes with additional obligations for nutrient planning and extra constraints on land management. The competent national authority shall carry out controls in respect of all farms benefiting from an individual derogation. Every year the competent authorities shall submit to the Commission a report containing, among other, information on the impact of the derogation on water quality and on the implementation of the derogation conditions on the basis of administrative controls and field inspections. So far, the following Member States have been granted derogations pursuant to third subparagraph of point 2 of Annex III: Austria, Denmark, the Netherlands, Germany, the United Kingdom, Ireland, Belgium and Italy. Derogations apply either to the whole territory or to some of their regions, they are time-bound and apply in conjunction with an action programme.

4.2. Technical Advice and Guidance

- In order to identify waters that are subject to eutrophication, common criteria — such as levels of chlorophyll-a, or the presence of excessive algal growths — should be established. Existing definitions developed by organisations such as PARCOM for coastal and estuarial waters (nitrate, algal blooms), and OECD for freshwater (phosphate, chlorophyll, Secchi disc) may be useful for this purpose. Sampling to establish eutrophication should take account of seasonal variations in the parameters selected. Guidance documents should be prepared prior to the final assessment. To provide a consistent application of the Directive throughout the country, a network of sampling points should be established. The guidance for this Directive must not conflict with that issued under the Urban Waste Water Treatment Directive (91/271/EEC) for the identification of sensitive areas. If different competent authorities are appointed, consultation should be arranged between them on this issue. (See the fiche on the Urban Waste Water Directive for guidance on defining the eutrophic status of waters.)

4.3. Regulation

- The competent authority, in collaboration with other relevant ministries and experts, should identify relevant measures to be included in the Code(s) of good agricultural practices and in Action Programmes, such as periods (for each zone or more generally) when application of fertilisers

including livestock manure must be prohibited (by reference to meteorological conditions, soil characteristics, risks of leaching and run off, length of growing season and farming practices). The Action Programmes are to be made mandatory within vulnerable zones or within the whole country. The codes of good agricultural practice shall refer to the use of fertilisers in terms of when and how they should be used, and the precautions to take to prevent run-off from land into watercourses that may occur during their application, particularly from land which is close to watercourses and where direct run-off may occur under conditions such as steeply sloping land, or in very wet periods. Nitrate release from ploughing of land should also be discussed in the codes. The need for livestock manure storage facilities should be covered both by the codes and the action programmes. The codes are voluntary but candidate countries should consider what means are available to encourage their general adoption by farmers.

- Adequate training in the new techniques of farming, including balanced fertilisation, is essential, and a training programme should be a feature of the action plans. A means of judging the effectiveness of training should be set up.

4.4. Monitoring

- It is a requirement of the Directive that Member States monitor the effectiveness of the measures implemented to prevent and reduce nitrate pollution, so to reinforce them in case the action programmes are found to be not sufficient for achieving the objectives of the Directive.

4.5. Consultation and Reporting

- It is important to involve the relevant stakeholders, including farming community in consultation over the action required by the Directive as the action plans may result in farmers having to alter the ways in which they have worked for many years, including changes to the cropping patterns, and how they deal with livestock and livestock manure. The storage of manure during parts of the year (when its application is not permitted) is required, and the construction of new storage facilities may be required, in addition to what is already available at the farm. It is important to provide information on the funding possibilities, when available. It is difficult to visit and inspect farms over a large area at frequent intervals, and therefore the co-operation of farmers in ensuring that they accept and incorporate the new methods into their everyday working practices is important. Consultation with farmers and their representative bodies is essential.
- The action programmes are to be subject to the Strategic Environmental assessment under Directive.
- Several studies have been developed to support the implementation of the Nitrates Directive, which are available at the following link: <http://ec.europa.eu/environment/water/water-nitrates/studies.html>

The available studies concern different aspects of the implementation and include:

- Study on variation of manure nitrogen efficiency throughout Europe

The overall objective of this study was to provide a detailed analysis of the different ways in which manure-N efficiency is defined and the methods by which it is determined throughout the EU-27, including variation at regional levels where applicable.

- The impact of the Nitrates Directive on gaseous nitrogen emissions: Effects of measures in nitrates action programme on gaseous nitrogen emissions

The general objective of this project was to assess the effects of measures in the Nitrates Directive on gaseous nitrogen emissions to the atmosphere.

- Manure processing activities in Europe

The study was aimed to make an inventory of the actual manure processing activities in the EU. The inventory indicates the amount of manure processed per MS and differentiated per type of manure, the scale of operations (farm scale – medium scale- industrial scale), the operational processing techniques and indicate the kind and general characteristics of end and by-products as well as their recovery markets.

- Recommendations for establishing Action Programmes under Directive 91/676/EEC concerning the protection of waters against pollution caused by nitrates from agricultural sources

The study was aimed to give an overview of processes that influence leaching and run off towards ground and surface waters and their link to farming practices. It also provides recommendations for each of the measures to be included in Action Programmes, according to the pedo climatic region in Europe, so to minimize risk of water pollution.

- Study on the behaviour of digestate in agricultural soils

The report summarizes the main aspect of agronomic use of digestate, with reference to scientific literature.

5. COSTS

Costs of preventing nitrate pollution are much lower than costs of cleaning up waters or restoring ecosystems. In accordance with the polluter pays principle of the Treaty establishing the European Community, the costs of measures necessary to change current practices to prevent or reduce nitrate pollution should mainly be borne by agricultural operators. The checklist below shows the main areas of cost generated from implementation of this Directive. Candidate Countries should assess costs also in relation to the WFD, as there will be certain overlaps.

Table 9: Checklist of the Types of Cost Incurred to Implement the Directive

<p>Initial set-up costs for public administration:</p> <ul style="list-style-type: none">• establishment of the competent authority/authorities;• laboratory facilities and capacity;• initial sampling programme and analysis;• data interpretation of first survey;• consultation with farmers;• designating vulnerable zones and preparation of action programmes and their publication;• preparation and publication of codes of good agricultural practice. <p>Capital expenditure for farmers:</p> <ul style="list-style-type: none">• construction of manure storage facilities. <p>On-going costs for farmers:</p> <ul style="list-style-type: none">• changes to farming practices;• Costs to farmers will be counterbalanced by savings in fertiliser use through the adoption of balanced fertilisation and the improved use of nutrients in livestock manures. <p>Cooperation with public administration, provision of information, and monitoring. On-going costs for the public administration:</p> <ul style="list-style-type: none">• monitoring programmes;• follow-up surveys at four-years intervals;• designation of additional zones (unless action programmes cover whole country);• preparation of additional nitrate action programmes.• These will be counter balanced by savings in water treatment programmes through reduced pollution of drinking waters. <p>EU funding opportunities (e.g. in the rural development programmes) may exist for those measures (e.g. manure storage) requiring an investment.</p>
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THE DRINKING WATER DIRECTIVE

Official Title: Council Directive 98/83/EC on the quality of water intended for human consumption (OJ L 330, 5.12.98), as amended by Regulation (EC) No. 1882/2003²⁰⁸(OJ L 284, 31.10.2003), Regulation (EC) No 596/2009²⁰⁹(OJ L 188, 18.7.2009)and Commission Directive (EU) 2015/1787²¹⁰(OJ L 260, 7.10.2015)

95/337/EC: Commission Decision of 25 July 1995 amending Decision 92/446/EEC of 27 July 1992 concerning questionnaires relating to Directives in the water sector (OJ L 200, 24.8.1995).

²⁰⁸Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty

²⁰⁹Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four

²¹⁰Commission Directive (EU) 2015/1787 of 6 October 2015 amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption

1. SUMMARY OF MAIN AIMS AND PROVISIONS

This Directive replaced the original Drinking Water Directive (80/778/EEC) in 1998. Member States had to ensure its application at the latest by 2003. It was necessary to adapt the original Directive in the light of scientific and technical progress, but also in accordance with the principle of subsidiarity by reducing the number of parameters for which Member States were obliged to set water quality objectives and by focusing on compliance with essential quality and health parameters.

The Directive provides for the safeguarding and promotion of the sustainable use of water intended for human consumption (and as such can be considered as foreshadowing the WFD). The key aim of the Directive is to protect human health from the adverse effects of the contamination of water intended for human consumption by ensuring that it is "wholesome and clean" (Arts. 2(1) and 3). It applies to all water intended for human consumption, as well as water used in the production and marketing of food, subject to certain exceptions including natural mineral waters that are regulated pursuant to Directive 2009/54/EC (former Council Directive 80/777/EEC (Art. 2(1)) and waters which are medicinal products within the meaning of Directive 2001/83/EC (former Council Directive 65/65/EEC). Member States are required to monitor the quality of drinking water and to take measures to ensure that it complies with the minimum quality standards (see Arts. 4, 5, 6 and 7). It also lays down a number of requirements for reporting to the Commission and for making information available to the public regarding the quality of drinking water (Art. 13).

The steps still required for the implementation and operation of this Directive in candidate countries should be effected bearing in mind the pervasive provisions of the WFD (2000/60/EC), which has altered the legislative framework generally for EU water-related legislation and provides an altered structure for the practical application of this Directive. It is recommended that any further implementation of this Directive take place after careful consideration of the WFD and the fiche on it in this Handbook. See also that fiche for details of the specific requirements for monitoring, regulation and implementation, for example under Articles 4, 5, 7, 10-13, 16 and Annex IV. Note, in particular, that under the WFD water control is affected on a river basin district basis, and that the WFD provides for particular administrative and regulatory control in the case of international river basin districts.

Directive 98/83/EC has been amended by Regulation (EC) No. 1882/2003 and Regulation (EC) No. 596/2009. These amending Regulations are procedural in character and are horizontal amendments to align the provisions of Directive 98/83/EC to comitology procedures.

The latest amendment to Directive 98/83/EC on the quality of water intended for human consumption took place in 2015 by adoption of the Commission Directive (EU) 2015/1787 of 6 October 2015 amending Annexes II and III to Council Directive 98/83/EC on the quality of water intended for human consumption. This Directive introduces flexibility in the monitoring of parameters and the frequency of sampling is framed by a number of conditions to be met, to ensure protection of citizens' health. The new rules follow the principle of 'hazard analysis and critical control point' (HACCP), already used in food hygiene legislation, and the water safety plan approach laid down in the World Health Organisation's Guidelines for Drinking Water Quality. Firstly it replaces Annex II, which sets out general objectives and monitoring programmes for water intended for human consumption, and further establishes parameters for monitoring. Secondly, it lays down some amendments to Annex III as regards microbiological parameters for which methods of analysis are specified, as well as chemical and indicator parameters for which performance characteristics are specified. Member States have two years to apply the provisions of this new legislation.

Provisions of the Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption supplement provisions of the Drinking Water Directive. In view of the importance for human health of the quality of water intended for human consumption, this Directive lays down at the European Union level standards, which have an indicator function and provide for the monitoring of compliance with those standards, as regards the presence of radioactive substances. In particular it lays down parametric values and frequencies and methods for monitoring radioactive substances. These provisions apply to:

- all water, either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, a tanker, or in bottles or containers;
- all water used in any food production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption unless the competent national authorities are satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form. National mineral waters are excluded.

The Commission is also currently evaluating the Drinking Water Directive. Results of the Directive review are available at the following link: http://ec.europa.eu/environment/water/water-drink/review_en.html

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Consider generally what steps to take in legislative, administrative and executive terms to implement this Directive, taking into account the requirements of the WFD.
- In so doing, consider what steps are required to meet the requirements of this Directive for the purpose of establishing programmes of measures for river basin districts. (WFD, Art. 11)
- Decide, further to any monitoring to be adopted in compliance with the WFD, whether to exempt any categories of water from the provisions of the Directive, pursuant to Article 3(2). (Art. 3)
- Decide whether to provide for any derogations from the parametric values set out in the Directive, and if so ensure that these are only granted in accordance with the conditions laid down. (Art. 9) (see also the WFD, Arts. 4 and 7).

2.2. Regulation

The WFD contains relevant provisions concerning the granting, review and amendment of permits or authorisation for the abstraction of surface water and groundwater.

- Take the necessary measures to ensure that water intended for human consumption (referred to in this fiche as "drinking water") is wholesome and clean, i.e. that it complies, as a minimum, with the requirements laid down in the Directive. (Art. 4 and Annex I, and see Articles 4 and 7 of the WFD).
- Ensure that measures taken pursuant to the Directive do not lead to a deterioration in the quality of drinking water, with regard to human health, or to an increase in pollution of waters used for the production of drinking water. (Art. 4)
- Establish water quality standards applicable to drinking water, for the parameters specified in the Directive and for other parameters where necessary for the protection of human health. (Art. 5 and Annex I, and see the WFD as to classification of the status of water bodies and Annexes II and III).
- Ensure that the water quality standards set in accordance with Article 5 of this Directive are complied with at the point at which the water is made ready for human consumption (as described in the Directive) (Art. 6).
- Where drinking water is supplied from a distribution network to premises or establishments, and the water does not comply with the water quality standards at the point where it emerges from the tap, Member States will not be in breach of the Directive provided that:
 - 17.9non-compliance is due to a domestic distribution system which is not the responsibility of the water supplier;

18. the water is not being supplied to the public (e.g. schools, hospitals and restaurants);
 19. appropriate measures are taken to reduce or eliminate the risk of non-compliance with the quality standards (e.g. advising property owners of possible remedial action); and
 20. consumers are informed and advised of any possible additional remedial action that they should take (Art. 6).
- Ensure that measures are taken to limit the quantity of substances or materials for new installations used in the preparation or distribution of drinking water. (Art. 10)

2.3. Monitoring

- Establish monitoring programmes, in accordance with the minimum requirements laid down in the Directive. (Art. 7 and Annex II, but see also the WFD, Arts. 7 and 8 and Annex V). Note the amendments introduced to Annex II by the Commission Directive (EU) 2015/1787.
- Ensure that regular monitoring of drinking water quality is carried out to ensure compliance with the requirements of the Directive and consider tying this activity in for the purposes of the WFD. Monitoring must be carried out in accordance with the requirements specified in the Directive, although other methods of analysis may be used if they achieve equally reliable results. (Art. 7 and Annex III, and see the WFD, Arts. 7, 8 and Annex V). Note the amendments introduced to Annex III by the Commission Directive (EU) 2015/1787.
- Where there is a potential danger to human health from the presence, in drinking water, of substances and micro-organisms for which no parametric value has been set, ensure that additional monitoring of these substances and micro-organisms is carried out, on a case-by-case basis. (Art. 7)
- Ensure that any failure to meet the water quality standards is immediately investigated in order to identify the cause, and that remedial action is taken to restore the water quality. (Art. 8)
- Where the supply of drinking water constitutes a potential danger to human health, ensure that the supply is prohibited or restricted or that other necessary action is taken to protect human health. (Art. 8)

2.4. Information and Reporting

- Inform the population concerned of any exemptions granted pursuant to Article 3(2)(b) and provide advice to them on measures to be taken to protect human health from the adverse effects of the contamination of drinking water. (Art. 3)
- Inform and advise consumers where the supply of drinking water constitutes a potential danger to human health, and (except in trivial cases of non-compliance) notify consumers of remedial action taken. (Art. 8)
- Inform the population affected by a derogation of the derogation and the conditions on which it is granted. (Art. 9)
- Publish a report every three years on the quality of drinking water. (Art. 13)
- Ensure that adequate and up-to-date information on the quality of drinking water is available to consumers. (Art. 13)
- Report to the Commission on:
 - cases of derogation from the requirements of the Directive (Art. 9);
 - the quality of drinking water (Art.13);
 - requests for an extension of time for implementation (Art. 15);
 - measures taken or to be taken to fulfil the obligations under the Directive pursuant to Article 6(3) and Annex I, Part B, note 10 (Art. 13); and
 - transposition, with texts of the main provisions of national law adopted in the field covered by the Directive. (Art. 17)
- Provide reporting pursuant to Directive 91/692/EEC on standardising and rationalizing reports on the implementation of certain Directives relating to the environment provided in the questionnaires and formats set out in Decision 95/337/EC.

2.5. Additional Legal Requirements

There are several other legal instruments that should be borne in mind during the implementation of this Directive. These include:

- WFD (2000/60/EC)
- Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption
- EQS Directive (2008/105/EC)
- Reporting Directive (91/692/EEC) and Decision 94/741/EEC

- Regulation (EC) no. 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
- Regulation (EU) no. 528/2012 concerning the making available on the market and the use of biocidal products
- Construction Products Regulation (EU) no. 305/2011 and subsequent acts

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the checklist below. The key tasks are arranged under subheadings and organised in chronological order of implementation whenever possible.

Table 10. Illustrative checklist with key implementation tasks

DRINKING WATER DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate a competent authority or authorities to review the process for implementing the requirements of the Directive and to set quality standards, to establish compliance procedures and monitoring systems, and to set up and implement information reporting procedures.
2	Regulation
2.2	Set quality standards for water intended for human consumption.
2.3	Establish compliance monitoring procedures to ensure compliance with monitoring standards according to the new Annex II (Directive (EU) 2015/1787) regarding the need to perform or not the risk assessment.
2.4	Establish procedures for dealing with incidents of non-compliance and the instigation of remedial action.
2.5	Establish procedures for informing the public of actions needed to address non-compliant sources of drinking water.
2.6	Establish a monitoring network able to fully meet the requirements of the Directive, including the relevant sampling protocols.
2.7	Establish procedures for assessing the efficiency of any disinfection treatment, which is applied to water for human consumption.
2.8	Establish analytical procedures in line with the requirements of the Directive, or where an equivalent alternative method is selected provide details to the Commission.
2.9	Develop and disseminate guidelines to assist the competent authorities to fulfil the obligations under the Directive, including guidance on deciding what actions to take to restrict use of waters that may pose a threat to human health.
2.10	Establish procedures for providing for derogations from the Directive, if justified by the relevant assessment.
2.11	Establish procedures for informing the public as to the nature and timescale of any derogations.
2.12	Establish procedures for the review of derogations.
2.13	Establish guidelines/criteria for the implementation of Article 15.

2.14	Establish guidelines and procedures to meet the requirements of Article 10 of the Directive on quality assurance of equipment and materials used in the preparation or distribution of water intended for human consumption.
2.15	Ensure that a programme of actions is developed to ensure that the quality of water intended for human consumption complies with the Directive within five years of its entry into force; this has to be considered in relation with the provisions of the Accession Treaty.
3	Reporting
3.1	Report on the measures taken to implement the Directive within two years of its entry into force
3.2	Reporting to the Commission on: <ul style="list-style-type: none"> • Information about granting second derogations (Art. 9(1)); • Requests to grant third derogations (Art. 9(2)) (in both cases the derogation request will contain the information specified in Article 9, Paragraph 3 of the Directive); • Any of the above derogations concerning individual sources of water supply exceeding 1,000 m³ a day as an average or serving more than 5,000 people (Art. 9), should be notified within 2 months. <p>The quality of water intended for human consumption with the objective of informing consumers (every three years). Reports are to be sent to the Commission within two months of their publication. The first triennial report will be accompanied by a report on measures taken to fulfil Article 6(3) and Annex I, Part B, note 10 of the Directive.</p>
3.3	Provide reporting pursuant to Directive 91/692/EEC on standardising and rationalizing reports on the implementation of certain Directives relating to the environment provided in the questionnaires and formats set out in Decision 95/337/EC; consider the most recent developments under the reporting in particular the approach undertaken to ensure the full integration into WISE.
4	Public Information
4.1	Inform consumers where there is a risk of water not complying with the required quality standards and advise them of any restrictions as to the use of drinking water.
4.2	Inform consumers of any remedial action taken by the authorities to deal with sources of water for human consumption not in compliance with the requirements of the Directive.
4.3	Inform any population affected by a derogation of the details of the derogation and any conditions that govern it.
4.4	Provide advice to any groups within the population for whom the derogation could present a special risk.

3.2. Phasing Considerations

This was a key Directive in the water sector when adopted because of its then role in regulating water quality for consumers. The primary place has been taken in this regard by the WFD. Nonetheless, time will be needed to develop the monitoring, sampling and information systems required by the Directive, and particularly with a view to any desired integration of the requirements of this Directive with those of the WFD in this regard.

Coherence with the WFD is ensured through its Article 7 requiring protection of sources of drinking water. Where existing water quality standards for drinking water will need to be replaced, this will also require careful planning and scheduling with the appropriate authorities, utilities, consumer groups, etc.

4. IMPLEMENTATION GUIDANCE

The provision of drinking water of acceptable quality is clearly fundamental to the wellbeing of the population, and any deterioration in water quality at the local or national level is likely to cause widespread concern among the general public.

Implementation of the Directive requires a system (intended to be part of the integrated system introduced by the WFD), which:

- sets clear water quality standards for water destined for human consumption;
- has the capacity to effectively monitor and sample sources of drinking water and to report on the results of these activities;
- has the resources to ensure that the public is kept informed of key action at national, regional and local level on this issue.

4.1. Planning

- The choice of a competent authority or authorities will require care, because of the need to consider the structure for the provision of drinking water, the role of utilities/water supply companies and the need to have a strong inspection and monitoring network, and also because of the need to have regard to the river basin management system to be implemented under the WFD, bearing in mind also the establishment, as necessary, of international river basin districts and relevant competent authorities in this regard (see further the fiche on the WFD). In addition, because of the health-related aspects of the Directive, health authorities may need to be involved in the implementation of the Directive. Similarly, bodies responsible for consumer issues may wish to become involved in implementing or monitoring certain elements of the Directive. Where more than one competent authorities is appointed, tasks must be clearly allocated between them so that all of the obligations of the Directive are met.
- This Directive has implications for a number of stakeholders and, especially where implementation of the Directive will necessitate the amendment or replacement of existing standards, it will be necessary to carry out consultation with a wide range of stakeholders. This activity, along with supporting information on the Directive, needs to be very carefully thought out by the competent authorities. This element of planning has all the more resonance bearing in mind the principle of costs recovery for water services to be implemented pursuant to the WFD (see especially Article 9 and Annex III of the WFD).
- Governments may benefit from consultation with the Commission, international agencies involved with drinking water and health standards such as WHO (the influence of which, in establishing water quality standards, is expressly recognised in the Directive, preamble, Para. 16) and other national governments (also bearing in mind the requirements in the WFD regarding international river basins, see Art. 13) by, for example, the exchange of information, discussion of best practices or the pooling of resources.

- Given that the implementation of this Directive, involves greater consideration of the integration of water services policy pursuant to the WFD, it is important for all relevant stakeholders to be involved in the development and implementation of national legislation and regulations to implement this Directive.
- The development of a monitoring programme and sampling protocols will require the involvement of a number of organisations and agencies and also representatives of accredited laboratories. It may also be necessary to provide guidance and training support.
- Consideration needs to be given to how to regulate the management of situations of non-compliance both in terms of responsibility for dealing with incidents of non-compliance and their remediation and in terms of the management and dissemination of information to consumers and other affected parties.
- It may be necessary to establish a specific agency/inspectorate to deal with drinking water issues. This will need to have clearly defined responsibilities. Care should be taken to make such a role consistent with, and to promote the achievement of, the objectives of the WFD.
- Existing providers of analytical services for the testing of drinking water samples will need to be advised of the requirements of the Directive and the WFD and may need to introduce new sampling and reporting procedures and quality standards.

4.2. Standards and Reporting

- The Directive requires Member States to report to the Commission on several aspects of implementation. These are summarised in the checklist in Section 3 of this fiche.
- The first report on the quality of water intended for human consumption (and all subsequent reports) must be published within one calendar year of the end of the reporting period and forwarded to the Commission within two months of its publication.
- It is important that reports comply with the formats stipulated by the Commission.

5. COSTS

The main costs associated with the implementation of this Directive relates to treatment costs and the costs of implementing and maintaining a monitoring system that is compliant with the requirements of the Directive. Costs may also be incurred when existing quality standards are superseded. This will relate mainly to new documentation, the training of staff, etc. If it is decided to create a specific agency to deal with drinking water issues, this too will clearly have cost implications. See also the WFD as to costs.

THE WATER FRAMEWORK DIRECTIVE

Official Title: Directive 2000/60/EC of the European Parliament and the Council establishing a framework for Community action in the field of water policy (OJ L 327/1 of 22.12.2000),

Amended by:

Commission Directive 2014/101/EU of 30 October 2014 amending Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for Community action in the field of water policy (OJ L 311, 31.10.2014)

Council Directive 2013/64/EU of 17 December 2013 amending Council Directives 91/271/EEC and 1999/74/EC, and Directives 2000/60/EC, 2006/7/EC, 2006/25/EC and 2011/24/EU of the European Parliament and of the Council, following the amendment of the status of Mayotte with regard to the European Union (OJ L 353, 28.12.2013)

Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy (OJ L 226, 24.8.2013)

Directive 2009/31/EC of the European Parliament and of the Council of 23 April 2009 on the geological storage of carbon dioxide and amending Council Directive 85/337/EEC, European Parliament and Council Directives 2000/60/EC, 2001/80/EC, 2004/35/EC, 2006/12/EC, 2008/1/EC and Regulation (EC) No 1013/2006 (Text with EEA relevance) (OJ L 140, 5.6.2009),

Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008)

Directive 2008/32/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, as regards the implementing powers conferred on the Commission (OJ L 81, 20.3.2008)

Decision 2455/2001/EC of the European Parliament and the Council establishing the list of priority substances in the field of water policy (OJ L 331/1 of 12.12.2001)

Consolidated version of the WFD from 2014 is available at:

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1460561205436&uri=CELEX:02000L0060-20141120>

Also relevant is Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers,

and

Commission Directive 2009/90/EC of 31 July 2009 laying down, pursuant to Directive 2000/60/EC of the European Parliament and of the Council, technical specifications for chemical analysis and monitoring of water status (OJ L 201, 1.8.2009)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The main objective of the Water Framework Directive 2000/60/EC (WFD) is to protect and improve quality of water through establishing rules to halt deterioration in the status of EU water bodies and achieving 'good status' for Europe's surface water and groundwater by 2015²¹¹. It establishes the basic principles of sustainable water policy in the European Union on an integrated basis through the establishment of a management structure for European water policy, relying on close co-operation and coherent action at the EU, Member State and local levels, with the close involvement of the public, and with the hope of close co-operation with non-Member States and the assistance of relevant international water protection bodies.

The Directive is an ambitious and far-reaching instrument in relation to which Member States may wish to consider whether they should repeal existing, possibly disparately organised water legislation and replace it under a single framework law, and, as part of that process, to consider whether to codify their water legislation.

The Directive embodies a new approach to environmental legislation including the combined approach of water quality control with emission limit values, and reflecting not only in a clear and practical manner the key environmental protection requirements of EU policy on the environment, but also key principles for EU legislation affecting the environment, such as the precautionary principle and the polluter pays principle. The Directive aims to integrate the water related legislation within one framework by their incorporation within the structure of the Directive and the consequent phased repeal of the individual pieces of such legislation. Coherence with the objectives of the WFD is also ensured with the water related Directives adopted at the later stage, such as the Groundwater Directive 2006/118/EC, the Environmental Quality Standards Directive 2008/105/EC, the Bathing Water Directive 2007/6/EC, the Floods Directive 2007/60/EC and the Marine Strategy Framework Directive 2008/56/EC.

The principle of integration can be seen as being given further effect by the explicit objective of contributing to compliance with EU and Member States' obligations under international conventions; by the provision of an obligation on Member States to establish co-operation on water management objectives with non-Member States in transboundary river basins; by the promotion of existing international water protection bodies; but also by encouraging the implementation of the principle of subsidiarity and by the express requirement for the publication of the river basin management plans.

The following are some key requirements of the Directive:

- the development of an integrated EU policy on and for the sustainable use of water, (Arts. 1 and 4);
- the adoption of a coherent, transparent and effective legislative framework pursuing common principles and, as necessary, laying down technical specifications and minimum requirements for common environmental quality standards (EQS) and emission limit values (ELVs) (Arts. 16 and 17, Annexes II and III, V, VI, VIII, IX and X);
- the further integration of the protection and sustainable management of water into other EU policy areas such as energy, transport, agriculture, fisheries and tourism (Arts. 1, 4, 5 and 9);
- contributing to enabling the EU and Member States to meet their obligations under various international agreements containing important obligations on the protection of marine waters from

²¹¹ Further deadlines have been introduced by Directive 2013/39/EC for certain substances under the chemical status for surface waters. See article 3 of Directive 2008/105/EC as amended by 2013/39/EU.

pollution and under other international agreements on water protection and management (Arts. 1, 3, 4(1), 12, 16(3) and (5));

- contributing to other areas of co-operation between Member States, such as the European Spatial Development Perspective;
- expanding the scope of water protection to all waters, surface waters, groundwater, coastal waters and, where relevant, territorial waters (Arts. 1-5, 7-8, 11-12, 16-17);
- contributing to mitigating the effects of floods (Art. 1 and 11(3)(l));
- protecting aquatic ecosystems, and the terrestrial ecosystems and wetlands directly dependent on them (especially Art. 6 and Annex IV);
- safeguarding and developing the potential uses of EU waters (esp. Arts. 1, 4, 9, 11, 13 and Annex VII);
- establishing a water management approach based on river basins, and providing for co-operation between Member States where river basins or the effects of the same are transboundary, and for further co-operation with non-Member States where river basins are only partly within the EU (Art. 3);
- establishing common definitions of the status of water in terms of quality, and where relevant for the purpose of environmental protection, of quantity (Arts. 2, 4(1)(a) and 16(7), and Annexes V, VIII and IX);
- maintaining and improving the aquatic environment in the EU, primarily through the combined approach of controls on quality, but also through regulation on quantity, both also to be more closely integrated (Art. 10 and Annex IX);
- ultimately the elimination of priority hazardous substances into water (Arts. 4 and 16);
- contributing otherwise to the progressive reduction of emissions of hazardous substances to water;
- contributing to achieving near background values for naturally occurring substances in marine waters (Art. 4);
- achieving "good" status for all waters by 2015 (subject to certain derogations and exemptions defined in Art. 4), and maintaining "good" status where it already exists (Art. 4);
- identifying and reversing any significant and sustained upward trend in the concentration of any pollutant in groundwater (Art. 4);
- requiring account to be taken of the principle of the recovery of costs of water services, including environmental and resource costs, establishing water pricing policies setting adequate incentives to use water efficiently, and requiring an adequate contribution to the recovery of the costs of water services from different water users (Art. 9 and Annex III);
- encouraging the active participation of all interested parties in the implementation of the Directive, especially as regards the production, review and updating of river basin management plans (Art. 14).
- Several pieces of legislation dating from about 1975 to 1980 have already been integrated into the WFD and have, consequently, been repealed in a phased approach. The Directives concerned are:

- the Dangerous Substances Directive (2006/11/EC) and its daughter Directives (repealed on 22 December 2013);
- Council Decision on Exchange of Information (77/795/EEC) (repealed on 22 December 2007);
- the Fish Water Directive (2006/44/EC) (repealed on 22 December 2013);
- the Shellfish Water Directive (2006/113/EC) (repealed on 22 December 2013);
- the Directive on the Measurement and Sampling of Surface Waters (79/869/EEC) (repealed on 22 December 2007);
- the Groundwater Directive (80/68/EEC) (repealed on 22 December 2013).

In addition, under the WFD complementary, ‘daughter’ directives have been adopted on the protection of the groundwater against pollution and deterioration and on environmental quality standards establishing the standards, which constitute the chemical status criteria for the WFD.

Thus, for groundwater protection there is an additional piece of legislation; Directive 2006/118/EC on the protection of groundwater against pollution and deterioration. It further stipulates specific measures provided for in Article 17(1) and (2) of the WFD, such as setting out criteria for the assessment of good groundwater chemical status and criteria for the identification and reversal of upward trends. It also introduces more specific requirements regarding the prevention and limitation of discharges of pollutants into groundwater in addition to those covered by the WFD.

The EQS Directive (2008/105/EC) is instrumental in the implementation of the WFD, particularly through the requirements for the list of priority substances and their related EQSs, the inventory of emissions, losses and discharges of priority substances, the requirement for the Commission to develop a watch list to be implemented by Member States, and finally for the requirement for the Commission to develop a strategic approach to pharmaceuticals in the aquatic environment and gives specifications regarding monitoring of priority substances. For instance, with reference to the monitoring of priority substances, section 1.3.4 of Annex V to Directive 2000/60/EC sets out monitoring frequencies suitable for checking compliance with the EQS. Member States have some discretion in introducing the (statistical) methods, and in determining, for the substances mentioned in points (a) and (b), the frequency of monitoring in biota and/or sediment. However, monitoring shall take place at least once every year, unless technical knowledge and expert judgment justify another interval. Also this Directive requires that the results of the monitoring, including monitoring of sediment and biota as far as required by Article 3 of Directive 2008/105/EC be made available.

Commission Directive 2009/90/EC of 31 July 2009 laying down, pursuant to Directive 2000/60/EC of the European Parliament and of the Council, technical specifications for chemical analysis and monitoring of water status further supplements provisions of the WFD. This Directive introduces technical specifications for chemical analysis and monitoring of water status, in accordance with Article 8(3) of the WFD.

There are strong links between the WFD and the Marine Strategy Framework Directive (MSFD). WFD relates to improving and protecting the chemical and biological status of surface waters throughout a river basin catchment from rivers, lakes and groundwaters through to estuaries (transitional) and coastal waters to one nautical mile out to sea and overlaps with MSFD in coastal waters. However, the MSFD applies in coastal waters only aspects, which are not covered by WFD (e.g. noise, litter, aspects of biodiversity). MSFD and WFD also have comparable objectives, with MSFD focussed on the achievement of Good Environmental Status in marine waters, and WFD aiming to achieve Good Ecological and Good Chemical Status. The Good Environmental Status is not exactly similar to Good Ecological/Chemical Status, but still there are some significant areas of overlap, particularly in relation to chemical quality, the effects of nutrient enrichment

(eutrophication) and aspects of ecological quality and hydromorphological quality. There are also differences between the Directives as the assessment scales, the approaches to protecting the marine environment, and the scope of Good Environmental Status under the MSFD, which is broader, covering a greater range of biodiversity components and pressures, which are not included in the WFD.

Provisions of the WFD complement other key pieces of water-related legislation: in particular, the Directive on urban waste water treatment (91/271/EEC) and Directive on nitrates pollution from agriculture (91/676/EEC); the body of rules governing the authorisation and use of pesticides and biocides as well as Industrial Emissions (Directive(2010/75/EU) (see Section 7 of the Handbook).

WFD has been amended by the following EU legislation:

- Commission Directive 2014/101/EU of 30 October 2014 amending Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for Community action in the field of water policy laying down some amendments to Annex V to Directive 2000/60/EC in order to ensure the quality and comparability of the methods used for the monitoring of type parameters generated under Member States responsibility to perform water ecological monitoring. The amendments concern in particular standards for monitoring of quality elements, standards for sampling of biological quality elements, standards for phytoplankton, standards for macrophyte and phytobenthos, standards for benthic invertebrate and standards for physico-chemical parameters.
- Council Directive 2013/64/EU of 17 December 2013 amending Council Directives 91/271/EEC and 1999/74/EC, and Directives 2000/60/EC, 2006/7/EC, 2006/25/EC and 2011/24/EU of the European Parliament and of the Council, following the amendment of the status of Mayotte with regard to the European Union. France is the sole addressee of this Directive.
- Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy. Provisions of this Directive lay down some amendments to Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy. It is hereby established that the Commission shall review the adopted list of priority substances at least every six years. Moreover, the list of priority substances in Annex X to Directive 2000/60/EC is replaced by the text in the Annex hereto.

Regulation (EU) No 182/2011 of 16 February 2011 of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers. This Regulation lays down the rules concerning the control of the exercise of the Commission's implementing powers. This control is applied through the comitology procedures – the Commission must submit each draft implementing act to committees composed of representatives of Member States. The regulatory procedure with scrutiny can either result in being classified as delegated or implementing acts.

- Directive 2009/31/EC of the European Parliament and of the Council of 23 April 2009 on the geological storage of carbon dioxide and amending Council Directive 85/337/EEC, European Parliament and Council Directives 2000/60/EC, 2001/80/EC, 2004/35/EC, 2006/12/EC, 2008/1/EC and Regulation (EC) No 1013/2006 TheWFD is amended by Directive 2009/31/EC to allow for injection of CO₂ into saline aquifers for the purposes of geological storage. Such storage and injections are subject to provisions protecting groundwater set out in Article 4(1)(b) of the WFD and also in Directive on Groundwater (2006/118/EC). The Directive amends Arts. 11(3)(j) in terms of adding injections of CO₂ into aquifers to the list of activities requiring prior approval.

- Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council
- Directive 2008/32/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2000/60/EC establishing a framework for EU action in the field of water policy, as regards the implementing powers conferred on the Commission Since the amendments made to Directive 2000/60/EC by this Directive are technical in nature and concern committee procedure only, they do not need to be transposed by the Member States. The amendments include:
 - Article 8(3) of WFD has been amended by stating that the technical specifications and standardised methods for analysis and monitoring of water status shall be laid down, but that these non-essential elements should be adopted in accordance with the regulatory procedure with scrutiny set out in Council Decision 1999/468/EC;
 - Article 20 stating that Annexes I, III and section 1.3.6 of Annex V should be adapted to scientific and technical progress, under the regulatory procedure with scrutiny taking account of the periods for review and updating of the river basin management plans as referred to in Article 13. Commission guidelines on the implementation of Annexes II and V should be adopted with the procedure. The same regulatory procedure should be applied setting out the formats for transmitting and processing data;
 - Section 1.4.1 of Annex V has been amended setting out the regulatory procedure for the preparation of a draft register of sites to form the intercalibration network and also regarding certain aspects of the intercalibration exercise and the values established for the Member State monitoring system classifications.
- Decision 2455/2001/EC of the European Parliament and the Council establishing the list of priority substances in the field of water policy:
- Decision 2455/2001/EC established a First list of priority substances to become Annex X of the WFD. These substances were selected from amongst those presenting a significant risk to or via the aquatic environment, using the approaches outlined in Article 16 of the WFD. (This first list has been replaced by Annex II of the EQS Directive (2008/105/EC) Principal Obligations of Member States

1.1. Planning

- Consider what water-related legislation might usefully and sensibly be co-ordinated under or with the implementing legislation required for this Directive. Provide for any relevant repeals of national law (see the timetable below as to the possible phasing of such legislation, and see Article 22).
- Conduct a review of the state of implementation, and in particular enforcement, of existing environmental legislation for the protection of waters, and take all necessary measures to ensure that such legislation is implemented and applied in full (Art. 4(8) and (9)).

- Provide for the adoption of all relevant measures necessary to implement the Directive, taking into account the matters suggested in the introduction above (Art. 24).
- Establish competent authorities, using either existing structures or creating new ones, and establish administrative arrangements to ensure that the Directive is implemented effectively within river basin districts (Art. 3(2)-(4)).
- Identify, in accordance with the definitions in the Directive, and establish in respect of all relevant waters within the territory of the Member State all required categories of waters, and further identify which are part of an international river basin district (Arts. 2 and 3, and Annex II).
- Identify river basins (and, as relevant, sub-basins) and assign them to individual river basin districts. Two or more river basins may be combined into one river basin district, where appropriate (Art. 3(1)).
- Assign all groundwater to the nearest or otherwise most appropriate river basin district. Likewise with coastal waters, which should be assigned to the nearest or most appropriate river basin district or districts (Art. 3(1)).
- Where Member States share a river basin, provide for co-ordination across the whole river basin (establishing any required international river basin districts). Where part of a river basin lies on the territory of a third country, this co-ordination is mandatory for the part lying within Member States, but Member States are still under an obligation to make efforts towards co-ordination with relevant non-Member States (Art. 3(4)-(5)).
- Ensure that, for each river basin district or relevant part of any international river basin district, an analysis of its characteristics, a review of the impact of human activity on the status of the surface waters and on groundwater, and an economic analysis of water use, according to the technical specifications in Annexes II and III are undertaken (Art. 5(1)), and provide for their necessary review and update (Art. 5(2)).
- Identify, within each river basin district, all waters used for the abstraction of drinking water and bodies of water intended for such future use (Art. 7(1)).
- Consider establishing safeguard zones for the bodies of water referred to in the previous bullet point (Art. 7(3)).
- Establish a register or registers of all areas lying within each applicable river basin district which have been designated as requiring special protection under specific EU legislation for the protection of their surface water or groundwater or for the conservation of habitats and species directly depending on water (Art. 6(1)), which must include all bodies of water identified under Article 7(1) and all protected areas covered by Annex IV (Art. 6(2)), and provide for them to be kept under review and up to date (Art. 6(3)).
- Provide for the conducting of the economic analysis in sufficient detail in order to make relevant calculations necessary under Article 9, taking account of long-term forecasts of water supply and demand for water in the river basin district, and any necessary estimates of volume, prices and costs associated with water services, and estimates of relevant investment including forecasts of such investments, and then make judgments as to the most cost-effective combination of measures in respect of water use for Article 11 based on estimates of potential costs (Art. 9 and Annex III).

- Establish steps planned towards implementing such economic measures, which will continue to achieve the environmental objectives in Article 1 and establish the contribution to be made by various water users towards the recovery of the costs of water services (Art. 9(2)).
- Provide for the application of water pricing policies providing adequate incentives for efficient water use, with adequate contributions from the different water users, disaggregating the same into at least industry, households and agriculture, based on the economic analysis identified above, and in so doing consider having regard, inter alia, to the social, environmental and economic effects of the recovery (Art. 9(1)).
- Ensure that relevant regulatory measures are in place to ensure the establishment or implementation, in accordance with existing EU legislation, of the emission controls and the relevant emission values set out in the Directives referred to in Article 10(2) and for the application of any more stringent measures necessary (Art. 10(3)).
- Member States should also consider whether any extensions of time are required to be provided for achieving the objectives of Article 4 and/or whether any derogations should apply (Art. 4), and/or whether there are grounds for providing that breach of the Directive will not take place in accordance with the provisions of Article 4(7).
- Provide for the production, in accordance with the timetable for consultation in Article 14, of work programmes for the drawing up of river basin management plans; of an interim overview of the significant water management issues identified; and of draft copies. Thereafter, following receipt of, and the taking into account of, comments from the public, provide for the publication of river basin management plans (Art. 13) (see also further below under consultation and reporting). In doing so, Member States should provide for the consideration of any more detailed plans, for example for sub-basins. Such plans must cover as a minimum the matters set out in Annex VII.
- They should, for international river basin districts wholly within the EU, ensure production of a single international river basin management plan, failing which they must produce such a plan for that part within their territory to achieve the objectives of the Directive. In the case of international river basin districts only partly within the EU, the relevant Member States should endeavour to produce a single plan, but in any event must produce one for that part within their own territory.

1.2. Regulation

- Ensure that necessary protection measures are in place for these bodies of surface water, with the aim of preventing deterioration in their quality, to reduce the level of purification treatment required in the production of drinking water (Art. 7(3)).
- Establish, for all groundwater, criteria for assessing groundwater chemical status in accordance with the requirements in Article 3 of Directive 2006/118/EC (including the groundwater quality standards set out in Annex I and the procedure for setting the threshold values referred to in Annex II).
- Take the necessary measures to prevent or limit inputs of pollutants into groundwater in conformity with Article 6 of Directive 2006/118/EC regarding the conditions and the possible exceptions to these mandatory measures.

- Identify threshold values for groundwater by 22 December 2008 and ensure that these are published in the river basin management plans (Art. 3(5), Directive 2006/118/EC).
- Initiate programmes to identify point and diffuse sources of pollution of all waters subject to the Directive and requiring control measures under the Directive, and consider whether to adopt generally binding rules for their prior authorisation or registration where permitted under EU legislation (Art. 11(3)).
- Establish, for each river basin district or relevant part of any applicable international river basin district, a programme of measures, taking account of the results of the analysis required under Article 5, in order to achieve the objectives of Article 4 in respect of the various categories of water bodies, and in accordance with any extensions of time, derogations or "exemptions" from compliance under Article 4 (Art. 11(1)). This may be achieved by reference to measures following from implementation legislation for this Directive and covering the whole of the Member State territory, and, where appropriate, may be applicable to all river basin districts or parts of international river basin districts within the territory of the Member State (Art. 11(1)). Each programme is to include "basic measures" and, where necessary, "supplementary measures" (Art. 11(2)).

Basic measures are minimum requirements and include (Art. 11(3)):

- measures required to implement EU legislation on the protection of water and set out in Article 10 and in Part A of Annex VI;
- measures deemed appropriate for the purpose of Article 9 and for the recovery of costs of water services;
- measures to promote efficient and sustainable water use to avoid compromising the achievement of the objectives of Article 4;
- measures necessary for Article 7;
- controls on and requirements for any necessary prior authorisations for the abstraction of surface waters and groundwater, and the impoundment of fresh surface waters; for artificial recharge or augmentation of groundwater bodies; for point source and diffuse source discharges; and for any other significant adverse effects on the status of waters identified under Article 5 and Annex II liable to cause pollution (also consider prior registration based on generally binding rules in accordance with and as permitted by EU legislation). Such measures should be periodically reviewed and, where necessary, updated;
- prohibitions (subject to the stated possible derogations and authorisations) of direct discharges to groundwater;
- measures, further to action required under Article 16, to eliminate the pollution of surface waters by priority list substances, and to progressively reduce pollution by other substances which would otherwise prevent Member States achieving the objectives for bodies of surface waters set out in Article 4;
- measures required to prevent significant losses of pollutants from technical installations, and to prevent/reduce the impact of accidental pollution, including as a result of floods;
- measures to detect or give warnings of events such as flooding or significant losses of pollutants from technical installations, and emergency plans to address the same should they materialise.

Supplementary measures to be considered have been set out in a non-exhaustive list in Annex VI, Part B. Part B includes measures such as economic or fiscal instruments, negotiated environmental agreements, codes of practice, demand management measures, efficiency and re-use measures, rehabilitation projects and research, development and demonstration projects. Member States should consider what further supplementary measures should be adopted to provide additional protection.

- For each river basin district, or portion of any international river basin district falling within its territory (Art. 5(1)) — in accordance with the technical specifications set out in Annexes II and III, by, at the latest, 2013 and every six years thereafter — undertake:
 - an analysis of its characteristics;
 - a review of the impact of human activity on the status of waters; and
 - an economic analysis of water use.
- Take action to prevent or reduce the impact of accidental pollution incidents including by flooding events (Art. 11(3)(e-i)):
- Establish controls regarding:
 - the abstraction of fresh surface water and groundwater, and the impoundment of fresh surface water. These controls include establishing register or registers of water abstractions and for abstraction and impoundment require prior authorisation. Exemptions from these controls may be provided if abstractions or impoundments have no significant impact on water status. (Art. 11(3)(e))
 - artificial recharge or augmentation of groundwater bodies, ensuring that any such schemes are compatible with the specifics of Article 11(3)(f). These controls include prior authorisation artificial recharge or augmentation of groundwater bodies.
 - point source discharges liable to cause pollution, in particular ensuring that emission controls or relevant emission values are established and implemented. Thus, controls include prior regulation, prior authorisation or registration based on general binding rules. In any event, adopt and apply more stringent emission controls where a quality objective or quality standard laid down in this Directive or otherwise in EU legislation so requires. (Art. 11(3)(g))
 - diffuse sources liable to cause pollution; Controls may take the form of a requirement for prior regulation, such as a prohibition on the entry of pollutants into water, prior authorisation or registration based on general binding rules. (Art.11(3)(h))
 - injection of CO₂ into saline aquifers for the purposes of geological storage. Such storage and injections are subject to provisions protecting groundwater set out in Article 4(1)(b) of the WFD and also in Directive on Groundwater (2006/118/EC). (Art. 11(3)(1), WFD, as introduced by Art. 32 of Directive 2009/31/EC
 - any other significant adverse impacts on the status of waters identified under Article 5 and Annex II, and, in particular, measures to ensure that the hydromorphological conditions of the bodies of water are consistent with the achievement of the required ecological status or good ecological potential for bodies of water designated as artificial or heavily modified (Art.11(3)(i)).

Note that controls referred to in Article 11(3) need to be periodically reviewed and, where necessary, updated.

- Provide for ability to review and amend such permits and authorisations in the event of breach of their conditions, and generally on a regular basis, but also in the event that monitoring or other data indicate that the objectives of Article 4 are unlikely to be achieved and need adjusting as appropriate (Art. 11(3) and (5)).
- Provide that the application or implementation of any measures under Article 11(3) does not lead to an increase in marine pollution and on no account leads either directly or indirectly to increased pollution of surface waters, save where to do so would lead to increased pollution of the environment as a whole (Art.11(6)).
- Prohibit the direct discharge of a list of dangerous substances into groundwater, and consider whether to provide for exemptions, and, if so, provide for exemptions in accordance with Article 11(3)(j).
- Adopt and apply measures to eliminate pollution of surface waters by agreed priority list substances, and to progressively reduce pollution by other substances that would prevent the Member State from achieving the objectives for the bodies of surface water as set out in Article 4 (Art. 11(3)(k)).
- Apply measures to give effect to and to ensure the effectiveness of any "supplementary measures" adopted (Art. 11(4)).
- Establish an effective system of penalties for non-compliance with national provisions adopted pursuant to the Article 23 of the Directive. The penalties thus provided for shall be effective, proportionate and dissuasive.
- Ensure that the price charged for services related to water as defined in Article 2(38) of the WFD is compatible with the requirements of Article 9 and Annex III (recovery of costs for water services) requiring account to be taken of the need to set pricing policies which provide adequate incentives for efficient water use and also for an adequate contribution from the various categories of water users (Art. 9(1)).

1.3. **Monitoring**

Article 8 of the Water Framework Directive (WFD) sets out the requirements for the monitoring of surface water status, groundwater status and protected areas: "Monitoring programmes are required to establish a coherent and comprehensive overview of water status within each river basin district. The objective of monitoring is to establish an overview within each River Basin District also permitting for the classification of all surface water bodies into one of five classes and groundwater into one of two classes. Monitoring under the WFD comprises of the following main requirements:

- Establish programmes for monitoring water status in order to establish a coherent and comprehensive overview of water status in each river basin district (Art. 8(1) and Annex V), and make these programmes operational at the latest six years after the Directive entered into force (Art. 8(2)).
- Identify, based on the results from these monitoring programmes, applicable as relevant to each water body, its ecological status, its chemical status, its quantitative status and applicable determinations of "surface water status" and "groundwater quantitative status" (Art. 8 and Annex V).

- Carry out sampling and analysis of surface waters used for the abstraction of drinking water, in accordance with the methods laid down in the WFD.
- Assess the extent to which surface waters used for the abstraction of drinking water comply with the quality standards, in accordance with specified assessment criteria.
- Co-ordinate activities with regard to international river basin districts with a view to achieve the objectives of the Directive.
- Monitoring obligations may be met by allocating responsibility between central and local government bodies, environmental protection agencies, utilities operators and private sector operators whose operations may impact on water bodies. In the case of private operators, such obligations may be made conditions of their permits or authorisations. However, it is important that, taken together, the monitoring and analysis undertaken meets the requirements of the Directive as a whole. The Member State remains responsible for any such failure regardless of any such allocation of responsibilities to monitor in practice.
- For waters within each river basin district, establish or provide for the establishment of (in accordance with Article 8 and Annex V, and any further technical specifications to be laid down pursuant to Article 21), and make operational by, at the latest, six years after the Directive entered into force, programmes for monitoring water status in order to establish a coherent and comprehensive overview of water status therein:
 - for surface waters, such programmes are to cover all elements necessary to determine status of the surface water e.g. the volume and level or rate of flow to the extent relevant for ecological and chemical status and ecological potential (Art. 8) (note, too, the requirements relevant here under Article 7);
 - for groundwater, such programmes are to cover monitoring of the chemical and quantitative status;
 - for protected areas, the above programmes, as supplemented by those specifications contained in EU legislation under which the individual protected areas have been established.
- Establish for each period to which a river basin management plan applies a surveillance monitoring programme and an operational monitoring programme, and in some cases programmes of investigative monitoring. The monitoring of ecological status and chemical status for surface waters is done on the basis of the characterisation and impact assessment carried out in accordance with Article 5 and Annex II. The objectives of the monitoring are:
 - for the surveillance monitoring programmes: to provide information for supplementing and validating the impact assessment procedure detailed in Annex II, the efficient and effective design of future monitoring programmes, the assessment of long-term changes in natural conditions, and the assessment of long-term changes resulting from widespread anthropogenic activity;
 - for the operational monitoring: to establish the status of those bodies identified as being at risk of failing to meet their environmental objectives, and assess any changes in the status of such bodies resulting from the programmes of measures;
 - for the investigative monitoring to ascertain the causes of a water body or water bodies failing to achieve the environmental objectives, or to ascertain the magnitude and impacts of accidental

pollution, and to inform the establishment of a programme of measures for the achievement of the environmental objectives and specific measures necessary to remedy the effects of accidental pollution.

- The Member States should aim to have a monitoring system in place to allow it to demonstrate that it is capable of, and is, achieving the objectives of the Directive, including, in particular, those set out under Articles 4, 7, 16 and 17.
- Provide for investigations to be conducted in the event that monitoring or other data indicate that the objectives set out in Article 4 for a body of water are unlikely to be achieved (Art. 11(5)); and similarly provide for review and modification as appropriate of relevant permits and authorisations and monitoring programmes, and for the tightening of environmental quality standards or adoption of additional measures (Art. 11(5)).
- In addition, Member States have to comply with Directive 2009/90/EC setting out technical specifications for chemical analysis and monitoring of water status in accordance with Article 8(3) of Directive 2000/60/EC. The methods of analysis for the monitoring of water status, sediment and biota have to comply with the minimum performance criteria and rules assuring the quality of analytical results. By 20 August 2011, Member States had to:
 - ensure that all methods of analysis, including laboratory, field and on-line methods, used for the purposes of chemical monitoring programmes under WFD are validated and documented in accordance with EN ISO/IEC-17025 standard or other equivalent standards accepted at international level (Art. 3, Directive 2009/90/EC)
 - apply the minimum performance criteria for methods of analysis regarding uncertainty of measurement and on the limit of quantification of the methods, use of the best available techniques not entailing excessive costs in the absence of relevant EQS for a given parameter or in the absence of methods of analysis meeting the minimum performance criteria (Art. 4, Directive 2009/90/EC)
 - apply the criteria and requirements set out in Art. 5 regarding calculation of mean values where the amounts of physico-chemical or chemical measurands in a given sample are below the limit of quantification and where a calculated mean value of the measurement results. In certain cases, results below the limit of quantification of the individual substances shall be set to zero (Art. 5, Directive 2009/90/EC)
 - ensure compliance with the quality assurance and control, only engaging laboratories or other parties that apply quality management system practices in accordance with EN ISO/IEC-17025 or other equivalent international standards and that have demonstrated their competences in analysing relevant physico-chemical or chemical measurands by participation in proficiency testing programmes covering the methods of analysis, referred to in Article 3 of this Directive and analysis is of available reference materials that are representative of collected samples which contain appropriate levels of concentrations in relation to relevant EQS referred to in Article 4(1).
 - ensure that the proficiency testing programmes is organised by (accredited) recognised organisations, which meet the requirements of ISO/IEC guide 43-1 or of other equivalent standards accepted at international level and the results of this participation is evaluated using

the scoring systems set out in ISO/IEC guide 43-1 or in the ISO-13528 standard (Art. 6, Directive 2009/90/EC)

1.4. Consultation and Reporting

The WFD obliges certain consultation of the public in the implementation activities. Amongst others Member States have to:

- Encourage the active involvement of all interested parties in the implementation of the Directive, in particular in the production, review and updating of river basin management plans (Art.14(1)).
- For each applicable river basin district, publish and make available for comment to the public: at least three years before the beginning of the period to which the plans refer, a timetable and work programme for the production of the river basin management plan (Art. 14(1)(a)); at least two years before the period to which the plan refers, an interim overview of the significant water management issues identified in the river basin (Art. 14(1)(b)); and at least one year before the period to which the plan refers, a draft copy of the river basin management plan (Art. 14(1)(c)); and allow at least six months for any comments (Art. 14(2)).
- Make available, on request, background documents and information used for the development of the draft river basin management plan (Art. 14(1)(c)).
- Establish a register or registers of all areas within each river basin district which have been designated as requiring special protection under specific EU legislation for the protection of their surface waters or groundwater or for the conservation of habitats and species directly depending on the water, and keep the same under review and up to date. The same shall include all bodies of water identified under Article 7(1) and all protected areas covered by Annex IV (Art.6).
- Publish river basin management plans and their updates (Art. 13(6) and (7)). Ensure that a river basin management plan is produced for each river basin district lying entirely within their territory. The river basin management plan shall include the information detailed in Annex VII. The first update of the river basin management plan and all subsequent updates shall also include:
 - a summary of any changes or updates since the publication of the previous version of the river basin management plan, including a summary of the reviews to be carried out under Article 4(4), (5), (6) and (7);
 - an assessment of the progress made towards the achievement of the environmental objectives, including presentation of the monitoring results for the period of the previous plan in map form, and an explanation for any environmental objectives which have not been reached;
 - a summary of, and an explanation for, any measures foreseen in the earlier version of the river basin management plan which have not been undertaken;
 - a summary of any additional interim measures adopted under Article 11(5) since the publication of the previous version of the river basin management plan.

- The WFD also sets out a number of provisions pertaining to the obligation to report certain data to the Commission but also to consult with other Member States in certain situations. Member States should for instance:
- Communicate to the Commission the text of the main provisions of national law adopted in the field of the Directive (Art. 24(3));
- Where an international river basin district extends beyond the territory of the EU, endeavour to establish appropriate co-ordination with the relevant non-Member States with the aim of achieving the objectives of the Directive throughout such an international river basin (Art.3(5));
- Submit to the Commission the list of the relevant competent authority or authorities including, as applicable, the competent authorities of all the international bodies in which the Member State participates, responsible for applying the rules of the Directive within each river basin management district or portion of any international river basin management district within their territory, together with the information in Annex I (Art. 3(8)); and any changes to the information within three months (Art. 3(9)). For this purpose, existing national or international bodies may be so identified (Art.3(6));
- Engage in the exchange of relevant information involving the Commission leading to the identification of a range of sites in each eco-region of the EU as regards the classification and presentation of ecological status, such sites then to form the intercalibration network (Annex V, 1.4.1(v));
- Send copies to the Commission, and to any other Member States concerned, of all river basin management plans and all subsequent updates within three months of their publication for all river basin districts wholly within their territory and for at least the part of any international river basin district within their territory ensuring that each such plan complies with Annex VII and contains such further specific information expressly provided for in the Directive, for example the reasons for not fully applying Article 9(1), second sentence (Art.15(1)(a) and (b));
- Submit summary reports to the Commission of the analyses required under Article 5 and the monitoring programmes designed under Article 8 undertaken for the first river basin management plan, within three months of their completion (Art.15(2));
- Co-ordinate with the Member States concerned, the application of all required programmes of measures for international river basin districts applicable to themselves, employing existing structures stemming from international agreements, and using the facilitating powers of the Commission as appropriate (Art.3(4)); Consider reporting to the Commission and any other Member State concerned, issues which have an impact on the management of its water but which that Member State cannot resolve on its own, and, as applicable, make recommendations for their resolution (Art.12(1));
- Submit an interim report describing progress in the implementation of the planned programme of measures identified for each river basin management plan or update required under Article 13 (Art.15(3));
- Consider what recommendations to make to the Commission concerning the identification of priority list substances (Art.16(5)).

1.5. Additional Legal Instruments

The WFD establishes a framework for the management of water quality. As indicated above, a large number of other legal instruments are linked to it, and should be borne in mind during the implementation of this Directive. These include all water sector Directives (Groundwater Directive 2006/118/EC, EQS Directive 2008/105/EC, Directive 2009/90/EC on technical specifications for chemical analysis and monitoring of water status, Floods Directive 2007/60/EC, UWWT Directive 91/271/EEC, Nitrates Directive 91/676/EEC, Drinking Water Directive 98/83/EC, Bathing Water Directive 2006/7/EC, Marine Strategy Framework Directive 2008/56/EC), as well as the following legislation:

- Habitats Directive 92/43/EEC
- Wild Birds Directive (2009/147/EC)
- Environmental Impact Assessment Directive (2011/92/EC)
- Strategic Environmental Assessment Directive (2001/42/EC)
- Industrial Emissions Directive (2010/75/EU)
- Seveso III Directive (2012/18/EU)
- REACH Regulation (EC) 1907/2006
- CLP Regulation (EC) 1272/2008
- Biocidal Products Regulation (EU) 528/2012
- Landfill Directive (99/31/EC)
- Sewage Sludge Directive (86/278/EEC)
- Regulation (EC) No 1107/2009 concerning the placing of plant protection products
- Directive 91/692/EEC on the standardisation and rationalisation of reports
- Directive (2007/2/EC) establishing an infrastructure for spatial information in the European Community (INSPIRE)
- Environmental Liability Directive (2004/35/EC)
- Environmental Crimes Directive (2008/99/EC)

Particularly relevant issues in these Directives concern their impact upon the development of programmes of measures within the river basin management plans of the WFD.

The Directive aims to complement a number of international conventions to which the EU and/or the Member States are parties, and attention should be paid to these when considering implementation plans. These conventions include:

- The Convention on the Protection of the Mediterranean Sea against Pollution (1976)
- The Protocol to the 1976 Convention for the Protection of the Mediterranean Sea against Pollution from Land-Based Sources (1980)

- The Protocol to the 1976 Convention for the Protection of the Mediterranean Sea against Pollution concerning Integrated Coastal Zone Management
- The Convention on the Protection of the Marine Environment of the North-East Atlantic (OSPAR) (1992)
- The Convention on the Protection of the Marine Environment of the Baltic Sea Area (1992)
- The United Nations Convention on the Protection and Use of Transboundary Water Courses and International Lakes (approved by the Council in 1995)
- The Convention on the Transboundary Effects of Industrial Accidents (1992)
- The Protocol on Civil Liability and Compensation for Damage Caused by the Transboundary Effects of Industrial Accidents on Transboundary Waters to the 1992 Convention on the Protection and Use of Transboundary Water Courses and International Lakes and to the 1992 Convention on the Transboundary Effects of Industrial Accidents

2. IMPLEMENTATION

2.1. Key Tasks

Some of the key tasks that the candidate countries should prepare for (see first section of the WFD fiche for concrete requirements with references to the relevant articles):

- Carry out a review of their existing legislation and monitoring, regulatory and reporting structures and practices. Having established the same, a comparison with the specific requirements of the Directive should be made, which should aim to allow for three main exercises to take place:
 - identification of gaps in legislation and practice between the current situation and the requirements of the Directive;
 - taking steps needed to eliminate those gaps and streamline the same; and
 - produce plans for re-organising existing legislation and practice to correlate with the requirements of the Directive.
- Establish competent authorities, using either existing structures or creating new ones, and establish administrative arrangements to ensure that the Directive is implemented effectively within river basin districts (Art. 3(2)-(4)).
- Member States should analyse the characteristics of the relevant water body types within each applicable river basin district, including impact of human activity.
- Set up programmes for the monitoring of all waters within each applicable river basin district in accordance with the detailed provisions in Annex V, and based on the same classify each relevant water body with its required status classifications, for example ecological status, chemical status, ecological potential, or groundwater quantitative status and chemical status, as well as setting applicable EQS (Annex V);
- Identify and register protected areas in accordance with Article 6 and Annex IV;
- Establish the programme of measures for each applicable river basin district required under Article 11. See above, under planning, for steps that are to be taken for the purpose of implementation here. Note, in particular, the provisions for, and the safeguards applying with regard to, extensions of time for compliance with relevant provisions, derogations or determinations of non-breach of the Directive, and consider the extent that the same are required to be provided for in any river basin management plan, and provide for the operation of the same;
- Carry out the economic analysis required under Article 9 and, in accordance with Annex III, make judgments as to the most cost-effective combination of measures in respect of water uses to be included in the Article 11 programme of measures, based on estimates of the potential costs of such measures. In doing so, draw up water pricing policy that provides adequate incentives and an adequate contributions from the different categories of water users towards the recovery of costs of water services. As part of this process, countries may choose to identify, analyse and have regard to the

social, economic and environmental effects of recovery, as well as the geographical and climatic conditions of the region(s) affected. (Art. 9(1))

- Provide for compliance with the public information and consultation provisions in Article 14 in relation to the production and review of river basin management plans.
- Produce and publish river basin management plans for each applicable river basin district, ensuring that they include the information in Annex VII as a minimum (Art. 13), taking into account the desirability of creating more detailed plans for e.g. sub-basins, sector, issue or water type to address particular aspects of water management.
- Make operational the programme of measures required under Article 11 in accordance with the requirements and provisions of Article 4, ensuring, at all times, compliance with the safeguards for extensions, derogations and provision for non-breach of the requirements of the Directive, but also ensuring the fall-back safeguards in Article 4(8) and (9).
- Ensure all relevant reporting requirements are complied with. See further under the section on consultation and reporting for further details.
- Provide for all necessary reviews and updates of all relevant registers, analyses, assessments and plans, and compliance with all necessary public consultation provisions regarding the same.
- Ensure on-going monitoring of all relevant water bodies and adjust programmes of measures as appropriate to ensure achievement of the objectives of the Directive.
- Ensure continuous regulation controls and the taking of any necessary enforcement action.

2.1.1. Obligations related to international river basin districts

Key obligations under the Directive may be regarded as of particular importance where river basins are shared between Member States or between Member States and third countries. The following points have been developed based on the experience on the co-ordination along the river Rhine aiming to highlight the tasks involved in such international river basins.

The most essential obligations within international river basin districts are:

- Co-ordination of water protection management based on river basin districts. Two or more river basins may be combined into one river basin district. Where Member States share a river basin, co-ordination across the whole river basin has to be ensured (establishment of an international river basin district). Where part of a river basin lies in the territory of a third country, this co-ordination is mandatory only for the part lying within Member States. For the part lying in the third country, co-ordination is a recommendation. Whilst co-ordination across the whole river basin is a binding obligation, Member States are free to choose the political and administrative tools for achieving this co-ordination. They are also free to use existing international bodies for this purpose.
- Assigning all groundwater to river basin districts. This is particularly important where groundwaters are not completely situated in one river basin district; in such cases they should be assigned to the nearest or best-suited district. In the case of transboundary groundwaters, appropriate co-ordination will be necessary.

- Establishment of a river basin management plan for the whole river basin district. For river basins within one country's territory there is an obligation for one plan; for river basins shared between countries this objective should be pursued. National and/or international river basin management plans may be complemented by more detailed programmes or management plans for sub-basins, sectors or individual management aspects.
- Information and consultation of the public and interested parties is an obligation for all Member States. Such information and consultation has to ensure involvement of the public on issues of major importance that are the subject of international co-ordination. The international river basin management plan has to address information and consultation as well.
- Reporting to the Commission following the provisions of the Directive is the obligation of Member States. However, Member States are free to make use of international bodies in complying with their reporting obligations.

2.1.2. Tasks entailing co-ordination requirements between Member States

Tasks under the Directive entailing co-ordination requirements between two or more Member States within an international river basin district are:

- assignment of transboundary catchments to international river basin districts: groundwater, coastal waters;
- identification of protected areas of importance beyond the region;
- identification of transboundary water quality objectives;
- identification of, and mapping the ecological quality of surface waters;
- co-ordination of those parts of the programmes of measures of importance beyond the region;
- establishment of international monitoring programmes;
- co-ordination in designating reference monitoring sites;
- co-ordination of analysis of characteristics, review of impact of human activities and economic analysis of water use;
- co-ordination of programmes of measures;
- co-ordination in identification of pollutants beyond the "priority substances", as well as developing water quality standards;
- basis for the structure for an international river basin management plan, in particular addressing issues of degree of detail and structure as regards necessary sub-basin plans and sectoral plans;
- establishment of an international river basin management plan;
- taking account of the results of consultation of the public as regards the entire river basin;
- development of a basic structure for reports to the Commission (Art. 15), and developing where possible a joint report.

2.2. Key implementation tasks

Already in 1999, well before the final adoption of the WFD, informal consultations had started between the Commission and Member States on specific issues of implementation, including those where further technical or scientific studies are required. The following checklist presents a non-exhaustive list in which key issues are grouped under key headings and arranged in chronological order where possible.

Table 11. Illustrative checklist with the key implementation tasks

WATER FRAMEWORK DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning and Regulation
1.1	Identify river basins and assign them to individual river basin districts.
1.2	Assign groundwater bodies to river basin districts.
1.3	Assign coastal waters to river basin districts.
1.4	Establish competent authorities, using either existing structures or creating new ones, and establish administrative arrangements to ensure that the Directive is implemented effectively within river basin districts.
1.5	The competent authority should make institutional arrangements to enable it to fulfil its implementation tasks, such as planning, monitoring and enforcing the requirements of the Directive.
1.6	The competent authority should undertake a review of the characteristics of the river basin using methods set out in the WFD. Organise data and, in co-operation with national and EU statisticians, carry out data analysis to ensure that the results are comparable throughout the EU.
1.7	The competent authority should assess the impact of human activity in the river basin.
1.8	Assess all relevant and available information on industrial discharges, dangerous substances and wastewater discharges and plants, i.e. those sources covered by the Industrial Emissions Directive (2010/75/EU) and the Urban Waste Water Treatment Directive (91/271/EEC).
1.9	Collect information on the extent and location of diffuse sources of pollution, in particular from agriculture.
1.10	Using data already available, identify waters that are affected by pollution.
1.11	Assemble data on water abstracted for drinking water, agricultural, industrial and other uses.
1.12	In collaboration with water suppliers, the competent authority should identify all existing and potential surface waters and groundwaters, which are used or intended to be used as drinking water abstractions in each river basin.
1.13	The competent authority should undertake an economic analysis of water use, including abstraction for drinking water, wastewater discharges, forecasts of supply and demand and trends, and assessment of infrastructure needs. Collaboration with economists; regional, municipal, and other planners; water suppliers; and industrial organisations may be necessary for this task.
1.14	Set up a register of protected areas in each river basin district, protected areas all being specified in the Directive, including those under EU nature protection legislation. Co-operation and co-ordination must be arranged between competent authorities, particularly those responsible for managing the protected areas.

1.15	Put in place arrangements to update the review of the river basin characteristics at six-yearly intervals and other reviews.
1.16	Having gathered the relevant data, establish environmental objectives to apply in the river basin. These must be designed to achieve good water quality and must lead to compliance with any standards needed in protected areas.
1.17	Within the defined river basins, establish the four basic types of surface water systems as rivers, lakes, estuaries and coastal, and assess the ecological status of each according to the range of physico-chemical, biological and hydromorphological characteristics as defined in the Directive.
1.18	Place each body of water into one of three classes — high quality, good quality and poor quality — by comparing the data with historical information for the site concerned or for a similar site.
1.19	As there are few sites in Europe which are unaffected by anthropogenic activity, the Directive sets out criteria for establishing similar eco-types based on a number of natural parameters.
1.20	For groundwater, the quantitative status must be assessed by comparing variations in groundwater levels with associated rates of recharge and abstraction (both natural and artificial) in order to ascertain that the rate of abstraction does not exceed the long-term available resource. In addition, the chemical status of groundwater which is susceptible to possible impacts from indirect discharges of contaminants from anthropogenic activities should be monitored.
1.21	Identify waters that, due to their natural condition, will not achieve good water quality although all measures to improve them as identified in the river basin management plan river basin management plan have been taken.
1.22	Identify specific bodies of water for which less stringent environmental objectives may be set. Include these objectives in the river basin management plan.
1.23	Establish a programme of measures, as part of river basin plans containing information as set out in Annex VII, to achieve the environmental objectives of the Directive, including the application of all mandatory measures in EU law specified within the Directive, particularly all of the compulsory requirements and the Directives listed in Annex VI, and other measures decided as necessary by the competent authority. This should result from an examination of all the information gathered by the above process. Supplementary measures are outlined in Annex VI.B, and for waters below "good" status, more intensive monitoring, the establishment of EQS for the pollutants concerned, investigations of polluting sources and the immediate review of all relevant authorisations are required, followed by action on the basis of the level of risk involved. Competent authorities must determine this.
1.24	River basin management plans may be supplemented by more detailed local action plans for particular aspects or for parts of the river network.
1.25	Establish a system of public consultation on river basin management plans which allows public access to draft copies of the plan at least one year prior to the start date, allowing six months for public comments to be received in writing.
1.26	Once public comments have been taken into account, a final plan must be published.
1.27	Ensure prior authorisation and control regarding injection of CO ₂ into saline aquifers for the purposes of geological storage. Such storage and injections are subject to provisions protecting groundwater set out in Article 4(1)(b) of the WFD and also in Directive on Groundwater (2006/118/EC). (Art. 11(3)(1), WFD, as introduced by Art. 32 of Directive 2009/31/EC.
1.28	Make sure that discharges comply with the EQS for the priority substances listed in Annex I of the EQS Directive (2008/105/EC)

1.29	On the basis of the information collected in accordance with Articles 5 and 8 of WFD, under Regulation (EC) No 166/2006 (E-PRTR) and other available data, establish an inventory, including maps of emissions, discharges and losses of all priority substances and pollutants listed in Part A of Annex I to this Directive for each river basin district or part of a river basin district lying within their territory including their concentrations in sediment and biota, as appropriate. (Art. 5, EQS Directive)
1.30	Where mixing zones adjacent to points of discharge have been designated under Directive 2008/105/EC (allowing for exceptional exceedance of EQS, the competent authorities have to ensure that these areas are clearly identified in the river basin management plans and commensurate with the approaches, methodologies and measures set out in Art. 13 and 11(3) of WFD. (Art. 4, EQS Directive)
1.31	Apply the EQS laid down in Part A of Annex I to EQS Directive for bodies of surface water. Note that Member States may opt to apply an EQS for an alternative matrix or, where relevant, an alternative biota taxon provided that the level of protection afforded by the EQS and the monitoring system applied by the Member States is as good as that provided by the EQS and matrix laid down in EQS Directive. (Art. 3, EQS Directive)
1.32	Apply the EQS in accordance with the requirements laid down in Part B of Annex I, which for instance give guidance on calculation of the arithmetic mean, the analytical method used to ensure at least that the minimum performance criteria is met. Part B should also be applied in conjunction with the requirements set out in Directive 2009/90/EC on technical specifications for chemical analysis and monitoring of water status, in accordance with WFD (especially Art. 8(3)) <ul style="list-style-type: none"> • Ensure compliance with particular requirements regarding metals. • Ensure that the assessment of monitoring results take into account
2	Monitoring and Enforcement
2.1	The competent authority must establish a monitoring programme to determine water status. Monitoring will include chemical and biological sampling, and will be capable of placing surface water into one of five classes of ecological quality and chemical quality. Annex V specifies the detailed monitoring and assessment criteria. Groundwater must be assessed for quantitative status and qualitative status. The technical specification establishes the methods of monitoring, and results must be comparable, in a common format. Use accredited methods and introduce quality assurance schemes. The level of confidence and precision of the results must be stated.
2.2	Designate monitoring sites according to Annex V, and monitor identified sites for parameters listed in Annex V.
2.3	The results of monitoring must be presented as: <ul style="list-style-type: none"> • biological: a numerical value representing departure from the reference conditions of the site; • chemical: a quality classification as "good quality" or "failing to achieve good quality"; • ecological: "high quality", "good quality", "fair quality", "poor quality" or "bad quality". These results must be presented on a map.
2.4	The competent authority/national agency will have to ensure that there is an exchange of biological data between the Member States to build up a set of data representing a selection of ecotype sites to be known as the intercalibration network. The Commission will co-ordinate an intercalibration exercise to test the methodologies used by Member States.
2.5	Monitoring frequencies vary between one sample per three months and one sample per three years. More intensive monitoring will be required for waters of less than "good" status.
2.6	Include, in national legislation penalties for non-compliance. This may comprise the regulatory system established for current water legislation and the legislation controlling industrial and other establishments which discharge to, or influence the quality of, water. Penalties must be clearly identified in relation to the

	issue of compliance and include criminal penalties for offences listed in the Environmental Crimes Directive (2008/99/EC).
2.7	The competent authority, in collaboration with the organisations responsible for treating and supplying drinking water under the WFD, should identify existing, future and potential surface water abstraction points and agree a sampling point in each case.
2.8	In conjunction with the laboratory appointed under the former Directive on the measurement of surface (drinking) water (79/869/EEC, repealed by the WFD), carry out a sampling programme to ascertain the quality of the water. Existing data may be used, provided the samples have been analysed using methods that are the same as, or equivalent to, those set out in the WFD.
2.9	In conjunction with the laboratory appointed under the former Directive on the measurement of surface (drinking) water (79/869/EEC, repealed by the WFD), the competent authority should issue guidance on sampling and analytical methods to ensure that these conform to the requirements of the said Directive.
2.10	The cost recovery system adopted must, however, allow for an affordable domestic water supply. Exemptions for payments may be granted within the river basin management plan. The social, environmental and economic effects of the recovery as well as the geographic and climatic conditions of the region or regions affected may be considered. In relation to water pricing it is important to ensure that water prices are consumption-based, reflecting the true value of the water resource and sufficiently differentiating between areas of water under more or less stress.
2.11	Member States may decide not to apply provisions of Art. 9(1). Exemptions from the application of such water pricing policies may be granted provided this does not compromise the purpose and achievement of the objectives of the Directive, but the reasons for the same must be explained in the river basin management plan. Note that if no decision is taken Art. 9(1) applies by default.
2.12	Note that nothing in Article 9 prevents the funding of particular preventive or remedial measures in order to achieve the objectives of the Directive.
2.13	From 20 August 2011 ensure compliance with Directive 2009/90/EC setting out technical specifications for chemical analysis and monitoring of water status in accordance with Article 8(3) of WFD, in terms of: <ul style="list-style-type: none"> • applying the definitions, i.e. ‘limit of detection’, ‘limit of quantification’ and ‘uncertainty of measurement’ (Art. 2, Directive 2009/90/EC) • ensuring validation and documentation in accordance with EN ISO/IEC-17025 standard or other equivalent standards accepted at international level information regarding analysis methods (e.g. laboratory, field and on-line methods), used for the purposes of chemical monitoring programmes under WFD (Art. 3, Directive 2009/90/EC) • apply the minimum performance criteria for methods of analysis regarding uncertainty of measurement, use of BAT in certain cases (Art. 4, Directive 2009/90/EC) • apply the criteria and requirements set out in Art. 5 regarding calculation of mean values where the amounts of physico-chemical or chemical measurands in a given sample are below the limit of quantification and where a calculated mean value of the measurement results. (Art. 5, Directive 2009/90/EC) • ensure compliance with the quality assurance and control, only engaging laboratories or other parties that apply quality management system practices in accordance with EN ISO/IEC-17025 or other equivalent international standards and that have demonstrated their competences in analysing relevant physico-chemical or chemical measurands by participation in proficiency testing programmes covering the methods of analysis • ensure that the proficiency testing programmes is organised by (accredited) recognised organisations, which meet the requirements of ISO/IEC guide 43-1 or of other equivalent international standards and the results of this participation is evaluated using the scoring systems set out in ISO/IEC guide 43-1 or in the ISO-13528 standard (Art. 6, Directive 2009/90/EC)

2.14	Observe the technical standards set at EU level, such as those set for monitoring in Directive 2009/90/EC, which lays down the technical specifications for chemical analysis and monitoring of water status, pursuant to Art. 8(3) of WFD. This Directive establishes minimum performance criteria for methods of analysis to be applied by Member States when monitoring water status, sediment and biota, as well as rules for demonstrating the quality of analytical results.
2.15	Ensure the monitoring of the water status pursuant to Art. 8 of WFD and implementing Directive 2009/90/EC setting out the technical requirements for this monitoring, On the basis of this monitoring, arrange for the long-term trend analysis of concentrations of those priority substances listed in Part A of Annex I that tend to accumulate in sediment and/or biota.
3	Consultation and Reporting
3.1	The government should establish contact with other countries whose river basins cross international boundaries. Use should be made of existing international bodies responsible for waters within international river basin districts. A jointly run international river basin authority should be set up where necessary, if this is feasible.
3.2	The competent authority must organise suitable consultation mechanisms in order for the public to see and comment upon the river basin management plans. It is important that other relevant government departments, local communities, water utilities, industry and commerce, consumers and environmental groups play a full part in the discussions on river basin management plans, as these are likely to affect all of these organisations, and rely upon actions by such organisations in the achievement of their objectives.
3.3	A reporting and recording system should be established on both a river basin and a national level with the associated databases to enable reports to be made to the public and to the Commission.
3.4	The competent authority must send copies of plans and programmes to the Commission.
3.5	Report to the Commission on: <ul style="list-style-type: none"> • river basin districts, including assigned groundwater and coastal waters; • assignment details of the competent authorities; • as desired, issues which fall outside the competence of the competent authorities but which affect water management; • river basin management plans for whole river basins; • programmes and plans dealing with sub-basins, particular water issues or particular water classes or ecosystems; • plans covering parts of international river basins.
3.6	Ensure that in cases of transboundary pollution, that Member States submit to the Commission the necessary information regarding the circumstances of the pollution and the measures taken in regard to the transboundary pollution in the relevant river basin management plan (Art. 6, EQS Directive)
3.7	Also take into account the template for questionnaires in the water management sector set out in Commission Decision 95/337/EC, which relates to the questions to be covered by authorisations for discharges of certain polluting substances to water bodies.

2.3. Phasing Considerations

The key phasing issues are:

- Organising and implementing a complete survey of the river basins, establishing the current status of the water in terms of quality and quantity, and setting operational quality objectives defining "good" status;
- Transposing the Directive into national legislation and integrating legislation covering existing Directives into the new scheme;
- Establishing co-ordination within the river basins and, in the case of shared basins, together with neighbouring countries, by using existing competent authorities or creating new ones;
- Preparing the programme of measures, consultation and the publication of the river basin management plan.

The implementation of the Water Framework Directive raises a number of shared technical challenges for the Member States, the Commission, the Candidate and EEA Countries as well as stakeholders and NGOs. In addition, many of the European river basins are international, crossing administrative and territorial borders and therefore a common understanding and approach is crucial to the successful and effective implementation of the Directive. In order to address the water challenges in a co-operative and coordinated way, the Member States, Norway and the Commission agreed on a **Common Implementation Strategy (CIS)**²¹² for the Water Framework Directive shortly after the entry into force of the Directive. The CIS also supports the Commission in further policy and legislative development, e.g. amounting to the WFD daughter Directives and the Directive on Floods (2007/60/EC), which has been closely coordinated with the WFD. A number of working groups were set up and their mandates and activities are governed by the Work Programmes.

The CIS has resulted in numerous guidance documents, technical reports, resource documents or key events related to different aspects of the implementation. The guidance has been produced to assist stakeholders to implement the WFD and aim at providing an overall methodological approach that will need to be tailored to specific circumstances of each EU Member State.

List of published CIS Guidance Documents

N° 1 - Economics and the Environment - The Implementation Challenge of the Water Framework Directive

N° 2 - Identification of Water Bodies

N° 3 - Analysis of Pressures and Impacts

N° 4 - Identification and Designation of Heavily Modified and Artificial Water Bodies

N° 5 - Transitional and Coastal Waters - Typology, Reference Conditions and Classification Systems

N° 6 - Towards Guidance on Establishment of the Intercalibration Network and the Process on the Intercalibration Exercise

N° 7 - Monitoring under the Water Framework Directive

N° 8 - Public Participation in Relation to the Water Framework Directive

N° 9 - Implementing the Geographical Information System Elements (GIS) of the Water Framework Directive

²¹²"[Common Strategy on the Implementation of the Water Framework Directive](http://ec.europa.eu/environment/water/water-framework/objectives/pdf/strategy2.pdf)", available at:<http://ec.europa.eu/environment/water/water-framework/objectives/pdf/strategy2.pdf>

- N° 10 - Rivers and Lakes - Typology, Reference Conditions and Classification Systems
- N° 11 - Planning Processes
- N° 12 - The Role of Wetlands in the Water Framework Directive
- N° 13 - Overall Approach to the Classification of Ecological Status and Ecological Potential
- N° 14 - Guidance on the Intercalibration Process (2004-2006)
- N° 15 - Groundwater Monitoring (WG C)
- N° 16 - Groundwater in Drinking Water Protected Areas
- N° 17 - Direct and indirect inputs in the light of Directive 2006/118/EC
- N° 18 - Groundwater Status and Trend Assessment
- N° 19 - Surface water chemical monitoring.pdf
- N° 20 - Exemptions to the environmental objectives
- N° 21 - Guidance for reporting under the WFD
- N° 22 - Updated WISE GIS guidance (November 2008)
- N° 23 - Eutrophication Assessment in the Context of European Water Policies
- N° 24 - River Basin Management in a changing climate
- N° 25 - Chemical Monitoring of Sediment and Biota
- N° 26 - Risk Assessment and the Use of Conceptual Models for Groundwater
- N° 27 - Deriving Environmental Quality Standards
- N° 28 - Preparation of Priority Substances Emissions Inventory
- N° 29 – Reporting under the Floods Directive
- N° 30 – Procedure to fit new or updated classification methods to the results of a completed intercalibration exercise
- N° 31 – Ecological Flows (final version)
- N° 31 - Ecological Flows Policy summary
- N° 32 – Biota Monitoring
- N° 33 – Analytical Methods for Biota Monitoring
- N° 34 – Water Balances Guidance (final version)

List of published Technical Reports

- N° 1 - The EU Water Framework Directive: Statistical aspects of the identification of groundwater pollution trends and aggregation of monitoring results
- N° 2 - Groundwater Body Characterisation
- N° 3 - Groundwater Monitoring

N° 4 - Groundwater Risk Assessment

N° 5 - Groundwater Management in the Mediterranean

N° 6 - Groundwater Dependent Terrestrial Ecosystems

N° 7 - Recommendations for the review of Annex I and II of the Groundwater Directive 2006/118/EC

N° 8 - Methodologies used for assessing Groundwater Dependent Terrestrial Ecosystems

N° 9 – Groundwater Associated Aquatic Ecosystems

Technical Report on Aquatic Effect-Based Monitoring Tools

Technical Background Document on Identification of Mixing Zones

Links to CIS guidance documents and Technical Reports listed above can be obtained at:
http://ec.europa.eu/environment/water/waterframework/facts_figures/guidance_docs_en.htm

Thematic CIS information sheets

The following thematic information sheets are available on [CIRCABC](#), providing more information and resource material publicly available on a variety of subject(s):

Topic n°1 : [River Basin Management](#)

Topic n°2 : [Reporting and WISE](#) (Water Information System for Europe)

Topic n°3 : [Ecological Status](#)

Topic n°4 : [Groundwater](#)

Topic n°5 : [Chemical Aspects](#)

Topic n°6 : [Flood Risk Management](#)

Topic n°7 : [Climate Change and Water](#)

Topic n°8 : [Water Scarcity and drought](#)

Topic n°9 : [Agriculture and Water](#)

Topic n°10 : [Biodiversity and Water](#)

Topic n°11 : [Hydromorphology](#)

Topic n°12 : [Economic Issues](#)

Topic n°13 : [Water Science-Policy Interface](#)

Topic n°14 : [Measures](#)

Further guidance is given through [WFD implementation links](#), which provide links to official WFD implementation web sites of the Member States, International River Basin Commissions and of the WFD Pilot River Basins.

All these guidance documents and the technical reports can be found on the [WFD CIRCABC library](#). Also an informative overview of the CIS and its various components can be obtained at:
http://ec.europa.eu/environment/water/water-framework/objectives/implementation_en.htm#cis

In addition, there is an [information exchange platform](#) for the implementation of the Water Framework Directive.

Finally, [12 Water Notes](#)²¹³ have been produced dealing with different topics from international coordination to public participation, via chemical pollution, groundwater, floods and intercalibration. These notes also describe links with other legislation such as the Marine Strategy Framework Directive (MSFD), and EU legislation on drinking and bathing water.

²¹³For more information on notes refer to: http://ec.europa.eu/environment/water/participation/notes_en.htm

3. TIMETABLE FOR ACTION

The following sets out key deadlines for the implementation of the various actions set out under the Directive required of Member States, where the dates set out below are the latest dates available in principle under the Directive.

- Bring into force the laws, regulations and administrative provisions necessary to comply with the Directive (Art. 24).
- Implement the necessary measures to prevent deterioration of the status of all bodies of surface waters (subject to the possibilities of derogation) (Art. 4(1)(a)(i)).
- Identify the relevant competent authority or authorities for each applicable river basin district within their territory (Art. 3(7)).
- Provide the Commission with the list of the relevant competent authority or authorities together with the information in Annex I (Art. 3(8); and any changes to the information within three months (Art. 3(9)).
- Consider what recommendations to make to the Commission with regard to the review of the adopted list of priority hazardous substances every four years (Art. 16(5)).
- Establish a register or registers of all areas lying within each applicable river basin district which have been designated as requiring special protection under specific EU legislation for the protection of their surface water or groundwater or for the conservation of habitats and species directly depending on water (Art. 6(1)).
- Undertake the analysis required under Article 5 for each applicable river basin within their territory, and in accordance with Annexes II and III (Art. 5(1)).
- Submit summary reports of the analysis required under Article 5 within three months of completion (Art. 15(2)).
- Establish and put into operation a monitoring programme of water status within each river basin district. (Art. 8(1) and (2)).
- For each river basin district, publish and make available for comments to the public, at least three years before the beginning of the period to which the plan refers, a timetable and work programme for the production of the river basin management plan (Art. 14(1)(a)).
- Submit summary reports to the Commission of the monitoring programmes established under Article 8 within three months of completion (Art. 15(2)).
- For each river basin district, publish and make available to the public for comments, at least two years before the period to which the plan refers, an interim overview of the significant water management issues identified in the river basin (Art. 14(1)(b)).
- For each river basin district, publish and make available to the public for comments, at least one year before the period to which the plan refers, a draft copy of the river basin management plan. (Art. 14(1)(c)).

- Provide at least six months for comments on each document under points 13, 16 and 17 (Art. 14(2)).
- Establish the programme of measures required under Article 11 for each river basin district. (Art. 11(7))
- Publish river basin management plans. (Art. 13(6))
- Start to implement the measures necessary to reverse any significant and sustained upward trend in the concentration of any pollutant resulting from human activity in order progressively to reduce pollution of groundwater. (Art. 4(1)(b)(iii)).
- Start to implement the necessary measures in accordance with Article 16(1) and (8), with the aim of progressively reducing pollution from priority substances and ceasing or phasing out emissions, discharges and losses of priority hazardous substances. (Art. 4(1)(a)(iv)).
- Start to implement the measures necessary to prevent or limit the input of pollutants into groundwater and to prevent the deterioration of the status of all groundwater (subject to the possibilities of derogations). (Art. 4(1)(b)(i))
- Ensure that there are water pricing policies in operation that provide adequate incentives for users to use water efficiently and for an adequate contribution of the different water users in accordance with Article 9(1). (Art.9(1))
- Submit copies of river basin management plans to the Commission, within three months of their publication and of any updates. (Art. 15(1))
- Ensure that the programme of measures established for each river basin district are made fully operational in accordance with Article 11. (Art. 11(7))
- Ensure that all discharges into surface waters are controlled according to the combined approach in accordance with Article 10(2), unless otherwise specified in EU legislation. (Art. 12(2))
- Submit an interim report, describing progress in the implementation of planned measures, within three years of the publication of the river basin management plan, to the Commission, by 22 December 2012. (Art. 15(3))
- Review, and if necessary update, the analysis required under Article 5 by 22 December 2013 and every six years thereafter (Art. 5(2)).
- Review and update river basin management plans by 22 December 2015, and every six years thereafter, and apply the relevant timetables set out in points 13,16, 17 and 18 (Arts. 13(7) and 14(3)).
- Review, and as necessary update, the programmes of measures required under Article 11 by 22 December 2015 and every six years thereafter, making reviewed measures operational at least three years after their establishment (Art. 11(8)).
- Protect, enhance and restore all applicable water bodies with the aim of achieving good water status (subject to the possibility of extensions) by 22 December 2015 (Art. 4(1)(a)(ii)).
- Protect and enhance all artificial and heavily modified bodies of water with the aim of achieving good ecological potential and good surface water chemical status (subject to the possibilities for extensions) by 22 December 2015 (Art. 4(1)(a)(iii)).

- Protect, enhance and restore all bodies of groundwater, and ensure a balance between abstraction and recharge of groundwater, with the aim of achieving good groundwater status (subject to the possibilities of extensions) by 22 December 2015 (Art. 4(1)(b)(ii)).
- Achieve, for protected areas, compliance with any standards and objectives (unless otherwise provided in specific EU legislation) by 22 December 2015 (Art 4(i)(c)).
- Achieve less stringent environmental objectives than those required for specific bodies of water when they are so affected by human activity, as determined in accordance with Article 5(1), or their natural condition is such that the achievement of these objectives would be infeasible or disproportionately expensive, and all the following conditions are met:
 - (a) the environmental and socioeconomic needs served by such human activity cannot be achieved by other means, which are a significantly better environmental option not entailing disproportionate costs;
 - (b) Member States ensure,
 - for surface water, the highest ecological and chemical status possible is achieved, given impacts that could not reasonably have been avoided due to the nature of the human activity or pollution,
 - for groundwater, the least possible changes to good groundwater status, given impacts that could not reasonably have been avoided due to the nature of the human activity or pollution;
 - (c) no further deterioration occurs in the status of the affected body of water;
 - (d) the establishment of less stringent environmental objectives, and the reasons for it, are specifically mentioned in the river basin management plan required under Article 13 and those objectives are reviewed every six years.
- Achieve the relevant objectives and results, in cases subject to extensions by 22 December 2027 at the latest (Art. 4(4)(c)). This is subject to the exception in cases where the natural conditions are such that the objectives cannot be achieved within this period. However, it should be noted that the obligation to comply with the WFD requirements does not stop in 2027, since 2015, 2021 and 2027 are set as milestones in achieving WFD objectives. Article 4(5) continues to apply.

Table 12. Key deadlines on the application of the WFD

Year	Issue	Reference
2000	WFD entered into force	Art. 25
2003	Transposition in national legislations Identification of RBDs and Authorities	Art. 23 Art. 3
2004	Characterisation of RBDs: pressures, impacts and economic analysis	Art. 5
2006	Establishment of monitoring network Start public consultation	Art. 8 Art. 14
2008	Present draft river basin management plan	Art. 13

2009	Finalise river basin management plan including programme of measures	Art. 13 & 11
2010	Introduce pricing policies	Art. 9
2012	Make operational programmes of measures	Art. 11
2015	Meet environmental objectives (<i>good status</i>) First management cycle ends Second river basin management plan & first flood risk management plan	Art. 4
2021	Second management cycle ends	Art. 4 & 13
2027	2027 Third management cycle ends, final deadline for meeting objectives	Art. 4 & 13

4. COSTS

The main types of costs incurred in implementing this Directive are illustrated in the table below.

As the Directive is largely an overarching framework for a number of other Directives, the costs of implementing the WFD itself might, in many cases, be marginal, the main cost factors apart from administrative costs being those for:

- an appropriate monitoring system covering groundwater and surface waters (unless already in place);
- wastewater treatment beyond the provisions of the objectives of the Urban Waste Water Treatment Directive;
- measures addressing diffuse pollution from agriculture
- compliance with the IED;
- compliance with new standards and requirements concerning the priority list substances.

However, the real cost impact depends on the extent to which candidate countries have already embarked on the process of providing/allowing for the charging of costs more closely aligned to true cost in pure financial terms, let alone taking into account environmental and resource costs. It also depends greatly on the extent to which compliance with the other water-related EU instruments and other associated legislation has been or is projected to be met, for example under the Urban Waste Water Treatment Directive (91/271/EEC), the Nitrates Directive (91/676/EEC) and the Industrial Emissions Directive (2010/75/EU).

It is also possible that further costs may be incurred by enhanced standards and/or more stringent conditions being applied for the use of water resources. Such extra costs are likely to be passed on ultimately to water resource users, spreading the impact across the countries.

Table 13. Examples of implementation costs incurred

<p>Initial set-up costs:</p> <ul style="list-style-type: none">• establishing a laboratory;• initial sampling programme and data interpretation;• preparation of river basin management plans;• consultation;• system for the checking of sampling methodology, frequency and analytical methods;• training;• preparation of technical guidance notes.
<p>Capital investment costs:</p> <ul style="list-style-type: none">• laboratory premises;• laboratory equipment and instrumentation.;• laboratory building and equipment (if not already available);• new or upgraded drinking water treatment plants;• new or upgraded wastewater treatment plants (as a result of improvement plans).
<p>On-going running costs:</p> <ul style="list-style-type: none">• annual sampling and analysis costs;• reporting to the Commission;• data processing and reporting.

The cost of implementing the provisions relating to drinking water and its abstraction will largely depend upon the availability of existing laboratories capable of undertaking water analysis to the performance standards indicated in the Directive. Although initial costs are likely to have been fairly small for the candidate countries and related to the institutional arrangements for sampling and the measurement and interpretation of results, this may not remain the case with organisation under river basin districts, especially in the case of international river basin districts. Moreover, once the initial programme has provided sufficient information, costs will be incurred in drawing up a programme of improvements and instigating the improvement measures themselves, particularly on the river basin district basis.

Where candidate countries have laboratory organisations, the costs will be limited to upgrading to the new requirements. Costs are likely to arise only if analytical methods currently in use for testing raw water used for drinking purposes do not meet the new specifications laid down. The specifications for accuracy and precision are straightforward and should be readily achievable by competent analytical laboratories. If no laboratories are in existence, then capital costs will be substantial. The use of accredited contract laboratories, not necessarily based in the territory of the candidate country, is one alternative method of reducing capital costs. Laboratories

are necessary for implementing a number of other Directives in the water sector, and costs for this particular Directive may be absorbed within the overall organisational costs for the sector.

Furthermore, water supply organisations will have additional costs where there is an immediate need to upgrade the water treatment processes, so that the water treatment process is appropriate for the quality of the water abstracted. Water suppliers may need to install equipment for carrying out physical treatment such as coagulation, filtration and disinfection where none exists at present, but the costs are unlikely to be greater than costs that would have to be borne to ensure that treated water meets the requirements of the WFD. Plans for the improvement of waters according to the classification of water status in the WFD will be part of general water quality and pollution controls in programmes of measures for river basin districts and costs are likely to be absorbed within the scope of the requisite river basin management plan. Such costs include pollution control measures for industry and changes to agricultural practices. However, costs should be borne by the polluters, where appropriate, under the polluter pays principle. Water charging is a tool to redistribute the costs incurred under the WFD and to ensure the sustainable consumption of drinking water. It should also be noted that the WFD does not prevent funding for particular preventive or remedial measures in order to meet the objectives of the Directive (see Art. 9(3)).

THE GROUNDWATER DIRECTIVE

Official Title: Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006)

Amended by:

Commission Directive 2014/80/EU of 20 June 2014 amending Annex II to Directive 2006/118/EC of the European Parliament and of the Council on the protection of groundwater against pollution and deterioration (OJ L 182, 21.6.2014)

95/337/EC: Commission Decision of 25 July 1995 amending Decision 92/446/EEC of 27 July 1992 concerning questionnaires relating to Directives in the water sector (OJ L 200, 24.8.1995).

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The EU regulatory groundwater framework has been developed at the end of the 1970's with the adoption of the Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances. This Directive has provided a groundwater protection framework by preventing the direct or indirect introduction of high priority pollutants into groundwater and limiting the introduction into groundwater of other pollutants so as to avoid pollution of groundwater by these substances. Until the WFD adoption, focus on groundwater mainly concerned its use as drinking water (e.g. about 75% of EU inhabitants depend on groundwater for their water supply). However, groundwater is also an important resource for industry (e.g. cooling waters) and agriculture (irrigation). The shift in viewing groundwater as not only the drinking water reservoir, but also valuable environmental component that needs to be protected resulted in different regulatory framework. In this context, the Water Framework Directive has put forward a challenging legislative framework, establishing "good status" environmental objectives for all waters – river, lake, coastal, transitional waters and groundwater – to be achieved by the end of 2015. With the WFD, for the first time groundwater became part of an integrated water management system, a very natural context for this essential component of the environment. The WFD includes groundwater in its river basin management planning, and sets milestones for (ground)water bodies in terms of delineation, economic analysis, characterisation, monitoring, pressures, impacts, status and the design of programmes of measures to ensure that, by the end of 2015, there is a sufficient quantity of groundwater of good chemical status. This new framework was complemented by the adoption of Directive 2006/118/EC - a daughter Directive laying down additional technical specifications (GWD). By adopting Directive 2006/118/EC the Commission fulfilled an obligation under Article 17 of the WFD, which calls for adoption of the daughter directive to set out detailed provisions on chemical status and other measures to identify and reverse pollution trends. GWD includes criteria for assessing good chemical status, criteria for the identification of pollution trends and the definition of starting points for trend reversal and complementary elements of the programmes of measures (prevention and limitation of pollutant inputs into groundwater). The GWD establishes EU-wide groundwater quality standards for 2 pollutants (nitrates and pesticides). If these groundwater quality standards are not adequate for achieving the environmental objectives set out in WFD, more stringent values have to be established by Member States (GWD Annex I.3). All of these elements are linked to the development and implementation of River Basin Management plans whose aim is to achieve “good status of waters” by 2015. GWD also ensured a continuity to the Directive 80/68/EEC on the protection of groundwater against pollution caused by dangerous substances, which is repealed as of 22 December 2013.

Thus, the key requirements of the Groundwater Directive are summarized below:

- Establishing groundwater quality standards (deadline was end of 2008). The pollutants to be addressed (nationally or within river basin districts) are those that are identified under the Water Framework Directive 2000/60/EC as contributing to groundwater bodies being ‘at risk’. These threshold values are to be set out in the River Basin Management Plans developed under the Water Framework Directive.
- Carrying out pollution trend studies by using existing data and data that are required to be collected by Directive 2000/60/EC (referred to as ‘baseline level’ data obtained in 2007–2008).
- Reverse pollution trends where there is ‘any significant and sustained upward trend’ so that environmental objectives are achieved by 2015 by using the programmes of measures set out in

Directive 2000/60/EC. Details of how Member States are to tackle such trends are to be set out in the River Basin Management Plans developed under WFD 2000/60/EC.

- Make operational measures to prevent or limit inputs of pollutants into groundwater so that WFD environmental objectives can be achieved;
- Reviews of technical provisions of the directive to be carried out in 2013 and every six years thereafter;
- Ensuring compliance with good chemical status criteria (based on EU standards of nitrates and pesticides and on threshold values established by Member States).

It is obvious that implementation of Directive 2006/118/EC should take place hand in hand with the WFD. For instance, WFD provides for particular administrative and regulatory control in the case of international river basin districts.

The Directive on Groundwater is amended by Directive 2009/31/EC to allow for injection of CO₂ into saline aquifers for the purposes of geological storage. Such storage and injections are subject to provisions protecting groundwater set out in Article 4(1)(b) of the WFD and also in Directive on Groundwater (2006/118/EC). The Directive amends Article 11(3)(j) in terms of adding injections of CO₂ into aquifers to the list of activities requiring prior approval.

Another amendment of the Groundwater Directive took place in 2014 by adoption of the Commission Directive 2014/80/EU. In particular the Directive 2014/80/EU amends certain provisions in Annex II, which sets forth threshold values for groundwater pollutants and indicators of pollution.

More information on the groundwater Directives and their integration into the WFD regime can be obtained at:

<http://ec.europa.eu/environment/water/water-framework/groundwater/pdf/brochure/en.pdf>

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Where water bodies are shared with other Member States, co-ordinate monitoring, the setting of threshold values and the identification of hazardous substances. (Art. 3(4), Directive 2006/118/EC and Art. 3(4) of Directive 2000/60/EC)
- Member States assessing the chemical status of groundwater bodies must:
 - use the criteria for groundwater quality standards as referred to in Annex I;
 - establish threshold values in accordance with the procedure in Part A of Annex II for pollutants placing groundwater bodies at risk. The threshold values applicable to good chemical status should have regard to the impact of the chemicals and their interrelationship with related surface waters and dependent terrestrial ecosystems and wetlands. (Art. 3(1), Directive 2006/118/EC)
- Assess groundwater chemical status in accordance with the procedures set out in Article 4 of Directive 2006/118/EC. For instance, bodies of groundwater may only be considered to be of good chemical status when monitoring provides evidence that the conditions set out in Annex V to Directive 2000/60/EC are met, or when the values for groundwater quality standards set out in Annex I and the threshold values established in accordance with Article 3 and Annex II are not exceeded at any monitoring point, or when a quality standard or threshold value is exceeded but where the concentrations do not pose a significant environmental risk.
- Decide whether to establish threshold values at national level, at the level of river basin district, or at the level of particular water bodies. (Art. 3(2), Directive 2006/118/EC)

2.2. Regulation

The more extensive regulatory control regime required with respect to water protection generally, but also with respect to the granting, review and amendment of permits or authorisation for discharges to groundwater should be noted.

- Establish threshold values by 22 December 2008 for the first time and ensure that these values are published in the river basin management plans (which must be submitted according to Article 13 of the WFD) along with a summary of the information set out in Part C of Annex II (Art. 3(5), Directive 2006/118/EC).
- Ensure that the monitoring sites satisfy the requirements of Section 2.4 of Annex V to the WFD.
- Identify significant and sustained upward trends in concentrations of pollutants or indicators of pollution and define the starting point for trend reversals in accordance with Annexes I and IV (Art. 5(1), Directive 2006/118/EC).

- Reverse trends that present a threat to aquatic or terrestrial ecosystems, to human health or to uses of the aquatic environment by taking the measures referred to in Article 11 of Directive 2000/60/EC (Art. 5(2), Directive 2006/118/EC).
- Take measures to prevent or limit discharges of pollutants into groundwater including:
 - a programme of mitigating measures to prevent or limit discharges of pollutants into groundwater, in accordance with Article 11 of the WFD and Article 6 of Directive 2006/118/EC (this programme shall particularly focus on entirely preventing the release of hazardous substances or groups of pollutants falling under points 1-6 and 7-9 of Annex VIII to the WFD into groundwater. The programme shall also define measures, based on BAT specified in EU legislation, to restrict discharges of non-hazardous pollutants including those non-hazardous substances listed in Annex VIII to the WFD;
 - restriction of discharges from diffuse pollution sources (Art. 6, Directive 2006/118/EC).
- Note that there are exceptions to this obligation regarding authorised discharges, inputs of insignificant quantity or concentration, and accidental or exceptional releases that could not have been foreseen, in the case of mitigating measures that would increase risk to human health and the overall environmental quality, disproportionately costly measures, and interventions in surface water to mitigate the effects of droughts and floods as well as the management of international watercourses.
- Ensure that injection of CO₂ into saline aquifers for the purposes of geological storage pursuant to Directive 2009/31/EC is allowed for but that these are subject to approval and controls set out in Directive 2009/31/EC, Article 4(1)(b) of the WFD and also are in line with the provisions of the Groundwater Directive.

2.3. Monitoring

- Pursuant to Article 8 of the WFD, establish programmes for the monitoring of water status in order to establish a coherent and comprehensive overview of water status within each river basin district. For ground waters such programmes shall cover monitoring of the chemical and quantitative status, such as detecting changes in chemical composition, and to reverse any anthropogenically induced upward pollution trend. Annex V of the WFD specifies further the parameters for this monitoring (e.g. classification parameters, density of monitoring sites, monitoring frequency). This monitoring has to be reported to the Commission through the REPORTNET facility of the EEA.

2.4. Consultation and Reporting

(See the WFD regarding detailed consultation and reporting requirements, and for cross-border arrangements in the case of international river basin districts.)

- Report to the Commission on transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 12, Directive 2006/118/EC).

- Publish all threshold values in the River Basin Management Plans (which must be submitted according to Article 13 of the WFD) along with a summary of the information set out in Part C of Annex II (Arts. 3(5) and 4(4), Directive 2006/118/EC). This summary must also explain how failure to comply with water standards and values at individual monitoring stations has been reflected in the final assessment.
- Report changes to the list of threshold values, in terms of the introduction of more stringent or more lenient values, at the time of the periodic review of the river basin management plans. (Art. 3(6), Directive 2006/118/EC)
- Keep an inventory of the exemptions referred to in Article 6(3) for the purpose of notification, upon request, to the Commission. (Art. 6(4), Directive 2006/118/EC)
- Provide reporting pursuant to Directive 91/692/EEC on standardising and rationalizing reports on the implementation of certain Directives relating to the environment provided in the questionnaires and formats set out in Decision 95/337/EC.
- Provide a report to the Commission pursuant to Article 15 of the WFD (regarding the monitoring programmes, River Basin Management Plan including the programme of measures and the analysis referred to in Article 5 of the WFD). The River Basin Management Plan has to be reported to the Commission at the latest three months after being drawn up. Member States are submitting their reports through the REPORTNET facility and the electronic data and information system on water called WISE (Water Information System for Europe) of the EEA.

2.5. Additional Legal Instruments

There are several other legal instruments that should be borne in mind during the implementation of this Directive. They are part of the set of measures that need to be operational to achieve the "good environmental status" objective by the end of 2015. They all seek to prevent or limit pollutants reaching groundwater. These include:

- WFD (2000/60/EC)
- Floods Directive (2007/60/EC)
- Marine Strategy Framework Directive (2008/56/EC)
- Nitrates Directive (91/676/EEC)
- Marketing of Plant Protection Products Directive (91/414/EEC)
- Marketing of Biocidal Products Regulation ((EU) 528/2012)
- Directive 98/83/EC on the quality of water intended for human consumption
- Directive 91/692/EEC on standardising and rationalizing reports on the implementation of certain Directives relating to the environment
- Commission Decision 95/337/EC concerning questionnaires relating to Directive in the water sector
- Waste Framework Directive (2000/98/EC)

- Sewage Sludge Directive (86/278/EEC)
- Industrial Emissions Directive (2010/75/EU)
- Seveso III Directive (2012/18/EU)
- Directive on access to environmental information (Directive 2003/4/EC)
- Regulation (EC) No. 166/2006 establishing a European Pollutant Release and Transfer Register
- Landfill Directive (99/31/EC)

The issues of particular relevance are:

- The expansion under the WFD of water protection to all waters, surface waters and groundwater, and the obligation to achieve/maintain "good status" for all these waters. Prohibition of direct discharge of pollutants into groundwater (WFD, Article 11.3.j).
- The expansion of the water protection to marine waters under MSFD, with the obligation to achieve and maintain good environmental status comprising adopting programmes of measures which should cover pollution from nitrates.
- The other Directives are largely concerned with the means to prevent dangerous substances affecting groundwater.

3. IMPLEMENTATION

As this legislation, including the ban on direct discharges of dangerous substances into groundwater, has been fully integrated into the WFD (in its operative obligations), along with a few new pieces of supplementary legislation. Hence, emphasis should be put rather on the content than on the formal transposition of this Directive. The main obligation will -- within the WFD and the MSFD -- be the establishment of an adequate sampling and monitoring system, which also should be seen together with the monitoring requirements set out in the Industrial Emissions Directive (2010/75/EU). This overall approach should also contribute to avoiding duplication of effort in the field of measuring and monitoring.

Effective implementation will however depend on a high level of cooperation between competent authorities-environment agencies or ministries, stakeholders representing different sectors (agriculture, industry, and urban), NGOs, the scientific community, etc.

In order to support Member States and ensure coherent implementation of the water legislation, a number of guidance documents and technical reports have been developed by the Common Implementation Strategy (CIS) working group on groundwater. These include:

Guidance Document N° 15 - Groundwater Monitoring

Guidance Document N° 16 - Groundwater in Drinking Water Protected Areas

Guidance Document N° 17 - Direct and indirect inputs in the light of Directive 2006/118/EC

Guidance Document N° 18 - Groundwater Status and Trend Assessment

Guidance Document N° 26 - Risk Assessment and the Use of Conceptual Models for Groundwater

Technical Report N° 1 on Groundwater Trends

Technical Report N° 2 on Groundwater Characterisation

Technical Report N° 3 on Groundwater Monitoring

Technical Report N° 4 on Groundwater Risk Assessment

Technical Report N° 5 on Groundwater Management in the Mediterranean

Technical Report N° 6 on Groundwater Dependent Terrestrial Ecosystems

Technical Report N° 7 on the Recommendations for the Review of Annexes I-II of the Groundwater Directive 2006/118/EC

Technical Report N° 8 on Methodologies used for Assessing Groundwater Dependent Terrestrial Ecosystems

Technical Report N° 9 on Groundwater Associated Aquatic Ecosystems

Guidance documents and technical reports are available at the following link:
<http://ec.europa.eu/environment/water/water-framework/groundwater/activities.htm>

Commission reports on the implementation of the Groundwater Directive are available at the following link:
<http://ec.europa.eu/environment/water/water-framework/groundwater/reports.htm>

4. COSTS

The costs associated with the implementation of this Directive are given in the table below.

Table 14. Examples of implementation costs incurred

Initial set-up costs: <ul style="list-style-type: none">• establishment of a competent authority;• survey work to identify any significant and sustained upward trend in concentrations of pollutants, groups of pollutants or indicators of pollution found in bodies or groups of bodies of groundwater identified as being at risk;• investigative work on classifying substances;• training.
Capital expenditure: <ul style="list-style-type: none">• setting up and monitoring the quality of groundwater and discharges into such water bodies;• taking the prevention and mitigating measures referred to in Article 11 of the Water Framework Directive and Article 6 of Directive 2006/118/EC.• action to be taken by dischargers to eliminate or reduce discharges of dangerous substances (borne by the polluters).
Ongoing running costs: <ul style="list-style-type: none">• implementing the measures to prohibit/limit the impact of dangerous substances on groundwater;• annual costs of monitoring, inspection and enforcement;• annual costs of maintaining inventory.

ENVIRONMENTAL QUALITY STANDARDS DIRECTIVE

Official Title: Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council, amended by Directive 2013/39/EU²¹⁴ (OJ L 226, 24.8.2013)

²¹⁴Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The Environmental Quality Standards Directive (EQSD) (2008/105/EC) directly relates to Article 16(7) of the Water Framework Directive (WFD), and is hence a daughter Directive to the Water Framework Directive. Article 16 of the WFD required the establishment of environmental quality standards applicable to water in order to achieve the ultimate goal - 'good status' of EU waters.

This Directive sets out environmental quality standards concerning the presence in surface water of certain substances or groups of substances identified as priority pollutants on account of the significant risk they pose to or via the aquatic environment. The priority substances are listed in Annex X to the WFD, 33 were specified by Decision 2455/2001/EC²¹⁵ and a further 12 by amending Directive 2013/39/EU. These substances include among others the metals cadmium, lead, mercury and nickel, and their compounds, benzene, polyaromatic hydrocarbons (PAH) and several pesticides. 21 priority substances are classed as hazardous.

The Environmental Quality Standards (EQS) are concentration of a particular pollutant or group of pollutants in water, sediment or biota, which should not be exceeded in order to protect human health and the environment.

Two types of environmental quality standard are set: a threshold for the average concentration of the substance concerned calculated from measurements over a one-year period (AA-EQS) and maximum allowable concentrations of the substance concerned, i.e. the maximum for any single measurement (MAC-EQS). Purpose of the former is protection against long-term and chronic effects, whereas purpose of the latter is protection against short-term, direct and acute eco-toxic effects. Furthermore, the environmental quality standards are differentiated for inland surface waters (rivers and lakes) and other surface waters (transitional, coastal and territorial waters). These standards are complemented by a requirement to establish inventories of the discharges, emissions and losses of these substances in order to ascertain whether the goals of reducing or eliminating such pollution have been achieved.

For certain substances, the EQSD defines EQSs for biota. Member States may decide to apply EQSs for another matrix or biota taxon than the preferred one identified in the EQSD, where an appropriate explanation for their choice needs to be provided. This means that Member State can choose to monitor in biota substances having water standards, but they can also choose to monitor in water or a different biota taxon substances having an EQS in biota.

The quality standards are differentiated for inland surface waters (rivers and lakes) and other surface waters (transitional, coastal and territorial waters). The annual average EQS for two metals takes account of their bioavailability. For some substances, biota EQS are set, meaning that the specified concentration of the relevant substance in biota (generally fish) must not be exceeded.

Directive 2008/105/EC also provides for Member States to establish mixing zones, where the EQS may be exceeded provided that the rest of the surface water body complies with those standards (Article 3 of the EQSD). These areas must be clearly identified in the river basin management plans established in accordance with the Water Framework Directive. Article 4.2 also provides that MS should take measures to reduce the extent of mixing zones.

²¹⁵Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive 2000/60/EC

Two more important elements refer to the requirement for trend monitoring in Directive 2008/105/EC as amended by 2013/39/EU, and to prevent increase of concentration in sediment and biota, and the requirement to prepare inventory of emissions, discharges and losses of priority and priority hazardous substances²¹⁶.

The EQS Directive repealed the following daughter Directives of Directive 76/464/EEC (Directive 2006/11/EC) with effect from 22 December 2012:

- Council Directive 82/176/EEC on limit values and quality objectives for mercury discharges by the chlor-alkali electrolysis industry;
- Council Directive 83/513/EEC on limit values and quality objectives for cadmium discharges;
- Council Directive 84/156/EEC on limit values and quality objectives for mercury discharges by sectors other than the chlor-alkali electrolysis industry;
- Council Directive 84/491/EEC on limit values and quality objectives for discharges of hexachlorocyclohexane;
- Council Directive 86/280/EEC on limit values and quality objectives for discharges of certain dangerous substances included in List I of the annex to Directive 2006/11/EC.

Directive 2008/105/EC was amended by Directive 2013/39/EU, which updates the EQS for seven of the 33 original priority substances in line with the latest scientific and technical knowledge concerning the properties of the substances. The revised EQS for those seven existing priority substances must be taken into account for the first time in Member States' river basin management plans from 22 December 2015 with the aim of achieving good surface water chemical status in relation to those substances by 22 December 2021. The 12 newly identified priority substances and their EQS should be taken into account in the establishment of supplementary monitoring programmes and in preliminary programmes of measures to be submitted by the end of 2018, with the aim of achieving good surface water chemical status in relation to those substances by 22 December 2027.

Directive 2013/39/EU also introduced amendments to Article 2 providing a definition for the terms 'matrix' and 'biota taxon'. Article 3 is amended to make it coherent with the new structure of Part A of Annex I and to amend the obligations of the Member States as regards the selection of the matrix for monitoring. A default monitoring matrix is specified for each substance, on the basis of its intrinsic properties. The existing flexibility for Member States to choose an alternative matrix is retained, but it is now conditioned to the fulfilment of the minimum analytical performance criteria in Article 4 of the Commission Directive 2009/90/EC. It also introduces a provision that the Commission will establish a watch list of substances for which Union-wide monitoring data are to be gathered for the purpose of supporting future prioritisation exercises²¹⁷. The watch list is to be updated every 2 years. A continuous watch list monitoring period for any individual substance may not exceed four years. The Commission has the requirement to develop a strategic approach to pharmaceuticals in the environment (Article 8c). A central portal is providing information on the river basin management plans and their reviews and updates accessible to the public electronically in each Member State (Article 5.a)

²¹⁶ The Guidance Document No. 28 provides Technical Guidance on the Preparation of an Inventory of Emissions, Discharges and Losses of Priority and Priority Hazardous Substances

²¹⁷ First watchlist has been published in 2015: Commission Implementing Decision (EU) 2015/495 of 20 March 2015 establishing a watch list of substances for Union-wide monitoring in the field of water policy pursuant to Directive 2008/105/EC of the European Parliament and of the Council

2. PRINCIPAL OBLIGATIONS ON MEMBER STATES

2.1. Planning and Regulation

- On the basis of the information collected in accordance with Articles 5 and 8 of the WFD, under Regulation (EC) No 166/2006 and other available data, Member States shall establish an inventory, including maps, if available, of emissions, discharges and losses of all priority substances and pollutants listed in Part A of Annex I to this Directive for each river basin district or part of a river basin district lying within their territory including their concentrations in sediment and biota, as appropriate. (Art. 5(1) EQSD)
- The reference period for the estimation of pollutant values to be entered in the first inventories referred to in paragraph 1 shall be one year between 2008 and 2010 (Art. 5(2) EQSD). For PS covered by Regulation (EC) No 1107/20097 on Plant Protection Products (PPPs) also the average of the years 2008-2010 may be used²¹⁸. Inventories of inputs of PPPs need to consider 3 - 5 years average so as to minimize the yearly variation in emission due to variation of climatic conditions involving variation of pest pressure and so significant difference in yearly use of PPPs.
- Member States shall update their inventories as part of the reviews of the analyses specified in Article 5(2) of Directive 2000/60/EC. Make sure to include the information stipulated in Article 3(5) in the updated RBMP produced pursuant Article 13(7) of the WFD. (Art. 3(5) EQSD)
- Apply the EQS laid down in Part A of Annex I for bodies of surface water in accordance with the requirements laid down in Part B of Annex I. (Art. 3(1) EQS Directive)
- Member States may opt in relation to one or more categories of surface water, to apply an EQS for a matrix or, where relevant, for a biota taxon other than those specified in Part A of Annex I. In those cases, Member States must comply with the minimum analytical criteria stipulated in Article 4 of the WFD that such concentrations do not significantly increase in sediment and/or relevant biota.
- Take measures aimed at ensuring, subject to Article 4 of Directive 2000/60/EC, that such concentrations do not significantly increase in sediment and/or relevant biota. (Art. 3(6) EQSD)
- Member States may designate mixing zones adjacent to points of discharge, where the quality standards may be exceeded provided that the rest of the surface water body complies with those standards (Art. 4 EQSD). Where mixing zones have been designated, ensure that:
 - these are included in river basin management plans referred to in Article 13 of WFD including description of approaches and methodologies applied to define such zones and steps to be taken to reduce the extent of the mixing zones in the future;

²¹⁸The specific 3-year-average option for PPPs is explained in Recital 23 of the EQSD, with the “fact that the losses from the application of pesticides may vary considerably from one year to another because of different application rates, for instance as a result of different climatic conditions.”

- that the mixing zone is a) restricted to the proximity of the point of discharge, and b) proportionate, having regard to the concentrations of pollutants at the point of discharge and to the conditions on emissions of pollutants contained in the prior regulations, such as authorisations and/or permits, referred to in Article 11(3)(g) of Directive 2000/60/EC and any other relevant EU law, in accordance with the application of best available techniques and Article 10 of Directive 2000/60/EC. (Art. 4(3)EQSD)

2.2. Monitoring and Enforcement

- Ensure that monitoring in surface waters is carried out for compliance assessment and MAC-EQS laid down in Part A of Annex I are applied in cases where a potential risk to, or via, the aquatic environment from acute exposure has been identified as a result of measured or estimated environmental concentrations or emissions and where a biota or sediment EQS is being applied. (Art. 3(3a)EQSD)
- Monitor the substance for which an EQS for sediment and/or biota is applied in the relevant matrix at least once every year, unless technical knowledge and expert judgment justify another interval. (Art. 3(4) EQSD). Member States have flexibility to use alternative matrices (water, sediment or biota) for monitoring provided the level of protection afforded by the EQS and the monitoring system is as good as that provided by the EQS and matrix laid down in the EQSD, which allows them to take advantage of their monitoring strategy and adapt it to their local circumstances. Taking into account the widespread distribution and long recovery times expected for substances behaving like ubiquitous PBTs²¹⁹, Member States are allowed to reduce the number of monitoring sites and/or the frequency of monitoring for those substances to the minimum level sufficient for reliable long-term trend analysis, provided that a statistically robust monitoring baseline is available.
- Arrange for the long-term trend analysis of concentrations of those priority substances listed in Part A of Annex I that tend to accumulate in sediment and/or biota, giving particular consideration to the substances: Anthracene, Brominated diphenylethers, and its compounds, Chloroalkanes C10-13, Di(2-ethylhexyl)phthalate (DEHP), Fluoranthene, Hexachlorobenzene, Hexachlorobutadiene, Hexachlorocyclohexane, Lead and its compounds, Mercury and its compounds, Pentachlorobenzene, Polyaromatic hydrocarbons (PAH), Tributyltin compounds, Dicofof, Perfluorooctane sulfonic acid and its derivatives (PFOS), Quinoxifen, Dioxins and dioxin-like compounds, Hexabromocyclododecanes (HBCDD) and Heptachlor and heptachlor epoxide listed in Part A of Annex I, on the basis of the monitoring of surface water status carried out in accordance with Article 8 of the WFD. Determine the frequency of monitoring in sediment and/or biota so as to provide sufficient data for a reliable long-term trend analysis. As a guideline, monitoring should take place every three years, unless technical knowledge and expert judgment justify another interval. (Art. 3(6) EQSD)

²¹⁹UPBT (ubiquitous Persistent, Bioaccumulative and Toxic substances) is a subset of priority substances (uPBTs) that have been identified under the amended EQS Directive (2013/39/EU).

- Monitor each substance in the watch list established pursuant Article 8b(1)²²⁰ at selected representative monitoring stations over at least a 12-month period. It shall also select at least one monitoring station, plus one station if it has more than one million inhabitants, plus the number of stations equal to its geographical area in km² divided by 60 000 (rounded to the nearest integer), plus the number of stations equal to its population divided by five million (rounded to the nearest integer). The frequency of monitoring shall be no less than once per year. (Art. 8b(3) EQSD)

2.3. Consultation and Reporting

- Report to the Commission on:
 - the inventories established according to Article 5 of the WFD, including reference periods, in accordance with the reporting requirements under Article 15(1) of the same Directive.
 - the circumstances for transboundary pollution and the measures taken in relation to this pollution in the relevant river basin management plan in accordance with the reporting requirements under Article 15(1) of WFD. (Art. 6, EQS Directive)
 - the results of the monitoring of substances included in the watch list pursuant to Article 8b(1) The report shall include information on the representativeness of the monitoring stations and monitoring strategy. (Art. 8b(4), EQS Directive)
 - the text of the main provisions of national law adopted to transpose the EQS Directive. (Art. 13(2), EQS Directive)
- In the implementation of the EQS and in particular the requirement set out in Art. 5 on compiling inventories, a useful link could be made to Regulation (EC) No. 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register. Under this Regulation, operators and Member States must report certain data regarding discharges to water bodies resulting from activities listed in Annex I to Regulation (EC) No. 166/2006 establishing a European Pollutant Release and Transfer Register, including the activities of chemical installations, paper and wood processing, intensive livestock production and aquaculture, and the large capacity food and beverage sector. Such operators must submit annual reports to the Member States of releases to water of the pollutants set out in Annex II where the threshold value is exceeded. This information shall cover/intentional and unintentional releases and records of the data shall be kept and made available for inspection for a period of five years. The Member States in turn have to report these data to the Commission every 15 months.
- Ensure that the updated river basin management plans, produced in accordance with Article 13(7) of WFD, containing the results and impact of the measures taken to prevent chemical pollution of surface water, and the interim report describing progress in the implementation of the planned programme of measures in accordance with Article 15(3) of Directive 2000/60/EC, are provided through a central portal which is accessible to the public electronically in accordance with Article 7(1) of Directive 2003/4/EC on public access to environmental information (Art. 3(5a), EQS Directive)

²²⁰First watchlist has been published in 2015: Commission Implementing Decision (EU) 2015/495.

- Take into account the template for questionnaires in the water management sector set out in Commission Decision 95/337/EC²²¹, which include explanatory notes and agreed fine-tuned tables in order to clarify the reporting obligations imposed on the Member States and to ensure that information provided to the Commission by Member States are comprehensive, consistent and comparable.

2.4. Additional Legal Instruments

The EQS Directive is closely linked to a number of legal instruments both in the water quality sector but also regarding horizontal legislation, industrial pollution prevention, and chemical management. The most relevant legal instruments include:

- WFD (2000/60/EC)
- Groundwater Directive (2006/118/EC)
- Drinking Water Directive (98/83/EC)
- Urban Waste Water Treatment Directive (91/271/EEC)
- Directive on chemical analysis and monitoring of water status (2009/90/EC)
- Industrial Emissions Directive (2010/75/EU)
- Reporting Directive (91/692/EEC)
- Directive on Access to Environmental Information (Directive 2003/4/EC)
- Regulation (EC) No. 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register
- Directive on Sewage Sludge (86/278/EEC)
- Marine Strategy Framework Directive (2008/56/EC)
- REACH Regulation ((EC) No. 1907/2006)
- Plant Protection Products Regulation (EC) No 1107/2009)
- Biocidal Products Regulation ((EU) 528/2012)
- POPs Regulation ((EC) No 850/2004)
- Waste Framework Directive (2008/98/EC)
- Environmental Crimes Directive (2008/99/EC)
- Environmental Liability Directive (2004/35/EC)

Regarding the above legislation, the following list provides some examples of issues of significance:

²²¹Commission Decision 1995/337/EC of 25 July 1995 amending Decision 92/446/EEC of 27 July 1992 concerning questionnaires relating to Directives in the water sector

- Many of the industries that discharge dangerous substances to water will be controlled through the IED permitting procedures. Also note the control measures set out in Art. 10 of the WFD, e.g. ELVs, emission controls based on BAT, which are prescribed by the other EU legislation (listed in Art. 10(2) and set out in Annex IX to the WFD).
- Under REACH Regulation, provide synergies with registration dossiers, Annex XV dossiers (SVHC), and evaluations.
- Access to Environmental Information Directive (2004/3/EC) requires environmental information held by public bodies to be made available to the general public on request. Most of the water Directives specify the collection of water quality information or information concerning permits. As a rule, any such information held by public bodies would be covered by this Directive, such as the information provided by the inventories of emissions, discharges and losses of priority substances, which are considered in the permitting process.
- Sewage Sludge Directive regulates the use of sewage sludge in agriculture in such a way that contamination of soil and pollution of water does not occur from metal contaminants, nitrates and phosphates. Due to the physical-chemical processes involved in the treatment, the sludge tends to concentrate heavy metals and poorly biodegradable trace organic compounds as well as potentially pathogenic organisms (viruses, bacteria etc) present in waste waters. Whilst the Sewage Sludge Directive sets limits on the concentrations of selected metals in sludge applied to agricultural land, the potential impact of many WFD priority and priority hazardous substances on human or environmental health has yet to be fully addressed. Appropriate use of sludge is an important factor in the definition of programmes of measures for river basin districts under the WFD.

3. IMPLEMENTATION

3.1. Key Tasks

The EQS Directive aims at efficient action supporting the efforts under WFD to control all discharges of priority substances into water by setting EQS to supplement the existing system of authorisation procedure.

Candidate countries are thus advised to focus on implementing WFD and the EQS Directive seen in the context of other controlling or permitting EU legislation (e.g. IED 2010/75/EU, Nitrates Directive 91/676/EC), other EU water legislation as well technical requirements laid down by the Directive 2009/90/EC on technical specifications for monitoring of water status.

Table 15. Illustrative checklist with key implementation tasks

EQS DIRECTIVE – KEY IMPLEMENTATION TASKS	
1	Planning and Administrative Framework
1.1	Appoint a competent authority to take responsibility for implementing the Directive.
1.2	On the basis of the information collected in accordance with Articles 5 and 8 of WFD, under Regulation (EC) No 166/2006 (REACH) and other available data, establish an inventory, including maps of emissions, discharges and losses of all priority substances and pollutants listed in Part A of Annex I to this Directive for each river basin district or part of a river basin district lying within their territory including their concentrations in sediment and biota, as appropriate.
1.3	Decide whether to designate mixing zones adjacent to points of discharge, where the quality standards may be exceeded provided that the rest of the surface water body complies with those standards. If yes, these areas must be clearly identified in the river basin management plans established under WFD providing for the approaches, methodologies and measures pursuant to WFD, Art. 13 and 11(3).
2	Regulation
2.1	Ensure that all definitions laid down in Article 2 are applied in the implementation of the EQS Directive.
2.2	Take measures to comply with the EQSD and thus eliminate the pollution of inland surface waters, territorial waters and internal coastal waters by priority substances referred to in WFD, which establishes a list of 45 priority substances. Twenty priority substances are classed as hazardous.
2.3	Apply the EQS laid down in Part A of Annex I to EQS Directive for bodies of surface water from the dates from which these EQSs have to be taken into account.
2.4	Apply the EQS in accordance with the requirements laid down in Part B of Annex I, which for instance give guidance on calculation of the arithmetic mean, the analytical method used to ensure at least that the minimum performance criteria is met. Part B should also be applied in conjunction with the requirements set out in Directive 2009/90/EC on technical specifications for chemical analysis and monitoring of water status, in accordance with WFD (especially Art. 8(3)) <ul style="list-style-type: none"> • Ensure compliance with particular requirements regarding metals; • Ensure that the assessment of monitoring results are taken into account in the risk assessments.

2.5	Arrange for the long-term trend analysis of concentrations of those priority substances listed in Part A of Annex I that tend to accumulate in sediment and/or biota, giving particular consideration to the substances numbered 2, 5, 6, 7, 12, 15, 16, 17, 18, 20, 21, 26, 28, 30, 34, 35, 36, 37, 43 and 44 listed in Part A of Annex I, on the basis of the monitoring of surface water status carried out in accordance with Article 8 of the WFD.
2.6	Verify that the concentrations do not significantly increase in sediment and/or relevant biota, in pursuance with Art. 4 of WFD.
2.7	Where mixing zones have been designated allowing for higher values, ensure that: <ul style="list-style-type: none"> • these are included in river basin management plans • that the mixing zone is a) restricted to the proximity of the point of discharge, b) complying with the conditions on discharges set out in authorisations and/or permits, requirements set out in Article 11(3) (g) of WFD and other relevant EU law, c) applies BAT, d) complies with any future technical specifications to be adopted under the EQS Directive pursuant to Art. 9(2).
2.8	Ensure that discharges of substances listed in WFD are subject to authorisation either under WFD and IED, as required. Investigate whether these authorisations need to be revised in the light of the EQS Directive, Directive 2009/90/EC on monitoring specifications and the more stringent emission limits set out in Annex IX of the WFD.
2.9	Ensure that in cases of transboundary pollution, that Member States submit to the Commission the necessary information regarding the circumstances of the pollution and the measures taken in regard to the transboundary pollution in the relevant river basin management plan.
3	Monitoring and Enforcement
3.1	Introduce a framework for monitoring, information gathering and dissemination and reporting to demonstrate in case of transboundary pollution full compliance with the EQS Directive. This framework has to include reporting mechanism to the Commission.
3.2	Carry out monitoring in accordance with Articles 5 and 8 of WFD regarding: <ul style="list-style-type: none"> • establishment of monitoring programmes for surface water status, groundwater status and protected areas, giving relevance to the technical specifications laid down at EU level.
3.3	Where Member States opt in relation to one or more categories of surface water, to apply an EQS for a matrix or, where relevant, for a biota taxon other than those specified in Part A of Annex I, they must comply with the minimum analytical criteria stipulated in Article 4 of Commission Directive 2009/90/EC. Member States shall ensure that monitoring is carried out using best available techniques not entailing excessive costs, in cases when the relevant environmental quality standard for a given parameter is missing, or in the absence of method of analysis meeting the minimum performance criteria.
3.4	Determine the frequency of monitoring in sediment and/or biota, which should be at least once every year, unless technical knowledge and expert judgment justify another interval.
3.5	Take measures aimed at ensuring, subject to Article 4 of WFD, that concentrations of priority substances listed in Part A of Annex I that tend to accumulate in sediment and/or biota, giving particular consideration to the substances numbered 2, 5, 6, 7, 12, 15, 16, 17, 18, 20, 21, 26, 28, 30, 34, 35, 36, 37, 43 and 44 listed in Part A of Annex I do not significantly increase in sediment and/or relevant biota.
3.6	Ensure the monitoring of the water status pursuant to Art. 8 of WFD and implementing Directive 2009/90/EC setting out the technical requirements for this monitoring, On the basis of this monitoring, arrange for the long-term trend analysis of concentrations of those priority substances listed in Part A of Annex I that tend to accumulate in sediment and/or biota.
3.7	Determine the frequency of monitoring in sediment and/or biota, which should be at least every third year, unless technical knowledge and expert judgment justify another interval, to ensure sufficient data for a reliable long-term trend analysis.

	Where a potential risk to, or via, the aquatic environment from acute exposure has been identified as a result of measured or estimated environmental concentrations or emissions and where a biota or sediment EQS is being applied, Member States shall ensure that monitoring in surface water is also carried out and shall apply the MAC-EQS laid down in Part A of Annex I to this Directive where such EQS have been established.
	Monitor each substance in the watch list established pursuant Article 8b(1) at selected representative monitoring stations over at least a 12-month period. The frequency of monitoring shall be no less than once per year. (Art. 8b(3) of the EQS Directive)
4	Technical Standards
4.1	Observe the technical standards set at EU level, such as those set for monitoring in Directive 2009/90/EC, which lays down the technical specifications for chemical analysis and monitoring of water status, pursuant to Art. 8(3) of WFD. This Directive establishes minimum performance criteria for methods of analysis to be applied by Member States when monitoring water status, sediment and biota, as well as rules for demonstrating the quality of analytical results.
4.2	Laboratories and laboratory methods for sampling should be subjected to regular quality control schemes.
4.3	Comply with the technical guidelines for the establishment of inventories adopted by the Commission pursuant to the regulatory procedure, e.g. CIS guidance on inventory of emissions, available at: https://circabc.europa.eu/sd/a/6a3fb5a0-4dec-4fde-a69d-5ac93dfbbadd/Guidance%20document%20n28.pdf
4.4	If need be prepare guidance on application of the EQS and the monitoring and reporting requirements
4.5	Comply with the technical guidelines for the identification of mixing zones adopted by the Commission pursuant to the regulatory procedure, e.g. the Technical document on mixing zones, available at: https://circabc.europa.eu/w/browse/b55f4c81-d664-43db-8b27-264b26a7424b
5	Communication and Reporting
5.1	Report to the Commission on: <ul style="list-style-type: none"> • the inventories including respective reference periods, in accordance with the reporting requirements under Article 15(1) of WFD; • pursuant to the mechanism laid down in Article 12 of WFD provide a summary of the circumstances for transboundary pollution and the measures taken in relation to this pollution under Article 15(1) of the WFD; • compliance with Articles 5, 8, 15 of the WFD; • the results of the monitoring of substances included in the watch list pursuant to Art. 8b(1); • the text of the main provisions of national law which they adopt to transpose the EQS Directive.
5.2	Operators and Member States must report certain data regarding discharges to water bodies resulting from activities listed in Annex I to Regulation (EC) No. 166/2006 establishing a European Pollutant Release and Transfer Register, including the activities of chemical installations, paper and wood processing, intensive livestock production and aquaculture, and the large capacity food and beverage sector. Such operators must submit annual reports to the Member States of releases to water of the pollutants set out in Annex II where the threshold value is exceeded.
5.3	Ensure that the updated river basin management plans, produced in accordance with Article 13(7) of WFD, containing the results and impact of the measures taken to prevent chemical pollution of surface water, and the interim report describing progress in the implementation of the planned programme of measures in accordance with Article 15(3) of Directive 2000/60/EC, are provided through a central portal which is

	accessible to the public electronically in accordance with Article 7(1) of Directive 2003/4/EC on public access to environmental information (Art. 3(5a), EQS Directive)
5.4	Also take into account the template for questionnaires in the water management sector set out in Commission Decision 95/337/EC, which relates to the questions to be covered by authorisations for discharges of certain polluting substances to water bodies.

3.2. Phasing Considerations and Priority Setting

With regard to measures to control pollution by Annex I, Part A substances, main points for considering in the planning phase and the most time-consuming elements are:

- The collection of sufficient data on water quality in the waterbodies. Additionally, there will be the need to establish an organisation to identify waters that are affected by priority substances and to collect quality information on the levels of the substances, in order to assess the impact of discharges and other sources on these waters.
- Establishing a prior authorisation procedure and the subsequent issuing of permits to the dischargers of dangerous substances (note that this permitting procedure is not directly covered by this Directive).
- Establishing a monitoring regime to measure the compliance of the discharges and/or the receiving watercourses with the water quality objectives.
- Establishing an inspection and enforcement programme, with suitably trained staff and resources to ensure the continued adherence of dischargers to their permit conditions.
- Taking action to improve the situation if the results are unfavourable. The preparation of pollution reduction programmes will be necessary as a result of compliance assessment work.

Table 16. The timetables for the key implementation stages

	Directive 2008/105/EC	Amending Directive 2013/39/EU
Adoption	13.01.2009	25.8.2013?
Transposition	2015	2015
Inventory of emissions	14.09.2015? ²²² , 22.12.2019	/
Supplementary monitoring programme and a preliminary programme of measures covering newly identified substances	/	2018

²²²Article 5 of the EQS Directive requires the compilation update and reporting of the inventory on a regular basis as part of the river basin management process.

Objectives achieved (in RBMPs)	2015	2021 for seven substances with revised EQS 2027 for 12 newly identified substances 2015 for other substances identified in the EQSD.
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4. IMPLEMENTATION GUIDANCE

4.1. Administrative Arrangements

(Note, generally, that the WFD establishes a regime for control based on river basin districts, and future administrative arrangements will have to be effective for providing the degree of regulation and co-ordination that such a regime requires. These tasks may be more challenging in the case of international river basin districts. Also note, the administrative arrangements required by the MSFD)

- The competent authority may be established as a national or local body, but it is essential that it has jurisdiction over the authorisation of discharges to the aquatic environment and the capacity to inspect, sample and analyse discharges and waters. In view of the potential for using the IED (2010/75/EU) as a means of authorising industrial producers and users of dangerous substances, and the links with the WFD, the competent authority should be in a position to establish links with the competent authorities responsible for these two Directives (if they are separate authorities).

Examples of Approaches in Member States

Sweden: the Swedish Protection Agency (Naturvårdsverket) was in 2008 commissioned to propose how the directive should be implemented in Swedish legislation. EPA had to assess the necessary amendments and new provisions as well as to undertake a consequence assessment. The WFD has been implemented largely through Chapter 5 of the Environmental Code, Water Management Ordinance and EPA regulations. The EPA proposes that Directive 2008/105/EC as daughter directive to WFD, to a large extent is implemented through regulations with the most elementary provisions set out in an ordinance.

Examples of Designation of Competent Authorities

Italy: Regarding designation of competent authorities on regional level, the Environmental Protection Agency of Region Veneto (ARPAV) has been delegated by Veneto Region as scientific/technical control agency to carry out monitoring and controls on different environmental sectors, including water protection.

During the last years ARPAV was involved, in collaboration with the National Environmental Agency and the Health Ministry, in many activities regarding WFD implementation, such as the drawing up of the guidelines for the monitoring (*Guidelines of monitoring for the WFD*, European Commission 2003) and the project of the Regional Water Protection Plan as provided by national legislation.

Sweden: Largely due to the WFD and its consequences, Sweden has introduced a system of water management, which comprises five Water Districts, each with a „Water Authority” (vattenmyndighet). The Water Authorities belong to one of the County Boards of the Water District. The main responsibility for water management, thus, rest with the country’s 21 County Boards

The Water Authority is amongst others responsible for ensuring compliance with the national EQS (miljökvalitetsnormer) in the Water Districts they belong to. Hence, the Water Authorities and the County Boards will be largely involved by in the implementation of the EQS Directive. The Municipalities are responsible for land and water usage according to the Planning and Construction Act (Plan- och bygglagen). They are also supervisory authorities for the local environmental work and waste water treatment and production of drinking water. The municipalities will thus have a much more restricted involvement then the Water Authority.

4.2. Regulation

- Implement the regulatory requirements relating to ensuring compliance with EQS (Annex I, Part A), ensuring compliance with the requirements set out in Annex I, Part B, ensuring an inventory, the long-term trend analysis of concentrations of Part A substances that tend to accumulate in sediment or biota, monitoring and reporting on transboundary pollution cases.
- Also since the EQS Directive largely reinforces and consolidates the legal framework for restricted substances and this legal framework aims at eliminating pollution from these substances, consideration should be given to setting more stringent standards where these are achievable. The setting of a particular standard should not allow dischargers to increase their input if the quality is already much better than required (EQSD para (18)).
- According to the WFD, Member States must implement the necessary measures in accordance with Article 16(1) and (8), with the aim of progressively reducing pollution from priority substances and ceasing or phasing out emissions, discharges and losses of priority hazardous substances but does not mention that certain discharges do not fall outside the scope of the directive. As water, fish, biota and sediments may be affected by discharges other than those controlled by the EQSD an investigation may be required to identify those discharges and to take additional steps to reduce their input of the restricted substances. This may involve controls on the use of the substance or changes to the ways in which it is used, the substitution of alternative substances where this is possible, controls on discharges into sewers, and controls on small discharges. A programme of pollution prevention may be required to deal with small discharges or diffuse sources where emission limits are not practicable.

4.3. Technical Guidance

CIS guidance documents relevant for the implementation of the EQS Directive should be consulted when planning implementation. Guidance documents and technical reports listed below are available at: http://ec.europa.eu/environment/water/water-framework/facts_figures/guidance_docs_en.htm

- Guidance Document No. 7- Monitoring under the Water Framework Directive

The focus of the document is on providing guidance on establishing programmes of measures with specific emphasis on the appropriate selection of quality elements and design of monitoring programmes in accordance with Articles 8 and 11 and Annex V.

- Guidance Document No. 19- Surface water chemical monitoring

The document presents the best practices, complement existing CIS guidance and give links to relevant guidance and international standards or procedures already in practice. It includes the monitoring of the WFD priority substances, other specific pollutants and all other chemical parameters relevant in the assessment of the ecological or chemical status of a water body or in the assessment of programmes of measures. The guidance focuses on monitoring including sampling and laboratory analyses, it covers also in-situ field monitoring of physico-chemical quality elements, but not the monitoring of hydromorphological elements.

- Guidance Document No. 25 on chemical monitoring of sediment and biota under Water Framework Directive

This guidance document addresses the requirements for compliance checking and temporal trend monitoring for biota and sediment, taking into account the obligations of the EQS Directive (under Art. 3). The recommendations included in the guidance take into account current scientific knowledge and they should allow a harmonised implementation of sediment and biota monitoring across Europe. The recommendations are mainly addressed to surveillance, operational and investigative monitoring and should be applied to the current list of Priority Substances (33) + 8 other pollutants, and to specific river basin pollutants which tend to accumulate in sediment or biota.

- Guidance Document No. 27 Technical Guidance for Deriving Environmental Quality Standards (2011).

The Guidance applies to the derivation of EQSs for PSs, PHSs and Specific Pollutants and focuses on the steps required to derive EQSs that comply with the requirements of Annex V of the WFD. It assumes that the chemicals for which EQSs are required have been identified, i.e. the guidance does not cover chemical prioritisation. However, it does address some aspects of the way an EQS is implemented, where this has a direct bearing on the way an EQS is derived and expressed, e.g. assessing compliance with an EQS.

- Guidance Document No. 28- Preparation of Priority Substances Emissions Inventory

This guidance document includes the Technical Guidance on the Preparation of an Inventory of Emissions, Discharges and Losses of Priority and Priority Hazardous Substances. The inventories will give information on the relevance of PS at the spatial scale of the RBD or the national part of an international RBD, and on the loads discharged to the aquatic environment, thus supporting MS in subsequent river basin management and WFD implementation.

- Guidance Document No. 32 on Biota Monitoring (the Implementation of EQSbiota) under the Water Framework Directive (2014)

This Technical Guidance Document aims to facilitate the implementation of environmental quality standards in biota under the Water Framework Directive by addressing in particular the sampling strategies appropriate for monitoring programmes designed to assess compliance with biota EQS.

- Guidance Document No. 33 on Analytical Methods for Biota Monitoring under the Water Framework Directive (2014)

This Technical Guidance Document on Analytical Methods for Biota Monitoring aims to facilitate the implementation of environmental quality standards (EQS) in biota under the Water Framework Directive by addressing the extraction and analytical processes required for the priority substances to be determined in biota samples. It complements Guidance Document No. 32, and the two documents together thereby address the requirement for guidance on biota monitoring mentioned in Article 3(8a) of Directive 2008/105/EC as amended by Directive 2013/39/EU.

In support of the EQSD implementation and enforcement of legislation via, the EU ensured a system of information exchange, the introduction of procedures for Member States to provide useful information for decision-making and improved access to information via a water information system (WISE). WISE is a partnership between the European Commission (DG Environment, Joint Research Centre and Eurostat) and the European Environment Agency, known as “the Group of Four”. DG Environment, leads the policy and strategic aspect of WISE. It liaises with Member States, especially on official reporting requirements of EU water legislation. For more information:<http://water.europa.eu>

5. COSTS

A significant cost of the entire EQS legal framework will be that of bringing the existing industrial and water treatment plants up to a level of operation that will allow them to be in full compliance with the EQS Directive, and reducing diffuse pollution from agriculture through implementation of agri-environmental measures (reduction of the use fertilisers and pesticides). It should be noted though that industrial installations and other relevant commercial activities have already been subject to similar control measures, such as introducing BAT, through the IED (2010/75/EU), the Waste Framework Directive and a number of chemical Directives.

Costs exclusively relating to the EQS Directive will mainly relate to monitoring requirements and the introduction of further EQS and priority substances.

There are specific costs for monitoring the priority substances. However, if national monitoring programmes are established for water pollution control and also in the context of environmental assessment, the additional cost should be relatively small and relate only to adding parameters to the suite of analysis undertaken. There may be additional costs to industry for improving their effluent discharges but also for agriculture contributing with diffuse pollution.

Table 17. Examples of implementation costs

<p>Initial set-up costs:</p> <ul style="list-style-type: none"> • establishment of the competent authority for WFD implementation; • complying with the EQS • identifying mixing zones (where deemed necessary) • identification of plants discharging dangerous substances; • establishment of data collection system and preparation of inventories of emissions, discharges and losses of priority substances • establishing a monitoring programme • training of staff in competent authority on issues such as monitoring, assessment methodologies or risk assessment, inspection and control • analysis of cost-efficient implementation ensuring synergies with WFD and other relevant EU legislation • pressures and impact assessment (Article 5 WFD) of discharges to estimate to what extent priority substances listed in Annex X to WFD and in Annex I, part A of EQS Directive are present in water bodies
<p>Capital expenditure:</p> <ul style="list-style-type: none"> • sampling and monitoring equipment (if not already available); • construction of new plants or upgrading of existing plants to meet EQS (and emission limit values under WFD) (born by industry and also falling under other industrial legislation such as Industrial Emissions Directive (2010/75/EU) and also from agri-industrial units);

- databases and reporting formats complying with requirements of EQS Directive, WFD and also with INSPIRE Directive, consistent with the guidance under the CIS (Common Implementation Strategy).

On-going costs:

- enforcement costs, including inspection and monitoring programmes;
- data processing for preparing the inventories of emissions, discharges and losses of priority substances, ensuring also consistency with the format provided by WFD, the INSPIRE Directive etc;
- reporting to the Commission also taking into account WISE (Water Information System for Europe) constituting the EU portal on water data and information collected by the EU.

Example of Cost Estimations in Member States:

Sweden: pursuant to a Swedish study by the EPA preparing for the implementation of the EQS Directive, the general view is that a lot of the costs for implementing this Directive are already incurred under the WFD. The costs for this particular Directive are mainly related to the monitoring of ensuring that all relevant parties comply with the EQS. The „water authorities” in Sweden are responsible for ensuring that the monitoring programme is being implemented but industrial operators will also to some extent be responsible for monitoring the compliance with the EQS through sampling of receiving water bodies (partly regulated through IED). To a large extent both issues relating to supervisory and necessary measures are already regulated by the WFD. However, the scale of the operational supervision, the necessary measures and the costs are affected by the EQS established.

More information about cost estimations for Sweden:

<http://www.swedishepa.se/>

UK: Costs to the UK environment agencies relating to new monitoring requirements have been estimated as £27.3 - £45.3 million over 20 years.

Source: *Explanatory Memorandum To The Water Environment (Water Framework Directive) (England And Wales) (Amendment) Regulation 2015* http://www.legislation.gov.uk/uksi/2015/1623/pdfs/uksiem_20151623_en.pdf

THE BATHING WATER DIRECTIVE

Official Title: Council Directive 2006/7/EEC concerning the quality of bathing water (OJ L 131, 5.2.76) (repealing Council Directive 76/160/EEC with effect from 31 December 2014), amended by:

Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four (OJ L 188, 18.7.2009.)

Council Directive 2013/64/EU of 17 December 2013 amending Council Directives 91/271/EEC and 1999/74/EC, and Directives 2000/60/EC, 2006/7/EC, 2006/25/EC and 2011/24/EU of the European Parliament and of the Council, following the amendment of the status of Mayotte with regard to the European Union (OJ L 353, 28.12.2013).

Implementing acts:

Commission Implementing Decision 2011/321/EU of 27 May 2011 establishing, pursuant to Directive 2006/7/EC of the European Parliament and of the Council, a symbol for information to the public on bathing water classification and any bathing prohibition or advice against bathing (OJ L 143, 31.5.2011)

2009/64/EC: Commission Decision of 21 January 2009 specifying, pursuant to Directive 2006/7/EC of the European Parliament and of the Council, ISO 17994:2004(E) as the standard on the equivalence of microbiological methods (OJ L 23, 27.1.2009)

95/337/EC: Commission Decision of 25 July 1995 amending Decision 92/446/EEC of 27 July 1992 concerning questionnaires relating to Directives in the water sector (OJ L 200, 24.8.1995)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Directive 2006/7/EC (the Bathing Water Directive) seeks to ensure the quality of bathing water throughout the EU, both for freshwater and coastal water bathing areas, in order to protect the environment and public health. Directive 2006/7/EC applies to surface waters that can be used for bathing except for swimming pools and spa pools, confined waters subject to treatment or used for therapeutic purposes and confined waters artificially separated from surface water and groundwater. This Directive replaces the previous Directive 76/160/EEC, which was repealed in its entirety on 31 December 2014.

The Directive defines two main parameters for analysis (intestinal enterococci and escherichia coli), instead of nineteen in the repealed Directive 76/160/EEC. These parameters are used to monitor and assess the quality of bathing water and to classify them. Other parameters could be taken into account, such as the presence of cyanobacteria or macro-algae.

The Bathing Water Directive provides for a simplified scope of monitoring and fewer parameters. It should be noted, however, that specific monitoring and regulatory requirements are set by Member States via the WFD and the MSFD (under their monitoring programmes), providing for administrative and regulatory control in the case of international river basin districts and in marine regions and sub regions. The WFD also classifies bathing waters as "protected areas" under Article 6 and Annex IV, for which specific protective measures are introduced under the WFD. The extensive provisions of the WFD on monitoring and classification are the main reason for introducing a more simplified monitoring scheme with fewer parameters and indicators.

The Directive contains a number of characteristic elements:

- monitoring, including the drawing up of a monitoring calendar comprising at least four samplings;
- assessment of bathing waters;
- classification, according to certain specific criteria, in one of four quality levels: poor, sufficient, good or excellent. The category "sufficient" is the minimum quality threshold that all Member States should attain by the end of the 2015 season at the latest;
- introduction of certain management measures, in particular banning bathing or posting a notice advising against it, providing information to the public, and suitable corrective measures where the quality is classified as "poor";
- determining the profile of bathing water at the latest by 2011, describing the area concerned, pollution sources, and the location of water monitoring points;
- providing the public with adequate information relating to the classification and description of bathing waters as well as information regarding protection measures, such as notices banning or advising against bathing.

So far Directive 2006/7/EC has been amended twice; Regulation (EC) No 596/2009 concerns provisions on regulatory procedure empowering Commission to adapt, in the light of scientific and technical progress, the methods of analysis for the parameters and sampling rules set out in Annex I and Annex V respectively, and to specify the EN/ISO standard on the equivalence of microbiological methods, whereas Directive 2013/64/EU amends Directive 2006/7/EC following the amendment of the status of Mayotte in regard to EU. Thus, France is the sole addressee of the later Directive.

In order to implement the Directive's provisions requiring timely information of the public during the bathing season, in particular notices banning or advising against bathing, the Commission adopted on 27 May 2011 a Decision 2011/321/EU establishing a symbol for information to the public on bathing water classification and any bathing prohibition. Further, Commission Decision 2009/64/EC specifies, pursuant to Directive 2006/7/EC of the European Parliament and of the Council, ISO 17994:2004(E) as the standard on the equivalence of microbiological methods.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Establish a framework allowing for more enhanced participatory processes, including more extensive consultation (more frequent and involving a wider range of people), especially in regard to the establishment, review and update of the lists of bathing waters according to Article 3(1). This public participation framework should make it clear how to participate and how to formulate suggestions, remarks or complaints (Art.11).
- Define a system to ensure that information is disseminated and promptly made available during the bathing season close to each area of bathing water, including information on applicable bathing water classification, possible bathing bans or advice against bathing, a general description of the bathing water based on the bathing water profile, notifications for waters subject to short-term pollution, and indications of where more detailed information can be obtained. The dissemination of the above information had to be achieved by the 2012 bathing season (Art. 12).
- Make sure that provisions of Decision 2011/321/EU establishing a symbol for information to the public on bathing water classification and any bathing prohibition are complied with.
- Identify relevant waters as "bathing water" and review and update this list annually to take account of newly identified bathing waters and to remove from the list those that no longer fulfil the requirements of the Directive as such (Arts. 1, 3 and 5).
- Establish bathing water profiles in accordance with Annex III and ensure that they are reviewed and updated according to the same annex (Art. 6(1)).
- Introduce a classification system for bathing waters by the end of the 2015 bathing season. Waters must be classified according to the following categories: "excellent", "good", "sufficient" and "poor" in accordance with the criteria set out in Annex II (Art. 5). "Poor" is for waters that entirely fail to reach the parametric values. "Excellent" is obtainable where the waters comply with the more stringent guide values for parametric values and if management measures have taken into account the range of recreational uses practised in the bathing area.
- Consider whether temporarily to classify bathing waters as "poor" beyond 2015 provided that all the conditions in Article 5(4) are complied with.
- Plan management measures to deal with unexpected situations that could have an impact on bathing water quality and bathers' health, including temporary bathing bans and the dissemination of information to the public (Art. 7).

2.2. Regulation

- Ensure the identification of all bathing waters and define the length of the bathing season before the first bathing season in 2008 (Art. 3(1)).
- Collect and compile sets of bathing water quality data through the monitoring of the parameters set out in Annex I (Art. 4(1)).
- Carry out bathing water quality assessments for each area of bathing water at the end of each bathing season, based on the bathing water quality data compiled for that bathing season as well as the three preceding seasons, in accordance with the procedures set out in Annex II. The set of data must comprise at least 16 samples or, in some special circumstances, 12 samples (Art. 4(2)).
- Ensure that all bathing waters reach at least the status of "sufficient" by the end of the 2015 bathing season (Art. 5(3)).
- Introduce appropriate measures in order to increase the number of waters classified as "good" or "excellent" (Art. 5(3)).
- Ensure that, for all bathing waters classified as "poor" beyond 2015, the following measures are taken: control measures (bans on or advice against bathing); the identification of causes and ways to achieve "sufficient" quality status; mitigating measures to prevent, reduce or eliminate the causes of pollution; and the alerting of the public by warning signs and other public information (Art. 5(4)).
- Where bathing waters have been classified as "poor" for five consecutive years, beyond 2015, Member States must introduce a permanent bathing prohibition or advice against bathing (Art. 5(4)(b)).
- Ensure that all potential bathers are duly informed about the quality of bathing waters and the pollution risks. A clear and simple symbol determined by the Decision 2011/321/EU needs to be placed close to each area of bathing water indicating the current bathing water classification and bathing water bans or advice against bathing.
- Ensure the availability and updating of information, using the most appropriate media and technologies, relating to the implementation of the Directive, including a list of bathing waters, the classification of each area of bathing water, monitoring results, information on the causes of pollution and measures taken to prevent the exposure of bathers to pollution in waters classified as "poor", and specifics regarding short-term pollution (Art. 12).
- Take additional precautionary measures for bathing waters having a potential for cyanobacterial proliferation, including monitoring to identify health risks and management measures to prevent exposure and to inform the public (Art. 8).

2.3. Monitoring

- Establish a monitoring calendar for each area of bathing water before each bathing season. Only temporary suspension of the monitoring calendar is allowed during abnormal situations (Art. 3(4) and (7)).
- Monitor the two key microbiological parameters set out in Annex I, complemented by visual inspection (algae bloom and oil) and pH measurement in freshwaters, in accordance with the requirements of Annex IV and the specifications regarding the selected monitoring point (Arts. 3 and 4).
- Implement appropriate monitoring if there is a risk of proliferation of algae. This include: taking management measures and providing information immediately if a proliferation of cyanobacteria (or blue algae) occurs as well as assessing health risks if there is a proliferation of macro-algae and /or marine phytoplankton. (Arts. 8 and 9)
- Introduce a monitoring regime providing for periodic sampling (Arts. 7, 10, 14 and Annex IV).
- Introduce the harmonised standards to be used in the handling, analysis, storage and transport of samples in order to reduce the risk of contamination of samples (Art. 3(9) and Annex V).
- Carry out visual inspections of bathing waters for pollution such as residues, plastic, rubber or any other waste, and take the necessary measures including information to the public (Art. 9(2)).
- Ensure that there is sufficient co-operation on the implementation of the Bathing Water Directive, also in relation to the WFD, in case of river basins that may result in transboundary impacts on bathing water quality (e.g. in terms of mitigating measures, management measures, classification) (Art. 10).

2.4. Reporting

- Member States must notify the Commission annually before the start of the bathing season of all bathing waters, justifying any change in definition. This should be done for the first time before the start of the bathing season in 2008 (Art. 13(2)).
- Report to the Commission on:
 - transposition, with texts of the main provisions of national law adopted to comply with Directive 2006/7/EC (Art. 18);
 - by 31 December for the preceding bathing season, the results of the monitoring, the bathing water quality assessment for each area of bathing water, and a description of significant management measures taken (bans, advice against bathing etc.) (Art. 13(1));
 - any temporary suspension of the monitoring calendar due to abnormal situations.
- Member States must submit written observations to the Commission on the report to be drawn up by the Commission on the results of the European epidemiological study and other scientific, analytical and epidemiological developments by 2014 (Art. 14(2)).

Provide reporting pursuant to Directive 91/692/EEC on standardising and rationalizing reports on the implementation of certain Directives relating to the environment provided in the questionnaires and formats set out in Decision 95/337/EC.

2.5. Additional Legal Instruments

A number of other legal instruments have particular relevance to the implementation of the Bathing Waters Directive. These include:

- Urban Waste Water Treatment Directive (91/271/EEC)
- Nitrates Directive (91/676/EEC)
- WFD (2000/60/EC)
- Reporting Directive (91/692/EEC)
- Directive on Access to Environmental Information (2003/4/EC)
- Directive on Public Participation (2003/35/EC)
- UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (the Aarhus Convention)
- Protocol on Integrated Coastal Management Planning to the Barcelona Convention (protection against marine pollution)
- EU principles on integrated coastal management planning
- MSFD (2008/56/EC)
- EQSD (2008/105/EC)

The issues of particular relevance are:

- The requirements of the Bathing Water Directive must be included in the programme of measures required under the WFD for river basin management plans.
- Implementation of the Urban Waste Water Treatment Directive will make a significant contribution to the bacteriological quality of bathing waters. However, depending on the particular situation, pollution from agricultural and industrial sources might provide a major negative impact on bathing water quality as well.

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks associated with implementation are set out in the checklist below. The tasks are grouped under key headings and arranged in chronological order wherever possible. General note should be taken of the changes to approach in relation to water protection that result from the WFD, and the possible need for new administrative structures to adequately meet the requirements for regulation on the river basin district basis, including, where applicable, on an international river basin district basis.

Table 18: Illustrative checklist with key implementation tasks

BATHING WATER DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Appoint a competent authority to take responsibility for implementing the Directive.
1.2	Appoint laboratory/laboratories to carry out analysis of samples of bathing water. The laboratory must be competent in the methods of analysis listed in the Directive.
1.3	Decide upon the criteria for the selection of bathing waters, and commence a survey of possible sites. Local councils often have knowledge of popular bathing places and may give guidance.
1.4	Plan management measures to deal with unexpected situations
1.5	Designate the chosen bathing areas.
1.6	Assess whether there is a need for waivers in accordance with the provisions of the Directive (certain exceptional conditions for allowing waters to be classified as "poor" and still remain in compliance).
1.7	Decide on the length of the bathing season, which will vary from country to country due to climatic conditions.
1.8	Establish a sampling and monitoring programme, which would include: <ul style="list-style-type: none"> • sampling points fixed in all designated bathing waters at the point where the highest density of bathing occurs. Prior knowledge of where most people bathe is needed to decide upon the precise sampling point. Once fixed, this should be the position at which all future samples are taken; • frequencies for carrying out sampling, complying at least with the minimum requirements of the Directive; • standard sampling methodology and analytical methods.
1.9	Introduce a classification system for bathing waters by the end of the 2015 bathing season. Waters must be classified according to the following categories: "excellent", "good", "sufficient" and "poor" in accordance with the criteria set out in Annex II. Establish a framework allowing for more enhanced participatory processes, including more extensive consultation (more frequent and involving a wider range of people), especially in regard to the establishment, review and update of the lists of bathing waters according to Article 3(1).
2	Regulation, Monitoring and Enforcement
2.1	Collect and compile sets of bathing water quality data through the monitoring of the parameters set out in Annex I.

2.2	Monitor the two key microbiological parameters set out in Annex I, complemented by visual inspection (algae bloom and oil) and pH measurement in freshwaters.
2.3	Establish bathing water profile to identify possible pollution. The profiles comprise an assessment of: the physical, geographical and hydrological characteristics of the bathing water and of other surface water in the catchment area; pollution and sources thereof and management measures.
2.4	Analyse the samples for the parameters specified in the annex, using methods, which are the same as, or equivalent to, those in the annex.
2.5	Use the results to assess compliance with the Directive at the end of each bathing season.
2.6	Ensure that all bathing waters reach at least "sufficient" status by the end of the 2015 bathing season.
2.7	Introduce appropriate measures to increase the number of waters classified as "good" or "excellent".
2.8	Ensure that, for all bathing waters classified as "poor", beyond 2015, the following measures are taken: control measures (bans on or advice against bathing); the identification of causes and ways to achieve "sufficient" quality status; mitigating measures to prevent, reduce or eliminate the causes of pollution; and alerting the public by warning signs and other public information.
2.9	Establish a monitoring calendar for each area of bathing water before each bathing season.
3	Preparation and Implementation of Improvement Plans
3.1	Where bathing waters fail the standards, determine the cause of the problem and what action is required to bring the waters into compliance. This may require investigation of inputs of pollutants from sewage treatment works, agricultural sources and run-off, industrial discharges or other sources.
3.2	As a result of the investigations, adopt the necessary measures to manage and eliminate pollution.
4	Technical Standards
4.1	Laboratories and laboratory methods should be subjected to regular quality control schemes, and the laboratories accredited to ensure inter-comparability of results as well as a sound basis for improvement schemes where necessary.
5	Preparation of Technical Advice and Guidance Notes
5.1	Prepare guidance on the identification of bathing waters. The Directive provides a definition of bathing waters, but the precise interpretation will depend upon local circumstances, as traditional practice as well as number might differ from country to country.
5.2	Prepare advice on the interpretation of the definition of exceptional weather or geographical conditions and how to assess natural enrichment, in order to ensure a coherent approach when assessing waivers.
5.3	Prepare and issue guidance on the analytical methods to be used in the laboratories, to supplement the information on the outline methods listed in the Directive.
6	Cross Border Communication
6.1	Where sea or inland freshwater bathing areas cross national boundaries, or may be affected by activities in other countries, establish means of communication between the countries on measures to be taken. The Commission may be involved in such discussions.

7	Reporting
7.1	Establish reporting systems and databases to ensure that the data are collected and collated on a national scale; the reporting to the Commission is done electronically, using a specific format. Establish a means of reporting to the public.
7.2	Report to the Commission on: <ul style="list-style-type: none"> • transposition, with the texts of the main provisions of national law adopted to comply with Directive 2006/7/EC; • by 31 December for the preceding bathing season, the results of the monitoring, the bathing water quality assessment for each area of bathing water, and a description of significant management measures taken (bans, advice against bathing etc.); and • temporary suspension of the monitoring calendar due to abnormal situations. Member States must notify the Commission annually before the start of the bathing season of all bathing waters, justifying any change in definition.
7.3	Provide reporting pursuant to Directive 91/692/EEC on standardising and rationalizing reports on the implementation of certain Directives relating to the environment provided in the questionnaires and formats set out in Decision 95/337/EC
8	Information to the public
8.1	Enable the public to obtain and to participate in water quality management. In this context the public should be able to make comments, suggestions or complaints. They may also participate in establishment, review and updating lists of water quality.
8.2	Ensure that adequate information is disseminated actively and that information is easily available during the bathing season. This concerns: the classification of water, prohibitions or advice against bathing using a symbols determined in Annex to the Decision 2011/321/EC; a general description of water in non-technical language; a description of the nature and duration of pollution.

3.2. Phasing Considerations

The main time-consuming tasks to implement this Directive are the following:

- establishment of the administrative arrangements to implement the Directive, including co-ordinating arrangements to ensure consistency with the WFD;
- identification of bathing waters by the competent authority;
- establishment and carrying out of the sampling and monitoring programme;
- identification of the causes of non-compliance; and
- preparation and implementation of a programme of improvement measures.

The time taken to establish the competent authority together with sampling, monitoring and data interpretation facilities will depend upon the existing institutional structure. The transposition of the legislation may be required before the planning can be undertaken.

Identifying bathing waters that fall within the remit of the Directive is often a lengthy process, requiring the collection of data on bathers using the waters, the investigation of local facilities, and discussions with local authorities. This phase should be introduced as early as possible.

Sampling and monitoring programmes for each area of bathing water will follow on from designation and should be instituted as soon as each area of bathing water is designated. Quite frequently one year's data alone might not be sufficient for a decision to establish an improvement plan.

The time taken to prepare an improvement plan may be considerable as it is not always easy to identify the causes of the problem and to determine strategies to resolve it. Taking account of the requirements for bathing waters to meet the quality standards the work required to prepare a plan for each area of water should be started as soon as possible after the first year's assessment.

4. IMPLEMENTATION GUIDANCE

4.1. Planning

- The competent authority has to identify bathing waters and carry out the sampling and monitoring programme, also taking into account the monitoring requirements under the WFD (2000/60/EC). This could be a national or locally based organisation. It should have sufficient resources to undertake a sampling and monitoring programme at all relevant waters, both inland and coastal locations, and analytical facilities to carry out bacteriological, chemical and physical testing of waters and to interpret the results.
- In view of the likely interaction between the results of testing and pollution control activities, in particular the need to assess what is required to bring waters up to standard, it is necessary that the required enforcement action against polluters can be taken without inadequate delay.
- To ensure sufficient compliance and to maximise efficiency and the wise use of resources, the candidate countries should implement the Bathing Water Directive in conjunction with other related water legislation, e.g. the Waste Water Treatment Directive (91/271/EEC), the Nitrates Directive (91/676/EEC), the WFD (2000/60/EC), the EQS Directive (2008/105/EC) and the MSFD (2008/56/EC). The Bathing Water Directive fits within the existing water-related framework in that the WFD provides for the objective of achieving the "good ecological status" of all waters and has specific objectives for "protected areas" such as bathing waters and that the MSFD obliges Member States with marine regions or sub-regions to take steps to achieve good environmental quality for marine waters. Furthermore, the Directive is consistent - in its provisions for the greater dissemination of and access to relevant information on the quality of bathing waters and the reasons for any detraction from the results to be achieved -- with Directive 2003/4/EC, and will take into account the principles of integrated coastal zone management.
- It is also crucial that this Directive is implemented and applied in close co-operation with the public and other stakeholders, including the dissemination of information regarding water quality, planned measures and monitoring results.

4.2. Monitoring

- It is necessary to obtain sufficient samples at the intervals set out in Article 3 and at appropriate monitoring points, according to the established monitoring calendar, to enable percentiles to be assessed. It should be borne in mind that specific compliance rates are required for the parameters. In cases where only the minimum number of samples is taken, the possibility for "failing" samples without the beach being assessed as "failing" is rather limited.
- Establish a standardised sampling protocol in accordance with Annex IV.

Implementation examples in some Member States

Ireland: *Legal framework*

The legislation governing the quality of bathing waters is set out in the Bathing Water Quality Regulations 2008 (SI No. 79 of 2008) which transposed the revised EU Directive on bathing water (2006/7/EC) that came into force on 24 March 2006.

Identifying Bathing Waters

Local authorities are required on or before 24 March each year to identify bathing waters in relation to the forthcoming bathing season and to notify the EPA of these. The local authority is required to identify a bathing water as, “all elements of surface water where the local authority expects a large number of people to bathe and where such water lies within the functional area of the authority or is immediately contiguous to the functional area of the local authority”. The Directive does not specifically define what constitutes a ‘large numbers of bathers’ so, in general, these identified waters are the more popular areas with adequate infrastructure such as car parking, toilets, and other facilities. Many smaller waters used for bathing are also monitored on a voluntary basis. Local authorities are required to ensure that appropriate measures have been taken in relation to public participation in the identification process.

Monitoring

The responsibility for sampling water quality (or arranging for sampling) at identified bathing waters lies with the relevant local authorities. They are required to establish a monitoring calendar for each identified bathing water and submit this to the EPA by 24 March each year. Sampling must be undertaken distributed evenly during the bathing season which extends from the 1st June until 15th September. A pre-season sample is required in late May approximately two weeks before the start of the season with a minimum of four samples to be taken during the season at the point of greatest bather density or where the greatest risk of pollution is expected in accordance with the bathing water profile. From 2011 onwards, two new microbiological parameters, Intestinal enterococci and Escherichia coli, have been monitored. Several studies have shown these bacteria to have a significant correlation between bathing and gastro-intestinal illness.

Reporting & Enforcement

The EPA’s Office of Environmental Assessment (OEA) is responsible for compiling the bathing water information and its submission to the European Commission. The Office of Environmental Enforcement (OEE), within the EPA, follows up on the cause of any bathing area failing the minimum EU mandatory values and the measures being taken by the relevant local authority to bring the bathing water into compliance. Local authorities are required to take the necessary measures to ensure that the standards are complied with and should a bathing water sample fail to meet the EU mandatory values that the public are notified. This is generally by means of advisory notices posted at the bathing water but other media may also be used. Local Authorities are required to report the results of sampling to the EPA during, and at the end of, each bathing season.

Source: <http://www.epa.ie/water/wm/bathing/background/#.VunK8Lfmqos>

Croatia

Legal framework

The legislation governing the quality of bathing waters is set out in the Regulation on sea bathing water quality (Official Gazette No. 73/08) and Regulation on bathing water quality (Official Gazette No. 51/14) which transposed the revised EU Directive on bathing water (2006/7/EC) that came into force on 24 March 2006.

Monitoring

The bathing season in Croatia is the period from 1 June until 15 September, unless due to weather conditions and local customs, the representative body of the county issues a decision on the bathing season lasting for a longer period of time. Monitoring of bathing water quality at sea beaches lasts from 15 May until 30 September. Before each bathing season the county is obliged to determine sampling points. Before the start of each bathing season the authorised person is obliged to determine monitoring calendar consistent with the relevant administrative body in the county. Bathing water monitoring has to start no later than four days from the date specified in the calendar.

Public information

Monitoring data are available for public on http://baltazar.izor.hr/plazepub/kakvoca?p_jezik=eng and <http://www.azo.hr/KakvocaMoraZa>

Moreover, users are allowed to make comments and suggestion considering each bathing water, to propose new sampling points, to get additional information of the beaches and even to report on possible sudden and short-term pollutions. The application for mobile phones, which makes uses of modern technologies, such as GPS was produced in 2012. Bathing water profiles are available for majority of bathing waters as well and the major parts of profiles are publicly available from 2014.

Source: BWD Report For the Bathing Season 2014 Croatia

4.3. Preparation of Bathing Water Profile

The Directive requires Member States to prepare a bathing water profiles, the description of bathing waters and the potential impacts and threats to water quality, both as an information for citizens and as an management tool for the responsible authorities. These bathing water profiles can cover one or more contiguous bathing waters. In order to support the member States in developing bathing water profiles a Guidance document 'Bathing water profiles: best practices and guidance' has been prepared and is available at: http://ec.europa.eu/environment/archives/water/report2011/profiles_dec_2009.pdf

5. COSTS

Table 19. Examples of implementation costs incurred

Initial set-up costs: <ul style="list-style-type: none">• establishment of competent authority;• establishment of laboratory facilities (if not already available);• identification of bathing waters;• sampling and analysis to establish compliance.
Capital expenditure: <ul style="list-style-type: none">• laboratory equipment (if not already available);• construction of infrastructure as part of improvement programme.
Ongoing running costs: <ul style="list-style-type: none">• annual sampling and monitoring programme;• annual operating costs of infrastructure;• administrative costs including reporting; information to the public.

Direct costs of implementation are related to the sampling and analysis programme and minor administration costs. After the first year's sampling programme has identified waters that fail the Directive, further direct costs are connected with work needed to identify the causes of failure and to propose solutions. This may involve the collection of far more detailed information in order to select the appropriate measures.

Indirect costs may be very substantial, but to a considerable extent they may overlap with those under other Directives such as the Urban Waste Water Treatment Directive (91/271/EEC).

FLOODS DIRECTIVE

Official Title: Directive 2007/60/EC of the European Parliament and of the Council of 23 October 2007 on the assessment and management of flood risks (OJ L 288, 6.11.2007)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The main aim of the Floods Directive is to reduce and manage the risks posed by floods to human health, the environment, cultural heritage and economic activity. The Directive establishes a framework for assessing, mapping and planning for the reduction of the risks of floods in Europe. Together with the Water Framework Directive, it reflects shift in regulating water management from simple flood defence to risk management approach.

The Directive covers all types of floods – including among other flood types, floods from rivers, mountain torrents, Mediterranean ephemeral watercourses, and also floods from the sea in coastal areas. The only types of flood which may be excluded from the scope of the Directive are floods from sewerage systems.

The Floods Directive requires Member States to take a long-term planning approach to reducing flood risks in three steps:

- Stage I: Preliminary flood risk assessment: Member States had to, by 22 December 2011, undertake a preliminary flood risk assessment to identify the river basins and associated coastal areas at potential risk of flooding. (Articles 4 and 5)
- Where real risks of flood damage exist or may be considered likely to occur, Member States had to, by 22 December 2013, develop flood hazard maps and flood risk maps showing the flood extent and assets and human populations at risk. (Articles 6 and 7)
- Finally, Member States had to, by 22 December 2015, develop flood risk management plans for these zones. These plans must include appropriate objectives and measures to reduce the probability of flooding and its potential consequences. They will address all phases of the flood risk management cycle but focus particularly on prevention, protection and preparedness. (Articles 7 and 8)

These three steps are to be repeated in a six-year cycle to ensure that long-term developments are taken into account.

The Directive shall be closely co-ordinated and synchronised with the implementation of the WFD, particularly through the co-ordination of flood risk management plans and river basin management plans, and through the co-ordination of the public participation procedures in the preparation of these plans. Member States shall, furthermore, co-ordinate their assessment and the management of flood risks in shared international river basins (with other Member States but also third countries outside the European Union), and, in solidarity, shall not undertake measures that would increase flood risks upstream or downstream in neighbouring countries.

The reporting will be carried out via WISE (Water Information System for Europe), available at: <http://cdr.eionet.europa.eu/>

A number of EEA reports and assessments have been developed on flooding issues, the latest is published in November 2012 - “River floods (CLIM 017)” and is available at the website of the EEA: <http://www.eea.europa.eu/data-and-maps/indicators/river-floods-1/assessment..>

Key messages of this report are:

- More than 325 major river floods have been reported for Europe since 1980; more than 200 have been reported since 2000.

- The rise in the reported number of flood events over recent decades results mainly from better reporting and from land-use changes
- Global warming has been projected to intensify the hydrological cycle and to increase the occurrence and frequency of flood events in Europe. However, estimates of changes in flood frequency and magnitude remain highly uncertain.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning and Regulation

- Consider which water-related legislation needs to be revised for the implementation of this Directive (Art. 17).
- Set up administrative arrangements -- identify the competent authorities (Art. 3). As a starting point, the river basin districts as identified for the WFD shall be used, however article 3 also allows for other units of management to be established.
- Set up a preliminary flood risk assessment to identify the river basins and associated coastal areas with potential significant flood risks or flood risks that might be considered likely to occur (Arts. 4 and 5).
- Ensure the exchange of relevant information from preliminary flood risk assessments between the competent authorities in international river basin districts (Arts. 4(3) and 5(2)).
- Develop flood hazard maps and flood risk maps for those areas where real risks of flood damage exist or might be considered likely to occur (Art. 6).
- Ensure the exchange of relevant information about the preparation of flood hazard and flood risk maps between the competent authorities in international river basin districts (Art. 6(2)).
- Establish flood risk management plans co-ordinated at the level of the river basin district (Art. 7).
- Establish appropriate objectives for the management of flood risks for those areas for which potential significant risks of flood damage exist or might be considered likely to occur (Art. 7(2)).
- Set up measures for achieving the appropriate objectives mentioned under Article 7(2)(Art. 7(3)).
- Address all aspects of flood risk management in the flood risk management cycle, focusing on prevention, protection and preparedness (Art. 7(3)).
- Ensure co-ordination with the aim of producing a single international flood risk management plan in international river basin districts shared with EU Member States (Art. 8(2)).
- Endeavour to produce a single international flood risk management plan in international river basin districts shared with third countries (Art. 8(3)).
- Establish appropriate steps for co-ordinating the application of Directive 2007/60/EC and Directive 2000/60/EC, focusing on opportunities for improving efficiency and information exchange and for achieving common synergies and benefits (Art. 9).
- Take into account the environmental objectives of Article 4 of the WFD, in particular in the framework of the development of flood hazard maps and flood risk maps as well as the development of the flood risk management plans and their review (Art. 9).
- Make available to the public preliminary risk assessments, flood hazard maps and flood risk maps, and flood risk management plans (Art. 10.1).

2.2. Consultation

- Co-ordinate the active involvement of all interested parties under the Floods Directive and interested parties under Article 14 of the WFD (Art. 9(3)).
- Encourage the active involvement of interested parties in the production, review and updating of the flood risk management plans (Art. 10(2)).

2.3. Reporting

- Make available to the European Commission the preliminary flood risk assessment, flood hazard and flood risk maps and flood risk management plans, as well as their review and, where applicable, their updates (Art. 15(1)).
- Inform the European Commission of decisions taken in accordance with the transitional measures in Article 13 (Art. 15(2)).
- Inform the European Commission about the bringing into force of the laws, regulations and administrative provisions necessary to comply with the Floods Directive (Art. 17(1)).
- Inform the European Commission about the text of the main provisions of national law adopted through the implementation of this Directive (Art. 17(2)).

2.4. Additional Legal Instruments

A number of other legislative instruments are closely linked to the assessment and management of flood risks and must be taken into account during the implementation of this Directive. This includes, in particular, the following legislative acts:

- WFD (2000/60/EC)
- MSFD (2008/56/EC)
- Council Regulation (EC) No. 2012/2002 of 11 November 2002 establishing the European Union Solidarity Fund (EUSF)
- 2007/779/EC, Euratom: Council Decision of 8 November 2007 establishing a Community Civil Protection Mechanism (recast)
- Industrial Emissions Directive (2010/75/EU)
- EIA Directive (2011/92/EC)
- Seveso III Directive (2012/18/EU)
- SEA Directive (2001/42/EC)

- Access to Environmental Information Directive (2003/4/EC)
- INSPIRE Directive (2007/2/EC)

The management of flood risks is an important component of climate change adaptation, and the Floods Directive therefore requires Member States to take climate change into account in the framework of the preliminary flood risk assessment, depending on their specific needs (Art. 4), as well as in the reviews of the preliminary flood risk assessment and flood risk management plans referred to in Article 14(1) and 14(3) (Art. 14(4)).

3. IMPLEMENTATION GUIDANCE

3.1. Key Tasks

The main tasks under the Directive include the preliminary flood risk assessment, the establishment of flood hazard maps and flood risk maps, as well as the setting up of flood risk management plans.

Member States had to carry out a preliminary assessment of risks for each river basin district or part of a district lying within their territory by 22 December 2011. This assessment must include information on the boundaries of river basins in the district concerned, floods that have occurred in the past, the likelihood of future floods, and the estimated adverse consequences for human health, the environment, cultural heritage and economic activity. This assessment of river basins must be published and reviewed by 22 December 2018 and every six years thereafter.

Where real risks of flood damage exist or might be considered likely to occur Member States must set up flood hazard and flood risk maps identifying all areas at risk of flooding and indicating the probability (high, medium or low) of flooding for each of those areas as well as the potential damage to inhabitants, economic activities and the environment. These maps must be drawn up and published by 22 December 2013 at the latest and reviewed every six years.

On the basis of the maps, Member States shall develop and implement flood risk management plans for each river basin district. Where the area concerned lies within an international river basin, Member States should cooperate in preparing a single flood risk management plan.

Member States shall establish appropriate objectives for the management of flood risks. In the flood risk management plans, Member States shall include measures for achieving these objectives, focusing on reducing the probability and the potential consequences of flooding. Those measures will address all phases of the flood risk management cycle but focus particularly on prevention (e.g. by avoiding the construction of houses and installations in present and future flood plain areas or by adapting future enlargement to the risk of flooding); protection (e.g. by taking measures to reduce the probability of floods and/or the impact of floods in a specific area, such as restoring flood plains and wetlands); and preparedness (e.g. making available instructions to the public on what to do and how to react in the event of flooding). In addition, flood risk management plans shall take into account relevant costs and benefits, flood extent and flood conveyance routes, the environmental objectives of Article 4 of the WFD, soil and water management, spatial planning, land use, nature conservation, navigation and port infrastructure. Flood risk management plans must be completed and published by 22 December 2015 and reviewed every six years.

All preliminary flood risk assessments, flood hazard and flood risk maps, as well as flood risk management plans shall be made available to the public. Member States shall encourage the active involvement of interested parties in the production, review and updating of the flood risk management plans.

As a transitional provision, assessments, maps and plans available before 22 December 2010 can be used for the first implementation cycle, provided these instruments provide equivalent information (Art 13(1)(a), 13(2) and 13(3)). It is also possible to opt out of the first step (to undertake the preliminary flood risk assessment with a view to identify areas of potential significant flood risk for river basins or coastal areas, provided that flood maps according to article 6 are prepared for the whole territory of theopt out. This is therefore not an exemption. (Art 13(1)(b))

The key tasks involved in implementing this Directive are summarised in the Table below.

They are arranged under subheadings and organised in chronological order of implementation whenever possible.

Table 20. Illustrative checklist with key implementation tasks

THE FLOODS DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Transpose the Directive into national legislation. Consider what water-related legislation needs to be revised for the implementation of this Directive (Art. 17).
1.2	Set up administrative arrangements -- identify the competent authority/ies and if applicable other units of management (UoM) than for the WFD (Art. 3).
1.3	Carry out a preliminary flood risk assessment to identify the river basins and coastal areas where there is a potential significant risk of floods or where the risk of flooding might be considered likely to occur (Arts. 4 and 5).
1.4	Ensure the exchange of relevant information from the preliminary flood risk assessment between the competent authorities in international river basin districts (Arts 4.3 and 5.2).
1.5	Establish appropriate steps for co-ordinating the application of Directive 2007/60/EC and Directive 2000/60/EC, focusing on opportunities for improving efficiency and information exchange and for achieving common synergies and benefits (Art. 9).
1.6	Take into account the environmental objectives of Article 4 of Directive 2000/60/EC, in particular in the framework of the development of flood hazard maps and flood risk maps as well as the development of flood risk management plans and their review (Art. 9). Make available to the public the preliminary risk assessment, flood hazard maps and flood risk maps, and flood risk management plans (Art. 10.1).
1.7	Develop flood hazard maps and flood risk maps for those areas where significant flood risks exist or might be considered likely to occur (Art. 6).
1.8	Ensure the exchange of relevant information about the preparation of flood hazard and flood risk maps between the competent authorities in international river basin districts (Art. 6.2).
1.9	Establish flood risk management plans co-ordinated at the level of the river basin district (Art. 7).
1.10	Ensure co-ordination with the aim of producing a single international flood risk management plan in international river basin districts shared with EU Member States (Art. 8.2).
1.11	Endeavour to produce a single international flood risk management plan in international river basin districts shared with third countries (Art. 8.3).
1.12	Establish appropriate objectives for the management of flood risks for those areas where significant risks of flood damage exist or might be considered likely to occur (Art. 7.2).
1.13	Set up measures for achieving the appropriate objectives mentioned under Article 7.2 (Art. 7.3).
1.14	Address all aspects of flood risk management in the flood risk management cycle focusing on prevention, protection and preparedness (Art. 7.3).

2	Consultation
2.1	Co-ordinate the active involvement of all interested parties under the Floods Directive and interested parties under Article 14 of Directive 2000/60/EC (Art. 9.3).
2.2	Encourage the active involvement of interested parties in the production, review and updating of the flood risk management plans (Art. 10.2).
3	Reporting
3.1	Inform the European Commission about the bringing into force of laws, regulations and administrative provisions necessary to comply with the Floods Directive (Art. 17.1).
3.2	Inform the European Commission about the text of the main provisions of national law adopted through the implementation of this Directive (Art. 17.2).
3.3	Inform the European Commission of decisions taken in accordance with the transitional measures in Article 13 (Art. 15.2).
3.4	Make available to the European Commission the preliminary flood risk assessment, flood hazard and flood risk maps and flood risk management plans, as well as their review and, where applicable, their updates (Art. 15.1).

3.2. Co-ordination in International River Basins

In the case of international river basins, Member States need to co-ordinate their action so that problems are not passed on from one Member State to another. In international river basins shared by Member States, Member States shall ensure co-ordination with the aim of producing a single international flood risk management plan for international river basin districts (Art. 8(2)). Where an international river basin is shared with third countries outside the European Union, Member States shall endeavour to produce a single international flood risk management plan co-ordinated at the level of the international river basin district (Art. 8(3)).

In addition, Member States - in the interests of solidarity - shall not include measures in their flood risk management plans that could significantly increase flood risk upstream or downstream in other countries in the same river basin, unless the measures have been co-ordinated and agreed among all Member States concerned in the framework of the above-mentioned activities to produce a single flood risk management plan in an international river basin (Art. 7(4)).

3.3. Co-ordination with the WFD

As the development of flood risk management plans under the Floods Directive and river basin management plans under the WFD are both elements of integrated river basin management, a strong linkage in the implementation of these two Directives is of utmost importance in order to avoid the duplication of efforts and the overlapping of procedures and institutions, to reduce costs and to maximise synergies and benefits.

The Floods Directive therefore includes a number of links with the WFD to ensure close co-ordination and consistency between the two implementation processes:

- The timetable of implementation cycles and reporting mechanisms should be co-ordinated and synchronised, in particular:
 - the deadlines for the development of flood hazard and flood risk maps are in line with the date of the first review of the pressure and impact analysis under Article 5 of the WFD;
 - the deadlines for the development of flood risk management plans are in line with the date of the first review of river basin management plans under Article 13 of the WFD.
- Actions should be carried out at the level of the river basin district (which includes not just river basins and sub-basins but also coastal areas).
- Co-ordination and the exchange of information in international river basins (shared with Member States, but also with third countries outside the European Union) are required.
- Member States shall make use, if they choose to do so, of the administrative arrangements and in particular the appointment of the competent authority for implementation made under Article 3 of the WFD.
- A link should be established between the three-step approach of the Floods Directive (the development of a flood risk assessment, flood hazard and flood risk maps as well as flood risk management plans) and the WFD, notably the environmental objectives of Article 4 of the WFD in the plans.
- The public participation and information mechanisms of the WFD shall be used: as the key tasks of the Floods Directive shall be made available to the public, further synergies can be set up with the electronic reporting mechanisms via the Water Information System for Europe (WISE).

3.4. Guidance Documents

To support the implementation of the Floods Directive, the EU Working Group on Floods (WG F) has been established under the Common Implementation Strategy (CIS). The Floods Working Group work programme for the period between 2016 and 2018 is expected to focus, inter alia, on the following issues:

- Support to MS, based on information exchange of good practice, in the implementation of the Floods Directive through the 2nd cycle, including reporting on the FRMPs (2016) and the review of the PFRA (2018);
- Meeting reports of WG F and reports of Short Workshops and of Thematic Workshops and/or ad-hoc documents on themes relevant to the implementation of the Floods Directive, subject to agreement on mandates for specific tasks;
- Revised reporting schema and tools (2017), if and as appropriate;
- Resource Documents;
- Further develop links with, and provide inputs to, other flood-related European Commission activities.

Several documents providing support in the implementation of the Floods Directive have been developed:

- UNECE 2009, Transboundary Flood Risk Management: Experiences from the UNECE Region, United Nations, New York and Geneva:
http://www.unece.org/fileadmin/DAM/publications/oes/Transboundary_Flood_Risk_Management_Final.pdf
- EU Water Directors (2003) Guidance document on Public Participation. Final version after the Water Directors' meeting. December 2002: http://www.eau2015-rhin-meuse.fr/fr/ressources/documents/guide_participation-public.pdf
- WG F: Resource document on flood risk management, economics and decision making support: http://ec.europa.eu/environment/water/flood_risk/pdf/WGF_Resource_doc.pdf
- Links between the Floods Directive (FD 2007/60/EC) and Water Framework Directive (WFD 2000/60/EC): <https://circabc.europa.eu/sd/a/124bcea7-2b7f-47a5-95c7-56e122652899/inks%20between%20the%20Floods%20Directive%20and%20Water%20Framework%20Directive%20-%20Resource%20Document>
- EXCIFF Guide: Good Practice for Delivering Flood-related Information to the General Public, http://publications.jrc.ec.europa.eu/repository/bitstream/11111111/4752/1/7224%20-%20EUR%2022760%20FINAL%20-%20FF%20guide_plus_annexes.pdf
- Handbook of good practices in flood mapping, an as part of that an Atlas of Flood Maps, with examples from 19 European countries, USA and Japan, http://ec.europa.eu/environment/water/flood_risk/flood_atlas/index.htm
- Member States' examples of Flood Hazard and Flood Risk Maps Document prepared for the 2015 EU Water Conference, http://ec.europa.eu/environment/water/flood_risk/pdf/MS%20examples.pdf
- CIS Guidance Document No. 29: A compilation of reporting sheets adopted by Water Directors Common Implementation Strategy for the Water Framework Directive (2000/60/EC), https://circabc.europa.eu/sd/a/acbcd98a-9540-480e-a876-420b7de64eba/Floods%20Reporting%20guidance%20-%20final_with%20revised%20paragraph%204.2.3.pdf

Furthermore, the CIRCABC platform is used to share documents (including meeting documents) under the WFD Common Implementation Strategy (CIS) and can be accessed here:

<https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp>

3.5. Timetable for Action

Table 21. Timetable for action

Issue	Deadline	Reference
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Entry into force of Directive	26 November 2007	Article 18
Transposition of Directive	26 November 2009	Article 17
Administrative arrangements to be in place and notified to the Commission	26 May 2010	Article 3
Deadline for availability of existing assessments maps and plans for the first cycle	22.12.2010	Article 13
Preliminary flood risk assessment	22 December 2011	Articles 4 and 5
Flood hazard and flood risk maps	22 December 2013	Article 6
Flood risk management plans	22 December 2015	Article 7
Review and update of preliminary flood risk assessment, specific requirement on climate change	22 December 2018	Article 14.1 and 14.4
Review and update of flood hazard and flood risk maps	22 December 2019	Article 14.2
Review and update of flood risk management plans, specific requirement on climate change	22 December 2021 ²²³	Article 14.3 and 14.4

These steps--the development of a preliminary flood risk assessment, the development of flood hazard and flood risk maps, as well as the development of the flood risk management plans--need to be reviewed every six years in a cycle co-ordinated and synchronised with the WFD.

Institutional Arrangements for Implementing the Floods Directive

In the UK, the two main central authorities involved in the implementation of the Floods Directive are the Environment Agency and the Department for Environment, Food and Rural Affairs (Defra).

The Environment Agency is the competent authority for the implementation of the WFD and will most probably be the lead competent authority for the Floods Directive. It also plays a key role in advising local authorities and regional planning bodies on flood risk issues via strategic documents such as catchment flood management plans. The local authorities and planning bodies should work in partnership with planners to achieve sustainable solutions within local communities. This will support an integrated approach to spatial planning and river basin management, in line with the WFD and the Floods Directive on the assessment and management of risk. Defra is co-ordinating the transposition of the Directive into UK law and is ultimately responsible for its timely and compliant implementation. A UK Floods Directive liaison group has been set up to monitor progress against the project timetable which, for the UK, is set out below. (Source: <http://www.defra.gov.uk/consult/files/epac-rlfac-consult-annexd.pdf>)

²²³The update of the flood hazard and flood risk maps and of the flood risk management plans will continue beyond 2021.

Examples of Member States incorporating the Floods Directive in the RBMPs: the UK undertook preliminary climate checks of the WFD measures needed to reduce pressures on the water environment and an assessment of the impact on flood risk was included in this preliminary climate check. France's RBMPs include a chapter on flood prevention (general principles), which will be updated in the next cycle (2015) and will be integrated in the FRMP in order to ensure the coherence between the two documents (WG F 2013). Also, in the Netherlands, both strategic plans (National Water Plan and Regional Water Plan of the provinces), the operational plans of the central and regional water authorities (water boards), deal with both water quality, water quantity and flood protection.

Source: Bakker, M.H.N, Green, C, Driessen, P, Hegger, D, Delvaux, B, Van Rijswick, M, Suykens, C, Beyers, J.C, Deketelaere, K, Van Doorn-Hoekveld, W & Dieperink, C 2013, Flood Risk Management in Europe: European flood regulation, STAR-FLOOD Consortium, Utrecht, The Netherlands. ISBN: 978-94-91933-04-2

Examples of integrating public participation between the Floods Directive and WFD

Bulgaria intends to consult simultaneously for both the RBMPs and FRMPs by using one web-site, concurrently sending information and publications to the media, and joint public opinion surveys to ask questions and seek solutions.

Latvia envisages joint RBMP and FRMP public consultation activities and procedures, involving consultative boards established in each RBD.

Austria's coordinated public information and consultation of RBMPs and FRMPs will be managed at a national level, supported by CAs in the nine federal states and at a regional level as appropriate.

Scotland intends to use Local Advisory Groups to engage with FD stakeholders that cover the same areas as RBMP Area Advisory Groups to maximise opportunities for coordination and information exchange.

France intends to consult simultaneously for both RBMPs and FRMPs

Romania uses the same institutional framework of River Basin Committees for WFD and FD public information and consultation set up for each River Basin Administrations.

Slovenia uses a RBMP Common Water Communication Strategy that covers different water related issues, which will include appropriate PFRA results in to the WFD consultation activities.

Source: Technical Report - 2014 - 078 Links between the Floods Directive (FD 2007/60/EC) and Water Framework Directive (WFD 2000/60/EC) Resource Document

4. COSTS

Floods have consequences on the economy, human health, the environment and cultural heritage. Flood risk management must be part of an integrated and sustainable water management. The Floods Directive is closely connected to the Water Framework Directive 2000/60/EC. Both directives make explicit and implicit references to economic assessments. Economic analysis is the key element in flood risk assessment and in selecting and prioritising measures to combat flood risks.

THE MARINE STRATEGY FRAMEWORK DIRECTIVE

Official Title: Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for Community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008)

2010/477/EU: Commission Decision of 1 September 2010 on criteria and methodological standards on good environmental status of marine waters (OJ L 232, 2.9.2010)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The Marine Strategy Framework Directive 2008/56/EC (MSFD) establishes minimum requirements for EU Member States to develop strategies aiming to protect the marine ecosystem and to ensure human activities linked to the marine environment are sustainable, the so-called 'marine strategies'. The Directive aims to ensure cooperation within the marine regions (North-East Atlantic Ocean, Baltic Sea, Mediterranean Sea and Black Sea) or subregion by following a common approach as regards the different elements of the marine strategies. These strategies include measures to meet agreed targets to allow the achievement of 'good environmental status' in the marine environment by 2020. It also contributes to the creation of a global network of marine-protected areas and launches a dialogue with countries outside the EU.

The Marine Strategy Framework Directive requires Member States to assess the environmental status of their marine waters and the impact of human activities (including a socioeconomic analysis), determine Good Environmental Status (GES) for their marine waters, set environmental targets, establish monitoring programmes and design and implement programmes of measures to achieve or maintain GES by 2020, using an ecosystem-based approach to marine management. It takes account both of socioeconomic factors and the cost of taking action in relation to the scale of the risk to the marine environment.

GES involves protecting the marine environment, preventing its deterioration and restoring it where practical, while using marine resources sustainably. The Directive sets out 11 high-level qualitative descriptors of Good Environmental Status, which cover all the key aspects of the marine ecosystem and all the main human pressures on them (Article 3(5) of MSFD).

GES will be achieved through marine strategies, applying an ecosystem-based approach to the management of human activities, which will be developed to:

- protect and preserve the marine environment, prevent its deterioration or, where practicable, restore marine ecosystems in areas where they have been adversely affected;
- prevent and reduce inputs in the marine environment with a view to phasing out pollution and to ensure that there are no significant impacts on or risks to marine biodiversity, marine ecosystems, human health or legitimate uses of the sea,
- that the capacity of marine ecosystems to respond to human-induced changes is not compromised, while enabling the sustainable use of marine goods and services by present and future generations.

In drawing up their strategies, Member States were required to:

- Assess current state of their waters by 15 July 2012;
- Determine a set of detailed characteristics of Good Environmental Status, associated targets and indicators by 15 July 2012;
- Establish and implement by 15 July 2014 a monitoring programme for the on-going assessment of their marine waters and to measure progress toward Good Environmental Status;
- Establish a programme of measures for achieving Good Environmental Status by December 2015.

The MSFD requires Member States to report these different elements to the Commission 3 months after their establishment and to update their strategies every six years.

The MSFD divides Europe's waters into four marine regions: (a) the Baltic Sea; (b) the North-east Atlantic Ocean; (c) the Mediterranean Sea; (d) the Black Sea, which are, for the North-east Atlantic Ocean and the Mediterranean Sea, further divided into sub regions. On the basis of these regions GES had to be determined using the qualitative descriptors in Annex I.

In terms of geographic scope, the MSFD applies to all marine waters as defined below, also taking into account the transboundary effects on the quality of the marine environment of third States in the same marine region or sub region:

- waters, the seabed and subsoil on the seaward side of the baseline from which the extent of territorial waters is measured extending to the outmost reach of the area where a Member State has and/or exercises jurisdictional rights, in accordance with UNCLOS
- coastal waters as defined by the WFD, their seabed and their subsoil, in so far as particular aspects of the environmental status of the marine environment are not already addressed through WFD and other EU legislation.

Pursuant to the MSFD and, in particular, Art. 9(3), the European Commission set down criteria and methodological standards to allow consistency in approach in evaluating the extent to which Good Environmental Status (GES) is being achieved. Hence, Commission Decision 2010/477/EU was adopted, which provides more detailed criteria and indicators of Good Environmental Status, which Member States must use when implementing the Directive. In accordance with Article 9, it is ultimately for Member States to determine the characteristics of GES and therefore define the precise specifications of this central MSFD objective. In its 2014 report²²⁴ on the implementation of the first phase of the Directive, the Commission set itself the task to review this Decision given the implementation of the MSFD had proven to be inconsistent and incoherent across the EU.

MSFD entered into force in July 2008 and its requirements had to be transposed by the Member States by 15 July 2010.

There are several links and partial overlaps with other important legislation, such as the WFD, Habitat and Birds Directives as well as international and regional sea conventions, which need to be taken into account in the planning of the legislative framework, in the designation and monitoring of marine protected areas. Overlaps also exist with legislation adopted after the MSFD itself, notably the Common Fisheries Policy and the Maritime Spatial Planning Directive.

²²⁴ COM(2014)97

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- For Member States with marine waters, ensure full transposition the MSFD (Art. 26(1), MSFD).
- Establish competent authorities with respect to their marine waters and for cooperation and coordination in the catchment area of each marine region or subregion. (Art. 7, MSFD). For this Member States can use or extend existing structures or creating new ones.
- Ensure interaction and coordination of efforts for marine protection areas in areas which already have been designated under the Habitats Directive (92/43/EC) and the Birds Directive (2009/147/EC)
- Develop a coherent approach to the marine strategy by already in the preparatory stage integrate the criteria for the achievement of good environmental status set out in Decision 2010/477/EC
- Decide whether to divide marine regions into sub-divisions, provided that these divisions are compatible with the marine subregions set out in Article 4(2). These subdivisions may be revised upon completion of the initial assessment (was due in 2012).
- Develop a marine strategy for its marine waters, based on each marine region or subregion concerned, having regard to the following stepped approach for preparation and programme of measures set out in Art. 5(2). Where marine regions and subregions are shared by Member States these measures should be implemented in close cooperation ensuring efficient coordination. (Art. 5, MSFD)
- Carry out an initial assessment of the status of waters and the environmental impact of human activities, which shall be subject to review/update every six years and to prior public consultation. The assessment shall include:
 - an analysis of the essential features and characteristics, and current environmental status of those waters, based on the indicative lists of elements set out in Table 1 of Annex III, and an analysis of the predominant pressures (qualitative and quantitative) and impacts, including human activity, on the environmental status based on the indicative lists of elements in Table 2 of Annex III, trends and cover the main cumulative and synergetic effects;
 - an economic and social analysis of the use of those waters.
 - build on assessments already undertaken under the WFD and other relevant EU legislation in terms of coastal, transitional and territorial waters as well as assessments carried out at international or regional level under sea conventions
 - carry out sufficient coordination to ensure assessment methodologies are consistent across the marine region or subregion. (Arts. 5, 8, 17 and 19)
- Determine GES for the water concerned, subject to review and update every six years and subject to prior public consultation, which:
 - take into account the initial assessment (Art. 8);
 - are based on the qualitative descriptors listed in Annex I

- taken into account the indicative lists of elements set out in Table 1 of Annex III and, in particular, physical and chemical features, habitat types, biological features and hydro-morphology;
 - take into account the pressures or impacts of human activities in each marine region or subregion, having regard to the lists in Table 2 of Annex III;
 - apply the criteria and methodological standards set out in the Annex to Decision 2010/477/EC. (Articles 5, 9, 17 and 19)
- Establish a comprehensive set of environmental targets and associated indicators for the marine waters of each marine region or subregions, which shall be subject to review/update every six years and subject to prior consultation. The targets should take into account:
 - the initial assessment under Art. 8;
 - the indicative lists of pressures and impacts set out in Table 2 of Annex III, and of characteristics set out in Annex IV;
 - existing environmental targets laid down at national, EU or international level in respect of the same waters, ensuring that they are compatible;
 - relevant transboundary impacts and transboundary. (Articles 5, 10, 17)
 - Establish and implement, on the basis of the initial assessment (Art. 8(1)), coordinated monitoring programmes for the ongoing assessment of the environmental status of their marine waters on the basis of the indicative lists of elements set out in Annex III and the list set out in Annex V, and by reference to the environmental targets established pursuant to Article 10.
 - Develop a programme of measures designed to achieve or maintain GES for each marine region or subregion concerned by December 2015. This programme has to involve prior consultation of the public and key stakeholders, and be put into operation at the latest by 31 December 2016 and be subject to review every six years. The programme of measures should:
 - be based on the initial assessment and the environmental targets also taking into consideration the types of measures listed in Annex VI;
 - take an integrative approach also taking into account relevant measures required under other EU legislation as well as international agreements;
 - give due consideration to sustainable development and, to the social and economic impacts of the measures envisaged;
 - be cost-effective and technically feasible and any new measure should be introduced only after being subject to impact assessments and cost-benefit analyses;
 - include spatial protection measures, contributing to coherent and representative networks of marine protected areas (having regard to areas protected under Habitats and Birds Directive and those protected under international or regional seas agreements);
 - explain how the measures will be implemented and how they will contribute to the achievement of the environmental targets;

- ensure that the measures have as small risk as possible for damage to neighbouring marine waters. (Arts. 5,13, 17 and 19)).
- Establish a plan of action, which includes early entry into force of programme of measures and possibly stricter measures in case of marine regions or sub-regions being shared with other Member States, where the status of the sea is critical and require urgent action. (Art. 5(3))
- Ensure efficient regional cooperation:
 - for marine regions and subregions shared by Member States the preparation and programme of measures should be implemented in close cooperation (Art. 5, MSFD);
 - use relevant international forums, including mechanisms and structures of Regional Sea Conventions, for the purpose of establishing and implementing marine strategies to coordinate their actions with third countries in the same marine region or subregion (Art. 6(2));
 - build upon relevant existing programmes and activities stemming from international agreements such as Regional Sea Conventions (Art. 6(2));
 - extended cooperation and coordination, where possible, to all Member States in the catchment area of a marine region or subregion, including land-locked countries, to optimise the compliance with the MSFD, using the cooperation structures set out in MSFD or the WFD. (Art. 6(2))

2.2. Regulation

- Consider to what extent the exceptions set out in Article 14 need to be used: 1) action or inaction for which the Member State concerned is not responsible; 2) natural causes; 3) force majeure; 4) modifications or alterations to the physical characteristics of marine waters brought about by actions taken for reasons of overriding public interest which outweigh the negative impact on the environment, 5) natural conditions which do not allow timely improvement in the status of the marine waters concerned. In such case it has to be ensured that:
 - these situations are being clearly identified in the programme of measures;
 - ad-hoc measures are being taken to progress towards the environmental targets and avoid further deterioration of the water status;
 - modifications or alterations covered by point 4 do not prevent the achievement of good environmental status at the level of the marine region or subregion;
 - the transboundary effects affecting other Member States are mitigated;
 - the Commission is informed about such cases, action taken and justification for lack of action. (Art. 14)
- Ensure that for each marine region or subregion concerned, marine strategies are kept up-to-date (Art. 17). This review shall be carried out every six years after their initial establishment in a coordinated manner of the following elements of the marine strategy:

- the initial assessment and the determination of GES;
- the environmental targets;
- the monitoring programmes;
- the programmes of measures.

2.3. **Monitoring**

- Establish and implement a monitoring programme for ongoing assessment of the environmental status of the marine waters and regular updating of targets (was due in July 2014). This monitoring programme should:
 - be based on the initial assessment pursuant to Article 8(1);
 - take into account the indicative lists of elements set out in Annex III and the list set out in Annex V, and by reference to the environmental targets pursuant to Article 10;
 - be compatible with EU provisions for assessment and monitoring laid down by EU legislation (e.g. under the Habitats and Birds Directives) or under international agreements;
 - for shared marine regions or subregions be coordinated to ensure consistency in monitoring results and taking into account relevant transboundary impacts and transboundary features;
 - apply the specifications and standardised methods for monitoring and assessment to be adopted by the Commission pursuant to Art. 25(3). (Articles 5 and 11)

2.4. Consultation and Reporting

- Consult with all interested parties to allow early and effective opportunities to participate in the implementation of the Directive, involving, existing management bodies or structures (e.g. Regional Sea Conventions, Scientific Advisory Bodies and Regional Advisory Councils).
- Publish, and make available to the public for comment, summaries of the key elements of their marine strategies (initial assessment, determination of GES, environmental targets, monitoring programmes and programmes of measures) and their updates. (Art. 19(2))
- Apply the provisions of the Directive on Access to Environmental Information (2003/4/EC) to documents produced under MSFD.

2.4.1. Reporting

- Inform the Commission of any subdivisions of marine waters (Art. 4(2), MSFD)
- Inform the Commission of cases of early entry into force of programme of measures in case of shared marine regions where the status of the sea is critical and require urgent action. Also invite the Commission to provide input, such as making the region a pilot project for enhanced efforts. (Art. 5(3), MSFD)
- Provide the Commission with a list of the competent authorities:
 - designated for implementing the MSFD;
 - designated for for cooperation and coordination pursuant to Art. 6 of the MSFD;
 - already designated for implementing international and regional conventions .
- Submit the data referred to in Annex II of the MSFD.
- Inform the Commission of changes to the information on designated authorities within six months after the change (Art 7(2))
- Notify the Commission of the initial assessment (under Article 8(1)) by three months after their establishment. (Art. 9(2))
- Notify the Commission of the determined set of characteristics for GES for each marine region or subregion. (Art. 9(2))
- Notify the Commission of the environmental targets. (Art. 10(2))
- Notify the Commission of the monitoring programmes. (Art. 11(3))
- Notify the Commission of the programme of measures within three months of their establishment. (Art. 13 (9)).
- Inform the Commission, as part of the notification on the programme of measures, about using the exceptions set out under Article 14 regarding certain unexpected situations where only some of the measures can be carried out or whether there could be certain time derogations considered in implementing the provisions relevant to achieving the GES. The notification shall include justifications. (Art. 14)

- Inform the Commission and provide it with justified views about issues which has an impact on the environmental status of its marine waters and which cannot be tackled by measures adopted at national level. Where considered necessary, a Member State can make recommendations to the Commission and the Council for EU-level measures regarding such issues. (Art. 15)
- Provide the details of any updates to the various elements of the marine strategies following the review required under Art. 17(2) to the Commission, to the Regional Sea Conventions and to any other Member States concerned within three months of their publication. (Art. 17(3))
- By 2013 at the latest, make publicly available, in respect of each marine region or subregion, relevant information on the protected areas referred to in Art. 13 paragraphs 4 and 5
- Allow the Commission access to spatial information deriving from this Directive, especially regarding data from the initial assessments and the monitoring programmes, allowing it to carry out its obligations under the INSPIRE Directive (2007/2/EC). Also the European Environmental Agency should be allowed to access information. (Article 19)(3))

2.5. Additional Legal Instruments

A number of other legal instruments are linked to the MSFD, and should be borne in mind during the implementation. The most important is the WFD, followed by the Urban Wastewater Treatment Directive (91/271/EEC) but regard should also be heeded to all other water sector Directives including the EQS Directive (2008/105/EC) as well as the Floods Directive (2007/60/EC). Also the Bathing Water Directive (2006/7/EC) is directly relevant as the efforts on achieving GES will also have beneficial effects for the overall status of the bathing waters.

In addition, the following legislation could be directly or indirectly relevant:

- Birds Directive (2009/147/EC)
- Habitat Directive (92/43/EC)
- EIA Directive (2011/92/EC)
- SEA Directive (2001/42/EC)
- Public Participation Directive (2003/35/EC)
- Access to Environmental Information Directive (2003/4/EC)
- Reporting Directive (91/692/EEC) and Decision (94/741/EC)
- INSPIRE Directive (2007/2/EC)
- Directive 91/692/EEC on the standardisation and rationalisation of reports
- Sewage Sludge Directive (86/278/EEC)
- Industrial Emissions Directive (2010/75/EU)
- Seveso III Directive (2012/18/EU)

- Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (No. 1907/2006)
- Landfill Directive (99/31/EC)
- Waste Framework Directive (2008/98/EC)
- E-PRTR Regulation (EC) No. 166/2006)
- Environmental Crimes Directive (2008/99/EC)
- Environmental Liability Directive (2004/35/EC)
- Directive on Maritime Spatial Planning (2014/89/EU)
- Nitrates Directive (91/676/EC)
- Common Fisheries Policy (Regulation (EU) No 1380/2013)

Particularly relevant issues in these Directives concern their impact upon the development of marine strategies within the marine areas and the overall planning and coordination of activities in marine and coastal areas.

For instance, some marine protected areas may also include areas already designated or to be designated under the Habitats or Birds Directives and under international or regional agreements to which the European Union or Member States concerned are Parties. This additional protection is welcome as it will enhance the efforts to achieve GES under MSFD and towards achieving the commitments undertaken i.e. at the World Summit on Sustainable Development, in Rio+20 and in the Convention on Biological Diversity. This will also contribute to the creation of coherent and representative networks of such areas. Also it is important to coordinate the efforts under the MSFD and the WFD. For instance, although coastal waters, including their seabed and subsoil are an integral part of the marine environment and covered by the MSFD, some particular aspects of the environmental status of the marine environment could also be covered by WFD.

The Marine Strategy Framework Directive serves as an environmental guideline for the Directive 2014/89/EU of the European Parliament and of the Council of 23 July 2014 establishing a framework for maritime spatial planning, which is a part of the Integrated Maritime Policy that aims for the implementation and optimal ocean management and maritime governance.

The Common Fisheries Policy should contribute to the protection of the marine environment, to the sustainable management of all commercially exploited species, and in particular to the achievement of good environmental status by 2020, as determined by the MSFD.

In addition, the following international conventions to which the EU and/or the Member States are parties should be considered in the implementation process:

- United Nations Convention on the Law of the Sea (Unclos) approved by Council Decision 98/392/EC of 23 March 1998
- The Convention on the Protection of the Mediterranean Sea against Pollution (1976)²²⁵ and its relevant protocols.
- The Convention on the Protection of the Marine Environment of the Baltic Sea Area (1992)²²⁶

²²⁵ Approved by Council Decision 77/585/EEC, and its amendments from 1995, approved by Council Decision 1999/802/EC.

²²⁶ Approved by Council Decision 94/157/EC.

- The Convention on the Transboundary Effects of Industrial Accidents (1992)
- Convention on Biological Diversity
- The Convention for the Protection of the Marine Environment of the North-East Atlantic(OSPAR)²²⁷
- Convention of the Black Sea Against Pollution (EU has observer status).

Each of these conventions lay down requirements on sea protection and cooperation which should be taken into account in the implementation of the MSFD. For instance, the United Nations Convention on the Law of the Sea (Unclos) sets out obligations at EU level, which should be taken fully into account in this Directive. For instance, the Unclos includes general obligations to ensure that activities under the jurisdiction or control of a Party do not cause damage beyond its marine waters.

Furthermore, the MSFD has clear links with the Convention on Biological Diversity and the objectives of the Seventh Conference of the Parties to the convention ensuring the conservation and sustainable use of marine biodiversity, on the creation of a global network of marine protected areas by 2012 and on the adoption of a programme of work on marine and coastal biodiversity with a number of goals, targets and activities aimed at halting the loss of biological diversity nationally, regionally and globally and at securing the capacity of the marine ecosystems to support the provision of goods and services, and a programme of work on protected areas with the objective of establishing and maintaining ecologically representative systems of marine protected areas by 2012.

²²⁷ Approved by Council Decision 98/249/EC (3), including its new Annex V on the Protection and Conservation of the Ecosystems and Biological Diversity of the Maritime Area and the corresponding Appendix 3, approved by Council Decision 2000/340/EC.

3. IMPLEMENTATION

Developing common approaches, pooling resources through experience-sharing, bringing together the best technical expertise and investing in joint research are crucial tools to ensure that marine strategies are coherent, consistent and built on the best advice of the political and scientific community.

Several challenges for the successful implementation have been identified:

- The need to devise appropriate financing strategies, tapping into all relevant financial resources within the EU, in coherence with Article 22 of the MSFD;
- The integration of sectoral policies, whether maritime sectors or activities on land affecting the marine environment;
- Active dissemination and communication on the marine environment;
- Enhanced participation of stakeholders at all levels: national, regional, European and international.

Implementation of the MSFD presents each candidate country with specific questions and challenges related to their national, regional and/or local situations and conditions. However, candidate countries should consult technical guidance documents jointly developed by Member States and the Commission within the Common Implementation Strategy (CIS), which has supported the implementation of the MSFD since its adoption. The aim of the CIS is to allow, as far as possible, a coherent and harmonious implementation of the MSFD within the EU. So far, quite a number of these technical documents (listed below) have been developed, which are available at the following link: <https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp>

- Common Implementation Strategy: Reporting on Programmes of Measures (Art. 13) and on exceptions (Art. 14) for the Marine Strategy Framework Directive (2015). This reporting guidance has been developed with the aim of assisting and facilitating reporting by Member States in their implementation of the Directive. It provides non-binding guidance on reporting on MSFD PoMs and on exceptions:
- Common Implementation Strategy: Guidance on Article 15 of the Marine Strategy Framework Directive (2015)
- Common Implementation Strategy: Programmes of measures under the Marine Strategy Framework Directive Recommendations for implementation and reporting (2014)
- Common Implementation Strategy: Reporting on monitoring programmes for MSFD Article 11 (2014)
- Common Implementation Strategy: Monitoring guidance on underwater noise (2013)
- Common Implementation Strategy: Guidance on monitoring of marine litter in European Seas (2013)
- Technical Guidance on monitoring for the Marine Strategy Framework Directive (2014)
- Common Implementation Strategy: Monitoring under Marine Strategy Framework Directive Recommendations for implementation and reporting (2013)
- Common Understanding of (Initial) Assessment, Determination of Good Environmental Status (GES) & Establishment of Environmental Targets (Articles 8, 9 & 10 MSFD)

- Guidance for 2012 reporting under the Marine Strategy Framework Directive, using the MSFD database tool
- Economic and social analysis for the initial assessment for the Marine Strategy Framework Directive: a guidance document (2010)

Also the candidate countries should take guidance from the various reports submitted by the Member States as well as by the Commission, such as the Report from the Commission to the Council and the European Parliament: The first phase of implementation of the Marine Strategy Framework Directive (2008/56/EC) - The European Commission's assessment and guidance (COM(2014)97 final) available at:

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52014DC0097>

3.1. Key Tasks

Member States' steps to implement the Directive may follow the path indicated above under the sections on planning, monitoring, regulation and reporting.

3.1.1. Planning

The main points for considering in the planning phase, which also go beyond the strictly legal requirements include:

- Strive to develop a transparent and coherent legislative framework, which should contribute to coherence between different policies and foster the integration of environmental concerns into other policies, such as the Common Fisheries Policy, the Common Agricultural Policy and other relevant EU policies.
- Determination of GES and performing the Initial assessment of marine water
- Early on identify in the programme of measures instances where the environmental targets or GES cannot be achieved through the programme of measures within the time schedule concerned, due to any of the following reasons: action or inaction for which the Member State is not responsible, natural causes, force majeure, modifications to the physical characteristics of marine waters taken based on overriding public interest, natural conditions which do not allow timely improvement of the water status.
- Organise a consultation process with ancillary impact assessment and cost analysis. This consultation process should normally have four main objectives: 1) provide an introduction to the provisions of the Directive, invite views on draft transposing legislation, invite comments on impact assessment and provide information on steps required to implement the Directive following transposition, including planning measures and a framework for cost-effective measures.
- Consider the geographic scope of the marine strategy. For countries with access to more than two marine regions or subregions, one of the first issues is whether to develop one single strategy or having separate strategies. Important factors to consider here are input from stakeholders in the consultation process and cost-effectiveness.

- Take into account bio-geographic differences within regions and sub-regions, which for countries with more than one region or sub-region, means clear ecological differences between the seas, which need to be taken into account in developing targets and indicators for GES, developing monitoring programmes and creating programmes of measures.
- Designate one or several competent authorities, which can be a ministry, other government body, a marine management body. Preferably there should be one main competent authority, having an overall coordinating role in relation to the development of the programme of measures. Also it is possible to form a national steering group, which includes interested parties, industry representatives and Government to enhance the cooperation and coordination to ensure fair and smooth implementation of the MSFD.
- Use, where practical and appropriate, the relevant Regional Sea Convention as a forum to achieve the regional cooperation and coordination envisaged by the Directive.
- Ensure sufficient coordination, especially in cases with many competent authorities and multiple marine strategies. This coordinated approach is particularly important when drawing up monitoring programmes and programmes of measures.
- Consider whether, in the case of marine regions or sub-regions being shared with other Member States, the status of the sea is critical, requiring urgent action, which entail a plan of action and early entry into force of programmes of measures which can also be subject to specific pilot project by the Commission (also subject to EU funding)
- Consider the possibility to establish marine protected areas also covering areas already designated or to be designated under the Habitats or Birds Directives and under other relevant international or regional agreements, as this will enhance the efforts to achieve GES under MSFD, achieving the commitments undertaken at the World Summit on Sustainable Development, Rio+20 and in the Convention on Biological Diversity and contribute to the creation of coherent and representative networks of such areas.
- Coordinate the efforts regarding coastal waters, including their seabed and subsoil, which although an integral part of the marine environment and covered by the MSFD, some particular aspects of the environmental status of the marine environment could also be covered by WFD.
- For the monitoring of whether the GES is being achieved for marine waters (also taking into account the criteria and methodological standards set out in Decision 2010/477/EC) and guidance produced by the CIS and JRC.
- In planning the implementation the candidate countries should seek as much information and advice as possible from Commission guidance, reports of various Marine Director meetings and conferences to obtain help in implementing the main provisions of the Directive. Information can be obtained at: <http://water.europa.eu/>

Example of Designation of Competent Authority

Malta: In view of the different maritime users within Malta's marine waters and the need for co-ordination to develop the national marine strategy, the Office of the Prime Minister has been designated the Competent Authority to co-ordinate the strategic approach and policy direction for the implementation of the Directive. Based on the implementing

regulations, other bodies may be designated as supplementing competent authority for different provisions and purposes. Currently Malta is working on the initial assessment, determination of Good Environmental Status and the establishment of environmental targets and indicators. The Environment and Resources Authority (ERA) has been entrusted with this task. An inter-ministerial technical working group is set up to ensure an integrated approach towards implementation.

Example of Approach to Develop Marine Strategies

UK: Pursuant to a public consultation in 2010, the UK Government and Devolved Administrations (DA) developed a single Marine Strategy covering the entire UK (Celtic seas and the North Sea). This strategy will take into account biogeographic differences within regions and sub-regions, entailing clear ecological differences between the North Sea and Celtic Seas in developing targets and indicators for GES, developing monitoring programmes and creating programmes of measures. A majority of the respondents gave the following main reasons for preferring a single strategy:

- a single strategy would better suit the implementation in the two seas and may guarantee that the interests of the numerous international organisations around the North Sea will not override the interests of the Celtic seas and its small number of international interests when the proposed UK wide approach is used.
- respondents representing ports reflected that since ports are particularly sensitive to competition issues, a single strategy reduced the uncertainty and costs to maritime businesses
- a single strategy would function at a European level applying to all nations equally but also having derogations at regional and even local levels that would allow the adaptation of assessment and monitoring plans to suit local conditions.

More information on the 2010 consultation can be obtained at:

<http://webarchive.nationalarchives.gov.uk/20100505154859/http://www.defra.gov.uk/corporate/consult/msfd-legal-framework/index.htm>

Following up on the public consultation in 2010, the UK Government and Devolved Administrations launched a new public consultation on 27 March 2012 on the following aspects for the implementation of the MSFD:

- A draft initial assessment of the state of the UK's seas
- Proposals for characteristics of Good Environmental Status for the UK's seas
- Proposals for more detailed targets and indicators of Good Environmental Status, through which we will measure progress towards achieving Good Environmental Status

The consultation documents and information on how to respond can be found at:

www.defra.gov.uk/consult/2012/03/27/marine-strategy-framework-1203/

In 2012, the UK produced Part One of the Marine Strategy containing information on the first three elements of the MSFD. It outlines path towards Good Environmental Status in UK seas by 2020. It covers: the initial assessment of the state of the UK's seas cover paper; proposals for characteristics of GES for the UK's seas and proposals for more detailed GES targets and indicators, through which we will measure progress towards achieving GES.

In 2014, Part Two of the Marine Strategy, which focuses on a co-ordinated monitoring programme for the ongoing assessment of GES, was published. The final part (part three) published in 2015 outlines a programme of measures that will contribute to the achievement and maintenance of GES.

More information can be found at:

<https://www.gov.uk/government/publications/marine-strategy-part-one-uk-initial-assessment-and-good-environmental-status>

Example of Transposition from Member States

UK: The MSFD was transposed into UK law via the [Marine Strategy Regulations 2010](http://www.legislation.gov.uk/ukxi/2010/1627/contents/made). (Available at: <http://www.legislation.gov.uk/ukxi/2010/1627/contents/made>)

Key requirements set out by the regulations are:

- An assessment of the current state of UK seas by July 2012
- A set of detailed characteristics of Good Environmental Status means for UK waters, and associated targets and indicators by July 2012
- Establishment of a monitoring programme to measure progress toward Good Environmental Status by July 2014
- Establishment of a programme of measures for achieving Good Environmental Status by 2016

The marine regulations are part of overall package of UK-wide policies for marine areas, all in line with the objective for 'clean, healthy, safe, productive and biologically diverse oceans and seas', such as the Marine and Coastal Access Act and the reform of the Common Fisheries Policy.

More information on the UK transposition process can be obtained at:

<http://www.defra.gov.uk/environment/marine/msfd/>

Malta: The MSFD was transposed into Maltese legislation through the publication of the Marine Policy Framework Regulations 2011, Legal Notice 73 of 2011 (available at: <http://justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=21805&l=1>)

3.1.2. Coordination and Consultation

Member States should make every effort to ensure close coordination with all Member States and third countries, especially when sharing marine regions or subregions. Although Member States are free to choose the political and administrative tools for achieving this coordination, there are several benefits of using existing institutional structures established in marine regions or subregions, in particular Regional Sea Conventions and the various institutional structures. In Europe, there are four cooperation structures which aim to protect the marine environment and bring together Member States and neighbouring countries that share marine waters: the Regional Sea Conventions.

The four European Regional Sea Conventions are:

- The Convention for the Protection of the Marine Environment in the North-East Atlantic of 1992 (further to earlier versions of 1972 and 1974) – the OSPAR Convention (OSPAR)
- The Convention on the Protection of the Marine Environment in the Baltic Sea Area of 1992 (further to the earlier version of 1974) – the Helsinki Convention (HELCOM)
- The Convention for the Protection of Marine Environment and the Coastal Region of the Mediterranean of 1995 (further to the earlier version of 1976) – the Barcelona Convention (UNEP-MAP)
- The Convention for the Protection of the Black Sea of 1992 – the Bucharest Convention.

Example of coordination measures in Member States

UK: In order to achieve the coherent and co-ordinated approach to implementation, the Devolved Administrations (DAs) participating in a UK wide transposition project led by the Department for Environment, Food and Rural Affairs (Defra), which involved the development of UK wide Regulations transposing the Directive, with input from the Department of the Environment in Northern Ireland (DOE NI), the Scottish Government and the Welsh Assembly Government throughout the transposition process.

Within the UK, in conjunction with Defra and the Devolved Administrations, there are a number of potential platforms to facilitate the necessary collaborative approach to implementation. The UK approach mainly envisages coordinating the marine strategy at two key levels - one at a policy level and another at an expert/technical level. Coordination between Defra and the Devolved Administrations will be based on strong mechanisms already in place for working together at a policy level. Concordats between Defra and each of the Devolved Administrations have been developed specifying how the administrations will work together to implement the Directive. Technical coordination related to monitoring and assessment will be facilitated through the UK Marine Monitoring and Assessment Strategy (UKMMAS), which will continue to play a key role and will provide input to the development of the UK initial assessment, UK targets and indicators.

OSPAR will be the main forum through which the UK will engage in the regional level coordination required by the Directive.

3.2. Key implementation tasks

Already before the final adoption of the Directive, informal consultations had started between the Commission and Member States on specific issues of implementation, including those where further technical or scientific studies are required. The following checklist presents a non-exhaustive list in which key issues are grouped under key headings and arranged in chronological order where possible.

Table 22. Illustrative checklist with key implementation tasks

MSFD - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Plan for full transposition of the MSFD
1.2	Designate competent authorities for each marine region or sub region concerned. (Art. 7, MSFD). Member States within the catchment area of each marine region or sub region shall also designate the authority or authorities competent for cooperation and coordination as referred to in Article 6. (Art. 7, MSFD)
1.3	Decide whether to divide marine regions or subregions into sub-divisions
1.4	Ensure efficient regional cooperation for marine regions and subdivisions shared by Member States in devising and implementing the marine strategies, taking use of existing international forums and mechanisms, building on existing international or regional programmes and activities stemming from international agreements such as Regional Sea Conventions. (Art. 6(2))
1.5	Carry out an initial assessment of the status of waters and the environmental impact of human, which shall be subject to review/update every six years and to prior consultation. (Arts. 5, 8, 17 and 19)
1.6	Determine the characteristics of GES for the water concerned, which shall be subject to review and if need be update every six years and subject to prior consultation, which take into account the initial assessment, the qualitative descriptors listed in Annex I, the indicative lists of elements set out in Table 1 of Annex III, the pressures or impacts of human activities in each marine region or sub region (lists in Table 2 of Annex III) and apply the criteria and methodological standards set out in the Annex to Decision 2010/477/EC. (Articles 5, 9, 17 and 19)
1.7	Establish a series of environmental targets and associated indicators for the marine waters of each marine region or sub regions, which shall be subject to review/update every six years and subject to prior consultation. (Articles 5, 10, 17)
1.8	Establish and implement a monitoring programme for ongoing assessment of the environmental status of the marine waters and regular updating of targets
1.9	Establish a plan of action and early entry into force of programme of measures in case of marine regions or sub-regions being shared with other Member States, where the status of the sea is critical and require urgent action. (Art. 5(3))
1.10	Develop a programme of measures designed to achieve or maintain GES for each marine region or sub region concerned. This programme has to involve prior consultation of the public and key stakeholders, be developed by 2015 and put into operation at the latest by 2016 and be subject to review every six years. (Arts. 5,13, 17 and 19))
1.11	Ensure efficient regional cooperation for marine regions and subdivisions shared by Member States in devising and implementing the marine strategies, taking use of existing international forums and

	mechanisms, building on existing international or regional programmes and activities stemming from international agreements such as Regional Sea Conventions. (Art. 6(2))
2	Regulation
2.1	Ensure compliance with the provisions of the MSFD.
2.2	Consider to what extent the exceptions set out in Article 14 needs to be used on the basis of the justifications of Art 14:: 1) action or inaction for which the Member State concerned is not responsible; 2) natural causes; 3) force majeure; 4) modifications or alterations to the physical characteristics of marine waters brought about by actions taken for reasons of overriding public interest, 5) natural conditions which do not allow timely improvement in the status of the marine waters concerned.
2.3	Ensure that the review and update of marine strategies for each marine region or sub region concerned. This review shall be carried out every six years after their initial establishment in a coordinated manner of the following elements of the marine strategy: <ul style="list-style-type: none"> • the initial assessment and the determination of GES • the environmental targets • the monitoring programmes • the programmes of measures (Article 17)
3	Monitoring and Enforcement
3.1	Establish and implement a monitoring programme for on-going assessment of the environmental status of the marine waters and regular updating of targets, by 15 July 2014. This monitoring should be based on the initial assessment, taking into account the indicative lists of elements set out in Annex III and the list set out in Annex V, referring to the environmental targets. (Articles 5 and 11)
3.2	Ensure that the monitoring above is compatible with EU provisions for assessment and monitoring laid down by EU legislation (e.g. under the Habitats, Birds Directives and WFD) or under international agreements. (Articles 5 and 11)
3.3	For shared marine regions or sub regions the monitoring programmes shall be coordinated to ensure consistency in monitoring results and taking into account relevant transboundary impacts and transboundary features. (Articles 5 and 11)
3.4	The monitoring should apply the specifications and standardised methods for monitoring and assessment to be adopted by the Commission pursuant to Art. 25(3). (Articles 5 and 11)
4	Reporting
4.1	Inform the Commission of any subdivisions (Art. 4(2), MSFD)
4.2	Inform the Commission of cases of early entry into force of programme of measures in case of shared marine regions where the status of the sea is critical and require urgent action. Also invite the Commission to provide input, such as making the region a pilot project for enhanced efforts. (Art. 5(3), MSFD)
4.3	Provide the Commission with a list of the competent authorities and the data referred to in Annex II of the MSFD. Inform the Commission of changes to the information on designated authorities within six months after the change (Article 7(2)).
4.4	Notify the Commission of the initial assessment by three months after their establishment. (Art. 9(2))
4.5	Notify the Commission of the determined set of characteristics for GES for each marine region or sub region (Art. 9(2))

4.6	Notify the Commission of the environmental targets (Art. 10(2))
4.7	Notify the Commission of the monitoring programmes (Art. 11(3))
4.8	Notify the Commission of the programme of measures (Art. 13(9)) by 31 March 2016.
4.9	Inform the Commission about using the exceptions set out under Article 14 regarding unexpected situations where only some of the measures can be carried out or whether there could be certain time derogations considered in implementing the provisions relevant to achieving the GES and implementing the marine strategy and programme of measures. The notification shall include justifications and shall be part of the notification of the programmes of measures mentioned under point 4.8. (Art. 14)
4.10	Inform the Commission and provide it with justified views about issues which has an impact on the environmental status of its marine waters and which cannot be tackled by measures adopted at national level. (Art. 15)
4.11	Provide the details of any updates to the various elements of the marine strategies to the Commission, to the Regional Sea Conventions and to any other Member States concerned within three months of their publication. (Art. 17(3))
5	Public Consultation and Access to Information
5.1	Consult with all interested parties to allow them early and effective opportunities to participate in the implementation of the Directive, involving, existing management bodies or structures (e.g. Regional Sea Conventions, Scientific Advisory Bodies and Regional Advisory Councils).
5.2	Publish, and make available to the public for comment, summaries of the key elements of their marine strategies (initial assessment, determination of GES, environmental targets, monitoring programmes and programmes of measures) and their updates.
5.3	Allow the Commission access to spatial information deriving from this Directive, especially regarding data from the initial assessments and the monitoring programmes, allowing it to carry out its obligations under the INSPIRE Directive (2007/2/EC). Also the European Environmental Agency should be allowed to access information. (Article 19)(3)

3.3. Phasing Considerations

The key phasing issues are:

- Designating competent authorities and ensuring that they have sufficient mandate, resources and coordination mechanisms to efficiently fulfill their tasks
- Transposing the Directive into national legislation and providing links and coordination with other relevant legislation and competent authorities;
- Undertaking a full assessment of the current state of the seas, establishing the current status of the water in terms of quality and quantity, and setting operational quality objectives defining "good" status;
- Establishing co-ordination mechanism both with WFD and the river basin districts and considering participating in international coordination mechanisms such as OSPAR;

- Preparing a set of detailed characteristics of Good Environmental Status associated targets and indicators
- Establishing a monitoring programme to measure progress toward Good Environmental Status;
- Preparing the programme of measures, consultation and the publication of the marine strategies;

The implementation of the Marine Strategy Framework Directive is supported by a Common Implementation Strategy (CIS), aiming to allow a coherent and harmonious implementation of the MSFD within the EU.

The Common Implementation Strategy for the Marine Strategy Framework Directive "Learning the lessons and launching a reinforced phase of implementation" is a strategic document including a work programme for 2014 and beyond.

The MSFD implementation is characterised by three main working areas, namely:

- a) Assessment and Monitoring of the marine environment (Good Environmental Status)
- b) Data, Information and Knowledge Exchange on the marine environment (WISE-Marine)
- c) Management, measures, economic and social analysis of human activities affecting the marine environment.

The mission and objectives of the CIS include:

- Ensure the best possible implementation of the MSFD and the 2020 objective to achieve GES
- Maintain or ameliorate the status of the marine environment through conservation and, where practicable, restoration of its ecosystems
- Improve the marine knowledge base for assessing and managing the marine environment Strengthen the regional capacities and coordination to implement the MSFD, in cooperation with the Regional Sea Conventions
- Enhance investments and (co-)financing for marine protection and management, where and when required or necessary.

The Commission shall publish a first evaluation report on the implementation of the MSFD within two years of receiving all programmes of measures and, in any case, by 2019 at the latest, and publish further reports every six years thereafter. It shall submit the reports to the European Parliament and to the Council.

4. TIMETABLE FOR ACTION

The following sets out key deadlines for the implementation of the various actions set out under the Directive required of Member States.

Table 23. Key deadlines on the application of the MSFD (also including past deadlines which are irrelevant for the candidate countries)

Year	Issue	Reference (Article)
15 July 2010	Bring into force the laws, regulations and administrative provisions necessary to comply with the Directive. Establish competent authorities for each marine region or sub region concerned and designate the authority or authorities.	Art. 26(1) Art. 7
By 15 January 2011	Member States shall provide the Commission with a list of the competent authorities designated, together with the items of information listed in Annex II.	Art. 7(2)
1st implementation cycle		
15 July 2012	An assessment of the current state of seas	Arts 5 and 8
15 July 2012	A set of detailed characteristics of Good Environmental Status means for waters, and associated targets and indicators.	Arts 5, 9 and 10
15 October 2012	Notify the Commission of the initial assessment and the determined set of characteristics for GES for each marine region or sub region. Notify the Commission of the environmental targets.	Art. 9(2) Art. 10(2)
15 July 2014	Establishment of a monitoring programme to measure progress toward Good Environmental Status.	Article 11
15 October 2014	Notify the Commission of the monitoring programmes.	Art. 11(3)
31.12.2015	Develop a programme of measures for achieving GES.	Art. 5 and 13
31 March 2016	Put into operation the programme of measures for achieving Good Environmental Status. Notify the Commission of the programme of measures	Arts. 5 and 13 Art 13(9)
31.12.2016	Entry into operation of programme of measures	Art 5
2 nd implementation cycle		
15 July 2018	An assessment of the current state of seas	Arts 5 and 8

15 July 2018	A set of detailed characteristics of Good Environmental Status means for waters, and associated targets and indicators.	Arts 5, 9 and 10
15 October 2018	Notify the Commission of the initial assessment and the determined set of characteristics for GES for each marine region or sub region. Notify the Commission of the environmental targets.	Art. 9(2) Art. 10(2)
15 July 2018	Establishment of a monitoring programme to measure progress toward Good Environmental Status.	Article 11
15 October 2020	Notify the Commission of the monitoring programmes.	Art. 11(3)
31.12.2021	Develop a programme of measures for achieving GES.	Art. 5 and 13
31 March 2022	Put into operation the programme of measures for achieving Good Environmental Status. Notify the Commission of the programme of measures	Arts. 5 and 13 Art 13(9)
3rd implementation cycle etc... ²²⁸		

²²⁸ The MSFD works in 6-year cycle and under Art 17 the different elements have to be reported every 6 years so the deadlines continue as shown for the 2nd cycle.

5. COSTS

The main types of costs incurred in implementing this Directive are illustrated in the table below.

The Directive is the main pillar for marine protection at EU level and it fits the overall framework of water protection legislation, nature protection legislation. Candidate countries should early in the planning phase – preferably in conjunction with the first consultation process to solicit views of the main stakeholders – make a general cost assessment, which should contain cost estimations preferably for more than one implementation approach. Since there are many connecting points and an overarching framework for a number of other Directives, the costs can be spread over the various sectors and government bodies. For instance, the management of coastal areas both fall under the WFD and the MSFD. Here it is important not to duplicate costs. A large part of the costs anticipated for the MSFD is expected to be linked to the administration and coordination. A holistic, integrated legislative and implementing framework tackling other key sectors such as the Common Agricultural Policy and the Common Fisheries Policy, will require initial coordination and management efforts but the costs for regulation and monitoring will be considerably less. The administrative costs will involve financing:

- an appropriate monitoring system covering marine regions and subregions (unless already in place);
- using existing mechanisms for cooperation and information with neighbouring countries, such as regional seas conventions (e.g. OSPAR and the Barcelona Convention), is likely to require less burden.

However, the real cost impact depends on the extent to which candidate countries have already embarked on the process of providing/allowing for the charging of costs more closely aligned to true cost in pure financial terms, let alone taking into account environmental and resource costs. It also depends greatly on the extent to which compliance with the other water-related EU instruments and other associated legislation has been or is projected to be met, for example under the Urban Waste Water Treatment Directive (91/271/EEC), the Nitrates Directive (91/676/EEC) and the Industrial Emissions Directive (2010/75/EU), the Habitats (92/43/EEC) and Birds Directives (2009/147/EC) for the designation and monitoring of protected areas. Membership, active participation and a pro-active approach in various other international and regional conventions targeting regional seas is also likely to reduce the overall costs for implementing the MSFD.

A part of the estimated costs can be offset by enhanced emission standards, tougher provisions on coastal protection, and efficient implementation of the WFD, Bathing Water Directive and the Urban Waste Water Directive. It will also be possible to generate some earmarked finances for the implementation of the Directive through water pricing, costs which are passed on to the water resource users. Finally, some of the measures under the MSFD are subject to co-financing by the EU. For instance, in the case of marine regions or subregions being shared with other Member States, the status of the sea is critical, requiring urgent action, which entail a plan of action and early entry into force of programmes of measures which can also be subject to specific pilot project by the Commission (also subject to EU funding).

Table 24. Examples of potential costs incurred to implement the Directive

Initial set-up costs: <ul style="list-style-type: none">• establishing competent authority(ies);• establishing the legislative framework comprising links and coordination with other relevant Directives;

<ul style="list-style-type: none"> • establishing planning process with links to relevant national, EU and regional processes and policies relevant for marine protection. This planning should set out clear objectives, targets, milestones and parameters making it possible to evaluate progress; • initial sampling programme and data interpretation; • preparation of marine strategies; • initial wide consultation process entailing impact assessment, cost estimations; • system for the checking of sampling methodology, frequency and analytical methods; • hiring additional human resources; • training of staff in competent authorities, laboratories; • creating awareness of the Directive, its objectives and desired impacts especially targeting key stakeholders and affected parties including the industry; • establish a coordination mechanism which either can be an existing one (e.g. for regional seas convention) or a new one; • initial assessment of the current state of seas; • setting detailed characteristics of Good Environmental Status , and associated targets and indicators; • establishing a monitoring programme to measure progress toward Good Environmental Status; • establishing a programme of measures for achieving Good Environmental Status; • preparation of technical guidance notes.
<p>Capital investment costs:</p> <ul style="list-style-type: none"> • laboratory premises; • laboratory equipment and instrumentation; • new or upgraded urban waste water treatment plants where there are discharges directly or indirectly into coastal areas.
<p>Ongoing running costs:</p> <ul style="list-style-type: none"> • annual sampling and analysis costs; • monitoring costs for measuring achievement of GES; • consultation and coordination comprising cross-border coordination; • reporting to the Commission; • data processing and reporting.

The cost of implementing the provisions relating to assessment of water status and the monitoring for achieving the GES will largely depend upon the availability of existing laboratories capable of undertaking water analysis. To the extent possible, laboratories for analysing water status under WFD and drinking water could be used. Although initial costs are likely to have been fairly small for the candidate countries and related to the

institutional arrangements for sampling and the measurement and interpretation of results, this may not remain the case with organisation under marine regions and sub-regions, especially in the case of shared waters. Moreover, once the initial programme of measures has provided sufficient information, costs will be incurred in drawing up a programme of improvements and instigating the improvement measures.

Where candidate countries have so far established no laboratories, then the capital costs will be substantial. The use of accredited contract laboratories, not necessarily based in the territory of the candidate country, is one alternative method of reducing capital costs. Laboratories are necessary for implementing a number of other Directives in the water sector, and costs for this particular Directive may be absorbed within the overall organisational costs for the sector.

**NATURE
PROTECTION**

Section 6

1. INTRODUCTION AND OVERVIEW	942
1.1. EU Policy.....	942
1.2. EU Legal Instruments.....	945
1.2.1. The Wild Birds Directive	945
1.2.2. The Habitats Directive	946
1.2.3. The Endangered Species Regulation.....	946
1.2.4. The Regulation on Leghold Traps.....	946
1.2.5. The Zoos Directive.....	946
1.2.6. Regulation on Invasive Alien Species.....	946
1.2.7. EU Timber and FLEGT Regulation.....	947
1.3. Related International Agreements on Nature Protection	948
1.3.1. Convention on Biological Diversity (CBD)	948
1.3.2. Convention on International Trade in Endangered Species of Wild Fauna and Flora	949
1.3.3. Convention on the Conservation of Migratory Species of Wild Animals	949
1.3.4. Convention on the Conservation of Arctic Marine Living Resources	950
1.3.5. Convention on the Conservation of European Wildlife and Natural Habitats	950
2. DEVELOPMENT OF SECTORAL STRATEGY AND IMPLEMENTATION PLAN	952
2.1. Introduction.....	952
2.2. Approach	952
2.2.1. Introduction	952
2.2.2. Set Policy.....	952
2.2.3. Planning	953
3. INSTITUTIONS AND RELEVANT PARTIES	954
3.1. Stakeholders.....	954
3.2. National Government Institutions	955
3.3. Competent Authorities	955
3.4. Communication and Consultation.....	958
4. TECHNICAL ISSUES	960
5. REGULATION AND ENFORCEMENT.....	961
5.1. Overview.....	961
5.2. Licensing and Permitting.....	962
5.3. Monitoring, Inspection and Enforcement.....	962
5.4. Designation of Qualifying Sites and Species	962

5.5.	Data Collection and Reporting.....	963
6.	PRIORITISING THE IMPLEMENTATION TASKS.....	964
7.	ECONOMIC AND FINANCIAL ISSUES.....	965
7.1.	Introduction.....	965
7.2.	Institutional Development.....	965
7.3.	Protection of Important Sites and Species.....	965
8.	SUMMARY OF KEY ISSUES.....	967
	THE HABITATS DIRECTIVE.....	968
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	969
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES.....	971
2.1.	Planning.....	971
2.2.	Regulation.....	972
2.3.	Monitoring and Research.....	972
2.4.	Information and Reporting.....	973
2.5.	Additional Legal Instruments.....	973
3.	IMPLEMENTATION.....	976
3.1.	Key Tasks.....	976
3.2.	Phasing.....	977
4.	IMPLEMENTATION GUIDANCE.....	979
4.1.	Planning.....	979
4.1.1.	Establishment of SACs.....	980
4.2.	Protection of SACs.....	981
4.3.	Protection of species.....	983
4.4.	Monitoring.....	985
4.5.	Reporting.....	985
5.	COSTS.....	988
	THE BIRDS DIRECTIVE.....	991
1.	SUMMARY OF MAIN AIMS AND OBJECTIVES.....	992
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES.....	993
2.1.	Planning.....	993
2.2.	Regulation.....	993
2.3.	Monitoring and Research.....	995
2.4.	Consultation and Reporting.....	995

2.5.	Additional Legal Instruments	996
3.	IMPLEMENTATION	997
3.1.	Key Tasks.....	997
3.2.	Phasing.....	998
4.	IMPLEMENTATION GUIDANCE	1000
4.1.	Planning.....	1000
4.1.1.	Establishment of Special Protection Areas (SPAs).....	1001
4.1.2.	Species Protection	1001
4.1.3.	Monitor Effectiveness of Measures.....	1002
4.1.4.	Conduct Appropriate Assessments	1002
4.2.	Reporting	1002
4.3.	Costs	1003
	THE REGULATIONS ON TRADE IN ENDANGERED SPECIES	1005
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1007
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1010
2.1.	Planning.....	1010
2.2.	Regulation.....	1010
2.3.	Monitoring and Enforcement.....	1015
2.4.	Information and Reporting.....	1015
2.5.	Additional Legal Instruments	1017
3.	IMPLEMENTATION	1018
3.1.	Key Tasks.....	1018
3.2.	Phasing.....	1020
4.	IMPLEMENTATION GUIDANCE	1022
4.1.	Planning.....	1022
4.2.	Inspection and Enforcement.....	1025
4.3.	Public Information	1027
4.4.	Monitoring.....	1027
4.5.	Reporting	1027
5.	COSTS.....	1028
	THE REGULATION ON LEGHOLD TRAPS.....	1030
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1031
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1032

2.1.	Planning.....	1032
2.2.	Regulation.....	1032
2.3.	Additional Legal Instruments	1032
3.	IMPLEMENTATION	1033
3.1.	Key Tasks.....	1033
3.2.	Phasing.....	1033
4.	IMPLEMENTATION GUIDANCE	1034
4.1.	Planning.....	1034
5.	COSTS.....	1035
	THE ZOOS DIRECTIVE.....	1036
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1037
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1038
2.1.	Planning.....	1038
2.2.	Regulation.....	1038
2.3.	Monitoring and Enforcement.....	1039
2.4.	Information and Reporting.....	1039
3.	IMPLEMENTATION	1040
3.1.	Key Tasks.....	1040
3.2.	Phasing.....	1040
4.	IMPLEMENTATION GUIDANCE	1041
5.	COSTS.....	1042
	THE REGULATION ON INVASIVE ALIEN SPECIES.....	1043
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1044
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1045
2.1.	Planning.....	1045
2.2.	Regulation.....	1045
2.3.	Monitoring and Reporting	1046
2.4.	Additional Legal Instruments	1047
3.	IMPLEMENTATION	1049
3.1.	Key Tasks.....	1049
3.2.	Phasing.....	1050
4.	IMPLEMENTATION GUIDANCE	1051
4.1.	Planning.....	1051

4.2.	Regulation and Monitoring	1051
5.	COSTS.....	1053
THE REGULATION ON ILLEGAL LOGGING (EUTR).....		1054
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1055
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1056
2.1.	Planning.....	1056
2.2.	Regulation	1056
2.3.	Monitoring and Reporting	1056
2.4.	Additional Legal Instruments	1057
3.	IMPLEMENTATION	1058
3.1.	Key Tasks.....	1058
3.2.	Phasing	1059
4.	IMPLEMENTATION GUIDANCE	1060
4.1.	Planning.....	1060
4.2.	Regulation and Monitoring	1060
5.	COSTS.....	1061
THE REGULATION ON LICENSING SYSTEM OF IMPORTS OF TIMBER TO THE EU (FLEGT REGULATION).....		1062
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1063
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1064
2.1.	Planning.....	1064
2.2.	Regulation	1064
2.3.	Monitoring and Reporting	1064
2.4.	Additional Legal Instruments	1065
3.	IMPLEMENTATION	1066
3.1.	Key Tasks.....	1066
3.2.	Phasing	1067
4.	IMPLEMENTATION GUIDANCE	1068
4.1.	Planning and Regulation.....	1068
5.	COSTS.....	1069

NATURE PROTECTION - OVERVIEW

1. INTRODUCTION AND OVERVIEW

This section of the Handbook deals with key EU legislation in the nature protection sector. It contains an introductory overview of the sector followed by individual fiches for selected pieces of legislation. The current update is a limited attempt to bring to the attention of the reader the most recent developments since the previous version of this handbook. For more information and the full scope of nature protection legislation, please consult the nature website of the European Commission at http://ec.europa.eu/environment/nature/index_en.htm.

1.1. EU Policy

In May 2011, the European Commission adopted a new EU biodiversity strategy to 2020²²⁹, with the headline target to 'halt the loss of biodiversity and ecosystem services by 2020, to restore ecosystems in so far as is feasible, and to step up the EU contribution to averting global biodiversity loss'.

The strategy is an integral part of the Europe 2020 strategy and the 7th Environmental Action Programme. The strategy is built around six targets, supported by a set of 20 actions to help Europe reach its goal.

The six main targets are outlined in the box below.

The strategy is in line with two commitments made by EU leaders in March 2010, relating to halting the loss of biodiversity and the degradation of ecosystem services in the EU by 2020 and ensuring by 2050 that EU biodiversity and the ecosystem services it provides are protected, valued and appropriately restored for biodiversity's intrinsic value and for their essential contribution to human wellbeing and economic prosperity. This biodiversity strategy is also in line with global commitments made in Nagoya in October 2010, in the context of the Convention on Biological Diversity, where world leaders adopted a package of measures to address global biodiversity loss over the coming decade.

During 2015 the mid-term review of the EU Biodiversity Strategy to 2020 was prepared and published. The mid-term review assessed the progress made in implementing the EU biodiversity strategy against the 2010 baseline and identified areas in which increased efforts are needed to meet the EU biodiversity objectives by 2020. Thus, the mid-term review calls for intensifying implementation and enforcement measures across all targets, in particular with respect to completing the Natura 2000 network for the marine environment, ensuring effective management of Natura 2000 sites and implementing the Invasive Alien Species Regulation, and considering the most suitable approach for recognizing our natural capital throughout the EU.

²²⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52011DC0244>

Table 1. Box summarizing EU 2020 biodiversity targets

Targets of EU Nature and Biodiversity Protection

Target 1: Halt the deterioration in the status of all species and habitats covered by EU nature legislation and achieve a significant and measurable improvement in their status so that, by 2020, compared with current assessments: (i) 100 % more habitat assessments and 50 % more species assessments under the Habitats Directive show an improved conservation status; and (ii) 50 % more species assessments under the Birds Directive show a secure or improved status.

Four specific actions are identified to help conserve and restore nature:

Action 1: Complete the Natura 2000 network and ensure its good management

Action 2: Make sure Natura 2000 sites get sufficient funding

Action 3: Raise awareness of Natura 2000, get citizens involved and improve the enforcement of the nature directives

Action 4: Make the monitoring and reporting of the EU nature law more consistent, relevant and up-to-date; provide a suitable ICT tool for Biodiversity

Target 2: By 2020, ecosystems and their services are maintained and enhanced by establishing green infrastructure and restoring at least 15 % of degraded ecosystems.

Strategy identifies three specific actions to ensure that ecosystems and their services are both restored and enhanced.

Action 5: Map and assess the state and economic value of ecosystems and their services in the entire EU territory; promote the recognition of their economic worth into accounting and reporting systems across Europe

Action 6: Restore ecosystems, maintain their services and promote the use of green infrastructure

Action 7: Assess the impact of EU funds on biodiversity and investigate the opportunity of a compensation or offsetting scheme to ensure that there is no net loss of biodiversity and ecosystem services.

Target 3: Increase the contribution of agriculture and forestry to maintaining and enhancing biodiversity.

Strategy identifies five specific actions to ensure that agriculture and forestry help maintain biodiversity.

Action 8: Enhance CAP direct payments to reward environmental public goods such as crop rotation and permanent pastures; improve cross-compliance standards for GAEC (Good Agricultural and Environmental Conditions) and consider including the Water Framework in these standards

Action 9: Better target Rural Development to biodiversity needs and develop tools to help farmers and foresters work together towards biodiversity conservation

Action 10: Conserve and support genetic diversity in Europe's agriculture

Action 11: Encourage forest holders to protect and enhance forest biodiversity

Action 12: Integrate biodiversity measures such as fire prevention and the preservation of wilderness areas in forest management plans.

Target 4: Achieve Maximum Sustainable Yield (MSY) by 2015. Achieve a population age and size distribution indicative of a healthy stock, through fisheries management with no significant adverse impacts on other stocks, species and ecosystems, in support of achieving Good Environmental Status by 2020, as required under the Marine Strategy Framework Directive (MSFD).

Two specific actions have been identified to deliver healthier fish stocks and seas.

Action 13: Ensure that the management plans of the Common Fisheries Policy are based on scientific advice and sustainability principles to restore and maintain fish stocks to sustainable levels.

Action 14: Reduce the impact of fisheries by gradually getting rid of discards and avoiding by-catch; make sure the Marine Strategy Framework Directive is consistently carried out with further marine protected areas; adapt fishing activities and get the fishing sector involved in alternative activities such as eco-tourism, the monitoring of marine biodiversity, and the fight against marine litter.

Target 5: By 2020, Invasive Alien Species (IAS) and their pathways are identified and prioritised, priority species are controlled or eradicated, and pathways are managed to prevent the introduction and establishment of new IAS.

Two specific actions to tackle the threat of invasive species are identified:

Action 15: Make sure that the EU Plant and Animal Health legislation includes a greater concern for biodiversity.

Action 16: Provide a legal framework to fight invasive alien species

Target 6: By 2020, the EU has stepped up its contribution to averting global biodiversity loss.

Strategy identified four specific actions to step up our contribution in the fight against global biodiversity loss.

Action 17: Reduce the impacts of EU consumption patterns on biodiversity and make sure that the EU initiative on resource efficiency, our trade negotiations and market signals all reflect this objective.

Action 18: Target more EU funding towards global biodiversity and make this funding more effective.

Action 19: Systematically screen EU action for development cooperation to reduce any negative impacts on biodiversity.

Action 20: Make sure that the benefits of nature's genetic resources are shared fairly and equitably.

In order to achieve these aims, a number of requirements are laid down, that follow a similar pattern in each legal instrument, namely:

- Planning. Setting targets and establishing administrative arrangements to enable appropriate nature protection mechanisms to be implemented effectively.
- Regulation. Identifying and implementing legal mechanisms to ensure compliance with EU requirements.
- Monitoring. Assessing the effectiveness of the application of each legal instrument.
- Reporting. Procedures for informing the Commission of each Member State's performance in complying with the legal instruments and reporting to the Commission on implementation.

1.2. EU Legal Instruments

The nature protection sector covers nine EU Directives and regulations in total, whereof six are dealt with in separate fiches in the Handbook. Their main provisions are aimed at protecting habitats and wild flora and fauna and to control trade in protected species or products thereof.

Table 2. EU nature protection legislation

Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds
Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora
Council Directive 83/129/EEC of 28 March 1983 concerning the importation into Member States of skins of certain seal pups and products derived therefrom
Council Directive 1999/22/EC of 29 March 1999 relating to the keeping of wild animals in zoos
Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein
Council Regulation (EEC) No 348/81 of 20 January 1981 on common rules for imports of whales or other cetacean products
Regulation (EC) No 1007/2009 of the European Parliament and of the Council of 16 September 2009 on trade in seal products (OJ L 286, 31.10.2009)
Council Regulation (EEC) No 3254/91 of 4 November 1991 prohibiting the use of leghold traps in the EU and the introduction into the EU of pelts and manufactured goods of certain wild animal species originating in countries which catch them by means of leghold traps or trapping methods which do not meet international humane trapping standards
Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species

Many of these instruments have been amended. The following text gives an overview of each of the legal instruments identified in the above Box (further information is provided in the fiches following this chapter).

1.2.1. The Wild Birds Directive

This Directive requires Member States to protect naturally occurring wild birds and their habitats, by measures including the designation and management of Special Protection Areas and prohibiting certain harmful activities. This involves, in particular, taking special conservation measures to ensure that wild birds and their habitats, in particular Annex 1 species, are protected. There are some exceptions that allow hunting of certain species, and allow governments to take action to prevent serious damage caused by birds.

1.2.2. The Habitats Directive

The aim of this Directive is to contribute to the protection of biological diversity in the EU. This is to be partly achieved by establishing a European ecological network of representative sites (known as Natura 2000) and ensuring that selected habitats and species are maintained and protected in order to maintain and/or restore them at a "favourable conservation status". Special Areas of Conservation (SACs) are to be designated in order to ensure habitat and species protection. In addition to site protection, the Directive provides for strict protection of certain species of European conservation concern.

1.2.3. The Endangered Species Regulation

This Regulation implements the Washington Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) by regulating trade in certain plant and animal species that are or may be threatened by trade.

1.2.4. The Regulation on Leghold Traps

The banning of the use of leghold traps and limiting imports into the EU of pelts of animals caught by these traps are the main objectives of this regulation.

1.2.5. The Zoos Directive

The Directive aims to protect wildlife and preserve biodiversity by providing for the adoption of measures by Member States for the licensing and inspection of zoos. It requires the enforcement of licensing regimes using appropriate measures including the closure of all or part of a zoo in breach of the licensing requirements and the imposition of effective, proportionate and dissuasive penalties.

1.2.6. Regulation on Invasive Alien Species

Invasive alien species (IAS) are considered to be the second leading cause of biodiversity loss, after habitat alteration. In November 2014, the European Union published a new Regulation on Invasive Alien Species as foreseen under target 5 of the EU's Biodiversity Strategy to 2020. The Regulation provides a legislative basis for several key interventions: prevention, early warning and rapid response to new IAS and the management of already established invasive species.

1.2.7. EU Timber and FLEGT Regulation

These two Regulations are key pieces of legislation to implement European Union’s policy to fight illegal logging and associated trade. A key element of the FLEGT Regulation is a voluntary scheme to ensure that only legally harvested timber is imported into the EU from countries agreeing to take part in this scheme. Complementary to the FLEGT Regulation is the EU Timber Regulation laying down measures to prohibit placing of illegal timber and timber products on the internal market.

The Table below summarises other EU legislation relevant to nature protection. These items of legislation are described in greater detail in the horizontal sector implementation planning framework.

Table 3. Summary of Key EU Legislation in Other Environmental Sectors of Relevance to Nature Protection

Related Legislation	Relevance
Horizontal legislation (see Section 2 of the Handbook)	
Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment	Prescribes an EIA for new projects, which are judged to have a significant impact on the environment. The results are to be made public, and the views of the public taken into consideration in the consenting procedure. One of the triggers for requiring an EIA is where sites of value to wildlife are potentially affected. Directive 2014/52/EU amending Directive 2011/92/EU requires Member States to establish coordinated and/or joint procedure in cases where the obligation to carry out assessments related to environmental issues arises simultaneously from the EIA Directive and Directive 92/43/EEC and/or Directive 2009/147/EC.
Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment	Prescribes a procedure to follow to ensure sufficient public participation in certain land development projects affecting the environment, and hence nature and local biodiversity
Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC	Access to Environmental Information Directive requires environmental information held by public bodies to be made available to the general public on request. Some of the nature protection Directives requires Member States to collect information relating to the protection of habitats and species. Most of this information held by public bodies would be affected by this Directive. The Directive, intends to ensure that EU law is consistent with the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters and to provide a single coherent legislative text.
Council Directive 91/692/EEC of 23 December 1991 standardizing and rationalizing reports on the implementation of certain Directives relating to the environment	Contains provisions on the transmission of information and reports concerning certain EU Directives from Member States to the European Commission. Nature protection Directives contain various reporting requirements
Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Union (INSPIRE)	Member States must establish a system for spatial information including biodiversity lists and other statistics and meta-data on nature protection areas and on specific types of flora and fauna.

<p>Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage</p>	<p>The Directive establishes a framework for environmental liability based on the polluter pays principle, with a view to preventing and remedying environmental damage. The Directive covers, amongst others, direct and indirect damage to species and natural habitats protected by the Birds Directive or the Habitats Directive. For damage affecting protected species and natural habitats, the Directive is aimed at restoring the environment to how it was before it was damaged. For this purpose, the damaged natural resources or impaired services must be restored or replaced by identical, similar or equivalent natural resources or services</p>
<p>Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law</p>	<p>The Directive only sets a minimum standard of environmental protection through criminal law to be adopted by the Member States. The Member States are free to maintain or introduce more stringent protective measures. The Directive lays down a list of environmental offences that must be considered criminal offences by all Member States, if committed intentionally or with serious negligence. Member States must ensure that legal persons can be held liable for offences committed for their benefit. This responsibility can be of criminal or other nature</p>
<p>Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for EU action in the field of marine environmental policy (Marine Strategy Framework Directive)</p>	<p>The Marine Directive aims to achieve Good Environmental Status (GES) of the EU's marine waters by 2020 and to protect the resource base upon which marine-related economic and social activities depend. In order to achieve GES by 2020, each Member State is required to develop a strategy for its marine waters (or Marine Strategy). In addition, because the Directive follows an adaptive management approach, the Marine Strategies must be kept up-to-date and reviewed every 6 years.</p>

1.3. Related International Agreements on Nature Protection

All Member States and candidate countries are parties to one or more of the major multilateral environmental agreements dealing with nature protection. The European Union itself is also a signatory to many of these agreements. These are briefly described below, but in any legal interpretation, EU constitutional (e.g. the Treaty on European Union, the Treaty establishing the EU and the Treaty of Lisbon) and secondary legislation will always take precedence for Member States.

1.3.1. Convention on Biological Diversity (CBD)

Opened for signature in Rio de Janeiro, Brazil: 1992

Entered into force: 1994

This treaty is the only one dealing comprehensively with biodiversity in its own right, as well as the sustainable use of biological resources. It not only complements other multilateral environmental agreements, but also addresses important issues such as access to genetic resources, the equitable distribution of benefits derived from the use of these resources, transfer of relevant technologies, and financial support. Parties to the convention undertake to prepare national biodiversity strategies, and plan to integrate the conservation of biodiversity and sustainable use of biological resources into relevant sectoral or cross-sectoral plans,

programmes or policies. In addition, parties are committed to survey their biodiversity; identify components that may need special protection; identify, monitor, and subsequently regulate or manage activities that may threaten biodiversity; encourage research and training; increase public education and awareness; and develop such techniques as impact assessment and contingency plans for emergencies to minimise any loss of biodiversity. The European Union is a signatory to the convention and has developed an EC Biodiversity Strategy²³⁰ to halt the loss of biodiversity and ecosystem services in the EU by 2020 as well as various other actions and policy measures, including measures dealing with the integration of biodiversity into different policy sectors.

Two Protocols have been adopted under the CBD:

1. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. It was adopted on 29 January 2000 and entered into force on 11 September 2003.
2. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity is an international agreement, which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way. It entered into force on 12 October 2014.

The EU is a Party to both Protocols.

1.3.2. Convention on International Trade in Endangered Species of Wild Fauna and Flora

Opened for signature in Washington: 1973

Entered into force: 1975

CITES has the basic aim of regulating trade in wild animals and plants that are considered to be threatened by such trade. Commercial trade in endangered species- listed in the Convention's Appendix I is prohibited; those species included in Appendix II are subject to limitations on their trade, controlled by a permit system that aims to ensure that exploitation is sustainable. Each party undertakes to establish a scientific authority (to advise on whether export levels are detrimental to national populations of the species concerned) and a management authority (to take care of the issuance of permits and ensure that trade takes place legally). The European Union is a Party to the Convention.

1.3.3. Convention on the Conservation of Migratory Species of Wild Animals

Opened for signature in Bonn, Germany: 1979

Entered into force: 1983

The Bonn Convention aims to conserve migratory animals over the whole of their range.

²³⁰ Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, „Our life insurance, our natural capital: an EU biodiversity strategy to 2020”, {SEC(2011) 540 final}

http://ec.europa.eu/environment/nature/biodiversity/comm2006/pdf/2020/1_EN_ACT_part1_v7%5b1%5d.pdf

Commonly referred to as the CMS, the convention provides both a framework and practical mechanisms for linking protected areas along migration paths, forming a common bond between them and a rationale for the increasingly popular trend of twinning protected areas. The international migration behaviour of animals should be included as part of any national or regional protected areas system plan review to highlight gaps in coverage of routes, especially geographic bottlenecks (e.g. narrow mountain corridors) and vital resting places. Such initiatives emphasise the need for close co-operation among CMS parties, especially developed and developing countries that host the same migratory species at different stages of their life cycles.

There are two appendices to the CMS that list migratory species that would benefit from conservation measures taken by range states — countries that exercise jurisdiction over any part of a species' distribution. Appendix I lists species that are in danger of extinction throughout all or a significant proportion of their range. The range states are required to give them full protection from such activities as hunting, fishing, capturing, harassing and deliberate killing and should endeavour to conserve their habitat, to counteract factors impeding their migration and to control other factors that might endanger them.

Those migratory species whose conservation status requires, or would benefit from, the implementation of international co-operative agreements are listed in Appendix II. Several such agreements have been, or are being, established, for example: the African-Eurasian Waterbird Agreement, the Sharks Memorandum of Understanding, the Raptors Memorandum of Understanding.

The European Union is a signatory to the convention and to some of the Agreements and Memoranda of Understanding.

1.3.4. Convention on the Conservation of Arctic Marine Living Resources

Opened for signature: 1980

Entered into force: 1982

The objective of this Convention is the conservation of Antarctic marine living resources. It was established in response to concerns that an increase in krill catches in the Southern Ocean could have a serious effect on populations of krill and other marine life, particularly on birds, seals and fish which mainly depend on krill for food. The Convention applies to all marine areas south of the Antarctic convergence and to all living organisms including birds found in that area. Whales and seals are, however, excluded to the extent that they are covered by other international agreements. The Convention introduces ecosystem-oriented approach to high-sea fisheries. Thus, it does not exclude harvesting as long as such harvesting is conducted rationally, i.e. in accordance with the following principles of conservation: prevention of decrease in the size of any harvested population to levels below those which ensure its stable recruitment, maintenance of the ecological relationships between harvested, dependent and related populations and prevention of changes or minimization of the risk of changes in the marine ecosystem which are not potentially reversible over two or three decades. The Commission for the Conservation of Antarctic Marine Living Resources was established to give effect to the objective of the Convention and to the principles of 'ecosystem approach' mentioned above.

1.3.5. Convention on the Conservation of European Wildlife and Natural Habitats

Opened for signature in Bern, Switzerland: 1979

Entered into force: 1982

The Bern Convention aims to conserve wild flora and fauna in their natural habitats, to promote co-operation between countries in their conservation efforts, and to give particular emphasis to endangered and vulnerable species. In its provisions, the convention lays out measures to be taken by the parties to maintain the populations of wild flora and fauna and their habitats in general, as well as special protection actions needed for species listed in Appendix I (strictly protected plants), Appendix II (strictly protected animals) and Annex III (protected animals). It should be noted that the convention is open to any country where European wildlife occurs naturally, whether or not the country is in Europe. This chiefly applies to migratory species moving to Asia and Africa. The European Union is a signatory to the Convention.

In the context of international agreements on nature protection, requirements of the Convention on Wetlands of International Importance as Waterfowl Habitats (commonly referred to as Ramsar Convention) are worth mentioning. The European Union is not a signatory to Ramsar Convention but through its nature Directives contributes significantly to the achievement of Ramsar's objectives in the Member States. The overall aim of the Ramsar Convention is to stem the encroachment on and loss of wetlands, which are defined as areas of marsh, fen, peatland or water, whether natural or artificial, permanent or temporary, with water that is static or flowing, fresh, brackish or salt, including areas of marine water the depth of which at low tide does not exceed six metres. To address this aim, the convention promotes the concept of wise use of wetlands through comprehensive national policies, and obliges parties to designate at least one site for inclusion in the List of Wetlands of International Importance. Sites included in the Ramsar list should be subject to conservation measures, which include the establishment of nature reserves. If a site has to be de-listed, the party should compensate for the loss by creating additional nature reserves or by protecting, in the same area or elsewhere, an adequate portion of the original habitat.

2. DEVELOPMENT OF SECTORAL STRATEGY AND IMPLEMENTATION PLAN

2.1. Introduction

EU legislation on nature protection requires Member States to restrict or prohibit the trade in certain wild plants and animals and to establish a system of protection for certain indigenous habitats and species. Another important element of EU nature protection law is prevention and management of the introduction and spread of invasive alien species. This section describes the key aspects of developing a strategy for the nature sector and is complemented by Section 3, which describes the organisational and logistic requirements.

The Wild Birds and the Habitats Directive are the two pillars of the EU nature protection legislation. Thus, it is recommended that candidate countries start to implement the EU nature legislation as early as possible. Nature conservation legislation needs early attention and must be taken into account when implementing other EU policies such as structural, transport and agriculture policy.

2.2. Approach

2.2.1. Introduction

In practice, there are a range of organisational options and in some cases it may be more efficient for one institution to be allocated responsibility for several tasks. The various options that can be adopted for developing a strategy for this sector are discussed in the following section.

2.2.2. Set Policy

Central government, normally in the form of the ministry responsible for the environment, must set nature conservation policy — having regard for the EU principles of wildlife protection. It must then determine the organisational and institutional structure for the key tasks identified in Section 1.1, namely:

- planning;
- establishing policies and guidelines;
- designating sites for enhanced protection;
- putting in place species protection measures;
- ensuring implementation of plans and policies;
- monitoring;
- data collection and reporting;
- capacity building ensuring sufficiently trained staff;

- efficient cooperation framework especially with natural or legal persons directly affected by nature protection legislation;
- sufficient financial framework.

It would be possible for the ministry to undertake almost all of these tasks itself, but there are a number of factors that point towards alternative options, such as delegating some of the supervisory, monitoring, reporting and communication activities to Environmental/Nature Protection Agencies or Institutes. Such delegation and division of powers support the premises of:

- political independence;
- clear accountability; and
- decentralisation and local self-determination.

Communication is an all-embracing task that must be undertaken by all the appointed institutions, under the overall co-ordination of the ministry (see Section 3).

2.2.3. Planning

There are two main approaches to planning: 1) top down — planning from the centre; 2) and bottom up — the aggregation of decentralised plans. In either case, the starting point is a national policy and the choice will, to a large extent, depend on the national and political philosophy of government. The competent authority will need to be responsible for planning, determining the actual mechanism for implementing the requirements of the Directives and Regulations. Within the nature protection sector there are three main aspects: protection of wild species from being negatively affected, including protecting biodiversity from invasive species; protection of valuable sites in terms of biodiversity and/or use by migratory species; and restrictions on the import/export of certain animals and plants and derivatives from them (skins, eggs, foodstuffs, cosmetics, etc.). Primary responsibility for planning, however, could be undertaken by the implementing authority. The choice will depend on the way in which implementation is achieved. If the initiative for implementation is likely to be taken, to a large extent, by government — whether local or central — it may be logical for the implementing authorities to prepare the plans, at least at the decentralised level.

3. INSTITUTIONS AND RELEVANT PARTIES

3.1. Stakeholders

A number of stakeholders have an interest in, or may be affected by, legislation in the nature sector. The principal stakeholders, and their roles in the process of developing and implementing a sectoral strategy to achieve compliance with EU policies and legislation on nature, are identified in the Table below. The following subsections focus on the main groups of organisations that need to be involved in nature protection followed by issues concerning communications.

Table 4. Principal Stakeholders and their roles in the nature sector

Principal Stakeholders and their roles in the nature sector	
Stakeholders	Roles
Central government (e.g. a ministry or department)	Implementation and maintenance of behalf of central government (e.g. nature conservation bodies and national research centres) procedures, collation of data on wildlife and preparation of lists for site designations, preparation of management plans, implementing provisions on SEA and EIA, partial reporting towards central government, advisory role, involved in preparation of legislation, issuing industrial or extraction permits.
Environmental agencies	Working on compliance with EU policies and legislation on nature protection, including establishing planning and designation procedures and reporting to the Commission.
Regional and local government	Involvement in the planning process, incorporating wildlife habitat and species protection, some supervisory functions.
NGOs and Civil Society organisations	Represent the public interest, also through legal cases before national and European courts (as their standing has improved with recent European court judgments). Lobbying on planning and environmental issues. Represent, hold data and undertake research into specialist wildlife aspects, such as birds or rare animals. Awareness raising and engaging activities for the public.
Research institutions and academia (e.g. universities)	Technical and scientific research, inter alia, specific species status, biology and requirements, habitat management and species and habitat conservation value criteria.

3.2. National Government Institutions

National governments are ultimately responsible for achieving and maintaining compliance with EU policies and legislation on nature protection. They have a duty and obligation to secure compliance in a manner and within a programme either stipulated in the relevant EU instrument, or agreed with the responsible EU institution. Typically, the primary responsibility for achieving and maintaining compliance is delegated to a single national institution, e.g. a ministry or department of the environment. However, other ministries or departments in national government will inevitably need to be involved in some way at various stages in the planning and implementation process. For example, ministries with responsibilities for agriculture, forestry, economy, tourism, energy, export/import, foreign affairs, local government, and trade and industry could all potentially be affected by the implementation of EU nature legislation.

The lead ministry (in the majority of cases the environment ministry) should identify which other ministries (see above), national government agencies and bodies need to be involved in the process of planning and implementing EU nature protection legislation. For example, the legislation related to restrictions to trade and invasive alien species will possibly require the involvement of the ministries of agriculture, forestry, economy, export/import, foreign affairs, trade and industry. In addition, a range of governmental agencies and departments are likely to have key roles, particularly as many Member States delegate the day-to-day work within the nature sector to specialist agencies, under the supervision of the ministry of environment (or similar). The role and input of each type of organisation to be involved must be carefully identified and agreed between the lead ministry and the organisation concerned. It will be necessary to resource the competent body with specialist staff, particularly ecologists and other scientists and also perhaps legal advisors and economists.

The lead ministry should take responsibility or identify and appoint the competent authorities required to take responsibility for functions described in the nature sector legislation.

3.3. Competent Authorities

The types of functions to be undertaken by competent authorities under the EU nature sector legislation are illustrated in the Box below. Some of this technical expertise may already exist in one or more agencies or bodies such as local and regional governments in the candidate countries. However, in some areas, the necessary expertise or sufficient staff resources may not be readily available.

Examples of Activities which are Required to Be Undertaken by Competent Authorities in Respect of EU Legislation on Nature Protection

Planning and Implementation:

- establish a system whereby general protection is afforded to all birds in the wild state (Directive 2009/147/EC);
- identify and designate Special Protection Areas (SPAs) for birds (Directive 2009/147/EC);
- implement procedures to prohibit the import of certain seal products (83/129/EEC);
- identify and establish a network of Special Areas for Conservation (SACs) (Directive 92/43/EEC);
- establish a system of protection for certain plant and animal species (Directive 92/43/EEC);
- establish management authorities (e.g. for permitting, enforcement and international cooperation) and scientific authorities (technical tasks such as amendments of appendices and applications for import/export permits) under Regulation (EC) No 338/97;
- designate customs offices, with trained personnel, for carrying out checks under Regulation (EC) 338/97);
- Designate responsible authorities for carrying out activities under Regulation (EU) 1143/2014;
- designate competent authorities responsible for cooperation and coordination within the catchment area of each marine region or subregion (Directive 2008/56/EC);
- an initial assessment of the current environmental status of the marine waters concerned and the environmental impact of human activities thereon (Directive 2008/56/EC).

Enforcement and Monitoring:

- prohibit the taking of certain species of plant and animal (Directive 92/43/EEC);
- take actions to prohibit certain damaging activities relating to the sale, capture and exploitation of certain bird species (Directive 2009/147/EC);
- encourage scientific research into the effects of protection measures for certain plants and animals (92/43/EEC) and (Directive 2009/147/EC);
- conduct appropriate assessments of developments that potentially damage the scientific interest of SACs and SPAs (Directive 92/43/EEC) and (Directive 2009/147/EC);
- carry out checks at border points to ensure that imports and exports of certain species of plants and animals are covered by the appropriate permits and certificates (Regulation (EC) 338/97);
- monitor internal trade in certain species of plants and animals (Regulation (EC) 338/97);
- establish a monitoring system to include review of import licensing procedures and compliance with leghold traps ban and the introduction into the EU of pelts and other goods made of certain animal species coming from countries using trapping methods (Regulation (EEC) 3254/91);

- ensuring that legal persons are liable for breaches against Directive 2008/99/EC and that effective, proportionate and dissuasive sanctions are imposed regarding deterioration of habitats or the killing, destruction, possession, taking or trading of specimens of protected wild fauna or flora species where the trading affects the conservation status (Directive 2008/99/EC);
- monitor the implementation of import permits required for trade in certain cetacean species (Regulation (EEC) 348/81);
- establish a surveillance system for early detection and rapid eradication of invasive alien species of Union concern, as well as implement effective management measures. If justified, Member States shall carry out appropriate restoration measures to assist the recovery of invaded ecosystems (Regulation (EU) 1143/2014).

Reporting:

Report to the Commission

- on the designation of a competent authority (Regulation (EEC) 83/129), (Directive 92/43/EEC), (Regulation (EC) 338/97/EC), (Regulation (EEC) 3254/91), (Regulation (EU) 1143/2014);
- on transposition and implementation (Directive 92/43/EEC), (Regulation (EEC) 83/129), (Regulation (EEC) 3254/91), (Regulation (EEC) 348/81), (Regulation (EU) 1143/2014);
- on the eligibility and designation of SACs (Directive 92/43/EEC);
- on the eligibility and designation of SPAs (Directive 2009/147/EC);
- on derogations from the Directive due to overriding interests (Directive 92/43/EEC);
- on the results of scientific investigations and research (Directive 92/43/EEC);
- on hunting regulations in the context of the Wild Birds Directive (Directive 2009/147/EC);
- on the introduction of non-native species (Directive 2009/147/EC);
- in the case of species listed in the appendices to the convention, the convention secretariat, on any steps taken by the competent authorities in relation to significant infringements of this regulation, including seizures and confiscations (Art. 14(2), Regulation (EC) 338/97);
- on information for CITES reports (Regulation (EC) 338/97).
- on subdivisions of Marine Waters (Directive 2008/56/EC, Art. 5(1)) on the established environmental targets for Marine Waters (Directive 2008/56/EC)
- on early detection of the introduction or presence of invasive alien species of Union concern and the eradication measures applied and derogations applied pursuant to the Regulation (EU) 1143/2014.

Within the nature protection sector, legislation falls broadly into two categories; firstly, protection of species and designation of valuable sites for them; and secondly, restrictions on imports and exports of certain animals and plants and their derivatives. It would therefore be possible for an environment ministry, for instance, to act as the single competent authority and oversee implementation as a whole. However, as the legislation

concerning import and export restrictions is inherently related to trade, a ministry of trade or agriculture could act as the competent authority. The same applies for the legislation on protecting biodiversity from invasive species. Either way, the competent authority will need to provide a co-ordination role for the legislation and interact with the supporting government agencies and departments and other organisations involved. The structure of the competent authority depends largely on the organisation of government (e.g. if it is of a central or federal nature). The competent authority should also be responsible for ensuring sufficient coordination and integrative approach regarding the implementation and application of other interlinked EU legislation, such as forestry regulations, the Marine Strategy Directive (2008/56), agricultural policies, including animal and health protection regulation, which can have positive or adverse effects on animal species and protected areas.

3.4. **Communication and Consultation**

Planning and implementation of legislation in the nature protection sector will require extensive consultation and communication with a range of organisations, including importers and exporters, landowners and managers, planning authorities and the general public. Consequently, comprehensive communication is very important for the effective implementation of this legislation.

The legislation related to protection of valuable wildlife habitats and species will require communication with, inter alia, the following:

- other government ministries, departments and agencies;
- regional and local government;
- authorities responsible for land-use planning (both local and regional);
- bodies and competent authorities, e.g. water (inland water, marine waters, coastal waters) authorities, coastal and flood defence agencies, forestry authorities;
- enforcement authorities (e.g. authorities ensuring compliance with Directive 2008/99/EC on environmental crimes)
- landowners and land managers;
- the general public;
- education facilities, such as schools and universities; and
- NGOs.

The legislation related to combating threats posed by the invasive alien species and to the protection of rare species through restrictions in their trading will require communication with, inter alia, the following:

- other government ministries, departments and agencies;
- regional and local government;
- customs departments;
- relevant industrial/commercial organisations;
- the general public; and

- education facilities, such as schools and universities.

Legislation on protection of biodiversity from invasive alien species also calls for enhanced cooperation and coordination of management programmes between neighbouring countries.

It is common in the EU for national governments, often through their specialist agencies, to undertake wide-ranging consultations prior to implementing new legislation concerning the protection of habitats and species; both land based and marine related ones. These consultations enable nature conservation agencies and non-statutory organisations to have an input into the implementation mechanism and prepare themselves for the implications of the new legislation. In an increasing number of countries, the NGO sector is already, or is becoming, a major player in the environmental sector. NGOs are also extending their original role as small landholders or managers to large landowners by becoming involved in policy and decision making (by lobbying and through consultations in land-use planning, especially under EIA and SEA procedures).

There are many examples of tremendous growth in the membership, activities and influence of NGOs involved in the nature sector. These include the World Wide Fund for Nature (WWF), which is a key player world-wide; BirdLife International; Greenpeace, which is one of the more activist NGOs in the world campaigning for environmental causes; and TRAFFIC, which is an NGO mainly involved in capacity-building activities to enhance the implementation of CITES. As such it is strongly recommended that comprehensive consultation is undertaken with the NGO sector. Consultation concerning this type of legislation is also important for landowners and managers who will be affected by, for instance, restrictions to land management practices. Other groups could also be affected by new legislation, such as hunting groups, including wildfowling and shooting organisations, which are often very popular in Europe. Such organisations are represented at the European level by the Fédération des Associations de la Chasse d'Europe (FACE).

In addition, international organisations should also be mentioned as they also are active on EU territory. One deserving to be mentioned here is the International Union for Conservation of Nature and Natural Resources (IUCN), which is the world's oldest and largest global environmental network with more than 1,000 government and NGO member organizations, and almost 11,000 volunteer scientists in some 160 countries. IUCN seeks pragmatic solutions to the most pressing environment and development challenges. Amongst others, IUCN publishes the IUCN Red List, compiling information from a network of conservation organizations to rate which species are most endangered. The IUCN supports scientific research, manages field projects worldwide and brings governments, non-government organizations, United Nations agencies, companies and local communities together to develop and implement policy, laws and best practice.

4. TECHNICAL ISSUES

EU legislation in the nature sector contains very little in the way of technical standards, particularly compared to some of the other sectors, such as waste, air or water. The legislation concerning trade restrictions for rare flora and fauna simply requires that Member States adhere to the trading restrictions by implementing complementary national legislation. Similarly, the legislation concerning invasive alien species requires Member States to enforce prohibitions on import, trade, movement and release into the environment of such species. It also requires devising an early warning system, including appropriate management measures for existing invasive species populations. The EU Directives regarding birds and habitats require Member States to safeguard, *inter alia*, migratory birds and habitats that are nationally representative within each Member State. These nationally representative sites will form an overall network of sites throughout the EU. The Birds and Habitats Directives include lists of species and habitat types that are to be afforded additional protection. Therefore, these lists in effect constitute the technical standards to be followed.

5. REGULATION AND ENFORCEMENT

5.1. Overview

All laws and regulations concerning nature protection must be put into practice by means of an effective administration and enforcement system in order for the desired results to be achieved. This requirement has now been reinforced through the Environmental Crimes Directive (2008/99/EC), which obliges Member States to introduce effective, proportionate and dissuasive sanctions (e.g. fines) for certain breaches of the CITES Regulation, the Habitats and the Wild Birds Directives.

The main regulatory functions covering most of the EU nature acquis involve the following primary tasks:

- the issuing of licenses and permits for import and export of certain listed species of plants and animals;
- the issuing of permits for the contained use of invasive alien species;
- border inspection and seizure of any shipments that do not conform with the restrictions imposed by the legislation on invasive alien species;
- monitoring and inspection of shipments and trading documentation to ensure compliance with legislation;
- designation of qualifying sites and species to afford them greater protection from damage;
- monitoring and inspection of sites and species to assess the effectiveness of protection mechanisms;
- control of development which can affect protected sites and ensure coordinated and/or joint procedures (one-stop shop) for project falling for assessments under EIA and/or Habitats/Birds Directives.
- ensure consistency with regulatory procedures under SEA for development of policies/programmes affecting habitats and wild bird populations;
- taking measures concerning the granting of licences and the carrying out of regular inspections in European zoos in order to check that the conditions related to the granting of licences are met;
- the introduction of complementary management practices to protect sites and species;
- the introduction of action plans to combat unintentional introduction and spread of IAS;
- the introduction of management measures to address existing populations as well as restoration measures to recover degraded, damaged or destroyed ecosystems.

5.2. Licensing and Permitting

In recognition of the need to strengthen the protection of rare and endangered wildlife, both flora and fauna, three regulations deal with the implementation of CITES (Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein; Regulation (EC) No 865/2006 on detailed rules concerning the implementation of Regulation No 338/97 on the protection of species of wild fauna and flora by regulating trade therein; and Regulation (EU) No 757/2012²³¹ on suspending the introduction into the European Union of specimens of certain species of wild fauna and flora). These regulations control trade in protected species by introducing import and export procedures, lists of protected species and suspension measures. Such restriction or control of trading is regulated by a system of licensing and permitting, usually under the responsibility of the environment or trade departments in the Member State concerned. Customs or control department or agency is likely to be the most appropriate body to actually enforce the import/export control requirements at the points of entry and in the territories of the Member States. A specialist wildlife agency or organisation would usually have a role in providing scientific advice and training to the customs staff.

5.3. Monitoring, Inspection and Enforcement

Central government, with the possible assistance of a designated central environmental protection agency, will need to maintain an overview of the implementation of the legislation.

This role may include development of additional guidance to government agencies or institutions and may also involve policy refinement and decision making, particularly in cases of overriding public interest or safety. It will also be necessary for central government to set targets for full compliance with the Directives and ensure that sites are selected and protected in accordance with the requirements of the Directives. In the case of trading restrictions/prohibitions for endangered species or invasive alien species, government will be required to maintain an overview of the effectiveness of prohibitions/trading restrictions and undertake consultations with other Member States as required by the nature *acquis*. Reporting within a Member State may involve several levels, including NGOs with specialist nature conservation interests, planning authorities, the specialist government agencies and the ministry itself.

5.4. Designation of Qualifying Sites and Species

Two of the Directives, i.e. Habitats Directive (92/43/EEC) and the Birds Directive (Directive 2009/147/EC) specify that certain qualifying sites within Member States should be classified (or designated) as such and that complementary management practices are introduced to ensure protection of their ecological interest. Thus, under the Birds Directive Member States select the most suitable sites and designate them directly as Special

²³¹ Commission Implementing Regulation (EU) No 757/2012 of 20 August 2012 suspending the introduction into the Union of specimens of certain species of wild fauna and flora.

Protection Areas (SPAs), whereas under the Habitats Directive Member States designate Special Areas of Conservation (SACs) to ensure the favourable conservation status of each habitat type and species throughout their range in the EU. Selection procedure differs depending on which of the two nature directives (Birds or the Habitats) requires creation of a particular site. There are requirements relating to the management of sites and restrictions on operations affecting sites where these are incompatible with the maintenance of their ecological interest. Where the sites are owned by the state this should be easier to implement, but where sites are under private ownership, mechanisms to encourage positive management will be needed. Where site management or restrictions on operations are necessary, different Member States have used a variety of implementation options, such as purchase of the site or payments to landowners to compensate for consequent loss of income. Either of these systems would require a consultative approach and a legal notification mechanism. Mechanisms must be introduced to notify potential developers and the public that a site is awarded protection and also to control activities that may negatively impact on the site.

Technical decision making is an important aspect of this work, which is more than merely an administrative task. The available human resources in terms of trained and experienced personnel should be assessed and future training and development and funding needs identified.

5.5. Data Collection and Reporting

An obligation exists in most Directives to report to the Commission on progress in implementation and the degree of compliance achieved. Accurate data on various aspects of wildlife protection is a vital input to the planning process and for site management. Data collection needs to cover information on individual species of interest as well as sites designated as being of national or EU interest. Reporting is also required in order to measure the degree to which the various Directives have been implemented; such reports must generally be submitted to the Commission. The implementing authority is usually best positioned to collect such data or identify data requirements. If a database is developed which is adequate for the internal needs of the country concerned, it should also fulfil the requirements for reporting to the Commission. To the extent possible such data collection and reporting could be harmonised also with such obligations under international nature related conventions (see above the list of the most relevant nature conventions). Such integrated reporting and data collection is more resource efficient, ensures better coordination and cooperation between the various departments in charge and allows a better general overview of implementation status and possible data gaps.

6. PRIORITISING THE IMPLEMENTATION TASKS

In preparing their strategies and implementation plans, the candidate countries will need to prioritise the major tasks to be undertaken. This process is discussed in each of the fiches dealing with individual pieces of legislation and includes undertaking tasks such as assessing the occurrences of particular habitats and species and monitoring and evaluating particular species and areas. This will require co-operation between specialist staff (and potentially prior training) of the various competent authority/ies, ensuring co-operation at national, regional and local levels, at this preliminary stage and also at later stages. The assistance of a specially trained expert where needed may be useful, particularly when it comes to designating sites. Competent authorities may also wish to liaise with farmers, private landowners, user groups, planning authorities, NGOs and so forth, as regards nature protection legislation implementation issues.

Striving for co-operation between all management authorities and enforcement agencies, such as customs and the police, and co-ordinating the necessary training programmes to ensure successful implementation of the legislation also needs to be considered in advance.

Candidate countries should look at Member State best practice, especially in those where similar conditions, challenges and other circumstances exist, in order to assist with the implementation of nature protection legislation.

7. ECONOMIC AND FINANCIAL ISSUES

7.1. Introduction

Implementation of nature protection sector legislation could lead to the need for a number of investments, unless a high degree of wildlife protection is already in place. In particular, finance will be required for:

- the establishment of the necessary institutional structure with competent authorities, competent and trained staff for general administration, monitoring, supervision and enforcement;
- the provision of adequate numbers of trained technical staff, such as customs officers trained to recognise endangered species and specimens and products thereof as well as to detect invasive alien species whose import is prohibited;
- the cost of establishing and maintaining the NATURA 2000 network and other protected sites in accordance with the Habitats and Bird Directives

7.2. Institutional Development

Implementation of the legislation in the nature protection sector requires a competent authority, such as a ministry of environment (MoE) to lead and set policies and plans. As much of this work is of a technical nature it requires the involvement of specialist personnel, including ecologists, wildlife experts and specialist biologists. In many Member States the MoE includes a number of specialists, whilst a specialist government agency (such as an environmental agency or a conservation agency) holds the majority of expertise necessary for this sector. The need for additional staff and possibly additional government departments or agencies will depend on the current organisational arrangements and the state of the existing nature protection legislation. Countries with strong nature protection legislation will probably already have effective organisational and staffing arrangements, whilst those with less well developed organisational structures will require extensive strengthening. Other key authorities are likely to include those for customs and trade enforcement and agriculture.

7.3. Protection of Important Sites and Species

The Birds Directive and the Habitats Directive require the establishment of certain areas or sites that are important for the protection and conservation of listed species of plants and animals. In practice, this requires that sites are identified and "protected" through a formal system, which varies between Member States. In view of the need to protect any bird species from harm, restrictions on land use, development or management are very often required. Furthermore, the Habitats Directive requires not only protection per se, but positive management of species and habitats to enhance their nature conservation status and value. The mechanisms

for achieving this require, at the least, restrictions on land management and development. These restrictions have been implemented by different mechanisms within Member States, but centre on limiting certain potentially damaging operations.

In some Member States the authorities make payments to landowners and managers for positive habitat conservation measures that maintain or restore the conservation status of habitats and species of EU interest for which the sites have been designated. In some cases, the authorities have resorted to the purchase of certain sites, as this has proved to be an effective mechanism for the long-term conservation of certain areas requiring a high level of protection.

8. SUMMARY OF KEY ISSUES

The governments of the candidate countries should focus on efforts and actions that are fundamental to EU approximation in this sector, in particular by ensuring that:

- the totality of policies, legislation, legal mechanisms and standards adopted at the national level achieve the objectives and results aimed at by EU policies and legislation;
- a single national government authority could be given the overall responsibility and requisite authority for planning and managing the process of achieving compliance with EU policies and legislation, some of the compliance responsibilities can be delegated to regional and local authorities;
- arrangements are put in place for the effective involvement and participation of all other bodies or interest groups which have a significant function to perform in relation to nature protection;
- appropriate competent authorities and related organisations are designated or established and their respective duties, functions and powers are clearly defined; and
- sufficient human and technical resources are allocated to allow all key functions and tasks to be performed properly, especially those related to monitoring, supervision and enforcement.

THE HABITATS DIRECTIVE

Official Title: Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.92)

Amendments:

Council Directive 97/62/EC of 27 October 1997 adapting to technical and scientific progress Directive 92/43/EEC on the conservation of natural habitats and of wild fauna and flora (OJ L 305, 8.11.1997)

Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty (OJ L 284, 31.10.2003)

Council Directive 2006/105/EC of 20 November 2006 adapting Directives 73/239/EEC, 74/557/EEC and 2002/83/EC in the field of environment, by reason of the accession of Bulgaria and Romania (OJ L 363, 20.12.2006)

Council Directive 2013/17/EU of 13 May 2013 adapting certain directives in the field of environment, by reason of the accession of the Republic of Croatia (OJ L 158, 10.6.2013).

Commission Implementing Decision of 11 July 2011 concerning a site information format for Natura 2000 sites (notified under document C(2011) 4892) (OJ L 198, 30.7.2011)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The aim of the Directive is to contribute to the maintenance of biological diversity (biodiversity) in the European Union, through the conservation of certain natural habitats and the protection of certain animal and plant species. In order to achieve this the Habitats Directive provides for two main instruments: the Natura 2000 network of protected sites and the species protection provisions.

Thus, the Habitats Directive establishes a common framework for the conservation of wild animal and plant species and natural habitats of EU importance. It provides for the creation of a network of special areas of conservation, called Natura 2000, to "maintain and restore, at favourable conservation status, natural habitats and species of wild fauna and flora of EU interest".

A habitat type is defined as being of EU interest if it is in danger of disappearance within its natural range or has a small natural range or represents an outstanding example of one or more of nine biogeographical regions: the Alpine, Atlantic, Black Sea, Boreal, Continental, Macaronesian, Mediterranean, Pannonian and Steppic biogeographical regions.

On the basis of the national lists of sites of EU importance and attendant information furnished by the Member States, in accordance with Article 4(1) of Directive 92/43/EEC, the Commission has adopted a number of Commission decisions setting out initial lists of sites of EU importance for these biogeographical regions, i.e. Alpine, Atlantic, Black Sea, Boreal, Continental, Macaronesian, Mediterranean, Pannonian, Steppic.

More information regarding the biogeographical regions can be obtained at:

http://ec.europa.eu/environment/nature/natura2000/biogeog_regions/index_en.htm

Species are of EU interest if they are endangered (with some exceptions) or vulnerable or rare or endemic and requiring particular attention. Two main concepts of protection can be distinguished, i.e. through the Natura 2000 network of protected sites and the species protection provisions. The Natura 2000 network is intended to ensure that selected habitats and species are maintained at, or restored to, a "favourable conservation status". A key means of achieving a "favourable conservation status" is the requirement on Member States to identify and designate Special Areas of Conservation (SACs) and to take various measures to protect habitats and species both within and beyond them, including prohibiting certain harmful activities. Annexes I and II set out natural habitat types and host species.

Provisions for species protection apply to the whole of a Member State's territory and concern the physical protection of specimens as well as their breeding sites and resting places. The Habitats Directive distinguishes two levels of protection- one referred to in Articles 12 and 13 calling for a "system of strict protection" for Annex IV species and the other related to measures to control the exploitation of species listed in Annex V (Articles 14 and 15). While the "system of strict protection" provides a stringent protection regime, species covered by Annex V can be exploited, although such exploitation should not jeopardise the objective of maintaining their favourable conservation status in any way.

As new countries joined Europe, they brought in a wealth of new species and habitats. The enlargement of the European Union with thirteen new member states in 2004, 2007 and 2013 brought amendments to both the Habitats Directive (92/43/EEC) and the Birds Directive (2009/147/EC). Most changes concern the annexes to the Directives, based on the negotiations of amendments to the lists of habitat types and species of the above Directives. New typical and endangered species and habitats in the new Member States have been added to the annexes, albeit with some geographical exceptions. The summary of how the two directives were amended to

reflect the impact of successive enlargements and take into account all the new species and habitats in need of protection can be obtained at:
http://ec.europa.eu/environment/nature/legislation/enlargement/index_en.htm.

Annex I lists today 233 European natural habitat types, including 71 priority habitats (i.e. habitat types in danger of disappearance and whose natural range mainly falls within the territory of the European Union). Annex I is based on the hierarchical classification of European habitats developed by the CORINE Biotopes project.

In 2011 the Commission adopted Decision (2011/484/EU) concerning a site information format for Natura 2000 sites, setting out an annex with the data format and details required for Natura 2000 sites, which also should be updated regularly.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Establish or delegate a competent authority to be responsible for implementing the requirements of the Directive. This will usually be an environment ministry or nature conservation agency.
- Compile a list of sites that contain natural habitat types according to Annex I or host species in Annex II in accordance with criteria specified in Annex III, plus supporting scientific information; and send the list to the Commission together with information on the sites, in accordance with the format laid down in Commission Decision 2011/484/EU (Art. 4 and Annexes I, II as amended by Council Directive 97/62/EC and Annex III). Member States have to identify and designate sites in proportion to the representation within their territory of the natural habitat types and the habitats of species specified in Annexes I and II. If their sites hosting priority interests represent more than 5% of their national territory they may, in agreement with the Commission, request that the criteria in Annex III be applied more flexibly (Art. 4(2)).
- Designate these sites once they have been agreed with the Commission, as Special Areas of Conservation (SACs); and establish priorities for the management of these sites (Art. 4).
- Establish the measures necessary for the conservation of SACs which may include management plans specifically designed for the sites or integrated into other development plans, and appropriate statutory, administrative or contractual arrangements which correspond to the ecological requirements of the habitats and species concerned (Art. 6).
- In respect of certain animal species (listed in Annex IV), establish a system of strict protection and prohibit certain activities including:
 - the deliberate capture, killing or disturbance of these species as well as the deterioration and destruction of breeding sites and resting places; and
 - the keeping, transport and sale of these species when taken from the wild (Art. 12).
- In respect of certain plant species (listed in Annex IV), establish a system of strict protection and prohibit certain activities including:
 - the deliberate picking, cutting and destruction of these species; and
 - the keeping, transport and sale of these species when taken from the wild (Art. 13).
- Establish a system to monitor incidental capture and killing of animal species listed in Annex IVa (Art. 12(4)).

2.2. Regulation

- Take appropriate steps to prevent the deterioration of SACs and the disturbance of the species for which they were created in so far as such disturbance could be significant in relation to the objectives of the Directive (Art. 6).
- Assess any plan or project, individually or in combination with other plans or projects, that is likely to have a significant effect on a SAC, and ensure that such plan or project is not approved if it would adversely affect the integrity of the site, unless there are no alternatives and there are "imperative reasons of overriding public interest" as specified in the Directive (Art. 6).
- If a plan or project is approved in spite of a negative assessment (for imperative reasons of overriding public interest), take all necessary compensatory measures to ensure that the overall coherence of Natura 2000 is protected and inform the Commission of the compensatory measures adopted (Art. 6).
- In land-use planning and development policies, seek to encourage the management of features of the landscape that are of major importance for wild plants and animals (Art. 10) with a view to improving the ecological coherence of the Natura 2000 network.
- Where deemed necessary, ensure that the taking and exploitation of certain species of wild plants and animals (listed in Annex V) is controlled to ensure that they are maintained at a "favourable conservation status" (Art. 14). In order to ensure that the favourable conservation status of these species is not compromised, Member States may establish a system of licences for taking specimens or may impose quotas. The periods and/or methods of taking, selling, purchasing and transporting specimens, breeding in captivity etc. are to be regulated, implying the need for a system of authorisation/registration. In some circumstances (specified in Art. 16), Member States may derogate from species protection measures provided that there is no satisfactory alternative and the derogation is not detrimental to the conservation status of the species.
- Prohibit the use of specified means of capturing and killing certain animal species (listed in Annexes IV and V) (Art. 15 and Annex VI).
- Regulate (and if necessary prohibit) the deliberate introduction into the wild of non-native animal and plant species (Art. 22).

2.3. Monitoring and Research

- Monitor:
 - the conservation status of natural habitats and species (Art. 11); and
 - the incidental capture and killing of animal species (Art. 12 and Annex IV).
- Encourage research and exchange information for the proper co-ordination of research, having regard to the objectives of the Directive (Art. 18).

- Study the desirability of re-introducing native species, where this might contribute to their conservation (Art. 22).

2.4. Information and Reporting

- Consult the public before:
 - agreeing to a plan or project that is likely to have a significant effect on a SAC (Art. 6); or
 - re-introducing native species (Art. 22).
- Promote education and general information on species protection and conservation (Art. 22).
- Report to the Commission on:
 - sites that host natural habitat types and species listed in Annexes I and II;
 - cases of derogation from species protection requirements (Art. 16);
 - estimates relating to possible co-financing by the EU (Art. 8);
 - research and scientific work (Art. 18);
 - implementation of the Directive (Art. 17);
 - transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 23); and
 - compensatory measures adopted (Art. 6).

2.5. Additional Legal Instruments

A number of other legislative instruments are relevant to the implementation of this Directive and must be borne in mind during implementation.

- Commission implementing Decision (2011/484/EU) of 11 July 2011 concerning a site information format for Natura 2000 sites (notified under document C(2011) 4892)(2011/484/EU). This Decision supersedes and repeals Commission Decision 97/266/EC. This Decision sets out the format for each designated Natura 2000 site, based on Art. 3(1) of Habitats Directive, which should include a map of the site, name, location, extent and the data resulting from application of the criteria used in selecting the site.
- Council Directive 2009/147/EC (referred to as the Wild Birds Directive), as the SACs that are to be identified under this Directive are to complement the Special Protection Areas (SPAs) established under the Birds Directive to form the Europe-wide network of protected sites known as Natura 2000. Moreover, Article 6 of this Directive sets out management obligations that, in so far as they relate to a

SAC that is also a SPA, replace the management obligations for SPAs set out in Article 4 of the Birds Directive (Art. 7).

- EIA Directive (2011/92/EU) (see Section 2 of the Handbook), as one of the criteria which triggers an environmental impact assessment is the value and sensitivity of sites affected by proposed developments. Thus SACs (and SPAs) are evaluated for possible damage under the EIA Directive and could be seen to benefit from this additional "protection".
- Directive 2008/99/EC on the protection of the environment through criminal law. Art. 3(h) of this Directive requires that Member States ensure that any conduct which causes the significant deterioration of a habitat within a protected site is regarded a criminal offense.
- The Environmental Liability Directive (2004/35/EC), which reinforces the „Polluter Pays Principle”, which is laid down in the EU Treaties. This Directive extends to cover damage to protected species and natural habitats, which is any damage that has significant adverse effects on reaching or maintaining the favourable conservation status of such habitats or species. This Directive obliges operators of certain activities that can affect protected nature areas (Natura 2000 sites, SPAs) to under certain circumstances take preventive measures and to in case of damage take remediating measures.
- Water Framework Directive (2000/60/EC) establishes a framework for the protection of all surface waters and groundwater with the aim to reach good status in all waters as a rule by 2015. To be more precise, the main objectives of the WFD for surface waters are: preventing the deterioration of any status; reaching good ecological status and good chemical status as a rule by 2015, and implementing all necessary measures to progressively reduce pollution from priority substances and ceasing or phasing out emissions, discharges and losses of priority hazardous substances. This refers to all surface water bodies, including those that form part of a Special Protection Area (SPA) under the Birds Directive and/or a Site of Community Importance (SCI) under the Habitats Directive. As for the groundwater, the main objectives of the WFD are to reach good quantitative status and good chemical status in all groundwater bodies, which includes not only the protection of the proper groundwater, but also the protection of directly dependent surface water and terrestrial ecosystems.
- Marine Strategy Framework Directive (2008/56/EC) establishes a framework within which Member States must take the necessary measures to achieve or maintain good environmental status in the marine environment by the year 2020 at the latest. The purpose of the Directive is to protect, preserve, prevent deterioration or, where practical, restore Europe’s oceans and seas where they have been adversely affected and to prevent and reduce inputs in the marine environment. This is to be achieved by applying an ecosystem- based approach to management of human activities whilst ensuring sustainable use of marine goods and services.

Convention on Biological Diversity adopted at the Earth Summit in Rio de Janeiro in June 1992, established participating governments' approach towards biodiversity conservation. The EU is a signatory to the convention and produced four biodiversity action plans in 2001. On 3 May 2011, the European Commission adopted a new strategy to halt the loss of biodiversity and ecosystem services in the EU by 2020, in line with two commitments made by EU leaders in March 2010 – halting the loss of biodiversity and the degradation of ecosystem services in the EU by 2020, and restoring them in so far as feasible, while stepping up the EU contribution to averting global biodiversity loss"- and a vision for 2050. This strategy, which supersedes the earlier 2006 Commission Communication on Biodiversity and the attached Biodiversity Action Plan sets out

actions at the EU level and of the Member States that respond to many of the obligations arising from this convention. More specific links to other international agreements are found in the Ramsar Convention on Wetlands of International Importance especially as Waterfowl Habitat, 1971; the Bonn Convention on Conservation of Migratory Species of Wild Animals, 1979; the Washington Convention on International Trade in Endangered Species, 1973; and the Bern Convention on the Conservation of European Wildlife and Natural Habitats, 1979.

3. IMPLEMENTATION

3.1. Key Tasks

Table 5. The Habitats Directive - Key Implementation Tasks

THE HABITATS DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Establish or delegate a competent authority to be responsible for implementing the requirements of the Directive.
1.2	On the basis of the criteria set out in Annex III, the competent authority should identify a suite of sites hosting natural habitat types according to Annex I or representing the habitat of species in accordance with Annex II. This list should be submitted to the Commission, which will then compile, in agreement with each Member State, a draft list of sites of EU interest. Once the composite list has been adopted by the Commission according to the procedure laid down in Article 21, Member States must designate the SACs in their territory as soon as possible and within six years at most, and establish priorities for the management of these sites.
1.3	The SACs to be selected are to include the full range of indigenous species, in particular habitat types listed in Annex I and habitats of the species listed in Annex II. The SACs will (with SPAs designated under the Wild Birds Directive) form a network of such sites throughout Europe (known as Natura 2000). The Natura 2000 sites 'data shall be compiled in accordance with the Annex to Commission implementing Decision concerning a site information format for Natura 2000 sites (2011/484/EU)
1.4	Where the area of potential SACs with priority interests in a Member State exceeds 5% of its territory, it may seek, in agreement with the Commission, a more flexible approach to the application of the criteria listed in Annex III.
2	Regulation
2.1	For the designated sites, establish the necessary conservation measures, which may include the development of management plans tailored to specific sites and statutory, administrative or contractual arrangements that will meet the ecological requirements of the natural habitat types in Annex I and the species in Annex II.
2.2	Maintain the wildlife population at appropriate levels, taking into account scientific and cultural requirements. Where considered necessary, Member States shall endeavour to improve the ecological coherence of Natura 2000 by maintaining, and where appropriate developing, features of the landscape that are of major importance to wildlife, such as linear habitat features and key traditional habitats.
2.3	Take the necessary measures to establish a system of strict protection for the animal species listed in Annex IV (a) in their natural range. In particular, prohibit the deliberate capture or killing of specimens of these species in the wild. Provide protection from disturbance of these species during the breeding, rearing, hibernation and migration periods and deliberate destruction or taking of eggs from the wild, and deterioration of breeding sites or resting places.
2.4	For the listed species, prohibit the keeping, transport and sale or exchange, and offering for sale or exchange, of specimens taken from the wild, except for those taken legally before this Directive is implemented.
2.5	Establish a system of strict protection for the plant species listed in Annex IV (b). This system must prohibit deliberate picking, collecting, uprooting or destruction of such plants in their natural range in the wild. It must also prohibit the keeping, transport, sale or exchange and offering for sale of these species taken from the wild, apart from those taken legally prior to the Directive being implemented. In both this case and the case of animals, the protection must cover all stages in the biological life cycle of the organism.
2.6	Where deemed necessary, ensure that the taking and exploitation of certain species of wild plants and animals (listed in Annex V) is controlled to ensure that they are maintained at a "favourable conservation status" (Art. 14).
2.7	Prohibit the use of specified means of capture and killing of certain animal species (listed in Annexes IV and V) (Art. 15 and Annex VI).
2.8	Regulate the deliberate introduction of non-native wildlife species, so as to protect the native populations.

2.9	Take steps to prevent the deterioration of SACs and the disturbance of species for which they were created.
2.10	Assess any plans or projects that are likely to have a significant effect on the SAC network and prohibit plans or projects that would adversely affect the integrity of the sites, unless they are necessary due to a lack of alternatives and the existence of imperative reasons of overriding public interest or safety. If a plan or project is permitted in spite of a negative assessment for reasons of public interest, take all necessary compensatory measures to ensure that the overall coherence of Natura 2000 is protected (Art. 6).
3	Monitoring and Research
3.1	Establish a system to monitor the incidental capture and killing of the animal species listed in Annex IV (a) and, following information collection, undertake further research or conservation measures as required to ensure that capture or killing activities do not have a significant effect on the species concerned.
3.2	Establish a monitoring system covering all of the monitoring activities required in the Directive. The monitoring should include population level analysis and species condition, as indicators of the conservation status of natural habitats and species. Encourage the necessary research and information exchange to achieve the objectives set out in Annex II (conservation of natural habitats and wild fauna and flora) and ensure the requisite monitoring (Annex II).
3.3	Encourage the necessary research and information exchange necessary to achieve the objectives of the Directive.
3.4	Where necessary, continue monitoring and surveillance after control of the taking and exploitation of certain species of wild plants and animals to ensure that they are maintained at a "favourable conservation status" has taken place. Further regulations may include those regarding access to property, local prohibitions on timing and taking of species, hunting and fishing rules, establishment of licenses, regulation of sale and keeping of species, regulation of captive breeding and propagation and evaluation of the effectiveness of the above measures.
3.5	Study the desirability of reintroducing native species where this might contribute to their conservation.
4	Information and Reporting
4.1	Report to the Commission, as appropriate on the following: <ul style="list-style-type: none"> • sites that host natural habitat types and species listed in Annexes I and II; • nomination of sites and designation of SACs; • cases of derogations from specified requirements of the Directive; • results of scientific investigations (Art. 18); • estimates relating to possible co-financing by the EU (Art. 8); • implementation of the Directive (Art. 17); • measures taken to comply with the Directive (Art. 23); • transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 23).
4.2	Consult the public before: <ul style="list-style-type: none"> • agreeing to a plan or project that is likely to have a significant effect on a SAC (Art. 6); • reintroducing native species (Art. 22)
4.3	Promote education and general information on species protection and conservation (Art. 22)
4.4	Data collection in the format given in Annex to Commission implementing Decision concerning a site information format for Natura 2000 sites (2011/484/EU)

3.2. Phasing

Experience within Member States suggests that the most demanding and time-consuming tasks associated with this Directive are:

- transposition of the requirements of the Directive into national legislation;
- identification of the suite of sites for designation as SACs, including rigorous assessment of the scientific and nature conservation value of the sites against the necessary criteria;

- the formal designation of the SACs, establishment of management plans and other necessary actions following discussions with landowners and managers and arrangements for site management and, if necessary, compensation measures.

These tasks should therefore be planned to commence during the initial phase of implementation.

Experience also reveals that extensive time is required for scientific analysis to identify the location and abundance of the characteristic species and habitats and also that lengthy periods of liaison with site owners may be necessary prior to designation. Particular consideration should therefore be given to these aspects, which should be programmed carefully into the implementation schedule.

Nature and biodiversity legislation is a horizontal legislation, requiring early attention and integration into other EU policies such as structural, transport or agricultural policy.

At EU level, in April 2013 the Commission issued the "Interpretation Manual of European Union Habitats – EUR28", which is a scientific reference document aiming to provide common definition for all habitat types and thus ensuring clear and unambiguous interpretation of Annex I. The EUR28 version of the Interpretation Manual includes descriptions of new habitats and one amendment to an existing habitat resulting from the Croatia joining the European Union in 2013.

For more information regarding this manual please refer to the following website:

http://ec.europa.eu/environment/nature/legislation/habitatsdirective/docs/Int_Manual_EU28.pdf

The European Topic Centre on Biological Diversity provides technical and scientific support to the European Commission, DG Environment and the Member States in implementing the Birds Directive (2009/147/EC) and Habitats Directive (92/43/EEC), particularly for the establishment of the Natura 2000 network. For more information regarding the European Topic Centre on Biological Diversity and for information and software packages for support to the Natura 2000 network, please consult:

<http://bd.eionet.europa.eu>

http://bd.eionet.europa.eu/activities/Natura_2000/index_html

4. IMPLEMENTATION GUIDANCE

New timing provisions are needed for the candidate countries. However, the first priority will be an assessment of the occurrence of habitats and species listed in Annexes I and II of the Directive as these provide the basis for site designation. It will also be important to consider whether certain species or habitats need adding to these annexes to reflect better the key nature conservation characteristics of the candidate countries. The next priority is the adoption and application of a methodology to monitor species and habitat conservation status.

Implementation of the specific requirements of this Directive will be influenced by the present status, needs and situation in each candidate country. However, drawing on the experience of selected Member States, a number of general observations and suggestions for implementing this Directive are presented below:

4.1. Planning

Decisions about how to implement the Habitats Directive are left to the discretion of the Member States. Monitoring of SACs and other species and habitats could be undertaken at a variety of levels, from local to national, although co-ordination would best be undertaken by a single competent authority. A common approach within existing Member States is to appoint a central ministry overseeing a specialist environmental agency. Some Member States have a further level of delegation to specialist government agencies dealing primarily or solely with nature conservation. This latter approach would seem to offer some advantages, as staffing tends to require specialists, trained in ecological and scientific aspects. However, the further down the line the specialist agencies are, the further they are from the decision-making process and the more they rely on recommendations and lobbying of decision makers.

The key actors are government ministries responsible for environmental protection and government agencies with environmental or nature conservation responsibilities, scientific research organisations and, increasingly, a suite of non-governmental organisations (NGOs) which often have an interest and expertise in wildlife or particular elements of wildlife protection. The NGO sector in Europe is actively participating in nature conservation activities, including the planning and development processes and formulation of conservation policies, in consultation with statutory agencies. In addition, there are many organisations involved in conducting research on wildlife and biodiversity, both in the private and public sectors.

The designation of land areas as SACs also involves land owners and land managers in the process. This is because, as designation seeks to maintain or restore (and enhance where possible) the conservation status of sites, restrictions on land management and development often prove necessary, thereby engaging owners and managers in negotiations and frequently, compensation agreements.

Examples of Institutional Arrangements and Regulatory Control

Croatia: The fundamental legal act regulating nature protection is the Nature Protection Act, which entered into force on 6 July 2013. This framework Law includes provisions for the protection and integrated conservation of nature and the parts thereof providing a legal basis for the adoption of secondary legislation regulating different aspects of the nature protection. List of national legislation regulating Natura 2000 ecological network and species protection can be obtained at: <http://www.mzoip.hr/en/nature/regulations-and-international-treaties.html>

As regards institutional set up, the overall responsibility for nature protection is with the Ministry of Environment and Nature Protection, while the Croatian Agency for Environment and Nature is the central implementing agency.

Sweden: Environmental legislation has been consolidated into the Environmental Code, a framework law aimed at promoting sustainable development. The Code includes regulations to preserve biological diversity, such as different types of area protection and special provisions concerning the protection of species protection. The Habitats Directive has been implemented in the Code, and also in the related Government Ordinance about Site Protection and Species Protection Ordinance (NFS 2009:10). The overall responsibility for nature conservation policy is with the Ministry of the Environment (MoE), whereas the Environmental Protection Agency (EPA) is the central executive agency. At the sub- national level the 21 County Administrative Boards (CAB) undertake much of the day-to-day work. The CABs are e.g. responsible for establishment and management of nature reserves, decide on permits, and conduct monitoring. The CABs have special environmental protection units dealing with biodiversity issues. At the local level the municipal councils have also been given power to establish nature reserves and are active in other areas.

4.1.1. Establishment of SACs

The Directive requires each Member State to prepare and propose to the European Commission a national list of sites for each of the features, which occurs in their European territory, for evaluation in order to form a European network of sites of community importance (SCIs). Once adopted as SCIs, the Member States must designate the sites as special areas of conservation (SACs) within six years.

Some Member States that have given more responsibility to regional authorities have had to overcome particular implementation issues. For instance, as central government has in effect delegated responsibility, it has been unable to act autonomously or independently from these regional agencies in the selection and designation of SACs.

A very common practice in many Member States is to make compensatory payments to landowners or managers for restricting land use or management. This is seen as a financial burden on the state, but one that is practically unavoidable when dealing with privately owned sites. All the Member States contacted reported that the designation of SACs entailed long and sometimes complex consultation periods, which required large inputs from agency staff over considerable time periods. A further consideration is that candidate countries may have habitat types not currently listed. This has occurred in the past for other Member States and has resulted in the addition of new habitat types to the list.

Example of Arrangements for Establishing SACs

Sweden: the implementation of the Habitats Directive, especially the requirement to identify pSCIs, raised some institutional and administrative issues. The identification of pSCIs and SPAs lies within the competence of the County Administrative Boards', which propose the identified sites to the Environment Protection Agency (EPA), which reviews them before passing them to the Ministry of the Environment for consideration and approval by the Government.

Sites proposed as SACs or SPAs are according to law to be a priority in the authorities ongoing efforts to formally protect areas, e.g. as nature reserves or with nature conservation agreements. The owners of SACs are awarded financial compensation if restrictions to land management are necessary to maintain the nature conservation interest. As many of the important habitats are forests, restrictive practices often mean no felling, thereby preventing income generation. Compensation is paid for restrictions in land use or part-acquisition, but the most common approach is for the state or municipality to purchase the land before the reserve is created. There is a distinct problem in the conservation of water areas. Restrictions and consideration might often be needed outside the protected core area, which calls for development of new management approaches in larger areas.

Ireland: The National Parks and Wildlife Service as a part of the Heritage Division of the Department of Arts, Heritage and the Gaeltacht is responsible for designating and advising on the protection of habitats and species identified for nature conservation: Special Areas of Conservation (SACs) and Special Protection Areas (SPAs) having particular regard to the need to consult with interested parties. Thus, at a national level, this Department consults regularly with stakeholders including the major non-government farming and conservation groups and other government departments. For consultation at a local level, owners of lands and/or rights in designated areas are identified and notified of proposals that may affect them and invited to attend public consultation meetings to develop conservation plans for the sites. The Department also places advertisements locally in press and on radio to maximise awareness of any new statutory proposals. The stages in procedure for designation of nature conservation sites, including SACs and SPAs are described in the document available at the following link:

<http://www.npws.ie/sites/default/files/general/Site%20Designation%20Process%2016%20Feb%202012.pdf>

4.2. Protection of SACs

The Directive requires that Member States implement a system of protection of vulnerable habitats and species listed in the Directive and for which SACs are designated.

Article 6 is the central provision covering management and protection of sites. Provisions of Article 6(1) and 6(2) put an emphasis on prevention, while provisions of Article 6(3) and (4) define a procedure applying to specific circumstances.

Article 6(1) require the implementation of positive and pro-active measures, involving if need be management plans and statutory, administrative or contractual measures, which aim to contribute to achieving the general objective of the Directive, whereas Article 6(2) makes provision for avoidance of habitat deterioration and significant species disturbance. The Commission has published in 2014 guidance document (see below), which

explains the various options available for establishing the necessary conservation measures in line with the provisions of Article 6(1) and examines, on a practical level, how these can best be implemented in a range of different circumstances, as illustrated by good practices from various Member States. In theory, there are several mechanisms that could be used in implementation of conservation measures and indeed Member States have different approaches. These include contracts with landowners/users, regulation on land use and restriction of activities, acquisition of land or rights and conservation and restoration activities carried out by skilled staff (site managers and/or stakeholders, e.g. experts and NGOs).

Article 6(3) and 6(4) set out the circumstances within which plans and projects with negative effects may or may not be allowed. Thus, Article 6(3) establishes a procedure intended to ensure, by means of a preliminary examination, that a plan or project not directly connected with or necessary to the management of the site but likely to have a significant effect thereon is authorised only to the extent that it will not adversely affect the integrity of that site. Article 6(4) is an exception of the general rule according to which authorisation can only be granted to plans or projects not affecting the integrity of the site concerned. Thus, provisions of Article 6(4) apply when the results of the preliminary assessment under Article 6(3) are negative or uncertain. Furthermore, this provision can only be applied to circumstances where all the conditions required by the Directive are fully satisfied. In particular, it must be documented that the alternative put forward for approval, is the least damaging for habitats, for species and for the integrity of the Natura 2000 site, regardless of economic considerations, and that no other feasible alternative, exists that would not affect the integrity of the site and that there are imperative reasons of overriding public interest, including 'those of a social or economic nature'.

Once the lack of suitable alternatives and the acceptance of imperative reasons of overriding public interest are fully ascertained and documented, all compensatory measures that are needed to ensure the protection of the overall coherence of the Natura 2000 network have to be taken. Therefore, compensatory measures should be considered only when the application of other safeguards, such as mitigation measures, is not sufficient.

The Commission, in close cooperation with Member States and stakeholders, has published guidance documents with regard to the management of Natura 2000 sites. Following links offer information on a large variety of approaches and best practices:

- Guidance on the management of Natura 2000 sites: http://ec.europa.eu/environment/nature/natura2000/management/guidance_en.htm

The web site contains selection of various studies and guidance documents providing valuable source of information for decision-makers and practitioners involved in implementation of Article 6 of the Habitats Directive. More recent studies include:

- Case studies on synergies between WFD, MSFD and Nature directives (October 2015)
- Study on evaluating and improving the Article 6.3 permit procedure for Natura 2000 sites (November 2013)
- Establishing conservation measures for Natura 2000 Sites, A review of the provisions of Article 6.1 and their practical implementation in different Member States (2014)
- Guidance document on Article 6(4) of the 'Habitats Directive' 92/43/EEC (2007/2012) This guidance document should be read in conjunction with the booklet published by the European Commission in 2000 and entitled "Managing Natura 2000 sites"
- Commission note on designation of Special Areas of Conservation (SACs) (May 2012)
- Commission note on setting conservation objectives for Natura 2000 sites (November 2012)

- Commission note on establishing conservation measures for Natura 2000 sites (September 2013)
- Best practices for the management of Natura 2000 sites: http://ec.europa.eu/environment/nature/natura2000/management/best_practice_en.htm
- Guidance on financing Natura 2000 sites: http://ec.europa.eu/environment/nature/natura2000/financing/index_en.htm
- Natura 2000 in the marine environment: http://ec.europa.eu/environment/nature/natura2000/marine/index_en.htm
- Guidelines for the management of wilderness and wild areas in Natura 2000: http://ec.europa.eu/environment/nature/natura2000/wilderness/index_en.htm
- Natura 2000- Addressing conflicts and promoting benefits: http://ec.europa.eu/environment/nature/natura2000/management/best_practice_en.htm

4.3. Protection of species

The Habitats Directive tackles issue of protection of species and sub-species in various ways. The species listed in Annex II where core area of their habitat is designated as Sites of Community Importance (SCIs) must be protected under the Natura 2000 network and the sites must be managed in accordance with the ecological requirements of the species. Protection of species is often referred to as a second pillar of the Habitats Directive. In principle, this second pillar deals with direct influences on the species themselves as well as (in the case of animal species) their eggs, breeding sites and resting places. The species and sub- species listed in Annex IV are subject to strict protection regime, which must be applied across their entire natural range within the EU, both within and outside Natura 2000 sites, whereas species listed in Annex V can be exploited, as long as the exploitation is compatible with maintenance in a favourable conservation status in any way. Managed exploitation of species listed in Annex V, includes sustainable hunting. Well-regulated hunting and the active involvement of hunters in the practical management of Natura 2000 sites can deliver mutual benefits both in terms of hunting and in terms of successful biodiversity conservation. In 2001 the European Commission launched the “Sustainable Hunting Initiative”, aimed at promoting dialogue and co-operation between environmental and hunters’ organisations in order to achieve and enhance sustainable. Some of the most important outcomes of the initiative have been the publication of a European Commission Guide to sustainable Hunting under the Birds Directive and the adoption of an EU Agreement on Sustainable Hunting: signed in 2004 by BirdLife International and FACE (Federation of Associations for Hunting and Conservation of the EU). Both documents are available at: http://ec.europa.eu/environment/nature/conservation/wildbirds/hunting/index_en.htm. Furthermore in 2007 the European Charter on Hunting and Biodiversity was adopted. This charter is meant to reinforce the implementation and coherence of global and European biodiversity instruments such as the Convention on Biological Diversity and the European Community’s Birds and Habitats Directives, and is fully supportive of the EC’s Sustainable Hunting Initiative.

Most species are covered by more than one annex (the most usual combination is a listing in both Annex II and IV. In this twofold regime conservation efforts are maximized through management (maintenance and

restoration) of the habitats in protected sites and the protection of the breeding sites and resting places as well as the species itself over the whole territory of a Member State.

The Commission, in close cooperation with Member States and stakeholders, has published guidance documents with regard to implementation of the 'system of strict protection' specified in Article 12 of the Habitats Directive. The Guidance document on the strict protection of animal species of Community interest under the Habitats Directive 92/43/EEC, available at: http://ec.europa.eu/environment/nature/conservation/species/guidance/index_en.htm aims to provide a common understanding of the relevant provisions among national and regional authorities, conservation bodies and other structures responsible for or involved in the implementation of the Habitats Directive, in particular its Articles 12 and 16.

Examples from Member States: Arrangements for Monitoring

United Kingdom: the government nature conservation agencies conduct regular monitoring and assessments of all statutorily protected sites, including SSSIs, SACs and SPAs. These assessments are conducted with regard to the "reasons for designation" and the objectives and priorities for each site. When monitoring indicates that species or habitats are not in keeping with the site's objectives, remedial measures are undertaken, including changes to site management, species conservation intervention and further detailed research. The costs of such measures can be considerable and will usually fall on central government. In some cases, EU funds may be available for management programmes (e.g. the LIFE Nature programme), particularly where these are of an innovative or "demonstration" nature. Other sites may also be monitored where they are managed under EU-funded agro-environment programmes.

Sweden: the Swedish Ministry of Environment oversees the monitoring of the environment, with Swedish Environmental Protection Agency (EPA) and the County Administrations Boards (regional level) submitting reports to the ministry. The EPA has a main responsibility for guidance on the supervision regarding the implementation and application of the Environmental Code. The guidance and its objective is wide, comprising general support, advice, coordination, monitoring and evaluation. The EPA operates an extensive information system to inform landowners and the public of ecologically valuable sites. The system includes information on the Internet and a range of publications.

4.4. Monitoring

The Directive requires the competent authority to conduct monitoring to evaluate the nature conservation status of designated sites (as well as outside such sites) and to take remedial measures where necessary to maintain or enhance the ecological value of these sites. Monitoring requires systematic and scientifically rigorous methodologies to be applied and the results to be assessed against clearly defined objectives. The authority may undertake the monitoring itself or contract out the work to a scientific research establishment. Expert field and technical staff, analytical facilities and data manipulation skills are required. Before an appropriate monitoring methodology can be designed and implemented, clear objectives must first be set. Indicators may be a useful tool and independent experts should contribute substantially to the task of setting objectives, and developing methodologies and indicators. Baseline data should be established as quickly as possible. It is likely that there are existing monitoring programmes, e.g. on the conservation status of habitats and species, that can be adjusted to fulfil the requirements of the directive. Any monitoring or inspections that relate to enforcement must follow objective procedures and may need to include facilities for the archiving of samples in the event that subsequent legal action is to be taken. Referring to enforcement, authorities should also have regard to Directive 2008/99/EC on the protection of the environment through criminal law. Pursuant to Art. 3(h), any conduct which causes the significant deterioration of a habitat within a protected site is a criminal offense that must be pursued with effective, proportionate and dissuasive sanctions.

4.5. Reporting

The Directive requires that Member States report to the Commission on several issues, including transposition and implementation, the list of sites eligible for designation, derogations, cost estimates for potential EU co-financing and research and scientific work. The Habitats Directive is one of the EU's most significant contributions to the aim of halting the loss of biodiversity by 2010 as set out by the EU heads of state at the Gothenburg Summit in 2001. Information gathered under the reporting requirements of the Habitats Directive will be an important source of data for that work. It should therefore be borne in mind that the monitoring, assessment and reporting of conservation status under the Habitats Directive is not only of importance in relation to the implementation of the Directive itself but is a crucial building block for an overall biodiversity trends assessment in Europe and as such will influence the strategic considerations that follow.

Article 6(4) of the Habitats Directive requires Member States to inform the Commission if they adopt compensatory measures in relation to projects that have a significant negative impact on Natura 2000 sites. This information has to be submitted using a standard reporting form. This form has been integrated into the Commission's guidance document on the application of Article 6.4 and can be found on:

http://ec.europa.eu/environment/nature/natura2000/management/docs/art6/new_guidance_art6_4_en.pdf

Pursuant to Article 16 of the Habitats Directive, Member States must also report to the Commission every two years about possible derogations from the strict species protection provisions. These reports are compiled and assessed, and summaries for derogations that were granted are available at http://ec.europa.eu/environment/nature/knowledge/rep_habitats/index_en.htm

Examples of a Member State's Reporting of Derogations Pursuant to Article 16

According to the Commission's composite report covering period 2007-2008, a total of 5,790 derogation licences were issued between 2007 and 2008. The distribution of the number of derogations issued by the Member States varies considerably, from two derogations granted in Estonia to several hundreds in others, such as Germany and Poland. With 1.010 derogations the United Kingdom is the country that issued the highest number of derogations in the biennial.

According to the data provided by the national reports, about half of derogations are issued “for research and education purposes, of repopulating and re-introducing these species and for the breeding operations necessary for these purposes, including the artificial propagation of plants”. This reason is broadly distributed among the MS. Most of these derogations allow capture of specimens followed by immediate release for species identification, marking/tagging. They usually concern inventories, census or genetic analyses or study on population dynamics to increase the knowledge on species listed in the Habitats Directive and/or to allow the restocking of eroded populations. Another substantial number of derogations was issued ‘in the interests of public health and public safety, or for other imperative reasons of overriding public interest, including those of a social or economic nature and beneficial consequences of primary importance for the environment’.

Non-destructive and/or reversible activities such as capture, disturbance, keeping, and transport are broadly applied among the five main reasons for derogation. Killing of specimens is mainly applied to prevent serious damage, in particular to crops, livestock, forests, fisheries and water and other types of property and, in some cases, to justify the annual harvesting quota relative to a species.

Mammals are the most derogated class followed by amphibians. More than half of the derogations concerning mammals affect different species of bats, while the other concern *Lynx lynx*, *Canis lupus*, *Ursus arctos* and *Castor fiber*, etc. Derogations affecting plants and insects are the minority.

For more information, please consult:

http://ec.europa.eu/environment/nature/knowledge/rep_habitats/index_en.htm

The Member States must also report every six years about the progress made with the implementation of the Habitats Directive, pursuant to Article 17. The second round of national reports under Article 17 on the conservation status of habitats and species under the Habitats Directive for the period 2007-2012 were assessed in the course of 2014 on EU-level, results were summarised and analysed. In May 2015, Report from the Commission to the Council and the European Parliament The State of Nature in the European Union Report on the status of and trends for habitat types and species covered by the Birds and Habitats Directives for the 2007-2012 period as required under Article 17 of the Habitats Directive and Article 12 of the Birds Directive (COM/2015/0219 final) was published. The Report describes the key results for the 2007-12 reporting period presenting and assessing results under both Habitats and Wild Birds Directive. It also provide an insight at the contribution of Natura 2000 to the status of, and trends for, nature.

More information on reporting under Article 17, including national summaries, can be obtained at:

http://ec.europa.eu/environment/nature/knowledge/rep_habitats/index_en.htm

The European Topic Centre on Biological Diversity maintains the reference portal containing reference documents related to the information provided in the reporting formats under Article 17 of the Habitats Directive:

http://bd.eionet.europa.eu/activities/Reporting/Article_17/reference_portal

5. COSTS

The main types of costs arising during the implementation of the Habitats Directive are summarised in the checklist below.

The cost of implementing the Habitats Directive will depend on the extent of existing systems for the classification, protection and management of sites, monitoring of sites and species, the occurrence of habitats and species to be protected, and the availability of EU funding.

The costs for provision of specialist staff to survey and identify the potential SACs should not be excessive and could be assisted by the voluntary sector. Perhaps the greatest potential costs relate to the practicalities of establishing the SAC system, especially if compensatory payments prove necessary in lieu of restricting development. Ongoing costs relate to continuing surveys and research into the nature conservation value of the SACs, preparation of management plans for SACs and implementation of management activities (proactive measures) to maintain and enhance the scientific value of the sites.

Some costs may be relatively minor, when compared to the expenditure required by other legislation that necessitates infrastructure development. However, where compensation or purchase of sites is required, or restoration measures are needed, costs can escalate quite rapidly.

Table 6. Checklist of the Types of Cost Incurred To Implement the Directive

<p>Checklist of the Types of Cost Incurred To Implement the Directive</p> <p>Initial set-up costs:</p> <ul style="list-style-type: none">• devising systems and procedures;• collating baseline data and filling out Natura 2000 information format sheets also to be updated;• applying criteria for site selection;• preparation of guidance documents;• provision of training;• consultation and communications. <p>Capital expenditure:</p> <ul style="list-style-type: none">• restoration projects;• one-off compensation payments to landowners and managers;• purchase of sites (if necessary). <p>Ongoing costs:</p> <ul style="list-style-type: none">• environmental impact assessments for developments affecting habitats also under EIA Directive continuing research and survey;• implementation of management activities to maintain or enhance value of sites;• communications, consultations, production of documents and reports and other public awareness activity (e.g. website maintenance, publications, hotlines);• reporting to the Commission;• supervision, monitoring and evaluation of nature protection;• enforcement activities.
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The Commission is trying, through various means, to facilitate the financing of the designation of SCIs and SACs, as well as the management of such areas, and in particular of Natura 2000 sites.

Firstly, it published a guidance handbook, which presents the EU funding options for Natura 2000 sites that are available at the national and regional level in the period 2014 to 2020. It provides guidance on complementarities between different funds and policies, which can be of benefit to the network. The Handbook has a two-part structure, with separate volumes for Part I: EU Funding opportunities in 2014-2020 and Part II: Analysis of Natura 2000 management measures eligible for financing in 2014-2020. Both documents are available at:

http://ec.europa.eu/environment/nature/natura2000/financing/index_en.htm

A new report has been published in 2013 estimating the overall economic value of the benefits provided by the Natura 2000 Network, available at:

http://ec.europa.eu/environment/nature/natura2000/financing/docs/ENV-12-018_LR_Final1.pdf

This report on economic value has been supplemented with a tool kit for practitioners in assessing the socio-economic benefits of Natura 2000 sites.²³² This tool kit is available at:

http://ec.europa.eu/environment/nature/natura2000/financing/docs/benefits_toolkit.pdf.

Finally, the Commission has also created a specific IT tool to facilitate access to this information and to create the opportunity to use the information in the framework of management planning.

The tool can be found at:

http://ec.europa.eu/environment/nature/natura2000/financing/docs/financing_it_tool.pdf

In addition, there are funding opportunities through LIFE+, which is the EU's financial instrument supporting environmental and nature conservation projects throughout the EU, as well as in some candidate, acceding and neighbouring countries. More information about LIFE+ can be obtained at:

<http://ec.europa.eu/environment/life/index.htm>.

²³² „Assessing socio-economic benefits of Natura 2000 – A toolkit for practitioners – Output of the EC project, Financing Natura 2000: Cost estimate and benefits of Natura 2000, Contract No.: 070307/2007/484403/MAR/B2. September 2009, IEEP (Kettunen, M., Bassi, S., Gantioler, S. & ten Brink, P.)

THE BIRDS DIRECTIVE

Official Title: Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010)²³³,

Amended by:

Council Directive 2013/17/EU of 13 May 2013 adapting certain directives in the field of environment, by reason of the accession of the Republic of Croatia (OJ L 158, 10.6.2013).

Commission Implementing Decision (2011/484/EU) of 11 July 2011 concerning a site information format for Natura 2000 sites (notified under document C(2011) 4892) OJ L 198, 30.7.2011, p. 39–70

²³³ This Directive is a recast of previous Directive and its amendments. Hence, Directive 2009/147/EC repealed Council Directive 79/409/EEC on the conservation of wild birds (as amended by Council Directives 81/854/EEC, 86/112/EEC and 94/24/EC and Commission Directives 85/411/EEC, 91/244/EEC, 97/49/EC and Council Directive 2006/105/EC.

1. SUMMARY OF MAIN AIMS AND OBJECTIVES

The aim of Directive 2009/147/EC on conservation of wild birds (hereafter referred to the „Birds Directive”), which recasts previous Directive from 1979 (79/409/EEC), is to provide for the protection, management and control of naturally occurring wild birds and their nests, eggs and habitats within the European Union. It serves to ensure that all wild birds receive basic protection from trapping and killing; that sufficient habitat is protected for wild birds, especially to assure the survival of threatened and migratory species; that large-scale or non-selective means of taking birds are prohibited; and that the sale or commercial exploitation of most species is prevented. Certain exceptions are made for legitimate sporting and hunting practices, and to allow governments to take action, under certain specified conditions, including those when birds pose serious risks for human health and safety, crops, livestock, fisheries, forests, water, or other flora and fauna. There is also a requirement for the provision of a sufficient diversity and area of habitats so as to maintain the population of all species. Article 7 of the Habitats Directive 92/43/EEC replaces certain habitat protection obligations arising from this Directive. Article 3(1) of the Habitats Directive provides that the Natura 2000 network shall include the special protection areas classified by the Member States pursuant to the Birds Directive. For each Natura 2000 site, the information format regarding these sites needs to provide for a map of the site, name, location, extent and the data resulting from application of the criteria used in selecting the site. Candidate countries should consult Decision 2011/484/EU on the information format for Natura 2000 sites set out in its annex.

The enlargement of the European Union with 13 new Member States in the period 2004- 2013 brought amendments to the Birds Directive, especially concerning the annexes. In the first place, new typical and endangered species and habitats in the new Member States have been added to the annexes, with a limited number of geographical exceptions, which was based on negotiations of modifications to the lists of habitat types and species²³⁴. Directive 2009/147/EC is a recast of the old Directive and its amendments and this version applies to both old and new Member States.

²³⁴ A summary of how the Wild Birds Directive was amended to reflect the impact of successive enlargements and take into account all the new species and habitats in need of protection can be obtained at: http://ec.europa.eu/environment/nature/legislation/enlargement/index_en.htm

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Establish or delegate a competent authority to be responsible for the implementation of the requirements of this Directive.
- Identify and designate as Special Protection Areas (SPAs) the most suitable territories, in number and size, for the species of wild birds listed in Annex I (Art. 4 and Annex I) and for other regularly occurring migratory species not listed in Annex I but needing protection on their breeding, moulting, staging and wintering grounds (with particular attention to wetlands, especially wetlands of international importance). Plan special conservation measures concerning their habitat in order to ensure the survival and reproduction in their area of distribution of Annex I species (Art. 4). Take into account the species' protection requirements in the geographical sea and land area where this Directive applies (Art. 4).
- Appropriate system for supervision, monitoring and enforcement of Directive provisions. Article 3 (f) of Directive 2008/99/EC on environmental crimes requires that Member States ensure that the killing, destruction, possession or taking of specimens of protected wild fauna or flora species (with certain exceptions) is labelled as a criminal offence, which leads to effective, proportionate and effective sanctions.

2.2. Regulation

- Take measures to ensure that wild bird populations are maintained at a level corresponding in particular to ecological, scientific and cultural requirements, both within and outside protected areas, while taking account of economic and recreational requirements, and take the requisite measures to preserve, maintain or re-establish a sufficient diversity and area of habitats (Arts. 2 and 3).
- Take special conservation measures concerning the habitats of the species of wild birds listed in Annex I, and for regularly occurring migratory species of other wild birds especially those dependent on wetlands of international importance to ensure their survival and reproduction in their area of distribution (Art. 4).
- Take steps to avoid the deterioration of habitats in SPAs and the significant disturbance of wild birds using them (Art. 6(2) together with Art. 6(3) and 6(4) of Council Directive 92/43/EEC superseding the obligation under the first sentence of Art. 4(4) of this Directive).
- Assess any plan or project that either by itself or in combination with other plans or projects is likely to have a significant effect on an SPA, and ensure that any such plan or project is not approved if it would adversely affect the integrity of the site (Art. 6(3) of Council Directive 92/43/EEC, the Habitats Directive), unless there are "imperative reasons of overriding public interest" as specified in Article 6(4) of Habitats Directive (92/43/EEC).

- If, in the absence of alternative solutions, a plan or project is approved in spite of a negative assessment (for imperative reasons of overriding public interest) take all necessary compensatory measures to ensure that the overall coherence of Natura 2000 is protected and inform the Commission of the measures adopted (Art. 6(4) of Habitats Directive).
- Establish a general system of protection for wild birds. This protection extends to nests and eggs (even empty ones) and, with regard to the birds themselves, includes prohibition of deliberate taking, capture, keeping or killing; deliberate disturbance which would affect any species adversely, and any activity related to the sale of live or dead birds or any of their parts or readily recognised derivatives with the exception of species listed in Annex III, after consultation with the Commission (Arts. 5 and 6).
- Exceptions to this general protection regime are allowed for:
 - species listed in Annex III, Part A which may be subject to commercialisation if legally killed or captured, or otherwise legally acquired (Art 6(2));
 - species listed in Annex III, Part B which may be commercialised after consultation with the Commission (Art 6(3));
 - species listed in Annex II, Part A which may be hunted in all Member States (Art. 7(2));
 - species listed in Annex II, Part B which may be hunted only in the Member States specified (Art. 7(3)); and
 - derogations for specific reasons such as public health and safety, prevention of damage to crops, the protection of flora and fauna etc. (Art. 9).
- Set up a system of authorisations for derogations under Article 9 (in the interests of public health, etc.), specifying the species concerned, the means of capture or killing, limits on time and place, etc. (Art. 9(2)).
- Ensure that any derogations under Article 9 are specified in accordance with the Directive, are closely supervised and monitored, and are reported annually to the Commission (Art 9(3)).
- Ensure that the hunting of species listed in Annex II does not jeopardise conservation efforts in their distribution area and that hunting is carried out in accordance with national legislation and complies with the principles of wise use and ecologically balanced control of the species concerned and is compatible with the requirements of this Directive. In particular, ensure that species to which hunting laws apply are not hunted during the rearing season nor during the various stages of reproduction or, in the case of migratory species, their return to their rearing grounds (Art. 7 and Annex II).
- Prohibit the use of methods and means of hunting, capturing or killing wild birds that are large scale, non-selective or capable of causing the local disappearance of a species and in particular the use of means, arrangements or methods listed in Annex IV, point a (Art. 8).
- In consultation with the Commission, ensure that the introduction of non-native species of wild birds does not adversely affect local flora and fauna (Art. 11).
- Ensure that measures taken pursuant to this Directive do not lead to a deterioration in the present situation regarding the conservation of wild birds (Art. 13).

2.3. Monitoring and Research

- Monitor:
 - compliance with conditions relating to the marketing of wild birds (Art. 6);
 - the effect of hunting on conservation efforts (Art. 7); and
 - the effect of introducing non-native species (Art. 11).
- Encourage research and any other work required as a basis for the protection, management and use of wild birds paying particular attention to the subjects listed in Annex V (Art. 10 and Annex V).
- Ensure collection and assembling of data for each designated Natura 2000 site, based on Art. 3(1) of Habitats Directive, also pursuant to the Birds Directive, in the format set out in the Annex to Commission implementing Decision (2011/484/EU) of 11 July 2011 concerning a site information format for Natura 2000 sites (e.g. information should include a map of the site, name, location, extent and the data resulting from application of the criteria used in selecting the site)

2.4. Consultation and Reporting

- Consult the public before agreeing to a plan or project that is likely to have a significant effect on an SPA (Art. 6(3) of Council Directive 92/43/EEC).
- Consult the Commission about the introduction of non-native species of birds to ensure that this does not adversely affect local fauna and flora (Art. 11).
- Report to the Commission on:
 - the designation of SPAs, providing all relevant information so that it can take the appropriate initiatives with a view to the co-ordination necessary to ensure that the designated areas form a coherent whole which meets the protection requirements of the Directive (Art. 4);
 - proposals to authorise certain activities (Art. 6);
 - the practical application of hunting regulations (Art. 7);
 - cases of derogation from the provisions of the Directive (every year, Art. 9);
 - research on monitoring and protection (Art. 10);
 - implementation of national provisions under the Directive (every three years, Art. 12);
 - measures taken to comply with the Directive (Art. 18);
 - transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 18); and
 - compensatory measures adopted pursuant to Article 6 of Council Directive 92/43/EEC.

2.5. Additional Legal Instruments

A number of other legal acts are relevant to the implementation of this Directive:

- The Birds Directive is linked to the Habitats Directive (92/43/EEC), especially through the replacement of site protection obligations under Article 4 of the Birds Directive by those set out in Article 6 of the Habitats Directive (see Article 7 of the Habitats Directive). The Habitats Directive also establishes (in Article 3) Natura 2000, a network of both Special Protection Areas (SPAs) and Special Areas of Conservation (SACs) throughout Europe, designed to maintain the overall viability and integrity of biodiversity across Member States.
- The EIA Directive (2011/92/EU) is used as a tool to assess the potential effects of projects and plans on SPAs and to devise necessary mitigation or compensatory measures. The amendments to the EIA Directive introduced by Directive 2014/52/EU requires member States to introduce one-stop shop, i.e. coordinated and/or joint procedure in cases where the obligation to carry out assessments related to environmental issues arises simultaneously from the EIA Directive and Directive 92/43/EEC and/or Directive 2009/147/EC.
- Directive 2008/99/EC on the protection of the environment through criminal law. Art. 3(f) of this Directive requires that Member States make the killing, destruction, possession or taking of specimens of protected wild fauna or flora species, except for cases where the conduct concerns a negligible quantity of such specimens and has a negligible impact on the conservation status of the species a criminal offense.
- The Environmental Liability Directive (2004/35/EC), which reinforces the „Polluter Pays Principle”, which is laid down in the Treaty of the Functioning of the European Union. This Directive extends to cover damage to protected species and natural habitats, which is any damage that has significant adverse effects on reaching or maintaining the favourable conservation status of such habitats or species. To assess whether a damage is covered by the Directive, member States should take into account of the criteria set out in Annex I. This Directive obliges operators of certain activities that can affect bird species and their habitats to under certain circumstances take preventive measures and to in case of damage take remedying measures.
- Other major international agreements having a bearing on the Birds Directive and for which the Directive is an implementation mechanism are the Ramsar Convention on Wetlands of International Importance especially as Waterfowl Habitat, 1971; the Bonn Convention on Conservation of Migratory Species of Wild Animals, 1979; the Washington Convention on International Trade in Endangered Species, 1973; and the Berne Convention on the Conservation of European Wildlife and Natural Habitats, 1979; the African Eurasian Waterbird Agreement, 1995; as well as the Convention on Biological Diversity to which the EU is a signatory.

Given the history of amending the Directive to reflect the changing geographical coverage of the EU (see the sector overview), Annex I (and Annex II) will be amended to take account of any threatened or hunted bird species found in the accession countries not already included in the annex(es).

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the following checklist, organised in chronological order (where applicable) within each subheading.

Table 7. The Wild Birds Directive - Key Implementation Tasks

THE WILD BIRDS DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Establish or delegate a competent authority to be responsible for the implementation of the requirements of the Directive.
1.2	The competent authority should develop a system to protect all birds in the wild state.
1.3	On the basis of ornithological criteria, the competent authority should identify and designate as SPAs areas that are important for rare or vulnerable bird species listed in Annex I of the Directive and those used by migrating species, with particular reference to wetlands (either inland or coastal, such as estuaries) and especially wetlands of international importance.
1.4	Ensure that the coordinated and/or joint procedure is established in cases where the obligation to carry out assessments related to environmental issues (projects affecting SPAs) arises simultaneously from the EIA Directive (2011/92/EU) and Directive 92/43/EEC and/or Directive 2009/147/EC.
2	Regulation
2.1	Take the necessary measures to maintain bird populations at appropriate levels, taking into account scientific and cultural requirements including measures to preserve, maintain or re-establish a sufficient diversity and area of habitats.
2.2	Take special conservation measures for the species listed in Annex I and for regularly occurring migratory species, especially those dependent on wetlands of international importance.
2.3	For each SPA, take actions to ensure appropriate management and to avoid deterioration of sites and their habitats and significant disturbance of species.
2.4	Establish a general system to protect all listed bird species referred to in Article 1, including protection from disturbance, keeping, killing and capture. Prohibit any activities relating to sale, unless for species under Annex III. This protection also extends to eggs and nests.
2.5	Provide under national legislation for hunting of species listed in Annex II and ensure that hunting of species listed in Annex II is carried out in accordance with the provisions of Articles 7 and 8, which aim to ensure humane killing methods and sustainable use of bird populations.
2.6	Ensure that any derogations from Articles 5 to 8 allowed under Article 9 are specified in accordance with the Directive, are closely supervised and monitored, and are subject to annual reporting to and review by the Commission.
2.7	Ensure that the introduction of non-native species of birds does not adversely affect local flora and fauna.
2.8	Assess any plan or project that either by itself or in combination with other plans or projects is likely to have a significant effect on an SPA, and ensure that such a plan or project is not approved if it would adversely affect the integrity of the site, unless there are imperative reasons of overriding public interest
2.9	If a plan or project is approved in spite of a negative assessment, take all necessary compensatory measures to ensure that the overall coherence of Natura 2000 is protected.
2.10	Carry out remedial measures to maintain or enhance the ecological value of SPAs, should monitoring indicate that there has been any deterioration in habitat quality and/or value to bird species listed in Annex I.

3	Monitoring and Research
3.1	Encourage specific research and scientific study to support the protection of designated sites and bird species. Particular attention should be paid to the subjects listed in Annex V, with Member States sending the Commission any information required to enable it to take appropriate measures for the coordination of research and work referred to in Article 10 of the Directive.
3.2	Establish a monitoring system covering the spectrum of activities within the Directive. The monitoring should include: assessment of population levels of Annex I species; ecological value and integrity of SPAs; and effectiveness of mechanisms to prevent undue harmful activities to bird species listed in Annex II.
3.3	Monitor compliance with the conditions relating to the marketing of wild birds, the effect of hunting on conservation efforts and the effect of introducing non-native species.
3.4	Ensure that the Natura 2000 site information covering sites of protected birds are collated using the format set out in the Commission implementing Decision (2011/484/EU).
4	Consultation and Reporting
4.1	Consult with the public before agreeing to a plan or project that is likely to have a significant effect on an SPA. Consult with the Commission about the introduction of non-native species of birds.
4.2	Report to the Commission, as appropriate, on the following: <ul style="list-style-type: none"> • transposition and implementation of the Directive; • designation of Special Protection Areas (SPAs); • granting authorisation for the sale of birds listed in Annex III; • the practical application of hunting regulations for species listed in Annex II; • derogations from the provisions of the Directive; • measures taken to comply with the Directive; • research activities; • compensatory measures adopted according to Article 6 of the Habitats Directive; • transpositions of national law adopted in the field covered by the Directive.
5	Enforcement
5.1	Sanction the killing, destruction, possession or taking of specimens of protected wild birds, except for cases where the conduct concerns a negligible quantity of such specimens and has a negligible impact on the conservation status of the species, pursuant to Directive 2008/99/EC on environmental crimes.
5.2	Ensure that industrial operators with activities that can potentially damage wild birds and their habitats, covered by the scope of the Environmental Liability Directive (2004/35/EC), to take preventive measures and in case of damages take remedying measures.

3.2. Phasing

Experience within Member States suggests that the most demanding and time-consuming tasks associated with this Directive are:

- transposing the requirements of the Directive into national legislation;
- identifying the suite of sites for designation as SPAs, including rigorous assessment of the scientific and nature conservation value of the sites against the necessary criteria;
- formally designating the SPAs, establishing management plans, and other necessary actions following discussions with landowners and managers and arrangements for site management and, if necessary, compensation for restricting management operations;

- fixing hunting seasons and managing hunting provisions in accordance with the requirements of the Directive.

These tasks should therefore be planned to commence during the initial phase of implementation. Experience also reveals the extensive time required for scientific analysis to identify the location and abundance of the listed bird species and areas of importance for birds, and also the lengthy periods of liaison with site owners prior to designation. Particular consideration should therefore be given to these aspects, which should be programmed carefully into the implementation schedule.

4. IMPLEMENTATION GUIDANCE

New timing provisions are needed for candidate countries. However, the first priority will be an assessment of the appropriateness and the occurrence of species listed in Annex I, as well as migratory species, as these provide the basis for site designation. The next priority is the adoption and application of a methodology to monitor species and habitat conservation status.

The present status, needs and situation in each candidate country will influence implementation of the specific requirements of this Directive. However, drawing upon the collective experience of the Member States, a number of general observations and suggestions for implementing this Directive are presented below.

4.1. Planning

- Decisions on how to implement the Birds Directive are the responsibility of the Member States. Monitoring of SPAs and other species and habitats could be undertaken at a variety of levels, from local to national, although there will be need for overall co-ordination by the competent authorities. Key actors are usually the ministries responsible for environmental protection and/or nature conservation and other government agencies with nature conservation responsibilities, scientific research organisations and increasingly NGOs, which have often developed an expertise in wildlife or particular elements of wildlife protection, such as birds. Many NGOs are actively participating in nature conservation activities, including the planning and development processes and formulation of conservation policies, in consultation with statutory agencies. In the context of this Directive, the most significant NGO is BirdLife International, which has national partners in most countries of Europe. Among other activities, it has specialised in gathering and publishing authoritative information on so-called Important Bird Areas (IBAs) which have been widely recognised in EU Member States and by the European Commission as checklists of potential SPAs. The second edition of the IBA inventory for Europe was published in 2000.
- In addition, there are many organisations involved in conducting research on wildlife, birds and biodiversity, both in the private and public sectors. The designation of land areas as SPAs under this Directive also involves landowners, land managers and user groups in the process. This is because, as designations seek to conserve (and enhance where possible) the nature conservation value of sites, this has implications for land management and land-use planning. This success in management of the sites is frequently dependent on engaging owners and managers in the discussions, and in providing incentives for positive management actions. The monitoring and research requirements of the legislation also lead to the involvement of specific scientific and research organisations, since much of the work is of a specialist nature.
- An approach in some Member States is for specialist government agencies to be responsible for nature conservation and all associated legislative issues, such as the Wild Birds Directive. These agencies report directly to the ministry responsible for environmental protection, which in turn reports to the Commission.

4.1.1. Establishment of Special Protection Areas (SPAs).

Protection of habitats for particularly threatened species listed in Annex I, and other regularly occurring migratory species is in the focus of the Articles 3 and 4 of the Birds Directive.

Thus, Member States must select the most suitable sites and designate them directly as the Special Protection Areas (SPAs). All SPAs are automatically included in the Natura 2000 ecological network. Identification and delimitation of SPAs must be entirely based on the scientific criteria, such as '1% of the population of listed vulnerable species' or 'wetlands of international importance for migratory waterfowl'.

Special conservation measures for the SPAs are set in Articles 4(1) and 4(2). They provide for a similar approach for the management of SPAs to that set out in Article 6(1) of the Habitats Directive. In this context, guidance documents on management of Natura 2000 sites available at the: http://ec.europa.eu/environment/nature/natura2000/management/index_en.htm should be consulted.

4.1.2. Species Protection

Under the Birds Directive, protection of species is ensured through general system of protection and habitats conservation, but also through regulated hunting and trade limited to few species. Provisions of Article 5 and 6 provide for basic species protection prohibitions related to hunting and trade. However, Directive provides for exceptions to the general prohibitions set out in Articles 5 and 6. The trade in species listed in Annex III of the Directive is permitted, provided that the conditions and restrictions within Articles 6 (2) and 6 (3) are observed. As regards hunting, species listed in Annex II may be hunted under Article 7 of the Directive owing "to their population level, geographical distribution level and reproductive rate throughout the Community". Where a species is not listed in Annex II, an exception to the prohibitions referred to in Article 5 is only possible where the strict requirements of Article 9 are fulfilled.

The Commission provides guidance on hunting practices. The 2004 Guide follows the Directive and extensive case law. It explains requirements of the Birds Directive relating to hunting, including issues of recreational hunting and identifies the possibilities and limitations for flexibility in fixing hunting seasons and addresses the derogation issue. The guide is supplemented by a Commission document providing clarification and interpretation of the key concepts of Article 7(4) of the Birds Directive which deals with the period of reproduction and of pre-nuptial migration (return to the breeding areas) for huntable bird species listed on Annex II of the Directive. Guidance documents on strict protection of species are available at: http://ec.europa.eu/environment/nature/conservation/wildbirds/action_plans/guidance_en.htm

With relevance are also Species Action Plans developed for around 50 bird species listed in Annex I of the Birds Directive available at: http://ec.europa.eu/environment/nature/conservation/wildbirds/action_plans/index_en.htm

Some Member States encountered problems related to the provision of protection for certain bird species, particularly in situations or areas where there is a long tradition of hunting. Hunting is not to be automatically excluded from SPAs. It is a management issue that needs to be considered on a case by case basis, ideally within the framework of a management plan for the site. Likewise for other human activities that have potential to cause significant disturbance to the birds for which the sites have been designated.

4.1.3. Monitor Effectiveness of Measures

In view of the need to provide site-based (SPA) protection for certain birds, as well as general protection for all species, the monitoring requirements within individual Member States are greater than might appear at first. Monitoring requires systematic and scientifically rigorous methodologies to be applied and the results to be assessed against clearly defined objectives. The authority may undertake the monitoring itself or contract out the work to a scientific research establishment. Expert field and technical staff, analytical facilities and data manipulation skills are required. Before an appropriate monitoring methodology can be designed and implemented, clear objectives must first be set. Indicators are the useful tool and independent experts can contribute substantially to the task of setting objectives and developing methodologies and indicators. Baseline data should be established as quickly as possible. It is likely that there are existing monitoring programmes, e.g. on the conservation status of habitats and species, that can be adjusted to fulfil the requirements of the Directive. Any monitoring or inspections, which relate to enforcement must follow objective procedures and may need to include facilities for the archiving of samples in the event that subsequent legal action is to be taken

4.1.4. Conduct Appropriate Assessments

The requirement for conducting appropriate assessments is included to ensure that SPAs — by definition sites of international importance — are afforded protection from developments or activities that could adversely affect their scientific and nature conservation importance. The meaning of "appropriate assessment" has been interpreted by individual Member States and has been taken to mean an assessment of the potential effects of a development on the scientific or conservation value of the site for which it was designated. Therefore an environmental assessment type approach is used, but this must focus in particular on the key features for which the site is a SPA or SAC.

As Member States have implemented the EIA Directive (2011/92/EU) and are in the process of implementing its amendment, Directive 2014/52/EU, planning applications for developments potentially affecting SPAs and SACs are normally subject to EIAs. Therefore potential damage to these sites from developments is assessed and considered at an early stage in the process. In practice, the carrying out of "appropriate assessments" under the Birds and Habitats Directives was largely an additional exercise, with the focus being more on the nature conservation status of the site and with the results being presented separately from the EIA to the decision makers. The requirement to conduct appropriate assessments has strengthened the protection afforded to SPAs. New amendments to the EIA Directive seek to minimize risk of inconsistencies within the EIA process itself and in relation to other legislation. Thus, the amending Directive introduced an EIA 'one-stop shop', allowing the coordination or integration of assessment procedures under the EIA Directive and other EU legislation, namely Habitats and Wild Birds Directive.

4.2. Reporting

The Directive requires Member States to report to the Commission on several aspects, including transposition and implementation, the list of sites eligible for designation, derogations, cost estimates for potential EU co-financing and research and scientific work. All Member States have to submit reporting on the status and trend in bird populations (Art. 12) as well as on derogations (Art. 9) they may apply to the directive's obligations. In

2011, the Commission in agreement with Member States has revised the reporting procedure and frequency in order to focus the reporting obligations on data that inform about the status and trend of bird populations, thereby streamlining the reporting under Art.12 of the Birds Directive with the reporting on conservation status under Art.17 of the Habitats Directive. More information on reporting under Article 12, including national summaries, can be obtained at:

http://ec.europa.eu/environment/nature/knowledge/rep_birds/index_en.htm

4.3. **Costs**

The main types of costs arising during the implementation of the Wild Birds Directive are illustrated in the checklist below.

The cost of implementing the Wild Birds Directive will depend on the extent of existing systems for the classification, protection and management of sites, the monitoring of sites and species, and the occurrence in the territory concerned of habitats and species to be protected.

The costs of providing specialist staff to survey and identify the potential SPAs should be relatively low and could be achieved with the assistance of the voluntary sector. Perhaps the greatest potential costs relate to the practicalities of establishing the SPA system, especially if payments are to be made for positive management or land purchases prove necessary in lieu of restricting development.

Table 8. Checklist of the Types of Cost Incurred to Implement the Directive

Checklist of the Types of Cost Incurred to Implement the Directive

Initial set-up costs:

- devising systems and procedures;
- compiling baseline assessments;
- provision of training;
- establishing and applying criteria for site selection;
- preparation of guidance documents;
- consultations and communications.

Capital expenditure:

- one-off compensation payments to landowners and land managers;
- purchase of sites (if necessary).

Ongoing costs:

- continuing research and survey;
- implementation of management activities to maintain or enhance the value of sites;
- ongoing management costs under multi-annual management agreements;
- regulatory and enforcement action including systems for ensuring supervision and enforcement including imposing if need be sanctions and making industrial operators remediate damage to bird species or their natural habitats caused by them
- communications, consultations, production of documents and reports and public awareness;
- reporting to the Commission.

THE REGULATIONS ON TRADE IN ENDANGERED SPECIES

Official Title: Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 61, 3.3.97)

Amended by

Commission Regulation (EC) No 938/97 of 26 May 1997 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 140, 30.5.1997)

Commission Regulation (EC) No 2307/97 of 18 November 1997 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 325, 27.11.1997)

Commission Regulation (EC) No 2214/98 of 15 October 1998 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 279, 16.10.1998)

Commission Regulation (EC) No 1476/1999 of 6 July 1999 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 171, 7.7.1999)

Commission Regulation (EC) No 2724/2000 of 30 November 2000 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 320, 18.12.2000)

Commission Regulation (EC) No 1579/2001 of 1 August 2001 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 209, 2.8.2001)

Commission Regulation (EC) No 2476/2001 of 17 December 2001 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 334, 18.12.2001)

Commission Regulation (EC) No 1497/2003 of 18 August 2003 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 215, 27.8.2003)

Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty (OJ L 284, 31.10.2003)

Commission Regulation (EC) No 834/2004 of 28 April 2004 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 127, 29.4.2004)

Commission Regulation (EC) No 1332/2005 of 9 August 2005 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 215, 19.8.2005)

Commission Regulation (EC) No 318/2008 of 31 March 2008 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 95, 8.4.2008)

Commission Regulation (EC) No 407/2009 of 14 May 2009 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 123, 19.5.2009)

Regulation (EC) No 398/2009 of the European Parliament and of the Council of 23 April 2009 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein, as regards the implementing powers conferred on the Commission (OJ L 126, 21.5.2009)

Commission Regulation (EU) No 709/2010 of 22 July 2010 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 212, 12.8.2010)

Commission Regulation (EU) No 101/2012 of 6 February 2012 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 39, 11.2.2012)

Commission Regulation (EU) No 1158/2012 of 27 November 2012 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 339, 12.12.2012)

Commission Regulation (EU) No 750/2013 of 29 July 2013 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 212, 7.8.2013)

Commission Regulation (EU) No 1320/2014 of 1 December 2014 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein OJ L 361, 17.12.2014)

A consolidated version of Regulation (EC) No. 338/97 from 2014, including all of its subsequent amendments, can be obtained at:

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1456763496287&uri=CELEX:01997R0338-20141220>

Regulation (EC) No. 865/2006, laying down detailed rules concerning the implementation of Council Regulation (EC) No. 338/97 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 166, 19.6.2006), as amended by Regulations (EC) No 100/2008(OJ L 31, 5.2.2008), (EC) No 791/2012 (OJ L 242, 7.9.2012), (EU) No 1283/2013 (OJ L 332, 11.12.2013), (EU) No 2015/870 (OJ L 142, 6.6. 2015) and Commission Implementing Regulation (EU No 792/2012 (OJ L 242, 7.9.2012) as amended by Commission Implementing Regulation (EU) 2015/57

A consolidated version of Regulation (EC) No. 865/2006 from June 2015, including all of its subsequent amendments, can be obtained at:

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R0865-20150205>

Commission Implementing Regulation (EU) 2015/736 of 7 May 2015 prohibiting the introduction into the Union of specimens of certain species of wild fauna and flora (OJ L 117, 8.5.2015)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Regulation (EC) No 338/97, and its supplementary legislation (hereafter referred to the Endangered Species Regulation), seeks to implement, in the EU, the Washington Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), which entered into force in 1975 and currently has 181 parties, although not all of the parties have accepted later amendments to the Convention. The European Union became a Party to CITES on 8 July 2015²³⁵. The reason for such late EU joining to CITES lays in the fact that initial text of the CITES Convention signed in 1973 foresaw that only States could be Parties to it. This has changed with the entry into force of the Gaborone amendment in November 2013, which opened CITES to accession by regional economic integration organisation.

The aim of the Convention is to protect species of wild fauna and flora and to guarantee their conservation by regulating their trade. To achieve this, it regulates international trade in certain species of wild fauna and flora that are, or may be, threatened by trade. It prohibits trade in the most endangered species threatened with extinction and establishes a licensing system to be applied to trade in other threatened species. It is based on a system of permits and certificates that must be presented before specimens of protected species are allowed to leave or enter a country, and that can only be issued if certain conditions are met. The CITES Convention has been implemented into EU law since 1984 through a set of Regulations. The Regulation introduced a number of measures that are even stricter than those provided for in CITES.

The Regulation (EC) No 338/97 lays down the provisions for import, export and re-export as well as internal EU trade in specimens of species listed in its Annexes. It provides for procedures and documents required for such trade (import and export permits, re-export certificates, import notifications and internal trade certificates) and it regulates the movement of live specimens. It also sets out specific requirements for Member States to ensure compliance with the Regulation and to impose adequate sanctions for infringements. There are four Annexes to the Endangered Species Regulation, which include:

Annex A includes:

- All CITES Appendix I species, except where EU Member States have entered a reservation
- Some CITES Appendix II and III species, for which the EU has adopted stricter domestic measures
- Some non-CITES species

Annex B includes:

- All other CITES Appendix II species, except where EU Member States have entered a reservation
- Some CITES Appendix III species
- Some non-CITES species

Annex C includes:

- All other CITES Appendix III species, except where EU Member States have entered a reservation

Annex D includes:

- Some CITES Appendix III species for which the EU holds a reservation
- Some non-CITES species in order to be consistent with other EU regulations on the protection of native species, such as the Habitats Directive and the Wild Birds Directive.

²³⁵ Council Decision (EU) 2015/451 of 6 March 2015 concerning the accession of the European Union to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) (OJ L 75, 19.3.2015)

The Endangered Species Regulation covers all specimens, whether alive or dead, including parts and derivatives, from animal and plant species listed in the Annexes. However, through an annotation to the listing, some parts and derivatives can be exempted from certain provisions. Hybrids are also covered by CITES and the EU Endangered Species Regulations when at least one of the two 'parents' is a species listed in one of the four Annexes. In cases where the 'parents' of hybrids are species listed in different Annexes, or when only one 'parent' is listed in the Annexes, the provisions of the more restrictive Annex apply.

Regulation (EC) No. 338/97 has been amended several times, mainly to add new species of protected wild fauna and flora to the list of protected and threatened species. These amendments are mainly based on changes to the Appendices of CITES. These Appendices are regularly updated to transfer certain species or populations of species between the three appendices and to add new species or to delete species to reflect the current situation in terms of number of populations and the level of protection required. Regulation (EC) No. 338/97 therefore needs to be updated to reflect these developments. The most recent version of the Annexes is contained in the Commission Regulation (EU) No 1320/2014 of 1 December 2014 amending Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade therein.

In accordance with Article 19 of Council Regulation (EC) No. 338/97, the provisions of the regulation have been further specified through Commission Regulation (EC) No. 865/2006. This regulation sets out detailed provisions for the implementation of Regulation (EC) No. 338/97 and transposes relevant decisions of the Conference of the Parties to CITES. It introduces:

- detailed conditions and criteria applying to permit and certificate applications and the issuing, validity and use of such documents;
- conditions and criteria applying to the treatment of specimens of animal species that are born and bred in captivity and of plants artificially propagated, in order to ensure consistent implementation of the derogations applicable to such specimens;
- streamlined requirements applying to derogations for specimens that are personal and household effects falling under Article 7(3) of Regulation No. 338/97;
- conditions and criteria for defining the general derogations from the internal trade bans set out in Article 8 of Regulation (EC) No. 338/97;
- procedures for the marking of certain specimens of species to facilitate their identification;
- detailed requirements regarding the content, form and submission deadlines of the provisions on obligatory periodic reports under Regulation (EC) No. 338/97;
- provisions implementing a number of resolutions adopted at COP12 concerning simplified procedures for the issuing of permits and certificates, provisions relating to travelling exhibitions, derogations regarding personal effects, alteration of codes used in permits and certificates and the list of standard references.

Commission Regulation (EC) No 865/2006 has been amended by Commission Regulation (EC) No 100/2008 of 4 February 2008, Commission Regulation (EU) No 791/2012 of 23 August 2012, Commission Implementing Regulation (EU) No 792/2012 of 23 August 2012 and Commission Regulation (EU) 2015/870 of 5 June 2015.

The latest amendments concern, amongst other things:

- import permit requirements for the import into the EU of hunting trophies from six CITES-listed species (African Lion, Polar Bear, African Elephant (for populations not included in Annex A of Regulation 338/97, for which the import permit requirement already applies), Southern White Rhinoceros (for populations not included in Annex A of Regulation 338/97, for which the import permit requirement already applies), Common Hippopotamus and Argali Sheep)),
- provision of a legal basis to refuse the issuing of an import permit in case of serious doubts as to the legality of a shipment of CITES products,
- establishment of a specific certificate for the non-commercial cross-border movement of musical instruments.

Article 4(6) of Regulation (EC) No. 338/97 enables the Commission to establish restrictions to the introduction of certain species into the EU. The list of species for which the introduction into the Union is prohibited was last established by Commission Implementing Regulation (EU) 2015/736 of 7 May 2015 prohibiting the introduction into the Union of specimens of certain species of wild fauna and flora.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

The key obligations regarding planning comprise:

- Designate management authorities (including issuing authorities), scientific authorities and other competent authorities, as well as customs offices, and possibly special enforcement units, to implement the requirements of the regulation; provide customs offices with properly trained staff and ensure enforcement and sanctions in case of non-compliance since breach of several provisions of the regulation is considered an environmental criminal offence under Directive 2008/99/EC. (Art. 12)
- Specify which of the offices are intended to deal with live specimens and create facilities for handling live animals and live plants (Arts. 12 and 13, Regulation (EC) No. 338/97).

2.2. Regulation

The key regulatory obligations comprise:

- Ensure that the import and export of species listed in the annexes to Regulation (EC) No. 338/97 (as amended) is subject to the presentation of relevant permits and certificates and to the checks and procedures laid down in the regulation (Arts. 4 and 5), taking account of the derogations allowed under Article 7.
- Ensure compliance with Article 71 of Regulation (EC) No 865/2006 and Regulation (EU) No 2015/2015 on the suspension of specimens of the species of wild fauna and flora, which can be entered into the EU. Ensure that no such specimens listed in the Annex to the latter are imported.
- Ensure that the issuance of permits and certificates for the following purposes is in accordance with the conditions laid down in Regulation (EC) No 338/97 and Regulation (EC) No 865/2006 and that possible Commission restrictions are fully complied with (e.g. Art. 9(6) on the holding or movement of live specimens of species for which restrictions on introduction into the EU have been established in accordance with Article 4(6)):
 - the importation of specimens of listed species (Art. 4, Regulation (EC) No 338/97 and Arts. 20-24, Regulation (EC) No 865/2006);
 - the export and re-export of specimens of listed species (Arts. 5 and 9, Regulation (EC) No 338/97 and Arts. 26-29, Regulation (EC) No 865/2006);
 - the cross-border movement of traveling exhibitions and pets (Arts. 30-44, Regulation (EC) No 865/2006);
 - the movement of certain live specimens of Annex A species within the EU (Arts. 9 and 10, Regulation (EC) No 338/97 and Regulation (EC) No 865/2006); and

- to allow exemptions from certain commercial activities (Arts. 8 and 10, Regulation (EC) No 338/97 and Art. 48, Regulation (EC) No 865/2006).

These provisions apply to applications, obligations of the issuing authority, to the issuing of documents, to the documents to be surrendered, the handling of documents by the customs office and procedures relating to the replacement of lost, stolen or destroyed permits and certificates. Applications must be made in sufficient time prior to the date of shipment and documents for specimens of species listed in Annexes A, B and C may only be issued retrospectively in exceptional cases (Arts. 13 and 15, Regulation (EC) No 865/2006).

For artificially propagated plants of species listed in Annexes B and C to Regulation (EC) No 338/97 and artificially propagated hybrids produced from species listed in Annex A, Member States have a choice between issuing phytosanitary certificates or export permits (Art. 17, Regulation (EC) No 865/2006).

- Ensure the possibility to apply a simplified procedure for trade in two cases:
 - trade that has only a negligent impact on the conservation of the species concerned. Such procedure should be based on pre-issued permits and certificates to be used for biological samples in accordance with Annex XI where these samples are urgently required. Such procedures have to be in conformity with the specifications set out in Article 18, amongst others involving the advice of the scientific authority (Art. 18, Regulation (EC) No 865/2006);
 - export or re-export of dead specimens listed in Annexes B and C of Regulation (EC) No 338/97.
- Ensure that applications for import permits concerning specimens that are subject to a restriction in accordance with Commission Implementing Regulation (EU) No 2015/736 (made pursuant to Art. 4(6) of Regulation (EC) No. 338/97) suspending the introduction of certain species of wild flora and fauna, except where the conditions in Article 71(4) of Regulation (EC) No. 865/2006 are satisfied.
- Ensure that imports of specimens from third countries are only allowed where the export or re-export documents are still valid (6 months from the date of issue). Where the shipment concerns artificially propagated plants of species listed in Annexes A, B and C, Member States have to accept either valid export permits or phytosanitary certificates (Arts. 14 and 17, Regulation (EC) No 865/2006).
- For imports into the EU of specimens of species listed in Annexes C or D, ensure that the import notifications to be surrendered by the importer to the customs office are in conformity with Articles 24 and 25 of Regulation (EC) No 865/2006 in terms of the notification form used and its handling by the customs office.
- Import and export permits, re-export certificates, import notifications, sample collection and travelling exhibition certificates and applications must be in conformity with Articles 46 to 51 of Regulation (EC) No 865/2006 must comply with Annexes I, II, III and IV (Art. 2, Regulation (EC) No 865/2006). More specific requirements applying to forms include:
 - the forms and applications referred to in Article 3 of Regulation (EC) No 865/2006 must comply with Annex I;
 - the forms and applications for certificates provided for in Articles 5(2), (b), 5(3), 5(4), 8(3) and 9(2)(b), Regulation (EC) No 338/1997, shall conform to the model set out in Annex V to Regulation (EC) No 865/2006 (Art. 2(5), Regulation (EC) No 865/2006);

- forms also have to comply with the technical specifications set out in Article 3 of Regulation (EC) No 865/2006 regarding the paper used, the size of the forms, the colour of the paper, and the languages used (including possible translations);
 - forms must normally be completed in typescript or in certain circumstances in manuscript for applications for import and export permits and certificates referred to in Article 4 of Regulation (EC) No 865/2006;
 - forms referred to in Article 4(2) of Regulation (EC) No 865/2006 that have been altered must be authenticated by the stamp/signature of the issuing competent management authority;
 - where annexes are attached to forms, the requirements in Article 6 of Regulation (EC) No 865/2006 apply.
- Ensure that sample collection certificates are only issued if covered by a valid ATA carnet and includes specimens, parts or derivatives of species listed in Annex A, B or C of Regulation (EC) No 338/97 and confirms with Chapter XIII of Regulation 865/2006 (Regulation (EC) No 865/2006, Article 44(a)). Further specific requirements relating to sample collection certificates are set out in Articles 44(b-g):
 - Regarding the use of the sample collection, i.e. as an import, export/re-export permit pursuant to Arts. 4-5 of Regulation (EC) No 338/97 or as certificate for public display for commercial purposes pursuant to Art. 8(3) of Regulation (EC) No 338/97 (Regulation (EC) No 865/2006, Art. 44(b))
 - Regarding the issuing authority, which can be the managing authority of the Member State where the sample collection originates and if it originates in a third country, the certificate shall be issued by the managing authority of the Member State of first destination (Regulation (EC) No 865/2006, Art. 44(c))
 - Other requirements and restrictions on the further sale, transfer of specimens covered by a sample collection certificate or the certificate itself which is non transferable as well as information duty in case of the specimens being stolen, destroyed or lost. (Regulation (EC) No 865/2006, Art. 44(d))
 - Requirements and formalities linked to the application for a sample collection certificate (Regulation (EC) No 865/2006, Art. 44(e))
 - Documents to be surrendered by the holder to the customs office, e.g. original and copy of the sample collection certificate and the original of the valid ATA carnet. (Regulation (EC) No 865/2006, Art. 44(f))
 - Requirements regarding a replacement certificate in the case a sample collection certificate has been lost, stolen or destroyed (Regulation (EC) No 865/2006, Art. 44(g))
 - Ensure that labels are provided in accordance with Article 7(4) of Regulation (EC) No 338/1997, and with the model contained in Annex VI to Regulation (EC) No. 865/2006 and Article 3(6) of the same regulation. In the case of labels for non-commercial purposes, including scientific research and museum uses, the labels should conform to the specifications in Article 52 of Regulation (EC) No 865/2006.
 - The content of permits, certificates and applications for the issuing of such documents must comply with Article 5 and Annexes VII, VIII and IX to Regulation (EC) No 865/2006 regarding codes describing specimens, the indication of units of quantity and weight, the taxa to which the specimens

belong, the nomenclature references, codes indicating the purpose of a transaction, and codes for the sources of specimens. In case of plant specimens that cease to qualify for an exemption from the provisions of the Convention or Regulation (EC) No 338/97 in accordance with the 'Notes on the interpretation of Annexes A, B, C and D', a new Article 5(a) stipulates how the form should be filled out and which country to indicate (Art. 5, Regulation (EC) No 865/2006).

- When deciding upon the acceptability of permits and certificates issued by third countries for specimens to be introduced into the EU, the requirements regarding the technical specifications of forms shall apply (Art. 7(1), Regulation (EC) No 865/2006). Article 7 also specifies the conditions under which re-export certificates and permits and certificates subject to voluntary or allocated export quotas may be accepted. Article 7(4) requires that permits and certificates issued by third countries with source code 'O' is only accepted if they cover specimens that conform to the definition of pre-Convention specimen set out in Article 1(10) and include either the date of acquisition of the specimens or a statement that the specimens were acquired before a specific date.
- Ensure that documents are issued and used in accordance with the provisions laid down in Regulation (EC) No 338/1997 and Regulation (EC) No 865/2006. The issuing competent management authority may also impose conditions and requirements to ensure full compliance with these regulations by setting out the conditions in the documents concerned (Art. 8(1), Regulation (EC) No 865/2006).
- The competent management authorities must have the capacity to be able to decide on the issuing of permits and certificates within one month of receiving a complete application, unless it is necessary to consult third parties (Art. 8(3), Regulation (EC) No 865/2006).
- Ensure that separate import permits, import notifications, export permits or re-export certificates are issued for each shipment of specimens where shipped together as part of one load (Art. 9, Regulation (EC) No 865/2006).
- Set the period of validity of import and export permits, re-export certificates, travelling exhibition certificates and personal ownership certificates in accordance with the specifications and time periods set out in Article 10 of Regulation (EC) No 865/2006.
- The custom procedures defined in Regulation (EC) No 865/2006 (e.g. Arts. 45 and 53) should be complied with, and the only derogations from the customs procedure that are allowed should be on the grounds set out in Article 53. Ensure that customs offices promptly forward to the competent management authorities of their Member State all documents presented to them and that the competent management authorities send documents issued by other Member States to their relevant competent management authorities (Art. 45, Regulation (EC) No 865/2006).
- Ensure that scientific authorities and management authorities carry out examinations, assessments and consultations in respect of the importation, exportation and movement of protected species, in accordance with the criteria laid down in the regulation (Arts. 4, 5 and 9, Regulation (EC) No 338/97). Such consultations between management authorities are necessary in case an application for a re-export certificate concerns specimens introduced into the EU under an import permit issued by another Member State. Here the management authority must first consult the management authority, which issued the permit.
- Prohibit certain commercial activities relating to protected species, including purchase and sale, and provide for exemptions thereto in accordance with Article 8, Regulation (EC) No 338/97.

- Take measures to protect live specimens during transport and comply with any such restrictions on the holding or movement of live specimens of species in relation to which restrictions on introduction into the EU have been established in accordance with Article 4(6). Art. 9, Regulation (EC) No 338/97).
- Where derogations from the requirements of the regulation have been defined by the Commission, ensure that these are in accordance with the specified conditions (Arts. 7 and 8, Regulation (EC) No 338/97). Such derogations must be in accordance with the requirements of other EU legislation on the conservation of wild fauna and flora.
- Ensure that the marking of live animals is carried out in a humane way suitable for the specimen concerned, that it complies with the recognised marking methods referred to in Article 66, and that the details of the marking are provided in the permit or certificate (Arts. 64-68, Regulation (EC) No 865/2006). Member States must comply with marking requirements regarding:
 - the individual marking of specimens for the purposes of import and commercial activities in the EU, which is a precondition for issuing an import permit (Art. 64);
 - the marking of specimens for export and re-export, which is a precondition for the issuing of export permits and re-export certificates (Art. 65).
- Only grant derogations from the prohibition laid down in Article 8(1) and (3) of Regulation (EC) No 338/1997 regarding the purchase, offer to purchase or acquisition of specimens of species listed in Annex A for commercial purposes under the circumstances set out in Articles 48, 59, and 60 to 62 in Regulation (EC) No 865/2006. These derogations are mostly granted on a case-by-case basis and require the approval of the competent management authority. Derogations include:
 - exemptions for specimens used for the benefit of scientific institutions aiming at the preservation and conservation of the species concerned;
 - exemptions for specimens referred to in Article 8(3)(a,b,c,d,e,h);
 - general exemptions from Articles 1 and 3, set out in Article 62 of Regulation (EC) No 865/2006 regarding specimens of animals born and bred in captivity belonging to species listed in Annex X to Regulation (EC) No 865/2006, where they are marked in accordance with Article 66(1), artificially propagated plants, and worked specimens acquired before 1947;
 - where specimens are covered by specimen-specific certificates.
- Ensure that derogations from restriction and control measures for import and reintroduction into the EU or export and re-export from the EU of personal and household effects comply with the conditions set out in Articles 57 and 58 of Regulation (EC) No 865/2006. Article 57(5) and Article 58(4) stipulate the conditions under which certain re-exports do not require the presentation of a (re-)export document.

2.3. Monitoring and Enforcement

- Monitor the issuing of export permits and take measures to counteract the use of false permits (Art. 5 and Art. 11(2), Regulation (EC) No 338/97).
- Monitor compliance with the regulation and take action in cases of non-compliance, including seizure and confiscation of specimens that are illegally imported or exported. Impose sanctions for specified cases of non-compliance with the regulation (Arts. 11, 14 and 16, Regulation (EC) No 338/97).
- Take appropriate measures to ensure the imposition of sanctions for at least the infringements listed in Article 16, Regulation (EC) No 338/97.
- Ensure enforcement and sanctions in case of non-compliance since the killing, destruction, possession or taking of specimens of protected wild fauna or flora species and the trading in specimens of protected wild fauna or flora species or parts or derivatives thereof (except for negligible quantity with negligible impact on the conservation status of the species) since these are environmental criminal offences under Article 3 of Directive 2008/99/EC.
- Ensure that customs offices carry out checks and observe the required procedures for the introduction into and export from the EU of specimens covered by the regulation (Art. 12).

2.4. Information and Reporting

- Inform the public about measures taken to implement Regulation (EC) No 338/97 (Arts. 12(5) and 15(1)).
- Notify the Commission and the CITES Secretariat of the legal and administrative provisions adopted for the application and enforcement of Regulation (EC) No 338/97 and Regulation (EC) No. 865/2006 and (Arts. 69(5) and 73).
- Notify the Commission about customs offices designated for carrying out the checks and formalities for the introduction into and export from the EU (Regulation (EC) No 338/97, Article 12(3))
- Whenever the scientific authority advises the competent management authority to limit the export of species for conservation reasons, set out in Art. 7(a) of Regulation (EC) No 338/97, the management authority must inform and send comments to the Commission, which can form basis for further restrictions on exports of the species (Regulation (EC) No 338/97, Art. 7(b))
- Inform the Commission, and in the case of species listed in the Appendices to CITES, the convention secretariat, of the outcome of investigations following infringements of the convention (Art. 14, Regulation (EC) No 338/97).
- Consult with the management authorities of other Member States in cases where specimens of protected species are re-exported (Art. 5, Regulation (EC) No 338/97).
- Communicate to the Commission the information necessary for implementing this Regulation (Art. 15(1)) and provide annual and biennial information according to the requirements of Article 15(4), Regulation (EC) No 338/97.

- Report to the Commission on:
 - all legal instruments used and measures taken to implement and enforce the Regulation (Art. 20, Regulation (EC) No 338/97);
 - the designation of competent authorities (Art. 13, Regulation (EC) No 338/97);
 - measures to limit exports of protected species (Art. 5(7), Regulation (EC) No 338/97);
 - significant cases where an application for a permit or certificate is rejected (Art. 6(1), Regulation (EC) No 338/97);
 - cases where a permit is issued in the light of new evidence, despite a previous rejection (Art. 6(4), Regulation (EC) No 338/97);
 - conditions and requirements which need to be incorporated into the design of permits or certificates (Art. 11(3), Regulation (EC) No 338/97);
 - all information required by the Commission to facilitate the amendment of the annexes (Art. 15(5), Regulation (EC) No 338/97); and
 - steps taken by the competent authorities in relation to significant infringements, including seizures and confiscations (Art. 14, Regulation (EC) No 338/97).
- The issuing competent management authority must inform the competent management authority of the country of destination and the CITES Secretariat about cases where an export permit or re-export certificate has been cancelled, lost, stolen or destroyed (Art. 12(2), Regulation (EC) No 865/2006).
- Notify the CITES Secretariat of export permits and re-export certificates issued in accordance with Article 15 of Regulation (EC) No 865/2006.
- Customs offices must forward to the relevant management authority of their Member State all documents presented to them.
- Member States must collect data on imports into and exports and re-exports from the EU on the basis of permits and certificates issued by their competent management authorities as well as information on seized and confiscated shipments. This information must be submitted to the Commission for each calendar year for species listed in Annexes A, B and C to Regulation (EC) No 338/97. The information must be communicated in two parts according to Article 69(2) of Regulation (EC) No 865/2006 and submitted in a computerised form Guidelines for the preparation and submission of CITES annual reports issued by the Secretariat of the Convention. The information referred to in paragraphs 1, 2 and 3 shall be communicated to the Commission for each calendar year before 15 June of the following year on a species-by-species basis and per country of (re-)export..
- Every second year, Member States must communicate to the Commission information on legislative, regulatory and administrative measures taken to implement and enforce Regulation (EC) No 338/97. The information communicated must also include the information set out in Article 69(5) of Regulation No. 865/2006 regarding registered persons, scientific institutions and breeders, and the use of phytosanitary certificates (Art. 69, Regulation (EC) No 865/2006).
- Submit information to the Commission as regards species already listed in the annexes to Regulation (EC) No 338/97 or those eligible for listing as regards their biological and trade status, their usage, and methods for controlling trade in those specimens (Art. 70(1), Regulation (EC) No 865/2006).

- Maintain records of species listed in Annexes A and B to Regulation (EC) No 338/97 regarding shipments of live animals that were dead when imported into the EU (Art. 69(3), Regulation (EC) No 865/2006).

2.5. Additional Legal Instruments

A number of other legislative instruments are relevant to the implementation of the above regulations and must be borne in mind during implementation.

- The above regulations aim to help protect rare and endangered species by controlling trade and, as such, is linked to other Directives and regulations, such as the Habitats Directive (92/43/EEC), the Wild Birds Directive (2009/147/EC), the Seal Pups Directive (83/129/EEC), Regulation (EC) No 1007/2009 on trade in seal products Regulation (EEC) No 3254/91 on leghold traps as well as Regulation (EU) 1143/2014 on invasive alien species..
- Directive 2008/99/EC on the protection of the environment through criminal law
- Whilst Council Regulation (EC) No. 338/97 does not specifically include protection of the species protected under the Birds Directive or Habitats Directive, species protected by the Birds Directive and Habitats Directive are listed in Annex A of that Regulation and trade in them is therefore controlled. This mechanism ensures compatibility between the different legislation and avoids confusion.

On 26 February 2016 the European Commission adopted a Communication on the EU Action Plan against Wildlife Trafficking²³⁶, which sets out a comprehensive blueprint for joined-up efforts to fight wildlife crime inside the EU, and for strengthening the EU's role in the global fight against these illegal activities.

The Action Plan comprises 32 measures to be carried out between now and 2020 by the EU (Commission services, EEAS, Europol, Eurojust) and its 28 Member States. It focuses on three priorities:

- Prevent trafficking and reduce supply and demand of illegal wildlife products: for example by the end of 2016 the Commission will prepare guidelines aiming to suspend the export of old ivory items from the EU.
- Enhance implementation of existing rules and combat organised crime more effectively by increasing cooperation between competent enforcement agencies such as Europol.
- Strengthen cooperation between source, destination and transit countries, including strategic EU financial support to tackle trafficking in source countries, help build capacity for enforcement and provide long term sources of income to rural communities living in wildlife-rich areas.

²³⁶ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions EU Action Plan against Wildlife Trafficking COM/2016/087 final

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing these regulations are summarised in the following checklist, organised in chronological order (where possible) within each subheading.

Table 9. The Endangered Species Regulations - Key Implementation Tasks

THE ENDANGERED SPECIES REGULATIONS - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Establish one or more management authorities responsible for implementing the requirements of the regulations, including issuing the required permits and certificates, and one or more scientific authorities to carry out the tasks specified in the regulation. Other competent authorities might need to be designated including specialized customs offices.
1.2	The competent authority(ies) must establish an effective organisational structure, as well as mechanisms for documentation and shipment inspection and also arrange for the necessary training of all involved organisations in the relevant disciplines.
1.3	Establish and maintain liaison with other Member States concerning information necessary to implement the legislation.
1.4	Establish arrangements for involvement of representatives in the ongoing discussion and review groups, such as the Scientific Review Group and Enforcement Group, to discuss progress in enforcement and the content of the annexes, including listed species and the introduction of species into the EU.
2	Regulation
2.1	Ensure that the import and export of species listed in the annexes (as last amended by Regulation (EU) No 1320/2014) are subject to checks and procedures laid down in the regulation, taking account of the derogations allowed.
2.2	Ensure that permits and authorisations are issued, in accordance with the conditions laid down in the regulation for the importation and export of species, the movement of live species within the EU and certain commercial activities.
2.3	Where imports from non-CITES countries are concerned, ensure that documentation similar to CITES permits and certificates is submitted; this includes requiring and inspecting accompanying documentation and implementing sanctions where necessary.
2.4	Customs offices are required to carry out the necessary checks of all documentation related to imports and exports of CITES species. In addition, they are required to undertake inspections of material, either by full inspection or appropriate sampling of the shipment. Member States must therefore make the necessary organisational arrangements for these inspections.
2.5	Transport of live specimens must be in accordance with the CITES Guidelines for Transport or the IATA Live Animals Regulations and live animals must be conveyed to their destination as soon as possible. Member States must therefore make the necessary provisions for complying with these rules.
2.6	Management authorities must make arrangements to control all commercial activities related to the import and export of CITES species, with the emphasis being on the prohibition of commercial activities for the most threatened species.
2.7	Management authorities of Member States may grant exemptions for certain situations, but these must comply with the requirements of other EU legislation, such as the Birds Directive and Habitats Directive.
2.8	Allow for a simplified procedure for trade in two cases: <ul style="list-style-type: none"> • trade that has only a negligent impact on the conservation of the species concerned. Such procedure should be based on pre-issued permits and certificates to be used for biological samples in accordance with Annex XI where these samples are urgently required;

	<ul style="list-style-type: none"> the export or re-export of dead specimens listed in Annexes B and C of Regulation No. 338/97.
3	Public Information
3.1	Member States are required to inform the public to ensure they are sufficiently informed of the provisions regarding implementation of CITES and EU Regulations.
4	Monitoring
4.1	Member States are required to monitor trade to achieve the aims of the CITES Convention. As such, scientific authorities are to monitor export permits granted for species and the export thereof set out in Appendices I to III. This advice should include suitable measures to limit the issue of export permits whenever they determine that the export should be limited to maintain a species at suitable levels, consistent with the particular ecosystem.
4.2	All parties are required to maintain trade records, which should be reported to the CITES Secretariat on an annual basis.
4.3	Monitor compliance with the Regulations.
4.4	Conduct monitoring of the effectiveness of the permitting system in controlling the import and export of endangered species within the Member State.
4.5	Participate in information exchange and discussion with other Member States and the Commission in relation to the overall effectiveness of the legislation in protecting endangered species and in amendments to the legislation, following ongoing research.
5	Reporting
5.1	Report to the Commission, as appropriate, on the following: <ul style="list-style-type: none"> designation of competent authorities (including at least one management authority and one scientific authority) and of customs offices; measures taken to implement the Regulations; conditions and requirements which need to be incorporated in the certificates; derogations; export suspensions and restrictions; steps taken by the competent authorities in relation to significant infringements, including seizures and confiscations; cases of rejection of permit applications; cases of issuance of a permit despite previous rejection; information necessary for CITES reports; and other information which may be necessitate further amendments of the annexes .
5.2	Member States must collect data on imports into and exports and re-exports from the EU on the basis of permits and certificates issued by their competent management authorities, as well as information on seized and confiscated shipments. This information must be submitted to the Commission for each calendar year for species listed in Annexes A, B and C to Regulation No. 338/97.
5.3	The issuing management authority must inform the competent management authority of the country of destination and the CITES Secretariat about cases where an export permit or re-export certificate has been cancelled, lost, stolen or destroyed.
5.4	Notify the CITES Secretariat of export permits and re-export certificates issued in accordance with Article 15 of Regulation No. 865/2006.
5.5	Customs offices must forward to the relevant competent management authority of their Member State all documents presented to them.

3.2. Phasing

Experience within Member States suggests that the most demanding and time-consuming tasks associated with these Regulations are:

- establishing the necessary organisational arrangements, including setting up the management authorities and scientific authorities;
- establishing the system of documentation, including the permit and certification arrangements, and ensuring that these documents are issued in accordance with Regulation (EC) No 865/2006, including applicable forms and specifications;
- establishing the working arrangements, including mechanisms to inspect documentation and licences, issue export licences and inspect shipments by customs departments.

These tasks should therefore be planned to commence during the initial phase of implementation.

Experience also reveals that extensive time inputs are required to keep up to date with the amendments to the legislation, ensuring compliance with the list of suspended species (Regulation (EU) No 2015/736), as well as the reporting arrangements to the Commission, and discussions involving management authorities, the scientific authorities and the CITES Secretariat.

Examples of Institutional Arrangements and Regulatory Controls

In the UK, CITES Convention and Endangered Species Regulation are implemented through:

- **UK CITES Management Authority** which includes:
 - a Defra policy team – acting as a liaison between international action (within CITES itself or the EU) and domestic application.
 - a CITES Licensing team (within Defra's Animal Health agency) who issue import and export permits and other CITES certificates.
- **UK CITES Scientific Authorities** who advise the Management Authority on scientific issues including an assessment of whether the proposed trade might have a harmful effect on the conservation of the species in the wild:
 - Joint Nature Conservation Committee (JNCC) (animal species)
 - Royal Botanic Gardens, Kew (plant species)
- **UK Enforcement Authorities** – the UK Management and Scientific Authorities work closely with the UK Border Agency (UKBA), at the ports and airports, and the Police (internally within the UK) to enforce laws relating to wildlife trade including:
 - the EU's Wildlife Trade Regulations
 - the UK's Control of Trade in Endangered Species (Enforcement) Regulations (COTES) 1997 (amended in 2005, 2007 and 2009) which set out the offences and penalties relating to CITES trade
 - the Customs and Excise Management Act 1979 (CEMA)

The UK Border Agency (UKBA) has a dedicated CITES team based at Heathrow Airport which has a UK-wide responsibility for enforcement of the endangered species laws at ports & airports.

Wildlife crime in the UK goes beyond the CITES trade offences and there are Police Wildlife Crime Officers (PWCOs) throughout the Police Service. In London, the Metropolitan Police has a dedicated Wildlife Crime Unit and a National Wildlife Crime Unit (NWCU) has also been set up (joint-funded by the Home Office and Defra) to coordinate intelligence in order to target enforcement efforts at particular areas of wildlife crime.

The processing and issuing of CITES permits and certificates are carried out through the Animal Health's Wildlife Licensing and Registration Service (see: <https://www.gov.uk/guidance/cites-imports-and-exports>) This service is part of the UK CITES management authority responsible for dealing with CITES applications. Furthermore, registerable endangered species are subject to inspections by the Wildlife Inspectorate.

There is now also a permanent body in the country, the Partnership for Action against Wildlife Crime (PAW). It is guided by a steering group, whose members include the police, Defra (which took on the responsibilities of the former DETR), HM Revenue and Customs, the Home Office, the Crown Prosecution Service, TRAFFIC International, the Royal Society for the Protection of Birds, the Royal Society for the Prevention of Cruelty to Animals, representatives of sustainable users (wildlife traders, keepers and hobbyists), and representatives of sporting groups (e.g. the Association for Shooting and Conservation). In June 1997, the DETR signed a memorandum of understanding with the CITES Secretariat to facilitate the flow of information between the secretariat's enforcement personnel and individual police and customs officers. PAW has also ensured that the country is represented at Interpol wildlife crime sub-group meetings where possible. These meetings are attended by police officers and other enforcement bodies from across the world, and provide an opportunity to discuss common problems associated with the enforcement of legislation on wildlife.

In addition, there are some frameworks for liaison at national level. First, the UK CITES Officers Group meets twice a year to discuss technical issues relating to UK implementation of CITES and EU regulations. The group includes representatives from the UK CITES management authority, scientific authorities and HM Revenue and Customs. Secondly, the Joint Liaison Group, comprising UK CITES officers and representatives from trade and conservation organizations, meets twice-yearly to discuss CITES issues relevant to trade and conservation.

4. IMPLEMENTATION GUIDANCE

The above regulations can be implemented effectively by a single national management authority, which needs at least a close relationship with central government if it is not part of the government machinery. One or more bodies must be appointed as the scientific authority and the tasks could be performed by a network of individuals. The regulations also require close co-operation between the management authorities and the enforcement agencies, particularly customs. Co-ordination and training structures may be useful and ideally should include the agencies responsible for domestic enforcement, e.g. the police, wildlife inspectorate etc.

Implementation of the Endangered Species Regulations (EC) 338/97 and (EC) 865/2006 in candidate countries can benefit from the detailed Reference Guide to the European Union Wildlife Trade Regulations²³⁷, which was updated in July 2015 and available at: http://ec.europa.eu/environment/cites/pdf/referenceguide_en.pdf

The present status, needs and situation in each candidate country will influence the implementation of the specific requirements of this regulation. However, drawing upon the collective experience of the Member States, a number of general observations and suggestions for implementing this regulation are presented below.

4.1. Planning

- The key actors are ministries responsible for foreign affairs and trade, environmental protection, customs authorities and government agencies. Due attention should be given to the establishment of the management authorities and scientific authorities, with personnel recruited from appropriate government departments or other organisations.
- The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) is managed by a Secretariat and a Conference of the Parties, which convenes every two and a half years. The provisions of the convention set out procedures for amending the convention and its appendices. The listing of species in Appendices I and II of the convention requires a two-thirds majority decision by the Conference of the Parties, whilst parties can list native species in Appendix III on their own initiative. Each party must designate one or more management authorities responsible for issuing permits and certificates, subject to advice from one or more scientific authorities designated for that purpose.
- As the subject of endangered species protection has a high international profile, several organisations are involved in this field. Amongst these are some of the large international non-governmental organisations, such as the World Wide Fund for Nature (WWF) and TRAFFIC (the wildlife trade monitoring programme of WWF and IUCN - The World Conservation Union). At a national level, a range of scientific and research organisations are involved and there is close liaison with specialist wildlife groups and statutory wildlife agencies and government departments.

²³⁷ European Commission and TRAFFIC (2015). Reference Guide to the European Union Wildlife Trade Regulations

- The World Customs Organisation and Interpol play key roles in the enforcement of the legislation.

Examples from Member States

United Kingdom: The new charging regime in the UK was introduced in 2009 by the Control of Trade in Endangered Species (Fees) Regulations 2009 (SI 2009/496). Fees recovered as a consequence of the 2009 increases did not reflect the true cost to the taxpayer of providing the licensing service and it was recognised that further increases would be necessary to recover the full cost of providing it. The income that will be generated by the current suite of charges in the 2012/13 financial year is forecast as £0.42m. This accounts for 43% of the total cost to the taxpayer of providing the service (forecast as £0.97m in 2012/13). Current fees do not reflect the true cost to government of providing this statutory service resulting in a subsidy for users and a financial cost to the general taxpayer.

Sweden: The EU CITES Regulation (EC) No. 338/97 is applied directly in Sweden as a legal ordinance. The national legislation is the "Species Protection Ordinance". This ordinance has its legal basis in the Environmental Code. The ordinance includes regulations stated by the Birds and Habitat Directives, and also the Zoo Directive. It supplements the EU CITES Regulation (EC) No. 338/97 and also the legislation concerning hunting. In addition, there is the Swedish Environmental Protection Agency's regulation (NFS 1999:7) on species protection, issued by the Swedish EPA to supplement the ordinance. The competent authorities in Sweden with respect to the EU CITES Regulation and species protection include:

- The Swedish Board of Agriculture (Jordbruksverket), acting under the Ministry of Agriculture. It is the competent authority to decide in CITES matters concerning import and export of CITES-listed species. The Swedish Board of Agriculture also issues CITES certificates for commercial activities on the legal basis in the EU CITES Regulation No. 338/97. The Swedish Board of Agriculture also makes decisions on the legal basis of the national legislation (the Species Protection Ordinance) on bans on the storage, transport, import and export of endangered species listed in the appendices to the national legislation.
- The 21 county administrative boards in Sweden (Länsstyrelsen) issue operation licences for trade and exhibitions and the keeping of species of wild animals (in zoos etc.). They also issue licences for keeping wild animals in other circumstances than as zoo exhibits.
- The Customs Department is in the frontline of enforcement. To ensure effective operation, there are dedicated points of entry for plant and animal materials.
- The Swedish Environmental Protection Agency (Naturvårdsverket), as a scientific authority on CITES, issues recommendations on referrals coming from the Swedish Board of Agriculture.

The Swedish EPA also issues certificates regarding exceptions from the national legislation concerning trade bans. The Swedish EPA co-ordinates and gives guidance to the 21 county administrative boards concerning CITES enforcement matters. The EPA is also the competent authority for the Hunting Act, the Hunting Ordinance and Hunting regulations.

The competent authorities meet in an informal constellation twice a year. In addition to the above-mentioned authorities, the prosecutor, the Swedish Museum of Natural History and the Coast Guard also participate. TRAFFIC/WWF also participates.

Sanctions for violations of the ordinances are prescribed in the Environmental Code (Chapter 29, Para. 2) and the Act on Sanctions for Smuggling (2000:1225). Chapter 29 includes fines and imprisonment for up to 2 years, unless the violation is very serious, in which case the term of imprisonment can be a maximum of 6 years.

4.2. Inspection and Enforcement

- Enforcement of the legislation demands an effective inspection system by customs officers, police and wildlife inspectorates regarding both compliance with documentation obligations and the actual shipments. Member States have made considerable efforts to establish the organisational and documentation arrangements and there is an ongoing time and manpower requirement for the inspection of licences and shipments.
- Directive 2008/99/EC on the protection of environment through criminal law require the Member States to ensure enforcement and sanctions in case of killing, destruction, possession or taking of specimens of protected wild fauna or flora species and the trading in specimens of protected wild fauna or flora species or parts or derivatives thereof (except for negligible quantity with negligible impact on the conservation status of the species) since these are environmental criminal offences under Article 3 of Directive 2008/99/EC.
- The Commission adopted Recommendation 2007/425/EC of 13 June 2007 identifying a set of actions for the enforcement of Council Regulation (EC) No. 338/97. Actions identified by this recommendation should be carried out by Member States in order to facilitate the enforcement of Regulation (EC) No. 338/97.

Examples of Enforcement

United Kingdom: In the UK, the national CITES management and scientific authorities work closely with HM Revenue and Customs and the police to enforce CITES controls nation-wide.

Also, the Partnership for Action against Wildlife Crime (PAW) is a multi-agency body comprising representatives of the organisations involved in wildlife law enforcement in the UK. This partnership provides opportunities for state and non-state organisations to join forces to combat wildlife crime. Its main objective is to promote the enforcement of wildlife conservation legislation (including CITES-related legislation), particularly through supporting the networks of police wildlife crime officers and HM Revenue and Customs officers.

The HM Revenue and Customs is responsible for enforcing CITES controls at external frontiers, and works closely with the police and wildlife inspectors. Every police force now has specialist police officers with expertise in wildlife matters, who are appointed as wildlife liaison officers (WLO) and who take a lead in enforcing wildlife laws within the country. The Department for Environment, Food and Rural Affairs (Defra) views good enforcement as the key to an effective convention and works closely with The HM Revenue and Customs and the police to enforce CITES controls. For example, there have been recent raids on oriental pharmacies, which were found to have material from endangered species, resulting in heavy fines for those involved.

The Wildlife Inspectorate consists of a small team based in Bristol and a panel of approximately 80 part-time fee-paid and home-based inspectors located throughout the UK. Its role is to undertake inspections of traders of CITES listed species to ensure that the CITES related provisions are being fully complied with. All inspections are generated, monitored and controlled by the headquarters staff within an overall inspection strategy, which is reviewed annually.

Sweden: The Ministry of Agriculture is responsible for the policy, execution and enforcement of CITES. The enforcement service of this ministry is the General Inspection Service (GIS), which is a policing service with all the competencies and powers of the regular police service. As the majority of trade in this area goes through the border customs, co-operation with customs was initiated years ago. A system of teaching and training customs officers was initiated, which has proved to be a very effective mechanism for checking and controlling CITES violations. The system was initially introduced at the main airport, before being extended to other airports and ports. Training for customs officers included on-the-job training and is guided by a steering group involving prosecutors, the GIS, customs and the police force. Statistics indicate that a container enters or leaves the country's main port every nine seconds; therefore it was necessary to introduce an efficient system of enforcement, as physical inspection of such vast numbers of shipments is not possible.

4.3. Public Information

Article 15 of Regulation (EC) (EC) No 338/97 requires the Commission and the Member States to ensure that the public is sufficiently informed of the provisions regarding the implementation of CITES and EU Regulations. Article 12 specifically provides that Member States shall ensure that the public is informed of the provisions of the Regulations at border crossing points.

4.4. Monitoring

Both the management authority and the scientific authority will have to carry out monitoring in accordance with the Regulation.

4.5. Reporting

The main reporting obligations include:

- Member States are required to collect data on imports, exports and re-exports on the basis of permits and certificates issued by their management authorities, irrespective of the actual place of introduction or (re)export. Article 69 of Commission Regulation (EC) No 865/2006 stipulates that Member States have to communicate this information to the Commission annually in a computerised form and in accordance with the guidelines for the preparation and submission of CITES annual reports issued by the CITES Secretariat.
- The information required has to be presented in two separate parts:
 - imports, exports and re-exports of specimens of species listed in the appendices to the convention; and
 - imports, exports and re-exports of specimens of other species listed in Annexes A to C to Regulation (EC) No 338/97 and on the introduction into the EU of specimens of species listed in Annex D. With regard to imports of shipments containing live animals, Member States have to, where possible, maintain records of the percentage of specimens of species listed in Annexes A and B to this Regulation which were dead at the time of introduction into the EU.
- The reports have to include information on seized and confiscated shipments.
- Biennial reports: every second year Member States must communicate to the Commission information on legislative, regulatory and administrative measures taken to implement and enforce Regulation (EC) No 338/97. The information communicated must also include the information set out in Article 69(5) of Regulation No. 865/2006 regarding registered persons, scientific institutions and breeders and the use of phytosanitary certificates (Art. 69, Regulation (EC) No 865/2006).

5. COSTS

The main types of costs arising during the implementation of (EC) Regulation No 338/97 are set out in the checklist below.

Since Regulation (EC) No 338/1997 goes beyond CITES in some regards, and requires a parallel system of information and reporting to the Commission, it is likely to entail some additional costs. To mitigate these costs, candidate countries are advised to try to coordinate and integrate reporting and Regulation of provisions under CITES Convention and Endangered Species Regulations to the extent possible for reasons of cost-efficiency, simplicity and transparency.

There will be costs for providing specialist staff to draft the national legislation and to develop guidance and procedures. Technical assistance could be provided by the public authorities but also by wildlife organisations. The training and provision of customs staff in this specialist area is a recognised cost, but should not be significant. On-going costs relate to the implementation of the import and export documentation system and inspections of shipments and documentation accompanying transported materials.

A proportion of the cost could be recovered from the importer or exporter by collecting a fee for licences and import taxes. Some costs are also likely to derive from the enforcement measures, which have also been strengthened with the adoption of Directive 2008/99/EC on environmental crimes, (whose Article 3 (f) and (g)) obliges the Member States to introduce effective, proportionate and dissuasive sanctions for the killing, destruction, possession or taking of specimens of protected wild fauna or flora species and for the trading in specimens of protected wild fauna or flora species or parts or derivatives thereof (except in a negligible quantity having a negligible impact on the conservation status of the species).

Regulation No. 865/2006, as amended, introducing more specific requirements regarding the technical specifications for forms for permits, certificates, notifications, continuation sheets and labels, will entail additional costs mainly for providing the relevant forms in the national language and for establishing a computerised permit/certification issuing process for the preparation and printing of forms and labels. Also, the revised provisions on the marking of species, ensuring a more humane marking method, will also entail some costs in terms of making changes to current marking procedures.

Table 10. Checklist of the Types of Cost Incurred to Implement the Regulation

<p>Initial set-up costs:</p> <ul style="list-style-type: none">• devising systems and procedures;• establishing one or more management authorities;• establishing one or more scientific authorities;• provision of training;• preparation of guidance and procedure documents;• consultations and communications;• studies and research.

Capital expenditure:

- any inspection or analytical equipment that may prove necessary.

Ongoing costs:

- continuing inspections and enforcement;
- monitoring the effectiveness of procedures;
- liaison with related government agencies and other Member States, internal communications, consultations, production of documents and reports and public awareness;
- reporting and providing information input to the Commission.

THE REGULATION ON LEGHOLD TRAPS

Official Title: Council Regulation (EEC) No. 3254/91 prohibiting the use of leghold traps in the EU and the introduction into the EU of pelts and manufactured goods of certain wild animal species originating in countries which catch them by means of leghold traps or trapping methods which do not meet international humane trapping standards (OJ L 308, 9.11.91)

Commission Regulation (EC) No 35/97 of 10 January 1997 laying down provisions on the certification of pelts and goods covered by Council Regulation (EEC) No 3254/91 (OJ L 8, 11.1.1997)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Regulation No. 3254/91 on leghold traps (referred to hereafter as Regulation on Leghold Traps) aims to contribute to the conservation of certain species of wild animals and contribute to animal welfare by banning the use of leghold traps and limiting imports into the EU of the pelts and related goods from animals caught by leghold traps. The Regulation also seeks to avoid distortion of competition by ensuring that external trade measures relating to this issue are applied uniformly throughout the EU. The Regulation on Leghold Traps is implemented by Commission Regulation (EC) No. 35/97, which prescribes the form of the certificate that must be presented in order to introduce into the EU pelts whose import is permitted.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Establish or delegate a competent authority to be responsible for inspecting import licences for wild animal products, to ensure that imports comply with the requirements of the Regulation.
- Develop a regulatory system to ensure that the import of all wild animal products from the list of animals in Annex I of the Regulation complies with the requirements of the Regulation.

2.2. Regulation

- Prohibit the use of leghold traps (Art. 2, Regulation on Leghold Traps).
- Prohibit the importation of pelts of animal species listed in Annex I, and other goods listed in Annex II in so far as they incorporate these pelts, unless the products are subject to one of the exceptions specified in the Regulation (Art. 3 and Annexes I and II, Regulation on Leghold Traps).
- Ensure that none of the goods listed in Annex II (in so far as they incorporate the pelts of animal species listed in Annex I) are imported unless a certificate (in the form prescribed by the Commission) is produced by the exporting country to show that the pelts originate in a country to which one of the exceptions specified in the Regulation applies (Art. 4 and Arts. 1 and 2 of Commission Regulation (EC) No 35/97, implementing the Regulation on Leghold Traps).

2.3. Additional Legal Instruments

Two other legislative instruments are relevant to the implementation of this Regulation.

- This Regulation is linked closely with the Berne Convention of 1979 on the Conservation of European Wildlife and Natural Habitats (Council Decision 82/72/EEC), which aims to conserve European wildlife and prohibit all large-scale or indiscriminate capture methods for certain wild animal species; and
- The Regulation uses a similar mechanism for nature conservation as that used by the Endangered Species Regulation (EC) No. 338/97 on the protection of species of wild fauna and flora by regulating trade therein, as "protection" is provided primarily through trade controls.

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks to implement this Regulation are summarised in the following checklist:

Table 11. The Regulation On Leghold Traps - Key Implementation Tasks

THE REGULATION ON LEGHOLD TRAPS - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Establish or delegate a competent authority to be responsible for inspecting import licences for wild animal products, to ensure that imports comply with the requirements of the Regulation.
1.2	Develop a regulatory system to ensure that the import of all wild animal products from the list of animals in Annex I of the Regulation complies with the requirements of the Regulation.
2	Regulation
2.1	Prohibit the use of leghold traps.
2.2	Prohibit the importation of pelts of animal species listed in Annex I, and other goods listed in Annex II in so far as they incorporate these pelts, unless the products are subject to one of the exceptions specified in the Regulation.
2.3	Ensure that none of the goods listed in Annex II (in so far as they incorporate the pelts of animal species listed in Annex I) are imported unless a certificate in the form prescribed by the Commission is produced by the exporting country to show that the pelts originate in a country to which one of the exceptions specified in the Regulation applies

3.2. Phasing

Experience from Member States suggests that the establishment of the competent authority often takes some time and therefore this activity should be undertaken as soon as possible. Arrangements should be less time-consuming where institutional systems are already in place for the Washington Convention on International Trade in Endangered Species (CITES), 1973.

The establishment of the competent authority should be followed by establishing a licensing system and day-to-day working arrangements, covering staffing and logistics.

4. IMPLEMENTATION GUIDANCE

Implementation of the specific requirements of this Regulation will be influenced by the present status, needs and situation in each candidate country. However, drawing upon the collective experience of the Member States, a number of general observations and suggestions for implementing this Regulation are presented below.

4.1. Planning

- The key actors are ministries responsible for foreign affairs, trade and environmental protection, customs authorities and government agencies. Due attention should be given to the establishment of the competent authority, with personnel recruited from appropriate government departments or other organisations. As the subject of cruelty to animals and endangered species protection has a widespread international profile, there are several organisations involved in this field. Amongst these are some of the large international non-governmental organisations, such as the World Wide Fund for Nature (WWF) and TRAFFIC (Trade Records and Analysis of Fauna and Flora in Commerce, an NGO that monitors trade in endangered species in order to ensure that it is in accordance with CITES). At a national level there are a range of scientific and research organisations involved and there is close liaison with specialist wildlife groups and statutory wildlife agencies and government departments.
- For many years there has been continued research into humane trapping methods, particularly in countries such as Canada, and as techniques are refined they are incorporated into the decision-making process. This ongoing research includes consideration of economics and trade, particularly the effects on indigenous people such as the Inuit of Canada. For example, in July 1997, Canada's European General Affairs Council approved the Agreement on International Humane Trapping Standards with the European Union. This was seen as accommodating both environmental and trade considerations. The agreement laid down stringent and scientifically based standards for all trapping methods involving mechanical devices used to catch 19 species of wild mammals, regardless of the reasons for their capture, whether for pest control, conservation, fur or food. Member States should therefore keep up to date with ongoing research and be ready to participate in discussions on the subject with the Commission and other Member States.
- Administrative arrangements will be simpler to implement in candidate countries where systems for implementing CITES are already in place.

5. COSTS

The main types of costs arising during the implementation of the Leghold Traps Regulation are illustrated in the checklist below.

Meeting the requirements laid down in this Regulation should not require significant expenditure, as the Regulation is concerned with administrative measures to protect certain animal species through prohibiting the use of leghold traps and restricting importation of animals or their products captured by these devices.

The costs of enforcement should also not be significant and should relate to the establishment of inspection procedures and import documentation systems. They can also be interfaced with those related to implementation of other EU trade legislation and CITES. A proportion of the cost should fall on the importing or exporting individuals or organisations through the collection of a fee for import or export licences and import taxes.

Checklist of the Types of Cost Incurred to Implement the Regulation

Initial set-up costs:

- devising systems and procedures;
- provision of training;
- preparation of guidance documents;
- consultations and communications;
- research.

Capital expenditure:

- any inspection equipment that may be required, such as laboratory or testing apparatus.

On-going costs:

- continuing research;
- regulatory and enforcement activities;
- communications, consultations, production of documents and reports and public awareness;
- reporting to the Commission.

THE ZOOS DIRECTIVE

Official Title: Council Directive 1999/22/EC of 29 March 1999 relating to the keeping of wild animals in zoos (OJ L 094, 09.04.1999)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

This Directive was adopted in order to address concerns that many animals in European zoos were being kept under unacceptable conditions. In addition, these animals are regarded as part of the EU's environmental heritage and natural resources. It was therefore considered desirable that the keeping of animals in zoos should be regulated to ensure the preservation of species while maintaining the role of zoos in education and scientific research.

The Directive aims to protect wildlife and preserve biodiversity by providing for the adoption of measures by Member States for the licensing and inspection of zoos. Zoos are defined to include all permanent establishments where live animals of wild species are kept for exhibition to the public for seven or more days per year. The Directive does not cover circuses and pet shops, which are expressly excluded. Nor does it cover establishments which Member States have exempted on the grounds that they do not exhibit a significant number of animals or species to the public and that the exemption does not undermine the objectives of the Directive.

The Directive requires the enforcement of the licensing regime using appropriate measures which include the closure of all or part of a zoo in breach of the licensing requirements and the imposition of effective, proportionate and dissuasive penalties.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Designate a competent authority or authorities to grant, refuse and amend licences, to inspect zoos, and to enforce compliance with licences (Art. 7).

2.2. Regulation

- Ensure that all zoos implement the conservation measures set out in Article 3:
 - participating in research, providing conservation training, exchanging information on conservation and, where appropriate, captive breeding, repopulation or reintroduction of species into the wild;
 - promoting public information and awareness in relation to the conservation of biodiversity (particularly information about species exhibited and their natural habitats);
 - keeping animals under conditions which satisfy the biological and conservation needs of the species;
 - preventing the escape of animals and the intrusion of outside pests and vermin;
 - keeping up-to-date records of the zoo's collection.
- Ensure that all zoos have a licence by 9 April 2003 or, in the case of new zoos, before they open to the public (Art. 4(2)). Each licence shall contain conditions to enforce the conservation requirements set out in Article 3 (Art. 4(3)).
- Ensure that before granting, refusing or amending a licence, the competent authorities carry out an inspection to determine whether actual or proposed licensing conditions are being met (Art. 4(4)).
- Member States may be exempted from the licensing requirements of the Directive if they satisfy the Commission that the objectives of the Directive and the conservation requirements in Article 3 are being met and maintained by a system of Regulation and registration that contains provisions for the inspection and closure of zoos equivalent to those in the Directive (Art. 5).

2.3. Monitoring and Enforcement

- Monitor the compliance of zoos with licences and conservation requirements by taking appropriate steps including regular inspection of zoos (Art. 4(3)).
- Enforce the licensing regime by closing part or all of a zoo when it is not licensed or when the licensing conditions are not being met. Alternatively, the competent authority may impose requirements to ensure that licensing conditions are met within a period not exceeding two years (Art. 4(5)).
- Where part or all of a zoo is closed, the competent authority shall ensure that the animals are treated or disposed of under appropriate conditions that are consistent with the purposes and provisions of the Directive (Art. 6).
- Member States shall ensure that there are effective, proportionate and dissuasive penalties for breaches of national provisions implementing the Directive (Art. 8).

2.4. Information and Reporting

- Member States shall communicate to the Commission the main provisions of national law which they adopt in the field covered by the Directive (Art. 9).
- Where Member States seek to be exempted from the licensing requirements of the Directive, they must satisfy the Commission that the objectives of the Directive and the conservation requirements in Article 3 are being met and maintained by a system of Regulation and registration which contains provisions for the inspection and closure of zoos equivalent to those in the Directive (Art. 5).

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are set out below:

- designate an authority responsible for drafting implementing legislation. Usually, this would involve the ministry/department of the environment;
- designate a competent authority or authorities to issue licences, carry out inspections and enforce licences;
- draft legislation establishing a licensing and inspection system and enforcement mechanisms, including the closure of zoos and the imposition of penalties;
- communicate national implementing legislation to the Commission;
- monitor operation of licensing, inspection and enforcement regimes.

3.2. Phasing

Implementation should be carried out in the following phases:

Phase 1:	Designate authority responsible for drafting implementing legislation. Draft implementing legislation.
Phase 2:	Designate competent authority or authorities to carry out licensing, etc.
Phase 3:	Communicate national implementing legislation to the Commission.
Phase 4:	Monitor operation of licensing, inspection and enforcement regimes.

4. IMPLEMENTATION GUIDANCE

The nature and extent of the measures necessary to implement the Directive will depend upon the systems already in place in candidate countries. In the event that a candidate country already has a system of regulation and registration in place that makes equivalent provision for inspection and closure of zoos, it may be possible to rely on the existing system, provided that permission from the Commission is obtained for this. It is more probable, however, that candidate countries will have to establish new licensing systems in order to comply with the provisions of the Directive.

With the objective of supporting the Member in the implementation of the Zoos Directive the European Commission has published in 2015 the EU Zoo Directive good practices document, which aims to present the current state of knowledge on good practices with particular regard to the provisions set out in Article 3 of the Directive.

The Document is available at:

http://ec.europa.eu/environment/nature/pdf/EU_Zoos_Directive_Good_Practices.pdf

5. COSTS

The initial burden of establishing the licensing and inspection regime will be borne by candidate countries. However, the size of the ensuing costs will depend upon the nature and extent of existing regimes for the Regulation and registration of zoos. Some of the costs may be recouped by charging fees for the submission of licensing applications and/or for the issue of licences. Funds recouped as a result of the imposition of penalties for breach of a licence might also help fund the licensing and inspection regime.

Further costs will be incurred by the owners of zoos in order to satisfy the conditions of their licences and to meet the Directive's conservation requirements. The extent to which such costs will also have to be borne by the state will depend upon whether most zoos are owned by private individuals/corporations or by the state.

THE REGULATION ON INVASIVE ALIEN SPECIES

Official Title: Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species (OJ L 317, 4.11.2014)

Commission Implementing Regulation (EU) 2016/1141 of 13 July 2016 adopting a list of invasive alien species of Union concern pursuant to Regulation (EU) No 1143/2014 of the European Parliament and of the Council (OJ L 189, 14.7.2016)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The Regulation (EU) No. 1143/2014 aims to prevent, minimise and mitigate the adverse effects of invasive alien species (IASs) on European Unions' biodiversity and ecosystems, but also on human health and the economy. The Regulation seeks to coordinate the efforts of Member States to combat threats posed by invasive alien species. The Regulation focuses on a List of IAS²³⁸ of the greatest concern across the EU. This List of IAS forms the basis for effective management of the listed species. The Regulation uses three key strategies for the control of the listed IAS, which are: prevention of introduction into Member States; early detection and rapid eradication upon new introduction or appearance of IAS populations; management of widely spread IAS populations.

Preventative measures contained within the Regulation include ban of the import, movement, keeping, trade and release into the environment of IAS. Exemption permits may be granted for research, ex-situ conservation and medicinal use. The Regulation also allows emergency measures to be taken if a non-listed IAS becomes an acute issue in a Member State.

Early detection system requires each Member State to develop its own surveillance strategy and report IAS data at the EU level.

Management of widely spread IAS requires Member States to develop management strategies to tackle existing populations.

²³⁸ Commission Implementing Regulation (EU) 2016/1141 of 13 July 2016 adopting a list of invasive alien species of Union concern pursuant to Regulation (EU) No 1143/2014 of the European Parliament and of the Council was adopted in July 2016 and published in the OJ L 189, 14.7.2016.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Establish or empower existing competent authorities to be responsible for implementing three types of interventions envisaged by the Regulation: prevention (controlling the movement and imports of IAS), early detection and rapid eradication, and management.
- Analyse pathways of IAS of Union concern, identify the most relevant pathways of unintentional introduction of IAS of Union concern and develop action plans to address the priority pathways (Art 13).
- Establish or delegate a competent authority to be responsible for issuing permits for research, ex-situ conservation or medicinal use of, invasive alien species of Union's concern. (Art. 8 & Art. 9).
- Adapt the regulatory system to successfully implement the regulation, including combat the threats posed by IAS of Union concern but also by IAS of Member State concern. Please note that beyond the IAS of Union concern, it is not an obligation for MS but rather something that each Member State is free to choose. (Art. 11&12)
- Consider maintaining or laying down more stringent national rules for the prevention of introduction, establishment and spread of invasive alien species. (Art. 23)

2.2. Regulation

- Ensure that definitions are correctly transposed into the national law.
- Prohibit the import and movement of IAS of Union concern, including keeping, breeding and release (Art.7)
- Envisage measures for combating unintentional introduction or spread of IAS of Union concern. (Art. 7(2))
- Establish a permit system allowing establishments to carry out research on, or ex-situ conservation of, invasive alien species of Union concern. Scientific production and subsequent medicinal use may also be included within a permit system (Art. 8)
- Ensure that inspections are carried out by the competent authorities to ensure that the establishments granted with a permit comply with the conditions set therein. (Art. 8)
- If appropriate, seek authorisation from the Commission in order to grant permits, for reasons of compelling public interest, including those of a social or economic nature, allowing establishments to carry out activities other than research on, or ex-situ conservation of, or medicinal use of invasive alien species. (Art. 9)

- Analyse pathways of IAS of Union concern, identify priority pathways and establish and implement action plans to address the priority pathways of unintentional introduction of IAS of Union concern. (Art. 13).
- Ensure that the public is given early and effective opportunities to participate in preparation, modification or review of action plans (Art. 26)
- Establish fully functioning structures to carry out the official controls necessary to prevent the intentional introduction into the Union of invasive alien species of Union concern. (Art. 15)
- Notify early detections of new appearances of IAS of Union concern and apply eradication measures within three months after the transmission of the early detection notification. (Art. 17)
- Establish effective management measures for IAS of Union concern that are widespread in their territory. (Art. 19)
- Carry out appropriate restoration measures to assist the recovery of an ecosystem that has been degraded, damaged, or destroyed by invasive alien species of Union concern unless a cost-benefit analysis demonstrates, on the basis of the available data and with reasonable certainty, that the costs of those measures will be high and disproportionate to the benefits of restoration. (Art. 20)
- Endeavour to recover the costs of the measures needed to prevent, minimise or mitigate the adverse impact of invasive alien species, including environmental and resources costs as well as the restoration cost by applying polluter pays principle. (Art. 21)
- Make every effort to ensure coordination and cooperation with other concerned states, when practical and appropriate. (Ar. 22)
- Ensure coordination and cooperation for what concerns action plans on pathways, exchange of best practices on management, public awareness programs. (Art. 22)
- Lay down the provisions on penalties applicable to infringements of the legislation on prevention and management of the introduction and spread of invasive alien species and take all the necessary measures to ensure that they are applied. (Art. 30)

2.3. **Monitoring and Reporting**

- Establish a surveillance system of invasive alien species of Union concern, or include it in the existing system. Such system should be able to collect and record data on the occurrence in the environment of invasive alien species by survey, monitoring or other procedures to prevent the spread of invasive alien species into or within the Union. (Art. 14). The surveillance system should be designed and used to monitor the effectiveness of eradication, population control or containment measures in minimising the impact on biodiversity, the related ecosystems services and, where applicable, on human health or the economy. (Art. 19)
- Notify the Commission and inform the other Member States of the competent authorities in charge of applying this Regulation. (Art. 24)

- By 1 June 2019, and every six years thereafter update and transmit to the Commission information stipulated in Article 24(1) (a)-(i).
- Notify the Commission of the early detection of the introduction or presence of invasive alien species of Union concern and inform the other Member States about the appearance or re-appearance of IAS on their territory. (Art. 16)
- Notify the Commission and other Member States of the eradication measures applied in case of early detection pursuant to Article 16 of the Regulation (Art. 17)
- Notify the Commission on its decision not to apply eradication measures pursuant to Article 18 of the Regulation.
- Member States in which the species concerned is present shall immediately notify the other Member States and the Commission, if there is a significant risk that an invasive alien species of Union concern will spread to another Member State. (Art. 19)

2.4. Additional Legal Instruments

Several other legislative instruments are relevant to the implementation of this Regulation.

- This Regulation is linked closely with the EU Animal and Plant Health Regime, which is currently under review. The Animal and Plant Health package of measures provide a modernised and simplified, more risk-based approach to the protection of health and more efficient control tools to ensure the effective application of the rules guiding the operation of the food chain.
- Regulations (EC) No 1107/2009 and (EU) No 528/2012 of the European Parliament and of the Council and Council Regulation (EC) No 708/2007 providing rules concerning the authorisation for the use of certain alien species for particular purposes.
- CITES Regulation (EC) No. 338/97. Its main focus is the implementation of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) but it also covers endangered EU species not threatened by international trade to ensure policy coherence e.g. with the Birds and Habitats Directives. It provides a legal basis to suspend the import into the EU of 'live specimens of species for which it has been established that their introduction into the natural environment of the Community presents an ecological threat to wild species of fauna and flora indigenous to the Community'. In this context, some invasive alien species are included in Annex B to the CITES Regulation (EC) No 338/97, and their importation into the Union is prohibited because their invasive character has been recognised and their introduction into the Union has an adverse impact on native species. Those species are: *Callosciurus erythraeus*, *Sciurus carolinensis*, *Oxyura jamaicensis*, *Lithobates (Rana) catesbeianus*, *Sciurus niger*, *Chrysemys picta* and *Trachemys scripta elegans*. To ensure a coherent legal framework and uniform rules on invasive alien species at Union level, the listing of those invasive alien species as invasive alien species of Union concern is considered as a matter of priority.
- Wild Birds Directive 2009/147/EC and Habitats Directive 92/43/EC. Both Directives contain an explicit IAS prevention obligation. The Habitats Directive, in its Article 22b, requires Member States

to 'ensure that the deliberate introduction into the wild of any species which is not native to their territory is regulated so as not to prejudice natural habitats within their natural range or the wild native fauna and flora and, if they consider it necessary, prohibit such introduction', whereas the Article 11 of the Wild Birds Directive impose more lenient requirement to 'see that any introduction of species of bird which do not occur naturally in the wild state in the European territory of the Member States does not prejudice the local flora and fauna'.

- Water Framework Directive 2000/60/EC and Marine Strategy Directive 2008/56/EC. Implementation of this Regulation is necessary for the achievements of the environmental objectives set as well as maintaining or achieving 'good environmental status' of the marine environment.

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks to implement this Regulation are summarised in the following checklist:

Table 12. The Regulation On Invasive Alien Species - Key Implementation Tasks

THE REGULATION ON IAS - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Establish or delegate a competent authority to be responsible for implementing the requirements of the regulations, including issuing permits for research or ex-situ conservation, inspection to ensure that establishments granted a permit comply with the requirements of the Regulation.
1.2	Adapt the regulatory system to ensure effective implementation of the requirements of the Regulation.
2	Regulation
2.1	Prohibit the intentional introduction of any species listed as an IAS of Union concern. Also, prohibit their reproduction, transport, sale, use, possession or release into the environment.
2.2	Ensure that customs authorities are mandated to carry out controls at borders, and that they have the power to seize any shipments that do not conform.
2.3	Establish a system of permitting for research or ex-situ conservation or other purposes subject to authorization by the Commission.
2.4	Establish and implement at least one action plan to address priority pathways of unintentional introduction of IAS. Action plans should include timetables for action and shall describe the measures to be adopted and, as appropriate, voluntary actions and codes of good practice, to address the priority pathways and to prevent the unintentional introduction and spread of invasive alien species.
2.5	In case of incursion, apply eradication measures, when feasible and not disproportionately costly.
2.6	Establish effective management measures for IAS of Union concern that are widespread in their territory. Member States are encouraged to coordinate their management programmes across national borders where there is a significant risk that an invasive alien species will spread to neighbouring countries or where joint action will lead to a more cost-effective result.
2.7	Carry out appropriate restoration measures to assist the recovery of an ecosystem that has been degraded, damaged, or destroyed by invasive alien species.
2.8	Lay down the provisions on penalties applicable to infringements of the legislation on prevention and management of the introduction and spread of invasive alien species. The penalties may be in a form of fines, seizure of specimens and withdrawal of the permit issued pursuant to Article 8. Take all the necessary measures to ensure that they are applied.
3	Monitoring and reporting
3.1	Undertake research, monitoring and surveillance of such species. Establish a surveillance system of invasive alien species, or include it in the existing system.
3.2	Notify the Commission and other MSs on the following: <ul style="list-style-type: none"> • competent authorities in charge of applying this Regulation

	<ul style="list-style-type: none"> • early detection of the introduction or presence of invasive alien species of Union concern and the eradication measures applied • derogations applied pursuant to Article 18 of the Regulation.
3.3	<p>Report to the Commission by 1 June 2019, and every six years thereafter, on the following:</p> <ul style="list-style-type: none"> • a description, or an updated version thereof, of the surveillance system pursuant to Article 14 and of the official control system on alien species entering the Union pursuant to Article 15; • the distribution of the invasive alien species of Union concern or regional concern in accordance with Article 11(2) present in their territory, including information regarding migratory or reproductive patterns; • information about the species considered as invasive alien species of Member State concern pursuant to Article 12(2); • the action plans referred to in Article 13(2); • aggregated information covering the entire national territory on the eradication measures taken in accordance with Article 17, the management measures undertaken in accordance with Article 19, their effectiveness, and their impact on non-targeted species; • the number of the permits referred to in Article 8 and the purpose for which they were issued; • measures taken to inform the public about the presence of an invasive alien species and any actions that citizens have been requested to take; • the inspections required under Article 8(8); and • information on the cost of action undertaken to comply with this Regulation, when available.
3.4	Communicate to the Commission provision on penalties applicable to infringements of this Regulation

3.2. Phasing

The establishment of the competent authority often takes some time and therefore this activity should be undertaken as soon as possible, especially as regards establishment of the border controls to prevent the intentional introduction into the country of invasive alien species. The establishment of the competent authority should be followed by establishing a permitting system and day-to-day working arrangements, covering staffing and logistics.

Another important issue that needs to be addressed is developing a comprehensive surveillance system to allow early detection of IAS on their territory and taking appropriate eradication measures.

Management of existing invasive alien species require development of surveillance strategy to monitor the existing population and assess the success of management programmes.

As regards unintentional introduction of IAS, a comprehensive analysis of the pathways of introduction or spread of IAS within the country needs to be carried out. Once the priority pathways have been identified, an action plan to address these should be prepared and implemented.

4. IMPLEMENTATION GUIDANCE

Implementation of the specific requirements of this Regulation will be influenced by the present status, needs and situation in each candidate country. However, a number of general observations and suggestions for implementing this Regulation are presented below.

4.1. Planning

- The key actors are ministries responsible for environmental protection, agriculture, health, foreign affairs, trade and customs authorities and government agencies (e.g. CITES authorities). Due attention should be given to the establishment of the competent authority, with personnel recruited from appropriate government departments or other organisations. At a national level involvement of a wide range of scientific and research organisations and close liaison with specialist wildlife groups and statutory wildlife agencies should be encouraged. Management of existing IAS could be delegated to regional or local level.
- There has been continued research into alien invasive species and their impact on the environment, economy and human health. For example, the DAISIE²³⁹ project established under the Sixth EU Research Framework Programme has identified more than 12 000 non-native species present in Europe, 10-15 % of which are expected to have a negative economic or ecological impact. More information on research results can be found at http://ec.europa.eu/environment/nature/invasivealien/index_en.htm.
- Another important source of information is the EASIN (European Alien Species Information Network available at: <http://easin.jrc.ec.europa.eu/about>), which aims to enable easy access to data and information on alien species in Europe from existing on-line databases to assist policy makers and scientists in their efforts to tackle alien species invasions. The EASIN provides a single interface for around 40 existing databases on IAS in Europe. Candidate countries should therefore keep up to date with ongoing research and be ready to participate in discussions on the subject with the Commission and other Member States.

4.2. Regulation and Monitoring

- Countries should prepare and implement an action plan to address identified pathways of introduction and spread of IAS. Whilst some measures are likely to be regulatory in nature (e.g. appropriate inspections, measures to minimise contamination...) it will also be important to organise extensive public awareness campaigns. A number of sectors have already introduced codes of good conduct and guidelines to address the risk of IAS for instance: the European code of conduct for botanic gardens on IAS and the European code of conduct on hunting and IAS. In addition, the United

²³⁹ Delivering Alien Invasive Species Inventories for Europe, www.europe-aliens.org

Nations Convention on Biological Diversity (CBD) has adopted guidelines to prevent and control biological invasions by pets, aquarium and terrarium species, live bait and live food. International Maritime Organisation (IMO) has adopted Guidelines for the control and management of ships' biofouling to minimize the transfer of invasive aquatic species (Biofouling Guidelines) representing important step towards reducing the transfer of aquatic invasive alien species by ships²⁴⁰.

- Countries are required to put in place a series of measures to control or contain populations of IAS of Union concern – or eradicate them completely from their territory if this is still feasible. When applying such measures to invasive animals, Member States must ensure that they are spared any avoidable pain, distress or suffering. Publication LIFE and Invasive Species (available at: http://ec.europa.eu/environment/life/publications/lifepublications/lifefocus/documents/life_ias.pdf) provides a wide range of effective and replicable management methods developed by LIFE projects across Europe.
- As regards establishing surveillance system, candidate countries should analyse whether existing systems of customs control, surveillance and monitoring already established by Union law in particular those set out in Directives 92/43/EEC, 2000/60/EC, 2008/56/EC and 2009/147/EC could be applied for the purpose of early detection and for the determination of the distribution of already established species. Those systems should include both targeted and general surveys and benefit from the involvement of different sectors and stakeholders, including regional and local communities.

²⁴⁰<http://www.imo.org/en/OurWork/Environment/Biofouling/Documents/RESOLUTION%20MEPC.207%5b62%5d.pdf>

5. COSTS

The main identified costs associated with IAS in Europe comprise eradication and control costs and damage to agriculture, forestry, commercial fisheries, infrastructure and human health. In 2008, an initial estimated assessed the total costs of IAS in Europe to be at least 12.5 billion EUR per year (according to documented costs) and probably over 20 billion EUR (based on some extrapolation of costs) per year. These costs result mainly from costs of damage due to IAS and costs of IAS control measures²⁴¹. The cost associated with IAS increases exponentially if the species is not eradicated immediately.

The main types of costs arising during the implementation of the IAS Regulation are illustrated in the checklist below.

Regulation encourages application of the Polluter Pays Principle.

Checklist of the Types of Cost Incurred to Implement the Regulation

<p>Initial set-up costs:</p> <ul style="list-style-type: none">• devising systems and procedures;• provision of training;• preparation of guidance documents;• consultations and communications;• research. <p>Capital expenditure:</p> <ul style="list-style-type: none">• management and eradication measures• restoration of the damaged ecosystems <p>On-going costs:</p> <ul style="list-style-type: none">• continuing research;• regulatory and enforcement activities;• communications, consultations, production of documents and reports and public awareness;• reporting to the Commission.
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²⁴¹ Kettunen, M., Genovesi, P., Gollasch, S., Pagad, S., Starfinger, U. ten Brink, P. & Shine, C. 2008. Technical support to EU strategy on invasive species (IAS) - Assessment of the impacts of IAS in Europe and the EU (final module report for the European Commission). Institute for European Environmental Policy (IEEP), Brussels, Belgium. 44 pp. + Annexes.

THE REGULATION ON ILLEGAL LOGGING (EUTR)

Official Title: Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market (OJ L 295, 12.11.2010)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The Regulation (EU) No. 995/2010 (commonly referred to as EU Timber Regulation or EUTR) aims to combat the problem of illegal logging, which generates significant negative economic, environmental and social impacts. The Regulation prohibits illegally harvested timber from being placed on the EU market through placing obligation on timber product importers to take adequate measures to minimize the risk of importing illegal timber products to the EU. Operators are held accountable for the products they bring into the EU and are required to have a due diligence system that is based on adequate documentation and risk assessment to assess the legal provenance of imported timber products. Thus, the key obligations arising from this Regulation may be summarized as follows:

Prohibition: The Regulation prohibits placing illegally harvested timber (both domestic and imported) or timber products on the EU market.

Due Diligence System: EU operators must exercise due diligence when placing timber or timber products on the market by implementing procedures so as to minimise the risk of illegal timber in their supply chain. Operators can apply due diligence by themselves or through the assistance of Monitoring Organizations (MO). Operators need to provide access to information on the timber product (country of harvest, logging concession, species, sizes, quantities), implement risk assessment (evaluate the risk of occurrence of illegally harvested products), and implement risk mitigation measures and procedures to minimize the likelihood of illegality.

Traceability: After placing timber products on the market for the first time, as part of their due diligence system, traders have to keep records with information from whom they bought and to whom they sold the timber product.

The EUTR covers wide range of timber products listed in the Annex, e.g. roundwood, primary-processed products such as sawn hardwood, and secondary-processed products such as wooden furniture and paper products. According to the EUTR two categories of timber are automatically considered as legally harvested. The first one consists of timber embedded in the timber products covered by VPAs established under the FLEGT Regulation (EC) 2173/2005. The second category consists of timber of tree species listed in Annex A, B and C of the CITES Regulation (EC) 338/97. For these two categories EUTR due diligence procedures need not be applied

The EU Timber Regulation was adopted in December 2010 and entered into application on 3 March 2013.

The Commission has adopted two non-legislative acts. The first one is the Commission Implementing Regulation (EU) No 607/2012 of 6 July 2012 on the detailed rules concerning the due diligence system and the frequency and nature of the checks on monitoring organisations. The second one is the Commission Delegated Regulation (EU) No 363/2012 of 23 February 2012 on the procedural rules for the recognition and withdrawal of recognition of monitoring organisations as provided for in Regulation (EU) No 995/2010.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Establish or empower existing competent authorities to be responsible for monitoring compliance of operators and monitoring organisations with the requirements of EUTR. (Art. 7)
- Adapt the regulatory system to successfully implement the Regulation, i.e. to combat the threats posed by illegal logging.
- Elaborate plans for checks. (Art. 10(2))
- Carry out awareness raising campaigns to inform operators, SMEs in particular, about the requirements of EUTR.
- Consider providing operators with technical and other assistance and facilitate the exchange of information. (Art. 13)
- Establish procedures for management of illegally harvested timber or timber products. In cases of infringements of the prohibition of placing on the internal market of illegally harvested timber and after imposing appropriate sanctions such timber and timber products should not necessarily be destroyed but may instead be used or disposed of for public interest purposes.

2.2. Regulation

- Ensure that definitions are correctly transposed into the national law.
- Prohibit the illegally harvested timber from being placed on the market.
- Establish fully functioning structures to carry out the official controls of monitoring organisations and operators. (Art. 8 and 10)
- Make every effort to ensure coordination and cooperation with other concerned states, including administrative authorities of third countries (Ar. 12(1))
- Establish a mechanism to exchange information on serious shortcomings detected through the checks referred to in Articles 8(4) and 10(1) and on the types of penalties imposed. (Art. 12(2))
- Ensure that infringements of this Regulation, including by operators, traders and monitoring organisations, are sanctioned by effective, proportionate and dissuasive penalties. (Art. 19)

2.3. Monitoring and Reporting

- Carry out checks at regular intervals on monitoring organisations to verify that they effectively fulfil the obligations laid down in this Regulation (Art.8). Furthermore, competent authority should be authorised to carry out checks when in possession of relevant information, including substantiated concerns from third parties. Make sure that frequency and nature of checks on monitoring organisations comply with Article 6 of the Commission Implementing Regulation (EU) 607/2012.
- Carry out official checks, in accordance with a plan as appropriate, which may include checks on the premises of operators and field audits. The competent authorities should be authorised to require operators to take remedial actions where necessary. Moreover, these checks should also be carried out in cases where the competent authorities come into possession of relevant information, including substantiated concerns from third parties. (Art. 10)
- Competent authority should keep the records of the checks referred to in Art. 8 and 10 and the relevant information should be made available in accordance with the Directive on access to environmental information (2003/4/EC). (Art. 8(4) and 11)
- Provide information to the Commission on:
 - competent authorities in charge of applying this Regulation. (Art. 7)
 - results of the checks of the monitoring organisations, i.e. where the competent authority concluded that a monitoring organisation no longer comply with the requirements stipulated in Art. 8(1) and 8(4).
 - by 30 April of every second year following 3 March 2013, submit a report on the application of this Regulation during the previous two years. (Art. 20)
- Notify the Commission on national rules on penalties applicable to infringements of the provisions of this Regulation (Art. 19(3))

2.4. Additional Legal Instruments

Several other legislative instruments are relevant to the implementation of this Regulation.

- This Regulation is linked closely with the Regulation (EC) 2173/2005 setting up the FLEGT licensing scheme. FLEGT Regulation and the EUTR are meant to reinforce each other, where the first one addresses the supply (export) and the second one the demand (import/placing on the market) side of the timber product trade.
- CITES Regulation (EC) No. 338/97. Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) places a requirement on parties to CITES only to grant a CITES permit for export when a CITES-listed species has been harvested, inter alia, in compliance with national legislation in the exporting country. Therefore timber of species listed in Annex A, B or C to Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein are considered to have been legally harvested provided it complies with that Regulation and any implementing provisions.

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks to implement this Regulation are summarised in the following checklist:

Table 13. The EU Timber Regulation - Key Implementation Tasks

THE EU TIMBER REGULATION - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Establish or delegate a competent authority to be responsible for implementing the requirements of the regulations, including inspection to ensure that monitoring organisations and operators comply with the requirements of the Regulation.
1.2	Adapt the regulatory system to ensure effective implementation of the requirements of the Regulation.
1.3	Consider possible approaches to dealing with seized timber.
1.4	Consider providing assistance and guidance to operators, especially SMEs, in order to facilitate compliance with the requirements of this Regulation, in particular in relation to the implementation of a due diligence system.
1.5	Carry out awareness raising campaigns on the problem of illegal logging amongst consumers.
2	Regulation
2.1	Prohibit the illegally harvested timber from being placed on the market.
2.2	Elaborate plans for checks to determine whether operators fulfil their due diligence obligations. Apply risk-based approach in preparation and review of these plans.
2.3	Establish systematic and robust system of checks. Ensure that competent authorities are mandated to carry out checks and that they have the power to require remedial actions to be taken by the operator, but also to seize timber and timber products which do not conform and to prohibit its marketing.
2.4	Take into account rules on frequency and nature of checks on monitoring organisations established by the Commission Implementing Regulation (EU) No 607/2012.
2.5	Establish a mechanism to exchange information with the administrative authorities of other countries and with the Commission.
2.6	Lay down the provisions on penalties applicable to infringements of the legislation on trade of timber and timber products. The penalties may be in a form of fines, seizure of timber and timber products and/or immediate suspension of authorisation to trade. Take all the necessary measures to ensure that they are applied.
3	Monitoring and reporting
3.1	Carry out checks in accordance with the Article 8 and 10 and ensure that the records of the checks referred to in Art. 8 and 10 are kept and the relevant information is made available to the public in accordance with the Directive on access to environmental information (2003/4/EC).
3.2	Notify/inform the Commission on the following: <ul style="list-style-type: none"> ● competent authorities in charge of applying this Regulation. ● national rules on penalties applicable to infringements of the provisions of this Regulation. ● results of the checks of the monitoring organisations.
3.3	Report to the Commission by 30 April of every second year following 3 March 2013 on the application of this Regulation during the previous two years.

3.2. Phasing

The establishment of the competent authority often takes some time and therefore this activity should be undertaken as soon as possible, especially as regards establishment of effective inspection system. The establishment of the competent authority should be followed by day-to-day working arrangements, covering staffing and logistics.

Another important issue that needs to be addressed is developing an effective inspection system that would be able to conduct comprehensive checks on the operators and monitoring organisations.

4. IMPLEMENTATION GUIDANCE

Implementation of the specific requirements of this Regulation will be influenced by the present status, needs and situation in each candidate country. However, a number of general observations and suggestions for implementing this Regulation are presented below.

Due to the relative short period of time elapsed since the Regulation entered into application it is very difficult to single out examples of best practices.

4.1. Planning

- The key actors are ministries responsible for forest management (usually Ministry of agriculture), trade and customs authorities and government agencies. It is important to ensure that sufficient human and financial resources are allocated to the application and enforcement of the EUTR. Due attention should be given to the establishment of the competent authority, with personnel recruited from appropriate government departments or other organisations.
- There has been continued Union's activity to fight illegal logging and associated trade since 2003 within the Forest Law Enforcement Governance and Trade. More information on EU policy can be found at http://ec.europa.eu/environment/forests/illegal_logging.htm

4.2. Regulation and Monitoring

- Countries should elaborate adequate sanction provisions for infringement of provisions related to prohibition, due diligence and traceability. Type of sanctions that may be imposed vary between notice of remedial actions, fines, seizure of timber or suspension of authorisation to trade. Violations of the relevant provisions can also be treated as criminal offences. Regardless of the type of sanctions, administrative or criminal, they must be effective, proportionate and dissuasive.
- Countries are required to put in place annual plans for checking operators following a risk-based approach. Examples of risk criteria: value of the imported timber and timber products in customs procedures, different countries of origin, various timber products, level of corruption in the country of origin (CPI-corruption perception index).
- To help align the interpretation of key provisions of the Regulation with a view to achieving a uniform application across the EU, an EUTR Guidance document was developed by the Commission in close collaboration with the Member States. The document is available at: http://ec.europa.eu/environment/forests/timber_regulation.htm

5. COSTS

The main identified costs are those related to establishing an effective system of checks on operators and monitoring organisations. The competent authorities should be equipped with sufficient financial and human resources.

The main types of costs arising during the implementation of the EUTR are illustrated in the checklist below.

Checklist of the Types of Cost Incurred to Implement the Regulation

Initial set-up costs:

- devising systems and procedures;
- provision of training;
- preparation of guidance documents, if appropriate;
- consultations and communications;

Capital expenditure:

- ensuring appropriate technical capacity and resources

On-going costs:

- regulatory and enforcement activities;
- communications, consultations, production of documents and reports and public awareness;
- reporting to the Commission.

THE REGULATION ON LICENSING SYSTEM OF IMPORTS OF TIMBER TO THE EU (FLEGT REGULATION)

Official title: Council Regulation (EC) No 2173/2005 of 20 December 2005 on the establishment of a FLEGT licensing scheme for imports of timber into the European Community (OJ L 347, 30.12.2005), amended by:

Regulation (EU) No 657/2014 of the European Parliament and of the Council of 15 May 2014 amending Council Regulation (EC) No 2173/2005 as regards the delegated and implementing powers to be conferred on the Commission (OJ L 189, 27.6.2014)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Forest Law Enforcement, Governance and Trade (FLEGT) Regulation establishes licencing scheme that ensures that the wood imported into the EU is harvested legally. The key element in the FLEGT regime is the voluntary partnership agreements (VPAs). These are the bilateral agreements between the EU and third timber producing countries that wish to sign such agreement. Six VPAs have been signed so far, and nine more are in process. The VPAs provide for the establishments of a FLEGT licensing system with a view to ensuring the legality of imports of timber products from these countries into the EU. All timber shipments from VPA countries must be accompanied by a FLEGT licence certifying compliance with the requirements of the FLEGT licencing scheme.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Establish or empower existing competent authorities to be responsible for implementing FLEGT Regulation. (Art. 7)
- Adapt the regulatory system to successfully implement the Regulation, i.e. to ensure that imports of relevant timber products are made subject to a system of checks and controls seeking to guarantee the legality of such products.
- Establish procedures for management of illegally harvested timber or timber products. In cases of infringements of the FLEGT licencing system and after imposing appropriate sanctions such timber and timber products should not necessarily be destroyed but may instead be used or disposed of for public interest purposes.
- Consider introducing fees to cover the necessary expenses arising from official acts by competent authorities required for control purposes. (Art. 5)

2.2. Regulation

- Ensure that definitions are correctly transposed into the national law.
- Ensure that import for VPA countries is prohibited unless the shipment is covered by a FLEGT licence. (Art. 4)
- Establish fully functioning structures to carry out the official customs controls of timber shipments from VPA countries. Customs authorities should be authorised to suspend the release of or detain timber products where they have reason to believe that the licence may not be valid.
- Ensure that infringements of this Regulation are sanctioned by effective, proportionate and dissuasive penalties. (Art. 5(8))

2.3. Monitoring and Reporting

- Ensure that competent authority verify that each shipment is covered by a valid licence prior to releasing the shipment covered by that licence for free circulation in the EU.
- Competent authority should keep the records of in electronic or paper format of the original FLEGT licence together with the corresponding customs declaration. (Art. 5(1))

- Submit by 30 April an annual report covering the previous calendar year containing information stipulated in Article 8(1).
- Provide information to the Commission on:
 - competent authorities in charge of applying this Regulation. (Art. 7)
- Notify the Commission of any information suggesting that the provisions of this Regulation are being, or have been, circumvented. (Art. 6)

2.4. Additional Legal Instruments

This Regulation complements EU Timber Regulation (EU) 995/2010, which aims to combat illegal logging. FLEGT Regulation and the EUTR are meant to reinforce each other, where the first one addresses the supply (export) and the second one the demand (import/placing on the market) side of the timber product trade.

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks to implement this Regulation are summarised in the following checklist:

Table 14. The FLEGT Regulation - Key Implementation Tasks

THE FLEGT REGULATION - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Establish or delegate a competent authority to be responsible for implementing the requirements of the regulation, including communicating with the Commission
1.2	Adapt the regulatory system to ensure effective implementation of the requirements of the Regulation.
1.3	Consider possible approaches to dealing with seized timber.
1.4	Consider introducing fees to cover the necessary expenses related to control of shipments.
2	Regulation
2.1	Prohibit the import for VPA countries unless the shipment is covered by a FLEGT licence
2.2	Ensure that official customs controls of timber shipments from VPA countries are carried out. Ensure that competent authorities have the power to seize timber and timber products, which do not conform with FLEGT licence.
2.3	Lay down the provisions on penalties applicable to infringements of the legislation on FLEGT licencing scheme. Take all the necessary measures to ensure that they are applied.
3	Monitoring and reporting
3.1	Verify that each shipment is covered by a valid licence prior to releasing the shipment covered by that licence for free circulation in the EU
3.2	Notify the Commission of any information suggesting that the provisions of this Regulation are being, or have been, circumvented. (Art. 6)
3.3	Inform the Commission about the designated competent authorities in charge of applying this Regulation.
3.4	Report to the Commission annually by 30 April on the following: (a) quantities of timber products imported into the Member State under the FLEGT licensing scheme, as per HS Heading specified in Annexes II and III and per each partner country; (b) the number of FLEGT licences received, as per HS Heading specified in Annexes II and III and per each partner country; (c) the number of cases and quantities of timber products involved where Article 6(1) has been applied.

3.2. Phasing

The establishment of the competent authority often takes some time and therefore this activity should be undertaken as soon as possible, especially as regards establishment of the border controls to prevent illegally harvested wood to be imported into the EU. The establishment of the competent authority should be followed by day-to-day working arrangements, covering staffing and logistics.

4. IMPLEMENTATION GUIDANCE

4.1. Planning and Regulation

- The key actors are ministries responsible for forest management (usually Ministry of agriculture) and customs authorities. It is important to ensure that sufficient human and financial resources are allocated to the implementation and enforcement of the FLEGT Regulation.
- Countries should elaborate adequate sanction provisions for infringement of provisions related to prohibition, due diligence and traceability. Type of sanctions that may be imposed vary between fines, seizure of timber or suspension of authorisation to trade. Regardless of the type of sanctions applied they must be effective, proportionate and dissuasive.

5. COSTS

The main identified costs are those related to establishing an effective system of control of FLEGT licences. The competent authorities should be equipped with sufficient financial and human resources to implement FLEGT licencing scheme.

**INDUSTRIAL
POLLUTION
CONTROL AND RISK
MANAGEMENT**

Section 7

1. INTRODUCTION AND OVERVIEW	1077
1.1. Overview.....	1077
1.2. EU Policy.....	1078
1.3. EU Legal Instruments.....	1081
1.3.1. Industrial Emissions Directive (2010/75/EU)	1081
1.3.2. Medium Combustion Plants Directive (EU) 2015/2193.....	1082
1.3.3. The Seveso III Directive (2012/18/EU).....	1082
1.3.4. Directive 2004/42/EC on VOC in varnishes and paints.....	1082
1.3.6. EU Ecolabel Regulation (EC) No 66/2010.....	1083
1.3.7. Regulation concerning the establishment of a European Pollutant Release and Transfer Register (166/2006)	1084
1.4. Links between legislation on industrial pollution and control with other EU environmental Legislation.....	1086
2. DEVELOPMENT OF A SECTORAL STRATEGY AND IMPLEMENTATION PLAN	1097
2.1. Key Factors Influencing Strategy Development	1097
2.2. Potential Difficulties in the Implementation Process.....	1101
2.3. Key Stages in Strategy Development	1102
2.3.1. Strategy development project team	1102
2.3.2. Review and analysis of the existing situation	1102
2.3.3. Development and evaluation of options	1103
2.3.4. Preparation of a draft strategy and options paper for consultation with stakeholders	1104
2.3.5. Review of strategy and options following the consultation process	1104
2.3.6. Preparation of strategy and implementation plan	1105
3. INSTITUTIONS AND RELEVANT PARTIES.....	1107
3.1. Key Stakeholders	1107
3.2. Institutional Requirements for Implementation and Operation of Industrial Pollution Control Sector	1107
4. TECHNICAL STANDARDS	1111
5. REGULATION AND ENFORCEMENT.....	1112
5.1. Introduction.....	1112
5.2. Industrial Emissions.....	1112
5.2.1. Overview.....	1112
5.2.2. Licensing/permitting and regulation.....	1112
5.3. Control of major industrial accidents involving dangerous chemicals (Seveso III Directive)	1113

5.4.	Eco-Management and Audit Scheme (EMAS).....	1114
5.5.	Ecolabel.....	1116
5.6.	European Pollutant Release and Transfer Register.....	1117
5.7.	Relationships between IED, Seveso, EIA and SEA Legislation	1117
5.8.	Reporting	1118
5.9.	Monitoring, Inspections and Enforcement.....	1119
6.	PRIORITIES AND TIMING.....	1120
6.1.	Introduction.....	1120
7.	ECONOMIC AND FINANCIAL ISSUES	1121
7.1.	Initial Costs.....	1121
7.2.	Costs to Industry	1122
7.3.	Cost recovery.....	1123
8.	SUMMARY OF KEY ISSUES	1124
	THE INDUSTRIAL EMISSIONS DIRECTIVE.....	1127
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1128
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1132
2.1.	Planning.....	1132
2.2.	Regulation and Enforcement.....	1137
2.3.	Monitoring and Inspections.....	1144
2.4.	Consultation, Information and Reporting.....	1146
2.5.	Related Legal Instruments.....	1149
3.	IMPLEMENTATION	1151
3.1.	Key Tasks.....	1151
3.2.	Phasing Considerations	1163
4.	IMPLEMENTATION GUIDANCE	1164
4.1.	Planning.....	1164
4.1.1.	Administrative system.....	1164
4.1.2.	Develop plans and strategies	1165
4.1.3.	Institutional and procedural structures	1165
4.1.4.	Setting ELV.....	1166
4.1.5.	Planning of Establishments	1166
4.1.6.	Technical guidance.....	1167
4.2.	Regulation and Enforcement.....	1169

4.3.	Monitoring and Inspection	1174
4.4.	Consultation and Reporting.....	1176
5.	COSTS.....	1177
	THE MEDIUM COMBUSTION PLANTS DIRECTIVE	1180
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1181
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1182
2.1.	Planning.....	1182
2.2.	Regulation	1182
2.3.	Monitoring.....	1183
2.4.	Reporting	1183
2.5.	Additional Legal Instruments	1184
3.	IMPLEMENTATION	1185
3.1.	Key Tasks.....	1185
4.	IMPLEMENTATION GUIDANCE	1186
5.	COSTS.....	1187
	THE SEVESO III DIRECTIVE.....	1188
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1189
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1190
2.1.	Planning.....	1190
2.2.	Regulation	1191
2.3.	Monitoring and Enforcement.....	1193
2.4.	Information, Public Consultation and Reporting.....	1194
2.5.	Additional Legal Instruments	1195
3.	IMPLEMENTATION	1196
3.1.	Phasing Considerations	1198
4.	IMPLEMENTATION GUIDANCE	1199
4.1.	Planning and Regulation.....	1199
4.2.	Standards and Guidance.....	1200
5.	COSTS.....	1203
	THE PAINTS DIRECTIVE	1204
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1205
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1206
2.1.	Planning.....	1206

2.2.	Regulation	1206
2.3.	Monitoring.....	1206
2.4.	Reporting and Information.....	1207
3.	IMPLEMENTATION GUIDANCE	1209
3.1.	Regulation.....	1209
3.2.	Monitoring and enforcement.....	1209
4.	COSTS.....	1210
THE ECO-MANAGEMENT AND AUDIT SCHEME REGULATION.....		1212
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1213
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1218
2.1.	Planning.....	1218
2.2.	Regulation	1220
2.3.	Information and Reporting.....	1222
3.	IMPLEMENTATION	1224
3.1.	Key Tasks.....	1224
3.2.	Phasing Considerations	1225
4.	IMPLEMENTATION GUIDANCE	1227
4.1.	Planning and Competent Authorities.....	1227
4.2.	Action for Organisations Participating in the Scheme	1230
4.3.	Regulation	1232
4.4.	Information and Reporting.....	1232
5.	COSTS.....	1233
THE EU ECOLABEL REGULATION		1237
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1238
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1240
2.1.	Planning.....	1240
2.2.	Regulation and Enforcement.....	1241
2.3.	Information and Reporting.....	1241
2.4.	Additional Legal Instruments	1241
3.	IMPLEMENTATION	1245
3.1.	Key Tasks.....	1245
4.	IMPLEMENTATION GUIDANCE	1247
4.1.	Planning.....	1247

4.2.	Information and Reporting.....	1249
5.	COSTS.....	1250
REGULATION ON EUROPEAN POLLUTANT RELEASE AND TRANSFER REGISTER .. 1251		
1.	SUMMARY OF THE MAIN AIMS AND PROVISIONS.....	1252
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1253
2.1.	Planning.....	1253
2.2.	Regulation.....	1254
2.3.	Reporting	1257
2.4.	Additional Legal Instruments	1257
3.	IMPLEMENTATION	1258
3.1.	Key Tasks.....	1258
3.2.	Phasing Considerations	1259
4.	IMPLEMENTATION GUIDANCE	1261
4.1.	Planning.....	1261
4.2.	Regulation	1262
5.	COSTS.....	1264

INDUSTRIAL POLLUTION CONTROL AND RISK MANAGEMENT - OVERVIEW

1. INTRODUCTION AND OVERVIEW

This section of the Handbook deals with EU legislation related to industrial pollution control and risk management. It contains an introductory overview of the sector followed by individual fiches for selected pieces of legislation.

1.1. Overview

This chapter focuses on EU legislation regulating industrial pollution at source. The main legislation includes those four Directives and three Regulations listed below:

Table 1. List of industrial pollution legislation

Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (Recast)
Directive (EU) 2015/2193 of the European Parliament and the Council of 25 November 2015 on the limitation of emissions of certain pollutants into the air from medium combustion plants
Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC
Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC
Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel
Regulation (EC) No 1221/2009 of the European parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No. 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC 2011/832/EU: Commission Decision of 7 December 2011 concerning a guide on EU corporate registration, third country and global registration under Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)
Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC and amended by Regulation (EC) 596/2009

It should be emphasised that, although these Directives and Regulations have been specifically selected under the sector of industrial pollution control, there is other EU legislation that has a direct or indirect impact on regulating pollution from industrial activities, especially in the water management, ambient air, chemical, climate change and waste management sectors. All these listed sectors and their requirements have implications for industrial pollution control and influence the content of permits granted under the industrial emissions (IED) regime.

Furthermore, the horizontal sector setting out requirements on environmental assessment procedures, obligation to consult stakeholders, access to environmental information, environmental liability procedures and ensuring sanctions for non-compliance also to a high degree affect industrial operations and other activities falling within the IED regime.

The Industrial Emissions Directive sets uniform Community-wide minimum emission limit values for certain sectors (large combustion plants, waste incineration and waste co-incineration plants, installations and activities using organic solvents). For these sectors, the emission limit values are the minimum values that have to be set

in permits and respected by relevant industry. In addition, and for all other sectors covered by the Industrial Emissions Directive, the Directive provides that operators can only operate under a valid environmental permit which sets emission limit values for polluting emissions to air, water and soil. These emission limit values shall be based on the Best Available Techniques (BAT) and Associated Emission Levels (BAT-AEL) set by the Commission in implementing decisions, for each sector, and further to an exchange of information with Member States and stakeholders.

Adoption of the new Medium Combustion Plants (MCP) Directive²⁴² in November 2015 filled the regulatory gap at EU level between large combustion plants (>50 MWth), covered by the IED and smaller appliances (heaters and boilers <1 MWth) covered by the Ecodesign Directive 2009/125/EC. The MCP Directive is based on the Commission Proposal, which was part of the Clean Air Policy Package adopted on 18 December 2013.

This section also covers the EU Eco-Management and Audit Scheme (EMAS) Regulation and the EU Ecolabel Regulation, which have a broader scope of application with emphasis also on SMEs, which may not fall under the IED regime. However, to date a majority of the companies, which have implemented EMAS are those that require an IED or other type of operational permit. The Ecolabel Regulation is a product or service-based, as opposed to process-based, regulation. However, the processes for manufacturing the products have of course some bearing on the implementability of the requirements of the EU Ecolabel Regulation.

1.2. EU Policy

The 7th Environment Action Programme (adopted in 2013) identifies nine key objectives, some of which are particularly important for the industrial emission policy, such as:

- to turn the Union into a resource-efficient, green, and competitive low-carbon economy
- to safeguard the Union's citizens from environment-related pressures and risks to health and wellbeing
- giving renewed impetus to implementation in order to maximise the benefits of the Union's environmental legislation.

According to the 7th EAP tackling pollution at source remains a priority and implementation of the Industrial Emissions Directive will further reduce emissions from major industrial sectors.

Under the current Commission, industrial emissions policy is framed by the priority areas established by President Juncker²⁴³, particularly on jobs, growth and investment, a forward looking climate change policy and the creation of a strengthened industrial base.

Until 2010, the IPPC Directive 96/61/EC (amended and consolidated by Directive 2008/1/EC) was the European Union's main regulatory instrument to tackle harmful emissions into the environment. Although the

²⁴² Directive (EU) 2015/2193 of the European Parliament and the Council of 25 November 2015 on the limitation of emissions of certain pollutants into the air from medium combustion plants

²⁴³ http://ec.europa.eu/priorities/docs/pg_en.pdf

former framework on industrial pollution prevention control has delivered benefits through significant emission reductions, many Member States had failed to fully implement integrated permitting. Furthermore, the level of application of Best Available Techniques (BAT) as required by the IPPC Directive has not been achieved across the European Union. As a result the Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions was adopted on 24 November 2010 following three years of inter-institutional negotiations on the Commission's original proposal. The IED recasts seven Directives related to industrial emissions into a single comprehensive Directive. The IED strengthens the IPPC regime and provides further consistency, transparency and consolidates existing legislation into a concise framework with streamlined monitoring and reporting requirements. The IED is expected to provide significant benefits for the environment and human health. The emission reductions achieved at large combustion plants alone are likely to offer net benefits ranging between €7 to 28 billion per year and should reduce premature deaths and years of life lost by 13,000 and 125,000 respectively. Significant health and environmental benefits are also expected in other sectors. The application of the IED is expected to reduce administrative costs for authorities and operators by between €105 and €255 million per year, thus contributing to sustainability of EU industry.

There are ample links between the IED and other legislation regulating the environmental impacts of industrial activities — for example the Environmental Impact Assessment Directive (2011/92/EU), Waste Directive (2008/98/EC), the Landfill Directive (1999/13/EC), the Mining Waste Directive, the Water Framework Directive (2000/60/EC), Council Directive 91/271/EEC concerning urban waste-water treatment, Directive 2008/105/EC on environmental quality standards in the field of water policy, Ambient Air Quality Directive (2008/50/EC), the Heavy Metals in Air Directive (2004/107/EC), the Directive on Greenhouse Gas Emissions Trading Scheme (2003/87/EC), the Seveso III Directive (2012/18/EU), the Geological Carbon Capture and Storage Directive (2009/31/EC), Regulation (EC) No 517/2014 on certain fluorinated greenhouse gases, the EU EMAS Regulation (1221/2009), the Environmental Noise Directive (2002/49/EC), the REACH Regulation (1907/2006), Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, the Environmental Crimes Directive (2008/99/EC) and the Environmental Liability Directive (2004/35/EC)). However, it must be stressed that not all installations that are required to be regulated under the provisions of the IED are covered by the other Directives, and vice versa. For example, some installations, but not all, covered under the IED will also require environmental impact assessments under the EIA Directive.

The general principles of IPPC are given in Box below. The Industrial Emissions Directive (IED) has, further, strengthened five main principles (1) an integrated approach, (2) best available techniques, (3) flexibility, (4) inspections and (5) public participation.

Key Principles of the Industrial Emissions Directive

The IED is based on five main principles, namely

- (1) an integrated approach

The integrated approach means that the permits must take into account the whole environmental performance of the plant, covering e.g. emissions to air, water and land, generation of waste, use of raw materials, energy efficiency, noise, prevention of accidents, and restoration of the site upon closure. The purpose of the Directive is to ensure a high level of protection of the environment taken as a whole. Should the activity involve the use, production or release of relevant hazardous substances, the IED requires operators to prepare a baseline report before starting an operation of an

installation or before a permit is updated having regard to the possibility of soil and groundwater contamination, ensuring the integrated approach.

(2) Best Available Techniques

The permit conditions including emission limit values (ELVs) must be based on the Best Available Techniques (BAT), as defined in the IED. BAT conclusions (documents containing information on the emission levels associated with the best available techniques) constitute the reference for setting permit conditions. To assist the licensing authorities and companies to determine BAT, the Commission organises an exchange of information between experts from the EU Member States, industry and environmental organisations. This results in the adoption and publication by the Commission of the BAT conclusions and BAT Reference Documents (the so-called BREFs). List of reference documents that have been drawn (or are planned to be drawn) as part of the exchange of information carried out in the framework of Art. 13(1) of the IED is available at: <http://eippcb.jrc.ec.europa.eu/reference/>

The Directive on Industrial Emissions reinforces the application of Best Available Techniques, as a way to reduce the harmful industrial emissions across the EU, translating into improved environment and human health. For the large combustion plants alone it will achieve net benefits of €7-28 billion per year, including the reduction of premature deaths and years of life lost by 13,000 and 125,000 respectively.

(3) flexibility

The IED contains certain elements of flexibility by allowing the licensing authorities to set less strict emission limit values in specific cases. Such measures are only applicable where an assessment shows that the achievement of emission levels associated with BAT as described in the BAT conclusions would lead to disproportionately higher costs compared to the environmental benefits due to

- geographical location or the local environmental conditions or
- the technical characteristics of the installation.

The competent authority shall always document the reasons for the application of the flexibility measures in the permit including the result of the cost-benefit assessment. Moreover, Chapter III on large combustion plants includes certain flexibility instruments (Transitional National Plan, limited lifetime derogation, etc.)

(4) inspections

The IED contains mandatory requirements on environmental inspections covering the inspection of industrial installations, the review of permits, reporting on compliance and protection of soil. Member States shall set up a system of environmental inspections and draw up inspection plans accordingly. The IED requires a site visit shall take place at least every 1 to 3 years, using risk-based criteria.

(5) public participation

The Directive ensures that the public has a right to participate in the decision-making process, and to be informed of its consequences, by having access to:

- permit applications in order to give opinions,
- permits,
- results of the monitoring of releases and
- the European Pollutant Release and Transfer Register (E-PRTR). In E-PRTR, emission data reported by Member States are made accessible in a public register, which is intended to provide environmental

information on major industrial activities. E-PRTR has replaced the previous EU-wide pollutant inventory, the so-called European Pollutant Emission Register (EPER).

Other relevant IED principles

Installations shall be operated in such a way that:

- all appropriate preventative measures against pollution must be taken, in particular through the application of best available techniques (BAT);
- no significant pollution shall be caused;
- waste production is avoided (the waste management hierarchy should be followed in accordance with the Waste Directive (2008/98/EC);
- energy is used efficiently;
- necessary measures are taken to prevent accidents and limit their consequences; and
- necessary measures are taken upon the cessation of activities to avoid pollution risk and to return the site of operation to a satisfactory state.

Guidance on IED principles, including on the drafting of a baseline report, on the determination of start-up and shut-down periods, and the implementing decisions adopting BAT conclusions can be found at <http://ec.europa.eu/environment/industry/stationary/ied/implementation.htm>

1.3. EU Legal Instruments

The basic aims of the European Union's legislation considered in this section are illustrated in the Table below. The relationship between the legislation considered in this chapter with other legislation is discussed in more detail in Section 1.4.

1.3.1. Industrial Emissions Directive (2010/75/EU)

The Industrial Emissions Directive (IED) is the key legal instrument in industrial emissions legislation. The IED defines the framework for the permitting of industrial activities with a major pollution potential with the aim to avoid or minimise polluting emissions to air, water and soil, and the generation and disposal of waste in order to achieve an overall high level of environmental and health protection, in particular through better application of Best Available Techniques (BAT). For certain activities, i.e. large combustion plants, waste incineration and co-incineration plants, solvent using activities and titanium dioxide production, the IED also sets EU wide emission limit values for selected pollutants. The IED is the successor of the IPPC Directive and in essence, it is about minimising pollution from various industrial sources throughout the EU. Operators of

industrial installations operating activities covered by Annex I of the IED are required to obtain an integrated permit from the authorities in the EU countries. About 50.000 installations are covered by the IED, which also covers some new activities as compared to its predecessor the IPPC Directive 2008/1/EC. More information is available at: <http://ec.europa.eu/environment/industry/stationary/ied/legislation.htm>

1.3.2. Medium Combustion Plants Directive (EU) 2015/2193

The MCP Directive regulates pollutant emissions from the combustion of fuels in plants with a rated thermal input equal to or greater than 1 megawatt (MWth) and less than 50 MWth. The Directive sets emission limit values for emissions of SO₂, NO_x and dust into the air with the aim of reducing those emissions and the risks to human health and the environment they may cause. It also lays down rules to monitor emissions of carbon monoxide (CO). The emission limit values set in the MCP Directive will have to be applied from 20 December 2018 for new plants and by 2025 or 2030 for existing plants, depending on their size. The MCP Directive also addresses the potential need for Member States to apply stricter emission limit values in areas where this can improve local air quality in a cost-effective way.

The Directive entered into force on 18 December 2015 and will have to be transposed by Member States by 19 December 2017.

1.3.3. The Seveso III Directive (2012/18/EU)

The Seveso III Directive was adopted in 2012 and became fully applicable on 1 June 2015, repealing the Seveso II Directive 96/82/EC. The main changes in the Seveso III Directive were:

- Technical updates to take account of changes in EU chemicals classification introduced by the Regulation on the Classification, Labelling and Packaging (CLP) of substances and mixtures, adapting the EU system to the new UN international chemicals classification (Globally Harmonised System - GHS).
- Better access for citizens to information about risks resulting from activities of nearby companies, and about how to behave in the event of an accident.
- More effective rules on participation, by the public concerned, in land-use planning projects related to Seveso plants.
- Access to justice for citizens who have not been granted appropriate access to information or participation.
- Stricter standards for inspections of establishments to ensure more effective enforcement of safety rules.

The Directive now applies to more than 10 000 industrial establishments in the European Union where dangerous substances are used or stored in large quantities, mainly in the chemical, petrochemical, logistics and metal refining sectors.

1.3.4. Directive 2004/42/EC on VOC in varnishes and paints

Directive 2004/42/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in decorative paints and varnishes and vehicle refinishing products and amending Directive

1999/13/EC ("the Paints Directive") is a harmonisation Directive which aims to ensure the free circulation of goods within the Internal Market. The products covered by the Paints Directive are paints for use on buildings, their trims and fittings and structures associated to buildings and products for vehicle refinishing. The specific sub-categories of products covered are listed in Annex I of the Directive. For the decorative paints and varnishes, Annex II A sets out two sets of transitional limit values for the maximum contents of VOCs. For vehicle refinishing products, Annex II B to the Directive sets out a single set of limit values for the VOC contents. Products must carry a special label when placed on the market, indicating the subcategory of the product, as defined in Annex I, and the legal limit value for VOC contents as indicated in Annex II and (b) the maximum content of VOC of the product in its ready-to-use condition.

Member States must set up a monitoring programme for the purpose of verifying compliance with the Directive and regularly report the results of the monitoring to the Commission²⁴⁴.

1.3.5. Eco- Management and Audit Scheme (EMAS) Regulation (EC) No 1221/2009

Regulation (EC) No 1221/2009 establishes a voluntary system allowing organisations to register one or more of their sites in an EU Eco-Management and Audit Scheme (EMAS). Organisations must be able to demonstrate that they meet various requirements, such as the adoption of an internal environmental management system (EMS), before they may qualify. Participants are required to establish and implement policies, programmes and management systems in relation to their sites, continuously improve their environmental performance, ensure on-going legal compliance, audit the environmental performance of each site, and inform the public of the results. The policies, programmes and systems have to be independently verified to verify ensure compliance with the requirements of the Regulation.

1.3.6. EU Ecolabel Regulation (EC) No 66/2010

The EU Ecolabel is a voluntary award scheme designed to promote products and services with reduced environmental impact throughout their life cycle compared with other products in the same category available on the market, allowing consumers to identify them easily.

The EU Ecolabel may be awarded to products and services available in the Community market meeting specific environmental and fitness-for-use criteria set for them.

These criteria are set through a transparent multi-stakeholder process involving the European Union Ecolabelling Board and are adopted in the form of Commission Decisions. They are revised periodically, in order to keep up with technical and market developments. They are defined in order to minimise the main environmental impacts of products during their entire life cycle from the extraction of the raw materials, to production, packaging and transport, right through the use and the waste/recycling phase. Fitness-for-use criteria also guarantee good product performance.

²⁴⁴ Studies: The "Decopaint" study on the "Potential or Reducing Emissions of Volatile Organic Compounds (OC) Due to the Use of Decorative Paints and Varnishes for Professional and Non-professional use" (available at: <http://ec.europa.eu/environment/pdfinfo.htm>), "Screening study to identify reductions in VOC emissions due to the restrictions in the VOC content of products" (http://ec.europa.eu/environment/air/pdf/paint_solvents/2002_02_bipro_final_report.pdf), "Reducing VOC emission from the Vehicle Refinishing Sector" (http://ec.europa.eu/environment/air/pdf/paint_solvents/2002_08_reducing_voc_emissions.pdf)

Even if the EU Ecolabel is a product/service label, the decision as to whether or not to award it may take into account the environmental impacts of the processes applied in manufacturing the products, hence the link between this Regulation and other legislation in the industrial pollution control sector.

1.3.7. Regulation concerning the establishment of a European Pollutant Release and Transfer Register (166/2006)

This Regulation sets up a pollutant release and transfer register (PRTR) at EU level in the form of a publicly accessible electronic database. The public is able to access this register free of charge on the Internet and to find a wide range of information (type of pollutant, geographical location, affected environment, source facility etc.)

The register contains information on releases of pollutants to air, water and land, as well as transfers of waste and pollutants, where emissions exceed certain threshold values and derive from specific activities. The register also covers releases of pollutants from diffuse sources (such as transport).

Annex II lists the waste and pollutants covered by the register, which include greenhouse gases, acid rain pollutants, ozone-depleting substances, heavy metals and dioxins. Annex I sets out the activities concerned, which are very similar to those covered by the IED, including power stations, mining, quarrying and metalworking industries, chemical plants, paper and timber industries and also waste and wastewater treatment plants. Operators of listed activities have to report periodically to the Member States as regards these activities and the resulting pollutants.

Consideration needs also to be given to certain Commission Decisions and Commission Communications that have relevance to the above legislation. These include:

<p>IED 2010/75/EU</p>	<p>2012/115/EU: Commission Implementing Decision of 10 February 2012 laying down rules concerning the transitional national plans referred to in Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions (notified under document C(2012) 612)</p> <p>2012/119/EU: Commission Implementing Decision of 10 February 2012 laying down rules concerning guidance on the collection of data and on the drawing up of BAT reference documents and on their quality assurance referred to in Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions.</p> <p>2012/134/EU: Commission Implementing Decision of 28 February 2012 establishing the best available techniques (BAT) conclusions under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions for the manufacture of glass.</p> <p>2012/135/EU: Commission Implementing Decision of 28 February 2012 establishing the best available techniques (BAT) conclusions under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions for iron and steel production</p> <p>2012/249/EU: Commission Implementing Decision of 7 May 2012 concerning the determination of start-up and shut-down periods for the purposes of Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions</p> <p>2012/795/EU: Commission Implementing Decision of 12 December 2012 establishing the type, format and frequency of information to be made available by the Member States for the purposes</p>
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	<p>of reporting on the implementation of Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions</p> <p>2013/84/EU: Commission Implementing Decision of 11 February 2013 establishing the best available techniques (BAT) conclusions under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions for the tanning of hides and skins.</p> <p>2013/163/EU: Commission Implementing Decision of 26 March 2013 establishing the best available techniques (BAT) conclusions under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions for the production of cement, lime and magnesium oxide</p> <p>2013/732/EU: Commission Implementing Decision of 9 December 2013 establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions, for the production of chlor-alkali.</p> <p>2014/687/EU: Commission Implementing Decision of 26 September 2014 establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for the production of pulp, paper and board.</p> <p>2014/738/EU: Commission Implementing Decision of 9 October 2014 establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions, for the refining of mineral oil and gas.</p> <p>2014/768/EU: Commission Implementing Decision of 30 October 2014 establishing the type, format and frequency of information to be made available by the Member States on integrated emission management techniques applied in mineral oil and gas refineries.</p> <p>Communication from the Commission — European Commission Guidance concerning baseline reports under Article 22(2) of Directive 2010/75/EU on industrial emissions (OJ C 136, 6.5.2014)</p> <p>Commission Implementing Decision (EU) 2015/2119 of 20 November 2015 establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for the production of wood-based panels</p>
SEVESO III 2012/18/EU	2014/895/EU: Commission Implementing Decision of 10 December 2014 establishing the format for communicating the information referred to in Article 21(3) of Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances
ECO LABEL (EC) 66/2010	Commission Decision 2010/709/EU of 22 November 2010 establishing the European Union Ecolabelling Board
EMAS III Regulation (1221/2009)	<p>2013/131/EU: Commission Decision of 4 March 2013 establishing the user's guide setting out the steps needed to participate in EMAS, under Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)</p> <p>2011/832/EU: Commission Decision of 7 December 2011 concerning a guide on EU corporate registration, third country and global registration under Regulation (EC) No 1221/2009 of the</p>

	<p>European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)</p> <p>2011/C 358/02: Communication from the Commission — Establishment of the working plan setting out an indicative list of sectors for the adoption of sectoral and cross-sectoral reference documents, under Regulation (EC) No 1221/2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)</p>
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1.4. Links between legislation on industrial pollution and control with other EU environmental Legislation

This section discusses in more detail those legal acts in the environmental acquis, which will influence or will be influenced by the implementation of the IED legislation. The following text summarises the requirements of the other EU environmental legislation, highlights links with IED sector legislation. Please note that the below list is indicative and not exhaustive. It lists some of the key instruments to take into account.

Table 2. Summary of Key Interrelationships between EU Legislation in the Industrial Pollution Control Sector and Selected EU Legislation in the Environmental Acquis

<i>Instrument</i>	<i>Reference to relevant legislation in the IPC sector</i>
<i>Air Quality</i>	
<p>Ambient Air Quality Directive (2008/50/EC)</p> <p>The most important instrument in relation to air quality management is the Air Quality Framework Directive (2008/50/EC). This Directive provides for the establishment of new ambient air quality standards and objectives, the assessment of air quality, the provision of information to the public, and the development and implementation of programmes to maintain air quality. "Limit values" and "alert thresholds". There are limit values and alert thresholds for sulphur dioxide, oxides of nitrogen, particulate matter, lead, benzene and carbon monoxide, sulphur dioxide and particulates, nitrogen dioxide and lead.</p>	<p>Industrial Emissions Directive (2010/75/EU)</p> <ul style="list-style-type: none"> • The IED specifies that conditions of permits should include emission limit values for various pollutants, in particular those listed in Annex III. Annex III lists the main air-polluting substances. • Where BAT Associated Emission Levels have been set in implementing decisions, these shall be taken into account when setting emission limit values. • Further, where necessary and appropriate to comply with environmental air quality standards, additional measures must be included in the permits
<p>Heavy Metals in Air Directive (2004/107/EC)</p> <p>This is the fourth daughter Directive setting emission limits under the Ambient Air Quality Directive.</p>	<ul style="list-style-type: none"> • Industrial Emissions Directive (2010/75/EU), Operators of permitted installations must comply with the relevant emission

<p>The Directive sets target values, "to be attained as far as possible" (para.(4)), for all the pollutants except mercury, effective from 31 December 2012 (Art.3). These are 6 ng/m³ for arsenic, 5 ng/m³ for cadmium, 20 ng/m³ for nickel and 1 ng/m³ for PAH, represented by benzo(a)pyrene (Annex I).</p> <p>- Critically, since industrial installations are the key sources of these pollutants, the law specifies that the target values are not environmental quality standards as defined in the air quality framework Directive (para. (6)).</p> <p>Member states must assess levels of the pollutants "throughout" their territories. For all except mercury they must draw up lists of areas where they are met and areas where they are exceeded (Art.4), and ensure "clear and comprehensible" information is made publicly accessible (Art.5(3), Art.7).</p> <p>- Where the targets are exceeded, member states shall identify pollution sources and demonstrate the application of "all necessary measures not entailing disproportionate costs" to meet them (Art.3 (3)).</p>	<p>limit values set for various pollutants, listed in Annex III. These include the air pollutants covered by the Heavy Metals in Air Directive.</p> <p>Where BAT Associated Emission Levels have been set in implementing decisions, these shall be taken into account when setting emission limit values.</p> <p>Further, where necessary and appropriate to comply with environmental air quality standards, additional measures must be included in the permits.</p>
<p>National Emissions Ceilings Directive (2001/81/EEC)</p> <p>This Directive establishes national emission ceilings to limit acidifying and eutrophying pollutants and ozone precursors using benchmarks from the years 2010 and 2020 and by means of successive reviews.</p>	<ul style="list-style-type: none"> Industrial Emissions Directive (2010/75/EU)
<p><i>Horizontal sector</i></p>	
<p>EIA Directive (2011/92/EU)</p> <p>The EIA Directive provides a means to assess and control the overall polluting effects of major industries and other activities on an integrated basis. The results of consultation and information gathered through the EIA process must be taken into account in considering applications for consents for relevant developments covered by the Directive</p>	<ul style="list-style-type: none"> Industrial Emissions Directive (2010/75/EU): For installations to which both the IED and EIA Directives apply, any relevant information obtained as a result of the latter Directive may be taken into account in determining whether to grant the IED permit. <p>Seveso III Directive (2012/18/EU):</p> <ul style="list-style-type: none"> All these Directives cover installations which normally require an EIA before establishment
<p>Environmental Liability Directive (2004/35/EC)</p> <p>The Directive covers direct or indirect damage to the aquatic environment and to species and natural habitats, where protected at Community level. The principle of liability applies to environmental</p>	<p>Industrial Emissions Directive (2010/75/EU)</p> <p>Seveso III Directive (2012/18/EU)</p>

<p>damage and imminent threat of damage resulting from occupational activities, where it is possible to establish a causal link between the damage and the activity in question. The first liability scheme applies to the dangerous or potentially dangerous occupational activities listed in Annex III to the Directive. These include industrial activities that require an IED licence, activities that discharge heavy metals into water or the air, installations producing dangerous chemical substances, waste management activities. Under this first scheme, operators may be held responsible even if they are not at fault.</p> <p>The second liability scheme applies to all occupational activities other than those listed in Annex III if there is damage, or the imminent threat of damage, to species or natural habitats protected by Community legislation. In this case, operators will be held liable only if they are at fault or negligent. Where there is an imminent threat of environmental damage, the competent authority designated by each Member State will require the operator to take the necessary preventive measures, or will take such measures itself and recover the costs incurred at a later date. Where environmental damage has occurred, the operator concerned will be requested to take the necessary restorative measures.</p>	
<p>Access to Environmental Information Directive (2003/4/EC)</p> <p>The Access to Environmental Information Directive aims to ensure that environmental information is systematically available and disseminated to the public and in a manner that is consistent throughout the Member States. Public information that can be obtained includes national, regional and local legislation concerning the environment; information on environment policies, programmes and plans; reports on the state of the environment (which are to be published at least every four years); data on activities affecting the environment; environmental authorisations and agreements, environmental impact studies and risk assessments.</p>	<p>Industrial Emissions Directive (2010/75/EU), Regulation on the Pollution Release and Transfer Register (PRTR) (EC) 166/2006 and Seveso III Directive (2012/18/EU):</p> <ul style="list-style-type: none"> Information on several industrial pollution control-related elements, particularly planning, EIA, operation, licensing and emissions are available under these Directives.
<p>Environmental Crimes Directive (2008/99/EC)</p> <p>Environmental crime covers acts that breach environmental legislation and cause significant harm or risk to the environment and human health. The most known areas of environmental crime are the illegal emission or discharge of substances into air, water or soil, the illegal trade in wildlife, illegal trade in ozone-depleting substances and the illegal shipment or dumping of waste.</p> <p>The Directive lays down a list of environmental offences that must be considered criminal offences by all Member States, if committed intentionally or with serious negligence.</p>	<p>Industrial Emissions Directive (2010/75/EU), Seveso III Directive (2012/18/EU):</p> <ul style="list-style-type: none"> All of the above legislation is listed in Annex I as legislative measures falling within the scope of the Environmental Crimes Directive. Member States must ensure that the commission of the offences listed in Article 3 of the Environmental Crimes Directive is subject to effective,

	<p>proportionate and dissuasive criminal sanctions. For legal persons the sanctions can be of a non-criminal nature.</p> <ul style="list-style-type: none"> • The Directive only sets a minimum standard of environmental protection through criminal law to be adopted by the Member States. The Member States are free to maintain or introduce more stringent protective measures.
<i>Chemicals</i>	
<p>Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures</p> <p>The Regulation on classification, labelling and packaging ("CLP Regulation") contributes to the GHS aim that the same hazards will be described and labelled in the same way all around the world. By using internationally agreed classification criteria and labelling elements, it is expected to facilitate trade and to contribute towards global efforts to protect humans and the environment from hazardous effects of chemicals. The new act will complement the REACH Regulation on the registration, evaluation, authorisation and restriction of chemicals.</p> <p>The Regulation provides a transitional period to allow a gradual migration from the existing system to the new regime. The transitional period ran to 1 December 2010 for substances, and to 1 June 2015 for mixtures (preparations).</p>	<p>Seveso III Directive (2012/18/EU)</p>
<p>REACH Regulation (1907/2006)</p>	<p>Industrial Emissions Directive (2010/75/EU):</p> <ul style="list-style-type: none"> • Annex I of IED covers large chemicals industries. • IED includes the requirement for periodic monitoring of dangerous substances likely to be on the site, as well as an obligation to establish a baseline report at the start of activities involving dangerous substances, and an obligation to put the site back to that state at the time of definitive cessation of activities.

Water Management

The Water Framework Directive (2000/60/EC)

The Water Framework Directive requires water resources to be managed on the basis of river basins, instead of administrative or political boundaries. A river basin management plan will have to be established for each river basin district and updated periodically in order to ensure that the objective of good water status is met. A combined approach to pollution control is anticipated, with Member States needing to include in their programmes both limit values to control emissions from point sources and environmental quality standards to limit the cumulative impact of emissions on water resources. Links will need to be established between the water management and regulation regime set up under the Water Framework Directive and the procedures under the IED. These links in particular should aim to ensure that the requirements of river basin management plans are given due consideration in issuing IED permits.

Industrial Emissions Directive (2010/75/EU):

- Installations regulated under the IED may impact on the direct or indirect discharges of pollutants, water abstraction, etc. Under IED installations have to operate to conditions in permits compliant with Best Available Techniques (BAT) and have to ensure, where appropriate, that environmental quality standards established in EU water law, are respected .
- The relationship between the two sets of obligations is often far from simple, such as different tests of disproportionate costs in the Directives, the presence of multiple pressures on water bodies affecting standards, different implementation timetables, etc.
- Ensuring integration of the implementation of the IED and WFD is a challenge tackling issues such as:
- How to take forward the Industrial Emissions Directive (IED) obligation to consider environmental issues in enforcement activity.
- Ensuring that Inspectorates also examine impacts on the local environment, providing a greater link to examining relationships between IED installations and water objectives.
- Ensure that IED permits issued before water objectives were defined are reviewed and brought into line with the objectives.
- Better integrate the monitoring obligations also integrating the need for

	<p>information transfer between different authorities.</p> <p>PRTR (Pollutant Release and Transfer Register) Regulation:</p> <ul style="list-style-type: none"> Data collection and reporting for activities covered by Annex I relating to amounts of releases of pollutants to water and off-site transfers of any pollutant specified in Annex II in waste water destined for waste-water treatment for which the threshold value specified in Annex II, column 1b is exceeded.
<p>Directive 2008/105/EC on environmental quality standards</p> <p>This Directive is a daughter Directive to the WFD. The WFD requires that all EU waters should achieve ‘good status’ by 2015 and, to assist this, it establishes a regime for the prevention and control of chemical pollution of water.</p> <p>The new Directive takes this forward by setting harmonised environmental quality standards (EQS) for surface waters regarding 33 ‘priority substances’ and eight other pollutants and by including a requirement to phase out discharges, emission and losses of 13 ‘priority hazardous substances’ within 20 years. The 33 priority substances include existing chemicals, plant protection products, biocides, metals (such as mercury and cadmium) and other groups like Polyaromatic Hydrocarbons (PAH) (mainly incineration by-products) and Polybrominated Biphenylethers (PBDE) (used as flame retardants).</p> <p>The Directive sets two types of EQS: annual average concentrations and maximum allowable concentrations. The former are for protection against long-term and chronic effects, the latter for short-term, direct and acute eco-toxic effects. Furthermore, the EQS are differentiated for inland surface waters (rivers and lakes) and other surface waters (transitional, coastal and territorial waters).</p> <p>By 2009, Member States were required to set up an inventory of discharges of pollutants for river basins on their territory. These inventories are to be published in their updated river basin management plans.</p>	<p>Industrial Emissions Directive (2010/75/EU):</p> <ul style="list-style-type: none"> Control and permitting of activities giving rise to certain dangerous discharges. There will be various EC water quality standards, which have to be respected under an IPPC permitting regime
<p>The Dangerous Substances Directive (2006/11/EC)</p>	<p>Industrial Emissions Directive (2010/75/EU):</p>

<p>This Directive should be considered within the regime provided for by the Water Framework Directive (2000/60/EC).</p> <p>Directive 2006/11/EC sets a framework for the elimination or reduction of discharges of dangerous substances to inland, coastal and territorial waters. An annex to the Directive contains a list I and a list II of families and groups of dangerous substances. To control the discharge of dangerous substances, Member States may choose between setting either emission standards based on Community limit values or rather by reference to quality objectives set in the daughter Directives. For controlling List II substances, Member States are to establish pollution reduction programmes with deadlines for implementation.</p>	<ul style="list-style-type: none"> Discharges of both List I and List II substances of Directive 2006/11/EC are to be subject to prior authorisation by a competent authority. <p>E-PRTR (Pollutant Release and Transfer Register) Regulation (EC) 166/2006:</p> <ul style="list-style-type: none"> Data collection and reporting for activities covered by Annex I relating to amounts of releases of pollutants to water and off-site transfers of any pollutant specified in Annex II in waste water destined for waste-water treatment for which the threshold value specified in Annex II, column 1b is exceeded.
<p>The Nitrates Directive (91/676/EEC)</p> <p>This Directive is aimed at reducing or preventing the pollution of water by nitrates from the application and storage of inorganic fertiliser and manure on farmland. It is intended both to safeguard drinking water supplies and to prevent wider ecological damage in the form of the eutrophication of freshwater and marine waters. Member States must identify waters affected by pollution from nitrates, and all known areas of land which drain into waters identified in this way and thus contribute to pollution are to be designated as "vulnerable zones". Action programmes relating to vulnerable zones must then be established. These must contain certain mandatory measures including periods when the application of certain fertilisers is prohibited, and limits on the quantities of fertilisers applied.</p>	<p>Industrial Emissions Directive (2010/75/EU):</p> <ul style="list-style-type: none"> There should be a link to ensure that action programmes for nitrate vulnerable zones and other requirements can be given due consideration when authorising IED installations which have the potential to affect the designated zones.
<p>The Urban Waste Water Treatment Directive (91/271/EEC)</p> <p>The Urban Waste Water Treatment Directive seeks to reduce the pollution of freshwater, estuarial and coastal waters by domestic sewage, industrial wastewater and rainwater run-off — collectively "urban wastewater". It sets minimum standards for the collection, treatment and discharge of urban wastewater. Different requirements are specified for different sizes of towns and villages (agglomerations). In brief, all towns and villages above a specified size will have to establish sewage collecting systems and provide "secondary treatment" (involving biological treatment with a secondary settlement) of wastewater entering these systems. Higher standards of treatment are required for discharges to particularly sensitive areas</p>	<p>Industrial Emissions Directive (2010/75/EU):</p> <ul style="list-style-type: none"> Biodegradable industrial wastewater from specified sectors of the food and drink industry that is discharged direct to receiving waters is also to be subject to prior authorisation. Controls introduced in fulfilment of these requirements will need to be respected in IED permits issued to relevant industrial installations. Any designation of sensitive or less sensitive areas should be relevant to the consideration of local factors particularly

<p>designated by Member States on the basis of criteria set out in the Directive (e.g. waters subject to eutrophication). The Directive sets emission limit values and minimum percentage reductions for discharges from secondary and tertiary treatment plants. The Directive also makes provision for Member States in some circumstances to identify less sensitive coastal and estuarial areas, where levels of wastewater treatment can be lower. In such areas, the Directive requires a minimum of "primary treatment" and evidence that the environment is not adversely affected. Any resulting sludge must be disposed of safely in an environmentally acceptable manner.</p>	<p>in determining best available techniques on which emission limit values and other technical measures to be included as part of the permit conditions must be based.</p> <ul style="list-style-type: none"> Industrial discharges to collecting systems are subject to prior regulation and/or specific authorisation, as well as forms of pre-treatment specified in an annex. <p>EMAS Regulation ((EC) 1221/2009)</p> <ul style="list-style-type: none"> Participants in EMAS have to continuously improve the environmental performance of production processes, resulting in fewer discharges. <p>E-PRTR (Pollutant Release and Transfer Register) Regulation (EC) 166/2006:</p> <ul style="list-style-type: none"> Data collection and reporting for activities covered by Annex I relating to amounts of releases of pollutants to water and off-site transfers of any pollutant specified in Annex II in waste water destined for waste-water treatment for which the threshold value specified in Annex II, column 1b is exceeded.
<p><i>Waste Directive</i></p>	
<p>The Waste Framework Directive (2008/98/EC)</p> <p>This Directive sets out a framework for the management of waste and its production in the EU. It requires Member States to avoid the production of waste and, where waste is produced, to encourage its recovery, including recycling, reuse or reclamation, and the use of waste as a source of energy. Where this is technically and economically impossible, waste must be disposed of in a manner which avoids or reduces environmental impacts.</p>	<p>Industrial Emissions Directive (2010/75/EU):</p> <ul style="list-style-type: none"> The IED includes the same principles governing the basic obligations of operators of relevant installations. The scope of the IED (Annex I) covers a number of installations also regulated under the Waste Framework Directive. These include: installations for the disposal of hazardous waste; installations for the recovery of hazardous waste; installations for the disposal of waste oils; installations for the incineration of municipal waste; large-scale installations for the biological or

	<p>physico-chemical treatment of non-hazardous waste; and large landfills.</p> <ul style="list-style-type: none"> The installations covered by these categories will have to meet the requirements of both regimes. A mechanism could be established allowing this to be achieved by a single permitting system. <p>EMAS Regulation ((EC) 1221/2009:</p> <ul style="list-style-type: none"> Participants in EMAS have to continuously improve the environmental performance of production processes, resulting in waste prevention and higher rates of waste recovery and recycling. <p>E-PRTR (Pollutant Release and Transfer Register) Regulation (EC) 166/2006:</p> <ul style="list-style-type: none"> Data collection and reporting for activities covered by Annex I relating to amounts of releases of pollutants to land and larger quantities of waste transported away.
<p>Mining Directive (2006/21/EC)</p> <p>Industries involved in the extraction, treatment and storage of mineral resources and the working of quarries must ensure that the resulting waste is managed in specialised facilities in accordance with specific rules. Operators of such facilities are subject to liability in respect of environmental damage caused by their operations according to the Environmental Liability Directive (2004/35/EC).</p> <p>Mining operators must obtain a permit from the competent authorities and must comply with the provisions of the Directive. There are also provisions on informing and involving the public in decision making on applications for permits. There are a number of conditions applicable to the establishment of new waste facilities or changes to existing waste facilities in terms of location, physical stability, monitoring and inspection, as well as mandatory arrangements after closure.</p>	<p>Industrial Emissions Directive (2010/75/EU):</p> <ul style="list-style-type: none"> Mineral extraction activity is one of the activities covered in Annex I of the IED, requiring permit and strict control measures. <p>Seveso III Directive (2012/18/EU):</p> <ul style="list-style-type: none"> Operators of so-called A facilities must establish a number of important policies and systems to ensure safe operation and the prevention of major accidents. <p>E-PRTR (Pollutant Release and Transfer Register) Regulation (EC) 166/2006:</p> <ul style="list-style-type: none"> Data collection and reporting for activities covered by Annex I relating to amounts of releases of pollutants to land and larger quantities of waste transported away.
<p>Landfill Directive (99/31/EC)</p>	<p>Industrial Emissions Directive (2010/75/EU):</p>

<p>The Landfill Directive sets standards for the operation of landfills. Its provisions cover the opening, management, closure and monitoring of sites and the acceptability of the waste for landfill. In particular, the Directive includes the need for pre-treatment of waste, limits on the landfilling of organic waste, and restrictions on the "co-disposal" of hazardous waste and municipal waste.</p>	<ul style="list-style-type: none"> • The Landfill Directive defines minimum technical requirements that must be reflected in IED permits issued to landfill operators. <p>EMAS Regulation ((EC) 1221/2009):</p> <ul style="list-style-type: none"> • Participants in EMAS have to continuously improve the environmental performance of operations, including waste operations to achieve fewer releases of pollutants. <p>E-PRTR (Pollutant Release and Transfer Register) Regulation (EC) 166/2006:</p> <ul style="list-style-type: none"> • Data collection and reporting for activities covered by Annex I relating to amounts of releases of pollutants to land and larger quantities of waste transported away.
<p><i>Greenhouse gas emission</i></p>	
<p>Emission Trading Directive (2003/87/EC)</p>	<p>Industrial Emissions Directive (2010/75/EU) (Article 9)</p> <ul style="list-style-type: none"> • Where emissions of a greenhouse gas from an installation are specified in Annex I to Directive 2003/87/EC in relation to an activity carried out in that installation, the permit shall not include an emission limit value for direct emissions of that gas, unless necessary to ensure that no significant local pollution is caused. • For activities listed in Annex I to Directive 2003/87/EC, Member States may choose not to impose requirements relating to energy efficiency in respect of combustion units or other units emitting carbon dioxide on the site. • Where necessary, the competent authorities shall amend the permit as appropriate. • Paragraphs 1 to 3 shall not apply to installations which are temporarily excluded from the scheme for greenhouse gas emission allowance trading within the

	<p>Union in accordance with Article 27 of Directive 2003/87/EC.</p>
<p>Carbon Capture and Storage Directive (2009/31/EC)</p>	<p>Industrial Emissions Directive (2010/75/EU):</p> <ul style="list-style-type: none"> Listed carbon capture and storage activities have to first obtain a permit under the IED

2. DEVELOPMENT OF A SECTORAL STRATEGY AND IMPLEMENTATION PLAN

2.1. Key Factors Influencing Strategy Development

The Industrial Emissions Directive is the key legislation in this sector. The key factors in the development of a strategy for implementation relate to the following:

- the need to consider the effects of industrial and other activities on the environment as a whole rather than on a medium-specific basis, using a holistic approach to include assessment of energy use and waste minimisation, and to effectively adopt a life cycle approach in the consideration of effects. This involves consideration of raw material consumption, including water, and whether adequate provision is made to avoid pollution risk on cessation of activities at a particular installation; and
- the requirement to issue permits authorising such activities which integrate all of these issues, and setting emission limit values for discharges which are based upon the best available techniques for the processes, in order to prevent emissions into the air, water or soil, or, where this is not practicable, to minimise them.

Furthermore, candidate countries should focus on the five overarching principles reinforced by the IED, i.e.

1) an integrated approach,

The integrated approach means that the permits must take into account the whole environmental performance of the plant, covering e.g. emissions to air, water and land, generation of waste, use of raw materials, energy efficiency, noise, prevention of accidents, and restoration of the site upon closure. The main aim of the industrial emissions legislation in general is to ensure a high level of protection of the environment taken as a whole. Should the activity involve the use, production or release of relevant hazardous substances, the IED requires operators to prepare a baseline report before starting an operation of an installation or before a permit is updated having regard to the possibility of soil and groundwater contamination, ensuring the integrated approach.

In initiating the implementation of the IED, candidate countries need to assess whether an "integrated" approach to controlling industrial installations is already practised, or whether the more traditional route of exercising separate control in respect of air, water and waste is followed. It is important to consider whether any such integrated approaches consider only polluting substances, or if, as the Directive requires, they also address related factors such as noise, energy efficiency and resource conservation.

Based on experience with the IPPC Directive, existing Member States can be divided into three categories:

- those with current legislation and practices that cover most if not all aspects of the IPPC regime, such that only minor changes will be needed;
- those applying an approach to permitting which is already integrated but which is different from IPPC in certain significant respects, and requires some modification to remedy this — for example, to bring additional issues from IPPC such as control of noise, energy efficiency and resource conservation into consideration alongside the current control of polluting releases; and

- those who apply medium-specific controls for air, water and waste, which will require dramatic modification to implement IPPC from square one.

The competent authority is the authority with responsibility for carrying out obligations arising from the IED and the other IPPC legislation. Depending on administrative structure in the country and the size of the installation concerned, this could be a national, regional or local body. Authorities at different levels of government responsible for different types of environmental impact may be involved in permitting the same installation. Under such circumstances, it is important to have an effective co-ordinating system for the various permitting regimes.

(2) best available techniques,

The permit conditions including emission limit values (ELVs) must be based on the Best Available Techniques (BAT), as defined in the IED. BAT conclusions (documents containing information on the emission levels associated with the best available techniques) constitute the reference for setting permit conditions. To assist the licensing authorities and companies to determine BAT, the Commission organises an exchange of information between experts from the EU Member States, industry and environmental organisations. This results in the adoption and publication by the Commission of the BAT conclusions and BAT Reference Documents (the so-called BREFs). For more information visit: <http://eippcb.jrc.ec.europa.eu/reference/>

(3) flexibility

The IED contains certain elements of flexibility by allowing the licensing authorities to set less strict emission limit values in specific cases. Such measures are only applicable where an assessment shows that the achievement of emission levels associated with BAT as described in the BAT conclusions would lead to disproportionately higher costs compared to the environmental benefits due to (a) geographical location or the local environmental conditions or (b) the technical characteristics of the installation. The competent authority shall always document the reasons for the application of the flexibility measures in the permit including the result of the cost-benefit assessment. Moreover, Chapter III on large combustion plants includes certain flexibility instruments (Transitional National Plan, limited lifetime derogation, etc.)

(4) inspections

The IED contains mandatory requirements on environmental inspections covering the inspection of industrial installations, the review of permits, reporting on compliance and protection of soil. Member States shall set up a system of environmental inspections and draw up inspection plans accordingly. The IED requires a site visit shall take place at least every 1 to 3 years, using risk-based criteria.

(5) public participation

The Directive ensures that the public has a right to participate in the decision-making process, and to be informed of its consequences, by having access to

- (a) permit applications in order to give opinions,
- (b) permits,
- (c) results of the monitoring of releases and
- (d) the European Pollutant Release and Transfer Register (E-PRTR). In E-PRTR, emission data reported by Member States are made accessible in a public register, which is intended to provide environmental information on major industrial activities. E-PRTR has replaced the previous EU-wide pollutant inventory, the so-called European Pollutant Emission Register (EPER).

The implementation strategy should particularly reflect the new legislative framework, which facilitates and consolidates existing provisions comprising new elements to provide more synergies with other sectoral legislation and to render certain reporting and monitoring procedures more transparent and streamlined. An implementation strategy focusing on the IED legislative framework, bringing the existing 7 Directives under the same legislative framework will maximise legal certainty and reduce the overall implementation and compliance costs. The Commission has drafted an informal transposition checklist for Directive 2010/75/EU on industrial emissions to assist Member States in the transposition process. The informal checklist is available at: <http://ec.europa.eu/environment/industry/stationary/ied/pdf/transposition%20checklist.pdf>

In addition to the IED, the candidate countries should ensure that the implementation strategy carefully deals with the Seveso III Directive (2012/18/EU), which repeals the Seveso II Directive 96/82/EC by 1 June 2015). The Seveso Directive applies to large installations using dangerous substances, and links health and safety issues to those of the environment. Because it also operates through regulatory control of the activities on a site, it is complementary to the operation of the IPPC Directive.

The IED applies to sixteen categories of industry as described in Annex I. Each facility covered by the Directive must be authorised through permitting. The basic technology requirement to be reflected in IED integrated permits is best available techniques (BAT), which are defined in the IED (Art. 3(10)) as follows:

- ‘best available techniques’ means the most effective and advanced stage in the development of activities and their methods of operation which indicates the practical suitability of particular techniques for providing the basis for emission limit values and other permit conditions designed to prevent and, where that is not practicable, to reduce emissions and the impact on the environment as a whole;
- ‘techniques’ includes both the technology used and the way in which the installation is designed, built, maintained, operated and decommissioned;
- ‘available techniques’ means those developed on a scale which allows implementation in the relevant industrial sector, under economically and technically viable conditions, taking into consideration the costs and advantages, whether or not the techniques are used or produced inside the Member State in question, as long as they are reasonably accessible to the operator;
- ‘best’ means most effective in achieving a high general level of protection of the environment as a whole;

The application of BAT will require significant input of technical resources and a high degree of support for both the regulator(s) and industry. The production of comprehensive advice and guidance notes will be essential for effective implementation of the integrated pollution control regime. The European IPPC Bureau (EIPPC) in Seville²⁴⁵ is charged with producing BAT reference documents (BREFs) for each of the categories of industrial activities listed in Annex 1 of the Directive²⁴⁶. Article 3(11) defines BREFs as:

‘BAT reference document’ means a document, resulting from the exchange of information organised pursuant to Article 13, drawn up for defined activities and describing, in particular, applied techniques, present emissions and consumption levels, techniques considered for the determination of best available techniques as well as BAT conclusions and any emerging techniques, giving special consideration to the criteria listed in Annex III’

²⁴⁵ <http://eippcb.jrc.ec.europa.eu>

²⁴⁶The web link to the existing and proposed BREF notes is: <http://eippcb.jrc.ec.europa.eu/reference/>

The BREFs will assist the regulatory authorities by describing reference techniques and reference levels for each sector. Competent authorities in each Member State will be able to use them to develop BAT, taking into account local considerations. This fine-tuning of BAT may take some time. To further provide guidance to the Member States, the Commission will organise an exchange of information between Member States, the industries concerned, non-governmental organisations promoting environmental protection and the Commission (Art. 13 IED). At the issue of this exchange, the Commission will adopt implementing Decisions establishing BAT conclusions for the various sectors concerned. These BAT conclusions shall be mandatory references for setting permit conditions (Article 14(3) IED).

The EMAS Regulation also has a similar provision as the application of BAT under the IED. The European IPPC Bureau (EIPPC) in Seville is charged with producing Sectoral Reference Documents (SRDs) for each of the 11 priority sectors as listed in EU Communication 2011/C 358/02. This Communication establishes a working plan setting out an indicative list of sectors for the adoption of sectoral and cross-sectoral reference documents, under Regulation (EC) No 1221/2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) Annex 1 of the Directive²⁴⁷.

Article 46 of the EMAS Regulation describes that the European Commission's Joint Research Centre (JRC) shall, in consultation with Member States and other stakeholders, develop Sectoral Reference Documents whose objective is to provide guidance to organisations and to facilitate the practical implementation of the requirements of EMAS and which shall include:

- a) best environmental management practice;
- b) environmental performance indicators for specific sectors;
- c) where appropriate, benchmarks of excellence and rating systems identifying environmental performance levels.

The best environmental management practice (BEMPs) that is mentioned under (a) means the most effective way to implement the environmental management system by organisations in a relevant sector and that can result in best environmental performance under given economic and technical conditions.

The JRC is producing two documents describing the BEMPs for each sector: a concise Sectoral Reference Document (SRD), and a detailed technical report. Documents from the pilot phase are available for the following sectors: Retail Trade, Tourism, Construction and Public Administration

The Retail Trade SRD was finalised by the European Commission and can be found here in Decision EU 2015/801 of 20 May 2015²⁴⁸, whereas pilot documents in the other sectors²⁴⁹ may be used as templates for the future development of additional reference documents.

This means, similar to the BREFs under the IED Directive, the SRDs under EMAS shall also help organisations/companies in certain sectors help to minimise their environmental impact while improving their environmental performance.

²⁴⁷ The web link to SRDs is: http://ec.europa.eu/environment/emas/documents/sectoral_en.html

²⁴⁸ Commission Decision (EU) 2015/801 of 20 May 2015 on reference document on best environmental management practice, sector environmental performance indicators and benchmarks of excellence for the retail trade sector under Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)

²⁴⁹ Available at: http://ec.europa.eu/environment/emas/documents/sectoral_en.html

2.2. Potential Difficulties in the Implementation Process

Different countries are likely to face different problems, and generally these can be divided into three main types as follows:

- **Constitutional:** Countries with a decentralised system of government may suffer from constitutional difficulties based on the fact that IED provides a site-specific approach to control which may lead to different conditions from one site to the next, while the countries' constitution rather guarantees equal treatment for everyone.
- **Administrative:** Several countries may have to adjust their present administrative and organisational arrangements to implement the IED. This constitutes a major task and there is a certain risk for political tension where bodies currently charged with regulating particular installations or media fear loss of power as a result of new arrangements for IED. The main institutional options available for implementing a system of integrated permitting are a choice between the appointment of a single body as competent authority with the capabilities and resources to be able to cope with an integrated approach or, alternatively, using a system of "co-ordinated pollution control" (CPC), in which separate organisations each responsible for different environmental media or different sectors (i.e. more than one competent authority) may be involved. In the latter case, candidate countries must take measures to ensure that procedures for the granting of permits and conditions attached to them is fully coordinated. Which particular route a country decides to take will depend largely on the existing situation. With the introduction of the IED, candidate countries have to ensure sufficient emphasis on monitoring and compliance, securing an efficient authority to detect and prosecute cases of non-compliance. The Environmental Crimes Directive (2008/99/EC) covers the majority of the IPC legislation and requires Member States to treat as criminal offences certain activities that breach EU environmental legislation.. The administrative system has to ensure sufficient coordination with the air, water and horizontal sectors to ensure a coherent, transparent legal framework, which is understandable for the regulated installations or activities on one hand and the general public on the other. The EIA Directive (2011/92/EU), Public Participation Directive (2003/35/EC), the Access to Environmental Information (2003/4/EC) and the Environmental Liability (2004/35/EC) brings an additional strong element of public participation and access to environmental information to the IPC sectoral legislation.
- **Technical:** The introduction of technical control of not only the releases but the process itself into pollution control regimes to fully satisfy IED may raise several difficulties, in part because the technical issues in question are themselves complex and largely outside the previous experience of regulatory regimes, but also because the text of the Directive itself allows for discretion and national interpretation. The obtaining of suitable expertise and training should be a subject for serious consideration by candidate countries. In the initial phase it is expected that the countries have to hire external experts (e.g. from experts from the existing Member States) to get the systems and procedures started. Sufficient resources should be reserved for training of ministry staff and personnel from the competent bodies as well as for producing technical guidance. The BREF documents are instrumental in understanding the IED and the interpretation of BAT to be applied in IED regulated installations.

2.3. Key Stages in Strategy Development

The development of an effective strategy for a fully integrated pollution control regime involves the following key stages:

- establishment of a strategy development project team;
- review and analysis of the existing situation;
- development and evaluation of options;
- preparation of a draft strategy and options paper for consultation with stakeholders;
- review of strategy and options following the consultation process; and
- preparation of strategy and implementation plan.

The main considerations for each of these stages are outlined below.

2.3.1. Strategy development project team

A strategy development project team could be established, drawn mainly from existing senior staff within the main pollution control organisation(s) and from governmental departments related to trade and industry and industrial representatives, with expertise in the following areas:

- the current EU industrial pollution control framework and its development;
- the current levels of environmental performance in industry and internationally;
- the capacity of industry to absorb additional pollution control costs;
- national and international environmental legislation;
- technical standards such as BAT and CEN standards
- integrated monitoring and reporting systems and
- the functioning and relationships of national, regional and local governmental organisations.

2.3.2. Review and analysis of the existing situation

The team could compile information relating to the industrial installations within the country likely to come under the control of IED in each of the sectors listed in Annex I of the Directive. The review should include:

- a quantitative review, by sector, of industries to be covered by IED, including volumes within each sector;
- a review of current regulation and permitting legislation and authorities, and the extent to which these cover requirements of the IED regime (here permitting and control measures should extend to other sectoral legislation, e.g. waste, water and air pollution control);
- a review of the permitting procedures, with particular reference to application, verification and permit renewal procedures,

- documentation requirements including environmental impact statements, demonstration of best practicable means for prevention, and disposal of residues. The review should also include permit issuing practices, whether it is appropriate to permit at national, regional or local levels, and whether splitting responsibility for environmental regulation along disciplinary lines will provide a better permitting framework than a single responsible permitting authority;
- an examination of the verification procedures prior to issue of the permit, and whether it is appropriate to consider the energy utilisation as part of the permitting procedure;
- an examination of the control procedures, and how conditions of permits are enforced.

The review should also consider any national regulations or standards related to the control of industrial accident risks and also make some assessment of the extent, if any, of the use of environmental management systems in industry, which could be integrated into the EU EMAS. The review team should also document to what extent the covered installations apply other means to measure or control their processes such as LCA (Life Cycle Assessments). Such a thorough review and assessment of status quo will help to ensure a more targeted and tailored strategy entailing optimal use of resources in the development and implementation of this strategy.

2.3.3. Development and evaluation of options

Completion of the review should result in sufficient information to allow options for implementation to be considered. These should include suggestions as to:

- how the requirements of BAT and environmental standards may be defined by the competent authority;
- how the existing permitting, monitoring, reporting and control procedures could be improved to incorporate an integrated approach;
- the competent authorities to be designated, the establishment of verification, licensing and accreditation bodies and in particular how to make best use of the existing institutions.
- how to ensure effective co-ordination between the competent authorities and ensure efficient division of mandates and responsibility;
- how to manage relationships with the industry and take into account industrial concerns, particularly in regard to applications for integrated permits and the continuous monitoring of compliance with permit conditions;
- how to monitor and control permitted processes and ensure that they remain within the limits imposed by the permits;
- how to ensure sufficient public participation and wide access to environmental information, while taking into account confidentiality issues;
- how to manage the archive of BREFs and similar technical guidance material, and ensure proper dissemination and explanation.

The initial options put forward should vary from doing the minimum, while ensuring full compliance with EU provisions to taking a more holistic, integrated option which may involve substantive reforms and establishment of new public bodies to ensure a long-term cost-efficient and transparent IED regime. The options should also

allow for integration or co-ordination with regulatory functions associated with the control of industrial accidents and the accreditation/verification of environmental management system instruments like EMAS, as well as taking into account the uptake and use of the EU Ecolabel.

Each option will require an assessment of the resource implications of implementation, which will include itemisation of the training, staffing and fixed resources required to complete the implementation. In addition, the timescales associated with the options will need to be established.

2.3.4. Preparation of a draft strategy and options paper for consultation with stakeholders

As part of the initial stages of implementation the candidate counties should undertake a series of consultation exercises in order to canvass the opinions of the various stakeholders. This would include the regulatory bodies, central, regional and local government, industry and industrial organisations, environmental organisations and NGOs and the general public. It would initially involve the preparation of a consultation document to be circulated to the various interested parties. The document would discuss the key issues associated with IED and the other key industrial legislation, potential difficulties and possible options clearly outlining the strengths and weaknesses of each option. Experience has shown this type of exercise to be very beneficial in smoothing the way forward for implementation, in helping to prepare all those likely to be involved and to achieve higher acceptance and compliance levels.

2.3.5. Review of strategy and options following the consultation process

Following the consultation process and feedback from the stakeholders, the strategy can be refined and the preferred options developed so that a detailed implementation plan can be drawn up. Some of the likely questions that will need to have been answered at this stage are listed below:

- Is it better to determine BAT generically for industry sectors, individually for particular sites or via some form of combined system?
- Should the general binding rules be used for the implementation of integrated permitting under the IED?
- How are the requirements of site restoration, especially in relation to obligations under the Environmental Liability Directive, to be tackled?
- How should the confidentiality provisions of the Directive be implemented striking a balance between industrial interests and obligations relating to public participation and free access to environmental information?
- How to make use of flexible mechanism (temporary derogations provided in Chapter III of the IED)?
- What should the permit review periods be?
- How should "substantial change" to a process be interpreted in the context of permit review and public consultation?
- How will IPPC link with other legislation (e.g. planning laws)?

The above illustrates the type of issues on which consultation could be beneficial or necessary.

The outcome of this task should be two or more options for each item of the IED where the country's competent authority would like opinions regarding the most appropriate method of implementation.

2.3.6. Preparation of strategy and implementation plan

At this stage, the main tasks, roles and responsibilities of the key bodies to be involved in the implementation process and the operation of the system need to be defined. Possible bodies that could be involved are as follows:

- the government;
- the competent authority (in some countries the main competent body is likely to be the Ministry of Environment);
- the permitting authority (this may be the same as the competent authority);
- licensing, verification and accreditation bodies (e.g. for EMAS Regulation);
- civil protection bodies (e.g. Seveso Directive);
- the supervising body;
- enforcing and sanctioning authority — this may be the same as the competent authority.

Note that the IED is likely to affect some of the current obligations of the competent authorities and the regulated activities such as:

- the frequency the supervising authority is carrying out inspections;
- the extent of testing of the land before an activity commences;
- the investment needed to meet the appropriate standards;
- change or deregulation of certain activities;
- new types of activities may need permitting in the waste, food and drink, and agricultural sectors.

The enforcement provisions are often carried out by departments of the organisation, which issues permits, but not in all cases, and it is considered advisable to have a clearly defined division between permitting and enforcement roles. The permitting and enforcement authorities may involve more than one body depending on whether a system of co-ordinated pollution control is to be employed.

The Table below shows the possible tasks that the key bodies listed above would be required to carry out as part of the implementation process.

Table 3. Possible Tasks for the Bodies Involved in the Implementation Process

National Government	Competent Authority	Permitting/Enforcing Authority

<ul style="list-style-type: none"> • Draft transposing legislation • Develop overall sectoral implementing strategy • Establish competent authority • Establish permitting and enforcement authorities • Appoint suitable personnel to staff competent authority and furnish authority with sufficient financial and technical resources • Establish a system and mechanism for transboundary consultation • Establish a data collection system for reporting to the Commission • Establish a system of IPPC decision appeals • Provide representation to various EU bodies, such as working groups facilitating the work on implementing legislation (e.g. EMAS, EU Ecolabel) 	<ul style="list-style-type: none"> • Establish a technical committee (TC) to lead the development of BAT and BAT guidance and for the interpretation of BREFs • Train personnel • Establish options for IED implementation • Consult with interested parties and the public • Set up a system for determination of BAT • Work to ensure co-ordination of IED with the mechanism for control of industrial accidents (including civil protection mechanisms) • Establish coordination mechanisms with competent bodies responsible for relevant sectoral legislation (e.g. water, waste, air) 	<ul style="list-style-type: none"> • Set up appropriate staff structure • Train personnel • Establish permitting system • Establish mechanism for public involvement in permitting • Establish system for permit review and variation • Establish system for public access to IED and other relevant industrial pollution control data (e.g. European Pollutant Release and Transfer Register)
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A technical committee could be set up to co-ordinate the introduction of BAT, including development of a time schedule, as this will need to be carefully phased to bring in each industrial sector at set intervals in order to allow the various bodies involved to cope with the workload. The technical committee could also act as a main focus for policy issues.

3. INSTITUTIONS AND RELEVANT PARTIES

3.1. Key Stakeholders

The legislation in this sector, particularly the IED, has major implications for industrial activities and environmental protection in a country. Therefore, many institutions and other parties need to be involved. Any implementation programme needs to be carried out in a transparent way with the maximum consultation of interested parties, as noted above. The key stakeholders likely to be involved and the nature of their involvement are listed in Table 3 below.

The involvement of stakeholders in the implementation process is critical if the legislation involved is going to be ultimately effective. It is important to have the opinions of all those likely to be involved and also to raise awareness of the issues involved. It is important for the national government to take on board the need for effective communication with stakeholders and to make resources available for consultation and support in understanding the technical and scientific issues involved.

3.2. Institutional Requirements for Implementation and Operation of Industrial Pollution Control Sector

In addition to the role of government in transposing the IED and establishing the legal and institutional basis for its implementation, the following main responsibilities will fall upon the competent authority and, if separate, the permitting and enforcement organisation:

- undertake supervision and regulation of the permitting and enforcement organisation if separate;
- conduct consultation on IED implementation options;
- act as the centre of excellence for IED via some form of technical committee;
- provide guidance documents on BAT;
- establish and maintain the system for tracking BAT;
- decide on interpretation of IED provisions which must be determined at Member State level;
- ensure that transboundary consultation is carried out;
- report to the European Commission on the continuous implementation of the IED regime and statistics in the country;
- act as appeal body against permit decisions under the IED system and possibly the appeal body for the enforcement decisions;
- provide representation to the committee assisting the European Commission;
- establish a public register and ensure public access to IED applications, compliance data and related materials;

- ensure reporting of emissions and discharges to the European Pollutant Release and Transfer Register (Regulation (EC) No 166/2006).

The permitting and enforcing organisation, which may be part of government or a separate national environmental agency or regional/local government, will be responsible for:

- establishing and operating the IED permitting system including the issuing of permits and their enforcement;
- conducting regular, planned permit review and variation of permit conditions;
- considering potential transboundary effects of IED sites and initiating consultation if necessary within the framework of international co-operation;
- maintaining and operating a system for public access to IED applications and related materials;
- establishing and operating an appropriate monitoring system.

Table 4. Principal Stakeholders and their Roles in the Industrial Pollution Control Sector

Stakeholder	Role or Interest
National government — principally the ministry of environment but likely to involve others such as those linked to economy, agriculture, trade and industry	<ul style="list-style-type: none"> • Transposition of legislation • Appointment of competent authority • Establishment and control of permitting and regulatory bodies • Support and technical guidance • Ultimate responsibility for compliance • Dissemination of information and direction from the commission e.g. BREF documents • Economy, trade and industry ministries also interested in the cost of compliance
Permitting and regulatory bodies —may include national environmental or health and safety agencies representing government, regional and local government bodies, and accreditation bodies	<ul style="list-style-type: none"> • Permitting and authorisation • Compliance monitoring and enforcement, e.g. by providing a tailor made approach to compliance monitoring taking into account the results of environmental management instruments that are in place • Support and technical guidance • Data collation and reporting • Verification of environmental management systems and ecolabelling of products

<p>Industry and agriculture — including state-owned and private sector</p>	<ul style="list-style-type: none"> • Key interest will be in the cost of compliance as this will be a significant factor in forward planning • Fear of prosecution and fines • Keen to protect public image and maintain competitiveness
<p>Private sector — retailers businesses, manufacturing</p>	<ul style="list-style-type: none"> • Opportunities for business in supplying of pollution abatement equipment or environmental consultancy • Opportunities for competitive advantage linked to better environmental performance e.g. through EU Ecolabel or EMAS
<p>Professional and technical institutions — linked to industrial or commercial sectors</p>	<ul style="list-style-type: none"> • Representation of industry views • Provision of technical support and guidance
<p>Public</p>	<ul style="list-style-type: none"> • Impact on public health due to industrial pollution • Environmental costs may eventually be passed on to the general public as consumers of goods etc.
<p>NGOs</p>	<ul style="list-style-type: none"> • Representation of public interest • Highlighting environmental issues • Exerting pressure on government and industry
<p>Universities and academic institutions</p>	<ul style="list-style-type: none"> • Research into improved environmental technology and techniques • Research into effects of pollution • Research into the acceptance of the results of environmental management instruments like EMAS by competent (enforcement) authorities.

International organisations	<ul style="list-style-type: none"> • Provision of technical guidance and information, e.g. the European IPPC Bureau in Seville • Sources of reference on environmental standards like the EMAS Sectoral Reference Documents and the BREFs. • Provision of grant support for technical assistance to improve environmental performance
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For the control of major-accident hazards pursuant to the Seveso Directive (2012/18/EU), the competent authorities are normally equipped by specialists in health and safety and civil protection, rather than environmental experts. The competent authorities, however, have similar duties, such as:

- planning to ensure that objectives for the prevention of major accidents are taken into account in land-use and other relevant policies;
- identifying establishments where there are increased risks;
- drawing up emergency plans;
- prohibiting the operation of establishments that do not comply with the standards laid down in the Directive;
- implementing a system of inspections to enforce obligations placed on operators;
- monitoring major accidents and ensuring that specified measures are taken;
- providing information to and consulting the public, and reporting to the Commission.

4. TECHNICAL STANDARDS

Standards and guidelines are vitally important in creating a harmonised system of integrated prevention and control of pollution in Europe. Directives and Regulations in themselves cannot contain the detailed technical information necessary for sound implementation; this is commonly provided by standards and guidelines. Relevant standards may be European — produced by the European Standards Organisation (CEN); or international — such as those produced by the International Standards Organisation (ISO). European standards often form the basis for, or are incorporated directly into, national standards. Standards are not legally binding by themselves. However, they are widely regarded by regulatory bodies as indicating best practice and they can become legally binding if incorporated into legislation. Moreover, in some instances compliance with harmonised European Community standards results in a presumption of conformity with the corresponding essential requirements laid down in European Community Directives or Regulations.

Standards apply to a range of targets that are important to the industrial sector. For example, installations that have and observe standard operating procedures are more likely to be reliable in pollution control. Laboratories observing good laboratory practice guidelines will probably be more effective in monitoring emissions than ones that do not. Usually, somebody other than the pollution control competent authority will have responsibility in such areas, which emphasises the need to establish good communications over a very wide area if requirements of the IED are to be achieved.

Also to note are the BREFs, which are drawn up for defined activities and describing, in particular, applied techniques, present emissions and consumption levels, techniques considered for the determination of best available techniques as well as BAT conclusions and any emerging techniques, giving special consideration to the criteria listed in Annex III of the IED. These are available at: <http://eippcb.jrc.ec.europa.eu/reference/>

Finally, please note that the EMAS Sectoral Reference Documents include:

- a) best environmental management practice;
- b) environmental performance indicators for specific sectors;
- c) where appropriate, benchmarks of excellence and rating systems identifying environmental performance levels are available via the website of the Institute for Prospective Technological Studies (IPTS), one of the seven scientific institutes of the European Commission's Joint Research Centre (JRC), via the following hyperlink: <http://susproc.jrc.ec.europa.eu/activities/emas/index.html>

5. REGULATION AND ENFORCEMENT

5.1. Introduction

Once the IED and supplementary legislation is fully applicable, measures are required to ensure its effective implementation and enforcement. Enforcement of the IED, as the framework legislation, will be considered primarily in this section. Control of industrial accidents, ecolabelling, EMAS, and the Regulation on the European Pollutant Release and Transfer Register will be given further attention at the end of the section.

5.2. Industrial Emissions

5.2.1. Overview

The previous sections have detailed the mechanisms needed to establish and implement a statutory system for the IED. Once this is established, there will be a need for administration and enforcement systems, procedures and resources to fulfil the requirements of the regulatory framework.

The regulatory function consists of the following primary tasks:

- issuing licences/permits for activities covered by IED;
- monitoring and inspecting IED licensed sites to ensure adherence to licence/permit conditions;
- taking enforcement action if they are not.

The IED is emphasising the need for effective enforcement with inspections and penalties in case of non-compliance.

Note that the new IED is likely to affect some of the current obligations of the competent authorities and the regulated activities such as:

- the frequency the supervising authority is carrying out inspections;
- the extent of testing of the land before an activity commences;
- the investment needed to meet the appropriate standards;
- change or deregulation of certain activities;
- new types of activities may need permitting in the waste, food and drink, and agricultural sectors.

5.2.2. Licensing/permitting and regulation

IED permits are intended to control the facilities and activities listed in Annex 1 of the Directive to control releases of substances to air, land and water. The main intention of the Directive is the control of the overall impacts of IED controlled sites on the environment and human health. The primary tasks in relation to the issuing of licences/permits are:

- receiving applications for licences/permits; and
- consideration of applications and granting of permits.

The granting of licences/permits will involve subsequent regulation of their operation. This should consider whether:

- all appropriate preventative measures have been taken through the use of BAT;
- significant pollution is caused;
- waste production is prevented or minimised;
- waste that is unavoidably produced is disposed of with minimal effect on the environment;
- energy is used efficiently;
- monitoring data indicate compliance with conditions including emission limit values (ELVs) and environmental quality standards (e.g. water standards under Directive 2008/105/EC or under Ambient Air Directive (2008/50/EC));
- specific conditions imposed by the Member State are complied with.

The granting of permits and their regulation will require the permitting and enforcement organisation to possess a detailed technical understanding of the processes involved and the potential environmental and health effects, as well as the ability to establish and administer the IED regime. The organisation may need to formulate licences/permits that define in detail substances that may be emitted and subject to emission limits. It may also need to consider the environmental fate of these substances once they have been released. The regime will provide and make use of guidance (such as BREF notes) produced at all levels of the regime. As a result of such considerations, conditions will be attached to licences. These must be justifiable, unambiguous and enforceable. These conditions should be applied consistently and constant reference to the above guidance, once it becomes available, will be required to ensure this. In drafting licence/permit conditions, the permitting authority should ensure that the operator is not unduly constrained from being able to operate in a cost-effective manner.

It will be necessary to upgrade permits from time to time, as a result of improved understanding of the environmental impacts of the released substance requiring reconsideration of the condition, or the licence holder may request modification in relation to a substantial change in operation of the process. The resulting administrative requirements must be taken into account in planning for the implementation of the Directive.

The granting of a licence/permit will usually require the establishment of a scheme to monitor releases from installations. The permit will specify monitoring requirements, frequencies and analytical techniques to be used. Routine surveillance visits may be undertaken by the enforcement organisation on a regular basis with occasional random, unannounced inspections.

5.3. Control of major industrial accidents involving dangerous chemicals (Seveso III Directive)

In order to improve safety and reduce the risk of human error, operators of industrial installations concerned will have to develop a policy for major accident prevention as well as a safety management system. The operator

must prepare a safety report and an internal emergency plan. The national competent authorities must prepare an external emergency plan, co-operating across borders where this is necessary to prevent or respond to major accidents.

Member States must prohibit the use of industrial installations where the prevention and mitigation measures taken by the operator are seriously deficient or where the operator does not submit the required information to the competent authority within a reasonable period of time. Public access to information is strengthened. A system of inspections must be organised by the competent authorities.

Some of the key implementing considerations

- Administrative knowledge and capacity needed to implement the Seveso III Directive are considerable. As a first step, competent authorities need to be identified at national and at local level.
- Procedures need to be put in place to ensure that all existing and new installations with major-accident hazards potential have taken the measures needed to prevent major accidents and limit their consequences. This requires the establishment of a registration system for notifications and the ability to assess the safety reports submitted.
- Local authorities are responsible for drawing up external emergency plans. The development of these emergency plans requires as a basis the internal emergency plan to be supplied by the operator containing information on the establishment and the specific arrangements for emergencies. Persons liable to be affected by a major accident need to be informed. Both, internal and external emergency plans need to be practically tested and reviewed. In case of an accident, interventions need to be co-ordinated.
- Collecting and disseminating information on accidents and near-misses is essential to allow to improve prevention methods and emergency response procedures. Procedures for the collection, exchange and dissemination of information need to be defined and established.
- Competent authorities need to set up a programme of inspections based upon either a systematic appraisal of major-accident hazards of the establishments concerned or one on-site-inspection per year.

It is common for control of industrial accidents to be outside the remit of those bodies associated with environmental regulation. Control is more often with health and safety regulators. However, due to the requirement in the IED that necessary measures be taken to prevent accidents and limit their consequences, there is a need for a linking and co-ordination mechanism to be established between the competent authorities for the two Directives.

5.4. Eco-Management and Audit Scheme (EMAS)

In order to minimise the environmental impact, improve the environmental performance and reduce the environmental risks of (industrial) installations and activities environmental management systems like EMAS are a useful tool. Often environmental management systems supplement the safety management systems mentioned in paragraph 5.3. The EMAS Regulation for example also adapts a risk-based approach to environmental effects

Some enforcement authorities are known to take into account/acknowledge the environmental benefits of having an environmental management system in place by adapting the permit conditions accordingly. This can for example be done by acknowledging having an environmental management system like EMAS in place has a direct influence on one the primary tasks of issuing of licences/permits, namely considering whether all appropriate preventative measures to avoid and minimise environmental effects have been taken by the organisation.

An environmental management system instrument as EMAS for example contains several provisions to control environmental effects under abnormal or emergency conditions. This means that all EMAS registered organisations have considered the direct environmental aspects of their operations. Direct environmental aspects that relate to, but are not limited to: risks of environmental accidents and impacts arising, or likely to arise, as consequences of incidents, accidents and potential emergency situations. This also means that all EMAS registered organisations have defined criteria for assessing the significance of the environmental aspects of their activities, products and services, and consequently determined which of their activities can have a significant environmental impact. These criteria shall take into account Community legislation and shall be comprehensive, capable of independent checking, reproducible and made publicly available. These criteria for assessing the significance of an organisation's environmental aspects must also include, but are not limited to, the organisation's existing data on material and energy inputs, discharges, wastes and emissions in terms of risk. In the assessment of the significance of the environmental impacts of the organisation's activities the organisation shall not only consider the normal operating conditions but also of start-up and shutdown conditions and of reasonably foreseeable emergency conditions. Evaluation of feedback from the investigation of previous incidents shall also feed into the assessment and in examining all existing environmental management practices and procedures.

Although EMAS is a voluntary tool, candidate countries are required to put in place the necessary implementation structures. Furthermore, the use of an environmental management system as EMAS is likely to benefit the relationship with both environmental and health and safety regulators. This is not just the case in relation to industrial accidents but also with meeting the requirements of IPPC and other requirement resulting from environmental legislation in general. Similar to the IED, EMAS also requires a more holistic systems type approach to the control of pollution. The principles behind both EMAS and IPPC are very similar. The difference is that one is effectively a voluntary code of practice for industry and the other is a mandatory regulatory tool.

The implementation of the EMAS Regulation in the Member States relies on use of external independent EMAS verifiers (third-party verification). The quality of the activities performed by these EMAS verifiers is, in turn, checked by independent EMAS Accreditation and Licensing Bodies installed by the Member States. Usually there is one Accreditation and Licensing verification body in a Member State to control the quality of the work of the environmental verifiers (individuals and organisations). Few Member States have a separate Accreditation Body for verification bodies and a separate Licensing Body for licensing individual environmental verifiers. EMAS registered organisations are free to use the services of environmental verifiers from another Member State. However, verification bodies and individual environmental verifiers themselves have to be approved by a national Accreditation and Licensing body within their own territory.

The most important mandatory implementation requirements of EMAS are:

- Member States must designate Competent Bodies (CBs), which are responsible for implementing the Regulation and establish procedures for the registration of organisations. The composition of these bodies is required to be such that it guarantees their independence and neutrality.

- The CBs shall participate in regular peer evaluations to assure a armonised implementation of the Regulation in all Member States.
- The CBs are responsible to maintain a register of EMAS registered organisations registered in their Member States, including information as to how their environmental statement or updated environmental statement can be obtained, and, in the case of changes, update that register every month.
- Member States must appoint Accreditation and/or Licensing Bodies (ALBs) who are responsible for the accreditation of environmental verifiers and the supervision of their activities.
- The ALBs must assess an environmental verifier's competence relevant to the scope of the requested accreditation or licence.
- ALBs must establish and update a list of environmental verifiers and their scope in their Member States and communicate changes to the European Commission and the CBs each month.
- Member States must also ensure and provide assistance to organisations in order to get access to the applicable legal requirements relating to the environment and help organisations identify the competent enforcement authorities for these requirements.
- Member States shall promote the EMAS scheme taking and provide information to the public and organisations about EMAS.
- Member States must also encourage the participation of small organisations and provide specific assistance to clusters of organisations, eventually by encouraging a step-by-step approach leading to EMAS registration.
- Acceding countries may, as an option, apply provisions analogous to the Eco-Management and Audit scheme (ISO 14001 or a national environmental management and audit scheme) prior to joining the European Union.

5.5. Ecolabel

Regulation (EC) No. 66/2010 on the EU Ecolabel award scheme seeks to promote the design, production, marketing and use of products, which have reduced environmental impacts during their life cycles.

Conditions for the awards for each product group are adopted through Commission Decisions after a consultation process involving interest groups from industry, commerce, consumer, environmental organisations and the European Union Ecolabelling Board. Product group ecolabel criteria are revised periodically every 4 years on average and are determined according to life cycle assessments of product groups based on the maintenance of a high level of environmental protection. More information on the development of EU Ecolabel criteria can be found on the following link: <http://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html>.

Some key implementation considerations:

- Member States have to designate the Competent Body or Bodies, the composition of which is to guarantee independence and neutrality, to receive the Ecolabel applications, assess the environmental

and quality performance of the product in relation to specified criteria, and decide on the award of the EU Ecolabel;

- Member States have to lay down the rules on penalties applicable to infringements of the provision of the EU Ecolabel Regulation;
- In order for the EU Ecolabel scheme to be successful, it needs to be known by the consumer and supported by industry and retailers. Consultation and information campaigns in support of the scheme are almost a prerequisite for its success.

5.6. European Pollutant Release and Transfer Register

The European Pollutant Release and Transfer Register (E-PRTR) is the Europe-wide register that provides easily accessible key environmental data from industrial facilities in European Union Member States and in Iceland, Liechtenstein, Norway, Serbia and Switzerland. It replaces and improves upon the previous European Pollutant Emission Register (EPER).

The register contains data reported annually by some 30,000 industrial facilities covering 65 economic activities across Europe.

For each facility, information is provided concerning the amounts of pollutant releases to air, water and land as well as off-site transfers of waste and of pollutants in waste water from a list of 91 key pollutants including heavy metals, pesticides, greenhouse gases and dioxins.

The register contributes to transparency and public participation in environmental decision-making. It implements for the European Community the UNECE (United Nations Economic Commission for Europe) PRTR Protocol to the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters.

Some key implementation considerations:

- Although Regulations may not be transposed into national law, Member States will need to designate a competent body, whose composition is to guarantee its independence and neutrality, to collect, process, store and, where relevant, disseminate data received from various industrial installations;
- Ensure that undertakings are informed about their obligations under the Regulation and the timetable for submitting data;
- Monitoring arrangements and, where relevant, enforcement action.

5.7. Relationships between IED, Seveso, EIA and SEA Legislation

The field of application of the EIA Directive (2011/92/EU) is very broad and essentially covers all projects that have a significant effect on the environment. Also plans and programmes for activities within the scope of the IED regime are subject to Union law under the SEA Directive 2001/42/EC. The IED applies to industrial

activities and some agricultural activities, and the Seveso III Directive applies to establishments where dangerous substances are present. All these Directives apply to new projects and, where required, to existing activities including changes and extensions. The EMAS Regulation applies to the operation of both industrial activities and non-industrial sectors.

There is a large degree of overlap in the categories of projects to which IED and EIA apply, and it is also likely that Seveso projects are included within both IED and EIA assessments. Projects involving installations mentioned in both the EIA Directive and the IED are subject to both directives' requirements. Where possible, assessment procedures should be conducted by using the joint procedure, thereby making data collection, public consultation and the assessment process itself more efficient.

5.8. Reporting

Environmental reports, information or documentation are required under the IED, Seveso III Directive, E-PRTR Regulation and the EMAS Regulation but also under the voluntary Ecolabel Regulation. Preferably links between should be established to avoid duplication, and consideration should be given to the co-ordination of the stages of the procedures where the submission of information is required. Note the requirements for reporting to the Commission on the application and operation of national law and practice intended to implement the IED.

The reports required under the IED procedures are focused on environmental effects and the measures for their prevention and reduction. The Seveso reports are focused on risk analysis and safety conditions, focusing on health risks rather than environmental protection. However, both reports examine in particular the design, construction and operation of plant.

Environmental reporting under EMAS is done by means of environmental statements. They provide comprehensive information to the public and other interested parties regarding an organisation's structure and activities, its environmental policy and environmental management system, the environmental aspects and impacts of the organisation as well as its environmental programme, (including objectives and targets) and finally the environmental performance and compliance with applicable legal obligations of the organisation.

The EMAS environmental statements should be produced and made publicly available periodically (yearly). In case EMAS sectoral reference documents are available for the specific sector of the organisation in question, the assessment of the organisation's environmental performance must take into account that document. The factual correctness and accuracy of the information in the environmental statement is validated by the EMAS environmental verifier.

Furthermore, data on emissions from IED installations have to be reported annually and stored in the European Pollutant Release and Transfer Register (E-PRTR) (<http://prtr.ec.europa.eu/>). This Europe-wide register provides easily accessible key environmental data from industrial facilities. It replaces the previous European Pollutant Emission Register (EPER). The register contains data reported annually by some 30,000 industrial facilities covering 65 economic activities across Europe. For each facility, information is provided concerning the amounts of pollutant releases to air, water and land as well as off-site transfers of waste and pollutants in waste water from a list of 91 key pollutants.

To the extent possible, candidate countries should try to integrate the reporting procedures rather than operating several different reporting systems by various competent bodies.

Also, in setting up information and reporting systems, candidate countries should take account of the need for public participation in the regulatory function and ensure that at least the minimum information referred to in the Access to Environmental Information Directive (2003/4/EC) and where requested by the separate industrial legislation is made available to the public in an easily accessible manner and media. Where candidate countries intend to use a common phase of public participation, the information provided must comply with the requirements of the Directives. The information supplied for the EIA Directive could be used as a basis, supplemented by other information as required by the other Directives. The provision of information to the public should be carefully timed where a common implementation approach is used.

Information exchange between neighbouring states is also required under the IED and Seveso III Directive where there are transboundary impacts, and these obligations may be achieved by establishing a single uniform procedure.

5.9. Monitoring, Inspections and Enforcement

The IED strengthens the existing requirements on monitoring and inspections aimed to ensure that the system of integrated prevention and control of pollution is applied and enforced in practice. Member States must ensure that permit conditions are in compliance with the requirements and that operators regularly provide competent authorities with results from monitoring of emissions. Monitoring and reporting obligations of the operator must be set out in permits. Monitoring obligations generally include the monitoring of concentrations of specified pollutants emitted from the installation and a range of other aspects, which have to be kept in mind when operating an installation (e.g. safety reporting, waste management, etc). In some cases, (e.g. for large installations), there may also be a requirement to monitor the surrounding environment. The IED includes the requirement for periodic monitoring of dangerous substances likely to be on the site and if there may be risk of soil and groundwater contamination.

The IED provides more detailed provisions for inspection and enforcement than the former IPPC Directive. Member States have to produce inspection plans, which apart from information on installations, must include a general assessment of relevant significant environmental issues. Based on the plans, inspection programmes shall be developed, which may target inspections based on a systematic appraisal of environmental risks. The risks shall include, at least, the criterion 'the potential and actual impacts of the installations concerned on human health and the environment taking into account the levels and types of emissions, the sensitivity of the local environment and the risk of accidents'. Operators must also grant the authorities necessary access and assistance to enable inspections and other monitoring functions to be carried out. Routine inspection shall be sufficient to examine the full range of relevant environmental effects of the installation and shall be sufficient to determine not only whether permit conditions are complied with, but also whether the permit conditions are effective. Thus, inspectors should consider why certain permit conditions have been applied and whether they serve the purpose why they were set.

6. PRIORITIES AND TIMING

6.1. Introduction

Within the sector, priority must be given to the IED, which is essentially a most important piece of industrial emissions legislation. The consolidation of seven Directives in the industrial emissions sector set out in the IED should significantly render the prioritisation and timing issue easier. The candidate countries should focus on establishing a solid institutional and legal framework with resource strong competent authorities, transparent and efficient permit system, solid monitoring and reporting procedures, a strengthened inspection and enforcement regime and emphasis on public participation and awareness rising. Regarding data collection and reporting candidate countries should focus on implementing the Pollutant Release and Transfer Register. This overall framework should also include institutional structures, administrative procedures and promotional measures for a high uptake of EMAS registered installations and companies as well as for using the EU Ecolabel for products and services.

Finally, the Seveso III Directive (2012/18/EU) must also receive priority, but as the competent authority is likely to fall within the health and safety area there should be no conflict in terms of resources. As Seveso III mainly is a recast of Seveso II, candidate countries are advised to carry out a conformity assessment of the transposition of the Seveso III Directive into the national law in order to ensure fully compliant legal framework.

Timescales

The IED entered into force on 6 January 2011 and had to be transposed by Member States by 7 January 2013. It is likely that the implementation process will take a minimum of four to five years once the strategy and implementation plan have been finalised. This in itself could take up to two years. It is imperative that a phased programme of implementation is employed for the introduction of control of each industrial sector under IED in order to be able to allow the resources of those organisations involved to cope. The particular order can be decided upon by each Member State. The order could reflect the timing of the production of BREF documents or the priorities of industry and environment in the country concerned, or be a combination of the two.

In terms of the Seveso III Directive it replaces the existing Seveso II (96/82/EC) as from June 2015. Member States had to adopt the necessary national transposing measures by 31 May 2015 and apply them as from 1 June 2015.

In terms of planning, it should be noted that on 18 December 2015 new Directive (EU) 2015/2193 of the European Parliament and the Council of 25 November 2015 on the limitation of emissions of certain pollutants into the air from medium combustion plants came into force. This new Directive regulates pollutant emissions from the combustion of fuels in plants with a rated thermal input equal to or greater than 1 megawatt (MWth) and less than 50 MWth. It is estimated that there are around 143 000 medium combustion plants in the EU. Medium combustion plants are used for a wide variety of applications (electricity generation, domestic/residential heating and cooling, providing heat/steam for industrial processes, etc.) and are an important source of emissions of sulphur dioxide (SO₂), nitrogen oxides (NO_x) and dust. The Directive will have to be transposed by Member States by 19 December 2017.

7. ECONOMIC AND FINANCIAL ISSUES

7.1. Initial Costs

Cost is a major consideration in meeting the approximation and implementation requirements of the accession process. Countries seeking to become Member States recognise that high costs will result from applying the Regulations and the overall costs of approximation.

In the fiches prepared for the IPC sector of this Handbook, the cost of the regulatory process itself was considered. It is clear from this that there are a variety of costs to be met, which can be grouped as follows:

- the preliminary costs of setting up, or restructuring, a regulatory body (e.g. a competent authority) and any agencies that it might require — this will include costs associated with physical and human resources and training;
- costs of introducing a permitting and enforcement regime and carrying out inspections;
- costs associated with identifying the installations to be covered by the Directives and assessing their current situation;
- costs associated with the development of BAT guidance documents for each industrial sector;
- costs associated with consultation;
- costs of data recording and reporting;
- training costs;
- the continued costs of operating the system.

These costs may be offset by the implementation of a cost recovery scheme in accordance with the polluter pays principle, whereby — through levying a charge for the permit and regulatory regime — the government recoups the costs of regulation from the operators of installations. There could be complete cost recovery for all the expenses associated with permits, and schemes such as EMAS and the EU Ecolabel scheme should be entirely self-financing as far as the managing bodies are concerned.

The Directive on industrial emissions, which brings seven Directives under the same legislative framework is estimated to save costs both for public administration and for industry. For instance, it reinforces the application of Best Available Techniques, as a way to reduce the harmful industrial emissions across the EU, translating into improved environment and human health. In terms of the Directive on large combustion plants alone, it estimated that the new legal framework will achieve net benefits of EUR 7 -28 billion per year, including the reduction of premature deaths and years of life lost by 13,000 and 125,000 respectively.

Furthermore, the streamlining of permitting, reporting and monitoring requirements as well as a renewed cooperation with Member States to simplify implementation will lead to a reduction in unnecessary administrative burden of between €105 and €255 million per year. IED could be read in conjunction with the Communication of 2007 setting out an IPPC Action Plan covering the period 2008-2010, which aims at supporting the implementation of the existing legislation.

7.2. Costs to Industry

It is clear that the costs to industry of compliance will be far greater than the direct costs of implementing the legislation. For example, the costs of ensuring that large combustion plants reduce emissions to an acceptable level may include the construction of new plants to replace out-dated ones, the addition of new units to less-polluting plants to compensate for the loss of energy from the shut-down of those that cause major pollution, the changing of units within a plant so that less-polluting fuel can be used and so on. The IED imposes far-reaching obligations and substantial costs on industry and government at all levels. There is no consensus as to the level of these costs, except that they will be very large indeed.

A study carried out for the Commission estimated that an overall figure for the cost of compliance with the various air pollution Directives in 10 CEEC countries would be EUR 48.2 billion, and of this, EUR 8.45 billion was attributed to the Baltic countries. In Estonia, for example, the costs of applying BAT to large combustion plants is estimated to require capital outlay of EUR 427.9 million by 2005 and EUR 801.8 million by 2010.

Application of the principles of BAT and BREFs will be a key determining factor in the costs to each industrial sector. The elements of cost benefit analysis will have a large role to play and how each Member State decides to incorporate the concept of sectoral affordability will come into play. The biggest price to pay ultimately could be the closure of certain industries. The BREF documents should be able to provide some guidance in this area and the assessment of local circumstances and conditions will also have a large influence. In general, as ample case studies shows that installations and companies applying EMAS make significant savings in overall IPPC compliance costs and also regarding costs for pollution abatement measures, energy consumption, costs for raw materials etc. In addition, EMAS and the EU Ecolabel scheme provide a high marketing value, which can result in higher market uptake and greater performance. In the 'Study on the costs and benefits of EMAS to registered organisations', participating organisations were asked to indicate which, from a list of impacts of EMAS, had been the most positive for them. The most positive impact, identified by 21% of respondents, was energy/resource saving, followed by "reduction in negative incidents" (18%) and "improved stakeholder relationships" (17%). For all sizes of organisations, the energy savings alone exceeded the annual costs of maintaining EMAS. Actual costs and benefits vary widely, depending on, for example, the size and activities of the organisation, the current state of the environmental management practices, the specific country, etc. But in general, EMAS generates significant annual cost savings. Various studies have shown that the increased revenue compensates the implementation costs within a relatively short payback period ranging between a year and two years in most cases²⁵⁰²⁵¹²⁵²²⁵³²⁵⁴.

²⁵⁰ EVER Study: Evaluation of EMAS and Eco-Label for their Revision (2005), IEFEE- Università Bocconi for DG Environment of the European Commission.

²⁵¹ Hamschmidt J., Dyllick T. (2001), "ISO 14001: profitable? Yes! But is it eco-effective?" Greener Management International, n. 34.

²⁵² CESQA SINCERT (2002), Indagine sulla certificazione ambientale secondo la norma UNI EN ISO 14001; risultati indagine Triveneto

²⁵³ Freimann, Walther (2001), The impacts of corporate environmental management systems: a comparison of EMAS and ISO 14001, Greener Management International, No.36, pp.91-103

²⁵⁴ IRIS (2000), Environmental management systems – paper tiger or powerful tool. The Swedish Institute of Production Engineering Research. Molndal.

7.3. **Cost recovery**

The systems of charges or fees and fines in each Member State tend to vary considerably. The economic conditions in any particular country will be influential. Enhancement of health and welfare and avoidance of unemployment are often likely to be higher up the list of priorities than environmental protection. Accordingly, there may be resistance to imposing high charges for impacts on the environment.

With regard to EMAS and the EU Ecolabel, these are systems that, if applied effectively, offer opportunities to organisations in terms of both environmental performance and cost savings. This is particularly true in terms of energy and water consumption, waste minimisation and levels of raw material consumption. The potential for cost savings and reduced environmental charges can often offset the costs of operating the system and other pollution control costs.

8. SUMMARY OF KEY ISSUES

Achieving and maintaining compliance with EU policies and legislation in the industrial pollution control sector presents a major challenge for the Member States which, in order to minimise the associated administrative burden and costs, needs to be managed in a systematic and cost-effective manner. With this in mind, the governments of the Member States should endeavour to focus their efforts and actions on addressing those issues and requirements, which are fundamental to the approximation of EU legislation in this sector, in particular by asking the following:

Table 5. Key Questions to Be Considered in Implementing the Legislation on Industrial Pollution Control

<p>Is there sufficient knowledge of the existing arrangements for managing pollution control and risk management including, particularly:</p> <ul style="list-style-type: none"> • existing legislative, institutional and regulatory arrangements? • permitting regimes in all environmental sectors — water, air, greenhouse gas emission control and land? • identification of installations requiring control by the IED and Major-Accident Hazards Directives? • organisations currently involved in pollution control and accident management?
<p>Have all the significant problems associated with the existing arrangements been identified, in particular:</p> <ul style="list-style-type: none"> • the legislative/institutional/regulatory framework? • the shortfalls in plant design and management to meet the required standards? • the training/expertise shortfalls? • the needs for communication between regulatory bodies? • the need for consultation with industry?
<p>Can the institutional framework operate on an integrated basis, in particular?</p> <ul style="list-style-type: none"> • Are there organisations that have the expertise and resources to act as competent authorities? • Can the organisations work in a co-operative fashion to ensure an integrated approach? • Do the organisations have sufficient knowledge of all environmental sectors? • Have sufficient provisions been made to ensure effective co-ordination to prevent areas of overlap and make the most effective use of resources?
<p>Are there clear links between the competent authorities, central government, and other organisations that have responsibilities for issues that affect pollution control and hazard management such as local authorities, health authorities and planning authorities?</p>
<p>Are arrangements in place for the effective involvement and participation of all other bodies or interested groups, including the public, which have a significant role or function to perform in relation to pollution control and major-accident hazard issues?</p>

<p>Have proper EMAS Competent Bodies and EMAS Accreditation and Licensing body been established (sometimes combined in the same organisation both for the EU EMAS Regulation and EU Ecolabel).</p>
<p>Has guidance been issued on:</p> <ul style="list-style-type: none"> • best available techniques? • permitting arrangements and procedures? • transitional arrangements for dealing with industrial air pollution and combustion plants? • preparation of an accident prevention policy? • preparation of emergency plans and safety reports? • environmental management systems and approaches to accreditation? • obligation to submit data to the PRTR (Pollutant Release and Transfer Register)? • new elements of the IED, in terms of reinforced reporting, inspections and enforcement of IED requirements?
<p>Is there an enforcement regime in place with clear lines of accountability and appropriate Penalties, which also takes into account provisions of the Environmental Crimes Directive?</p>
<p>Is there sufficient structures and procedures for inspections (periodic and ad-hoc) to ensure compliance with IPC legislation?</p>
<p>Are there sufficient coordination and synergies with other applicable sector legislation, e.g. water, air, waste but also with overarching EU Directives such as the EIA Directive, Directive on Environmental Liability?</p>
<p>Do the competent authorities have sufficient legal powers to:</p> <ul style="list-style-type: none"> • enter premises? • inspect and sample? • require co-operation? • authorise processes and emissions? • review and revoke authorisations? • take legal proceedings against operators? • prohibit operations?
<p>Are there arrangements in place for monitoring and for inspections of premises?</p> <p>Is there an adequate data-processing system in place for:</p> <ul style="list-style-type: none"> • recording data? • processing data and preparing reports?

Are there adequate means of consultation with/reporting to:

- the Commission?
- the public?
- organisations affected by IED?
- organisations that undertake major-accident prevention activities?
- other countries where cross-border issues are concerned?

Has a means of funding been established to cover the costs of regulatory activities in the sector?

Has industry been made aware of the likely costs of implementation and has it established a source of capital for improvement works in IED and major-accident prevention?

Are there adequate training expertise and resources available?

THE INDUSTRIAL EMISSIONS DIRECTIVE

Official Title:

Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (Recast)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Industrial production processes account for a considerable share of the overall pollution in Europe (for emissions of greenhouse gases and acidifying substances, wastewater emissions and waste). The main aim of the Industrial Emissions Directive (IED) is to ensure a high level of protection of the environment taken as a whole. Thus, to control industrial emissions, the EU has developed a general framework based on integrated permitting. This means the permits must take account of a plant's complete environmental performance to avoid pollution being shifted from one medium - such as air, water and land - to another. Priority should be given to preventing pollution by intervening at source and ensuring prudent use and management of natural resources.

The IED is based on several principles²⁵⁵, namely (1) an integrated approach, (2) best available techniques, (3) flexibility, (4) inspections and (5) public participation.

The IED recasts seven Directives related to industrial emissions into a single comprehensive document. These are:

- Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control (repealed as of 7 January 2014)
- Directive 2001/80/EC on the limitation of emissions of certain pollutants into the air from large combustion plants (repealed as of 1 January 2016)
- Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations (repealed as of 7 January 2014)
- Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste (repealed as of 7 January 2014)
- Council Directive 78/176/EEC of 20 February 1978 on waste from the titanium dioxide industry (repealed as of 7 January 2014)
- Council Directive 82/883/EEC of 3 December 1982 on procedures for the surveillance and monitoring of environments concerned by waste from the titanium dioxide industry (repealed as of 7 January 2014)
- Council Directive 92/112/EEC of 15 December 1992 on procedures for harmonizing the programmes for the reduction and eventual elimination of pollution caused by waste from the titanium dioxide industry (repealed as of 7 January 2014).

Installations covered by the IED must be operated in accordance with permits which include conditions based on the best available techniques (BAT) designed to prevent and, where that is not practicable, generally to reduce emissions to air, water and soil and the impact to the environment as a whole. The installations can only operate if in possession of a permit and have to comply with the conditions set therein. The BAT conclusions adopted by the Commission are the reference for setting the permit conditions. Emission limit values must be

²⁵⁵ See chapter 1.2 of the Section 7

set at a level that ensures pollutant emissions do not exceed the levels associated with the use of BATs. However they may, if it is proven that this would lead to disproportionate costs compared to environmental benefits.

Key elements of the IED:

- Use of BAT: The permit conditions including emission limit values (ELVs) must be based on the Best Available Techniques (BAT), as defined in the Directive. BAT conclusions (documents containing information on the emission levels associated with the best available techniques) shall be the reference for setting permit conditions. To assist the licensing authorities and companies to determine BAT, the Commission organises an exchange of information between experts from the EU Member States, industry and environmental organisations. This work is co-ordinated by the European IPPC Bureau of the Institute for Prospective Technology Studies at the EU Joint Research Centre in Seville (Spain). This results in the adoption and publication by the Commission of the BAT conclusions and BAT Reference Documents (the so-called BREFs).
- Flexibility in applying ELV: The IED contains certain elements of flexibility by allowing the licensing authorities to set less strict emission limit values in specific cases. Such measures are only applicable where an assessment shows that the achievement of emission levels associated with BAT as described in the BAT conclusions would lead to disproportionately higher costs compared to the environmental benefits due to: 1) geographical location or the local environmental conditions or 2) the technical characteristics of the installation. The competent authority shall always document the reasons for the application of the flexibility measures in the permit including the result of the cost-benefit assessment.
- Stricter requirements on large combustion plants (LCP): Significantly stricter emission limits for LCP regulated in Chapter III of the IED. These requirements will be phased in and differ between the various installations. New installations, that is, those that apply for a permit after 7 January 2013 or are put into operation after 7 January 2014, are subject to the most stringent conditions. For such installations the new requirements were applicable as from 7 January 2013. For existing installations, the existing conditions have been strengthened but only as from 1 January 2016. Key amendments are summarized below:
 - Aggregation rules: where waste gases are discharged through a common stack, the combination of these plants shall be considered as a single combustion plant (to calculate total capacity which may influence the emission limit values), including, for plants permitted after 1 July 1987, in case of a virtual common stack (i.e. if technically it would be feasible for the various plants to discharge through one common stack).
 - In estimating the total capacity, plants with a rated thermal input below 15 MW shall not be included. Stationary motors are though counted but emission limit values only apply to motors propelled with gas based fuels
 - New rules on extension of combustion installations and on malfunctioning of pollution abatement equipment
 - Gas turbines and certain motors with a operation time of less than 500 hours/year are exempted from the emission limit values
 - New requirements on CO for gas base fuels
 - Emissions of mercury to ambient air from coal plants should be measured once a year.

- Chapter III on large combustion plants includes four flexible mechanisms, allowing temporary derogations from the emission limit values set out in Annex V for some plants meeting the specified conditions. However, the emission limit values set out in the permits of these combustion plants on 31 December 2015 should not be weakened. It should be emphasised that these derogations should be interpreted restrictively and these provisions should be transposed into the national law only if the candidate country chooses to apply these provisions.

- Transitional national plan

It is designed for plants which were granted the first permit before 27 November 2002 or the operators of which had submitted a complete application for a permit before that date, provided that the plant was put into operation no later than 27 November 2003. The derogation may cover period from 1 January 2016 to 30 June 2020. Combustion plants covered by the TNP may be exempted during that period from compliance with the emission limit values referred to in Article 30(2) of the IED for the pollutants which are subject to the TNP or, where applicable, with the rates of desulphurisation referred to in Article 31 of the Directive. They will have to comply though with decreasing national emission ceilings, set for each year on the basis of calculations implying the applicable emission limit values to the various plants under the LCPD (for the first year) and the IED (for the last year).

- Limited life time derogation

This option allows operator not to apply the ELVs for existing plants set out under Annex V part 1, but instead remain under the existing and outdated ELVs set out under the LCP Directive 2001/80/EC (i.e. ELVs applicable on 31 December 2015), provided the plant does not operate more than 17.500 operating hours, starting from 1 January 2016 and ending on 31 December 2023. This derogation may apply to plants which had not been granted an exemption as referred to in Article 4(4) of the LCP Directive 2001/80/EC or which had not entered the Transitional National Plan scheme.

- Small isolated systems

Until 31 December 2019, Member States may choose not to apply the site specific BAT based ELVs or the desulphurisation rates for combustion plants being part of a small isolated system, i.e. a system with a consumption of less than 3 000 GWh in the year 1996, where less than 5 % of annual consumption is obtained through interconnection with other systems. For these systems that make use of the derogation, the existing ELVs under the current LCP Directive (2001/80/EC) need to be maintained.

- District heating plants

This derogation applies to plants with a total rated thermal input of 200 MW or less, which were granted a first permit before 27 November 2002 or the operator of which had submitted a complete application for a permit before that date, provided that it was put into operation no later than 27 November 2003 and where at least 50 % of the useful heat production of the plant, as a rolling average over a period of 5 years, is delivered in the form of steam or hot water to a public network for district heating. Time frame for this derogation is from 1 January 2016 to 31 December 2022. For these plants that make use of the derogation, the existing ELVs under the LCP Directive (2001/80/EC) need to be applied.

- More stringent provisions on environmental inspections:

- The IED contains mandatory requirements on environmental inspections.
- Member States shall set up a system of environmental inspections and draw up inspection plans accordingly.
- The IED requires a site visit shall take place at least every 1 to 3 years, using risk-based criteria.
- The Directive ensures that the public has a right to participate in the decision-making process, and to be informed of its consequences, by having access to
- Reinforced provisions on access to information, public participation in permitting procedures and access to review procedures: More detailed provisions on procedural requirements and legal rights of the public. The public may for instance participate and be informed of 1) permit applications in order to give opinions and 2) results of the monitoring of releases and emissions.

The Commission has established implementing rules for certain provisions linked to Chapter III on large combustion plants. These are:

- 2012/249/EU: Commission Implementing Decision of 7 May 2012 concerning the determination of start-up and shut-down periods for the purposes of Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions
- 2012/115/EU: Commission Implementing Decision of 10 February 2012 laying down rules concerning the transitional national plans referred to in Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions

More information about the IED can be obtained at:

- DG ENV: <http://ec.europa.eu/environment/industry/stationary/lcp/chapter3.htm>.
- Europa Site (summaries of EU legislation): http://europa.eu/legislation_summaries/environment/air_pollution/ev0027_en.htm

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Ensure that transposing legislation, and especially general binding rules complementing or replacing some permit conditions, take an integrated approach and a high level of environmental protection equivalent to that achievable with individual permit conditions. These rules must be based on BAT and must thus be updated to correspond to BAT development. (Art. 17)
- Ensure that the implementation of the IED is closely co-ordinated with other permit and monitoring schemes, including, notably, EIA (2011/92/EU), the Urban Waste Water Treatment Directive (91/271/EEC) (also see SEA Directive 2001/42/EC on the assessment of certain plans and programmes). The interrelationships of these provisions and procedures must be clarified and the proper timing and positioning of these procedures in the line of permitting procedures for large, environmentally significant investments shall be determined.
- Take measures, including introducing incentives, for the development and application of emerging techniques, in particular for those emerging techniques identified in BAT reference documents. (Art. 27)
- Establish or designate competent authorities for implementing the IED, which must comprise responsible for sending information to the Commission on the implementation of the Directive and for the exchange of information with Member States. (Art. 71)
- Define the permitting procedure and ensure that a permit is granted where the installation complies with the IED. This procedure has to take an integrated approach involving other relevant competent authorities and several operators in case of the permit covering more than one operator. Ensure taking into account the provisions of the EIA Directive (2011/92/EU) where applicable for new installations or those undergoing a substantial change. (Art. 5)
- Ensure that the permit application contains the items set out in Article 12, e.g. description of installation and its activities, the raw materials, other substances and energy used or generated, source of emissions, conditions of the site, a baseline report (Art. 22(2)), the nature and quantities of likely emissions and estimate of effects on the environment, proposed technology for pollution prevention and abatement, measures to prevent and prepare for re-use, recycling of waste generated, measure for complying with general principles, monitoring requirements and conditions regarding site closure. Where an environmental quality standard requires stricter conditions than those achieved by BAT, additional measures are required in the permit. This application shall also contain a non-technical summary. To the extent reasonable information supplied within the procedures of EIA Directive (2011/92/EU) or the Seveso III Directive (2012/18/EU) is available this should be included in the application. (Art. 12, 18 and 22(1))
- Develop systems to ensure that the competent authority maintains informed of developments in best available techniques and of the publication of any new or updated BAT conclusions and make that information available to the public concerned. (Art. 19)

- Ensure that permits are periodically review and update permit conditions and that the operator supplies all information necessary for this purpose, such as monitoring results. A permit shall in any event be reviewed:
 - no later than 4 years after publication of decisions of BAT conclusions
 - in case of activities not being covered by BAT conclusions, whenever there are developments in BAT
 - the pollution caused by the installation is of such significance that the existing emission limit values of the permit need to be revised or new such values need to be included in the permit;
 - the operational safety requires other techniques to be used;
 - where it is necessary to comply with a new or revised environmental quality standard. (Art. 21)
- Put in place the procedures and systems ensuring compliance with the reporting obligations set out in Art. 72.
- Determine what relevant types of permitting procedures shall be merged into the IED permitting procedure or ensure full co-ordination of the authorisation procedures and conditions between the competent authorities. In the case of a new installation or a substantial change requiring an assessment under the EIA Directive (2011/92/EU), any relevant information obtained or conclusion arrived at pursuant to Articles 5, 6, 7 and 9 of that Directive shall be taken into account in the granting of an IED permit. (Art. 5)
- Set the emission limit values, taking into account the possibility to use equivalent parameters and technical measures to arrive at the same result. Ensure that the emission limit values for polluting substances apply at the point where the emissions leave the installation, and any dilution prior to that point shall be disregarded when determining those values. The ELVs may take into account the effect of water treatment plants. The ELVs, equivalent parameters or technical measures must be based on BAT not prescribing any particular technique or technology and BAT conclusions in terms of periods of time and reference conditions. These baseline conditions are subject to some limited exemptions as long as BAT and the emission limit values set out in the Annexes to this Directive are maintained and that lenier values does not mean higher pressure on the environment:
 - It is possible to use other values, periods of time and reference conditions but only if the installation is subject to annual emission monitoring to conform that emission levels are at least complying with BAT;
 - In specific cases, the competent authority may set less strict emission limit values where it has been demonstrated that the achievement of emission levels associated with the BAT described in BAT conclusions would lead to disproportionately higher costs compared to the environmental benefits;
 - It is possible to grant temporary derogations from the requirements from applying ELVs based on BAT in BAT conclusions for the testing and use of emerging techniques for a total period of time not exceeding 9 months. (Art. 15)
- Put in place procedures and systems to ensure access to environmental information, public participation in decision-making and access to review procedure. Determine the stages where decisions, acts or omissions may be challenged and what constitutes a sufficient interest an

impairment of a right. NGOs should be included as those having such rights. The review procedures should be fair, timely and not expensive. (Art. 24 and 25)

- Define procedures for consultation and information exchange with other Member States with specific emphasis on consulting the other effected Member State on permit applications in cases where an installation is likely to have significant effects on the environment in the other state. (Art. 26)
- Review the existing sanctioning system and if need make changes to ensure that non-compliance with the IED is subject to penalties (as from 7 January 2013). (Art. 79)

Chapter III on large combustion plants

- Ensure that combustion plants as defined in Art. 28 are covered by the IED, the permitting, monitoring and inspection requirements. In general, IED applies to combustion plants, the total rated thermal input of which is equal to or greater than 50 MW, irrespective of the type of fuel used but there are excepted plants listed in Art. 28.
- Ensure that the aggregation rules apply when considering number of combustion plants and their total capacity. For instance, where the waste gases of two or more separate combustion plants (having a rated thermal input of 15 MW or more) are discharged through a common stack, this combination is considered as a single plant and their joint capacities will count towards calculating the total rated thermal input. This method also applies to two or more separate plants having a permit on or after 1 July 1987, if in the opinion of the competent authority, their waste gases can be discharged through a common stack. (Art. 29)
- Determine whether to make use of one of the temporary derogations
 - For combustion plants firing indigenous solid fuel, including plants which co-incinerate waste: Apply minimum rates of desulphurisation set out in Part 5 of Annex V, in accordance with the compliance rules set out in Part 6 of that Annex and after validating the technical report referred to in Art. 72(4)(a), for the above combustion plants where they cannot comply with the emission limit values for sulphur dioxide referred to in Article 30(2) and (3) and points 3.1 or 3.1 of Part 4 of Annex VI, respectively, due to the characteristics of this fuel. (Art. 31(1), (2))
 - Limited life-time derogation: this derogation can be applied between 1 January 2016 to 31 December 2023. During this period combustion plants do not have to comply with the ELVs referred to in Article 30(2) and with the rates of desulphurisation referred to in Article 31 and do not have to be covered in the transitional national plan referred to in Article 32 provided that the conditions in Article 33(1) are fulfilled (e.g. the operator declares by 1 January 2014 the latest to the competent authority that the plan will not be operated for more than 17500 operating hours between the above mentioned period, the operators submits record of number of hours for every year starting 1 January 2016, the ELVs set out in the permit applicable on 31 December 2015 are complied with during the remaining period of the plan, plants with a total rated thermal input of more than 500MW firing solid fuels, which were granted the first permit after 1 July 1987, complies with the emission limit values for nitrogen oxides set out in Part 1 of Annex V; and plant is not already subject to exemption under the LCP Directive. In regard to certain combustion plants the provisions of Art. 33(3) and (4) fix the number of operating hours until 2023. (Art. 33(1))

- Limited derogation for small isolated systems: a derogation from the ELVs referred to in Art. 30(2) and the rates of desulphurisation referred to in Art. 31, can be applied until 31 December 2019 for combustion plants being, on 6 January 2011, part of a small isolated. Until then the ELVs set out in the permits of these combustion plants and provisions of IPPC and CLP Directives must be complied with. However, combustion plants with a total rated thermal input of more than 500 MW firing solid fuels, granted the first permit after 1 July 1987, must comply with the ELVs for nitrogen oxides set out in Part 1 of Annex V. (Art. 34(1), (2))
- Temporary exemption for district heating plants: a temporary exemption until 31 December 2022 from meeting the ELVs in Art. 30(2) and the rates of desulphurisation (Art. 31) if the total rated thermal input does not exceed 200 MW, the plant was granted a first permit prior to 27 November 2002 or had submitted a full application by that date and plant was in operation by 27 November 2003; at least 50% of the heat production (over 5 years) is in certain form for public district heating network and the plant complies with the ELVs set out in the permit applicable on 31 December 2015 and provisions of IPPC and LCP Directives. (Art. 35(1))
- Decide whether for the transitional period from 1 January 2016 to 30 June 2020, draw up and implement a transitional national plan covering combustion plants which were granted the first permit before 27 November 2002 or the operators of which had submitted a complete application for a permit before that date, provided that the plant was put into operation no later than 27 November 2003. Make sure that requirements of the Commission Implementing Decision 2012/115/EU concerning the transitional national plans are duly taken into account.
 - For each of the combustion plants covered by the plan, the plan shall cover emissions of one or more of the following pollutants: nitrogen oxides, sulphur dioxide and dust;
 - For gas turbines, only nitrogen oxides emissions shall be covered by the plan;
 - The transitional plan shall not apply to the combustion plants listed in Art. 32(1) (a)-(d);
 - Plants covered by this plan may be exempted from compliance with ELVs set out in Art. 30(2) or the rates of desulphurization referred to in Art. 31;
 - Plants covered by this plan must at least comply with ELVs set out in the permit for the plan applicable on 31 December 2015 (applying requirements of LCP Directive and former IPPC Directive) (Art. 32(2));
 - Plants with a total rated thermal input of more than 500 MW firing solid fuels, which were granted the first permit after 1 July 1987, must comply with the ELVs set out in Part 1 of Annex V. (Art. 32(2));
 - The national plan must set a ceiling defining the maximum total annual emissions for all of the plants covered by the plan on the basis of each plant's total rated thermal input on 31 December 2010, its actual annual operating hours and its fuel use, averaged over the last 10 years of operation. The ceiling for the year 2016 shall be calculated on the basis of the relevant ELVs set out in Annexes III to VII to LCP Directive, where applicable, on the basis of the rates of desulphurisation set out in Annex III to LCP Directive. For gas turbines, the ELVs for nitrogen oxides in Part B of Annex VI to LCP applies. The ceilings for the years 2019 and 2020 shall be calculated on the basis of the relevant ELVs set out in Part 1 of Annex V to this Directive or, where applicable, the relevant rates of desulphurisation set out in Part 5 of Annex V to this

Directive. The ceilings for the years 2017 and 2018 shall be set providing a linear decrease of the ceilings between 2016 and 2019;

- Closure of a plant covered by the plan shall not mean an increase in total annual emissions for remaining plants (Art. 32(3));
- The plan must contain monitoring and reporting obligations in line with the rules in Article 41(b) and measures to ensure that the covered plants comply with the ELVs as from 1 July 2020.
- Determine whether to grant a time-limited derogation from the obligation to comply with the ELVs:
 - A derogation of up to 6 months from the obligation to comply with the sulphur dioxide ELVs (Part 1 and Part 2 of Annex V) in respect of a combustion plant which normally uses low-sulphur fuel, in cases where the inability to comply with those ELVs due to a serious shortage of low-sulphur fuels. The Commission must be notified of such derogations immediately. (Art. 30(5));
 - A derogation of not more than 10 days from the obligation to comply with the ELVs in Annex V where a plant using only gaseous fuel has to exceptionally use other fuels due to shortage/interruption in gas supply. The operator must inform the competent authority of such cases and Member States must inform the Commission without delay (Art. 30(6)).

Chapter IV on waste incineration and co-incineration plants

- Identify and classify the waste incineration plants and waste co-incineration plants which incinerate or co-incinerate solid or liquid waste and are covered by the IED, taking into account the scoping in Article 42, exempting certain plants dealing with specific waste, which may produce a health hazard. The Chapter IV covers all incineration lines or co-incineration lines, including waste reception, storage, on site pre-treatment facilities, waste-, fuel- and air-supply systems, boilers, facilities for the treatment of waste gases, on-site facilities for treatment or storage of residues and waste water, stacks, devices and systems for controlling incineration or co-incineration operations, recording and monitoring incineration or co-incineration conditions. Take into account the criteria in Art. 42 for the differentiation of waste incineration plants and waste co-incineration plants.
- Ensure co-ordination with the implementation measures under Directives establishing emission limits for certain pollutants, i.e. Directive 2008/50/EC and Directive 2004/107/EC relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air.
- Ensure that the permit for an incineration or co-incineration plant takes into account the applicable requirements established in Directive 91/271/EEC on urban wastewater treatment, Landfill Directive 1999/31/EC, and Water Framework Directive 2000/60/EC.

Chapter VI on titanium dioxide installations

- Identify installations producing titanium dioxide (Art. 66)

Chapter V on VOC installations

- Decide whether to require a permit for Chapter V installations (VOC installations) or introduce a registration procedure. (Art. 4)
- Identify VOC installations and activities listed in Part 1 of Annex VII taking into the account the consumption thresholds set out in Part 2 of that Annex. For the purpose of IED existing installations are those that were in operation on 29 March 1999 or which were granted a permit or registered before 1 April 2001 or the operator of which submitted a complete application for a permit before 1 April 2001, provided that that installation was put in operation no later than 1 April 2002. (Art. 56)
- Ensure correct transposition and application of the various definitions set out in Art. 57.
- Take the necessary measures to ensure substitution of substances or mixtures which because of their content of VOCs are classified as carcinogens, mutagens, or toxic to reproduction under Regulation (EC) No 1272/2008, and thus are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F. These substances or mixtures must be replaced by less harmful substances or mixtures within the shortest possible time. (Art. 58)
- Determine whether to apply the ELVs set out in Parts 2 and 3 of Annex VII for VOC reductions or to apply the reduction scheme set out in Part 5 of Annex VII if reduction achievements are the same.
- Determine whether to allow certain exceedances or derogations in case compliance is not technically and economically feasible provided that the BAT are being used:
 - Allow exceedance of the ELVs laid down in Parts 2 and 3 of Annex VII, provided that the exceedance does not lead to significant risks to human health or the environment and that the BAT are applied. (Art. 59(2))
 - Exempt coating activities covered by item 8 of the table in Part 2 of Annex VII for applying ELVs in Annex VII or the equivalent reduction schedule set out in Part 5 of Annex VII. (Art. 59(3))

2.2. Regulation and Enforcement

- Ensure that definitions are correctly and accurately transposed into the national law. (Art. 3)
- Ensure that installations are operated in such a way that specified conditions and principles laid down in Art. 11 are met. Among these general principles are that preventive measures are taken, application of BAT; that no significant pollution is caused; that the generation of waste is prevented and where not possible that waste is dealt with in accordance with the waste management hierarchy set out in the Waste Framework Directive (2008/98/EC) (i.e. preparation for reuse, recycling or recovery or, if this is not possible, environmentally sound disposal); that energy is used efficiently; that necessary measures are taken to prevent accidents and limit their consequences; and that when activities cease the necessary measures are taken to avoid any pollution risk and to return the site to a satisfactory condition. (Art. 11)
- Ensure that no installation or combustion plant, waste incineration or waste co-incineration plant operate without a permit, with the exception of installations covered by Chapter V (VOC installations) for which registration and prior notification to the competent authority may be sufficient. (Art. 4)

- Where integrated permits are provided covering more than one installation or parts of installations, either operated by the same operator on the same site or different operators, it has to be ensured that this permit provide sufficient conditions to ensure that each installation complies fully with the Directive and that the responsibilities of the operators are specified. (Art. (2), (3))
- Ensure that applications for permits contain specified information, are subject to predetermined procedures, and that coordination is provided in case of the procedure involving more than one operator or competent authority. In granting permits, take into consideration any relevant information obtained through the EIA procedure that may apply in the case of new installations or a substantial change, including data on transboundary effects (under Directive 2011/92/EU). (Art. 5)
- Refuse to grant a permit if the installation is unable to comply with the Directive, in particular if it cannot be established that the installation is able to keep to the pollution standard limits in the long term without unacceptably wide-scale differences in the actual emission values. (Arts. 5, 14 and 15)
- Introduce legal provisions for the application of stricter permit conditions, in comparison to those based on BAT conclusions. (Art. 14(4))
- Take into account the existing scheme for greenhouse gas emission allowances and requirements under Directive 2003/87/EC and not include ELV for direct emissions of greenhouse gases in the permit unless necessary to prevent significant local pollution and for temporary excluded installations. (Art. 9)
- Ensure that permits contain such conditions as are necessary to ensure that the installation can be operated in compliance with Article 11 and 18 of the Directive, including:
 - emission limit values for substances listed in Annex II and for other polluting substances on grounds of their nature and quantity and conditions and criteria for assessing compliance with these;
 - other technical requirements supplementing or replacing the ELVs providing the same result;
 - requirements for protection of soil and ground water, including maintenance and surveillance and periodic monitoring of these media in regard to hazardous substances;
 - monitoring requirements specifying measurement methodology, frequency and evaluation procedure also taking into account time periods and reference conditions associated with BAT;
 - waste management;
 - measures for other than normal operation conditions, including start-up, leaks, malfunctions and definitive stop of operations;
 - provisions on minimizing transboundary pollution;
 - reporting requirements;
 - reference to BAT conclusions but conditions may be stricter than the BAT or where the permit conditions are based on BAT not described in BAT conclusions (such as in the case that an activity is not covered by a BAT conclusion or is insufficient) ensure that criteria in Annex III and Art. 15 are applied;
 - where relevant address issues of animal welfare. (Art. 14)

- Ensure that operators comply with the conditions of their permit and where there is a breach of conditions, ensure that the operator immediately informs the competent authority thereof and takes measures to restore compliance as soon as possible. Where there is immediate danger to human health or the environment, the competent authority may order the operator to suspend activities until full compliance is restored. (Art. 8)
- Ensure that in case of incidents and accidents, which significantly affect the environment, the operators inform the competent authority immediately and takes the necessary measures, including those ordered by the competent authority to limit the consequences and prevent further incidents or accidents. Also examine whether the incident is subject to the Environmental Liability Directive 2004/35/EC requiring remedial action by the competent authority. (Art. 7)
- On the basis of information from the operator regarding planned changes or extensions, consider whether to update the permits or the conditions thereof if necessary and that at least substantial changes (as defined in Annex I) are subject to a permit granted under this Directive. (Art 12)
- In line with the permit conditions regulating site closure the operator has to take the following main measures:
 - Prior to starting operation of an installation involving hazardous substances, which may pollute soil and groundwater or prior to the first update of the permit (after 7 January 2013) submit a baseline report to the competent authority. The baseline report shall cover the issues set out in Art. 22(2), e.g. describe current and past use of the site, information on soil and groundwater measurements, taking into account Commission guidance on this report²⁵⁶;
 - Take all the relevant measures prior to start of operations, during operations and at time of site closure in accordance with the Water Framework Directive (2000/60/EC), Groundwater Directive (2006/118/EC) and the Environmental Liability Directive (2004/35/EC);
 - After cessation of activities, assess contamination of soil and groundwater and in case of significant pollution take remedial measures to bring back the soil or water to state in baseline report. (Art. 22)
- Ensure that non-compliance with the provisions of the IED and the permits are sanctioned with effective, dissuasive and proportionate sanctions. (Art. 79)

Chapter III on large combustion plants

- Ensure that waste gases from combustion plants are always discharged in a controlled way by means of a stack, containing one or more flues, and that the height of this stack is sufficient to safeguard human health and the environment. (Art. 30(1))
- Ensure that the permits include conditions to ensure compliance with the ELVs set out in Annex V (exempted are diesel engines and certain recovery boilers in pulp industry):

²⁵⁶ Communication from the Commission — European Commission Guidance concerning baseline reports under Article 22(2) of Directive 2010/75/EU on industrial emissions (OJ C 136, 6.5.2014, p. 3–18); available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2014.136.01.0003.01.ENG.

- Permits for installations containing combustion plants which have been granted a permit before 7 January 2013, or having submitted a complete application for a permit before that date, provided that such plants are put into operation no later than 7 January 2014, shall include conditions ensuring that emissions into air from these plants do not exceed the ELVs set out in Part 1 of Annex V. (Art. 30(2));
- All permits for installations containing combustion plants which had been granted an exemption under Article 4(4) of Directive 2001/80/EC and which are in operation after 1 January 2016, must include conditions ensuring that their air emissions do not exceed the ELVs set out in Part 2 of Annex V. (Art. 30(2));
- Permits for all other combustion plants (not permitted prior to 7 January 2013 nor having received an exemption and are in operation after 1 January 2016, must include conditions to ensure that air emissions do not exceed the ELVs set out in Part 2. (Art. 30(3))
- Ensure that the ELVs set out in Parts 1 and 2 of Annex V, along with the minimum rates of desulphurisation set out in Part 5 of that Annex apply to the emissions of each common stack in relation to the total rated thermal input of the entire combustion plant. Where Annex V allows ELVs to be applied for a part of a combustion plant with a limited number of operating hours, these shall be set in relation to the total rated thermal input of the entire combustion plant. (Art. 30(4))
- Ensure that where combustion plants are extended, the ELVs set out in Part 2 of Annex V applies to the extended part(s) and are set in relation to the total rated thermal input of the entire combustion plant. (Art. 30(7))
- Ensure that a change to a combustion plant, which may have consequences for the environment and which affects a part of the plant with a rated thermal input of 50 MW or more, the ELVs in Part 2 of Annex V apply to that part of the plant. (Art. 30(7))
- Ensure that operators of all combustion plants with a rated electrical output of at least 300 megawatts for which the original construction licence or the original operating licence is granted after the entry into force of Directive 2009/31/EC on the geological storage of carbon dioxide, have assessed whether suitable storage sites are available, transport facilities are technically and economically feasible, and it is technically and economically feasible to retrofit for carbon dioxide capture. In such cases, the competent authority is responsible for ensuring that suitable space on the installation site for the equipment necessary to capture and compress carbon dioxide is set aside. (Art. 36)
- Ensure that permits issued provide for procedures regarding malfunction or breakdown of the abatement equipment. This shall include:
 - Reduction or closure of operation in case of breakdown or use low polluting fuels in case of the breakdown cannot be solved within 24 hours (unless need to maintain energy supplies and replacement plant is more polluting);
 - Operator must notify the competent authority within 48 hours after the malfunction or breakdown;
 - Maximum cumulative duration of operation with malfunctioning abatement equipment must not exceed 120 hours over the period of one year (unless need to maintain energy supplies and replacement plant is more polluting). (Art. 37)

- Compliance with Part 4 of Annex V shall be taken as presumption that the ELVs for air are complied with. (Art. 39)
- Set ELVs following the procedural steps set out in Art. 40 for multi-fuel firing combustion plant either involving the simultaneous use of two or more fuels, e.g.
 - applying the ELV relevant for each individual fuel and pollutant corresponding to the total rated thermal input of the entire combustion plant as set out in Parts 1 and 2 of Annex V;
 - determining fuel-weighted ELVs, calculated in accordance with Art. 40(1)
 - aggregating the fuel-weighted emission limit values. (Art. 40(1))
- Determine whether for multi-fuel firing combustion plants, which use the distillation and conversion residues from the refining of crude-oil for own consumption apply ELVs for the determinative fuel referred to in Art. 40(2), e.g. those set out in Part 1 of Annex V where the proportion of the determinative fuel is at least 50% and pursuant to Art. 40(2) if the proportion of the determinative fuel is less as well as in accordance Part 7 of Annex V regarding the average emission limit values for sulphur dioxide. (Art. 40)
- Ensure compliance with Commission Implementing Decision 2012/249/EU concerning the determination of start-up and shut-down periods for the purpose of assessing compliance with the emission limit values set out in Annex V to Directive 2010/75/EU, as well as for determining the number of operating hours of the combustion plants, where it is relevant for the implementation of temporary derogations set out in IED.
- As from 1 January 2016, establish an annual inventory of the sulphur dioxide, nitrogen oxides and dust emissions and energy input for all combustion plants covered by Chapter III of this Directive. This inventory should be made available to the Commission (at least the summary). (Art. 72(3))

Chapter IV on waste incineration and co-incineration plants

- Ensure that waste incineration and waste co-incineration plants are subject to a permit.
- Ensure that the permit application procedure conforms to Article 44 and that the application contains all the necessary information, including a description of measures to be taken to ensure that the plant is designed, equipped and operated in accordance with the provisions of the IED; that the heat is, where possible, recovered through the generation of heat, steam or power; that the amount of residues is minimised, especially through recycling; and that residues are disposed of in accordance with relevant EU legislation. (Art. 44)
- Permits must include a list of waste which may be treated (referring to the European Waste List), information on the quantity of each type of waste, the total capacity of the plant, the ELVs for emissions into air and water, the requirements for pH, temperature and flow of wastewater discharges, the sampling and measurement procedures and their frequencies, the maximum permissible period of any unavoidable stoppages, disturbances or failures of purification devices or measurement devices. Member States may choose to list the categories of waste to be included in the permit. (Art. 45(1) and (3))
- Permits for plants using hazardous waste must in addition to the above include a list of the quantities of the categories of hazardous waste, the minimum and maximum mass flows of those hazardous

wastes, and estimated maximum calorific values and their contents of polychlorinated biphenyls, pentachlorophenol, chlorine, fluorine, sulphur, heavy metals and other polluting substances. (Art. 45(2))

- Competent authority must periodically review and, where necessary, update permit conditions. (Art. 45(4))
- Ensure that operators take all necessary measures to reduce the number of stoppages and, in the case of breakdown, that the operator reduces or closes down operations until normal operations can be restored. The maximum uninterrupted period during which emission limit values may be exceeded due to unavoidable stoppages, disturbances or failure of the purification devices is four hours. (Art. 46(6) and 47)
- Lay down a general obligation for operators to prevent negative environmental effects and limit pollution of air, soil, water bodies and direct risks to human health in concern to the delivery and reception of waste. Furthermore the operators must be required to, prior to accepting waste at the plant:
 - Determine the mass of each type of waste and collect available information about it (e.g. physical and chemical composition and handling precautions) with a view to verify compliance with the permit requirements;
 - Comply with certain procedures, e.g. checking documents required by the Directive on Waste (2008/98/EC) and the Waste Shipment Regulation (EC) No 1013/2006, take representative samples before unloading for verification purposes and keep these samples for 1 month;
 - Certain exemptions may be granted for obligation to carry out these steps for plants part of an installation covered by Chapter II and only incinerate waste generated within that installation (Art. 52).
- Lay down specific/technical requirements on how incineration plants shall be designed, equipped, built and operated to achieve certain results in terms of the total organic carbon content, raising the gas to a certain temperature. Further, there are requirements:
 - to comply with certain pre-treatment techniques and temperature measuring techniques;
 - to equip each combustion chamber with minimum one auxiliary burner;
 - to operate an automated system to prevent waste feed in certain situations such as start-up, when the temperature is not sufficiently high, when the ELVs are exceeded;
 - for recovery of heat where possible;
 - how to place infectious clinical waste. (Art. 50)
- Ensure that exhaust gas does not exceed the emission limit values for air emissions laid down in parts 3 and 4 of Annex VI or determined pursuant to Part 4 of that annex (concerning, for example, heavy metals, dioxins and furans, carbon monoxide and dust). (Art. 46(2))
- Ensure that wastewater discharges are:
 - in accordance with the emission limit values set out in Part 5 of Annex VI;
 - measured at the point where wastewater from the cleaning of exhaust gases is discharged;

- special rules when waste waters are treated outside the incineration plant at a specialised treatment plant,
- not diluted for the purposes of complying with the emission limit values (Art. 46(3), (4)).
- Ensure that change in operating conditions are subject to prior authorisation and that plants granted an exemption from fulfilling some of conditions set out in Article 50, still comply with the other conditions of the chapter of waste incineration and that more residues or more polluting residues are not caused by the changes. Emissions of total organic carbon and carbon monoxide must comply with the ELVs set out in Part 3 of Annex VI to which also some existing bark boilers within the pulp and paper industry are subject. (Art. 51)
- Ensure that incineration plants have a stack of sufficient height to safeguard human health and the environment. (Article 46(1))
- Ensure that incineration plant sites, including associated storage areas for waste, are designed, operated and controlled by a natural person competent to manage the plant in a manner to prevent unauthorized and accidental release of polluting substances into soil and water bodies. This include having:
 - stack of sufficient height to safeguard human health and the environment;
 - storage capacity for contaminated rain water run-off or other contaminated water;
 - controls to ensure that waste are not incinerated of more than 4 hours uninterrupted where ELVs are exceeded. (Art. 46(1), (5), 50(6), (7))
- Ensure that substantial changes in a plant are followed by review of permit conditions, for instance a substantial change is when an incineration plant treating only non-hazardous waste starts to incinerate hazardous waste. (Art. 54)
- Require operators to minimise residues resulting from incineration; to ensure that such residues are recycled; to prevent the dispersal of dry residues, especially during storage or transportation; and carry out tests to determine the physical and chemical characteristics of residues for the purposes of handling residues in the most environmentally safe way. (Art. 53)
- Require operators to monitor emissions in accordance with Parts 6 and 7 of Annex VI. They must also install automated measuring systems, subject to control and annual surveillance tests pursuant to point 1 of Part 6 to Annex VI. Measuring must be carried out at the sampling or measurement points as determined by the competent authority. All monitoring results must be recorded, processed and presented in a way to allow competent authority to verify compliance with operating conditions and ELVs set out in the permit. (Art. 48)

Chapter V on VOC in installations

- Ensure that VOC installations comply with one of the two options:
 - VOC emission do not exceed the ELVs in waste gases and the fugitive ELVs, or the total ELVs, and installation complies with the other requirements laid down in Parts 2 and 3 of Annex VII;

- the requirements of the reduction scheme set out in Part 5 of Annex VII provided the emission reduction achieved is equivalent to that achieved through the application of the ELVs set out in Annex VII. (Art. 59(1))
- Ensure control of emissions of VOCs of the category hazard statements H340, H350, H350i, H360D or H360F or halogenated VOCs of the category hazard statements H341 or H351, as far as it is technically and economically feasible to safeguard public health and the environment and must not exceed the ELVs in Part 4 of Annex VII. (Art. 59(5))
- Ensure compliance with the conditions for installations carrying out two or more activities, where each of them exceeds the thresholds in Part 2 of Annex VII. These must comply with Art. 59(5) as regards to VOCs of the category hazard statements H340, H350, H350i, H360D or H360F or halogenated VOCs of the category hazard statements H341 or H351, individually and as regards other substances comply with Art. 59(1). (Art. 59(6))
- Take all precautionary measures to minimise emissions of VOCs during start-up and shut-down operations. (Art. 59(7))
- Ensure that where conditions set out in Part 8 of Annex VII are fulfilled, it is presumed that the ELVs in waste gases are fully complied with. (Art. 61)
- Identify substantial change to existing installations including those installations, which previously was not covered by the thresholds in Annex VII and for such installations ensure that they are treated either as a new installation or as an existing installation in accordance with Art. 63(2), taking into account the definition of substantial in terms of a change of the maximum mass input of organic solvents and the increased emissions of VOC referred to in Art. 63(1).
- Ensure that in case of substantial changes the competent authority check compliance with the provisions of the IED. (Art. 63)

Chapter VI on titanium dioxide

- Ban the disposal into any water body, sea or ocean of titanium dioxide waste, either as solid waste, as liquors arising from the filtration phase, waste from installations applying the chloride process, filtration salts, sludges and liquid waste arising from the treatment of waste containing titanium dioxide, where the content is exceeding the limits in Art. 67. (Art. 67)
- Ensure that emissions from installations into water or into air shall not exceed the emission limit values set out in Part 1 of Annex VIII and Part 2 of Annex VIII, respectively. Emissions of acid droplets into ambient air from installations must also be prevented. (Arts. 68 and 69)

2.3. Monitoring and Inspections

- Determine the monitoring requirements either as general binding rules or in the permit conditions. These requirements must be based on the relevant BAT conclusions and the frequency should be at least every five years for groundwater and every 10 years for soil. (Art. 16)

- Set up a system of environmental inspections of installations examining the full range of relevant environmental effects from the installations and develop an environmental inspection plan at national, regional and local level covering all installations. The plan must include a general assessment of the environmental issues, the geographic coverage of the plan, a register of the covered plan, procedures for drawing up programmes for routine and non-routine environmental inspections, cooperation mechanisms between various inspection authorities. (Art. 23(1), (2))
- Draw up programmes for routine inspections, tailoring the frequency to the different types of installations, based on the environmental risks, taking into account the risk criteria set out in Art. 23(4), such as compliance record and participation in EMAS. The minimum frequency is once a year for installations posing the highest risk to the environment and 3 years interval for those with the lowest risks. (Art. 23(4))
- Apart from the routine inspections carry out the following inspections
 - follow-up inspections within six months after identification of significant non-compliance with permit;
 - non-routine inspections before granting or updating a permit, in case of complaints, serious accidents, incidents or cases of non-compliance (Art. 23(5));
- Ensure that operators cooperate with the competent authorities during site visits, providing them with the necessary assistance in taking samples and collecting information. (Art. 23(1));
- Ensure that a report is provided for each inspection, outlining the findings, measures to be taken and that this is communicated to the operator within two months from the site visit and within four months made available to the public (Art. 23(6)).

Chapter III on large combustion plants

- Ensure that the monitoring of air polluting substances is carried out in accordance with Part 3 of Annex V and that operators record, process and present the monitoring result to allow the competent authority to verify compliance with the terms of the permit. (Art. 38(3), (4))
- The competent authority determines the location of the sampling or measurement points and ensures that annual surveillance tests of the automated monitoring equipment are carried out according to Part 3 of Annex V. (Art. 38(2), (3))

Chapter IV on waste incineration and co-incineration plants

- Ensure that all monitoring results are recorded, processed and presented in a way to allow competent authority to verify compliance with operating conditions and ELVs set out in the permit. (Art. 48)

Chapter V on VOC in installations

- Set out the monitoring requirements and measurements of emissions complying with Part 6 of Annex VII either in the permit or by other legally binding rules. (Art. 60)

Chapter VI on industries producing titanium dioxide

- Ensure monitoring of emissions into water and air to enable the competent authority to verify compliance with the permit conditions and Article 68 and 69 respectively. In case of air emissions monitoring must include at least monitoring of emissions as set out in Part 3 of Annex VIII.
- Ensure that monitoring is carried out in accordance with CEN standards or, if CEN standards are not available, ISO, national or other international standards (Art. 70)

2.4. Consultation, Information and Reporting

- Make information available to the public, including information on permit applications and the results of monitoring of releases and allow the public the right to participate in the permit procedure. This shall at least include:
 - Early and effective opportunities to participate in permit applications for new installations, a renewed permit for substantial changes, other new or updated permits under Art. 15(4) and Art. 21(5) pursuant to the procedure set out in Annex IV (Art. 24(1));
 - Access to the information on a new, updated permit decision, reasons on which the decision was based, results of consultations and how the comments were taken into account, title of BAT reference documents applicable to the installation, how the permit conditions refer to BAT, reasons for granting derogations, measures taken by the operator in case of site closure, results of emission monitoring (subject to restrictions on ground of confidentiality laid down in the Environmental Information Directive. (Art. 24(2))
- Ensure that individuals, having sufficient interest, have access to a review procedure before a court or an impartial body to review decisions (procedural and substantive grounds), acts or omissions. (Art. 25(1))
- Consult and provide information regarding permit applications for an installation, which is likely to have significant effects on the environment in the other state. The comments of the other Member State and the general public in that Member State must be taken into account in the final decision and this decision has to be made available to the public in that Member State. (Art. 26)
- Ensure that the operator takes the following reporting and notifying obligations vis-à-vis the competent authority:
 - immediately informs the competent authority about cases of non-compliance with the permit conditions and incidents and accidents which may result in environmental damage (Arts. 7 and 8(2));
 - supplies the competent authority regularly, and at least annually, with information on the basis of results of emission monitoring and other required data that enables the competent authority to verify compliance with the permit conditions; and, where applicable, a summary of the results of emission monitoring which allows a comparison with the emission levels associated with the best available techniques (Art. 14(1));

- informs it of any changes planned in the operation of the installations or any extensions which might have environmental consequences (Art. 20(1));
 - submit all the information necessary for the purpose of reconsidering the permit conditions, including, in particular, results of emission monitoring and other data, that enables a comparison of the operation of the installation with the best available techniques described in the applicable BAT conclusions (Art. 21(2));
 - prior to starting activities involving hazardous substances or prior to update of permit pursuant to IED procedures, submit a baseline report giving information set out in Art. 22(2) and in accordance with the Commission guidance.
- Report to the Commission on:
 - transposition with texts of the main provisions of national laws, regulations and administrative provisions to comply with the Directive (Art. 80(2));
 - information on the practical implementation of the Directive with the content and at intervals to be determined in implementing regulations drafted by the Commission. This data shall include representative data on emissions and other forms of pollution, on emission limit values, on the application of best available techniques in accordance with Articles 14 and 15, in particular on the granting of exemptions in accordance with Article 15(4), and on progress made concerning the development and application of emerging techniques in accordance with Article 27. This information shall be in an electronic format (Art. 72(1));
 - Submit an annual report regarding combustion plants falling under Article 31, as regard the sulphur content of the indigenous solid fuel used and the rate of desulphurisation achieved, averaged over each month. For the first year where Article 31 is applied, the technical justification of the non-feasibility of complying with the emission limit values referred to in Article 30(2) and (3) shall also be reported; and for combustion plants which do not operate more than 1 500 operating hours per year as a rolling average over a period of 5 years, the number of operating hours per year;
 - National provisions introducing effective, dissuasive and proportionate penalties for non-compliance (Art. 79)
 - The competent authority must communicate to the operator concerned a report on environmental inspections, setting out the relevant findings regarding compliance of the installation with the permit conditions and conclusions on whether any further action is necessary within two month from the date of the inspection. This report must be made publicly available within 4 months from the site visit. (Art. 23(4))

The Commission has developed questionnaires to define the set of information to be made available by the Member States for the purposes of reporting on the implementation of Directive 2010/75/EU during the period 2013-2016 (2012/795/EU: Commission Implementing Decision of 12 December 2012 establishing the type, format and frequency of information to be made available by the Member States for the purposes of reporting on the implementation of Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions).

Chapter III on large combustion plants

Reporting obligations listed below are relevant if country has opted to apply specific derogations stipulated in Articles 30-35.

- Ensure that where a time-limited derogation is granted regarding sulphur dioxide ELVs or for plant using gaseous fuels on the basis of shortage of obtaining low-sulphur fuels or gaseous fuels, such derogations are notified to the Commission immediately. (Art. 30(5), (6))
- Communicate transitional national plans to the Commission and inform the Commission about changes to it. (Art. 32(4), (5), and (6))
- Communicate a list of combustion plants, which are subject to the limited life-time derogation (Art. 33(1)). This information must include information on their total rated thermal input, the fuel types used and the applicable emission limit values for sulphur dioxide, nitrogen oxides and dust. For these plants, the Member States must communicate annually to the Commission a record of the number of operating hours since 1 January 2016.
- Report to the Commission a list of combustion plants that are part of a small isolated system, indicating the total annual energy consumption and the amount of energy obtained through interconnections with other systems. (Art. 34(3))
- Communicate to the Commission a list of any combustion plants for which a temporary exemption for certain district heating plants may be granted indicating their total rated thermal input, the fuel types used and the applicable emission limit values for sulphur dioxide, nitrogen oxides and dust. Also during the time of derogation (until 31 December 2022), Member States must annual inform the Commission of the proportion of useful heat production of each plant which was delivered in the form of steam or hot water to a public network for district heating, expressed as a rolling average over the preceding 5 years. (Art. 35(2))

Chapter IV on waste incineration and co-incineration plants

- For a waste incineration plant with a nominal capacity of two tonnes or more per hour, the operator must provide the competent authority with an annual report on the functioning and monitoring of the plant and the emission levels, compared to the ELVs. This report has to be prepared according to Art. 72. (Art. 55(2))
- Communicate to the Commission changes to the initial operating conditions authorized under Art. 51 and the results of verifications to the information reported Article 72. (Art. 51(4))
- The competent authority must make available to the public:
 - a list of plants with a nominal capacity of less than two tonnes per hour must be drawn up by the competent authority;
 - applications for a new permits for incineration plants, which must be made available at one or more locations for a sufficient time period to allow the public to comment on it prior to a decision by the authority (Art. 55(1));
 - the decision regarding the permit application, a copy of the permit and any updates of it (Art. 55(1));

- the report by the operator (pursuant to Article 72) for incineration plants with a nominal capacity of 2 tonnes or more per hour, reporting on functioning and monitoring and emission levels. (Art. 55(2))

Chapter V on VOC in installations

- Report to the Commission in accordance with Article 72(1) on the progress in achieving the equivalent emission reduction when applying a reduction scheme for VOC installations.
- Report to the Commission on the derogations to applying ELVs I Part 1 and 2 of Annex VII or the equivalent reduction scheme if such conditions are not technically and economically feasible and operator applies BAT. (Art. 59(4))
- Ensure that the operator reports data to the competent authority enabling to verify compliance with the ELVs in waste gases, fugitive ELVs and total ELVs, the requirements of the reduction scheme under Part 5 of Annex VII; and the derogations granted in accordance with Article 59(2) and (3). Such reporting obligations may comprise a solvent management plan prepared in accordance with Part 7 of Annex VII. (Art. 62)
- Participate and contribute with information in the forum for exchange of information on substitution of organic solvents organized by the Commission, comprising data relevant to fitness for use, human health effects, effects on the environment and cost-benefit analysis. (Art. 64)
- Ensure that the following are made publically available: the decision of the competent authority, a copy of the permit, and any subsequent updates, the general binding rules applicable for installations, the list of VOC installations subject to permitting and registration, the results of the monitoring of emissions, taking into account restrictions (e.g. confidentiality grounds) set out in Directive 2003/4/EC. (Art. 65)

2.5. Related Legal Instruments

A number of other legislative instruments are relevant to the IED and should also be borne in mind during the implementation of this Directive. These include:

- Seveso III Directive (2012/18/EU)
- Air Quality Framework Directive (2008/50/EC)
- National Emissions Ceilings Directive (2001/81/EC)
- Heavy Metals in Air Directive (2004/107/EC)
- Waste Framework Directive (2008/98/EC)
- Landfill Directive (99/31/EC)
- Water Framework Directive (2000/60/EC)
- Groundwater Directive (2006/118/EC)

- Drinking Water Directive (98/83/EC)
- Environmental Quality Standards Directive (2008/105/EC)
- Urban Waste Water Treatment Directive (91/271/EEC)
- EIA Directive (2011/92/EU)
- SEA Directive (2001/42/EC)
- Directive on Access to Environmental Information (2003/4/EC)
- INSPIRE Directive (2007/2/EC)
- Public Participation Directive (2003/35/EC)
- Environmental Liability Directive (2004/35/EC)
- Environmental Crimes Directive (2008/99/EC)
- Emissions Trading Directive (2003/87/EC)
- Carbon Capture and Storage Directive (2009/31/EC)
- Regulation (EU) No 517/2014 on certain fluorinated greenhouse gases
- VOC from Petrol Stations (94/63/EC and 2009/126/EC Stage II)
- Regulation (EC) No. 166/2006 concerning the establishment of the European Pollutant Release and Transfer Register
- REACH Regulation ((EC) No 1907/2006)
- Classification, Labelling and Packaging of Dangerous Substances and Mixtures Regulation ((EC) No 1272/2008)
- Biocides Products Regulation ((EU) No 528/2012)

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the following Table, organised in chronological order (where possible).

Table 6. The IED - Key Implementation Tasks

THE INDUSTRIAL EMISSIONS DIRECTIVE- KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Appoint a competent authority (or authorities) to implement and enforce the requirements of the Directive.
1.2	Require existing competent authorities and relevant bodies to take on new functions and responsibilities both as regard permitting and supervision and enforcement.
1.3	Introduce the necessary legal, regulatory and administrative provisions to ensure compliance with the Directive's requirements.
1.4	Plan for phasing in the provisions of the IED, in particular the strengthened requirements on monitoring, reporting, inspections and public participation in decision-making. Ensure that the competent authorities are sufficiently strengthened with human, financial and technical resources to bring on board implementation of a larger legislative framework consisting of 7 previous Directives.
1.5	Competent authorities should also make changes to the permitting and reporting procedures to take into account that seven Directives have been integrated into one legal framework. Hence, the monitoring, reporting and permitting requirements under Directives such as the Waste Incineration Directive and the Large Combustion Plans Directive.
1.6	Put in place procedures and systems to ensure access to environmental information, public participation in decision-making and access to review procedure
1.7	With the leading role of the competent authority, prior authorisation procedures shall be established for new and existing industrial installations of the categories listed in Annex I, involving the issuing of permits using an integrated approach to the control of releases to all environmental media.
1.8	Determine what relevant types of permitting procedures shall be merged into the IED permitting procedure. Determine the interrelationship between EIA and IED procedures and the proper timing and positioning of these procedures in the line of permitting procedures for large, environmentally significant investments.

1.9	Determine whether to allow for one permit for several installations either operated by the same operator or different ones.
1.10	Based on proper legal arrangements, the competent authority should establish liaison arrangements with authorities responsible for the permitting of installations in respect of other legislation such as the Waste Framework Directive (2008/98/EC), Urban Waste Water Treatment Directive (91/271/EEC)
1.11	The competent authorities, by survey or other means, should identify the installations to which the Directive applies throughout the territory.
1.12	Ensure that permit conditions are set on the basis of BAT. Where the Commission has adopted implementing decision establishing BAT conclusions for the given sector, the permit must take these BATs as a reference and set the emission limit values to ensure that Associated Emission Levels (AELs) are not exceeded. Consider setting rules under which the competent authority may set stricter permit conditions than those achievable by the use of BATs as described in BAT conclusions.
1.13	The government should take a decision on whether to adopt general rules for specified categories of installations as an alternative to individually determined permit conditions.
1.14	Establish emission limit values, equivalent parameters or technical measures for all releases to the environment for all installations having regard to BAT as described in the BAT Conclusions applicable to the individual installation or activity. Where BAT AELs have been set, emission limit values should be set so as to ensure that emissions do not exceed the BAT AELs.
1.15	Establish a means of acquiring information on developments in BAT (through the reports of the Commission prepared as a result of the exchange of information on BAT and limit values) and ensure that the competent authorities are kept informed.
1.16	Provide training for the technical staff of the competent authorities.
1.17	Develop a system of environmental inspections of installations examining the full range of relevant environmental effects from the installations and develop an environmental inspection plan at national, regional and local level covering all installations.
1.18	Draw up programmes for routine inspections, tailoring the frequency to the different types of installations, based on the environmental risks, taking into account the risk criteria set out in Art. 23(4), such as compliance record and participating in the EMAS. Set the minimum frequency, which should be at least once a year for installations posing the highest risk to the environment and 3 years interval for those with the lowest risks.
1.19	Develop procedures and protocols for follow-up inspections after identification of significant non-compliance with permit and non-routine inspections before granting or updating a permit, in case of complaints, serious accidents, incidents or cases of non-compliance
1.20	Define procedures and measures to ensure that operators cooperate with inspection bodies

1.21	Develop a reporting format for the report to be submitted to the operator after inspections.
1.22	Review the existing sanctioning system and if need make changes to ensure that non-compliance with the IED is subject to penalties
	<i>Planning for LCPs</i>
1.23	Identify and classify all the combustion plants subject to the permitting, monitoring and inspection requirements
1.24	Consider whether the aggregation rules apply when considering number of combustion plants and their total capacity.
1.25	Determine whether to apply minimum rates of desulphurisation set out in Part 5 of Annex V for combustion plants firing indigenous solid fuel, including those plants which co-incinerate waste
1.26	Decide whether to adopt a National Transitional Plan covering existing combustion plants (i.e. which were in operation no later than 27 November 2003). Ensure that such plants must be subject to the minimum ELVs listed in Art. 32 and set a ceiling for the maximum total annual ELVs for all of the plants covered on the basis of each plant's total rated thermal input on 31 December 2010, its annual operating hours and its fuel use. The ceilings for 2016, 2017-2018 and 2019-2020 are calculated in accordance with Art. 32. The closure of a plan may not lead to an overall increase in total emissions for remaining plants. The plan must define monitoring and reporting obligations and set out measures to ensure that the covered plans comply with ELVS as from 1 July 2020.
1.27	<p>Determine whether to make use of one of the temporary derogations for complying with ELVs in Art. 30(2) and desulphurisation rates in Art. 31 for certain existing installations</p> <ul style="list-style-type: none"> • For combustion plants firing indigenous solid fuel, including plants which co-incinerate waste; • Limited life time derogation for plants which were granted the first permit after 1 July 1987 and that will not be operated for more than 17500 operating hours during the entire applicable period: this derogation can be applied between 1 January 2016 to 31 December 2023. • Limited derogation for small isolated systems: can be used until 31 December 2019 for combustion plants being, on 6 January 2011, part of a small isolated; Temporary exemption for district heating plants where the total rated thermal input does not exceed 200 MW and the plant was in operation prior to 27 November 2003 and at least 50% of heat production goes to public district heating: can be used until 31 December 2022. <p>For most of these derogations, the concerned plants have to apply the ELVs set out in the permit applicable on 31 December 2015, comply with certain of the ELVs set out in Annex V (especially plants with a total rated thermal input of more than 500 MW) , the provisions of the IPPC and LCP Directives</p>

1.28	The competent authority should use monitoring methodologies given in Part 3 of Annex V, ensure monitoring of emissions by operators using the approved methodologies, and collate the results of monitoring.
1.29	Assess and prepare an inventory of total annual emissions of sulphur dioxide, nitrogen oxides and dust.
1.30	The competent authority should establish an inspection and monitoring facility to enable it to assess compliance with the emission limit values and the effects on air pollution.
	<i>Planning for waste incineration and co-incineration</i>
1.31	Identify and classify the waste incineration plants and waste co-incineration plants, which incinerate or co-incinerate solid or liquid waste and are covered by the IED, taking into account the scoping in Article 42. Classify incinerators in terms of their nominal capacity.
1.32	Take measures to ensure that new permits issued for waste incineration and waste co-incineration waste comply with the conditions of Art. 45 in terms of indicating the list of waste that may be treated, other technical and biological requirements and sampling and measurement procedures. Periodically review the permits and update the conditions if need be.
1.33	Evaluate the performance of existing incinerators and determine whether they can be upgraded economically to meet the standards of the Directive.
1.34	Develop a plan to upgrade existing incinerators and construct new plants. Ensure that adequate plant capacity is provided by the date of implementation of the Directive.
1.35	Ensure co-ordination with the implementation measures under Directives establishing emission and discharge limit values for certain pollutants, i.e. UWWT Directive, 91/271/EEC, Landfill Directive 1999/31/EC, and Water Framework Directive 2000/60/EC.
1.36	Take an integrated approach to monitoring and reporting obligations arising from various sectoral legislation, including the Regulation on the European Pollutant Release and Transfer Register (No. 166/2006) and the Access to Environmental Information Directive 2003/4/EC.
	<i>Planning for VOC installations</i>
1.37	Determine whether to introduce a registration and notification procedure for Chapter V installations (VOC installations)
1.38	Identify VOC installations and activities listed in Part 1 of Annex VII taking into the account the consumption thresholds set out in Part 2 of that Annex.
1.39	Introduce measures to ensure replacement, within the shortest time possible, of substances or mixtures which because of their content of VOCs are classified as carcinogens, mutagens, or toxic to reproduction under Regulation (EC) No 1272/2008.

1.40	Determine whether to apply the ELVs set out in Annex VII for VOC reductions or to apply the reduction scheme set out in Part 5 of Annex VII and estimate for each option the reduction achievements. Opt for the option with the highest reduction achievement.
1.41	Determine whether to allow certain exceedances or derogations in case compliance is not technically and economically feasible provided that the BAT are being used.
	<i>Planning for titanium dioxide industry</i>
1.42	Determine how many, if any, existing or planned facilities will be regulated under these Directives. As part of the survey, include details on which processes they will operate (sulphate or chlorine).
1.43	Determine whether there is a need for, and if so draw up and implement, programmes for the reduction and elimination of pollution caused by titanium dioxide waste from existing industries. Programmes should include: <ul style="list-style-type: none"> • general targets for the reduction of pollution from liquid, solid and gaseous waste; • intermediate objectives; • information on the state of the environment concerned; • measures for reducing pollution; • methods for treating waste directly caused by the manufacturing process; • total number of establishments for which reduction/elimination programmes have been established.
2	Regulation and Monitoring
2.1	Require the operators of all existing and proposed new installations to apply to the competent authority for authorisation to operate.
2.2	Require applicants for authorisations to supply details of the installation and its activities, materials and energy used on the site, the sources of emissions, conditions on the site, likely emissions to the environment and their possible effects, techniques to prevent or reduce emissions, measures for the prevention and recovery of waste, operational parameters of the site, and monitoring proposals. Information relating to applications under other specified Directives may be included.
2.3	The competent authority should issue guidance on the procedure to be followed, including guidance on the information to be included in applications, and the definitions of BAT for the sector or the specific installation.
2.4	The competent authority should establish a procedure by which the proposals put forward in the application are examined for their ability to prevent pollution through the use of BAT and to ensure that no significant pollution is caused, that waste production is minimised or that there is adequate recycling or disposal in such a way that pollution is avoided, that energy is used efficiently, that accidents are prevented, and that the site will be returned to a satisfactory state on completion of activities

2.5	As a result of the examination of the application, the competent authorities should propose emission limit values for releases from the site into all environmental media. Other competent authorities should be consulted, where more than one such authority is involved.
2.6	Proposals should be available to the public early in the procedure for a period of time to allow them to comment to the competent authority. The public must have opportunities to participate in procedures for reviewing or updating the permits and shall have access to legal remedies before a court of law or another independent and impartial body.
2.7	The final decision on granting or refusing the permit together with its reasoning and with a reference to the results of public participation must also be made available to the public.
2.8	<p>Establish a procedure and rules for the monitoring of facilities to ensure compliance with permit conditions. The system would set minimum sampling frequencies; and the requirement on operators to monitor emissions and notify competent authorities in the event of non-compliance with permit conditions. The monitoring procedure may involve both the competent authority in inspecting and taking samples, and a degree of self-monitoring undertaken by the operator. The competent authority should decide the amount of self-monitoring, which is appropriate for particular installations, and it should specify the conditions to be upheld by the operator in carrying out self-monitoring. An audit procedure should be applied to such results.</p> <p>The monitoring requirements can be either general binding rules or permit conditions. These requirements must be based on the relevant BAT conclusions and the frequency is at least every five years for groundwater and every 10 years for soil.</p>
2.9	<p>Set up a system of environmental inspections of installations examining the full range of relevant environmental effects from the installations which include:</p> <ul style="list-style-type: none"> • develop an environmental inspection plan at national, regional and local level covering all installations. • draw up programmes for routine inspections. The minimum frequency is once a year for installations posing the highest risk to the environment and 3 years interval for those with the lowest risks. • carry out follow-up inspections within six months after identification of significant non-compliance with permit and non-routine inspections before granting or updating a permit, in case of complaints, serious accidents, incidents or cases of non-compliance
2.10	Establish procedures with tasks and timeframe for the consultation and provision of information regarding permit applications for an installation, which is likely to have significant effects on the environment in the other state and to take into account the comments from that state.
2.11	Establish procedure so that the competent authority is regularly informed by the operator of the results of monitoring or of any incident affecting the environment.

2.12	Set rules and systems for dealing with non-compliance events, including periods when emission limit values may be breached due to unavoidable stoppages, disturbances or failures of purification or measuring equipment. Such should be subject to penalties.
2.13	A legal obligation should be placed on the operators of installations to inform the competent authorities of any changes planned in their operation so that the competent authority can update the permit conditions.
2.14	A legal obligation should be placed on operators to inform the competent authorities of any substantial changes in operation so that prior authorisation may be obtained. Guidance on what constitutes substantial change should be issued to operators.
2.15	A legally binding review period should be set requiring the periodic review of authorisations by the competent authority. The review may be undertaken at any time for situations specified in the Directive.
	<i>Regarding LCPs</i>
2.16	Apply the significantly stricter emission limits for LCP regulated in Chapter III and Annex V of the IED. These requirements will be phased in and differ between the various installations. New installations that are those that apply for a permit after 7 January 2013 or are put into operation after 7 January 2014 are subject to the most stringent conditions. For such installations the newer requirements apply already as from 7 January 2013. Chapter III on large combustion plants includes certain flexibility instruments (Transitional National Plan, limited lifetime derogation, etc.
2.17	Ensure that for existing installations, the existing conditions will be strengthened as from 1 January 2016. Older installations already obtaining its first environmental permit prior to 2002 or 1987 are subject to less stringent requirements provided that the maximum annual capacity, measured as an average over a period of five years, is not more than 1,500 hours. Note that this will only apply to a very few installations.
2.18	Ensure that existing installations with combustion plants undergoing extension or modification which may significantly the pollution levels comply with the ELVs in Part 2 of Annex V
2.19	Determine whether to grant a time-limited derogation from the obligation to comply with the ELVs for combustion plants using low-sulphur fuels or for combustion plants only using gaseous fuels in cases of serious fuel shortage
2.20	Take into account the new aggregation rules. For instance, furnaces older than 1987 can be counted together if the smoke gas channels are through the same smoke stack.
2.21	In estimating the total effect of the installation furnaces of an effect below 15 MW shall not be included. Stationary motors are though counted but emission limit values only apply to motors propelled with gas based fuels.
2.22	Ensure compliance with the new rules on extension of combustion installations and on malfunctioning of pollution abatement equipment.

2.23	Calculate emission limit values for multi-fuel firing units, and for extensions to plants, in accordance with specified provisions. Gas turbines and certain motors with an operation time of less than 500 hours/year are exempted from the emission limit values.
2.24	Apply the emission standards for sulphur dioxide, nitrogen oxides and dust from plants to (the authorisation of) new combustion plants, except where derogations are allowed by the Directive or permitted by the Commission.
2.25	Inspect and monitor plants and evaluate the results of measurements to assess compliance with emission limit values. Ensure that emissions of mercury to ambient air from coal furnaces are measured once a year.
2.26	For all combustion plants with a rated electrical output of at least 300 megawatts having a construction licence or operating licence granted after the entry into force of Directive 2009/31/EC on the geological storage of carbon dioxide, assess the suitability for retrofitting plants for carbon dioxide capture. In such cases, the competent authority is responsible for ensuring that suitable space on the installation site for the equipment necessary to capture and compress carbon dioxide is set aside.
2.27	Take the measures and define procedures to ensure compliance with monitoring requirements, that information is sufficient for verifying compliance with permit conditions and there is annual surveillance tests of automated monitoring equipment in accordance with the methodology and location of sampling determined by the competent authority in accordance with Part 3 of Annex V.
2.28	Set ELVs following the procedural steps set out in Art. 40 for multi-fuel firing combustion plant either involving the simultaneous use of two or more fuels or for multi-fuel firing combustion plants, which use the distillation and conversion residues from the refining of crude-oil for own consumption. Here the ELVs shall be determined in accordance to Parts 1 and 2 of Annex V, or Part 7 of Annex as well as Art. 40 regarding fuel-weighted ELVs and their aggregation.
2.29	Establish an annual inventory of the sulphur dioxide, nitrogen oxides and dust emissions and energy input for all combustion plants covered by Chapter III of this Directive.
	<i>Regarding waste incineration and co-incineration</i>
2.30	Draw up list of plants with a nominal capacity of less than two tonnes per hour
2.31	Ensure that all covered waste incineration and waste co-incineration plants covered in Chapter IV are subject to permit and that the permit application procedure is in accordance with Art. 44 including all relevant information including a list of waste to be treated.
2.32	Ensure that changing operating conditions are subject to prior authorisation and that plants granted an exemption from fulfilling some of conditions set out in Article 50, still comply with the other conditions of the chapter of waste incineration
2.33	Provide guidance to the operators in respect to the application procedures, the information to the submitted and how to compose a list of waste using the categories set out in the European Waste List.

2.34	Periodically review and, where necessary, updates permit conditions.
2.35	Define permit conditions or general binding rules to minimise number of stoppages and breakdown and the time-period of abnormal operations, which may lead to exceedance of ELVs
2.36	Ensure that operators have procedures for general pollution prevention and in particular regarding delivery and reception of waste taking into account procedures in other EU legislation
2.37	Provide operators with sufficient guidance on how the incineration plants shall be designed, equipped, built and operated to fulfil conditions of the IED, including height of stack and specifics of storage places
2.38	Provide guidance on understanding the applicable ELVs to ambient air and for wastewater discharges.
2.39	Determine provisions and technical guidance on measurement methods and sampling points, including for wastewater discharge points, including cases where the wastewater is treated outside the plant.
2.40	Ensure that incineration plant sites, including associated storage areas for waste, are designed, operated and controlled by a natural person competent to manage the plant in a manner to prevent unauthorized and accidental release of polluting substances into soil and water bodies.
	<i>Regarding VOC installations</i>
2.41	Take measures to ensure that emissions of VOCs are minimised especially during start-up and shut-down operations.
2.42	Take decisions and devise procedures in regard to deciding on applying ELVs in waste gases and the fugitive ELVs or the total ELVs as laid down in Parts 2 and 3 of Annex VII or rather apply a reduction scheme (Part 5 of Annex VII). This involves assessing that this reduction scheme at least achieves a result equivalent to that achieved through complying with ELVs.
2.43	Ensure that ELVs are complied with and that where conditions set out in Part 8 of Annex VII are fulfilled, it is presumed that the ELVs in waste gases are fully complied with
2.44	Devise procedures to ensure sufficient control of emissions of particularly hazardous VOCs.
2.45	Ensure compliance with the conditions for installations carrying out two or more activities falling under the scope of Annex VII, taking into accounts the various options
2.46	Identify substantial change to existing installations including those installations, which previously was not covered by the thresholds in Annex VII and for such installations ensure that they are treated either as a new installation or as an existing installation and that these installations comply with the provisions of the IED.
2.47	Determine whether to set out the monitoring requirements and measurements of emissions either in the permit or by general binding rules.

	<i>Regarding titanium dioxide</i>
2.48	Take the necessary measures to ensure that there is no disposal into any water body, sea or ocean of titanium dioxide waste, either as solid waste, as liquors arising from the filtration phase, waste from installations applying the chloride process, filtration salts, sludge and liquid waste arising from the treatment of waste containing titanium dioxide
2.49	Ensure that emissions from installations into water or into air shall not exceed the emission limit values set out in Part 1 and 2 of Annex VIII
2.50	Establish specifications for analysis of samples of titanium dioxide waste. These should include all the parameters and reference methods (or equivalent reference methods).
2.51	<p>Develop procedures for identifying what and when remedial action should be taken in the event that regarding titanium dioxide installations:</p> <ul style="list-style-type: none"> • authorisation conditions are exceeded; • toxicity limits are exceeded; • monitoring results indicate a deterioration in the environment; or • a deleterious effect on the legitimate use of water and the environment is observed. <p>The procedures should include the possibility of requiring the suspension of waste disposal operations; and of consultation with other Member States where the discharges from establishments in one country affect the environment of other countries.</p>
2.52	Carry out monitoring of emissions into water and air to enable the competent authority to verify compliance with the permit conditions and Article 68, 69 and set ELVs. Apply CEN standards or, ISO, national or other international standards
3	Consultation and Reporting
3.1	For IED installations and facilities (including waste incineration facilities and LCPS) that may have transboundary effects, establish channels of communication with competent authorities in neighbouring Member States so that consultation may take place.
3.2	<p>Establish a consultation mechanism to publicise applications for permits and to allow for public responses to proposals. Capacity-building efforts, such as informing the public on legal remedies and the use thereof, shall be part of the public participation provisions.</p> <p>Send the Commission every three years the available representative data on the limit values laid down by specific category of activities in accordance with Annex I and, if available, the BAT from which these values are derived.</p>
3.3	<p>Ensure that operators supplies the competent authority:</p> <ul style="list-style-type: none"> • regularly, and at least annually, with information on the basis of results of emission monitoring and other required data that enables the competent authority to verify compliance with the permit conditions;

	<ul style="list-style-type: none"> • With information regarding any changes planned in the operation of the installations or any extensions which might have environmental consequences; • with all the information necessary for the purpose of reconsidering the permit conditions, including, in particular, results of emission monitoring and other data, that enables a comparison of the operation of the installation with the best available techniques described in the applicable BAT conclusions; • submit a baseline report giving information set out in Art. 22(2) and in accordance with the Commission guidance
3.4	Establish a reporting system and database to enable reports to be made to the Commission and information to be available to the public.
3.5	Establish a system for ensuring immediate reporting towards the competent authority in cases of non-compliance with the permit conditions and incidents and accidents which may result in environmental damage
3.6	Report to the Commission on: <ul style="list-style-type: none"> • transposition and implementation; • national provisions introducing penalties for non-compliance – by 7 January 2013 • data on emission limit values and BAT on which emission limit values are based pollutant emissions register data. • submit an annual report regarding combustion plants falling under Article 31, as regard the sulphur content of the indigenous solid fuel used and the rate of desulphurisation achieved, averaged over each month. • national provisions introducing effective, dissuasive and proportionate penalties for non-compliance
3.7	Determine the precise content of the report that the inspection authority or competent authority must communicate to the operator after a site visit (inspection) and ensure that this report is available to the public.
3.8	For LCPs report to the Commission, if appropriate, about: <ul style="list-style-type: none"> • Time-limited derogations granted under Art. 30 regarding sulphur dioxide ELVs or for plant using gaseous fuels on the basis of shortage of obtaining low-sulphur fuels or gaseous fuels • Transitional national plans and any changes to it. • List of combustion plants which are subject to the limited life time derogation, providing information on the their total rated thermal input, the fuel types used and the applicable ELVs for sulphur dioxide, nitrogen oxides and dust. For these plants, the Member States must communicate annually to the Commission a record of the number of operating hours since 1 January 2016.

	<ul style="list-style-type: none"> • List of combustion plants that are part of a small isolated system, indicating the total annual energy consumption and the amount of energy obtained through interconnections with other systems. • List of any combustion plants for which a temporary exemption for certain district heating plants may be granted indicating their total rated thermal input, the fuel types used and the applicable ELVs sulphur dioxide, nitrogen oxides and dust. Until 31 December 2022 the latest), inform the Commission of the proportion of useful heat production of each plant which was delivered in the form of steam or hot water to a public network for district heating on a yearly basis • Establish an annual inventory of the sulphur dioxide, nitrogen oxides and dust emissions and energy input for all combustion plants covered by Chapter III of this Directive. This inventory should be made available to the Commission (at least the summary). (Art. 72(3))
3.9	<p>For waste incineration plants:</p> <ul style="list-style-type: none"> • Inform the Commission changes to the initial operating conditions authorized under Art. 51 • Adopt procedures and guidance on how to make information on waste incineration and waste co-incineration plants available to the public: <ul style="list-style-type: none"> - The list of plants with a nominal capacity of less than two tonnes per hour; - applications for a new permits for incineration plants,; - the decision regarding the permit application, a copy of the permit and any updates of it; - the report by the operator (pursuant to Article 72) for incineration plants with a nominal capacity of 2 tonnes or more per hour,
3.10	<p>For VOC installations:</p> <ul style="list-style-type: none"> • Report to the Commission: on the progress in achieving the equivalent emission reduction when applying a reduction scheme for VOC installations and on the derogations to applying ELVs or the equivalent reduction scheme due to grounds of what is technically and economically feasible • Establish procedures to ensure that the permit, generally binding rules, the list of covered VOC installations, monitoring results are made publically available, particularly in electronic format. • Ensure that the operator reports data to the competent authority enabling to verify compliance with the ELVs in waste gases, fugitive ELVs and total ELVs. Such reporting obligations may comprise a solvent management plan
3.11	<p>Establish a public register of information on the incineration of hazardous waste. This information would include applications for permits; decisions of competent authorities; and the results of monitoring hazardous waste incineration facilities.</p>

3.2. Phasing Considerations

Experience within Member States suggests that the most demanding and time-consuming tasks associated with implementing this Directive are:

Phase 1:

- Assessing the changes needed to accommodate for the changes and new extended legislative framework introduced by the IED, also in the context of industrial policy and the need for integrated permitting taking into account other sectoral permitting and supervisory obligations, e.g. under Waste Directive, EIA Directive.
- Establishing and developing the institutional structure for integrated permitting of installations, including the enforcement regime.
- Surveying and identifying the installations to which the Directive applies.
- Establishing a reporting and database system.

Phase 2:

- Establishing technical standards for BAT and determining emission limit values.
- Implementing the authorisation procedures, including preparation of applications, public consultation and issuing permits.

Phase 3:

- Detailed planning, design, permitting and construction of new or upgraded facilities to conform to the new environmental standards.
- Monitoring of compliance with permitting conditions, period review of permits, inspections and enforcement

4. IMPLEMENTATION GUIDANCE

This Directive differs from previous EU Directives on industrial pollution as it establishes a system of integrated pollution prevention and control applying to a wider array of industrial installations and facilities, now also including LCPs, waste incineration plants and installations producing titanium dioxide. Integrated means that pollution (which includes air, water, land, solid waste and noise) of all environmental media must be minimised. The Directive also requires minimising the use of energy and raw materials, noise abatement and preventing accidents. Prevention means that pollution should be reduced at source as well as at the point of discharge.

The IED requires the use of best available techniques to prevent and reduce pollution. It applies to a list of specified installations which includes both industrial, agricultural undertakings as well as activities that not necessarily are falling directly into these categories such as waste incineration and geological carbon capture and storage. Many categories have a scale threshold, below which the IED does not apply. It is effectively a framework Directive controlling the procedures to be used for more specific Directives in several sectors, such as waste, ambient air quality, water management and supply activities.

Implementation of this Directive will be influenced by the present status and organisation of permitting in each candidate country, such as whether permitting and monitoring is carried out primarily by central or decentralised authorities. Given that the IED was adopted in 2010 and Member States had until 7 January 2013 to transpose its provisions, only limited number of observations, good practices and implementing examples can be drawn from the Member States. However, the Commission has requested support in identifying and documenting 'success stories' resulting from the application of the European industrial emissions policy i.e. the IED and its seven predecessor Directives. The outputs from the requested study will be used to communicate on the successes of industrial emissions policy.²⁵⁷

4.1. Planning

4.1.1. Administrative system

- A competent authority will need to be appointed to issue permits and inspect the industrial facilities, which fall within the domain of the Directive. The Directive does not specifically require a single permitting authority to deal with the permitting of pollution to all different media, although co-ordination of separate organisations would be required as the permit will have to take account of all such releases in an integrated manner. Where an institution covering all environmental media does not already exist, the establishment of such an integrated authority is recommended. Another possible solution is to appoint a lead authority, which is responsible for collecting and integrating the consent of the other relevant authorities with a view to harmonising their procedures (e.g. using the same application form/requirements for the permit, managing the whole of the evidence taking and expert opinion in a single procedure, summarising the decisions in a single decision etc.).

²⁵⁷ For more information visit: <http://ec.europa.eu/environment/industry/stationary/studies.htm>.

- Plan for phasing in the provisions of the IED and in particular the strengthened requirements on monitoring, reporting, inspections and public participation in decision-making. Ensure that the competent authorities are sufficiently strengthened with human, financial and technical resources to bring onboard implementation of a larger legislative framework consisting of seven Directives.
- Competent authorities should also make changes to the permitting and reporting procedures to take into account that seven Directives have been integrated into one legal framework.

4.1.2. Develop plans and strategies

- The competent authority should examine the status of existing waste incinerators and develop a plan to improve or replace them to ensure that they meet the standards of the Directive by the implementation date. In addition, new plants may be required, where incineration is the only method acceptable under the Waste Directive (2008/98/EC). Such plans should identify the method by which the provision of new facilities is to be financed and ensure that such finance is provided. This will require an effective cost recovery scheme but may also require subsidy in the short term to phase in the financial burden to industry over an acceptable period. Smaller Member States producing small quantities of hazardous waste for incineration, have found that the construction of facilities that meet the requirements of the Directive is not economic. Consequently, they rely on facilities established in larger Member States, to which they export wastes for incineration.
- Regarding large combustion plants (LCPs) the allocation of emission reduction targets to different classes of combustion plants will require decisions on energy policy, which may have significant social and economic consequences. These will need to be taken into account by central government and will involve, amongst others, ministries dealing with environmental and energy issues.
- Determine whether there are any titanium dioxide installations or processes likely to be subject to IED. Many countries do not have such facilities, in which case no further action is required, although transposition into national law is still necessary to cover the eventuality of a facility being developed at some time in the future.
- In the event the candidate countries have titanium dioxide installations, it will be necessary to evaluate the pollution and to draw up and implement programmes for the reduction and elimination of pollution caused by titanium dioxide waste from existing industries and to determine sources of finance for improvement schemes.

4.1.3. Institutional and procedural structures

- The competent authority should establish a technical assessment system to enable it to assess whether the design and conditions under which installations operate meet the emission limits and other requirements of the Directive. The competent authority must also have the technical capability to assess the implications of changes in design. This will involve training staff in assessment techniques, including assessment of measurement information from the operators.

- The competent authority must establish a monitoring and inspection regime to assess the operating conditions of each installation and measure emissions. This would also include regulations/guidelines concerning the installation and use of measurement equipment as well as its maintenance.
- The analysis of samples requires the existence of laboratories with the appropriate facilities and recognised quality assurance/control procedures.
- The competent authority must ensure that industrial plants covered by this Directive are properly authorised, that emission reduction targets are set for individual plants, that plants comply with standards and that the required reporting is undertaken.
- The competent authority may be a centralised body or decentralised and under the control of local or regional government. The former offers the advantage of a better use of scarce resources and greater national consistency of approach, while the latter offers local accountability.

4.1.4. Setting ELV

- Candidate countries should provide sufficient flexibility to competent authorities to set emission limit values that ensure that, under normal operating conditions, emissions do not exceed the emission levels associated with the best available techniques. The competent authority may set emission limits that differ from the emission levels associated with the best available techniques in terms of the values, periods of time and reference conditions applied, so long as it can be demonstrated, through the results of emission monitoring, that emissions have not exceeded the emission levels associated with the best available techniques.
- Where it is proposed to set emission limits for substances not included in the Directive, the competent authority must collect data on the harmfulness of these substances. A decision-making procedure should be set up to evaluate the data and adopt suitable emission limits.
- Candidate countries have certain right to derogate from the application of emission levels associated with the best available techniques if these would lead to disproportionately high costs compared to the environmental benefits. Such deviations have to be based on well-defined criteria. The emission limit values set out in the IED though cannot be exceeded and derogations may not lead to significant pollution.

4.1.5. Planning of Establishments

- Oblige operators to evaluate the performance of existing installations and determine whether they can economically be upgraded to meet the standards of the Directive. Lay down format and requirements as regards the content of the evaluation.
- Estimate the impact that the IED will have on existing installations, in terms of their capacity to comply with the new, more stringent emission limit values and the costs that these more stringent requirements will have for industry and for the public sector in terms of revising operating licences, monitoring and inspections.

- Oblige the operators on this basis to develop a plan to upgrade or replace existing installations (including waste incinerations, LCPs and titanium dioxide installations). Establish requirements regarding the format and content of the plan.
- Possible improvement plans should identify the method by which the provision of new facilities is to be financed. This is particularly relevant concerning publicly owned LCPs and waste incinerators. This may require an effective cost recovery scheme.

4.1.6. Technical guidance

- The competent authority should establish a technical assessment system to enable it to assess whether the design of incinerators and the conditions under which they operate will meet the emission standards in the Directive. This will involve training staff in assessment techniques. The competent authority must also have the technical capability to assess the implications of changes in design.
- BAT will have to be established for each industrial sector or for individual establishments in each country. These will need to be appropriate for the prevailing conditions and established environmental quality standards, having reference to the BAT reference documents (BREFs) that are issued by the Commission. (see text box below on BREFs and current developments)
- The definition of what constitute "economically and technically viable" techniques is somewhat unclear. Economically viable is usually taken to apply to the category of installations as a whole, rather than to individual operators. However, what is economically viable may be different between different sectors of industry, and may be different in the case of existing plants as against new ones. In practice, the competent authority should, in consultation with representatives of the industrial sector concerned, examine the viability of proposed processes to arrive at an acceptable definition of a BAT, which is achievable by the installations. Reference to worldwide examples of techniques and assessment of availability in the country concerned should feature in the examination.
- In order to assist regulators and permit applicants, the competent authority or other appropriate body should issue guidance on the design, equipment and operation of municipal waste incinerators and the use of waste heat. This can be made the standard against which permit applications are evaluated. Alternatively, specific standards can be made mandatory. The former approach provides for greater flexibility, especially since there are rapid advances in the technology and guidance notes are easier to reissue than mandatory standards.
- Develop detailed requirements concerning heat recovery in installations, particularly in regard to waste incineration plants.
- Develop guidelines for the content of waste reception procedures in the individual plants. Develop detailed regulation concerning the treatment of residues resulting from the operation of plants.
- The competent authority should issue guidance on the design, equipment and operation of hazardous waste incinerators and the use of waste heat. The competent authority should take account of compliance with this guidance in the examination of applications for permits.

BAT Reference Documents (BREFs)

The European IPPC Bureau was set up to organise an exchange of information between Member States and the industries concerned, on the dynamic concept of best available techniques (BAT) associated monitoring and developments in them as required by Article 17(2) of the IPPC Directive (2008/1/EC). The objective of the information exchange exercise is to assist the efficient implementation of the Directive across the European Union.

The process to elaborate and review Best Available Techniques (BAT) Reference documents, the BREFs, has been enshrined into law with the adoption on 8 November 2010 of the new Industrial Emissions Directive (IED), 2010/75/EU, which replaces the Integrated Pollution Prevention and Control (IPPC) Directive (2008/1/EC) and related legislation on industrial emissions. In 2012 the European Commission adopted guidance on the collection of data and on the drawing up of BAT reference documents and on their quality assurance including the suitability of their content and format as referred to in points (c) and (d) of Article 13(3) of Directive 2010/75/EU (2012/119/EU: Commission Implementing Decision of 10 February 2012 laying down rules concerning guidance on the collection of data and on the drawing up of BAT reference documents and on their quality assurance referred to in Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions)

BREFs are the main reference documents used by competent authorities in Member States when issuing operating permits for the installations that represent a significant pollution potential in Europe. A BREF is the vehicle through which best available techniques (BAT) and emerging techniques are determined in a transparent manner, based on sound techno-economic information. A BREF gives predictability to the process of determining conclusions on BAT and provides confidence in the quality of the end result. A BREF is not meant to be a textbook on pollution prevention and control techniques since extensive literature exists on the subject. Therefore, its content is limited to the information relevant for this purpose of enabling the determination of BAT and emerging techniques under the IED.

The BREFs inform the relevant decision makers about what may be technically and economically available to industry in order to improve their environmental performance and consequently improve the whole environment.

The elaboration of BREFs at EU level is considered to be an efficient exercise because in their absence, each Member State would have to conduct a similar exercise.

In 2006, the European IPPC Bureau completed the first series of 33 BREFs and launched the review of the first documents that were finalised. Each BREF is the outcome of a two to three year process involving up to 100 experts. A report from 2007 analyses the first series of chemical BREFs.

More information on BREFs is available at: <http://eippcb.jrc.ec.europa.eu/reference/>.

4.2. Regulation and Enforcement

- The IED strengthens the existing requirements on monitoring and inspections aimed to ensure that the system of integrated prevention and control of emissions from industrial installations is applied and enforced in practice. Member States must ensure that permit conditions are in compliance with the requirements and that operators regularly provide competent authorities with results from monitoring of emissions. Monitoring and reporting obligations of the operator must be set out in permits. Monitoring obligations generally include the monitoring of concentrations of specified pollutants emitted from the installation and a range of other aspects, which have to be kept in mind when operating an installation (e.g. safety reporting, waste management, etc.). In some cases (e.g. for large installations), there may also be a requirement to monitor the surrounding environment. IED includes the requirement for periodic monitoring of dangerous substances likely to be on the site and if there may be risk of soil and groundwater contamination.
- The IED provides more detailed provisions for inspection and enforcement than the former IPPC Directive. Member States have to produce inspection plans, which apart from information on installation, must include a general assessment of relevant significant environmental issues. Based on the plans, inspection programmes shall be developed, which may target inspections based on a systematic appraisal of environmental risks. The risks shall include, at least, the criterion ‘the potential and actual impacts of the installations concerned on human health and the environment taking into account the levels and types of emissions, the sensitivity of the local environment and the risk of accidents’. Operators must also grant the authorities necessary access and assistance to enable inspections and other monitoring functions to be carried out. Routine inspection shall be sufficient to examine the full range of relevant environmental effects of the installation and shall be sufficient to determine not only whether permit conditions are complied with, but also whether the permit conditions are effective.
- In order to issue a permit for installation, the competent authority must be satisfied that the plant is constructed and operated in such a way that all the obligations in the Directive are met and that the agreed BAT (as described in the BAT conclusion) for the type of installation are applied. The operators should therefore submit applications, which contain full information on the process. This could include information on the technical process, raw materials, how these are used, the end-products, what waste is likely to be generated and how it is recycled or disposed of, how much energy will be used and of what type, water usage, precautions against accidents, management regimes, staffing levels and responsibilities, competence of staff, and training of staff. The application could contain flow diagrams to assist the competent authority in understanding the process. The process must comply with the recognised BAT or evidence must be provided that the process is equivalent to this, or reasons given why such BAT cannot be used. A consultation process between the operator and the competent authority is helpful in resolving problems. There must also be an opportunity for public consultation on the proposal to issue a permit before it is issued. The non-technical summary should be drawn up in such a way as to be understandable by the public.
- Because the application of BAT under this Directive will often require significant changes to the way individual installations are operated (and investments may be required), all stakeholders, especially the relevant industries, should be consulted during the development of the BAT and emission limit standards. The requirements for legally binding methods of operating as well as the need to meet

more stringent emission limit values will require a programme of information dissemination to the industries by the competent authority, followed by training programmes for plant operators within the industries concerned.

- Permits must be issued such that the requirements for different environmental media are integrated even if different authorities are involved. This condition is most easily fulfilled by an integrated environmental protection agency to handle all permitting requirements under IED. If more than one authority is involved, clear guidelines for co-ordination must be established. The same coordination is also required for monitoring conditions, permit review, environmental inspections and site closure.
- If temporary derogations are requested by the operator, details of the expected reduction in pollution must be provided.
- It is helpful for the competent authority to formulate standardised forms of application and to issue guidance on the procedure to be used, outlining the information, which must be submitted by those wishing to apply for authorisation to operate under the Directive.
- Bringing existing plants within the permitting regime will require development of the national implementation programme. A timetable needs to be established at the outset, probably based on tackling one sector at a time.
- Public participation in monitoring activities is encouraged by the Directive and the rights of directly interested parties have been reinforced by the IED.
- There is an overriding requirement to ensure a high level of protection for the environment as a whole and to ensure the maintenance of environmental quality standards, even if this requires additional measures over and above the use of BAT. In practice, this is likely to mean that some proposed installations may have to be relocated to sites where existing pollution is lower so that compliance with environmental quality standards can be achieved.
- Permits have to be periodically reviewed to take account of changes in BAT, operational safety requirements or new legislation, or when the significance of the pollution requires review. No fixed timescale for reviews is given in the Directive, but Member States should place a legal obligation on the competent authorities to undertake reviews after a specified period of time, and the review period should be incorporated in the permit. The minimum frequency of the reviews should be regulated by law, although the frequency of the reviews might differ from activity to activity or according to groups of activities in Annex I.
- It will also be necessary to establish a procedure to revise permits if there is a significant change to an operation. New permits must be issued if there is a substantial change. The competent authority should issue guidance on what it considers to be 'substantial change'. Substantial change may be the use of different raw materials, alterations to the process or the way in which it is managed, or the production of different end-products or intermediate products, any of which may give rise to an environmental effect which the competent authority considers significant. The competent authority may have to undertake investigations to determine the significance of such alterations at a particular installation by assessing the sensitivity of the local environment to the proposed changes.
- In order to ensure that the operators inform the competent authorities of any changes planned to the operation of the installations or of any changes in circumstances, countries should introduce a system of sanctions. Encouraging public participation with proper capacity-building elements (trainings,

leaflets, explanatory materials on the homepage of the authorities etc.) might also ensure a better rate of reporting on substantial changes.

- Installations regulated under the IED may impact on the water environment, such as through direct or indirect discharges of pollutants, water abstraction, etc. The IED requires installations to operate to conditions in permits compliant with Best Available Techniques (BAT) and they are also required to respect environmental quality standards established in EU law, including those derived under EU water law (e.g. Water Framework Directive 2000/60/EC, Directive 2008/105/EC on environmental quality standards and Groundwater Directive 2006/118/EC). However, differences between them such as differences in legal interpretation, the presence of multiple pressures on water bodies affecting standards, different implementation timetables may pose challenges. Candidate countries should try to interpret and implement these Directives in an integrated manner. IMPEL report- “Linking the Water Framework Directive and the IPPC Directive”²⁵⁸ serves a good source of information in understanding the links between the two sets of legislation and how to take an integrative approach in implementation.
- Legal remedies shall be fair, equitable, timely and not prohibitively expensive. A fair procedure is even-handed for all parties, while an equitable procedure offers more help to those parties that are not fully in a position to represent their cases in the most effective way (usually to members of the public or public associations). As concerns timeliness, countries should take into consideration ensuring expedited procedures for legal remedies in certain cases of public participation in the permitting procedure.
- Elaborate adequate means of enforcement, notably the power to shut down plants that are operating unsatisfactorily. Penalties applicable to infringements should be effective, proportionate and dissuasive.

²⁵⁸ Farmer, A and Cherrier, V, Institute for European Environmental Policy, Linking the Water Framework Directive and the IPPC Directive, 2010. Information on the IMPEL Network is available at: <http://europa.eu.int/comm/environment/impel> and www.impeltfs.eu

Examples from Member States:

Sweden: In Sweden Emission Limit Values (ELVs) are set for each individual plant in the permit. The ELVs are based on Best Available Techniques (BAT) at the time the permit is granted and taking into account the local conditions.

Sweden's system of individual ELVs means that for a given sector, e.g. iron or steel, conditions in permits for similar plants may not be the same. The differences are a consequence of several factors including the development of BAT over time and the fact that the environmental situation varies from plant to plant, for example the sensitivity of the local environment. Although the ELV for a specific pollutant may vary from plant to plant, there is a tendency that the permit authorities set conditions similar to those that are given in recent permits for other plants in the same industrial sector. This is often the case when there has been no substantial change in BAT.

Conditions in a permit are not permanent, as they are reconsidered when permits are updated. Any substantial changes in the operation calls for an update of the permit and therefore the ELVs are reviewed. If the change in the operation is restricted to certain aspects, only the relevant conditions of the permit are reviewed. Even if no substantial change has been made at a plant, the conditions may be revised at the initiative of the regional supervisory authority or the Swedish Environmental Protection Agency (Swedish EPA).

A review of permit conditions at the initiative of the authorities is possible if the permit is older than ten years. Moreover, a review can be made at any time under certain circumstances, e.g. if the introduction of a new technology would enable a reduction of emissions.

Permits for major polluting industries are issued by Land and Environmental courts. There are five such courts that service different parts of the country and on Supreme Court, the Land and Environmental Court of Appeal. The 21 regional administrative boards issue permits for industries regarded less environmentally hazardous.

Source: <http://www.swedishepa.se/Guidance/Guidance/Environmentally-hazardous-activities/Permits-and-conditions-under-Swedish-legislation/>

Examples from a Member State: Application for an IPPC Permit

United Kingdom: Operators of installations under IED have to apply for a permit from the Regulator (the Environment Agency or Local Authority) prior to operation. The applicant must consider all the environmental impacts associated with the installation when preparing the application.

A copy of the application will be placed on a public register, held in the local office of the Environment Agency and the Local Authority, which the public is free to view.

Applications for permits have to undergo a public consultation; the operator is required to advertise the application in one or more local papers and in the London Gazette. Statutory Consultees and the public are required to submit their comments during the consultation process.

Once the consultation period is over the Regulator considers all the representations reviewed and will either grant the permit subject to conditions or reject the application. If an operator is dissatisfied with a decision made regarding an application, an appeal to the Secretary of State can be made.

If a permit is granted, the Regulator must ensure that the following general principles are met:

- All appropriate preventative measures are taken against pollution, in particular through application of Best Available Techniques
- No significant pollution is caused.
- Waste production is avoided and where waste is produced, it is recovered. Where that is not possible it is disposed of in a way producing the least impact on the environment, if any impact is produced at all.
- Energy is used efficiently.
- Measures are taken to avoid accidents and limit their consequences.
- Necessary measures are taken on the closure of an installation to avoid any pollution risk and return the site to a satisfactory condition.

Once a permit has been granted, under IPPC operators have significant responsibility for monitoring emissions and supplying the Regulator with data required to check compliance with the permit. The Regulator has to undertake independent monitoring and inspections of the installation to check compliance with the set emission limits.

<https://www.gov.uk/government/collections/industrial-emissions-directive-ied-environmental-permits-issued>

Examples from a Member State

Germany: Germany is one of the countries employing general binding rules. In the event that BREFs or advanced drafts existed at the time of the adoption of the German general binding rules, their information was taken into account in determining the emission control requirements. A system for automatically updating the basic emission law (TA Luft) when a BREF provides new BAT standards has been established. When a new or revised BREF is published by the Commission, an Advisory Committee set up by the Federal Environmental Ministry (BMU) examines to what extent the new BREF contains requirements that go beyond, or that supplement the requirements in the TA Luft. If the committee concludes that the state of techniques has developed or that the specifications of the TA Luft need to be supplemented, the BMU provides notification of this following a defined procedure. The licensing and monitoring authorities must then take into account changes to the state of techniques

4.3. Monitoring and Inspection

- The competent authority needs to ensure that monitoring is undertaken to verify compliance with the permit conditions. Permit conditions should include a requirement that plant operators develop and implement monitoring programmes. A system for recording the results and relaying them to the competent authority should be defined in the permit. These monitoring programmes may then be inspected by the competent authorities, which will also undertake their own monitoring to ensure the reliability of the work done by the operators. The competent authority should undertake periodic inspections to ensure that the permit conditions are complied with and that monitoring is undertaken correctly. At least a proportion of these inspections should be made unannounced.
- An environmental monitoring and surveillance programme, particularly in regard to titanium dioxide waste should be defined and co-ordinated with other similar programmes as defined in the Member State's waste management plan.
- Cross-border consultation will be necessary where discharges affect the environment of another Member State. Consultation should also take place between Member States on the monitoring programme.
- Inspection and monitoring will require analysis of samples at laboratories that have appropriate facilities and recognised quality assurance procedures. An analytical quality control regime should be introduced. Only methods of analysis that are approved by the competent authority and that are at least equivalent to those in the Directive should be used. Laboratories that undertake monitoring should have proven quality assurance/quality control procedures and should be approved by the national certification body or the competent authority.
- A system for recording the results of monitoring by plant operators and relaying them to the competent authority must be agreed between it and the operators and defined in the permit.
- An analytical quality control regime should be introduced. Only methods of analysis approved by the competent authority, and which must be at least equivalent to those in the Directive, should be used. The laboratory (or laboratories) that undertake monitoring should have proven quality assurance/quality control procedures and should be approved by the national certification body or the competent authority.
- Inspection procedures are fundamental to IED. Article 23 requires that operators of installations allow competent authority representatives to carry out inspections and co-operate fully with them as required according to an overall inspection plan with permit programmes for routine inspections and requirements for follow-up and non-routine inspections. For non-routine inspections, it is helpful for competent authorities to notify operators well in advance of the potential for such co-operation and what this would entail, while the exact timing and number of inspections should not be communicated to the operators. The obligations on routine environmental inspections constitute a new challenge for the EU member states. IMPEL has already done some work in this field: e. g. Guidance Book on Environmental Inspections, Risk Assessment in Inspection Planning, and Inspection Targets and Performance Monitoring. These approaches to environmental inspections should be adapted to the demands of the IED and can serve as a source of good practice for the candidate countries. IMPEL assists the Commission in collecting and disseminating good inspection practices.

IMPEL developments

Under the 2012 IMPEL project: Environmental inspections of industrial installations in accordance with the Industrial Emissions Directive (IED) Guidance for the implementation of the IED in planning and execution of inspections was produced (available at: <http://impel.eu/wp-content/uploads/2015/01/Step-by-step-guidance-for-IED-Inspections-June-2013-final-080713.pdf>.)

The main objective of this project was to organise an exchange of information concerning best practices for the implementation of article 23 of the IED taking into account the guidance on inspection planning and risk appraisal already developed by IMPEL and the requirements described in Article 23 of the IED.

Pursuant to the EU Recommendation providing for minimum criteria for environmental inspections (RMCEI) and the EU Industrial Emission Directive (IED) inspection activities should be planned in advance and conditions are set regarding the execution and reporting of inspections. This guidance takes as a starting point the Environmental Inspection Cycle. The inspection cycle was mainly developed within the IMPEL project “Doing the right Things”. During the IED Inspections project it was adapted to the demands of the IED. In the last chapter of this guidance the inspection obligations derived from the IED are discussed and linked to the different steps of the previous chapters.

There is an ongoing IMPEL project Supporting the IED implementation, which aims at better implementing the IED with special regard to permitting, participation of the public, and increasing the efficiency and effectiveness of environmental inspections and surveillance, through:

- application of risk criteria in a strategic way with a view to assessing, evaluating and mitigating the most serious types of non-compliance with the IED;
- development of best practice examples in the application of BAT conclusions and the compilation of baseline report on soil and ground water contamination;
- optimising the communication with and active dissemination to the public of the results of inspection and surveillance work;
- fostering cooperation and coordination between different inspection and surveillance bodies with a view to streamlining and optimising the use of inspection and surveillance resources;
- development of reaction methods after serious environmental complaints;
- creation and use of electronic records of inspection and surveillance work with a view to enabling the efficiency and effectiveness of such work to be more easily measured and evaluated.

4.4. Consultation and Reporting

- Public participation might give rise to a series of practical issues. While the notification shall come early in the procedure, it should contain substantial data. If data important for meaningful public participation emerge later, the competent authority might decide on additional information dissemination activities. The form of notification should be prescribed by law in the form of minimum requirements. The best solution is most probably a combination of written and electronic media and local means of disclosing public information (such as billboards, flyers etc.).
- Candidate countries have discretionary power of the national legislation to determine at what stage the decisions, acts or omissions might be challenged. While legal remedies are usually practical at the very end of the administrative procedures, in certain cases the end of a lengthy procedure is too late, and irreversible, irrecoverable harm to significant public interest might occur. Therefore, in certain matters, such as the very fact of the possibility of public participation in respect to certain groups or associations, an immediate legal remedy seems to be the most effective solution.
- The Directive requires permit applications to be made available to the public for consultation, prior to a decision being made on them. Implementation of this provision will vary from country to country, but may involve the publication by the competent authority of a notice in a local newspaper summarising the nature of the application, where further information can be obtained, and to whom comments should be directed. Sufficient time must be allowed for the public to present comments. Where land-use planning permission for the installation is also required (for example in the case of new installations), and similar public comment is part of the procedure, it may be possible to combine the public consultation arrangements for IED with the consultation procedures regarding land use. The procedures under EIA should be taken into account and if possible integrated.
- Member States are to ensure that they have a relevant authority capable of compiling and transmitting the information required to be reported on the application of national law and practice.
- The requirement for public consultation will require the establishment of special procedures to ensure effective communication and public hearing facilities in order to make it easy for the public to participate meaningfully in such consultations. An essential element will be rules guaranteeing this right of citizens by making an appropriately completed consultation a pre-condition for the validity of any permit issued.
- Establish requirements regarding the content of and procedures for annual reporting for large-scale plants.
- Candidate countries also have to report to the European Pollutant Release and Transfer Register (E-PRTR) (established by Regulation (EC) No 166/2006). This register covers more than 91 substances emitted from industrial installations in 65 different sectors of activity. Operators carrying out one or more of the activities listed in Annex I of the PRTR Regulation have to submit information to the competent national authority if their activities involve releases or transfers of pollutants exceeding certain threshold values. The PRTR will include transfers of waste and wastewater from industrial facilities to other locations, as well as data on emissions caused by accidents on facilities' sites.

5. COSTS

The IED which brings seven Directives under the same legislative framework is estimated to save costs both for public administration and for industry. For instance, it reinforces the application of Best Available Techniques, as a way to reduce the harmful industrial emissions across the EU, translating into improved environment and human health. Furthermore, the streamlining of permitting, reporting and monitoring requirements as well as a renewed cooperation with Member States to simplify implementation will lead to a reduction in unnecessary administrative burden of between €105 and €255 million per year. IED will reinforce the application of Best Available Techniques, as a way to reduce the harmful industrial emissions across the EU, translating into improved environment and human health. For the large combustion plants alone it will achieve net benefits of €7-28 billion per year, including the reduction of premature deaths and years of life lost by 13,000 and 125,000 respectively.

The main types of costs arising during the implementation of the IED are illustrated, as far as possible, in the Table below. There are a few main aspects:

- the cost of setting up the administrative arrangements to deal with allocating and implementing operating permits as well as for their periodic review and updating;
- the costs of application of BAT for new plants mentioned in Annex 1 of the Directive;
- the costs of applying BAT for existing plants after 2016;
- the costs for reinforcing existing authorities and giving them new tasks in regard to the provisions on waste incineration, regulation of titanium dioxide waste and large combustion plants, that might previously have been dealt with by other competent authorities;
- the costs for monitoring compliance with permit conditions, other emission limit values and other operator's responsibilities;
- the costs for consultation with other competent authorities from other sectors (e.g. water management basin authorities, waste management authorities, ambient air monitoring authorities) and with authorities from other neighbouring Member States.

In accordance with the polluter pays principle, the costs for the administrative arrangements, in so far as they relate to individual installations, should be recovered from operators under a system of fees for authorisation applications and renewals. The extent of the costs involved in setting up the competent authority, including equipment and staff training, will depend on the nature of existing arrangements in that state for permitting discharges to the environment. The major costs will relate to the application of BAT.

Table 7. Types of Cost Incurred to Implement the Directive

Initial set-up costs:
<ul style="list-style-type: none">• Preparation of a strategy to achieve the objectives of the IED and integrate former strategies on waste incineration and large combustion plants into this strategy (borne by the public sector);• Reorganisation of permitting institutions;• Establishing BAT and emission limit values;

<ul style="list-style-type: none"> • Devising systems and procedures for permitting, reviews, monitoring, inspection and enforcement; • Carrying out surveys of existing titanium dioxide plants and prepare an improvement plan; • Provision of training of staff of competent authorities, relevant ministries, verification bodies and other relevant authorities involved in the implementation of the IED; • Preparing technical guidance notes.
<p>Capital expenditure:</p> <ul style="list-style-type: none"> • constructing plants in accordance with BAT, including pollution abatement facilities at new installations; • altering existing plants to incorporate BAT and pollution abatement facilities and for industries such as the titanium dioxide, ensure that efficient effluent treatment plants have been installed; • Establishment of testing and verification laboratories.
<p>On-going running costs:</p> <ul style="list-style-type: none"> • annual operating costs of upgraded and new installations or replacement facilities; • operating costs of abatement facilities; • inspections of permitted installations; • collecting data for reporting to the Commission; • issuing permits for new IED installations and renewed permits for existing (comprising waste incinerators and LCPs); • permitting to the Commission.

Regarding costs for the titanium dioxide industry, these should be preferably borne by the industry on a cost recovery basis. As the titanium dioxide industry is highly specialised, the costs of monitoring and surveillance could be charged on the basis of work done, or could be related to the general cost recovery programmes that will be in place for the regulation of other industries. The costs of sampling and biological survey work carried out in estuary and coastal areas are significantly higher than for discharges to inland waters or to land and air. Improvement costs will result from the need to incorporate effluent treatment at existing titanium dioxide production facilities, to neutralise acidic discharges and to eliminate metallic contaminants. The removal processes themselves will produce solid wastes or sludge that will also incur a disposal cost.

Due to the very high cost of upgrading existing incinerators, many have been closed and replaced by new plants. Costs are borne by the operators, many of which operate the plants on a commercial basis. This usually leads to increased charges. Costs associated with applications for permits, inspections and monitoring are borne by the operators.

The application of the IED will not only bring about costs. Compliance with BAT will in the longer term lead to a range of benefits not only in terms of cost savings but to human health and the state of environment. For instance LCPs are the main contributors to overall air pollution, contributing to about 90% of total industrial emissions of the pollutants SO₂, NO_x and particulate matter. Significant health and environmental benefits would arise if European power plants apply BAT. These benefits would largely outweigh the costs: considering wider positive impacts the total annual EU net benefits vary between 13.9 – 58, 7 billion Euros if LCPs apply

the stricter level of BAT. The Cafe (Clean air for Europe) evaluation method also suggests that for the 100 major plants the estimated health benefits are 3.4 times bigger than the estimated control costs (without including damage to ecosystems and building) and that 22,823 premature deaths could have been avoided (243,657 life years gained) had the 200 largest emitters applied BAT.

THE MEDIUM COMBUSTION PLANTS DIRECTIVE

Official Title: Directive (EU) 2015/2193 of the European Parliament and of the Council of 25 November 2015 on the limitation of emissions of certain pollutants into the air from medium combustion plants (OJ L 313, 28.11.2015)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Directive (EU) 2015/2193 on pollution from medium combustion plants (hereinafter referred to as the MCP Directive) regulates pollutant emissions from the combustion of fuels and applies to medium combustion plants (MCPs) with a rated thermal input equal to or greater than 1 megawatt (MW) and less than 50 MW, irrespective of the type of fuel that is used. The main aim of the Directive is to reduce potential harm to human health and the environment.

The MCP Directive also ensures implementation of the obligations arising from the Gothenburg Protocol under the UNECE Convention on Long-Range Transboundary Air Pollution.

Coke battery furnaces, gas turbines and engines used offshore, reactors used in the chemical industry and plants already covered by other EU legislation regulating their emissions, such as Directive 2010/75/EU on industrial emissions are excluded from the scope of the Directive. Also, the MCP Directive does not apply to ancillary research, development and testing activities.

The MCP regulates emissions of SO₂, NO_x and dust into the air with the aim of reducing those emissions and the risks to human health and the environment they may cause. It also lays down rules to monitor emissions of carbon monoxide. The emission limit values set therein will have to be applied from 20 December 2018 for new plants and by 2025 or 2030 for existing plants, depending on their size. It also introduces flexibility provisions for district heating plants and biomass firing plants. The MCP Directive allows Member States to apply stricter emission limit values in areas where this can improve local air quality in a cost-effective way.

The MCP Directive entered into force on 18 December 2015 and will have to be transposed by Member States by 19 December 2017.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Designate the competent authority responsible for implementation of this Directive. (Art. 10)
- Specify the procedure for granting a permit or for registration in respect of medium combustion plants. Member States may choose between applying permitting regime or registration regime. (Art. 5(3))
- Consider including requirements for certain categories of medium combustion plants in general binding rules. (Art. 5(6))
- Assess the possibility to apply derogations provided for existing medium combustion plants which are part of district heating systems or used to drive gas compressor stations required to ensure the safety and security of a national gas transmission system or firing solid biomass. It should be emphasised that these derogations should be interpreted restrictively and these provisions should be transposed into the national law only if the Member State chooses to apply these options. (Arts. 6(5)&6(6))
- Assess the possibility to apply derogations envisaged to MCP operating limited hours under specified conditions. (Arts. 6(3)&6(8)). These provisions should be transposed into the national law only if the Member State chooses to apply these options
- Determine whether to grant a time-limited derogation from the obligation to comply with the emission limit values in cases of emergency. Although this provides an option for the competent authority, it needs to be transposed into national legislation in order to provide the possibility for the competent authority to grant temporary derogations. (Arts. 6(11)&6(12))
- Assess the need to apply stricter emission limit values to individual medium combustion plants in zones or parts of zones not complying with the air quality limit values laid down in Directive 2008/50/EC. (Art. 6(9))

2.2. Regulation

- Ensure that scope and definitions are correctly transposed into the national law.
- Ensure that the aggregation rules apply when considering number of combustion plants and their total capacity. (Art. 4)
- Ensure that by 19 December 2018 all new medium combustion plants have a permit or are registered. (Art. 5(1))
- Ensure that by 1 January 2024, all existing plants with a rated thermal input greater than 5 MW have a permit or are registered. (Art. 5(2))
- Ensure that by 1 January 2029, all existing plants with a rated thermal input less than or equal to 5 MW have a permit or are registered. (Art. 5(2))

- Ensure that the operator informs the competent authority of any planned change to the MCP, which would affect the applicable emission limit values. (Art. 9)
- Establish a publicly available register with information on each plant, such as the type of fuel used and expected number of annual operating hours. (Art. 5(5))
- Set out emission limit values for SO₂, NO_x and dust by fuel category in accordance with Annex II (Art. 6(1))
- Ensure that limit values are applied from 20 December 2018 to new plants. (Art. 6(7))
- Ensure that limit values are applied from 1 January 2025 to existing plants with a rated thermal input greater than 5 MW. (Art. 6(2))
- Ensure that limit values are applied from 1 January 2030 to existing plants with a rated thermal input less than or equal to 5 MW. (Art. 6(2))
- Make sure that operator of the plant monitors emissions and maintain a record, for at least 6 years, of the results of emission monitoring, of operating hours, type and quantities of fuel used and details of any malfunction or breakdown. (Art. 7)
- Lay down rules for the type, frequency and format of information concerning events of non-compliance to be provided by operators to the competent authority. (Art.7(7))
- Lay down effective, proportionate and dissuasive penalties applicable to infringements of the national provisions adopted pursuant to this Directive and ensure that they are adequately enforced.

2.3. Monitoring

- Establish effective inspections to check compliance with emission limit values. (Art. 8)
- Monitor emissions from plants in accordance with specified methods, ensuring that operators, upon request, report the results of monitoring to the competent authorities and evaluate the results of monitoring in accordance with specified criteria. (Art. 7 and Annex III)
- Where emission limit values are exceeded, ensure that action is taken to achieve compliance within the shortest possible time. Such measures, in cases of significant degradation of local air quality, may include suspension of the operation of the MCP until compliance is restored (Arts. 7 and 8)

2.4. Reporting

- Submit a report to the European Commission with an estimate of the total amount of annual emissions of CO by 1 January 2021. (Art. 11(2))
- Provide the Commission with qualitative and quantitative information on the Directive's implementation by 1 October 2026. This must include estimated total annual emissions of SO₂, NO_x

and dust (particles) from plants, according to their type, fuel used and capacity. The second implementation report is due on 1 October 2031.

- Notify the Commission by 19 December 2017 the national provisions on penalties applicable to the infringements. Any subsequent amendment to those provisions should be notified without delay.
- Inform the Commission on derogations granted pursuant to Articles 6(11) and 6(12) related to certain specific circumstances where the application of emission limit values would not be possible without entailing disproportionately high costs compared to the environmental benefits.

2.5. Additional Legal Instruments

The following legislation should be borne in mind when implementing this Directive:

- Industrial Emissions Directive (2010/75/EU)
- Ecodesign Directive (2009/125/EC)
- Air Quality Framework Directive (2008/50/EC)
- National Emission Ceilings Directive (2001/81/EC)
- Access to Environmental Information Directive (2003/4/EC)

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the following Table.

Key tasks are organised in chronological order, wherever applicable.

Table 8. Medium Combustion Plants Directive - Key Implementation Tasks

MEDIUM COMBUSTION PLANTS DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Appoint the competent authority for the implementation of this Directive.
1.2	Introduce a system for defining and classifying medium combustion plants to which the Directive applies.
1.3	The competent authority should establish an authorisation procedure requiring existing and new medium combustion plants specified in the Directive to be registered or to obtain permit.
1.4	Determine whether to apply any of the flexible mechanisms provided in the Directive.
2	Regulation
2.1	Ensure that each medium combustion plant is operated only if it is at least registered by the competent authority. Any change to the medium combustion plant should be notified to the competent authority and the permit or the registration should be updated accordingly.
2.2	Apply emission limit values for sulphur dioxide, nitrogen oxide and dust to new and existing plants from the date specified therein.
2.2	Establish and maintain publicly available register with information on each plant.
2.3	Determine rules for the type, frequency and format of information concerning events of non-compliance to be provided by operators to the competent authority.
2.4	Where necessary, apply sanctions, which should be effective, proportionate and dissuasive.
2.5	Establish a reporting system to enable reports to be made to the Commission and information to be available to the public.
3	Monitoring
3.1	The competent authority should establish an inspection to assess compliance with the emission limit values.
3.2	Require operators to monitor emissions and keep records for at least 6 years, of the results of emission monitoring, of operating hours, type and quantities of fuel used and details of any malfunction or breakdown and measures taken to restore compliance with the emission limit values.
3.3	Ensure that operators inform the competent authority of any event of non-compliance and take necessary measures to achieve compliance with the limit values within the shortest possible time.
4	Reporting
4.1	<ul style="list-style-type: none"> ● Submit a report to the European Commission: <ul style="list-style-type: none"> - containing an estimate of the total amount of annual emissions of CO - on the implementation of Directive's requirements ● Notify the national provisions on penalties applicable to the infringements ● Inform the Commission on on derogations granted pursuant to Articles 6(11) and 6(12)

4. IMPLEMENTATION GUIDANCE

This Directive applies only to combustion plants which burns fuel and uses the heat generated, with a rated thermal input equal to or greater than 1 MW and less than 50 MW, irrespective of the type of fuel it uses.

The key implementation issues are ensuring that:

- An authorisation system (permitting or registration) is established;
- existing plants are modified to meet the required emission levels; and
- new plants comply with the specified emission limits.

Implementation of this Directive will be influenced by the present status and organisation of permitting in each candidate country, such as whether permitting and monitoring is carried out primarily by central or decentralised authorities. Given that the MCP Directive was adopted in 2015 and Member States have until 19 December 2017 to transpose its provisions, there are no examples of good practices and implementing examples that can be drawn from the Member States.

5. COSTS

The main types of cost arising during the implementation of the Medium Combustion Plants Directive are illustrated, as far as possible, in the Table below.

Table 9. Types of Cost Incurred to Implement the Directive

Initial set-up costs: <ul style="list-style-type: none">• establishment of competent authority;• devising systems and procedures for registration or granting a permit;• provision of training;• preparing technical guidance notes, if appropriate.
Capital expenditure: <ul style="list-style-type: none">• alteration of existing plant to meet emission limit values;• construction of new plant to meet the emission limit values
On-going running costs: <ul style="list-style-type: none">• processing permit/register applications;• maintaining publicly accessible register with information on each medium combustion plant;• reporting to the Commission.

Significant costs will be incurred by the competent authority in administering the Directive, including permitting/registration, monitoring and reporting. However, the costs incurred by operators in complying with the Directive and abating emissions will be many times higher.

Arrangements should be made to recover at least some of the costs from operators through fees for permitting/registration in accordance with the polluter pays principle.

Candidate Countries are advised to consult the IED in the planning and introduction of legislative and administrative provisions and frameworks concerning the MCP legislation. This has a large potential of saving administrative and financial resources in the permitting, reporting and monitoring of industrial emissions. Furthermore, the streamlining of permitting, reporting and monitoring requirements as well as a renewed cooperation with Member States to simplify implementation will lead to a reduction in unnecessary administrative burden.

THE SEVESO III DIRECTIVE

Official Title: Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC Text with EEA relevance (OJ L 197, 24.7.2012)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The aim of the Directive is to prevent major accidents that involve dangerous substances and to limit their consequences for people and the environment. The Directive applies to establishments at which certain dangerous substances are present in sufficiently large quantities to create a major-accident hazard. As well as requiring the operators of such establishments to take preventive measures, the Directive places a number of procedural requirements on Member States relating to planning, policy integration, inspection, reporting and public access to information.

Adoption of the first piece of EU legislation on prevention and control of accidents involving dangerous substances, namely Directive 82/501/EEC, was provoked by the catastrophic accident in the Italian town Seveso in 1976. This Directive was later amended in view of the lessons learned from later accidents such as Bhopal, Toulouse or Enschede resulting into Seveso-II Directive 96/82/EC.

In 2012 Seveso III Directive 2012/18/EU was adopted taking into account, amongst others, the changes in the Union legislation and increased rights for citizens to access information and justice. One of the main reasons for the adoption of Seveso III Directive is aligning the EU legislation on major accidents hazards with the new classification scheme for chemical substances provided for by the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. In this context, Seveso III Directive had to be implemented by the Member States by 31 May 2015, in order to coincide with the entry into force of the last CLP phase on 1 June 2015.

In brief the main changes that will be introduced by 1 June 2015 are:

- Updating and aligning the list of substances covered by the Directive to the EU legislation on the classification of dangerous substances;
- Better access for citizens to information about risks resulting from activities of nearby companies, and about how to behave in the event of an accident.
- More effective rules on participation, by the public concerned, in land-use planning projects related to Seveso plants.
- Access to justice for citizens who have not been granted appropriate access to information or participation.
- Stricter standards for inspections of establishments to ensure more effective enforcement of safety rules.

More information on the Seveso III Directives are available from DG ENV at: <http://ec.europa.eu/environment/seveso/index.htm>.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Establish competent authorities to implement the requirements of the Directive and, if necessary, technical assistance bodies to assist the competent authorities. (Art. 6(1))
 - Ensure that these authorities cooperate with the Commission in activities to reinforce implementation also involving stakeholders. (Art. 6(2),
 - Ensure that these authorities accept information submitted by operators in accordance with other relevant EU legislation (e.g. under IED), fulfilling any of the requirements of this Directive. (Art. 6(3),
 - Ensure that objectives for the prevention of major accidents are taken into account in land-use policies and other relevant policies, and establish consultation procedures to facilitate the implementation of these policies. There should be an appropriate distance between Seveso establishments and residential areas, buildings and areas of public use as well as major transport routes and sensitive nature areas. (Art. 13)
 - Ensure full compliance with EIA procedures, which may be applied in parallel to the Seveso requirements (Art. 13(4).
- Identify establishments or groups of establishments where the risks of major accidents are increased because of their location and their dangerous substances, so-called lower and upper tier establishments and ensure that provision is made for co-operation in informing the public and supplying information to each other and to the competent authorities (Art. 9). This information has to be taken into account in each others' major-accident prevention policy (MAPP), safety management systems, safety reports and internal emergency plans. (Art. 9(3))
- Draw up external emergency plans to be implemented in the event of a major accident, and review, test and revise these plans and ensure that the facilities supply the competent authorities with the necessary information to enable the Member States to draw up such plans, including an internal emergency plan
 - Operator must ensure that the internal and long-term external personnel in the Seveso establishments are involved in the drafting of the internal emergency plans,
 - Competent authority must consult the public at an early phase for the drafting of new or substantially modified external emergency plans;
 - Ensure that internal and external emergency plans are reviewed, tested, and updated at, no longer than three years taking into account changes in the establishment, technical progress and improved response to accidents, also involving cooperation with civil protection bodies;
 - Ensure that the emergency plans are put into effect in case of a major accident or risk of such (Art. 12 and Annex IV)

- Ensure that installations covered by the Seveso III Directive, fully complies with the new CLP Regulation (EC) 1272/2008 as from June 2015

2.2. Regulation

- Prohibit the operation of establishments that do not comply with the standards laid down in the Directive. (Art. 19(1))
- Ensure that operators may appeal against a prohibition order issued by the competent authority. (Art. 19(2))
- Ensure that operators of establishments fulfil their obligations as laid down in the Directive:
 - to prepare and implement a major-accident prevention policy, taking into account principles in Annex III. (Arts. 8 and 11 and Annex III)
 - to prepare an internal emergency plan in consultation with those working within the facility, including subcontracted personnel. (Art. 12)
 - to prepare a safety report demonstrating compliance with key obligations regarding preparing an internal emergency plan, that a MAPP and safety management have been put into operation, that major-accident hazards have been identified and that safety aspects have been adequately been taken into account in the construction, operation and maintenance of establishments and storage places. (Arts. 10, 11 and Annex II)
 - to review and revise the MAPP, safety report and internal emergency plan referred to above in changes to installations, establishments and storage places which may significantly impact the risk for major-accidents. (Arts. 10, 11, 12)
 - to take measures to prevent major accidents and limit their consequences and prove compliance with directive's provisions, especially in the context of inspections and controls. (Art. 5)
 - to provide all relevant information to competent authorities about their operations and their measures to prevent major accidents and limit their consequences. (Art. 5, 7, 8, 10, 11 and 12)
 - to exchange information and co-operate with competent authorities and other establishments as regards domino effects. (Art. 9)
 - to involve stakeholders and the public to the extent possible in implementing Seveso III Directive. (Art. 6(2))
 - following a major accident, to provide specific information to competent authorities and ensure that both the operator and the competent authority take the action and remedial measures referred to. (Arts. 16 and 17)
- Ensure that MAPP is drawn up within the following time-limits (note that this does not apply to establishments which have submitted their MAPP under Seveso II Directive prior to 1 June 2015 and the information therein is accurate):

- for new establishments, a reasonable period of time prior to the start of construction or operation, or prior to the modifications leading to a change in the inventory of dangerous substances;
 - for all other cases, one year from the date from which this Directive applies to the establishment concerned;
- Ensure that operator periodically review the MAPP and update it at least every five years and send it to the competent authority if so requested (Art. 8(4)). Pursuant to Art. 11, operator has to amend the MAPP in case of changes that increase risk for accident or that makes a lower-tier establishment a upper-tier establishment;
 - Ensure that MAPP is implemented by means proportionate to the major-accident hazards, the complexity of the organisation and the activities leaving the possibility for lower-tier establishment to use other means, provided that they are in compliance with principles in Annex III. (Art. 8(5))
 - As regards to internal emergency plans, such plans only have to be produced by upper-tier establishments and in accordance with the following time-limits:
 - for new establishments, a reasonable period of time prior to the start of operation, or prior to the modifications leading to a change in the inventory of dangerous substances;
 - for existing upper-tier establishments, by 1 June 2016 unless the internal emergency plan drawn up under the requirements of national law before that date;
 - for other establishments, two years from the date from which this Directive applies to the establishment concerned. (Art. 12(2))
 - As regard to safety reports, such reports only have to be produced by upper-tier establishments and in accordance with the following time-limits:
 - for new establishments, a reasonable period of time prior to the start of construction or operation, or prior to the modifications leading to a change in the inventory of dangerous substances;
 - for existing upper-tier establishments, 1 June 2016;
 - for other establishments, two years from the date from which this Directive applies to the establishment concerned.(Art. 10(3))
 - Following a major accident, ensure that specified measures are taken, including the gathering and analysis of information, the remediation of damage, and the making of recommendations for the prevention of future accidents. As from 1 June 2015, competent authorities have to ensure that the persons likely to be affected, of the accident and, where relevant, of the measures undertaken to mitigate its consequences are duly informed. (Arts. 16 and 17)

2.3. Monitoring and Enforcement

- Introduce stricter standards for inspections of establishments to ensure more effective enforcement of safety rules, i.e. establish and implement a system of inspection of establishments to ensure that they comply with the Directive:
 - These inspections should be tailored to the establishment concerned and be sufficiently planned to allow for ongoing examination of the systems of the establishment to ensure compliance with the provisions of the Directive, i.e. to prevent accidents and to limit the consequences of major accidents, verify the accuracy of key documents such as the safety report and that the public is being informed;
 - The competent authority should draw up programme for routine inspections indicating the frequency for each type of establishment, which shall not exceed one year for upper-tier establishments and three-years for lower-tier establishment;
 - Operators must provide the competent authorities with all necessary assistance and information to facilitate the inspection in particular to allow the authorities to fully assess the possibility of a major accident and to prepare an external emergency plan;
 - Competent authority must report on conclusions of the inspection and all necessary action, taking into account the timeframe indicated. (Art. 20(1), (2), (4), (7) and (11))
- Ensure that the following requirements on inspections are fulfilled:
 - all establishments are covered by an inspection plan at national, regional or local level and ensure that this plan is regularly reviewed and, where appropriate, updated;
 - each inspection plan include the specifics set out in Art. 20(4), e.g. a general assessment of relevant safety issues;
 - the geographical area covered by the inspection plan; a list of the establishments covered by the plan;
 - procedures for routine and non-routine inspections, including the programmes for such inspections and provisions on the co-operation between different inspection authorities.
 - appraisal of the hazards of the establishments concerned are based on at least the potential impacts of the establishments concerned on human health and the environment and the record of compliance with the requirements of this Directive.
 - non-routine inspections are carried out to investigate serious complaints, serious accidents and ‘near misses’, incidents and occurrences of non-compliance as soon as possible.
 - carry out an additional follow-up inspection within six months of an inspection identifying non-compliance.
 - coordinate and combine inspections with other inspections under other EU legislation (e.g. IED).
 - develop tools and mechanisms for exchange of experience and transfer knowledge and participate in such mechanisms at EU level. (Art. 20)

2.4. Information, Public Consultation and Reporting

- Make certain information relating to the implementation of the Directive available to the public, subject to specified exemptions such as confidentiality; (Art. 22)
- Provide information on safety measures and procedures to people who are liable to be affected by a major accident. This information should relate to requisite behaviour in the event of an accident and should be submitted periodically, in appropriate and user- friendly formats, to all persons and public establishments in the vicinity of the establishment. In cases of accidents with possible transboundary effects, inform other potentially affected Member States. (Art. 14, 15(1) and Annex V)
- Ensure compliance with requirements on public consultation and information provision set out in Article 15, such as:
 - Regarding new establishments or significant modifications of existing or developments in surrounding areas affecting risk of major accident, ensure that public is informed by appropriate means, including electronic media, preferably before taking a decision regarding the subject of the specific project; whether the project is subject to an EIA or transboundary consultations, details of the competent authority and where more information is available and timeline for submitting comments or questions, nature of decision, indication of places and times where information will be made available any arrangements for public participation and consultation. The public concerned must also receive main reports and advice available from the competent authority and relevant information for the decision (even if not yet made publicly available) and be allowed to express comments and opinions prior to a decision is taken and that this input is taken into account in the decision-making
 - Ensuring that decisions taken are made available to the public including the reasons on which it was based and the results and integration of consultations
 - Allowing the public, including relevant environmental NGOs, possibility to participate in preparation, modification or review of general plans and programmes regarding major accident prevention, taking into account procedures in Directive 2003/35/EC (Art. 15(2) to (7))
- Determine the consultation procedures ensuring compliance with the provisions of the Public Participation Directive (2003/35/EC) and the EIA Directive (2011/92/EU) where relevant, allowing reasonable timeframes for commenting and taking into account the comments in decision-making. (Art. 15(7))
- Comply with the requirements on access to justice, where Member States must ensure that:
 - any applicant requesting but is refused certain information (Article 14(2) or Article 22(1)) can seek a review in accordance with Article 6 of Directive 2003/4/EC to appeal the decision or omission to provide information;
 - the national legal system provide the public concerned access to the review procedures set up in Article 11 of the EIA Directive (2011/92/EU) for cases subject to Article 15(1) of Seveso III Directive. (Art. 23)
- Report to the Commission on:
 - major accidents and results of the analysis of such accidents. (Art. 18)

- experience acquired in preventing and limiting major accidents. (Art. 21(1))
- the name or trade name of the operator, its address and the activities involved. (Art. 21(3))
- implementation of the Directive. (Art. 21(2)) First report of the implementation of the Seveso III Directive is due on 30 September 2019 and every four years thereafter;
- transposing measures and other steps taken to comply with the Directive, including legislative and administrative provisions introduced. (Art. 31)

2.5. Additional Legal Instruments

A number of other legal acts need to be borne in mind in implementing this Directive. These include:

- EIA Directive (2011/92/EU)
- Directive on access to environmental information (2003/4/EC)
- Industrial Emissions Directive (2010/75/EU)
- Water Quality Framework Directive (2000/60/EC)
- Decision No 1313/2013 of the European Parliament and of the Council on a Union Civil Protection Mechanism
- Council Directive 2008/114/EC of 8 December 2008 on the identification and designation of European critical infrastructures and the assessment of the need to improve their protection
- Directive 2006/21/EC on mining waste
- Regulation concerning the establishment of a European Pollutant Release and Transfer Register (166/2006)
- Directive 2007/2/EC establishing an infrastructure for spatial information in the European Community (INSPIRE)
- Environmental Liability Directive (2004/35/EC)
- Directive 2013/30/EU of the European Parliament and of the Council of 12 June 2013 on safety of offshore oil and gas operations and amending Directive 2004/35/EC
- Environmental Crimes Directive (2008/99/EC)
- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency
- Regulation (EC) No 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury
- Regulation (EC) No 1221/2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)

3. IMPLEMENTATION

Table 10. The Seveso III Directive - Key Implementation Tasks

THE SEVESO III DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Establish a system of notification of the use, processing or storage of certain dangerous substances above specified thresholds at establishments, and prohibit the operation of establishments where dangerous substances are present and are capable of creating a hazard unless safety measures are adequate.
1.2	Appoint a competent authority to carry out the duties detailed in the Directive. This might be an institution that already has responsibility for health and safety issues. If necessary, appoint a body for the provision of technical assistance to the competent authority in matters relating to the Directive.
1.3	Appoint an institution to be responsible for preparing external emergency plans (possibly the competent authority or often local authorities).
1.4	Establish and implement a programme of training for issues related to the Directive for both regulators and operators.
1.5	Elaborate procedures for collecting, exchanging and disseminating information on accidents and near-accidents to improve prevention methods and emergency procedures. This can probably best be done by creating committees with representatives from affected establishments in defined areas, chaired by a representative of the competent authority.
1.6	Adopt efficient and transparent procedures to ensure regular inclusive consultation with the affected public (e.g. people in the vicinity, public institutions and other interested or affected stakeholders) and to ensure that they are informed about the risks arising from the facility, safety measures and requested behaviour in the event of an accident.
1.7	<p>Introduce the procedures and mechanisms to ensure compliance with requirements on access to environmental information, public participation and consultation and access to justice in Seveso III Directive ensuring that requests for information are dealt with on the basis of provisions of Directive 2003/4/EC and that public consultation follows procedures set out in the Public Participation Directive. Also cases of refusal (confidentiality) to information must be based on sound grounds and that applicants can appeal such decisions. Also ensure that the national legal system provide review procedures taking into account procedures in the EIA Directive.</p> <p>Review and if need be improve the procedures to ensure access to certain Seveso related information and that interested parties are consulted in various issues, such as land-use projects. The legal apparatus must provide efficient and timely access to redress and appeal in case of failure to grant access to information or ensure public participation.</p>
1.8	Ensure that land-use planning prevents the approval of the location of new Seveso installations unless there is sufficient distance from residential areas and areas of public use.
1.9	Apply chemical classification rules for substances and mixtures to ensure that installations covered by the Seveso III Directive fully complies with the new CLP Regulation.
2	Regulation and Enforcement
2.1	Establish a system of notification of the use, processing or storage of certain dangerous substances above certain thresholds at establishments, and for the assessment of notifications, the approval of major-accident prevention policies, and, where appropriate, safety reports and emergency plans.
2.2	Ensure that operators notify competent authorities of their location, operations and use of dangerous substances.

2.3	Identify establishments incapable of creating a major-accident hazard.
2.4	Establish and implement a system of inspection, and carry out periodic inspections to ensure that operators are fulfilling the Directive's requirements. Ensure that the periodicity and procedures for inspections are such as to ensure more effective enforcement of safety rules. Ensure compliance with the new requirements on routine and non-routine inspections as from 1 June 2015. Ensure compliance with periodicity and those inspections identifying non-compliance is followed up with additional inspections. This inspection system might require hiring additional staff and to train existing and new staff in the new routines.
2.5	Establish procedures for investigating major accidents (with the assistance of the technical assistance body if necessary).
2.6	Ensure that designated institutions have prepared external emergency plans on the basis of the information supplied by the operator.
2.7	Ensure that internal and external emergency plans are reviewed, tested and where necessary revised and updated regularly and that the public is fully informed about them
2.8	Determine effective, proportionate and dissuasive penalties applicable to infringements of the national provisions adopted pursuant to this Directive and ensure that they are implemented.
3	Standards and Guidance Notes
3.1	Establish criteria for the assessment of potential hazards for identifying establishments where risks are increased.
3.2	Provide guidance notes on safety issues associated with the storage and use of dangerous substances, including information to be included in a notification and the content of safety reports and emergency plans.
4	Land-Use Planning
4.1	Incorporate criteria for land that can be allocated for developments involving dangerous substances in land-use planning policies.
4.2	Indicate in land-use plans the most appropriate land for establishments presenting hazards from dangerous substances.
4.3	Review individual applications for land-use permits in the light of the potential hazards from dangerous substances and policies
5	Communication and Consultation
5.1	Establish a procedure to ensure adequate public consultation when applications are made for land-use planning permits for establishments where dangerous substances are present.
5.2	Establish a procedure to ensure that the public has the opportunity to express its opinions on relevant matters and take account of those opinions when assessing notifications, safety reports and emergency plans.
5.3	Establish a procedure to ensure that the safety report from the operator and the inventory of dangerous substances are made available to the public. Provide safety information on major-accident hazards to the public.
5.4	Establish a procedure to ensure that the public is consulted during the preparation of, and is fully aware of, the actions outlined in external emergency plans.
5.5	Establish procedures to ensure that information is exchanged between establishments where the likelihood and the possibility or consequences of a major accident may be increased.
5.6	Provide sufficient information to Member States that may potentially be affected by major accidents with transboundary effects.
6	Reporting
6.1	Establish reporting systems to ensure that the data required (see below) are collected.
6.2	Report to Commission on: <ul style="list-style-type: none"> • establishments considered incapable of creating a major-accident hazard;

	<ul style="list-style-type: none"> • major accidents and results of analysis; • experience acquired on the prevention of major accidents; and • the implementation of the Seveso III Directive, which is due by 30 September 2019, and every four years thereafter
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3.1. Phasing Considerations

This Directive has a high technical content. Training, particularly for regulatory staff, will therefore be necessary in the early stages for successful implementation. Sufficient time should be allowed early in the implementation phases to properly undertake this training. It is equally useful to take into consideration experiences and successful procedures in other Member States. The assessment of notifications for both new and existing installations will require a high level of resources as large amounts of technical information will need to be reviewed. It may be practical to introduce requirements for existing establishments in phases on a sector-specific basis or gradually depending on size. Before implementation, technical criteria will need to be defined for assessments as identified in Section 3.1 above.

Candidate countries are advised to phase in the requirements of Seveso III Directive already from the start since this Directive mainly recast and reinforces some of the existing provisions. Such an integrated approach will be both more cost-efficient and ensure better compliance and enforcement. Given that Seveso III strengthens the provisions on public participation, access to environmental information and more efficient inspection procedures, these improvements will not only increase the safety in operating Seveso installations but will also improve the enforcement with other related IPC and chemicals legislation, such as the Industrial Emissions Directive (2010/75/EU), and the Classification, Labelling and Packaging of Substances and Mixtures Regulation ((EC) No. 1272/2008).

4. IMPLEMENTATION GUIDANCE

4.1. Planning and Regulation

- This Directive is concerned with health and safety and involves competent authorities concerned with these issues. The original Directive was introduced following an accident at Seveso, Italy, where dioxins were released into the atmosphere. However, further accidents, including the fireworks accident in Enchede, the Netherlands, and the cyanide spill from a mining facility in Baia Mare, Romania, have underlined the need for a broad scope of application to ensure coverage of the main activities involving dangerous substances.
- The key actors in the implementation of this Directive are the ministries responsible for industrial safety and land-use planning, the competent authority(ies) and the operators of industrial establishments where dangerous substances are present. Increasingly, insurance companies have a role to play, as do specialised consultants who are experienced in risk assessments and hazard analysis procedures.
- Address the issue of financial responsibilities of the operator in relation to major accidents, including issues related to insurance in consultation with key stakeholders.
- Plan the implementation of the strengthened requirements on providing access for citizens to information about risks resulting from activities of nearby companies, ensuring that cases of confidentiality are in line with the provisions of the Directive on Access to Environmental Information (2003/4/EC).
- Plan the procedures and national provisions in Seveso III Directive allowing for effective public participation especially in relation to individual projects involving new establishments, modifications to existing or changes in the surrounding environment which may increase the risk for major accidents. The candidate countries have discretion to decide these procedures in line with the national legal and procedural systems but compliance have to be ensured with the Public Participation Directive (2003/35/EC) and the EIA Directive (2011/92/EU). These procedures should ensure sufficient timeframes for consultation and taking into account comments and opinions in the final decision.
- Seveso III Directive emphasises the need to provide access to justice for citizens who have not been granted appropriate access to information or public participation. There must be a system of redress with reasonable timeframes.
- Ensure that new requirements on routine and non-routine inspections are fully applicable. This inspection system might require hiring additional staff and to train existing and new staff in the new routines. To save financial and human resources and ensure consistency and transparency, the inspection authority should aim at coordinate and combine the inspections with other relevant inspections deriving from legislation such as the Industrial Emissions Directive (2010/75/EU). For more information and advice on inspection practices, advise on IMPEL's studies.

4.2. Standards and Guidance

The Joint Research Center (JRC) through the Major Accident Hazards Bureau (MAHB) provides scientific and technical support to the DG ENV in implementation of the Seveso III Directive. The JRC serves as a centre of reference for risk assessment of industrial accidents, providing guidance and offering EU member States a means to evaluate, compare and improve technical approaches for designating land-use planning, emergency planning and public information zones. The JRC also provides technical support to capacity building for industrial accident preparation and preparedness in new EU and Candidate Countries, and in third countries in collaboration with other international organisations.

The Major Accident Hazards Bureau of the European Commission's Joint Research Centre has created the MINERVA portal <https://minerva.jrc.ec.europa.eu/en/minerva> to provide access to all information on current activities, relevant publications, and tools on control of major chemical hazards which MAHB produces on its own or in collaboration with others, or has received in its role as a centre of information exchange.

In order to assist Member States with the interpretation of certain provisions of the Seveso II Directive, the Commission in co-operation with Member States has elaborated the following guidance documents that are available from the Minerva Portal of Major-Accident Hazards Bureau (MAHB) <https://minerva.jrc.ec.europa.eu/en/content/minerva/f30d9006-41d0-46d1-bf43-e033d2f5a9cd/publications>.

Although the guidance documents have no legal status, they provide valuable guidance to industrial operators as well as to enforcement authorities, taking into account the fact that they represent the unanimous view of all Member States.

Major Accident reporting

In the context of reporting, the European Commission has established an official online reporting system eMARS to facilitate the exchange of information on accidents and near misses occurred in Seveso establishments and promoting lessons learned among the EU Member States and other OECD countries as well as the general public. The system contains events on chemical accidents and near misses reported to the eMARS system by the Member States themselves. Reporting an event into eMARS is compulsory for EU Member States when a Seveso establishment is involved and the event satisfies one or more of the six criteria set out in the Seveso Directive. The database is available at: <https://minerva.jrc.ec.europa.eu/en/emars/content>.

The SPIRS database was established in 2001 by the JRC at the request of the European Commission's Directorate General for the Environment (DG-ENV) as a voluntary database to which Member States could identify their Seveso establishments to the European Commission. In 2005, following an amendment to the Seveso II legislation (Directive 2003/105/EC), reporting of establishments to the European Commission's SPIRS database became mandatory. This obligation has subsequently been reconfirmed in the Seveso III Directive (2012/18/EU). The JRC manages this reporting system on behalf of DG-ENV in fulfillment of the Commission's obligations under the Seveso Directive and is the main point of contact for Member States in this regard. In early 2013, the Major Accident Hazards Bureau of the Joint Research Centre of the European Commission, in consultation with DG ENV, began developing the framework for eSPIRS. The purpose of the database is to support the Member States and the Commission in their risk management-related decision making processes by giving an insight into the geographical distribution of risk from Seveso establishments.

Another useful tool developed by the MAHB is ADAM (Accident Damage Analysis Module) designed to assess physical effects of an industrial accident in terms of thermal radiation, overpressure or toxic concentration resulting from an unintended release of a dangerous substance. For such a purpose, suitable models have been used and combined, to simulate the possible evolution of each accident: from the time of release to the final damage. This tool is specifically intended to guide the EU competent authorities for assessing the consequences of potential major accidents, when required. The outcome of ADAM calculations is of fundamental importance for any risk estimate, but it is also essential for decision support related activities such as for instance: the identification of cost effective protection measures, the organization of the internal and the external emergency plans, the provision of the correct information to the public, and the definition of land use around the industrial facility. In addition, the analysis of the physical effects of an accident involving a certain dangerous substance can also be used to assess the inherent potential of the substance to produce harm.

Example of Practice in a Member State

Netregs has produced Environmental Guidance for businesses in Northern Ireland and Scotland. This guide describes the types of business and the dangerous substances that the COMAH Regulations apply to. It explains the responsibilities of regulated sites, including assessing risks, how to deal with incidents and notifying with details of a site.

Information available at:

http://www.netregs.org.uk/library_of_topics/emergency_response/comah.aspx

Examples from a Member State:

United Kingdom: The SHAPE-RISK project is a European Commission (EC) funded co-ordination action undertaking work to share experience on accident and risk management relevant to the Seveso II, IPPC and ATEX Directives. The Environment Agency and the Health and Safety Laboratory (HSL) are members of SHAPE RISK consortium.

The overall objective of the SHAPE-RISK initiative is to optimise the efficiency of integrated risk management in the context of the sustainable development of the European process industry.

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More information available at: http://cordis.europa.eu/result/rcn/51077_en.html.

5. COSTS

The cost of implementing this Directive will primarily fall on the operators who will have to introduce safety equipment and implement safety procedures to prevent major accidents and hazards. This may result in increased capital and operating costs, as the Seveso requirements may necessitate changes into the structures of the facilities and storage places holding hazardous substances as well as protective shielding (buffer zones) in the immediate surroundings. There will also be costs associated with introducing the new regulatory structure and, in particular, set-up costs associated with training regulatory staff and assessing safety information submitted by the operators of existing establishments. For new installations, new to the Seveso procedures and requirement it may be necessary to hire external health and safety experts, especially in the initial phase involving the drafting of the MAPP, the safety report and the internal emergency plan.

For the public sector, most costs are related to the setting up of a competent authority and furnishing it with the necessary financial, human and technical resources as well as to review the documents submitted by the operators and to prepare an external emergency plan as well as to establish procedures for the consultation of stakeholders and the general public, devise an information system in case of a major accident and for collating and making available Seveso related information to the general public. Another significant cost is the on-going system of inspections with routine and non-routine inspections as well as ensuring that the relevant information including the first implementation report of Seveso III Directive, due in 2019, is submitted to the Commission. There will be some marginal costs also for ensuring coordination and consistency with the provisions and procedures of relevant EU legislation, such as the IED permitting and inspection scheme, the civil protection measures and the application of the Public Participation Directive (2003/35/EC), the Environmental Information Directive (2003/4/EC) and the EIA Directive (2011/92/EU). Furthermore, competent authorities have to produce some guidance material and possible technical criteria. These costs can be minimised by transferring approaches developed elsewhere in Europe. The requirement to review information regularly will mean that on-going costs will also be incurred. In addition, there will also be the costs of developing and communicating external emergency plans. These costs may be passed through to the operator. On the other hand, all these costs have to be set against the very high costs that could arise in the event of a major accident.

THE PAINTS DIRECTIVE

Official Title: Directive 2004/42/EC of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC (OJ L143/87, 30.4.2004),
as amended by:

Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008 adapting a number of instruments subject to the procedure laid down in Article 251 of the Treaty to Council Decision 1999/468/EC, with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part One (OJ L 311, 21.11.2008)

Directive 2008/112/EC of the European Parliament and of the Council of 16 December 2008 amending Council Directives 76/768/EEC, 88/378/EEC, 1999/13/EC and Directives 2000/53/EC, 2002/96/EC and 2004/42/EC of the European Parliament and of the Council in order to adapt them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (OJ L 345, 23.12.2008)

Commission Directive 2010/79/EU of 19 November 2010 on the adaptation to technical progress of Annex III to Directive 2004/42/EC of the European Parliament and of the Council on the limitation of emissions of volatile organic compounds (OJ L 304, 20.11.2010)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Directive 2004/42/EC of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in decorative paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC (commonly known as ‘the Paints Directive’) aims to prevent the negative environmental effects of emissions of volatile organic compounds (VOC) from decorative paints and vehicle refinishing products. The Directive is limiting the total content of VOCs in certain paints and varnishes and in vehicle refinishing products for reducing VOC emissions and thus reducing generation of ozone in lower atmosphere.

The Paints Directive covers products such as paints used on buildings, their trims and fittings and structures associated to buildings and products for vehicle refinishing. The specific sub-categories of products covered are listed in Annex I of the Paints Directive. For the decorative paints and varnishes, Annex II A to the Directive sets out two sets of limit values for the maximum contents of VOCs (in grammes per litre of the product ready for use). The first set of limit values applied from 1 January 2007 on. The second, and stricter, set of limit values apply since 1 January 2010.

Products belonging to these two product categories (decorative paints and vehicle refinishing products) can only be marketed in the EU if they comply with the specifications in Annex II and if they are labelled appropriately. Member States must develop a market surveillance system to verify the VOC content of the products covered by the Paints Directive. Each Member State has to designate an authority to be responsible for ensuring conformity with the provisions of this Directive and must put in place a system of effective, proportionate and dissuasive penalties for infringements.

The Paints Directive has been amended by Directive 2008/112/EC regarding changes brought by Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures. Amendments introduced by the Commission Directive 2010/79/EU concern adaptation to technical progress of Annex III concerning methods referred to in Art. 3(1).

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Designate a national authority to be responsible for ensuring compliance with VOC ceilings in products, for issuing labels for conforming products to be placed on the EU market, and for setting up a monitoring programme to verify compliance with Directive 2004/42/EC and to ensure that the Commission is informed about the designation. (Art. 5)
- Introduce a monitoring system to verify the phased-in VOC limit values applying from 2007 and 2010. This system should allow for products already on the shelves prior to these dates to be marketed for one additional year. (Arts. 3(4) and 6)

2.2. Regulation

- Ensure compliance with emission limit values set out for certain paints and varnishes and vehicle refinishing products, laid down in Annex I to Directive 2004/42/EC.
- Ensure that effective, proportionate and dissuasive sanctions are determined and applied to breaches of national provisions adopted pursuant to the Directive (Art. 10)
- Introduce adequate administrative and regulatory procedures and the legal requirement to ensure that for sub-categories of decorative paints and vehicle refinishing products listed in Annex I, these products are only allowed to be marketed in the EU if they comply with the specifications in Annex II in terms of the limit values and where they bear the appropriate labelling. (Arts. 3 and 4)
- Introduce a licensing system for the granting of individual licences for the sale and purchase of limited quantities of paints and varnishes with a VOC content exceeding the values in the annex, where such products are used for the restoration and maintenance of buildings and vintage vehicles designated by the competent authorities as having a particular historic and cultural value. (Art. 3(3)).
- Ensure that paints, varnishes and vehicle refinishing products listed in Annex I to Directive 2004/42/EC, which meet the requirements regarding maximum VOC content in Annex II, bear a label showing the relevant sub-category of the product and the relevant VOC limit values and the maximum content of VOC of the product in a ready-to-use condition (Art. 4).

2.3. Monitoring

- Set up a monitoring programme for verifying compliance with Directive 2004/42/EC in regard to ensuring that paints, varnishes and refinishing vehicle products that are allowed to circulate freely on

the EU market comply with the limit values for VOC concentrations and are appropriately labelled (Art. 6, Directive 2004/42/EC).

2.4. Reporting and Information

- Member States must also report to the Commission on:
 - the implementation of the Directives (Art. 14)
 - national provisions setting out rules on penalties, which are effective, proportionate and dissuasive (Art. 10).
- Member States had to inform the Commission about the competent authority designated by the Member State to ensure compliance with the requirements of Directive 2004/42/EC (Art. 5)
- Member States have to report the results of the monitoring programme to verify compliance with Directive 2004/42/EC and the categories and quantities of products licensed according to Article 3(3). (Art. 7)

The first reports had to be submitted by 30 October 2005 and thereafter a report must be submitted every five years. The second report covering the year 2010 was due by 1 July 2012 in view of the more stringent Phase II VOC limits (Annex II to the Paints Directive) that applied for paints and varnishes from 1 January 2010. Member States reported using a common format established by the Commission Decision 2010/693/EU of 22 July 2010 establishing a common format for the second report of Member States on the implementation of Directive 2004/42/EC of the European Parliament and of the Council on the limitation of emissions of volatile organic compounds. Based on the Member States' reports the Commission has adopted second report to the European Parliament and to the Council providing an overview of the implementation of the Paints Directive by Member States, i.e. Report on the implementation of Directive 2004/42/EC of the European Parliament and of the Council on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC (<http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A52013DC0704>.)

Examples from a Member State: Legislative Approach

United Kingdom: The Volatile Organic Compounds in Paints, Varnishes and Vehicle Refinishing Products Regulation, 2005, as amended (repealed by Volatile Organic Compounds in Paints, Varnishes and Vehicle Refinishing Products Regulations 2012 (S.I. No. 1715 of 2012)/ <http://faolex.fao.org/docs/pdf/uk115667.pdf>), is a statutory instrument that sets technical specifications for the maximum content limit values of solvents for decorative paints and varnishes, and for vehicle refinishing products in line with the obligations under Directive 2004/42/EC. From 1 January 2007, manufacturers will only be permitted to sell products that meet the solvent limits for the products in their ready-to-use state. The Regulation transpose the new analytical methods for determining VOC content contained in Directive 2010/79/EU on the adaptation to technical progress of Annex III to Directive 2004/42/EC .

The UK Government consulted over 300 stakeholders: industry bodies; product manufacturers; product retailers; environmental organisations; organisations with an interest in the preservation of historic buildings or vehicles; and local authorities on the implementation of the Directive between 1 April and 27 June 2005

The UK has chosen to take advantage of the derogation allowing continued use of limited amounts of "old-style" paints for the authentic restoration and maintenance of historic buildings and vehicles. This can be done either directly in implementing regulations or, as in the case of the UK, in separate regulations that implement the derogation.

In terms of considering the implementation of Directive 2004/42/EC so as to ensure cost-efficiency, potential effects/results from the national measures and acceptance by all major stakeholders, and taking into account equity aspects, the UK considered three main options.

Options 1-2: Implement CEPE Phase I and II voluntary agreement — proposed limit values for 2007 and 2010.

This option illustrates what might have happened if European legislation had not been adopted, as there has already been a considerable voluntary shift away from solvent-based paint products to water-based products. The European Paint Manufacturers Association (CEPE) asked its national members to comply voluntarily with a product-based "Decorative Paints Directive". The 26 members of the British Coatings Federation (BCF) adopted this voluntary agreement in 1998. There are five or six small companies that are not members of the BCF but that would be required to adopt VOC limit values under the Directive.

Although CEPE proposed limit values for the first phase of their voluntary agreement that correspond to the 2007 limit values under the Directive and the first phase has almost been met in the UK, CEPE Phase II proposals are less stringent. Furthermore, the UK took the position that a legislative approach will ensure equality across the whole European sector. It was also concluded that this option represented a lower limit of benefits for the UK from VOC reductions.

Option 3: Implement the limit values for products as contained in the Directive.

This option fully implements the UK's obligations under Phase I and Phase II of the Directive. The UK assessed the VOC reductions as a result of implementing this option, the physical benefits of this option, and putting a value on these benefits where possible.

3. IMPLEMENTATION GUIDANCE

3.1. Regulation

It would be cost-efficient to ensure that the competent authorities designated to ensure the implementation and application of Directive 2004/42/EC carry out their regulatory, supervisory and monitoring activities in close coordination with the authorities responsible for implementing air emission legislation, including Directive 2001/81/EC on national emission ceilings.

3.2. Monitoring and enforcement

Article 6 of Directive 2004/42/EC requires Member States to set up a monitoring system to verify compliance with the Directive. It is recommended to have this monitoring system linked to efficient and dissuasive sanctions and even to impose some level of self-regulation on operators to reduce the administrative costs. However, where such self-regulation is introduced it is crucial to ensure that sanctions in the case of non-compliance are stringent.

Based on the 2013 Report on the implementation of Directive 2004/42/EC of the European Parliament and of the Council on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC Member States have a variety of approaches to monitoring compliance. These may involve physical checks (e.g. sampling and analysis of paint products; visual inspection of labels) and/or a more remote auditing approach with checks on the documentation submitted by producers. In some cases, the more onerous process of inspecting / sampling is only undertaken if triggered by auditing observations. To promote more effective monitoring, some Member States indicated consideration of alternative approaches to compliance verification e.g. requiring manufacturers to complete a questionnaire, which is returned with product samples, self-certification schemes²⁵⁹.

As regards actions to ensure compliance the most common sanction in case of non-compliance with the VOC content limits is withdrawal of products from the market, as required by the Paints Directive, whereas in case of a breach of labelling requirements operators are usually requested to correct the mistake within a certain period of time, before they are prosecuted or before imposing financial sanctions.

²⁵⁹COM/2013/0704 final, <http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A52013DC0704>.

4. COSTS

A large part of the costs for ensuring compliance with the Directives must be borne by operators and industry. They have to make the necessary investments to ensure that their activities and their products comply with the VOC limit values. Producers of paints and varnishes have to take the necessary steps to substitute VOCs with other less harmful substances.

However, there are several costs linked to the implementation and application of Directive 2004/42/EC. Most of the costs are related to administrative procedures and the monitoring system. These include:

- costs for setting up a regulatory system to ensure that products listed in Annex 1 to Directive 2004/42/EC meet the maximum concentrations of VOCs;
- cost of designing and implementing a monitoring programme;
- costs of setting up a regulatory and administrative system to ensure that paints and varnishes conforming to the maximum levels of VOCs are labelled appropriately and that products not conforming and/or not appropriately labelled are not allowed to be placed on the EU market;
- cost of compiling and processing data for the mandatory reporting according to Directive 2004/42/EC;
- costs for administering the labelling system.

It should be noted that the implementation of this Directive not only involves costs to the Member States and to the industrial sector but also has benefits that should equally be emphasised. For instance, the UK is highlighting the benefits of Directive 2004/42/EC in terms of benefits from national VOC emission reductions and their impact on human health and the environment etc.

Examples from a Member State:

United Kingdom:

A UK report (Explanatory memorandum to the Volatile Organic Compounds in Paints, Varnishes and Vehicle Refinishing Products Regulations 2005, No. 2773) estimated that the main costs for implementing Directive 2004/42/EC will be incurred by industry. If the Directive were to be transposed, each of the 32 UK paint manufacturers might expect to face an annualised cost of £1.5 million, of which £0.25 million will be capital costs and £1.25 million will be operating costs. Costs for a solvent manufacturer and a resin manufacturer are estimated at £0.57 million and £1.58 million respectively. For an average small body shop in the vehicle refinishing sector, the mean annualised cost is £604. This is made up of £493 capital costs and £111 operating costs.

Although the costs to the government to fulfil the monitoring and reporting obligations still had to be established, it was estimated that these will be minimal administration costs. Furthermore, the government introduced a system of reduced regulatory fees but will review the fee level after either 12 or 18 months, to ensure that local authority regulators are reimbursed to cover all the costs involved in regulation. The costs for implementing Directive 1999/13/EC will be of a greater magnitude but here also most of the costs are expected to be borne by industry.

Source: http://www.legislation.gov.uk/uk/si/2005/2773/pdfs/uk-siem_20052773_en.pdf

THE ECO-MANAGEMENT AND AUDIT SCHEME REGULATION

Official Title:

Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009)

2011/832/EU: Commission Decision of 7 December 2011 concerning a guide on EU corporate registration, third country and global registration under Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)(OJ L 330, 14.12.2011)

2013/131/EU: Commission Decision of 4 March 2013 establishing the user's guide setting out the steps needed to participate in EMAS, under Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) (OJ L 76, 19.3.2013)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The Eco-Management and Audit Scheme, EMAS, is a voluntary environmental management tool for companies and other organisations to evaluate report and improve their environmental performance. The key features of EMAS are performance, credibility and transparency. Performance through annually updating the environmental policy, including targets and actions, and the regular evaluation of the environmental performance of the registered organisations and the on-going demonstration of legal compliance with all applicable environmental legislation creates credibility, which further is enhanced through the third-party verification by independent environmental verifiers. This ensures that the EMAS registered organisations live up to their environmental commitments, guarantees the effectiveness continuous improvement of environmental performance and ensures that information in the environmental statement is reliable, credible and accurate. Transparency is attained through the public disclosure of the environmental statement and the correctness of the environmental information in it. In August 2014, more than 4,000 organisations and approximately 7,500 sites were EMAS registered.

The EMAS Regulation 1836/93 was first introduced in July 1993 as an environmental policy tool towards the Community's goal of sustainable development. The EMAS scheme was open for voluntary participation by organisations from 1995, and its scope restricted participation to sites operating industrial activities. In 1996, the international environmental management system standard, EN ISO 14001:1996 was introduced.

In 2009 the EMAS Regulation was revised and modified for the second time leading to the EMAS Regulation (EC) No 1221/2009), which entered into force on 11 January 2010.

The aim of the EMAS Regulation is to encourage organisations whose activities have an adverse environmental impact to continuously improve their environmental performance through a voluntary eco-management and audit scheme. This aim is achieved through:

- Performing an environmental review that cover the areas identified in out in Annex I of the to this Regulation. The main aim of the environmental review is the identification of the applicable legal requirements relating to the environment and the identification of all direct and indirect environmental aspects with a significant impact on the environment, qualified and quantified as appropriate by compiling a register of those identified as significant.
- Introduction and implementation of environmental management system by organisations as well as providing an objective and periodic assessment of the effectiveness the management system to ensure on-going legal compliance and achieve continuous improvements of the environmental performance;
- Training and active involvement of the employees of such organisations;
- Provision of information to the public and other interested parties.

Participating organisations are required to establish and implement policies, programmes and management systems for their sites. These must be independently examined to ensure that they comply with the requirements of the EMAS Regulation. Information about the environmental policy, its environmental programme and environmental management systems must be made available to the public. According to the Regulation "organisation" means a company, corporation, firm, enterprise, authority or institution, or part or combination thereof, whether incorporated or not, public or private, that has its own functions and administrations.

Any organisation that would like to take part in the scheme must:

- adopt an environment policy establishing the objectives and principles of its environmental measures;
- conduct an environmental review of its activities, products and services, unless the organisation has a certified, recognised environmental management system;
- introduce an environmental management system, setting out the specifics of EN ISO 14001:2004 (in accordance with Annex I and II). These requirements, which are mandatory for organisations participating in the EMAS scheme, cover items such as:
 - general requirements;
 - environmental policy;
 - planning (environmental aspects, legal requirements, objectives, targets and programmes);
 - implementation and operation (e.g. resources, roles and responsibility, competence, training and awareness raising, communication, documentation, control of documents, operational control, emergency preparedness and response);
 - checking (e.g. monitoring and measurement, evaluation of compliance and non- conformity, control of records, internal audit);
 - management review.
- carry out regular internal environmental audits (in accordance with the requirements set out in Annex III) and make an environmental statement, including a description of the organisation and its activities, products and services; the organisation's environmental policy and environmental management system; a description of its environmental impact and the aims with regard to the impact; the environmental performance of the organisation and the date of the statement. That statement must be validated by an environmental verifier whose name and number must appear in the statement;
- register the validated statement with the relevant Member State body; and make the statement available to the public.

Annex V sets out the logo that may be used by an EMAS-registered organisation.

The EMAS Regulation introduced the following novelties, which are strongly linked to the improvement of the applicability and credibility of the scheme as well as to strengthen the visibility and outreach:

- Transitional registration procedures to facilitate introduction of EMAS;
- Revised audit cycles to further improve applicability for SMEs;
- Corporate registration to ease administrative and financial burdens on organisations with several EMAS registered sites;
- Cluster approach to provide specific assistance to clusters of organisations in the development and implementation phases of EMAS registration;
- Environmental core indicators to adequately document environmental performance and create multi-annual comparability within and between organisations;
- Assistance from Member States to organisations on compliance with legal requirements relating to the environment to ease EMAS registration for organisations;

- Enhanced legal compliance to further strengthen the credibility of the scheme;
- Single EMAS logo to communicate EMAS in one coherent and distinctive way;
- EMAS Global to enable the global uptake of the scheme by making EMAS certification possible for organisations and sites located outside the EU Community;
- Informational and promotional activities of EU Member States and the European Commission to support EMAS;
- Recognition of other Environmental Management Systems to facilitate upgrade from existing Environmental Management Systems to EMAS;
- The concept of sectoral reference documents (SRD) that identify best environmental management practices, sector specific environmental performance indicators and set benchmarks of excellence and rating systems identifying environmental performance levels, where appropriate.

Other instruments that are useful for applying the EMAS Regulation include:

- Commission Decision 2013/131/EU of 4 March 2013 establishing the user's guide setting out the steps needed to participate in EMAS, under Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS). The guide outlines the main elements and steps to be undertaken by an organisation that intends to participate in the scheme. The document aims to increase the overall uptake of the EMAS management system by facilitating the entry of organisations into the scheme.
- Commission Decision 2011/832/EU concerning a guide on EU corporate registration, third country and global registration under Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS). In December 2011 the Commission published the first guidance document in compliance with EMAS III Regulation. Commission Decision 2011/832/EU of 7 December 2011 provides further clarifying information and guidance on Articles 3 and 46(4) of Regulation (EC) No 1221/2009 which allows EU corporate registration, third country and global registration.
- Communication from the Commission — Establishment of the working plan setting out an indicative list of sectors for the adoption of sectoral and cross-sectoral reference documents, under Regulation (EC) No 1221/2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS). In December 2011, the Commission established the working plan setting out an indicative list of sectors for the adoption of sectoral and cross-sectoral reference documents, under Regulation (EC) No 1221/2009.

Sectoral reference documents (SRDs)

Though the primary aim for developing sectoral reference documents is to help and guide EMAS companies in a specific sector, contributing to a harmonised and enhanced application of the EMAS Regulation, the help and guidance provided in these documents can also be used in a given sector to improve environmental performance independently of an EMAS registration.

EMAS Sectoral reference documents will also help pave the way on resource efficiency, through the definition of sector specific benchmarks and indicators of good performance. The European Commission established an indicative list of priority sectors for which Sectoral Reference Documents should have been elaborated. This

was published in a European Commission Communication in 2011, i.e. Establishment of the working plan setting out an indicative list of sectors for the adoption of sectoral and cross-sectoral reference documents, under Regulation (EC) No 1221/2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS). The indicative list of priority sectors include:

- Wholesale and Retail trade,
- Tourism,
- Construction,
- Public Administration,
- Agriculture,
- Crop production and Animal production,
- Manufacture of electronic and electrical equipment,
- Car manufacturing,
- Manufacture of fabricated metal products, except machinery and equipment,
- Food and beverage manufacturing,
- Waste management,
- Telecommunications.

So far, draft Sectoral Reference Documents were elaborated for the tourism and construction sectors. Work is at the final stage for the public administration sector, for agriculture - crop and animal production and for the food and drink industry. Work is undergoing for car manufacturing and manufacture of electronic and electrical equipment. It has also recently started for the three following sectors: waste management, fabricated metal products manufacturing and telecommunications. The Retail trade SRD was completed in 2015 and can be found in Commission Decision (EU) 2015/801 of 20 May 2015 on reference document on best environmental management practice, sector environmental performance indicators and benchmarks of excellence for the retail trade sector under Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS). More information about the work carried out for specific sectors can be found on <http://susproc.jrc.ec.europa.eu/activities/emas/>.

The main criteria taken into account in producing this list of sectors were the following:

- The environmental impact of the sector within the Community (e.g. taking into account four indicators: Global Warming Potential (GWP), Acidification Potential (AP), Photochemical Ozone Creation Potential (POCP) and Marine Eutrophication Potential (MEP) and their relevance to the Analysis of the Life Cycle Environmental Impacts related to the final Consumption of the EU-2.
- The level of EMAS uptake in the sector (it is important that sectoral reference documents cover sectors where the EMAS uptake is higher, thereby contributing to a faster harmonised application of the Regulation.
- The potential for environmental improvements in the 'value chain' of the sector (value chain commonly refers to a sequence of related activities stemming from design and product/service development, manufacturing, marketing and sales, after sales service, disposal and recycling).

EMAS registered sites are classified according to NACE Regulation (EC) 1893/2006. These codes represent the statistical classification of economic activities within the EU.

More information on the EMAS can be obtained at:

- DG ENV, EMAS site: <http://ec.europa.eu/environment/emas/>.
- Commission Decision (2011/832/EU) concerning a guide on EU corporate registration, third country and global registration under Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS): <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011D0832:EN:NOT>
- Communication from the Commission (2011/C 358/02) — Establishing the working plan setting out an indicative list of sectors for the adoption of sectoral and cross-sectoral reference documents, under Regulation (EC) No 1221/2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS): <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:358:0002:0005:EN:PDF>
- NACE codes: http://eurlex.europa.eu/LexUriServ/site/en/oj/2006/l_393/l_39320061230en00010039.pdf
- Case studies: http://ec.europa.eu/environment/emas/casestudies/index_en.htm
- EMAS register/database: <http://ec.europa.eu/environment/emas/register/>
- Annual EMAS AWARD: <http://ec.europa.eu/environment/emas/emasawards/index.htm>
- Study on Costs and Benefits²⁶⁰: http://ec.europa.eu/environment/emas/pdf/news/costs_and_benefits_of_emas.pdf
- Publications on best environmental practices: <http://susproc.jrc.ec.europa.eu/activities/emas/>

²⁶⁰ Milieu Environmental Law and Policy, RPA, *Study on the Costs and Benefits of EMAS to Registered Organisations*, Study Contract No. 07.0307/2008/517800/ETU/G.2, October, 2009

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Designate an independent competent body, having sufficient financial and human resources to be responsible for registration of organisations and sites and overall control the entry, maintenance, suspension and deletion of organisations on the register. Member States have to decide whether:
 - The competent body shall also be responsible for the registration of organisations located outside. (Art. 11)
 - The competent body shall be at national, regional or local level the EU. (Art. 11)
 - The competent authority shall issue a fee for registration, accreditation, verification, suspension etc. (has to be reasonable and in line with conditions set out in Article 39). (Art. 13(2))
- Ensure that the Competent Bodies carry out their obligations regarding the registration procedures:
 - establish procedures for the registration of organisations, which shall include rules for taking into account observations of interested parties (e.g. Accreditation and Licensing Bodies, enforcement authorities, representation bodies of the applying organisations), refusal of registration, suspension or deletion of organisations and how to resolve appeals and complaints against decisions of the competent bodies. (Art. 12(1))
 - establish and maintain up-to-date a register of organisations registered in their Member States, comprising reference to their environmental statement and publicly available on a website (Art. 12(2))
 - register organisations and provide them with registration number if conditions in Art. 13(2) are fulfilled and documents referred to in Article 5(2) are submitted, verification and validation has been carried out in accordance with Arts. 25-27, documents verify that the applying organisations comply with legal requirements on the environment, absence of open complaints from third parties, evidence received assures that organisation meets the requirements of the Regulation. Ensure that a negative decision to register is sufficiently justified (Art. 13)
 - renew the registration if conditions in Art. 14 are met (received an environmental statement, a completed form with the content set out in Annex VI) and no evidence regarding irregular verification or validation, non-compliance with environmental provisions, no open complaints from third parties and no evidence of failure to meet requirements in EMAS III Regulation. (Art. 14)
 - suspend or delete non-complying organisations from the register, after giving them a chance to submit their views and supporting documentation (environmental statement, information in Annex VI) and after having consulted the concerned parties including the registered organisation. Non-compliance can for instance be a supervision report from the Accreditation or Licensing Body or the enforcement authority. However, suspension shall be lifted in case the Competent Body receives satisfactory information on compliance with EMAS Regulation. (Art. 15)

- The Competent Bodies have to take the necessary measures to ensure active participation in the Forum of Competent Bodies referred to in Art. 16 and in the Peer Evaluations organised by this forum (as referred to in Art. 17). This includes:
 - Prepare for and participate in the annual meetings of the Forum of Competent Bodies and comply with the rules of procedures and guidance established (e.g. guidance on registration procedures). (Art. 16)
 - Prepare for and participate in the peer evaluation organised by the Forum of Competent Bodies with the view to assess conformity with registration system of all Competent Bodies. The peer evaluation shall be carried out at least every four years and be in the form provided by the Commission. (Art. 17)
- Appoint Accreditation Bodies, and possibly also a Licensing Body, pursuant to Art. 4 and 5(2) of Regulation (EC) No 765/2008, which will be responsible for the accreditation of environmental verifiers, issuing of licences and the supervision of the activities carried out by environmental verifiers (Art. 28(1)). Some of their tasks are:
 - Assess the verifiers' competence;
 - Determine the scope of the accreditation or the licence of environmental verifiers taking into account Regulation (EC) No 1893/2006;
 - Establish accreditation and licensing procedures (approval, suspension, withdrawal, supervision) including hearing observations from concerned parties;
 - Establish and maintain a list of environmental verifiers and scope of activities to be communicated towards the Commission and the Competent Body;
 - Issue supervision report on whether the tasks of the environmental verifier were adequately performed and send the report to the relevant Competent Body;
 - If need be suspend or withdraw accreditation or licence after first consulting the concerned parties;
 - Meet at annual basis in the Forum of the Accreditation and Licensing Bodies;
 - Take part of the peer evaluation of Accreditation and Licensing Bodies as organised by the Forum of Accreditation and Licensing Bodies. (Arts. 28-31)
- Take adequate measures to encourage the participation of small organisations, inter alia, by: facilitating access to information and support funds specially adapted to them; ensuring that reasonable registration fees encourage their participation; promoting technical assistance measures. (Art. 36)
- Encourage local authorities to provide, in participation with industrial associations, chambers of commerce and other concerned parties, specific assistance to clusters of organisations to meet the EMAS requirements. Take measures to encourage organisations to implement an environment management system, particularly encouraging a step-by-step approach leading to EMAS registration while keeping in mind the objective of avoiding unnecessary costs for participants. (Art. 37)
- Take appropriate legal or administrative measures in case of non-compliance with the EMAS Regulation and put in place effective provisions against the use of the EMAS logo in violation of this Regulation. (Art. 40)

- Take measures to promote the use of EMAS both among organisations and companies highlighting the environmental and economic benefits. These measures should include consultation with key stakeholders, particularly involving companies in the sectors listed to the EC Communication of 2011 (i.e. the indicative list of priority sectors for the Sectoral Reference Documents). The measures set out in Articles 34-38 have to be taken into account and Member States should consider adopting a promotional strategy. Some examples of promotional measures:
 - Furnish the public and the interested organisations with relevant information;
 - Exchange of knowledge and best practices on EMAS;
 - Development and dissemination of EMAS promotional tools;
 - Provision of technical support to organisations relevant to their EMAS marketing activities;
 - Encouragement of partnerships for enhanced EMAS promotion;
 - Specific measures targeting SMEs (facilitate information access and access to support funds, reduced participation fee);
 - Promotion at local level to provide specific assistance to clusters of organisations.
- Take into account EMAS organisations in development of new legislation, public procurement. (Art. 33)
- Consider whether in the case of existing non-formal environmental management schemes, to upgrade to EMAS. In such case comply with the provisions in Article 45 of the EMAS Regulation, e.g. concerning submitting a request for transition to the Commission
- Establish the procedures and systems to ensure that Competent Bodies, upon request of a SME, extend for that organisation the three-yearly frequency referred to in Article 6(1) up to four years or the annual frequency referred to in Article 6(2) from one to two years, provided that the environmental verifier verifies compliance with certain conditions. (Art. 7(1))

2.2. Regulation

- Ensure that the EMAS is also open to non-European organisations and European organisations operating in third countries (Articles 1 and 11 of EMAS Regulation).
- Ensure that participants in the eco-management and audit scheme take the actions required in order for their sites to be registered in the scheme, including:
 - conducting an environmental review;
 - introducing an environmental programme and environmental management system;
 - carrying out environmental audits at registered sites;
 - establishing an environmental management system document including the specifics in Annex II;
 - preparing an environmental statement;

- having the environmental programme, management system, audit procedure and environmental statements independently reviewed to verify that they meet the requirements of the Regulation;
 - making the environmental statement available to the public;
 - establishing and implementing procedures for emergency preparedness and response;
 - carrying out training and developing awareness procedures in regard to environmental aspects and the EMAS;
 - developing checking procedures regularly to monitor and measure operations that can have a significant environmental impact and to document information to monitor performance and conformity with the set environmental objectives and targets;
 - repeated reviews of the organisation's environmental management system to ensure that the system is adequate and effective, also reviewing the results of internal audits, communications, environmental performance and the meeting of objectives and targets (Arts. 4, 5, and annexes).
- Ensure that organisations with multiple sites located in one or more Member States or third countries can register these multiple sites under EMAS and that these companies/organisations receive additional information and guidance about the possibilities of EMAS registration in line with the Global Guidance set out in Commission Decision 2011/832/EC. (Arts. 3 and 46(4), EMAS Regulation).
 - Ensure that organisations have the updates of their environmental statement validated in accordance with the guidance set out in Annex VII to EMAS Regulation.
 - Ensure that the environmental verifiers comply with all relevant requirements and that they perform the duties set out in Arts. 19-27.
 - Ensure that only one logo is used by EMAS registered organisations. The EMAS logo using the wording 'Verified Environmental Management' in conjunction with the registration number (set out in Annex V of EMAS) may be used only by registered organisations and only as long as their registration is valid. The logo shall always bear the registration number (except where used by the Competent Bodies, Accreditation and Licensing Bodies, national authorities and other stakeholders for marketing reasons). (Arts. 10 and 35)
 - any environmental information published by a registered organisation may bear the EMAS logo provided that such information makes reference to the organisation's latest environmental statement or updated environmental statement.
 - the logo shall not be used on products or their packaging and in conjunction with comparative claims concerning other activities and services or in a way that may create confusion with environmental product labels.
 - Monitor that the environmental verifiers used for EMAS comply with requirements in Art. 18 of EMAS Regulation, e.g. that they assess/verify:
 - whether the organisation's environmental review, environmental policy, management system, audit procedures and their implementation comply with the requirements of EMAS Regulation and are appropriate and reliable;
 - whether the organisation comply with environmental legal requirements;

- whether the organisation is continuously improving its environmental performance;
 - the reliability, credibility and correctness of the data and information in the environmental statement (using Annex IV), the sectoral reference documents and other environmental information;
 - prior to registration whether the environmental management system is in accordance with Annex II and that the audit programme has commenced pursuant to Annex III;
 - prior to renewal of registration check, whether an internal audit of environmental performance has been carried out, whether ongoing compliance with environmental requirements and whether the organisation has produced an updated environmental statement.
- Take legal or administrative measures in cases of non-compliance with the provisions of the Regulation, which should include penalties in case of mis-use of the EMAS logo and suspension of EMAS registration in case of non-compliance with EMAS provisions and procedures. Member States should consider using provisions concerning unfair business-to-consumer commercial practices in the internal market set out in Directive 2005/29/EC (Art. 40).

2.3. Information and Reporting

- Provide information, in conjunction with Competent Bodies, enforcement authorities and other relevant stakeholders, to promote the EMAS scheme and provide information to the public about the objectives and principal components of EMAS and information to organisations about the contents of the Regulation. (Art 33 and 34)
- Inform companies and the public about the objectives of the Regulation and how the eco-management and audit scheme works. This information might include promotional campaigns and publications and tasks be carried out in cooperation with industry organisations and relevant stakeholders. Also a number of documents have to be made publicly available such as EMAS register, guidance documents or peer evaluation report (produced by the Forum of Competent Bodies), Peer evaluation of Accreditation and Licensing Bodies. In addition, the Commission makes publicly available a register of environmental verifiers and registered organisations; a database of environmental statements in electronic format; a database of best practices on EMAS and a list of Community resources for the funding of EMAS implementation and related projects and activities. (Arts. 34, 16(4), 17(5), 31(2), and 42(2))
- Carry out promotion activities for EMAS. These activities may include the promotion of exchange of knowledge and best practices on EMAS among all concerned parties, the development of effective tools for EMAS promotion and sharing them with organisations. These activities may also include the provision of technical support to organisations implementing EMAS-related marketing activities and the encouragement of partnerships among organisations for EMAS promotion. (Art. 35)
- Member States or their delegated bodies shall provide organisations with information and assistance possibilities regarding their environmental legal obligations, especially focusing on SMEs. Enforcement authorities should reply to queries regarding applicable legal requirements falling within their competence. (Art. 32)

- The Member States or their competent bodies or accreditation or licensing bodies must report to the Commission on:
 - the structure and procedures relating to the functioning of the Competent Bodies and Accreditation and Licensing Bodies (Art. 41(1))
 - on the measures to implement EMAS Regulation every two years (Art. 41(2))
 - changes in the register of EMAS organisation on a monthly basis, directly or via the national authorities as decided by the Member States concerned (Art. 12(3))
 - ensure that the Forum of Competent Bodies submit guidance documents and documents referring to the peer evaluation as well as the peer evaluation report (Arts. 16(3) and 17(5))
 - a list of environmental verifiers and their scope of accreditation or licence on a monthly basis, comprising changes to that list (Art. 28(8))

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Regulation are summarised in the Table below.

Table 11. The Eco-Management And Audit Scheme Regulation - Key Implementation Task

THE ECO-MANAGEMENT AND AUDIT SCHEME REGULATION - KEY IMPLEMENTATION TASK	
1	Planning
1.1	Appoint a competent body that will be responsible for the registration of organisations. The composition of the competent body must be independent and neutral.
1.2	Designate parties to represent the Member State at the Forum of Competent Bodies chaired by a Commission representative.
1.3	Establish an accreditation body responsible for the assessment and accreditation of environmental verifiers. A consultation procedure should be established between the parties involved.
1.4	Set up the relevant systems, mechanisms and ensure sufficient resources for Competent Bodies in carrying out their tasks, particularly under Art. 12-16
1.5	Take promotional measures and envisage adopting a promotional strategy to be updated regularly
1.6	Undertake training of personnel in the competent body and the accreditation body to ensure that: <ul style="list-style-type: none"> • they are fully conversant with the objectives and provisions of the Regulation; • they fully understand the administrative requirements; • the accreditation body has the capability to assess those individuals or organisations wishing to become accredited environmental verifiers and to supervise them, as well as verifiers accredited in other countries.
1.7	Establish a mechanism for application to be an accredited verifier.
1.8	In accordance with current practice in the Member State, establish a system of fees to cover the cost of administration of the system (option).
1.9	The government should implement a programme of dissemination of information on the scheme to organisations and local government and the public.
1.10	The government should develop mechanisms for training and technical support to small and medium-sized enterprises. In particular, this should include measures to provide organisations with the expertise necessary to set up environmental policies, programmes and management systems, conduct audits and prepare and validate statements.
1.11	The competent body should develop a mechanism for application to the scheme (this is done by the accreditation system).
1.12	Take the necessary measures to ensure that the scheme is open to non-European organisations and European organisations operating in third countries.
2	Regulation
2.1	The accreditation body must establish and maintain a list of accredited environmental verifiers.
2.2	The competent body must establish and maintain a list of registered sites.
2.3	Ensure that organisations with multiple sites located in one or more Member States or third countries can register these multiple sites under EMAS and that these organisations receive additional information and guidance in line with the Global Guidance

2.4	The competent body must establish mechanisms of communication with other environmental regulatory bodies so that it has the ability to check whether a site is in compliance with all relevant environmental legal requirements before awarding registration. Lines of communication should also be established to ensure that the competent body will be made aware of any future breaches of environmental regulations.
2.5	The government must ensure that there are mechanisms and structures in place to be able to take legal or administrative measures in the event of non-compliance with the provisions of the Regulation.
3	Information and Reporting
3.1	The Member State must inform the Commission of the designation of the competent body.
3.3	Provide organisations with information and assistance possibilities regarding their environmental legal obligations, especially focusing on SMEs
3.4	Ensure that the following information is reported to the Commission: <ul style="list-style-type: none"> • the structure and procedures relating to the functioning of the Competent Bodies and Accreditation and Licensing Bodies • on the measures to implement EMAS Regulation every two years • changes in the register of EMAS organisation on a monthly basis, directly or via the national authorities as decided by the Member States concerned • ensure that the Forum of Competent Bodies submit guidance documents and documents referring to the peer evaluation as well as the peer evaluation report • a list of environmental verifiers and their scope of accreditation or licence on a monthly basis, comprising changes to that list

3.2. Phasing Considerations

In order to implement the Regulation, some procedures must be established. In establishing these procedures, it is advisable to keep in mind the requirements of ISO 14001, the EMAS Global Guidance and the novelties brought by the EMAS Regulation.

The phasing of key tasks is outlined below:

Phase one:

- Establish competent body and accreditation body.
- Put into place the various procedures for registration, verification etc.
- Promote EMAS widely informing organisations about the benefits and its operation.
- Prepare and issue guidance to organisations on the application of the scheme.

Phase two:

- Organisations' take-up of scheme.
- Monitoring of running of EMAS

One of the most time-consuming factor associated with implementation is probably trying to promote EMAS, ensuring a wide take up among organisations. It may take a number of years before there is any significant take-

up. However, as more organisations take part in the scheme, this will create momentum in the growth of the scheme through pressure along the supply chain. For instance, clients with environmental management systems will exert pressure on their suppliers by requesting information about the supplier's environmental performance. This will stimulate the suppliers to improve their environmental performance and participate in the scheme.

4. IMPLEMENTATION GUIDANCE

This section outlines practical guidance on the implementation of this Regulation.

4.1. Planning and Competent Authorities

Each Member State designates a national — independent and neutral – Competent Body to organise the registration process of sites within its own territory. The Competent Body has to issue registration numbers to organisations, which have submitted a validated environmental statement, collect any payable registration fee, refuse, suspend and delete organisations from the register and respond to enquiries concerning organisations on the national EMAS register. Consistency of procedures relating to the registration process is ensured by a peer review process of all Competent Bodies, which meet at least once a year to exchange information.

- Designate an Accreditation/Licensing Body, which is an independent, impartial institution or organisation responsible for the accreditation/issuing of licenses to and supervision of environmental verifiers designated by Member States. Member States may use existing accreditation/licensing institutions or the EMAS Competent Body, or designate any other appropriate body. The Accreditation/Licensing Body establishes, revises and updates a list of environmental verifiers and their scope of accreditation (according to NACE codes) in their Member State. Changes to this list have to be communicated to the Competent Body and the Commission.
- Where national Accreditation Bodies and Competent Bodies have already been established under former EMAS Regulation ((EC) No 761/2001) these will continue their activities but their procedures have to be modified to ensure full compliance with the EMAS Regulation (EC) 1221/2009.
- The EMAS Regulation represents an initiative designed to involve enterprises — on a voluntary basis — in improving their environmental performance. It anticipates that the introduction of an effective and efficient environmental management system (EMS) will provide an enterprise with the opportunity to reduce its costs, reduce its environmental impact, increase its efficiency, and enhance its reputation. Like the ecolabelling of products, the Eco-Management and Auditing Regulation represents a move towards the philosophy that the market will reward improvements in an enterprise's environmental performance.
- In some Member States, larger companies have been more prominent in the introduction of environmental management practices. This is because they have the resources available to commit to the scheme and often have dedicated environmental staff. Larger organisations can also perceive greater cost savings through EMS due to economies of scale. Although it is important to keep larger enterprises aware of the benefits of schemes like EMAS, it is also important to inform, instruct and support the small and medium-sized enterprises (with less than 250 employees) that often have more limited resources to apply in this area. In the European Commission ‘Study on the Costs and Benefits of EMAS to Registered Organisations’²⁶¹, participating organisations were asked to indicate which,

²⁶¹ http://ec.europa.eu/environment/emas/pdf/other/costs_and_benefits_of_emas.pdf

from a list of impacts of EMAS, had been the most positive for them. The most positive impact, identified by 21% of respondents, was energy/resource saving, followed by "reduction in negative incidents" (18%) and "improved stakeholder relationships" (17%). For all sizes of organisations, the energy savings alone exceeded the annual costs of maintaining EMAS. Actual costs and benefits vary widely, depending on, for example, the size and activities of the organisation, the current state of the environmental management practices, the specific country, etc. But in general, EMAS generates significant annual cost savings.

- In addition, gaining access to public contracts was highlighted as a key benefit for SMEs. Therefore, in order to facilitate wider participation in the scheme, candidate countries should promote their participation, which could also be in the form of grants or soft loans should be considered at national, regional or local governmental levels (ensure though that this support does not qualify as illegal state aid).
- For the purposes of verification and validation, the accredited environmental verifiers, who can be individuals or organisations, could be the first point of contact with the scheme participants. However, organisations deciding to implement EMAS must also liaise with the competent body from the very beginning of the process. The body for accrediting the environmental verifiers could be an existing national accreditation organisation, or the competent authority referred to in Article 5. The competent body (responsible for the registration of organisations and legal compliance) could be a government ministry or an independent organisation appointed by a government ministry.
- The Regulation does not replace, nor does it remove, any obligation to comply with any existing EU environmental legislation. In fact, registration under the EMAS scheme requires that a site should be in compliance with all relevant environmental legislation including all applicable European legislation.
- Take the necessary measures to ensure that the scheme is also open to non-European organisations and European organisations operating in third countries. Where the candidate country decides to allow registration of organisations located outside the Community (EMAS Global), these organisations have to address their request for registration to a Competent Body of that Member State. The organisation has to contact an environmental verifier from the same Member State. For the relevant rules and procedures, EMAS Global Guidance has to be consulted.
- EU Member States should encourage local authorities to provide specific assistance in the development and implementation phases towards EMAS registration to clusters of organisations such as industrial associations or regional chambers of. Each organisation from the cluster will be registered separately. A cluster approach is possible for a group of organisations located in one EU Member State or located in different EU Member States.
- Consider whether in the case of existing non-formal environmental management schemes, to upgrade to EMAS. In such case comply with the provisions in Article 45 of EMAS Regulation, e.g. concerning submitting a request for transition to the Commission. In this case consult the Study on Guidelines for Transition from Non-Formal EMAS and ISO 14001 to EMAS', providing useful information to organisations that have adopted other Environmental Management Systems and to the competent bodies considering submitting a request for transition pursuant to Art. 45.
- As a promotional measure contemplate devising incentives for promoting the participation of organisations and companies and especially SMEs.

Consult the various EU financial programmes, which could be partly used for supporting SME participation in the EMAS scheme:

- European Commission's EMAS Promotion & Policy Support in the Member States Compendium 2015 serving as a reference tool for Member State policy makers, EMAS representatives and Competent Bodies to aid in selecting and designing future EMAS support measures:
http://ec.europa.eu/environment/emas/pdf/other/EMAS_Compndium_2015.pdf
- Guide on Community funding entitled 'Grants and Loans from the European Union':
http://ec.europa.eu/contracts_grants/index_en.htm
- The European Community's LIFE-Environment programme. LIFE-Environment actions aim to implement Community environmental policy and legislation in the EU and candidate countries. One focus of this section of the programme is to fund of innovative projects directed at the implementation of environmental management systems and in particular EMAS:
<http://ec.europa.eu/environment/life/>
- General information on funding opportunities available from the Directorate-General Environment: http://ec.europa.eu/environment/funding/intro_en.htm

4.2. Action for Organisations Participating in the Scheme

- If a company or organisation within a Member State has been working towards, or has been certified according to, a standard other than EMAS, it should make an assessment of how its current management system compares with the requirements of EMAS and whether to ask for transition into EMAS.
- There is need for commitment to the scheme at the highest management level within the organisation and the recognition that adequate staff resources must be made available and sufficient training given. As can be seen from the case studies available on DG ENV EMAS website, the organisations participating in EMAS highlighted the following challenges:
 - preparation of the environmental effects register;
 - the content of the environmental statement and uncertainty as to the distribution requirements;
 - how continuous improvement could be measured and assessed;
 - lack of senior management support and qualified staff to administer EMAS;
 - need for training and hiring external staff in the initial phase of EMAS;
 - need for capital investments into processes, systems including production systems;
- Prepare for the registration, which will be one of the most time consuming initial steps of the affiliation to EMAS. The organisation has to take the following steps:
 - conduct an environmental review considering all environmental aspects of the organisation's activities, products and services, methods to assess them, the organisation's legal and regulatory framework and existing environmental management practices and procedures.
 - adopt an environmental policy and to commit itself both to compliance with all relevant environmental legislation and to achieve continuous improvements in environmental performance.
 - adopting an environmental programme, where the organisation translates general objectives established in the environmental policy into specific targets. This programmes needs to specify concrete measures, responsibilities and means taken or envisaged to achieve environmental objectives and targets and the deadlines for achieving the objectives.
 - establish an effective environmental management system to achieve the organisation's environmental policy objectives as defined by the top management. The management system needs to set responsibilities, roles, operational procedures, training needs, monitoring and communication systems.
 - carry out an internal environmental audit, assessing, in particular, whether the management system is in place and in conformity with the organisation's policy and programme. The audit also checks if the organisation is in compliance with relevant environmental regulatory requirements.

- provide a public statement of its environmental performance, stating the results achieved against the environmental objectives and the future steps to be undertaken in order to continuously improve the environmental performance.
 - an environmental verifier accredited with an EMAS Accreditation/Licensing Body of a Member State must examine and verify the environmental review, the Environmental Management System, the audit procedure and the environmental statement.
 - once the environmental statement has been validated by the environmental verifier, the Competent Body will register the company after receipt of the registration fee. The company now has the right to use the EMAS logo.
 - The organisation can use information from the validated environmental statement to market its activities with the EMAS logo, assess suppliers against EMAS requirements and give preference to suppliers registered under EMAS.
- Organisations should consult the Commission Decision 2013/131/EU of 4 March 2013 establishing the user's guide setting out the steps needed to participate in EMAS, under Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), which outlines the main elements and steps to be undertaken by an organisation that intends to participate in the EMAS scheme. The guide aims to increase the overall uptake of the EMAS management system by facilitating the entry of organisations into the scheme. It is also important to keep in mind the general objective of the European Regulation, which is to harmonize implementation across all Member States and create a common legislative framework.
 - For specific "EMAS Global" related issues the reader is referred to the "Commission Decision 2011/832/EU, of 7 December 2011 concerning a guide on EU corporate registration, third country and global registration under Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)" That guide facilitates the registration and the understanding of the various options for corporate registration, third country and global registration.
 - In order to facilitate the process towards EMAS-registration and to facilitate maintenance of EMAS registration for small and medium sized organisations (SME's), EMAS Easy, a lean and standardized methodology has been developed with small and micro businesses in mind. This methodology, which covers all requirements of the environmental management standards for EMAS and/or ISO 14001, is based on the Eco-mapping concept, where the business is mapped in terms of both location and internal processes to identify its environmental aspects. Using simple and sequential tables and prompts, smaller businesses can develop an Environmental Management System (EMS) and either register for EMAS or achieve certification to ISO 14001. Under the slogan "in 10 days, with 10 people, on 10 pages, in 30 steps", the methodology is set out in a brochure which walks the user through each step on the way to EMAS in an easy way (<http://www.emas-easy.eu>).

4.3. Regulation

- Many European countries are members of the European Co-operation for Accreditation (EA). The EA brings together the national accreditation systems of each of these countries and has developed guidelines for the accreditation of certification bodies for EMS that are used as a basis for the EMAS verifiers also in most of the Member States. This provides a useful mechanism in helping to ensure consistency in the approach of the appointed accreditation bodies in the Member States.
- Consistency of procedures relating to the registration process is ensured by a peer review process of all Competent Bodies, which meet at least once a year to exchange information.
- Although participation in EMAS is voluntary mis-use of EMAS logo or other non-compliance issues for participating organisations have to be subject to penalties. This is important to maintain the integrity of the EMAS logo.

4.4. Information and Reporting

- The key stakeholders involved are as follows:
 - the national accreditation body;
 - the verification bodies;
 - industries specified in Regulation (EC) No. 1893/2006;
 - environmental regulators;
 - the public; and
 - company shareholders.
- The key area of consultation initially needs to be in the provision of information and the education of industry regarding the benefits of employing environmental management systems. This is key to the success of the scheme. In addition, it is important to highlight the benefits to company image and for companies to demonstrate environmental performance to shareholders and also potentially loan providers and insurance companies.
- Changes to the register of EMAS organisations have to be communicated to the Commission.
- The Accreditation/Licensing Body has to communicate changes to the list of environmental verifiers and their scope of accreditation (according to NACE codes) to the Competent Body and the Commission.

5. COSTS

EMAS Regulation entail costs on the one hand for the implementing public bodies and on the other for the participating organisations. Regarding the public bodies, the main types of costs arising during the implementation of the Eco-Management and Audit Scheme Regulation are shown in the Table below:

Table 18. Types of Cost Incurred by the Member States and the Competent Authorities to Implement the Regulation

Initial set-up costs: <ul style="list-style-type: none">• establishing competent body;• establishing the accreditation body;• devising systems and procedures;• provision of training;• preparing technical guidance notes and promotional literature about the scheme.
Capital expenditure: <ul style="list-style-type: none">• establishment and funding of grant support facility.
On-going running costs: <ul style="list-style-type: none">• evaluation of applications to the scheme;• collecting data for reporting to the Commission.

Prior to the implementation of the Regulation the main costs will be the administrative costs of setting up the competent body and the accreditation body. While these may be existing organisations there will nevertheless be costs related to staff deployed in the operation of the scheme and the various reporting functions. For an effective implementation of the scheme there will also need to be expenditure on the production of literature for the promotion and explanation of the scheme and for technical guidance and training. The administrative costs described can, to some extent, be offset by the generation of revenue income from the introduction of a system of fees.

The costs to organisations of implementing the requirements of the scheme will include:

- staff time in the planning, implementation and operation of the system;
- application fees;
- consultants fees, where necessary;
- training; and
- verification costs.

The potential cost savings, environmental benefits and image promotion could far outweigh these initial costs. The most positive impact, identified by 21% of EMAS registered respondents in a survey, was energy/resource savings, followed by "reduction in negative incidents" (18%) and "improved stakeholder relationships" (17%). For all sizes of organisations, the energy savings alone exceeded the annual costs of maintaining EMAS. In general, EMAS generates significant annual cost savings. Various studies have shown that the increased revenue

compensates the implementation costs within a relatively short payback period ranging between a year and two years in most cases²⁶². Actual costs and benefits vary widely, depending on, for example, the size and activities of the organisation, the current state of the environmental management practices, the specific country, etc.

Table 19: Costs and potential annual efficiency savings in EMAS²⁶³

Organisation size ²⁶⁴	Potential annual efficiency savings (€)	First year implementation costs ²⁶⁵ of EMAS (€)	EMAS Annual costs ²⁶⁶ (€)
Micro	3,000 – 10,000	22,500	10,000
Small	20,000 – 40,000	38,000	22,000
Medium	Up to 100,000	40,000	17,000
Large	Up to 400,000	67,000	39,000

The data in table 19 originate from the study on the Costs and Benefits of EMAS to Registered Organisations performed for the European Commission in 2009. Implementing EMAS via the EMAS Easy methodology is one way for SME's to reduce their first year and annual implementation costs. For more information visit: <http://www.emas-easy.eu>.

It must be noted that in general implementation costs for organisations increase relative to the size of the organisation. As a whole, micro and small organisations face proportionally higher fixed and external costs than medium and large organisations, since medium and large organisations benefit from economies of scale, with a higher proportion of costs borne internally by environmental departments and lower external costs associated

²⁶² EVER Study: Evaluation of EMAS and Eco-Label for their Revision (2005), IEFEE- Università Bocconi for DG Environment of the European Commission. Hamschmidt J., Dyllick T. (2001), "ISO 14001: profitable? Yes! But is it eco-effective?", Greener Management International, n. 34. CESQA SINCERT (2002), Indagine sulla certificazione ambientale secondo la norma UNI EN ISO 14001; risultati indagine Triveneto. Freimann, Walther (2001), The impacts of corporate environmental management systems: a comparison of EMAS and ISO 14001, Greener Management International, No.36, pp.91-103. IRIS (2000), Environmental management systems – paper tiger or powerful tool. The Swedish Institute of Production Engineering Research. Molndal.

²⁶³ The figures in Table 1 are indicative and related to the category sizes. Therefore they cannot be applied directly to any organisation in any situation.

²⁶⁴ Organisation sizes as defined in Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises [Official Journal L 124 of 20.05.2003]

²⁶⁵ SME's can often reduce their first year implementation costs by implementing EMAS via the EMAS Easy methodology. Recent estimates show that in some cases costs can be reduced down to EUR 11,500 for micro organisations and EUR 17,000 for small organisations in the first year of implementation. These estimates are purely indicative and based on data provided by SME's following seminars for SME's in different Member States.

²⁶⁶ SME's can often reduce their first year implementation costs by implementing EMAS via the EMAS Easy methodology. Recent estimates show that in some cases costs can be reduced down to EUR 2,200/year for micro organisations and EUR 3,300/year for small organisations. These estimates are purely indicative and based on data provided by SME's following seminars for SME's in different Member States.

with the use of consultants. However, also for very large organisations it can be advisable to assess the implementation costs in more detail and in an organisation specific context.

As a final remark on costs and benefits when implementing EMAS, account should be taken of the technical and financial support and subsidies offered by Member States, national, regional or local authorities and the EMAS Competent Bodies.

The below Table below indicates the most important costs:

Table 20. Types of Cost Incurred by the Participating Organisations

<p>Fixed costs faced by organisations to register are assumed to be unrelated to staff numbers. These costs include:</p> <ul style="list-style-type: none"> • Validation and verification fees Environmental verifiers are private consultants and therefore charge the usual market prices for consultancy services. Small and medium-sized enterprises (SMEs) without complex environmental impacts can be verified in one or a few days. • Registration fees Registration fees are different from verification costs and can vary from zero to € 1500 in the case of large companies. EMAS III Regulation foresees reduced registration fees for SMEs to encourage higher participation. • Capital expenditure and IT system costs Costs can stem from the need for modifications to IT systems such as new software. • Adding EMAS logo to stationary and producing publicity material
<p>External costs</p> <ul style="list-style-type: none"> • External consultant Support may be needed for the initial review, auditing, training and on-going implementation of EMAS.

Internal costs:

Internal costs are incurred by organisation staff to implement, administer and report on EMAS. The costs include the following aspects:

- **Environmental review**
- **Development of environmental management system**
- **Internal audit**
- **Preparation of EMAS statement**
- **Internal staff training**
- **Attaching EMAS logo**
- **Modifications to IT systems**
- **Publication of environmental statement**
- **Other administrative related costs**

A significant part of internal costs is the internal resources required to implement the scheme. Depending on the organisation's size, number of sites, previous experience with management systems and the complexity of environmental impacts, the typical personal commitment to implement EMAS varies from a few persons per month in a small company in the service sector to several persons per year in large corporations with many sites. Costs in subsequent years are on average around half of those in the first year. Higher costs in the first year result from learning EMAS requirements and establishing the necessary management and administrative systems, often requiring expert advice from outside the organisation.

Maintenance costs:

System **maintenance** is significantly less resource demanding than the initial set-up phase, since many activities required for the first registration are no longer needed (e.g. the initial review, installation of measurement and data management systems, and distribution of responsibilities). External consultancy costs show the largest reduction, with costs declining in subsequent years to approximately one third of those incurred in the first year.

THE EU ECOLABEL REGULATION

Official Title:

Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 27, 30.1.2010)

Commission Decision of 22 November 2010 establishing the European Union Ecolabelling Board (2010/709/EU) (OJ L 308/53, 24.11.2010)

Commission Regulation (EU) No 782/2013 of 14 August 2013 amending Annex III to Regulation (EU) No 66/2010 of the European Parliament and of the Council on the EU Ecolabel (OJ L 219, 15.8.2013)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Regulation (EC) No 66/2010 replaces and revises the previous Regulation (No 1980/2000) on voluntary scheme for awarding eco-labels to certain products, which has existed since 1992, when it was originally established under Regulation (EEC) 880/92. The aim of the scheme is to promote products, which have the potential to reduce negative environmental impacts, as compared to other products in the same product group available on the market, and to allow consumers to easily recognise them. The label may be awarded to all goods or services distributed, consumed or used on the Community market whether in return for payment or free of charge, on condition that the ecological criteria have been clearly established. It does not apply to medicinal products for human or veterinary use, or to medical devices. The label cannot be awarded to products containing substances classified by Regulation (EC) No 1272/2008 as toxic, hazardous to the environment, carcinogenic or mutagenic, or substances subject to the REACH Regulation (EC) No 1907/2006.

In 2013, the Commission has adopted a Regulation (EU) No 782/2013 replacing Annex III of Regulation No 66/2010 in order to amend the maximum fees allowed to finance the evaluation and processing of requests for the Ecolabel made by product manufacturers.

The label shall be awarded in consideration of European environmental and ethical objectives. In particular:

- the impact of goods and services on climate change, nature and biodiversity, energy and resource consumption, generation of waste, pollution, emissions and the release of hazardous substances into the environment;
- the substitution of hazardous substances by safer substances;
- durability and reusability of products;
- ultimate impact on the environment, including on consumer health and safety;
- compliance with social and ethical standards, such as international labour standards;
- taking into account criteria established by other labels at national and regional levels;
- reducing animal testing.

The criteria for awarding the EU Ecolabel are determined (for each product group) through a multi-stakeholder process involving the European Union Ecolabelling Board, and using a "cradle-to-grave" assessment of the impact of the product throughout its whole life cycle. They are adopted as Commission Decisions. The European Union Eco-Labeling Board (EUEB) has been established by Commission Decision 2010/709/EU and is composed as described below.

Structure:

- EU Ecolabelling Board (EUEB) (see Decision 2010/709/EU):
 - Members: Competent Bodies from each Member States, representatives of the Member States of the European Economic Area and the representatives of the following organisations: European Environmental Bureau (EEB), Bureau Européen des Consommateurs (BEUC), European Confederation of Associations of Small- and Medium-Sized Enterprises (CEA-PME), Business Europe, EUROCOOP, European Association of Craft, Small- & Medium-Sized Enterprises (UEAPME) and EUROCOMMERCE

- Responsibilities: The EUEB contributes to the development and revision of EU Ecolabel criteria and to any review of the implementation of the EU Ecolabel scheme. It also provides the Commission with advice and assistance in these areas and, in particular, issues recommendations on minimum environmental performance requirements.
- European Commission:
 - Role and responsibilities: management of the scheme at EU level to ensure correct implementation of the Ecolabel Regulation
 - “Owner“ of the scheme (The Commission adopts EU Ecolabel criteria for each product group as “Commission decisions” after the Ecolabel Regulatory Committee supports the criteria by a qualified majority)
- Competent Bodies:
 - Members: Independent & impartial organisations
 - Responsibilities: implementation of the EU Ecolabel at national level. They specifically assess applications and award the EU Ecolabel to products that meet the criteria set for them, they ensure market surveillance and participate in the criteria development.

Today the EU Ecolabel covers a wide range of products and services (30 categories of products), with further groups being continuously added. The criteria for each product group have been identified on the basis of comprehensive studies of the environmental aspects related to the entire life cycle of the product. Since it was launched in 1992 the EU Ecolabel now has 44 711 products and services comprised by 2031 licences.

. Every four years on average, the criteria are revised to reflect technical innovation such as evolution of materials, production processes or in emission reduction and changes in the market.

At the moment the Joint Research Centre's Institute for Prospective Technological Studies is leading the majority of the criteria revisions and developments.

More information about the EU Ecolabel scheme and its coverage can be obtained at:

- The EU Ecolabel website: <http://ec.europa.eu/environment/ecolabel/>
- EU Ecolabel newsalert: <http://ec.europa.eu/environment/ecolabel/news-alerts.html>
- The EU Ecolabel Catalogue: <http://ec.europa.eu/ecat/>
- Products groups and criteria: <http://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html>
- Current criteria development and revision projects: http://susproc.jrc.ec.europa.eu/product_bureau/projects.html

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Designate an independent competent body (or bodies) to administer the EU Ecolabel Scheme:
 - In case of several bodies Member States have to determine division of powers and coordination measures;
 - They have to be independent and work in a transparent way involving interested parties;
 - They have to comply with Annex V of the EU Ecolabel Regulation;
 - Competent bodies shall ensure sound verification process from independent verifier in accordance with international, European or national standards and procedures. (Art. 4)
- Promoting public procurement of products having the same environmental performance of EU Ecolabelled ones. (Art. 12 (3))
- Ensure that the Competent Body (or bodies) carry out the following tasks:
 - process applications from operators for the award of an EU Ecolabel to their products, pursuant to the procedure and time limitations set out and verifying that all relevant information is submitted by the operator (Art. 9)
 - review the documents regarding the product and assess the compliance with the ecolabel criteria and other assessment criteria referred to in Art. 8 and 9 and decide, whether to award an EU Ecolabel to the product (tests accredited according to ISO 17025 and EN 45011 standard should be preferred) (Art.9)
 - provided that the documentation is complete and the product complies with the criteria and there are no objections from the Commission, the competent body shall award the EU Ecolabel and assign a registration number to the product (Art.9)
 - verify that the EU Ecolabel has the form depicted in Annex II (Art. 9(2))
 - establish fees taking into account the costs for processing applications and eventual costs related to an on-site verification outside the Member State where the competent body is established (Art. 9(5) and Annex III)
 - conclude a contract with the operator, covering the terms of use of the EU Ecolabel using the contract template in Annex IV (Art. 9(8))
 - collaborate with other competent bodies and in the working group referred to in Art. 13(2).

2.2. Regulation and Enforcement

- The Competent Bodies should ensure that the operator only uses the EU Ecolabel on the product and their associated promotional material only after conclusion of the contract and that the product bears the registration number. (Art. 9(9))
- The Competent Bodies should ensure that the EU Ecolabel is only used in connection with products complying with the EU Ecolabel criteria applicable to the products concerned and for which the EU Ecolabel has been awarded and that the fee referred to in Annex III first has been paid. (Art. 9(2))
- The Competent Bodies should take the relevant measures to ensure market surveillance and control of products bearing the EU Ecolabel
 - verify on a regular basis that the labelled product complies with EU Ecolabel criteria and assessment requirements and that there is no false or misleading advertising or use of the logo. Such verifications should also be carried out upon complaint and may be in the form of random spot-checks;
 - prohibit the use of EU Ecolabel in case of non-compliance. (Art. 10(5))
- Establish effective, proportionate and dissuasive penalties for non-compliance and ensure that they are applied. (Art. 17)

2.3. Information and Reporting

- Member States should inform consumers and undertakings about the EU Ecolabel scheme. (Art. 12)
- Report to the Commission on:
 - decisions to award or reject an Ecolabel (Art. 9(10))
 - national provisions establishing effective, dissuasive and proportionate penalties for infringements (Art. 17)
 - cases of non-compliance in connection with market surveillance and where the use of the EU Ecolabel is prohibited. (Art. 10(5))

2.4. Additional Legal Instruments

Decisions are regularly made setting out ecological criteria for the award of the eco-labels for various product groups. These include:

- Commission Decision (EU) 2015/2056 of 13 November 2015 amending Decisions 2009/300/EC, 2009/563/EC, 2009/894/EC, 2011/330/EU and 2011/337/EU in order to prolong the validity of the ecological criteria for the award of the EU Ecolabel to certain products

- Commission Decision (EU) 2015/877 of 4 June 2015 amending Decisions 2009/568/EC, 2011/333/EU, 2011/381/EU, 2012/448/EU and 2012/481/EU in order to prolong the validity of the ecological criteria for the award of the EU Ecolabel to certain products
- Commission Decision (EU) 2015/345 of 2 March 2015 amending Decisions 2009/563/EC, 2009/564/EC, 2009/578/EC, 2010/18/EC, 2011/263/EU, 2011/264/EU, 2011/382/EU and 2011/383/EU in order to prolong the validity of the ecological criteria for the award of the EU Ecolabel to certain products
- 2014/893/EU: Commission Decision of 9 December 2014 establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products
- 2014/763/EU: Commission Decision of 24 October 2014 establishing the ecological criteria for the award of the EU Ecolabel for absorbent hygiene products
- 2011/383/EU: Commission Decision of 28 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners
- 2014/313/EU: Commission Decision of 28 May 2014 amending Decisions 2011/263/EU, 2011/264/EU, 2011/382/EU, 2011/383/EU, 2012/720/EU and 2012/721/EU in order to take account of developments in the classification of substances
- 2011/263/EU: Commission Decision of 28 April 2011 on establishing the ecological criteria for the award of the EU Ecolabel to detergents for dishwashers
- 2012/49/EU: Commission Decision of 26 January 2012 amending Decisions 2011/263/EU and 2011/264/EU in order to take account of developments in enzymes classification in accordance with Annex I to Council Directive 67/548/EEC and Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council
- 2012/720/: Commission Decision of 14 November 2012 establishing the ecological criteria for the award of the EU Ecolabel for Industrial and Institutional Automatic Dishwasher Detergents
- 2011/382/EU: Commission Decision of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to hand dishwashing detergents
- 2011/264/EU: Commission Decision of 28 April 2011 on establishing the ecological criteria for the award of the EU Ecolabel for laundry detergents
- 2012/721/: Commission Decision of 14 November 2012 establishing the ecological criteria for the award of the EU Ecolabel for Industrial and Institutional Laundry Detergents
- 2014/350/EU: Commission Decision of 5 June 2014 establishing the ecological criteria for the award of the EU Ecolabel for textile products
- 2009/563/EC: Commission Decision of 9 July 2009 on establishing the ecological criteria for the award of the Community eco-label for footwear
- 2014/312/EU: Commission Decision of 28 May 2014 establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes
- 2013/806/EU: Commission Decision of 17 December 2013 establishing the ecological criteria for the award of the EU Ecolabel for imaging equipment

- 2011/337/EU: Commission Decision of 9 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for personal computers
- 2011/330/EU: Commission Decision of 6 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for notebook computers
- 2009/300/EC: Commission Decision of 12 March 2009 establishing the revised ecological criteria for the award of the Community Eco-label to televisions
- Commission Decision of 26 November 2009 on establishing the ecological criteria for the award of the Community Ecolabel for wooden floor coverings
- 2009/607/EC: Commission Decision of 9 July 2009 establishing the ecological criteria for the award of the Community eco-label to hard coverings
- 2009/967/EC: Commission Decision of 30 November 2009 on establishing the ecological criteria for the award of the Community Ecolabel for textile floor coverings (notified under document
- 2009/894/EC: Commission Decision of 30 November 2009 on establishing the ecological criteria for the award of the Community eco-label for wooden furniture
- 2013/295/EU: Commission Decision of 17 June 2013 amending Decisions 2006/799/EC, 2007/64/EC, 2009/300/EC, 2009/543/EC, 2009/544/EC, 2009/563/EC, 2009/564/EC, 2009/567/EC, 2009/568/EC, 2009/578/EC, 2009/598/EC, 2009/607/EC, 2009/894/EC, 2009/967/EC, 2010/18/EC and 2011/331/EU in order to prolong the validity of the ecological criteria for the award of the EU Ecolabel to certain products
- Commission Decision (EU) 2015/2099 of 18 November 2015 establishing the ecological criteria for the award of the EU Ecolabel for growing media, soil improvers and mulch
- 2006/799/EC: Commission Decision of 3 November 2006 establishing revised ecological criteria and the related assessment and verification requirements for the award of the Community eco-label to soil improvers
- 2014/336/EU: Commission Decision of 5 June 2014 amending Decisions 2006/799/EC, 2007/64/EC, 2009/300/EC, 2009/894/EC, 2011/330/EU, 2011/331/EU and 2011/337/EU in order to prolong the validity of the ecological criteria for the award of the EU Ecolabel to certain products
- 2011/331/EU: Commission Decision of 6 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for light sources
- 2007/742/EC: Commission Decision of 9 November 2007 establishing the ecological criteria for the award of the Community eco-label to electrically driven, gas driven or gas absorption heat pumps
- 2014/314/EU: Commission Decision of 28 May 2014 establishing the criteria for the award of the EU Ecolabel for water-based heaters
- 2011/381/EU: Commission Decision of 24 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to lubricants
- 2014/391/EU: Commission Decision of 23 June 2014 establishing the ecological criteria for the award of the EU Ecolabel for bed mattresses

- 2013/250/EU: Commission Decision of 21 May 2013 establishing the ecological criteria for the award of the EU Ecolabel for sanitary tapware
- 2013/641/EU: Commission Decision of 7 November 2013 establishing the ecological criteria for the award of the EU Ecolabel for flushing toilets and urinals
- 2014/256/EU: Commission Decision of 2 May 2014 establishing the ecological criteria for the award of the EU Ecolabel for converted paper products
- 2012/448/EU: Commission Decision of 12 July 2012 establishing the ecological criteria for the award of the EU Ecolabel for newsprint paper
- 2012/481/EU: Commission Decision of 16 August 2012 establishing the ecological criteria for the award of the EU Ecolabel for printed paper
- 2014/345/EU: Commission Decision of 6 June 2014 amending Decision 2012/481/EU establishing the ecological criteria for the award of the EU Ecolabel for printed paper
- 2011/333/EU: Commission Decision of 7 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for copying and graphic paper
- Commission Decision of 9 July 2009 establishing the ecological criteria for the award of the Community Eco-label for tissue paper
- 2009/564/EC: Commission Decision of 9 July 2009 establishing the ecological criteria for the award of the Community eco-label for campsite service
- 2009/578/EC: Commission Decision of 9 July 2009 establishing the ecological criteria for the award of the Community eco-label for tourist accommodation service

For more information on the product groups and criteria visit:
<http://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html>

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Regulation are summarised in the following Table and organised in chronological order wherever possible.

Table 21. EU Ecolabel Regulation - Key Implementation Tasks

EU ECOLABEL REGULATION - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Appoint a Competent Body to implement the Regulation. The Member State must ensure that the competent body is independent and neutral.
1.2	Establish a scale application and annual fees to be paid by applicants for the award and use of the EU Ecolabel in line with Annex III of the EU Regulation. The amount application fee should reflect the real administrative costs for processing an application.
2	Regulation
2.1	Competent Bodies should receive and process applications for the award of the EU Ecolabel from operators supplying goods or services for distribution, consumption or use on the Community market whether in return for payment or free of charge eligible for EU Ecolabel. Retailers can apply for products placed on the market under their own brand name.
2.2	The Competent Body should decide if the application falls within a product group for which criteria have been established and they should assess the product/service conformity with the related EU Ecolabel criteria. Environmental criteria take the whole product life cycle into account – from the extraction of the raw materials, to production, packaging and transport, right through to the use and disposal/recycling phase. They aim e.g. at minimising waste, soil pollution and degradation, water and air contamination, noise pollution, energy consumption, consumption of natural resources and effects on ecosystems.
2.3	On the basis of the evidence provided by the applicants, Competent Bodies should decide whether or not the EU Ecolabel should be awarded.
2.4	If it is decided to award the EU Ecolabel, a contract using the standard form set out in Annex IV, setting out the rights and conditions of use of the label must be issued and signed by the Competent Body and the applicant.
2.5	The Competent Body is responsible for monitoring compliance with the scheme, including inspections of premises, to ensure that the conditions under which the Ecolabel is issued continue to be met for the period of issue. Operators are obliged to allow inspections of their premises.
2.6	The Competent Body should prohibit the use of the EU Ecolabel if conditions specified in the contract fail to be observed.
3	Information and Reporting
3.1	Inform the public and raise public awareness of the EU Ecolabel through promotion actions, information and education campaigns. Inform the potential applicants about the scheme, its benefits and the procedures for applying.
3.2	Inform the Commission: <ul style="list-style-type: none"> • of any product for which the EU Ecolabel is awarded

	<ul style="list-style-type: none">• of any product for which the EU Ecolabel has been prohibited.• of national rules on penalties applicable to infringements.
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4. IMPLEMENTATION GUIDANCE

4.1. Planning

An important aspect of the EU Ecolabel scheme is the establishment and involvement of a national Competent Body in the development of criteria and in assessing the compliance of products with the criteria. The Competent Body should be an independent body, work in a transparent manner and collaborate with interested parties in its tasks. The Regulation foresees the possibility of other stakeholders, including industry, to propose and lead the development of EU Ecolabel criteria. They must demonstrate expertise in the product area, as well as the ability to lead the process with neutrality and in line with the aims of the EU Ecolabel Regulation, working with all interested stakeholders.

Competent Bodies should establish EU Ecolabel application and annual fees in accordance with Annex III of the EU Ecolabel Regulation. In a further attempt to increase the interest of companies in participating in the scheme, efforts are to be made to inform the public about the merits of the EU Ecolabel.

Examples from a Member State:

Croatia: The competent authority for the EU Ecolabel scheme is the Ministry of Environment and Nature Protection. The Ministry is responsible for two eco-labels: the national environmental protection label 'Environmentally Friendly' (*Prijatelj okoliša*) and the European Union environmental protection label EU Ecolabel. They belong to Type I environmental labels and declarations in line with the definition of the international standard for classification of environmental labels EN ISO 14024:2000. Type I environmental labels are voluntary, include various environmental criteria throughout the life cycle of a product or service and have an independent system for qualified assessment/verification by third parties.

The EU Ecolabel awarding procedure is carried out in line with the Ordinance on the EU Ecolabel (Official Gazette No. 110/2014) and envisages the following key steps:

- development of an elaborate
- submission of the application
- proceeding upon application
- conclusion of a contract and obtaining the certificate
- fees (determined in Annex III of the Ordinance on EU Ecolabel in accordance with the Regulation (EU) 782/2013. The fees vary depending on the size of the enterprise.)

Penalties for infringements of provisions related to EU Ecolabel scheme are determined in the Environmental Protection Act, Arts. 243 and 260 (Official Gazette No. 80/2013,78/2015).

Source: <http://www.mzoip.hr/en/environment/eco-labels.html>

Examples from a Member State: competent authority and fees

Czech Republic: The Czech Ecolabelling Agency, one of the units of CENIA, is the body responsible for the Czech National Eco-labelling Programme. Its functions include:

- it receives proposals from producers, importers, institutions and relevant organisations, as well as the public, and issues written standpoints,
- it prepares and publishes technical reports and draft Directives,
- it provides application forms, relevant materials, information and guidelines to the applicants,
- it registers and administers the applications and prepares reports on products which are to be labelled as environmentally friendly,
- it enters into license agreements with applicants and collects registration fees for this service,
- maintain records of experts and professional units, authorised and accredited laboratories and test rooms to recommend to an applicant,
- submits reports of its activities to the Minister of the Environment and to the Council twice a year and biannually organises inspection dates of its activities,
- based on the requirements of the guidelines, the Agency may verify compliance with its conditions before granting a trademark to an ecolabel holder.

Fee structures:

A) Obtaining the eco-label "Environmentally Friendly Product"

- 1) Registration fee: CZK 20,000.

Possible discounts:

- for micro-enterprises (up to 10 employees): 50 %, i.e. CZK 10,000
- for small and medium-sized enterprises (SME): 25 %, i.e. CZK 15,000
- for companies which have implemented an environmental management system (registered with EMAS, ISO 14 001 certified), obtained a cleaner production certificate and/or for companies which are currently the holders of an eco-label awarded in accordance with ISO 14 024 (foreign or Czech eco-labels): 15 %, i.e. CZK 17,000.

- 2) Annual fee: CZK 0.

B) Obtaining the eco-label: "Environmentally Friendly Service"

This applies to the categories: "Tourist accommodation services" and "Camp site services" (the category: "Schools and educational facilities" is subject to specific rules, for more information please contact Environmentally Friendly Products Agency).

- 1) Registration fee: CZK 10,000.

Possible discounts: for micro-enterprises, small and medium-sized enterprises (SME), enterprises registered with EMAS, having obtained an ISO 14 001 certificate, a cleaner production certificate, an eco-label in accordance with ISO 14 024 50 %, i.e. CZK 5,000.

- 2) Annual fee CZK 5,000.

Possible discounts: for micro-enterprises, small and medium-sized enterprises (SME), enterprises registered with EMAS, having obtained an ISO 14 001 certificate, a cleaner production certificate, an eco-label pursuant to ISO 14 024 50 %, i.e. CZK 2,500.

4.2. Information and Reporting

There are four specific shareholder groups, namely consumers, producers, retailers and environmental groups. In each case, representative bodies need to be consulted and informed about implementation. The general public should be recognised as a fifth and more diffuse group which should be informed about implementation via the media in its various formats.

The Ecolabel Regulation further strengthens the transparency element of the scheme and in particular the work of the competent bodies, which should involve interested stakeholders.

Examples from Member States: information campaigns

Hungary: Launched in 2009, the Hungarian campaign for the EU Ecolabel aims to increase public awareness of the EU Ecolabel and the Hungarian national ecolabel through a wide range of communication channels. Visitors can get information, leaflets, brochures, and ask questions. The Hungarian Ecolabelling Organisation homepage has been improved, providing Hungarians with comprehensive information on the EU Ecolabel scheme. The website is available in both English and Hungarian. So far, the results of the Hungarian marketing campaign are very encouraging. A survey conducted in April 2010 showed an eight % increase in public awareness of both the EU Ecolabel and the Hungarian ecolabel compared to before the beginning of the campaign in 2009. For more information, visit the Hungarian ecolabel website: <http://www.kornyezetbarat-termek.hu/?lang=en>

Italy: Regional efforts to support the EU Ecolabel have been made in Piedmont, a region in northwest Italy. A number of activities took place in October 2012 to increase awareness of the EU Ecolabel. The events targeted a wide audience and aimed to educate consumers, students, and families on environmentally conscious consumption by promoting the EU Ecolabel all over the region. This is an annual event in Piedmont, organised by ARPA (Environmental Protection Agency), Unioncamere, and the Italian Competent Body ISPR Ambiente, representing a long term strategy to raise sustained awareness of EU Ecolabel practices. Events took place in schools, supermarkets, enterprises, and public spaces, including 2 seminars (attended by 60 enterprises and public authorities), 4 exhibitions and a guided tour in a firm with an EU Ecolabel licence. Over 1 000 brochures were distributed in super-markets informing consumers of the importance of making smart shopping decisions that took the environment into account.

More information on similar stories: <http://ec.europa.eu/environment/ecolabel/success.html>

5. COSTS

The following Table summarises the types of costs, which are likely to be incurred to implement the Regulation.

Table 22. Types of Cost Incurred to Implement the Regulation

Types of Cost Incurred to Implement the Regulation
Initial set-up costs (mainly for governments and the Competent Bodies): <ul style="list-style-type: none">• establishment of competent body(ies) and furnish them with sufficient financial and human resources;• devising systems and procedures;• publicity costs;• provision of training;
Capital expenditure (for applicants): <ul style="list-style-type: none">• costs relating to design changes to products or change in production process to qualify for the EU ecolabel. The energy and resource savings made to comply with EU Ecolabel criteria could allow to off-set these costs.
On-going running costs: <ul style="list-style-type: none">• continuing publicity;• collecting data for reporting to the Commission• financial and human resource to run the scheme on an everyday basis, including assessing application, monitoring of compliance participating in the criteria developing process, in the CB Forum and European Union Ecolabelling Board activities.

REGULATION ON EUROPEAN POLLUTANT RELEASE AND TRANSFER REGISTER

Official Title: Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 33, 4.2.2006)

Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four (OJ L 188, 18.7.2009)

1. SUMMARY OF THE MAIN AIMS AND PROVISIONS

This Regulation sets the European Pollutant Release and Transfer Register (E-PRTR), a Europe-wide register that provides easily accessible key environmental data from industrial facilities in European Union Member States and in Iceland, Liechtenstein, Switzerland, Serbia and Norway.

The register contains data reported annually by some 30,000 industrial facilities covering 65 economic activities across Europe. The register covers 91 pollutants listed in Annex II, including greenhouse gases, other gases, heavy metals, pesticides, chlorinated organic substances and other inorganic substances.

Releases are reported when the level of the emissions exceeds a certain threshold and results in one of the 65 activities listed in Annex I, including releases of pollutants from diffuse sources.

This register is available to the public free of charge on the internet. The information it contains can be searched using various search criteria (type of pollutant, geographical location, affected environment, source facility, etc.).

Pollutant Release and Transfer registers (PRTRs) are one of the basic elements for supplying significant, systematic environmental information connected to definite geographical sites, therefore this is a basic starting point for ensuring the right to access to environmental data. Apart from this basic function, experience has shown the PRTR to be an important decision-making tool for environmental administrations and also a legal institution that is successful in pollution prevention without any direct administrative measures. The secret of this last function of PRTRs lies in the fact that a PRTR creates a connection between the facilities dealing with dangerous materials and the communities living around them. This connection represents a huge incentive for the management to reduce the use and emission of such dangerous materials about which they are obliged to report regularly, since they are aware that their neighbours are closely following these data.

This database meet the requirements of the United Nations Economic Commission for Europe (UN-ECE) Protocol on Pollutant Release and Transfer Registers, signed by the EU in May 2003. However, the European register covers more substances than the UN-ECE Protocol, to take account of existing EU legislation on water and persistent organic pollutants. Furthermore, the deadlines for reporting information set in the Regulation are shorter than those laid down in the Protocol.

The E-PRTR Regulation was amended by Regulation (EC) No 596/2009 introducing the regulatory procedure for non-essential elements of the Regulation.

As a part of the European Commission's Regulatory Fitness and Performance programme (REFIT) to make EU law lighter, simpler and less costly the Regulation is now subject to extensive evaluation of the effectiveness, efficiency, coherence, relevance and the EU added value.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

A survey shall be carried out into the responsibilities ensuing from the Regulation and from the protocol (in particular if the country is a party to the Kiev Protocol). This list of responsibilities shall be compared with the relevant existing data collection systems, first of all under IPC laws and other relevant environmental laws, in particular hazardous waste laws, and also laws and regulations in connection with chemical safety and major industrial accidents prevention.

- Public participation should be a part of all planning and regulation steps if possible (Recital 15 of the Preamble and Art. 12 of the Regulation). In designing effective public participation, the country should identify the concerned professional NGOs to be directly notified and the way in which the broader public will be notified (via Internet, if appropriate). The notification time shall properly respond to the requirement of early participation at a stage when all options are still open. Further information about the planning procedure shall be disclosed during the planning procedure if necessary.
- Central and, if appropriate, regional data collection, processing, reporting and disseminating organisations or departments within existing organisations shall be designated, together with the proper budgetary, staffing and training conditions. The IT aspects of these plans is significant, and the capacity and operation of the hardware element of the PRTR system must also be carefully designed.
- Integrated software shall be selected for collecting (defining how operators, facilities, owners, activities, chemicals, sites and other relevant locations etc. are identified), processing, reporting and disseminating the relevant environmental information. International requirements in terms of comparability, completeness, consistency and credibility and maximum ease of public access through the Internet shall be taken into consideration. (Recitals 7 and 12 of the Preamble)
- The extent to which diffuse pollution sources can be taken into consideration in the PRTR system shall be decided, if viable with a time schedule allowing for gradual introduction. (Recitals 6 and 11 of the Preamble and Art. 8)
- The handling of the categories of confidential information in relation to the Information Directive, and under which conditions and what manner the public may have access to aggregated, partly aggregated and non-aggregated information, shall be determined. (Recitals 7 and 14 of the Preamble and Art. 11)
- Reasonable time-frames shall be designed for all steps of information collection, processing, reporting and disclosure, taking into consideration the deadlines given by the Regulation. (Recital 10 of the Preamble and Art. 5 and 7 of the Regulation)
- Specific data needs and the interests of future users other than members of the public and public organisations, such as scientists, journalists, local authorities, insurance companies and economic organisations, shall be noted and taken into consideration in designing the national-level PRTR systems. (Recital 4)

2.2. Regulation

Although the rules of the Regulation are directly binding on the Member States, these rules primarily target the creation of the European-level PRTR system, therefore the Member States and candidate countries shall create their own detailed rules in order to be able to respond to the needs of the European system on the one hand, and, on the other hand, to create their own national-level PRTR systems in harmony with the protocol that has become a part of Community law as a result of its ratification by the EU. (Recital 5 of the Preamble and Art. 1)

Definitions of Article 2 shall be inserted into the national law first of all by transposing them into the national PRTR law and also by harmonising the text of the relevant laws with the definitions of:

- the public;
- competent authority;
- installation;
- facility;
- site;
- operator;
- reporting year;
- substance;
- pollutant;
- release;
- off-site transfer; and
- diffuse sources.

Definitions of "waste", "hazardous waste", "wastewater", "disposal" and "recovery" will already exist in the national laws if the relevant Directives have already been harmonised. General provisions should form an important chapter in the national PRTR law, including the relevant general principles of environmental law, primarily:

- the precautionary principle;
- whistleblower protection;
- the requirements to eliminate parallel environmental information collection and dissemination rules in the national law (Art. 3 of the protocol).

A list of the main elements of the PRTR system as a summary of the essence of this legal institution (serving the best interpretation of the detailed rules, inter alia) can also be part of the general provisions:

- facility-specific reporting;
- reporting on diffuse sources;
- pollution or waste specific as appropriate;

- concerning multiple dimensions such as releases to soil, air and water;
- contains transfer data;
- is based on regular reporting;
- has a limited number of confidentiality rules, if any;
- is coherent and timely;
- is user friendly and accessible in electronic format, among other ways;
- has public participation in its formulation and modification; and
- the result of these efforts is a structured, computerised database or several interconnected databases operated by the competent authority (Art. 4 of the protocol).

The first substantial chapter of the national PRTR law may cover the design and structure of the PRTR system. It shall contain data about:

- all the relevant facilities (including parent company);
- facility owners or operators;
- activities;
- occurrences at national level;
- amount of pollutant or waste;
- the concerned environmental medium;
- off-site transfers of waste and wastewater;
- technical (methodological) solutions for achieving maximum ease of public access;
- up to at least the last ten previous reporting years; and
- links to facilities' websites if they are volunteered for this (Art. 4 of the Regulation).

The chapter on the reporting responsibility of the operators shall encompass the following issues:

- determination of the reporting responsibility by activity and thresholds;
- determination of the frequency of reporting (annual as a minimum);
- determination of the exact timing of the reporting responsibility in harmony with Article 7(1) of the Regulation;
- prescriptions about reporting on the methods of obtaining information (measuring, calculation or estimation) (Art. 5(1), (3) and Annex I);
- the authority to which the reports shall be sent;
- the way in which information identifying the facility is communicated (Art. 5(1) and Annex III);
- the use of best available information (Art. 5(4));
- the responsibility to keep available records of the data from which the reported information was derived for a minimum period of five years (Art. 5(5));

- the way the competent authorities shall monitor whether all the responsible operators have duly performed their reporting obligations (UNECE guidance).

Types of data to be reported shall be at least:

- releases to air, water and land of any pollutant specified in Annex II of the Regulation, for which the applicable thresholds were exceeded (Arts. 5(1) and 6);
- off-site transfers of hazardous waste and non-hazardous waste, if the amounts exceeded;
- the minimum amounts in Article 5(1), Point b);
- off-site transfers in wastewater for which the threshold value of Annex II of the Regulation is exceeded (Art. 5(1) and Annex II);
- releases from deliberate, accidental, routine and non-routine activities (Art. 5(2));
- releases from diffuse sources with an appropriate geographical disaggregation (Art. 8 and Art. 7(4) of the protocol).

Quality assurance (validation) and control rules shall, as a minimum, contain details of checks by the competent authorities on the completeness, consistency and credibility of the data reported by the operators. (Art. 9 and EU guidance)

Public participation rules shall contain rules for all pillars of public participation: access to information, participation and access to justice. Capacity building is an important additional part of the effective public participation regulations. The detailed rules on public participation shall encompass:

- access to information in the European PRTR system -- where information is not easily accessible to the public by direct electronic means, the national authorities shall facilitate electronic access to it at publicly accessible locations (Art. 10(2));
- access to information in the national PRTR systems in national language(s), including legal and procedural guarantees of easy accessibility, good search functions, proper grouping of data and the non-technical display of data (UNECE guidance);
- rules for handling confidential information (parts) in harmony with Directive 2003/4/EC (Art. 11);
- rules for public participation in forming and revising the national-level PRTR systems, possibly, inter alia, by creating a committee comprising the concerned stakeholders (UNECE guidance);
- specific public participation provisions might ensure participation in the quality assurance and control activities;
- rules on access to justice in cases of the infringement of the above access to information or participation rights, including a clear entitlement on the part of the courts to substantially remedy the infringement by directly ordering the proper administrative measures (UNECE guidance);
- capacity-building measures, including the promotion of public awareness of the national and European PRTR systems and providing assistance in accessing them and in understanding and using the information contained in them. (Art. 15)

The provisions of the national PRTR law or regulation shall include, in general, sanctions against infringement of the provisions of the regulation and the accompanying national laws and regulation; and, specifically, against

the most prominent types of infringements such as the refusal of reports, the sending of false information or the abuse of confidentiality rules. (Art. 20 and EU guidance)

2.3. Reporting

- All data referred to in Article 5(1) and (2) shall be reported to the Commission by electronic transfer in the format set out in Annex III. (Art. 7(2))
- Together with the report in the previous bullet point, but as a separate section, a report shall be made on each of the occasions when a facility successfully claimed confidentiality, including the type of information that was withheld and the reason for withholding it. (Art. 11)
- Together with the report in the first bullet point, but as a separate section, Member States shall report every three years, based on the previous three years' data, on the practices and measures taken regarding the following:
 - reporting requirements for operators according to Article 5;
 - quality assurance and assessment measures according to Article 9;
 - public participation measures in accordance with Articles 10(2), 11 and 15;
 - penalties provided for according to Article 20. (Art. 16(1))
- A different report shall be sent to the Commission one year after the entry into force of the Regulation in the country regarding the provision of sanctions. A report is also due without delay regarding any amendments to these provisions. (Art. 20(2))

2.4. Additional Legal Instruments

- Regulation (EC) No 401/2009 on the European Environment Agency and the European Environment Information and Observation Network
- The Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters (the Aarhus Convention), 1998.
- The Industrial Emissions Directive (2010/75/EU)
- The Directive on Access to Environmental Information (2003/4/EC)
- INSPIRE Directive (2007/2/EC)
- The Reporting Directive (91/692/EEC)

3. IMPLEMENTATION

3.1. Key Tasks

Table 23. Regulation on European Pollutant Release and Transfer Register (E-PRTR) - Key Implementation Tasks

EUROPEAN POLLUTANT RELEASE AND TRANSFER REGISTER - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Carrying out a survey of responsibilities arising from the Regulation and from the protocol.
1.2	Putting together a list of relevant data collection activities in the country and the possible level of interconnection with the PRTR system (ranging from full integration to simply creating links between the databases).
1.3	Establishing the conditions for early and effective public participation in designing the PRTR system.
1.4	Designating the data collection, processing, reporting and information disseminating organisation(s).
1.5	Estimating the hardware needs for the new PRTR system and designing its set-up and operation conditions.
1.6	Designing the software for the PRTR system, taking into consideration the international requirements of comparability, completeness, consistency, credibility and maximum ease of public access through the Internet.
1.7	Evaluating the situation from the point of view of the quantity of data available or the amount of data that can reasonably be made available regarding diffuse pollution sources (e.g. transport or certain branches of agriculture). In this respect, the rate of the contribution of such diffuse pollution sources to the overall pollution of certain environmental media shall also be taken into consideration.
1.8	Gradual introduction as a compromise solution should also be considered.
1.9	Acknowledged confidentiality claims and the reasons for them shall be reported.
1.10	Legislative measures and practice on reporting requirements, quality assurance and assessment, public participation and sanctions shall be reported every three years.
1.11	A separate report shall be sent to the Commission on the creation of provisions on sanctions within one year of the entry into force of the European PRTR rules in the country, and on subsequent amendments immediately.
1.12	Designing time-frames for all steps of information collection, processing, reporting and disclosure, taking into consideration the deadlines given in the Regulation.
1.13	Contacting other stakeholders, such as scientists, journalists, local authorities, insurance companies and concerned professional and economic organisations, in order to allow them to express their views on the planning of the new PRTR system.
2	Regulation
2.1	Key definitions of the Regulation shall be inserted into the national PRTR law, or the existing

	definitions in relevant laws shall be referred to.
2.2	General provisions of the Regulation shall be inserted into the national PRTR law or be referred to, including general principles and the summary of the main elements of the effective PRTR system.
2.3	The design and structure of the national-level PRTR system shall be regulated, including the reporting units, the types of data included in the system, and its links to relevant websites.
2.4	The reporting obligations of the operators shall be regulated, including the thresholds that trigger reporting obligations, the frequency and timing of reporting, and also the monitoring responsibilities of the competent authorities.
2.5	The types of data to be reported shall be regulated, including releases to the environmental media, off-site transfers and releases from diffuse sources.
2.6	Quality assurance and assessment shall be regulated, including the validation effects of the opinion of the competent authorities on the data servicing of the operators.
2.7	Public participation in the design and operation of the national PRTR systems shall be regulated, including effective access to the data of the European and the national PRTR systems, clarification of the establishing and handling of confidential information parts, public participation in the design and modification of the national PRTR system and in the quality assurance and control activities of the competent authorities, access to justice in all relevant access to information and access to participation matters, and capacity building in all the previously mentioned topics.
2.8	Effective, proportionate and dissuasive sanctions shall also be regulated for infringement both of the provisions of the Regulation and of the relevant national PRTR laws.
3	Guidance and Training
3.1	Guidance and regular training for officials dealing with the collection, processing, reporting and dissemination of PRTR information shall encompass, in particular, the determination of reporting obligations on operators, activities within quality assurance and quality control, responsibilities in the field of ensuring early and effective public participation, and the implementation of effective, proportionate and dissuasive sanctions.
3.2	Guidance and regular training for operators with reporting responsibility shall be ensured, with a special emphasis on the details of reporting responsibility, the types of data to be reported, quality assurance and control, and public participation.
3.3	Guidance and regular training for interested members of the public and public organisations, and also for other interested stakeholders, shall be produced, encompassing, in particular, reporting responsibility, the data to be reported, quality assurance and control, public participation and sanctions.
4	Reporting
4.1	Data reported by the operators shall be reported to the Commission in the format given in Annex III of the Regulation

3.2. Phasing Considerations

- The first reporting year for the Member States was 2007. Subsequent reports are due annually.
- In all reporting years after the first reporting year the national reports shall be sent to the Commission within 15 months of the end of the reporting year.

- All activities related to reporting from the operators and processing the data into a national-level report shall be phased within this 15 months. In dividing up this time, the countries shall take into consideration that there is usually a need from the side of the operators to control the correct transposition of their respective data into the national report, thus time should be allocated for this last phase of feedback from the operators.
- When deciding the specific amount of time to be allocated for public participation in planning activities, the time required for internal communication processes within the non-governmental organisations and for their communications with their experts should be taken into consideration.
- The phasing of regular reporting activities ranges from every year to every three years.

4. IMPLEMENTATION GUIDANCE

4.1. Planning

- The guidelines issued by the Commission and by the UNECE on the implementation of the Regulation and the protocol shall be taken into consideration as primary sources of information for planning activities. Guidance documents for implementation of the E-PRTR is available at: <http://ec.europa.eu/environment/industry/stationary/eper/implementation.htm> and <http://prtr.ec.europa.eu/#/static?cont=about>
- Fields of administrative law, of which the rules for information collection, processing etc. may be taken into consideration during the planning phase of the national PRTR systems, include:
 - chemical safety laws;
 - catastrophe prevention laws;
 - hazardous waste;
 - sewage treatment;
 - packaging waste;
 - electric and electronic waste;
 - waste from cars and car batteries;
 - transportation of waste;
 - surface and underground water protection, including protection against nitrates etc.;
 - air quality protection, including ozone, PCBs, greenhouse gases and VOC protection etc.
- When designing the methods and procedures for handling requests from operators concerning confidential data, Article 4(2) of the Access to Environmental Information Directive (2003/4/EC) shall be taken into consideration. According to this provision, the grounds for refusal shall be interpreted in a restrictive way, taking into account, with respect to the particular case, the public interest served by disclosure. It is also relevant, based on the same provision, that, in the majority of cases, a request shall not be refused where it relates to information on emissions into the environment. Since the major focus of the PRTR system is on emissions, the scope of possible admissions of requests for confidentiality is very narrow.
- When designing the database of the PRTR system, the following practical issues shall be taken into consideration:
 - The requirement of specificity. In harmony with this requirement, the data in the PRTR system shall allow for easy identification of the emitted and transferred materials and the locations and data of the operators. However, in certain cases, broader categories of materials (such as volatile organic substances, heavy metals or greenhouse gases) may also convey substantial information.

- An unambiguous determination of the materials and threshold values that trigger the reporting obligation, with the presumption of responsibility in questionable instances. Persistency, bioaccumulation and toxicity are the leading criteria for the selection of possible additional materials to the list given in the Regulation. While existing financial and technical conditions might preclude the compilation of the most ambitious list of materials and thresholds, the system shall make possible its gradual extension in the future,
- The problem of SMEs (small and medium-sized enterprises) must also be handled. Even where required by the relevant laws, SMEs frequently fail to fulfil their reporting obligations due to a lack of resources and expertise. Within the framework of the provisions of the Regulation and the protocol, rules relating to SMEs should ensure the highest level of flexibility. Procedural and institutional solutions, such as support, specific training and free consultations provided by the competent authorities, would be good examples.
- A basic planning consideration is the goal of creating a consumer-driven system within the framework of the internal legal requirements. In order to make the dissemination and explanation of PRTR data effective, the most interested stakeholders should actively be approached with proper packages of information products, including a geographical information system (GIS) exhibition, publications, press conferences, information hotlines etc.
- Plan the continuous (annual or biannual) training of the concerned officials.

4.2. Regulation

- The guidelines issued by the Commission and the UNECE on the implementation of the Regulation and the protocol shall also be taken into consideration as primary sources of information.
- The definitions of the PRTR system can be complex and difficult to implement in practice. The definitions of "installation", "facility", "site" and "operator" form a complex system that might determine the whole scope of the Regulation in several ways, depending on where the legislator places the emphasis in their interrelationships. It should be noted that the protocol handles the definition problem by providing one single definition of "facility" that gives adequate consideration to the problem of neighbouring sites and to the problem of several facilities being under the control of the same natural or legal person.
- The UNECE guidance provides useful tools for addressing the important issue of revealing those operators that have not entered into the PRTR system voluntarily, contrary to the relevant PRTR rules. It is advised to use the registers of several chambers of commerce and industry, national statistical records and even international organisations of which the operators in question might be part. To facilitate the search, the competent authorities can use standardised codes such as ISIC (International Standard Industrial Classification) or NACE (Nomenclature générale des activités économiques dans les Communautés Européennes). Naturally, the lists of already existing reporting responsibilities should also be used within the country.
- The mother company is a company that exerts control over the facility with the responsibility to report to the PRTR system either as an owner or in another capacity. This category is similar to that of

operator, although the operator exerts direct control over the operation of the facility on an everyday basis. However, in certain cases these two definitions might overlap.

- The EU guidance prescribes that the site shall be entered into the format prescribed in Annex III with the co-ordinates of the centre of the facility with a 500 meters tolerance. Naturally, if there are several significant point sources further than that from the centre given in the format, these co-ordinates shall also be given.
- The EU guidance also prescribes that Member States shall add further lines to the form provided in Annex III in order to offer to the operator an opportunity to submit additional voluntary information, inter alia about production capacities, number of installations, operation hours or number of employees. Under certain circumstances, the operator might consider including such additional data that are necessary to put the mandatory reported data into a better context for the authorities, the public and other stakeholders. A further line may be attached to the format in which the operator can provide links to their environmental reports or EMAS certificates; describe the history, in particular the environmental history, of the facility and current trends; provide explanatory drawings; and show materials and contact information enabling members of the public to obtain further data. Such additional information shall not be used for the sole purpose of advertisement or be otherwise abused but shall be restricted strictly to environmental data. Furthermore, environmental information shall be even-handed and fair, balanced and trustworthy.
- When reporting on methodology and measurements, operators are entitled to report on measurements made not by them but by other authorities. While any further data attached by the operators may not be in contradiction with these official data, they might be more accurate, more frequent, use more sensitive devices etc. Such measurements may not be made by environmental authorities but, for example, by labour protection authorities, although on this point operators shall take into account the fact that measuring methodologies in respect to indoor and outdoor environments differ significantly.
- Apart from the various forms of active disclosure of PRTR information, the competent authorities shall remain open to the passive disclosure of environmental information, that is, they shall receive requests for information and, where necessary, they shall provide the proper additional information and explanation in order to enable members of the public effectively to use and understand the PRTR information.

5. COSTS

Table 24. Types of Cost Incurred to Implement the Regulation

<p>Initial set-up costs:</p> <ul style="list-style-type: none">• establishment of complex professional teams within the competent authorities for the• collection, processing, reporting and dissemination of PRTR information;• establishment of contact points within the authorities that handle relevant information for• the PRTR system;• provision for initial training;• preparation of technical and legal guidance materials.
<p>Capital expenditure:</p> <ul style="list-style-type: none">• information technology for the PRTR databases within the relevant authorities;• purchase and development of the necessary software.
<p>On-going running costs:</p> <ul style="list-style-type: none">• continuous (annual or biannual) training of the concerned officials;• continuous (annual or biannual) training of the concerned operators;• capacity-building efforts for the concerned NGOs;• costs related to public participation

CHEMICALS

Section 8

1. INTRODUCTION AND OVERVIEW	1273
1.1. EU Policy.....	1273
1.2. EU Legal Instruments.....	1275
1.2.1. Directive on the Protection of Animals Used for Scientific Purpose (2010/63/EU).....	1276
1.2.2. Asbestos Directive (87/217/EEC)	1276
1.2.3. Regulation on Persistent Organic Pollutants ((EC) No 850/2004)	1277
1.2.4. Regulation concerning the making available on the market and use of biocidal products ((EU) No 528/2012).....	1277
1.2.5. Regulation on the Export and Import of Hazardous Chemicals ((EU) No 649/2012).....	1278
1.2.6. Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ((EC) No 1907/2006)	1279
1.2.7. Regulation on Classification, Labelling and Packaging of Substances and Mixtures ((EC) No 1272/2008).....	1280
1.2.8. Regulation on the Banning of Exports of Metallic Mercury and the Safe Storage of Metallic Mercury ((EC) No 1102/2008)	1280
1.2.9. Selection of other directly relevant legislation	1281
2. DEVELOPMENT OF A SECTORAL STRATEGY AND IMPLEMENTATION PLAN	1283
2.1. Key Factors Influencing Strategy Development	1283
2.2. Potential Difficulties in the Implementation Process.....	1285
2.3. Key Stages in Strategy Development	1285
2.3.1. Strategy Development Project Team	1286
2.3.2. Review and Analysis of the Existing Situation	1286
2.3.3. Development and Evaluation of Options.....	1287
2.3.4. Preparation of a Draft Strategy and Options Paper for Consultation with Stakeholders	1288
2.3.5. Review of Strategy and Options Following the Consultation Process	1288
2.3.6. Preparation of Strategy and Implementation Plan.....	1288
3. INSTITUTIONS AND RELEVANT PARTIES	1289
3.1. Stakeholders.....	1289
3.2. Central Government	1290
3.3. Competent Authority.....	1291
3.4. Regional and Local Government	1292
3.5. Private Sector Involvement.....	1292
3.6. Communication and Consultation.....	1292
4. TECHNICAL ISSUES	1295
5. REGULATION AND ENFORCEMENT.....	1296
	1266

5.1.	Licensing, Inspection and Monitoring	1296
5.2.	Data Collection and Reporting.....	1296
6.	PRIORITIES AND TIMING.....	1298
6.1.	Prioritising the Implementation Tasks.....	1298
6.2.	Time-scales	1299
7.	ECONOMIC AND FINANCIAL ISSUES	1300
7.1.	Principal Cost Areas.....	1300
7.2.	Cost Recovery and the Application of Economic Tools	1300
8.	SUMMARY OF KEY ISSUES	1302
	THE ASBESTOS DIRECTIVE.....	1303
1.	SUMMARY OF MAIN AIMS AND OBJECTIVES.....	1304
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1305
2.1.	Regulation.....	1305
2.2.	Monitoring.....	1305
2.3.	Reporting	1305
2.4.	Additional Legal Instruments	1305
3.	IMPLEMENTATION	1307
3.1.	Key Tasks.....	1307
3.2.	Phasing Considerations	1308
4.	IMPLEMENTATION GUIDANCE	1309
4.1.	Regulation.....	1309
4.2.	Monitoring.....	1310
5.	COSTS.....	1311
	THE BIOCIDAL PRODUCTS REGULATION	1312
1.	SUMMARY OF THE MAIN AIMS AND PROVISIONS.....	1314
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1317
2.1.	Planning.....	1317
2.2.	Regulation.....	1318
2.3.	Monitoring.....	1321
2.4.	Information and Reporting.....	1321
3.	IMPLEMENTATION	1323
3.1.	Key Tasks.....	1323
3.2.	Phasing Considerations	1325

4. IMPLEMENTATION GUIDANCE	1326
4.1. General.....	1326
4.2. Planning and Administration.....	1329
4.3. Regulation.....	1330
4.4. Monitoring.....	1333
4.5. Enforcement.....	1333
5. COSTS.....	1334
THE REGULATION ON PERSISTENT ORGANIC POLLUTANTS.....	1335
1. SUMMARY OF MAIN AIMS AND PROVISIONS.....	1336
2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	1339
2.1. Planning.....	1339
2.2. Regulation.....	1340
2.3. Information and Reporting.....	1342
2.4. Additional Legal Instruments	1344
3. IMPLEMENTATION	1346
3.1. Key tasks	1346
3.2. Phasing Considerations	1346
4. IMPLEMENTATION GUIDANCE	1349
4.1. Planning.....	1350
4.2. Regulation.....	1353
4.3. Information and Reporting.....	1355
5. COSTS.....	1356
THE REGULATION ON THE EXPORT AND IMPORT OF HAZARDOUS CHEMICALS...	1357
1. SUMMARY OF MAIN AIMS AND PROVISIONS.....	1358
2. PRINCIPAL OBLIGATIONS OF MEMBER STATES	1360
2.1. Planning.....	1360
2.2. Regulation	1360
2.3. Information and Reporting.....	1363
2.4. Additional Legal Instruments	1363
3. IMPLEMENTATION	1365
3.1. Key tasks	1365
3.2. Phasing Considerations	1366
4. IMPLEMENTATION GUIDANCE	1367

4.1.	Planning.....	1367
4.2.	Regulation.....	1369
4.3.	Obligations of the Exporter.....	1370
4.4.	Monitoring and Reporting.....	1371
5.	COSTS.....	1372
REGULATION ON REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (REACH).....		
1373		
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1377
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES.....	1379
2.1.	Planning.....	1379
2.2.	Regulation.....	1379
2.3.	Information and Reporting.....	1380
2.4.	Additional Legal Instruments.....	1380
3.	IMPLEMENTATION.....	1382
3.1.	Key Tasks.....	1382
3.2.	Phasing Consideration.....	1384
4.	IMPLEMENTATION GUIDANCE.....	1385
4.1.	Planning.....	1388
4.2.	Regulation and Monitoring.....	1391
4.3.	Obligations for manufacturer, importer, or downstream user of chemicals or distributor.....	1392
4.3.1.	Obligations of Manufacturers and Importers.....	1393
4.3.2.	Downstream user obligations.....	1397
4.4.	Reporting.....	1402
5.	COSTS.....	1403
REGULATION ON CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES.....		
1405		
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1407
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES.....	1411
2.1.	Planning.....	1411
2.2.	Regulation.....	1412
2.3.	Information and Reporting.....	1417
2.4.	Additional Legal Instruments.....	1418
3.	IMPLEMENTATION.....	1419
3.1.	Key Tasks.....	1419

3.2.	Phasing considerations.....	1423
4.	IMPLEMENTATION GUIDANCE	1425
4.1.	Planning.....	1425
4.2.	Regulation.....	1429
4.2.1.	Classification	1429
4.2.2.	Labelling.....	1431
4.2.3.	Notification	1435
4.2.4.	Safety Data Sheets	1436
4.2.5.	Technical Guidance.....	1437
4.2.6.	Information and Reporting.....	1437
5.	COSTS.....	1438
THE DIRECTIVE ON THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES.....		
1439		
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1440
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1442
2.1.	Planning.....	1442
2.2.	Regulation.....	1443
2.3.	Information and Reporting.....	1446
2.4.	Additional Legal Instruments	1447
3.	IMPLEMENTATION	1449
3.1.	Key Tasks.....	1449
3.2.	Phasing Considerations	1451
4.	IMPLEMENTATION GUIDANCE	1453
4.1.	Planning.....	1455
4.2.	Regulation.....	1457
4.3.	Reporting	1458
4.4.	Technical guidance	1458
5.	COSTS.....	1460
THE DIRECTIVE ON THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES.....		
1463		
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1464
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1466
2.1.	Planning.....	1466
2.2.	Regulation.....	1467

2.3.	Information and Reporting.....	1470
2.4.	Additional Legal Instruments	1471
3.	IMPLEMENTATION	1473
3.1.	Key Tasks.....	1473
3.2.	Phasing Considerations	1475
4.	IMPLEMENTATION GUIDANCE	1477
4.1.	Planning.....	1479
4.2.	Regulation	1481
4.3.	Reporting	1482
4.4.	Technical guidance	1482
5.	COSTS.....	1484
REGULATION ON THE BANNING OF EXPORTS OF MERCURY AND SAFE STORAGE OF MERCURY		
1487		
1.	SUMMARY OF MAIN AIMS AND PROVISIONS.....	1488
2.	PRINCIPAL OBLIGATIONS OF MEMBER STATES	1491
2.1.	Planning.....	1491
2.2.	Regulation	1491
2.3.	Information and Reporting.....	1492
2.4.	Additional Legal Instruments	1493
3.	IMPLEMENTATION	1494
3.1.	Key tasks	1494
3.2.	Phasing Considerations	1497
4.	IMPLEMENTATION GUIDANCE	1498
4.1.	Planning.....	1498
4.2.	Technical Specifications	1500
5.	COSTS.....	1503

CHEMICALS LEGISLATION AND POLICY - OVERVIEW

1. INTRODUCTION AND OVERVIEW

This section of the Handbook deals with EU legislation related to chemicals and, partly to, biocidal products. It contains an introductory overview of the sector followed by individual fiches for selected pieces of legislation. The Handbook covers chemical legislation up until 31 December 2014 but in certain cases brief references are provided to legislation also adopted in 2015.

In the following section, a brief overview is given on EU chemical policy, leading up to the present situation on chemicals which is much governed by the principles and approach of the REACH system, complemented with the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC.

1.1. EU Policy

The EU legislation on chemicals has a long history, which started in late 1960s with the Directive 67/548/EEC on classification, labelling and packaging of dangerous substances. This Directive provided the first controls over the use of hazardous chemicals at EU level. It was followed by Directive 1999/45/EC on classification, packaging and labelling of dangerous preparations. These two directives established a common system for the classification and labelling of such substances and preparations before they are marketed, and laid down procedures to be used to establish the physico-chemical properties and hazards to human health and the environment of substances that might present a risk under conditions of normal usage. The main aim of these pioneers of chemicals legislation was to establish a common system across EU Member States and so prevent barriers to trade by the introduction of different national standards, but also to ensure high level of environmental protection through application of the precautionary principle.

Another milestone in developing EU chemicals policy is the adoption of the Commission's White Paper on the Strategy for Future Chemicals Policy (COM(2001)88) which has highlighted some weaknesses in the existing legal framework for chemical controls. The central element of the White Paper was establishing a single coherent system for all chemical substances, i.e. the REACH model (system of registration, evaluation and authorisation/restriction for new and existing chemical substances). This REACH system was finally introduced by Regulation (EC) 1907/2006 in 2007.

Consequently, REACH and the legislation on classification, labelling and packaging, which have evolved considerably from the original Directive from 1967, are the two main cornerstones of EU chemicals policy. However, there are several other regulations in addition to these two regulations, listed further in this section of the Handbook covering the risk assessment and control of existing substances or the export of chemicals. One such piece of legislation is Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals, which has as main objective, amongst others, to promote shared responsibility and cooperative efforts in the international trade of hazardous chemicals in order to protect human health and the environment. The introduction of restrictions on the marketing and use of chemical substances is an example of the 'substance-orientated approach' to chemicals control. This approach was put forward in the Fourth Environmental Action Programme, and early example of such an approach is the directives on the prevention

and reduction of environmental pollution by asbestos (87/217/EEC), which is aimed at controlling pollution of air, water and land by asbestos. Other examples of this approach are Biocidal Products Regulation ((EU) 528/2012) and the Regulation on banning exports of and promoting safe storage of metallic mercury ((EC) 1102/2008).

Another stream of the EU policy on chemicals focusing on certain priority substances is the one tackling persistent organic pollutants (POPs). In this context the EU adopted Regulation (EC) No 850/2004 to ensure effective implementation of two environmental agreements, the Protocol to the Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants and the Stockholm Convention on Persistent Organic Pollutants.

Since 1986, the EU has had in place specific legislation covering the use of animals for scientific purposes. The legislation was fully revised in 2010 by Directive 2010/63/EU on the protection of animals used for scientific purposes which took effect in January 2013. It regulates the use of live animals in areas of basic and applied research, efficacy and safety testing (including safety testing of chemicals) as well use of live animals for the purposes of education and training.

The European Commission is currently working on a proposal for science-based criteria for endocrine disruptors, as required in the Plant Protection Regulation (EC) 1107/2009 and the Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. There is growing concern in the EU and worldwide about negative human health and environmental impacts possibly caused by endocrine disruptors. The EU has introduced specific legislative obligations aimed at phasing out endocrine disruptors in water, industrial chemicals, plant protection products and biocides. In REACH endocrine disrupting chemicals are considered of similar regulatory concern as substances of very high concern.

The Union goal is to ensure ‘the minimisation of significant adverse effects’ of chemicals on human health and the environment by 2020 and to respond to new and emerging issues and challenges in an effective, efficient, coherent and coordinated manner. This goal is agreed at the World Summit on Sustainable Development in 2002, reaffirmed at Rio + 20, and accepted also as the goal of the Strategic Approach to International Chemicals Management.

Today, environmental policy is guided by the 7th Environmental Action Plan²⁶⁷, which builds upon the same objective that chemicals are produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment. This programme sets forth a general European Union action programme in the field of the environment for the period up to 31 December 2020 and it is based on the precautionary principle, the principles of preventive action and of rectification of pollution at source and the polluter-pays principle. It has the following priority objectives:

- (a) to protect, conserve and enhance the Union’s natural capital;
- (b) to turn the European Union into a resource-efficient, green and competitive low-carbon economy;
- (c) to safeguard the European Union’s citizens from environment-related pressures and risks to health and well-being;
- (d) to maximise the benefits of European Union environment legislation by improving implementation;
- (e) to improve the knowledge and evidence base for European Union environment policy;
- (f) to secure investment for environment and climate policy and address environmental externalities;
- (g) to improve environmental integration and policy coherence;

²⁶⁷ Decision on a General Union Environment Action Programme to 2020 ‘Living well, within the limits of our planet’ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013D1386&from=EN>

- (h) to enhance the sustainability of the European Union’s cities; and
- (i) to increase the European Union’s effectiveness in addressing international environmental and climate-related challenges.

The third key action area – objective, covers challenges to human health and wellbeing, such as air and water pollution, excessive noise, and toxic chemicals. The EAP also sets out a long-term vision of a non-toxic environment and proposes to address risks associated with the use of chemicals in products and chemical mixtures, especially those that interfere with the endocrine system. In parallel, a more predictable framework combined with more investment in knowledge is intended to encourage innovation and the development of more sustainable solutions.

Further to this, on 20 February 2013 the European Commission adopted a policy framework more closely linking EU social and health policies to Europe 2020: The Social Investment Package (SIP)²⁶⁸ including a document dedicated to ”Investing in Health”²⁶⁹. This paper extends the EU Health Strategy by reinforcing its key objectives, firmly anchors health in the Europe 2020 policy framework and reaffirms that health is a value in itself and health spending is a growth friendly expenditure.

1.2. EU Legal Instruments

The chemical sector considered in this Handbook, presented as individual fiches, covers eight pieces of legislation, comprising two directives and six regulations. This legislation can be subdivided into five categories —CLP legislation and REACH system, specific chemicals, biocidal products, imports and exports of chemicals and good laboratory practice involving animals.

Table 1. Legislation covered in separate fiches in the Section on Chemicals

Chemicals – classification, labelling, packaging, assessment, evaluation
Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) 1907/2006
Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency
Specific substances
Council Directive 87/217/EEC of 19 March 1987 on the prevention and reduction of environmental pollution by asbestos
Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC <i>OJ L 158, 30.4.2004</i>

²⁶⁸ COM(2013) 83 final

²⁶⁹ European Commission Staff Working Document – Investing in Health SWD(2013) 43

Biocides
Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal product
Imports and exports
Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals
Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury
Laboratory practices – animal protection
Directive 2010/63/EU of the European Parliament and of the Council of the 22 September 2010 on the protection of animals used for scientific purposes

1.2.1. Directive on the Protection of Animals Used for Scientific Purpose (2010/63/EU)

Since 1986, the EU has had in place specific legislation covering the use of animals for scientific purposes. In 2010 the EU adopted Directive 2010/63/EU which updates and replaces the 1986 Directive 86/609/EEC on the protection of animals used for scientific purposes. This Directive sets up the horizontal legal framework to carry out scientific procedures on animals in the EU, including testing required for areas such as chemicals, medicines, biocides and pesticides. The aim of this Directive is to strengthen legislation, and improve the welfare of those animals still needed to be used, as well as to firmly anchor the principle of the Three Rs, to Replace, Reduce and Refine the use of animals, in EU legislation. Directive 2010/63/EU took full effect on 1 January 2013.

In addition, some Regulations in the area of chemicals legislation specifically mention the reduction of animal experiments as one of their objectives. Thus, Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, relates closely to Directive 2010/63/EU. It contains several provisions beneficial to animal protection, including a prohibition on the marketing of cosmetics containing ingredients or combinations of ingredients tested on animals.

1.2.2. Asbestos Directive (87/217/EEC)

Directive 87/217/EEC of 19 March 1987 on the prevention and reduction of environmental pollution by asbestos aims at reducing exposure to asbestos so as to lessen the risk of diseases occurring and to establish limit values and specific harmonised minimum requirements for the protection of workers. For the purpose of the Directive, Member States of the European Union shall take the necessary measures to ensure:

- a) Asbestos emission limit value of 0.1 mg/Nm³ in discharge air.
- b) The limit value of 30 grams of total suspended matter per m³ aqueous effluent discharged shall apply.

- c) Measurements are taken on regular intervals of emissions in the air and discharges of aqueous effluent from facilities.
- d) In the course of the transport and deposition of wastes containing asbestos fibres or dust, no such fibres or dust are released in the air and no liquids, which may contain asbestos fibres, are spilled.
- e) Where waste containing asbestos fibres or dust is landfilled at sites licensed for this purpose such waste is treated, packaged or covered with account being taken to local condition, in a way that prevents the release of asbestos particles into the environment.

1.2.3. Regulation on Persistent Organic Pollutants ((EC) No 850/2004)

Persistent organic pollutants (POPs) are chemical substances that persist in the environment, bio accumulate through the food web, and pose a risk of causing adverse effects to human health or the environment. This group of priority pollutants consists of pesticides (such as DDT), industrial chemicals (such as polychlorinated biphenyls, PCBs) and unintentional by-products of industrial processes (such as dioxins and furans). At international level, two legally binding instruments have been concluded, which aim at eliminating the production, use and releases of these substances. These instruments establish strict international regimes for initial lists of POPs (16 in the UNECE Protocol and 12 in the Stockholm Convention). Both instruments also contain provisions for including additional chemicals into these lists:

- The Protocol to the regional UNECE Convention on Long-Range Transboundary Air Pollution (CLRTAP) on POPs, was opened for signature in June 1998 and entered into force on 23 October 2003
- The global Stockholm Convention on POPs, opened for signature in May 2001 and entered into force on 17 May 2004

Regulation (EC) No 850/2004 of 29 April 2004 implements into EU legislation the provisions of the international agreements on POPs. To a certain extent the Regulation goes further than the international agreements emphasising the aim to eliminate the production and use of the internationally recognised POPs. The Regulation contains provisions regarding production, placing on the market and use of chemicals, management of stockpiles and wastes, and measures to reduce unintentional releases of POPs. Furthermore, Member States must set up emission inventories for unintentionally produced POPs, national implementation plans (NIPs) and monitoring and information exchange mechanisms.

1.2.4. Regulation concerning the making available on the market and use of biocidal products ((EU) No 528/2012)

Biocidal products are used to control unwanted organisms that are harmful to human or animal health, or that cause damage to human activities. These harmful organisms include pests (e.g. insects, rats or mice) and microorganisms (e.g. moulds or bacteria).

Biocidal products include: insecticides (except those used for plant protection purposes which are regulated by Regulation (EU) No 1107/2009, insect repellents, disinfectants, preservatives for materials such as wood, plastics and fibers, anti-fouling paints for the protection of ship hulls. Because of their intrinsic properties, biocidal products can pose risks to humans, animals and the environment. As a result, the EU has set up strict rules and procedures to ensure a high level of protection for human health, animal health and the environment.

Thus, Regulation (EU) 528/2012 aim to harmonise the European market for biocidal products and their active substances. At the same time, it aims to provide a high level of protection for humans, animals and the environment. This Regulation repealed the Biocidal Product Directive 98/8/EC in its entirety on 31 August 2013.

The Regulation concerning the making available on the market and use of biocidal products sets out rules for: approving active substances in biocidal products, authorising the selling and use of biocidal products and selling articles treated with biocidal products.

It simplifies the approval of active substances and authorisation of biocidal products and introduces timelines for Member State evaluations, opinion-forming and decision-making. The Regulation also promotes the reduction of animal testing by introducing mandatory data sharing obligations and encouraging the use of alternative testing methods.

As in the previous Directive 98/8/EC, the approval of active substances takes place at Union level and the subsequent authorisation of the biocidal products at Member State level. This authorisation can be extended to other Member States by mutual recognition. However, the new regulation also provides applicants with the possibility of a new type of authorisation at Union level (Union authorisation).

In summary some key elements of the Regulation:

- Provide for the authorisation at the Union level of certain biocidal products;
- Improve the functioning of national authorisations and mutual recognition by introducing binding deadlines and strengthening the system of mutual recognition dispute settlement;
- Reduce the number of animal tests by obligatory data sharing with respect to vertebrate animal studies;
- Strengthen the rules on data waiving (i.e. not request data which is not necessary); furniture treated with wood preservatives, which are imported from third countries;
- Harmonised fee structure which will harmonise the conditions and criteria for setting the fees in all Member States;
- The European Chemicals Agency (ECHA) will be involved in the scientific work on biocidal products;
- Persons placing biocidal products on the market will have to hold an authorisation
- Extend the scope to cover additional articles and materials treated with biocidal products

1.2.5. Regulation on the Export and Import of Hazardous Chemicals ((EU) No 649/2012)

Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals is the latest in a series of measures over the years that seek to address international trade with hazardous chemicals. It implements, within the Union, the Rotterdam Convention on the Prior Informed Consent Procedure (PIC) for certain hazardous chemicals and pesticides in international trade, with a view to protecting human health and the environment from potential harm and contributing to the environmentally sound use of such chemicals.

The Regulation reaffirms the Union's commitment towards ensuring proper control in the trade and use of hazardous chemicals at the global level, based on the principle that it should help to protect human health and the environment beyond its borders as well as within. The Regulation (EU) 649/2012 regulates the import and export of certain hazardous chemicals and places obligations on companies who wish to export these chemicals

to non-EU countries. It aims to promote shared responsibility and cooperation in the international trade of hazardous chemicals, and to protect human health and the environment by providing developing countries with information on how to store, transport, use and dispose of hazardous chemicals safely.

The Regulation applies to banned or severely restricted chemicals listed in Annex I, containing industrial chemicals, pesticides and biocides, for example, benzene, chloroform, atrazine and permethrin. The export of these chemicals is subject to two types of requirement: export notification and explicit consent. It also applies to chemicals that are banned for export as listed in Annex V and to all chemicals when exported regarding their packaging and labelling, which must comply with relevant EU legislation, unless this would conflict with any specific requirements of the importing country.

Regulation (EU) 649/2012 entered into operation on 1 March 2014.

1.2.6. Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ((EC) No 1907/2006)

REACH is an integrated system for the registration, evaluation, authorisation and restriction of chemicals, which is partly operated by the European Chemicals Agency (ECHA) and supervised by the European Commission. REACH requires firms which manufacture and import substances to evaluate the risks resulting from the use of those substances and to take the necessary steps to manage any identified risk. Industry has the burden of proving that substances produced and placed on the market are safe. The purpose of the Regulation is to ensure a high level of protection of human health and the environment as well as the competitiveness of the chemicals sector and promote innovation.

Registration is the key component of the REACH system. As from June 2008, it is compulsory to register in a central database substances which are manufactured or imported in quantities of one tonne or more per annum and substances which are intended to be released from articles in quantities of one tonne or more per annum. The database is managed by ECHA. If a substance is not registered it cannot be manufactured or placed on the European market.

An evaluation system is developed by the ECHA in cooperation with the competent authorities. It makes it possible for ECHA to check that industry is fulfilling its obligations and avoiding tests on vertebrate animals when unnecessary.

Substances of very high concern due to their particular hazard properties may be subject to authorisation by the Commission, meaning that the industry is not allowed to place on the market or use such a substance of very high concern unless industry has an authorisation granted by the Commission. The objective of the authorisation procedure is to ensure that the risks associated with the use of these substances are adequately controlled and that these substances are gradually replaced by other appropriate substances or technologies where this is economically and technically viable. The use of substances may only be authorised where their use is of overall benefit to society.

The Agency publishes and updates a 'list of candidate substances' identified as having characteristics of very high concern. These may include the following CMRs (carcinogens, mutagens and reproductive toxins); PBTs (persistent, bio accumulative and toxic substances); vPvBs (very persistent and very bio accumulative substances); and, some substances of equivalent concern which have irreversible serious effects on humans and the environment, such as endocrine disrupters.

Restrictions are a tool to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions may limit or ban the manufacture, placing on the market or use of a substance. A restriction applies to any substance on its own, in a mixture or in an article, including those that do not require registration. It can also apply to imports. A Member State, or ECHA on request of the European Commission, can propose restrictions if they find that the risks need to be addressed on a Community wide basis.

1.2.7. Regulation on Classification, Labelling and Packaging of Substances and Mixtures ((EC) No 1272/2008)

This Regulation harmonises requirements concerning the classification, labelling and packaging of chemical substances and mixtures in line with the international system - Globally Harmonised System (GHS) approved by the United Nations. This harmonisation enhances protection of health and the environment, and improves the free circulation of chemical substances and mixtures. This Regulation supplements the [REACH system](#) for registration, evaluation, authorisation and restrictions concerning chemical substances.

Before placing chemicals on the market, the industry must establish the potential risks to human health and the environment of such substances and mixtures, classifying them in line with the identified hazards. The hazardous chemicals also have to be labelled according to a standardised system so that workers and consumers know about their effects before they handle them.

The classification of chemical substances and mixtures is based on categories which take into account the degree of hazard and the specific nature of the hazardous properties. These include inflammable substances or mixtures, those which are highly toxic, those which are dangerous for the aquatic environment, etc. Annex I establishes the criteria for the classification and labelling of hazardous substances and mixtures. The Annexes of the Regulation also include the list of hazard statements, the list of precautionary statements, pictograms for each hazard class and the lists of classifications and labelling harmonised at EU level.

Concerning labelling, it must mention: the name of the substance or mixture and/or an identification number; the name, address and telephone number of the supplier; and the nominal quantity of the substance or mixture. The Regulation sets out hazard pictograms to apply, also referring to signal words, hazard statements, precautionary statements and the need for supplementing information regarding properties or hazards (Annexes II, III, IV and V).

Packaging containing hazardous substances or mixtures must be of certain standard, e.g. must prevent any of the contents escaping; be made of materials which are resistant if they come into contact with the contents; be strong and solid; and have sealable fastenings. In some cases, child-resistant fastenings and tactile warnings are required.

This Regulation repealed Directive 67/448/EEC on chemical substances and Directive 1999/45/EC on mixtures with effect from 1 June 2015.

1.2.8. Regulation on the Banning of Exports of Metallic Mercury and the Safe Storage of Metallic Mercury ((EC) No 1102/2008)

This Regulation, which entered into force on 4 December 2008, has two principal objectives:

- Establishing an EU ban on all exports of metallic mercury and certain mercury compounds and mixtures from 15 March 2011. The ban on exports of mercury from the European Union (EU) shall

contribute to reducing the global mercury supply, and, indirectly, to limiting the emissions of this heavy metal, which is extremely toxic to the environment.

- Characterising as waste and ensuring the safe storage of significant quantities of mercury used in or produced by certain industrial activities (applicable as from 15 March 2011).

The ban on exports and the safe storage of surplus mercury are essential elements of the EU strategy concerning mercury adopted in 2005²⁷⁰ and reviewed in 2010²⁷¹. This strategy aims to combat pollution caused by mercury in the EU and globally. It includes 20 actions which aim to reduce mercury emissions, limit supply and demand and protect against exposure, particularly to methylmercury present in fish.

1.2.9. Selection of other directly relevant legislation

This section presents a number of selected pieces of legislation which have direct relevance to the implementation of chemicals legislation.

- The Industrial Emissions Directive (2010/75/EU) establishes an integrated system of pollution prevention and control for a range of industrial activities, comprising an integrated system of permits, monitoring, inspections. Annex I of the IED covers specifically the chemicals sector and require permitting authorities to set emission limit values or other technical measures to ensure that the sector minimises pollution of chemical substances, for instance through application of best available techniques (BAT).
- Seveso III Directive (2012/18/EU) applies to any establishment where dangerous substances are present or likely to be produced as a result of an accident, in quantities equal to or in excess of the quantities listed in the Annex I to the Directive. Member States must ensure that the operator takes all measures necessary to prevent major accidents and to limit their health and environmental consequences and is required to prove to the competent authority that all the necessary measures provided for by the Directive have been taken.
- Waste Framework Directive (2008/98/EC) sets out a framework for handling and disposing of waste. This also affects installations handling dangerous chemicals. It is important to take note of the processes which result in dangerous substances becoming hazardous waste to be dealt with under the waste legislation rather than under the chemicals legislation.
- European Pollutant Release and Transfer Register Regulation (EC) No 166/2006 sets up a European Pollutant Release and Transfer Register (PRTR) in the form of a publicly accessible electronic database. This database meets the requirements of the United Nations Economic Commission for Europe (UNECE) Protocol on Pollutant Release and Transfer Registers. This register is available to the public free of charge on the internet. The register contains information on releases of pollutants to air, water and land, as well as off-site transfers of pollutants present in wastewater and waste. The register covers 91 pollutants listed in Annex II, including greenhouse gases, other gases, heavy metals, pesticides, chlorinated organic substances and other inorganic substances. Releases are reported when the level of the emissions exceeds a certain threshold and results in one of the 65 activities listed in Annex I. Information gathered at national level by Member States and reported to the Commission is fed into

²⁷⁰ Communication from the Commission of 28 January 2005, "Community Strategy concerning Mercury" [COM(2005) 20 final- Not published in the Official Journal].

²⁷¹ [COM/2010/0723 final](#), 7.12.2010

the database on a regular basis. This information is submitted annually to the competent national authority by the operators of the establishments concerned. Member States must also gather information on releases from diffuse sources using internationally approved methods. Member States must report the information they have collected to the Commission by the stipulated deadline (within 15 months of the end of each reporting year). Member States are permitted to keep certain information confidential; if they do, they must notify the Commission of the type of the information that is being withheld and the grounds for withholding it.

In addition to the abovementioned legislation, there is ample legislation in several sectors which also have to be taken into account when implementing the chemical acquis. Note that the list is not exhaustive.

- EIA Directive (2011/92/EU)
- Environmental Liability Directive (2004/35/EC)
- Air Quality Framework Directive (2008/50/EC), including the 4th Daughter Directive (2004/107/EC)
- National Emission Ceilings Directive (2001/81/EC)
- F-gases Regulation ((EU) No 517/2014)
- Regulation on substances that deplete the ozone layer ((EC) No 1005/2009)
- Batteries Directive (2006/66/EC)
- PCB/PCT Directive (96/59/EC)
- End of life vehicles Directive (2000/53/EC)
- RoHS Directive (2011/65/EC)
- WEEE Directive (2012/19/EU)
- Landfill Directive (1999/31/EC)
- Mining Waste Directive (2006/21/EC)
- Shipments of Waste Regulation ((EC) No 1013/2006)

2. DEVELOPMENT OF A SECTORAL STRATEGY AND IMPLEMENTATION PLAN

2.1. Key Factors Influencing Strategy Development

In Section 2.4 of the introductory chapters of this Handbook, the key activities to be undertaken in preparing a plan to implement environmental legislation are summarised in the implementation planning framework checklist.

The chemicals sector is regulated through a wide range of measures. These include requirements for prior notification to and authorisation from the competent authority; risk assessment procedures; the classification, packaging and labelling of regulated substances (or organisms); registration requirements, evaluation and market intervention requirements, restrictions on production, supply and use, applying good laboratory practices, as well as control and notification regarding imports and exports. The following text outlines considerations to be taken into account when planning the implementation strategy for the chemical sector:

- Identify stakeholders and arrange discussions between them, especially on the choice of a competent authority or (authorities).
- Following consultation, appoint a competent authority to implement the requirements of each Directive and/or Regulation.
- Specific provision has to be made for dealing with potentially hazardous chemicals at the planning stage. Issues to be resolved will include how and where a substance is to be kept or used, the times when the substance may be present and the permanent removal of the substance (whenever possible).
- Provision must be made for controlling potentially dangerous activities before they commence, with competent authorities having appropriate powers to impose safety requirements. In principle, REACH applies to all chemical substances; not only those used in industrial processes but also in our day-to-day lives, for example in cleaning products, paints as well as in articles such as clothes, furniture and electrical appliances. Most of the activities involving production or use of dangerous substances on a large scale are subject to the Industrial Emissions Directive (2010/75/EU) requiring an integrated permit prior to commencing operations. Also installations with dangerous substances may be subject to the Seveso III Directive requiring additional precautionary and safety measures to prevent and contain effects in case of major accidents. Substances falling within the scope of the controls are usually defined by reference to their hazardous qualities as well as threshold quantities.
- Provide financial resources for undertaking monitoring and other forms of assessment, for enforcement activities, and for collating and disseminating the results and other relevant data. A number of directives already call for extensive access to environmental information and data as well as the right of the public to be consulted on certain developments, projects and activities in which they may have a direct or indirect interest. Such legislation include Environmental Information Directive (2003/4/EC), Public Participation Directive (2003/35/EC), EIA Directive (2011/92/EU). In addition, the E-PRTR (pollution release transfer register) under Regulation provides a systematic

framework for collation, reporting and dissemination of information on an installation's pollution levels. In addition, the Industrial Emissions Directive reinforces the reporting framework. Financial resources have to be identified and allocated to ensure effective implementation.

- Make the necessary changes to the sanctioning system to ensure efficient enforcement of the chemical legislation. The common law countries have based enforcement of REACH mostly on criminal law, with an emphasis on the use of notices before applying criminal sanctions. Other countries are divided between those enforcing REACH mostly at the administrative level and those combining administrative and criminal approaches.
- Take measures to ensure compliance with the polluter pays principle which includes a responsibility to remediate any environmental damage made to a chemical site. The Environmental Liability Directive (2004/35/EC) sets out a dual responsibility scheme where for serious pollution, the liability is strict.
- Appoint an appropriate institution (or institutions) to undertake inspections and monitoring. Enforcement of REACH and CLP means, generally, a range of actions that national authorities initiate to verify the compliance of the duty holders with REACH and CLP Regulations. For example, this includes checking whether the substance has been registered or pre-registered or verifying the presence and correctness of the Safety Data Sheets.
- The REACH and CLP regulations provide new challenges for enforcement authorities due the shift from the pre-marketing to the premanufacturing model and the introduction of a new system for classification, packaging and labelling. Before REACH, chemical enforcement was primarily focused on the placing of the market of substances, now enforcers must also enforce the manufacturing of substances. National enforcement strategies should allow planned, structured, coordinated and consistent enforcement actions, involving all inspection bodies concerned. In this context the role of customs authorities has to be pointed out, considering the key role of importers under the REACH and CLP Regulations placing substances on their own, in mixtures or in articles on the EU market. Enforcement systems are generally based on minimum criteria for inspections, with the one originally developed by IMPEL for environmental inspections and the one developed by the ECHA Forum of Exchange of Information on Enforcement for the REACH and CLP inspections. It should be noted that with the entry into force of the Industrial Emissions Directive (IED) and the Seveso III Directive, industrial installations covered by those Directives are subject to much stricter requirements on routine and ad-hoc inspections, monitoring, reporting and ensuring that provisions on public participation and access to environment are fully applied.
- Where relevant, once emission limit values and/or product specifications have been established, introduce regulations and/or other legislative measures to implement and enforce them.
- Set up suitable quality assurance and technical advice and guidance for the assessment/inspection/monitoring programme, to include third-party accreditation for the analytical services.
- Prepare and implement action programmes to reduce adverse human and environmental health effects in the short term, when emission or critical limit values are in danger of being exceeded, as well as programmes aimed at identifying and mitigating long-term effects on health, biodiversity and other environmental parameters.
- Prepare and implement integrated plans covering all the hazards concerned, also taking into account the need for preparing an external emergency plan under the Seveso III Directive (2012/18/EC).

- Prepare and introduce procedures for prior notification for imports and exports of chemicals. This procedure should be supplemented with guidance to the key players, e.g. the competent authorities, customs authorities, the industry regarding their obligations under the import/export regime. The various documents have to be prepared in the formats indicated in the Regulation (EU) 649/2012 concerning the export and import of hazardous chemicals.
- Introduce a timetable for phasing out the use of POPs (persistent organic pollutants), where applicable, taking into account obligations at international and EU level. Ensure that air quality monitoring stations also can detect levels of POPs to be able to assess concentration levels.
- Prepare a report at specific time intervals informing the Commission (and sometimes also other Member States, national authorities or the public) about implementation of the legislation throughout the national territory.

2.2. Potential Difficulties in the Implementation Process

The development of an effective strategy for the implementation of the legislation relating to the control of chemicals involves the following key stages:

- 1) Establishment of a strategy development project team.
- 2) Review and analysis of the existing situation.
- 3) Development and evaluation of options.
- 4) Preparation of a draft strategy and options paper for consultation with stakeholders.
- 5) Review of strategy and options following the consultation process.
- 6) Preparation of strategy and implementation plan.

It is essential that financial resources are identified and allocated to the various steps in the strategy development and for the ongoing implementation activities. This should be done at a very early stage and examine means to reduce costs by integrating certain cross-sectoral activities such as monitoring, reporting and inspections. In certain cases, it can be cost-efficient and increase overall transparency to have a larger competent authority covering several pieces of legislation. The main considerations for each of these stages are outlined below.

2.3. Key Stages in Strategy Development

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2.3.1. Strategy Development Project Team

The project team should be drawn mainly from existing senior staff within the main pollution control organisation(s) and from governmental departments related to health and safety and trade and industry. However, it is useful to bring in, or at least consult with, senior technical and managerial staff from industry. Also in the initial phase, it might be necessary to hire external experts, which in turn can help train the staff of ministries and competent authorities.

Essentially the team needs to have in-depth knowledge of the following:

- the current legal framework for the control and assessment of chemicals and coming changes. This will comprise the obligations on classification, labelling and packaging, evaluation and registration of substances, market surveillance measures, and measures ensuring the safe transport of chemicals;
- the current activities regarding risk assessment of chemicals as conducted by industry;
- the capacity of industry to absorb costs relating to the testing of chemical substances and ensure correct classification, labelling and packaging;
- national and international legislation in the field of chemicals;
- the links with other sectoral legislation, e.g. water management, ambient air protection, industrial pollution control and climate change;
- the need for various technical measures including setting up laboratories for testing and verification and issuing of technical guidance;
- application of BAT in the chemicals sector and
- the functioning and relationships of national, regional and local governmental organisations.

It is likely that the team will need to work together for a number of years with at least a core staff dedicated to the project on a full-time basis.

2.3.2. Review and Analysis of the Existing Situation

This stage involves compiling information relating to the control and assessment of chemicals.

This should include:

- a review of current legislation and its implementation;
- a review of permitting and notification procedures with particular reference to application procedures and documentation requirements. The review should also include an assessment of who is responsible for issuing permits and licences and handling notifications and at which level it is most appropriate for these tasks to be carried out (national, regional or local);
- an examination of current guidance made available to industry in these areas; and an examination of control procedures and enforcement practices.

2.3.3. Development and Evaluation of Options

Once the review and analysis is complete, sufficient information should be available to allow options for implementation to be put forward. The options put forward will include suggestions as to:

- how the requirements of the legislation may be met by the relevant institutions;
- how the existing permitting, licensing, notification, monitoring and control procedures could be improved;
- how the existing institutions may be strengthened, and whether interdisciplinary approaches would improve compliance;
- how to ensure effective co-ordination between the controlling authorities and the designation of responsibilities;
- how to manage relationships with industry during their applications for permits and licences and submission of notification, and what those permits, licences and notifications should cover;
- what guidance should be made available to industry on how to comply with this legislation;
- how to monitor and control permitted or licensed processes, and ensure that they remain within the limits imposed by the permits;
- how to set up and maintain the data collection inventories to cover all the data requirements under the chemical legislation also taking into account data collection requirements under other sectoral legislation such as waste management, water management and industrial emissions. Specific attention to the requirements on collecting and processing data on pollutant releases under Regulation on Pollutant Release and Transfer Register;
- what measures and procedures to establish to ensure timely and sufficient reporting from operators vis-a-vis the competent authorities, inspection authorities vis-a-vis competent authorities, custom authorities vis-a-vis competent authorities and competent authorities vis-a-vis the Commission;
- how to ensure full compliance with provisions on access to environment and public participation in decision-making, which will require procedures and guidance on how and when to provide access to information and how to involve interested stakeholders and to ensure a review procedure;
- how to manage the repository of notifications and similar material and ensure proper dissemination.

The initial options put forward should vary from doing the minimum relative to the existing situation (whilst still complying with the requirements of the relevant directives and regulations) to introducing more extensive reforms. For each of the options put forward there will need to be an assessment of the resource implications

of implementation, which will include itemisation of the training, staffing and fixed resources required to complete the implementation. In addition, the time-scales associated with the options will need to be established.

2.3.4. Preparation of a Draft Strategy and Options Paper for Consultation with Stakeholders

As part of the initial stages of implementation it is advisable to undertake a series of consultation exercises in order to canvass the opinions of the various stakeholders. This would include the regulatory bodies; central, regional and local government; customs authorities, monitoring and supervisory public bodies, technical bodies, industry and industrial organizations; environmental and health related organisations; and other relevant NGOs. It would initially involve the preparation of a consultation document to be circulated to the various interested parties. The document would discuss the key issues associated with the implementation of the legislation relating to chemicals, potential difficulties and possible options. Experience has shown this type of exercise to be very beneficial in smoothing the way forward for implementation, and in helping the preparation of all those likely to be involved.

2.3.5. Review of Strategy and Options Following the Consultation Process

Following the consultation process and feedback from the stakeholders, the strategy can be refined and the preferred options developed so that a detailed implementation plan can be drawn up. The various options should be weighed against each other with pros and cons and financial implications. This implementation plan and draft strategy should reflect the opinions of the stakeholder and take into account time limitations.

2.3.6. Preparation of Strategy and Implementation Plan

At this stage, the main tasks, roles and responsibilities of the key bodies to be involved in the implementation process and the operation of the systems need to be defined. Possible bodies that could be involved are as follows:

- the government;
- the competent authority (CA);
- the permitting authority (PA) if required; and
- the regulatory body (RB) (in some cases this may be the same body as the PA).

A technical committee could be set up to co-ordinate the development of guidance notes and to act as an advisory body for policy issues.

3. INSTITUTIONS AND RELEVANT PARTIES

3.1. Stakeholders

A large number of stakeholders have an interest in, or may be affected by, the legislation covered in the chemicals sector. The principal stakeholders and their role in the implementation of the legislation in this sector are summarised in the Box below. The following sub-sections focus on particular issues relating to key groups of stakeholders.

Table 3. Box with Principal Stakeholders and Their Roles in the Sector on Chemicals

Principal Stakeholders and Their Roles in the Sector on Chemicals	
Stakeholders	Roles
Central government (e.g. a ministry or department)	<ul style="list-style-type: none"> • Implementation and maintenance of compliance with EU policies and legislation on chemicals, good laboratory practice (GLP) and protection of animals used for scientific purposes. • Providing a general legislative framework for implementation of the REACH Regulation.
Environmental agencies working on behalf of central government (e.g. regulatory authority, national standards laboratory, veterinary service)	<ul style="list-style-type: none"> • Provision of planning, regulation and technical assistance. • Assistance in risk assessment. • Maintaining databases and inventories of manufactured, traded and used chemicals. • Enforcement of legislation.
Regional and local government, municipalities	<ul style="list-style-type: none"> • Planning consent and agreement of localised activities (including enforcement of coexistence) • Air emission control and waste disposal. • Notification to higher bodies with respect to water supply. • Trade descriptions. • Forum for public concerns
Chemical industry (manufacturing and marketing of dangerous substances and mixtures, as well as production of	<ul style="list-style-type: none"> • Import, export, transportation and manufacture of dangerous substances and mixtures.

products containing such dangerous substances and mixtures)	<ul style="list-style-type: none"> • Play a larger role in ensuring the risk evaluation of existing and new chemicals covered by the REACH framework. • Communicate to the competent authorities new information about the properties and risks associated with chemicals. • Restrict and control the use of animals in experiments.
Construction industry	<ul style="list-style-type: none"> • Demolish buildings and develop brownfield sites that may be contaminated with asbestos
Private laboratories	<ul style="list-style-type: none"> • Chemical waste use and discharge. Experiments on animals. • Test the properties of chemicals.
Public	<ul style="list-style-type: none"> • Health and safety concerns for workers handling dangerous substances and residents living near chemical installations. • Lobby government on issues such as animal welfare and chemical control.
NGOs and civil society	<ul style="list-style-type: none"> • Represent specific interest groups such as animal welfare. Lobby government about the siting and activities at chemical plants and experimental activities.
Research industries (including innovation clusters and universities)	<ul style="list-style-type: none"> • Technical research, inter alia, into alternatives for dangerous chemicals and non-animal testing methods

3.2. Central Government

Several ministries will be directly involved in the implementation of the legislation on chemicals, while others will need to be informed and consulted. The principal ministries involved directly in implementation will be those responsible for the environment, health and welfare, labour, and industry. Implementation of the Directive on the protection of animals used for scientific purposes (2010/63/EU) will also involve the ministry with responsibility for veterinary affairs.

There will also be a need to liaise with other ministries on the implementation of the legislation.

Ministries responsible for industry, water and waste management at least need to be consulted, particularly in regard to permitting and reporting requirements and in the setting of emission limit values or other emission restricting parameters. Given the economic importance of the chemicals sector, the need to ensure free movement of goods and avoid arbitrary restrictions, extensive consultation should be carried out. The ministry with responsibility for foreign affairs will have an interest because of the interactions of EU legislation with international organisations and treaties, such as the Rotterdam Convention on Prior Informed Consent (PIC), the Stockholm Convention on Persistent Organic Pollutants (POPs), the 1998 Aarhus Protocol on Persistent Organic Pollutants (POPs). The ministry responsible for health and safety of workers would have particular interests in legislative fields concerning pollution from asbestos and mercury.

A well-structured mechanism to provide governments with external advice is essential to meet the need for specialist inputs. Many matters arising in implementation in this sector require expertise which is not routinely present in government departments or being spread over many departments. In areas like chemicals, it could be beneficial to create formal advisory committees to ensure the participation of the affected departments. Candidate countries should also consider hiring external experts, including international experts for a limited time, to acquire practical and technical knowledge on implementation and the various aspects and implications. To the extent possible candidate countries should try to draw on the experience of the existing Member States. The Commission is increasingly establishing various EU-level forums for the exchange of information and consultation. Candidate countries should follow developments in these forums and where possible participate.

3.3. Competent Authority

The choice of competent authority will depend on the existing structure of government and the remit of the different ministries within the candidate countries.

In the chemicals area it could be useful to establish a chemicals supervisory service as competent authority responsible for risk assessments, notification, prior informed consent procedures etc. Such service could rationalise the administration. Candidate countries have discretion in deciding on whether to engage one or more competent authorities for the chemicals legislation. There are several advantages of having one and the same competent authority responsible for the implementation of the CLP legislation and the REACH Regulation given the close links and the central role of the ECHA (and the Commission), with which the candidate countries have to coordinate their activities. Such a competent authority has to be furnished with the necessary mandate, resources and capacity to be able to carry out the many tasks. Competent authorities are also needed for implementing the Regulation on import and export of hazardous chemicals and the Regulation on mercury export ban (i.e. Regulation (EU) No 649/2012 and Regulation (EC) No 1102/2008). The competent authority to be designated for implementing the Asbestos Directive and the Biocidal Product Regulation may not be necessarily linked to the Ministry responsible for environmental protection but rather to the Ministry of Health and/or Labour and the Agriculture (for biocides). Responsibilities under Directive on the use of animals for scientific purposes is often covered by Ministry of Agriculture or Research, or State Veterinary services.

Where two or more competent authorities are appointed, there must be clear agreement about spheres of responsibility and a coordination mechanisms needs to be established to ensure continuous consultation and coordination of activities. It is also necessary to ensure coordination with the competent authority in charge for the Waste Directive (2008/98/EC) and the Industrial Emissions Directive (2010/75/EU).

It is important that the various stakeholders including industry and the public are thoroughly informed about the competent authorities and their responsibilities and tasks and to what extent they can turn to them for information. Many of these tasks require specialist technical knowledge.

3.4. Regional and Local Government

In general, regional and local governments are playing a minor role in relation to the implementation of legislation related to chemicals. However, where the implementation will affect issues related to air quality, waste disposal, water management and integrated pollution prevention control, the regional and local governments will be involved. Also, activities that involve the handling of hazardous substances are often regulated at the stage of planning and development control at the regional and local levels.

3.5. Private Sector Involvement

Industrial companies working in chemicals, pharmaceuticals, biotechnology, laboratory research, and their significant sub-sectors, will have legitimate interests in legislation covering chemicals. Major industries will often make individual representations to government, but a principal contact should be made with the relevant trade and branch organisations.

The interests of workers should be considered through consultation with trade unions and with relevant professional bodies.

3.6. Communication and Consultation

Regarding communication of certain relevant information, such as initial plans on establishing new chemical installations, extending the installations of existing ones, pollution release data and annual environmental reports, there is a range of legislation applying. The basic requirements and procedures on access to environmental information are set out in Directive on Access to Environmental Information (2003/4/EC). In addition to this key directive, the individual legislation often contains provisions on access to information and the duty to consult in certain instances. In addition to providing information directly to the public by radio, TV and press, some legislation requires data to be made available in public registers. Consultation with NGOs is also important. Although NGOs may present a wide range of views consultation with them is invaluable in demonstrating the transparency of legislation and its implementation. ECHA has a specific role in these aspects of communication and consultation. As from 20 January 2016, information on up to 120 000 chemicals is enriched and structured in three layers: infocard, brief profile and detailed source data. The information is available at the ECHA website: <http://echa.europa.eu/information-on-chemicals>

The Competent Authorities in the member states have specific functions that refer to evaluation, authorisation and restriction, providing a helpdesk function at national scale, with compliance and enforcement.

Table 4. Box illustrating some tasks by competent authorities

Examples of Activities Undertaken by Competent Authorities

Planning:

- design procedures for e.g. communication and compliance programmes,
- design systems and procedures for the evaluation, authorisation and restrictions of substances in line with requirements of REACH Regulation ((EC) No 1907/2006)
- design systems to ensure that the industry will fulfill their obligations for the classification, labelling and packaging of substances and mixtures in line with GHS (global harmonised system) (Classification, Labelling and Packaging Regulation (EC) No 1272/2008)
- Establish procedures for controlling the import and export of hazardous chemicals (so-called PIC procedure), under the Rotterdam Convention and Regulation (EU) No 649/2012, which includes guidance notes, making available notification documents etc.
- Establish procedures, including monitoring and inspection to oversee the manufacture, trade and use of POPs under the Stockholm Convention on POPs and the Regulation (EC) No 850/2004 on POPs
- Establish procedures for banning exports of metallic mercury and to ensure that metallic mercury being the result of certain ore, natural gas cleaning and other activities is being safely stored. This storage involves procedures for granting storage permits for above-ground and underground safe storage
- Establish consultation procedures to involve stakeholders and the general public in implementing of the chemical acquis. These procedures should also involve cross-border consultation and notification to the competent authorities. The consultation procedures should take into account provisions of Environmental Information Directive,
- Establish the procedures and compliance with project authorisation requirements under Animal Testing Directive (2010/63/EU) when the testing of substances require the use of live animals.
- Establish procedures for reporting to the Commission and, regarding REACH Regulation, to the European Chemicals Agency,
- Establish systems for monitoring regarding restricted substances (e.g. under POPs Regulation, Asbestos Directive, Biocidal Product Regulation and REACH Regulation). Guidance should be produced to clarify the restrictions applicable and the obligations of manufacturers, importers, suppliers and users.
- Establish a solid inspection system with routine and non-routine inspections which might involve increasing capacity of inspection authorities and ongoing training
- Establish an enforcement system to detect and sanction non-compliance.

Regulation:

- set limits for discharges from installations processing asbestos (Directive 87/217/EEC);
- monitor asbestos emissions and ensure controls are in place (87/217/EEC);
- ensure that activities involving chemicals, especially the production or large-scale use of chemicals, are subject to permitting under the Industrial Emissions Directive (2010/75/EU);
- ensure that establishments involving dangerous chemicals comply with the Seveso III Directive (2012/18/EU) , requiring certain emergency plans and assessments;

- ensure that installations comply with the requirements *inter alia* on personnel, care and accommodation of animals and record keeping (Directive 2010/63/EU on the protection of animals used for scientific purposes)
- inspect laboratories to verify compliance with Directive 2010/63/EU and REACH Regulation;
- set up a data collection system and publish statistical information (2010/63/EU, REACH Regulation, Regulation on Pollutant Release and Transfer Register ((EC) No 166/2006);
- evaluate data supplied by manufacturers and importers of chemical substances (CLP Regulation (EC) No 1272/2008);
- evaluate risks to human health and the environment (REACH Regulation (EC) No. 1907/2006), Regulation (EC) No 1272/2008);
- ensure that no metallic mercury is exported from the EU and that all temporary or permanent storage of metallic mercury is subject to a permit (Regulation (EC) 1102/2008) including specific acceptance criteria for metallic mercury;
- develop a strategy to limit risks (REACH Regulation (EC) No. 1907/2006));
- ensure that testing on vertebrate animals is carried out in controlled environment, complying with the principles of 3Rs in terms of replacing, reducing and refining the use of animals in testing (Directive 2010/63/EU);
- control the placing of dangerous substances on the market,
- control the import and export of certain chemicals (Regulation (EU) No 649/2012 (PIC procedure)).

Reporting:

- ensure compliance with rules on confidentiality of information (2010/63/EU, REACH Regulation (EC) No 1907/2006, Access to Environmental Information Directive (2003/4/EC), Biocide Regulation (EU) No 528/2012 and CLP Regulation (EC) No 1272/2008)
- ensure that third parties comply with notification and reporting requirements;
- publicise requirements to relevant manufacturers, importers, exporters, etc. (REACH Regulation (EC) No 1907/2006, CLP Regulation (EC) No 1272/2008); Regulation (EU) No 649/2012 on exports and imports of hazardous chemicals, POPs Regulation (EC) No 850/2004;
- ensure health and safety information, such as safety data sheets is available to workers;
- ensure the public is informed (virtually all legislation);
- report to the Commission (all legislation).

4. TECHNICAL ISSUES

Technical standards and guidelines are important in providing maximum compatibility across and between industries. They provide detailed technological information on, for example, methodologies for testing, construction, or use of materials. This type of information is not normally incorporated into primary legislation, often being very detailed and complex, and requiring periodic updates as technology advances.

Relevant standards may be prepared at different levels. The international level includes those produced by worldwide organisations such as the International Standards Organisation (ISO) or WHO, and European standards such as the European Standards Organisation (CEN). European standards are widely applied in Member States and national standardisation bodies commonly adopt them as national standards. However, standards do not have legal force in many European countries; in spite of this they are widely regarded by regulatory bodies as indicating best practice and their use often becomes obligatory for this reason.

A list of bodies producing standards which are significant in the chemical sector in Europe include:

- European Chemicals Agency (ECHA) guidance documents on REACH and CLP implementation: <http://www.echa.europa.eu/en/web/guest/support/guidance-on-reach-and-clp-implementation>
- international e.g. World Health Organisation (WHO) guidelines and standards and ISO standards (e.g. ISO 14001);
- OECD guidelines for testing methodologies;
- European e.g. EU guidelines and standards;
BREFs or BAT Conclusions (for instance BREFs for Large Volume Organic Chemical Industry can be obtained at JRC: <http://eippcb.jrc.ec.europa.eu/reference/>)
- national e.g. technical instructions/regulations developed and introduced by government; formal standards issued by national standards bodies; and
- sectoral e.g. technical guidelines or specifications developed by industrial or professional associations applicable to a particular sector or type of activity.

In the chemicals sector, competent authorities are required to set standards and prepare procedures on a variety of issues. Technical standards prepared for other environmental sectors are also relevant here. For example, some Member States have prepared technical guidance on integrated pollution control, which may be relevant to the implementation of legislation in this sector, such as the Asbestos Directive. The adoption of standards and guidelines to meet performance requirements will inevitably create the need to train staff and this must be recognised by regulatory authorities. In some cases, it might be difficult to implement legislation fully until training needs are met.

5. REGULATION AND ENFORCEMENT

5.1. Licensing, Inspection and Monitoring

The regulatory requirements in this sector relate mainly to notification, registration and authorisation of substances and authorisation of certain activities involving substances. The latter is also subject to legislation such as the Industrial Emissions Directive (2010/75/EU) requiring an integrated permit and the Seveso III Directive on prevention of major-accident hazards (2012/18/EU). In either case, monitoring, inspections and enforcement are key components of implementation of the legislation. The importance of actually enforcing legislation is emphasised both in the individual pieces of legislation and in the Environmental Crimes Directive (2008/99/EC) setting out a long list of offences which it considers an environmental offence subject to penal sanctions in case of non-compliance. The main aspects of regulation are the same for most environmental legislation in this sector.

Specific issues include:

- authorisation of establishments such as laboratories;
- the collection and evaluation of written or computerised information such as notifications from manufacturers, and exporter/importers;
- inspection and monitoring of activities to check that the correct procedures are being carried out; and
- enforcement action.

With REACH Regulation ((EC) No 1907/2006) and the CLP Regulation (EC) No 1272/2008) in conjunction with the Industrial Emissions Directive ((EU) No 1075/2010), the monitoring and reporting framework has been strengthened. Inspections, both routine and non-routine, are more important than ever.

5.2. Data Collection and Reporting

Several pieces of legislation require Member States to gather and analyse data, for example to collect statistical information on laboratory experiments on animals or make detailed chemical assessments of the risk of certain substances.

The legislation requires Member States to inform the Commission about the text of legislation to transpose directives and actions taken to implement the legislation. Often Member States are required to submit periodic implementation reports. There are also requirements to report other types of information to the Commission, for example:

- lists of licensed laboratories;
- instances of non-compliance;
- summaries of statistical data;

- sampling and analytical methods;
- alternative action taken;
- derogations; and
- notifications.

The CLP Regulation and the REACH Regulation both require extensive efforts to fill current information gaps in the identification and assessment of the risks of substances and mixtures. Competent authorities work together with manufacturer, importers and user of substances to collect information and to fill gaps with new assessments. The frequency of reporting varies: sometimes reporting is required once, in other cases reports must be submitted annually, or three-yearly to the Commission. A number of directives, including Council Directive 87/217/EEC on asbestos, require that reporting be carried out in accordance with the Reporting Directive (Council Directive 91/692/EEC).

Other Member States must also be informed of certain actions taken by an individual Member State, for example, when environmental or single market issues (e.g. market surveillance action such as withdrawing certain products) are involved. Member States also have to provide information to various third parties, particularly manufacturers, exporters, importers, trade unions, workers and the public. The main reasons for publication of such information are to ensure that the relevant bodies are aware of their duties under the legislation, to advise people of health and safety issues and to promote public participation as outlined by the legislation. The duty to inform the general public about risks of dangerous substances and activities involving such substances is enhanced in newer generation EU legislation and the public, including various directly interested NGOs, have a right to be consulted in certain decision-making. Further information on information providing and reporting requirements is provided in the relevant fiches following this sector overview.

6. PRIORITIES AND TIMING

6.1. Prioritising the Implementation Tasks

In the chemical sector, the prioritisation of implementation tasks may be influenced by the economic importance or size of the industry; the potential health risks from that industry; and the existing degree of concordance between EU and national legislation. In some countries, for instance, the production and use of POPs is likely to be minor. Also not all candidate countries will be affected, significantly, by the Regulation (EC) No 1102/2008 on banning mercury exports and regulating mercury storage. This will mainly be relevant for those countries carrying out certain ore operations as well as activities where metallic mercury is used or generated as part of production or refinement processes (e.g. chlor-alkali, cleaning of natural gas). Hence, the candidate countries should start with an impact assessment, ranking all the chemical acquis in order of relevance. In any event, REACH Regulation and the CLP Regulation should be given high priority. Particularly, due to their large overarching scope and the extensive resources required for effective implementation. Regulations also have direct effect, applying from the date of entry into force or after the expiry of a transitional period, which means that third parties have certain rights and in case of non-compliance these parties can turn to national courts to enforce these rights. The REACH Regulation and the CLP Regulation lay down an extensive framework for the identification, classification, registration, assessment, authorisation, restriction of substances and mixtures. In addition, Directive 2010/63/EU on the protection of animals used for scientific purposes use also need to be implemented as this Directive sets out important criteria and principles for testing chemicals on live animals. This overall framework involves a rather complex institutional structure ensuring coordination between several competent authorities and also extensive cooperation with the Commission, the European Chemical Agency and the competent authorities of other Member States. Once this structure has been built, it is probably easier and more cost-efficient to implement legislation addressing certain individual substances such as asbestos, POPs, biocides, metallic mercury. However, some candidate countries are likely to already be Party of the Stockholm Convention restricting POPs and in this case the additional efforts to implement the EU Regulation (850/2004) is relatively minor. As a parallel effort, the Regulation (EU) No 649/2012 has to be implemented to ensure compliance with the PIC procedure relating to certain banned or restricted substances.

In prioritising national measures in the chemical sector, the candidate countries should undertake an initial assessment of the major risks to the population and the environment that may arise from chemical use. Are there any particular hotspots in terms of specific chemical installations? What kind of health impacts or damage to the environment is there linked to the chemical industry?

As a general principle it is essential to involve the key actors in the chemical sector, including relevant NGOs, civil society groups in the planning of the chemical policy and implementation of the EU chemical acquis. Wide stakeholder consultation and awareness raising campaigns clearly indicating the priorities, the health risks and the benefits of the chosen implementation strategy is likely to result in better overall achievements and compliance rates.

6.2. Time-scales

Considerable time is required to implement the chemical acquis fully, even for countries that aim to implement it as soon as possible. The REACH Regulation and CLP Regulation require new structures and procedures for identification, assessment, registration, notification and control of substances and mixtures. This will most likely require an overall implementation plan with designated implementing authorities, their resources and the financial means allocated for these tasks. Compared to earlier, most new legislation in the chemical sector is in the form of regulations and not directives. Although, regulations often contain some kind of transitional periods or temporary derogations, they apply directly without the candidate countries having to first transpose them into national legislation. All regulations are directly applicable meaning that they create rights and obligations enforceable before national and European courts. In principle, the candidate countries will need to ensure that the requirements of all the existing directives and regulations are in place by the date of accession. However, there may be instances where implementation of a specific requirement cannot be achieved by the desired date of accession, and in these cases candidate countries will have to negotiate appropriate transitional arrangements with the Commission.

The programme for implementing the legislation in this sector would be influenced considerably by the extent to which candidate countries have already adopted the measures and procedures required. For example, countries which have already ratified international conventions and protocols, such as the Rotterdam Convention on PIC procedure for import and export of hazardous chemicals and the Stockholm Convention on persistent organic pollutants, or which already have an established, regulated chemical industry, may be well placed to implement some of the legislation in this sector.

Implementation tasks that will tend to be especially time-consuming in the chemical sector are:

- setting up structures and procedures for implementing REACH and CLP Regulations
- procedures for implementation and enforcement ;
- verification and accreditation processes to validating assessments and tests
- inventory of all affected industry and their individual functions or requirements;
- reporting, data collation and statistical interpretation.

7. ECONOMIC AND FINANCIAL ISSUES

7.1. Principal Cost Areas

The principal cost areas associated with the implementation of legislation in the chemical sector consists of costs of establishing the implementation systems, the day-to-day costs of maintaining them and ongoing costs for tasks such as the classification, assessment and registration of new chemical substances, dealing with permits for chemical installations (under Industrial Emissions Directive), which will require the establishment of certain technical facilities for verification and validation service. Another cost, especially in the initial phase-in period, is the hiring of specialist advisors/consultants. Costs will also be incurred by the competent authority to manage notifications and reporting obligations.

In general, costs to industry will be greater than those borne by the regulatory authority. In the chemical sector, manufacturers of new substances will bear the major part of the ongoing costs of implementation.

It is critical in assessing the costs of the regulatory authority to consider the expected development in the sector in the future. For example, a relatively large implementation organisation will be necessary if the government, as a matter of policy, wishes to encourage research and development in the chemical sector. If it does not, a much smaller body will be appropriate.

Few studies have been undertaken on the cost of implementing legislation in the chemical sector. Some examples are given below:

- A DISAE project in Lithuania²⁷² estimated that the implementation of the chemicals legislation would require an investment of EUR 476,000 (for institutions, laboratories etc.) in the public sector and EUR 12.1 million in the private sector (hazard communication unit, safety data sheets, modification of equipment for transport of dangerous goods etc.).
- In a separate study²⁷³, the implementation cost of the chemicals legislation sector in Bulgaria alone was estimated at EUR 63 million.
- A study by EDC²⁷⁴ failed to find reliable information on the use of asbestos in the construction industry in CEECs. However, they point out that asbestos was used in construction in the CEECs, and that it is extremely expensive to control asbestos emissions during demolition and land clearance operations.

7.2. Cost Recovery and the Application of Economic Tools

Candidate countries need to decide whether charges will be introduced for various notifications and authorisations. For instance, the European Chemical Agency will take out a number of charges and fees for

²⁷² DISAE Project LIT-109. Development of Action Programme for Implementation of EU Legislation on Chemicals in Lithuania. Soil & Water Ltd. November 1999.

²⁷³ DISAE, 1998. Review of the Assessment of Accession Costs. Seminar Paper, June 1998.

²⁷⁴ EDC, 1997. Compliance costing for approximation of EU environmental legislation in the CEEC.

various administrative procedures. Some of these revenues will be reallocated to competent authorities, e.g. for assessment procedures finalised by a particular Member State. The charges and fees must however be reasonable and not be prohibitive.

For high levels of chemical activity, charging may be adopted sufficient to meet the costs for operation of the various chemical control procedures. However, if confined activity is expected, the costs of setting up and operating a charge scheme may be much larger than the income from the scheme.

The expenditures caused by the implementation of the Directive on the protection of animals used for scientific purposes 2010/63/EU (in conjunction with the Good Laboratory Practice Directives 2004/9/EC and 2004/10/EC) can at least partly be recovered by charging a fee for the inspection of the laboratories. There are different schemes possible. The Member State might charge a fee for every single inspection performed in a specific laboratory. The other alternative is the creation of a so-called monitoring programme with obligatory membership of all laboratories applying GLP. Then an annual membership fee might cover part of the costs for the monitoring programme.

8. SUMMARY OF KEY ISSUES

Implementation of EU legislation in this sector requires a large number of activities as described in more detail in the fiches.

A checklist of key questions to be considered in preparing and implementing EU legislation for chemicals and biocides is presented below.

Table 5. Checklist of Key Questions to be Considered in Preparing and Implementing EU Legislation for Chemicals

Checklist of Key Questions to be Considered in Preparing and Implementing EU Legislation for Chemicals	
1	Has a national strategy for implementation in the sector been developed?
2	Has a policy and legislative framework including transposing legislation to implement directives been produced?
3	Has a competent authority or authorities been designated and attempts made to take an integrative approach, such as having one larger competent authority furnished with sufficient technical expertise, resources and infrastructure implement several instruments?
4	Is the competent authority adequately staffed and equipped?
5	Has the competent authority taken steps to consult stakeholders and has it prepared helpdesks and published guidance notes for stakeholders and produced informative material for the general public (e.g. on health risks of chemicals)?
6	Has the competent authority demonstrated that it can manage notification and permitting procedures?
7	Is the competent authority able to monitor compliance with the regulations and carry out enforcement measures?
8	Has the competent authority established adequate data collection and data handling procedures to allow it to meet the reporting requirements of the directives and regulations?
9	Has the competent authority created formal reporting procedures?
10	Has the competent authority taken measures to provide a summary of the collected statistical information?
11	Can the competent authority ensure that commercially sensitive information is not published?

THE ASBESTOS DIRECTIVE

Official Title: Council Directive 87/217/EEC on the prevention and reduction of environmental pollution by asbestos (OJ L 85, 28.3.87), as amended by Regulation (EC) 87/2003 (OJ L 122, 16.5.2003)

1. SUMMARY OF MAIN AIMS AND OBJECTIVES

The aim of the Directive is to prevent and reduce pollution by asbestos, in order to protect human health and the environment. It requires Member States to restrict emissions of asbestos into the air and discharges of asbestos into water, and to take precautions when carrying out certain activities involving asbestos, such as the demolition of buildings and the transport and disposal of waste. It also lays down monitoring requirements.

For the purpose of the Directive, Member States of the European Union shall take measures to ensure that:

- Asbestos emission limit value of 0.1 mg/Nm³ in discharge air is not exceeded;
- The limit value of 30 grams of total suspended matter per m³ aqueous effluent discharged is not exceeded;
- Measurements are taken at regular intervals of emissions in the air and discharges of aqueous effluent from facilities;
- In the course of the transport and deposition of wastes containing asbestos fibres or dust, no such fibres or dust are released in the air and no liquids, which may contain asbestos fibres, are spilled;
- Where waste containing asbestos fibres or dust is landfilled at sites licensed for this purpose such waste is treated, packaged or covered with account being taken to local condition, in a way that prevents the release of asbestos particles into the environment.

Directive 87/217/EEC was amended by Regulation No. 87/2003. The Regulation amends Articles 11 and 12 regarding the adaptation of the annexes to scientific and technical progress by fine-tuning the requirements regarding the procedure adhered to.

This Directive should be read in conjunction with the Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work. This Directive has as its aim the protection of workers against the risks to their health, including the prevention of such risks, arising or likely to arise from exposure to asbestos at work. It lays down the limit values for this exposure, as well as specific requirements.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Regulation

- Take measures to prevent and reduce emissions of asbestos into the air, discharges of asbestos into water, and the production of solid asbestos waste (Art. 3).
- Ensure that asbestos is used in accordance with best available techniques not entailing excessive cost (BATNEEC), and that emissions of asbestos into the air comply with specified limit values (Arts. 3 and 4).
- Where asbestos cement or asbestos paper or board is manufactured, ensure that the effluent is recycled or, in the case of asbestos cement, that it is disposed of in accordance with specified conditions (Art. 5).
- Ensure that activities involving asbestos, including the demolition of buildings, the removal of asbestos, and the transport and disposal of waste containing asbestos, are carried out in accordance with the requirements of the Directive to ensure that they do not cause pollution (Arts. 7 and 8).

2.2. Monitoring

- Monitor emissions of asbestos into the air and discharges of asbestos into water, in accordance with specified methods of sampling and analysis (Art. 6).

2.3. Reporting

Report to the Commission on:

- methods of sampling and analysis (Art. 6);
- implementation of the Directive (Art. 13 and Council Directive 91/692/EEC);
- measures taken to comply with the Directive (Art.14); and
- transposition, with texts of the main provisions of national law adopted in the field covered by the Directive (Art. 14).

2.4. Additional Legal Instruments

A number of other legislative instruments are relevant to the implementation of this Directive.

- Directive 2009/148/EC on the protection of workers from the risks related to exposure to asbestos at work.
- REACH Regulation (EC) No 1907/2006 on assessments, evaluation and registration of dangerous substances
- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
- Waste Directive (2008/98/EC) and the Landfill Directive (1999/31/EC) contain provisions on the safe treatment and disposal of waste, and controlling pollution to air
- Industrial Emissions Directive (2010/75/EU) concerning permitting requirements and emission limit values and application of BAT
- The Reporting Directive (91/692/EEC) and the Pollution Release and Transfer Regulation (EC) No 166/2006 on general reporting requirements
- Water Framework Directive (2000/60/EC) and the Environmental Quality Standards Directive (2008/105/EC) regarding general control measures and the setting of applicable environmental quality standards relating to releases of dangerous substances to water bodies and also concerning sampling and analysis methods.
- The Ambient Air Quality Directive (2008/50/EC)

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the following checklist.

The key tasks are arranged under subheadings and organised in chronological order of implementation wherever possible.

Table 6. Checklist with Key Implementation Tasks

THE ASBESTOS DIRECTIVE - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate the competent authority to be responsible for implementation.
1.2	Ensure that the competent authority is adequately staffed with trained personnel.
2	Regulation
2.1	Publicise the requirements of the Directive to those affected by it (e.g. relevant manufacturers and others working with asbestos).
3	Monitoring
3.1	In consultation with manufacturers and other relevant parties, set limits for total discharges and the solid content of liquid wastes, ensure that liquid wastes containing asbestos are recycled and that the sampling and analytical methods set out in the annex to the Directive — or equivalent measures — are used.
4	Reporting
4.1	Supply the Commission with information about the implementation of the Directive.
4.2	Report to the Commission on: <ul style="list-style-type: none">• methods of sampling and analysis and related information; and• transposition and implementation.

3.2. Phasing Considerations

It is important to control the hazards of inhalation of asbestos by implementing the appropriate directives. The relative urgency of implementing this Directive, together with those relating to worker protection and marketing, will depend on the current situation for controlling asbestos in the country. Where production, use and marketing are relatively well controlled, attention should be focused on the removal of asbestos from buildings and other sources of contamination. This will point to the implementation of this Directive as of the greater urgency. However, in certain Member States, the implementation of the various directives lead to interlocking regulations and, recently, the regulations have been extended to deal with all types of work which may lead to exposure. It may be beneficial to implement all the asbestos-related directives at the same time, rather than to deal with them separately.

Issues which may affect or retard the implementation programme would be related to a) the lack of necessary technical skills to measure dispersal of asbestos in the atmosphere and water, which may not be widely available; and b) the fact that asbestos is an essential commercial material for some purposes and that alternatives are less effective or much more expensive. This latter point indicated the need for substantial and possible lengthy consultation as a preliminary to implementation.

4. IMPLEMENTATION GUIDANCE

Health problems caused by asbestos are primarily associated with the lungs, where inhalation of asbestos fibres can cause cancer. Much of the health hazards and fatalities in regard to exposure to asbestos is in relation to past exposure rather than new exposure (i.e. workers that have been in exposure to asbestos in their previous working lives). Nevertheless, there are still substantial risks and some research has shown that currently workers in building-related trades are most at risk from asbestos.

This Directive is one of a group of measures to control hazards which asbestos presents to people and the environment. This Directive supplements the provisions of REACH Regulation (EC) No 1907/2006 and Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos to, on the one hand, prevent, as far as possible, emissions of asbestos to the environment by reduction at source and, on the other, to take all preventive and precautionary measures to restrict exposure to asbestos at work. Member States are allowed to introduce more stringent measures than those laid down in the Directive in order to protect health and the environment.

A number of general observations and good practice suggestions for implementing this Directive are presented below based upon the collective experience of Member States.

4.1. Regulation

The implementation of this Directive has had relatively few implications for current Member States, due to the existing system of controls in those countries. For some of the candidate countries it seems that current controls are less satisfactory and that implementation of this and related legislation is urgent. It is important that the Directive requires the use of BAT to reduce or eliminate asbestos emissions. This allows the possibility of discussion with the competent authority about the use of one or other technology when the costs of these differ significantly. In enforcing the requirements of this Directive, competence in the technical skills of analysis and sampling is required. Training will be needed in many cases for technicians and technical managers to ensure that sensitivity and precision targets are achieved. Staff carrying out this work will possess technical qualifications and their laboratories must be operating good laboratory practices (GLPs).

Current Member States encourage public awareness of the Directive by use of the media.

As a result, the public is very well aware of the possibility of harm arising from contact with asbestos and that much of the impetus for remedial action in buildings has arisen from public pressure. The use of asbestos has decreased considerably in recent decades as the effects of asbestos on health have become more widely understood. Nevertheless, the consequences of past uses of asbestos are that many houses and commercial buildings contain substantial quantities of dangerous asbestos and that remedial work is still underway. Asbestos remains relevant within certain types of industries, in the demolition of buildings containing asbestos, and in the clean-up of sites contaminated with asbestos, e.g. old landfill sites.

A complication of media exposure is that the public has come to believe that all uses of asbestos are harmful. Thus, there is unjustifiable concern that asbestos water pipes are unsafe, though there is no evidence that this is true. The World Health Organisation's guidelines for drinking water quality supports this view of their safety.

Example from a Member State:

Sweden: In Sweden asbestos was extensively used for many years, particularly in the 1940s and 1950s. Imports peaked in the 1950s at 20,000 tonnes per year. In the mid 1970s a ban on asbestos use was introduced, due to suspicions concerning its effect on human health, based on research on worker exposure and disease. The National Board of Occupational Health and Safety (NBOHS) was created in 1949 and in 1963 the ordinance was extended to include protection against asbestosis. The NBOHS has since been responsible for regulating, monitoring and permitting the handling and usage of asbestos in the workplace. It monitors the health of workers and produces statistics on behalf of the government.

4.2. Monitoring

The Directive lays down emission limit values for emissions to air and water, and requires that measures be taken to ensure that asbestos is not released in the course of work such as demolishing buildings or transporting waste containing asbestos. Other limits (e.g. volume of discharges of suspended matter) must be set by the competent authority. The competent authority will also need to carry out monitoring to ensure that the emission and discharge limits are complied with.

5. COSTS

The main regulatory costs consist of establishing and implementing the legal framework. The ongoing costs for monitoring and enforcement can be substantial. In addition to these, there are high compliance costs, which will be borne by the asbestos-using industry and equally by the owners of buildings that require remedial treatment. Highest cost for dealing with exposure to asbestos is probably incurred by the construction industry in terms of demolishing or renovating older buildings.

Example from a Member State: Tax Relief for Asbestos Removal

UK: If company owns a building containing asbestos containing materials (ACMs) and those ACMs were incorporated before it was purchased, company can reclaim 150% of the removal costs of the ACM.

This concession was introduced in the 2001 Finance Act to provide an incentive to use brown field sites. The concession only applies to companies and does not apply to sole traders, partnerships trustees or individuals.

Essentially, if a company spends £10,000 removing ACMs, it can then obtain a deduction against profits, reducing its tax liability by up to £4,500 (£10,000 x 150% x 30%). This can even mean that if the company made a loss, there can be a tax rebate paid in cash.

Source: Asbestos Information Centre, <http://www.aic.org.uk>

THE BIOCIDAL PRODUCTS REGULATION

Official Title: Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012)

Amended by:

Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (OJ L 103, 5.4.2014)

Commission Delegated Regulation (EU) No 837/2013 of 25 June 2013 amending Annex III to Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the information requirements for authorisation of biocidal products (OJ L 234, 3.9.2013)

Commission Delegated Regulation (EU) No 736/2013 of 17 May 2013 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the duration of the work programme for examination of existing biocidal active substances (OJ L 204, 31.7.2013)

Implemented and delegated acts:

Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council

Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition

Commission Implementing Regulation (EU) No 88/2014 of 31 January 2014 specifying a procedure for the amendment of Annex I to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

Commission Delegated Regulation (EU) No 837/2013 of 25 June 2013 amending Annex III to Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the information requirements for authorisation of biocidal products.

Commission Delegated Regulation (EU) No 736/2013 of 17 May 2013 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the duration of the work programme for examination of existing biocidal active substances.

Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of some biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

Article 3(3) Commission Decisions

Commission Implementing Decision (EU) 2015/1985 of 4 November 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on an anti-viral tissue impregnated with citric acid

Commission Implementing Decision (EU) 2015/646 of 23 April 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on bacterial cultures intended to reduce organic solids and to be placed on the market for that purpose

Commission Implementing Decision (EU) 2015/655 of 23 April 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on a polydimethylsiloxane-based formulation placed on the market to control mosquitoes

Commission Implementing Decision (EU) 2015/411 of 11 March 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on cationic polymeric binders with quaternary ammonium compounds incorporated in paints and coatings

Commission Implementing Decision (EU) 2015/1985 of 4 November 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on an anti-viral tissue impregnated with citric acid

Commission Implementing Decision (EU) 2016/678 of 29 April 2016 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on a product consisting of dried lavender blossoms contained in a pad placed on the market to repel moths

1. SUMMARY OF THE MAIN AIMS AND PROVISIONS

The main aim of the Regulation (EU) 528/2012 is to improve functioning of the internal market through harmonising EU's rules concerning the sale and use of biocidal products, while ensuring high levels of protection of human and animal health and of the environment.

This Regulation repealed Directive 98/8/EC²⁷⁵ and entered into application on 1 September 2013.

The scope of the Regulation has been extended compared to the former Directive 98/8/EC ("the BPD") to cover articles and materials treated with biocidal products, including furniture and textiles. The Regulation also applies to active substances generated in situ, and to biocidal products used in materials that come into contact with food. Other products that are sufficiently covered by existing legislation (including food and feed, food and feed additives and processing aids) are excluded from the scope of the Regulation. Furthermore, biocidal products approved under the International Convention for the Control and Management of Ships' Ballast Water and Sediments are considered as authorised. When determining scope of application the Regulation contains provision on dual use to address the case of biocidal products (and not of treated articles), which have a dual function, such as those that are used as both plant protection products and biocidal products. It stipulates that such products fall under the scope of two different legislative instruments (plant protection legislation and the Biocidal Products Regulation).

The key principle addressed by the Regulation is that a biocidal product cannot be placed on the market or used unless it:

- only contains approved active substances and
- has been authorised.

However, the former BPD has established a transitional period for the assessment of these active substances that were on the market when it entered into application on 14 May 2000: until a decision has been taken on the approval of the active substances, the biocidal products containing these active substances can still be placed on the market in accordance with Member States national practices.

The evaluation of biocides' active substances is carried out at EU level. For each active substance that needs to be evaluated, an EU country is appointed 'rapporteur'. It is responsible for producing an assessment report, which is then discussed by all the EU countries with a view to reaching a decision at EU level to approve (or not) the substance. The coordination of the evaluation is managed by the European Chemicals Agency (ECHA), which is in charge of delivering opinions to the Commission as to whether or not an active substance can be approved. Active substances that meet the exclusion criteria are normally not approved. These are substances that are carcinogenic, mutagenic or toxic to reproduction, endocrine disruptors, persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). Exemptions are possible, however, if the risks are negligible for instance. The risks associated with nanomaterial biocides must be specifically assessed. The approval of an active substance is granted for a period not exceeding 10 years. Approved active substances are listed on the ECHA web site.

Once an active substance is approved, companies must apply for the authorisation to place their product on the market. This can be done in one of the following procedures:

²⁷⁵ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998)

'National authorisation procedure' the EU country where the biocidal products are to be placed on the market is responsible for authorising the product. If permission is granted by other Member States, companies can put the product on the market of other EU countries based on the principle of mutual recognition of the authorization of the product.

'EU authorisation procedure' where the Commission grants authorisation on the basis of an ECHA opinion. This authorisation entitles the relevant products to be placed on the market anywhere in the Union without the need to obtain separate national authorisations or going through the mutual recognition procedure.

The Regulation makes Union authorisation optional – companies can choose to either have their products authorised by one EU country with this being recognised afterwards by EU countries (through national authorisations), or be authorised at EU level directly.

There is also a simplified authorization procedure for the least harmful products that meet certain criteria, such as those that do contain specific active substances and do not contain substances of concern or nanomaterials.

The Regulation also established that, as from 1st September 2015, only biocidal products containing sources of actives substances registered at ECHA level (Article 95). A list is established by ECHA and available on its website.

The Regulation also includes provisions to reduce animal testing by making data sharing compulsory and encouraging a more flexible and intelligent approach to testing.

The Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products provides for a number of measures to facilitate the transition from the system of the Biocidal Products Directive to the new Regulation. Hence, from 1 September 2013, the active substances contained in a biocidal product used in the treatment of the treated articles, have to be either already approved or under evaluation for the relevant product-type. For active substances, which are not yet in the approval process, there is a transition period until 1 September 2016. In order to continue to place it on the market, the company will need to submit a complete application dossier on the active substance by that date. The active substance dossier must include data to apply for the approval of active substance for use for the relevant product-type. After 1 March 2017 it will not be possible any more to place on the EU market articles treated with a biocidal product (or intentionally incorporating a biocidal product) containing an active substance which is not already approved, listed in Annex I, under evaluation or for which a complete application dossier was not submitted for the relevant product-type by 1 September 2016. If the active substance is not approved for the relevant product-type, articles, which were treated or incorporated a biocidal product containing this active substance should no longer be placed on the market as from 180 days from the decision of non-approval on the active substance.

So far, the Regulation has been amended three times.

Regulation (EU) No 334/2014 lays down some amendments to Regulation (EU) No. 528/2012 as regards certain conditions for access to the market of biocidal products. The definition of biocidal product family is modified. Further amendments concern Article 19, which regulates the conditions for the issue of authorizations for biocidal products.

Commission Delegated Regulation (EU) No 837/2013 supplements Annex III to Regulation (EU) No. 528/2012 of the European Parliament and of the Council by inserting further information requirements to be included in the dossier for authorization of biocidal products.

Commission Delegated Regulation (EU) No 736/2013 extends the deadline for the work programme for the evaluation of all existing active substances from the previous target date of 14 May 2014 to 31 December 2024.

This new deadline corresponds to 14 years later than that envisaged in the original Biocidal Products Directive (it was planned to be over on 14th May 2000), as the task proves to be more important and time-consuming than originally anticipated. This timescale has consequences for the authorisation of biocidal products, as such an authorisation can only be initiated when all the active substances in a product have been approved for the particular product-type under the work programme.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Designate competent authorities and furnish them with sufficient capacity and resources to ensure that they can carry out their functions, e.g. nation-level product authorisation, mutual recognition or renewals within the deadlines set by the Regulation, participation in EU related discussions and committees, co-ordination duties, monitoring, inspection and reporting to the Commission efficiently and effectively (Art. 81(1), Regulation (EU) No 528/2012).
- Plan the procedure for granting product authorisations (full and simplified procedures) at Member State level
- Consider whether to establish national-level helpdesks, to provide advice in addition to that provided by the competent authorities. Helpdesks set up under the REACH Regulation may fill this function. (Art. 81(2), Regulation (EU) No 528/2012)
- Ensure that the institutional framework for Poison Control under Article 45 of the CLP Regulation (EC) 1272/2008 also applies to biocidal products.
- Plan possible training and capacity building in applying the new Regulation, which comprises the use of the EU-level Register for Biocidal Products and the new possibility to have product authorisations directly at EU level, which means the need to ensure coordination between the Member State level authorisation procedure and the one at EU level
- Prepare, possibly in consultation with the stakeholders, the groundwork for procedures relating to the authorisation, classification and the placing on the market of biocidal products in accordance with the requirements of the Regulation (EU) No 528/2012.
- Evaluate existing and new active substances to ascertain whether or not they will be included in Annex I (note the many amendments to Annex I adding new substances)
- Set up the system to allow for applications for mutual recognition of a national authorisation shall be made in accordance with the procedures set out in Article 33 (mutual recognition in sequence) or Article 34 (mutual recognition in parallel) of the Regulation (EU) No 528/2012.
- Set up a procedure for dealing with applications for a parallel trade permit for a biocidal product that is authorised in another Member State ('Member State of origin') to be made available on the market and used in the Member State of introduction, if it determines in accordance with paragraph 3 that the biocidal product is identical to a biocidal product already authorised in the Member State of introduction ('the reference product'). (Art. 53, Regulation (EU) No 528/2012)

2.2. Regulation

- Put into place a national legal instruments to set up a competent authority, furnished with sufficient resources, to be responsible for establishing and maintaining the procedures, systems and reporting streams referred to below.
- Ensure the proposer use of biocidal products. Proper use shall involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary and appropriate precautionary steps are taken. (Art. 17(5), Regulation (EU) No 528/2012). The use of biocidal products must be in compliance with the terms and conditions of the authorisation stipulated in accordance with Article 22(1) and the labelling and packaging requirements laid down in Article 69. (Art. 17(5), Regulation (EU) No 528/2012)
- Ensure that biocidal products are not made available in the market or used unless first being authorised (Art. 17(1), Regulation (EU) No 528/2012)
- Establish an authorisation procedure for the:
 - placing on the market and the use of biocidal products that contain active substances that are listed in Annex I (referred to in Art. 25 of Regulation (EU) No 528/2012);
 - active substance approval;
 - use of unauthorised products (i.e. products containing substances not yet included in Annex I).
- Pursuant to Article 17 of Regulation (EU) No 528/2012, ensure that:
 - Applications for authorisation are made by, or on behalf of, the prospective authorisation holder.
 - Applications for national authorisation are submitted to the competent authority (“the receiving competent authority”).
 - Applications for EU authorisation are submitted to the European Chemicals Agency set up under Regulation (EC) No 1907/2006.
 - An authorisation can be granted for a single biocidal product or a biocidal product family.
 - An authorisation may be granted for a maximum period of 10 years.
 - Ensure that the authorisation holder notifies each competent authority that has granted a national authorisation for a biocidal product family of each product within the biocidal product family at least 30 days before placing it on the market, except where a particular product is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. In the case of a Union authorisation, the authorisation holder shall notify the Agency and the Commission. (Art. 17(5), Regulation (EU) No 528/2012)
- Ensure that the national authorization of biocidal products in accordance with Art. 17, comply with Articles 29-31, which includes amongst others the following steps:
 - Validation (Art. 29)

- Applicant submits an application to the receiving competent authority and pays the applicable fees. (Art. 29(1), Regulation)
 - Within 30 days of acceptance, the receiving competent authority shall validate the application if it complies with the requirements in Art. 29(2) regarding information referred to in Art. 20 and if application has not been made in another competent authority for the same biocidal products for the same use:
 - Competent authority informs applicant if it considers that the application is incomplete. The applicant normally has 90 days to submit complementary information. If this information is deemed sufficient it will validate the application within 30 days (Art. 29(3), Regulation)
 - Where the Register for Biocidal Products referred to in Article 71 shows that a competent authority other than the receiving competent authority is examining an application relating to the same biocidal product or has already authorised the same biocidal product, the receiving competent authority shall decline to evaluate the application. In that event, the receiving competent authority shall inform the applicant of the possibility of seeking mutual recognition in accordance with Article 33 or 34. (Art. 29(4), Regulation)
- Evaluation (Art. 30)
- The receiving competent authority shall, within 365 days of the validation of an application in accordance with Article 29, decide whether to grant an authorisation in accordance with Article 19. It shall take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable. If need be the competent authority shall ask for additional information, which may lead to a suspension period of not more than 180 days.
 - Within the 365-day period referred to in paragraph 1, the receiving competent authority shall:
 - draft a report summarising the conclusions of its assessment and the reasons for authorising the biocidal product or for refusing to grant an authorisation (the ‘assessment report’);
 - send an electronic copy of the draft assessment report to the applicant and provide it with the opportunity to submit comments within 30 days; and
 - take due account of those comments when finalising its assessment.
- Renewal of a national authorisation (Art. 31)
 - An application by or on behalf of an authorisation holder wishing to seek the renewal of a national authorisation for one or more product-types shall be submitted to the receiving competent authority at least 550 days before the expiry date of the authorisation. Where renewal is sought for more than one product-type, the application shall be submitted at least 550 days before the earliest expiry date.
 - The receiving competent authority shall renew the national authorisation, provided that the conditions set out in Article 19 are still satisfied. It shall take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable.
 - When applying for renewal, the applicant shall submit:
 - without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial authorisation or, as appropriate, previous renewal; and
 - its assessment of whether the conclusions of the initial or previous assessment of the biocidal product remain valid and any supporting information.

- On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for authorisation or, as appropriate, the previous renewal, the receiving competent authority shall, within 90 days of accepting an application in accordance with paragraph 4, decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary taking account of all product-types for which renewal is requested.
- Where the receiving competent authority decides that a full evaluation of the application is not necessary, it shall decide on the renewal of the authorisation within 180 days of accepting the application in accordance with paragraph 4 of
- Ensure compliance with the conditions for the use and sharing of data and conditions and time limitations for data protection, as well as for use in subsequent applications according to the requirements of Articles 60, 62, 63, 64, Regulation (EU) No 528/2012).
- Put in place procedures to authorise the use of unauthorised biocidal products, for a limited time, under the following circumstances:
 - because of a danger to public health, animal health or the environment which cannot be contained by other means (Art. 55(1), Regulation (EU) No 528/2012)
 - for use in research and development as specified in Article 17(1). (Art. 56, Regulation (EU) No 528/2012)
- Ensure that where relevant Safety data sheets for active substances and biocidal products are prepared and made available in accordance with Article 31 of Regulation (EC) No 1907/2006, where applicable (Art. 70, Regulation No 528/2012)
- Ensure compliance with the rules set out in Annex IV of the Regulation when the applicant proposes to adapt the data requirements set out in Annexes II and III in accordance with Article 6(2) and (3) or Article 21(1) and (2), without prejudice to the specific rules set out in Annex III on the use of the calculation methods for classification of mixtures to avoid testing on vertebrates
- Authorisation holders must ensure that biocidal products are classified, packaged and labelled in accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in Regulation (EC) No 1272/2008. Additional measures for products that can be mistaken for food or drinks and for products available to the general public. (Art. 69(1), Regulation (EU) No 528/2012)
- Ensure that applications for mutual recognition of a national authorisation can be made to the Competent Authority in accordance with the procedures set out in Article 33 (mutual recognition in sequence) or Article 34 (mutual recognition in parallel).
- Comply with the provisions (Art. 47-49) relating to the cancellation, review and amendment of authorisations, including requests coming from the applicant and decide on possible grace periods for limited stock pursuant to Art. 52.
- Ensure that advertisement for biocidal products, complies with Regulation (EC) No 1272/2008, and includes the sentences ‘Use biocides safely’.

- Lay down the provisions on penalties applicable to infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. (Art. 87, Regulation (EU) No 528/2012)

2.3. **Monitoring**

- Member States shall make the necessary arrangements for the monitoring of biocidal products and treated articles which have been placed on the market to establish whether they comply with the requirements of this Regulation. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products shall apply accordingly. (Art. 65(1), Regulation (EU) No 528/2012)
- Member States shall make the necessary arrangements for official controls to be carried out in order to enforce compliance with this Regulation (Art. 65(2), Regulation (EU) No 528/2012)
- Ensure that manufacturers of biocidal products placed on the Union market maintain in relation to the manufacturing process, appropriate documentation in paper or electronic format relevant for the quality and safety of the biocidal product to be placed on the market and shall store production batch samples. The documentation shall include as a minimum:
 - safety data sheets and specifications of active substances and other ingredients used for manufacturing the biocidal product;
 - records of the various manufacturing operations performed;
 - results of internal quality controls;
 - identification of production batches. (Art. 65(2), Regulation No. 528/2012)

2.4. **Information and Reporting**

- Ensure that every five years, starting from 1 September 2015, a report is submitted to the Commission a report on the implementation of this Regulation. These must be submitted by 30 June of the relevant year and shall cover the period until 31 December of the year preceding their submission. The reports include:
 - information on the results of official controls carried out in accordance with paragraph 2;
 - information on any poisonings and, where available, occupational diseases involving biocidal products, especially regarding vulnerable groups, and any specific measures taken to mitigate the risk of future cases;
 - any available information on adverse environmental effects experienced through using biocidal products;

- information on the use of nanomaterials in biocidal products and the potential risks thereof. (Art. 65(2), Regulation (EU) No 528/2012)
- The competent authority must establish a mechanism regarding the database on authorised biocidal products to exchange information with other Member States and the Commission. Mechanisms must be established also for the EU Biocidal Products Register.
- Legal instruments making it obligatory to report/provide information to the public both upon request and also at regular intervals such as, for example, in state of the environment reports. Information must be made available to the public in cases of suspected poisoning.
- The Competent Authority should take necessary measures to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use.
- Ensure that the authorisation holder notifies each competent authority that has granted a national authorisation for a biocidal product family of each product within the biocidal product family at least 30 days before placing it on the market, except where a particular product is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. In the case of a Union authorisation, the authorisation holder shall notify the Agency and the Commission. (Art. 17(6), Regulation (EU) No 528/2012)
- Inform the Commission of the names and addresses of the designated competent authorities and, where they exist, helpdesks by 1 September 2013. Member States shall, without undue delay, inform the Commission of any changes to the names and addresses of the competent authorities or helpdesks (Art. 81(3), Regulation (EU) No 528/2012)
- Notify national provisions on penalties to the Commission and of any subsequent amendment affecting them. (Art. 87, Regulation (EU) No 528/2012)

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Regulation are summarised in the checklist below. The tasks are arranged under subheadings and organised in chronological order of implementation wherever possible.

Table 7. Checklist with Key Implementation Tasks

BIOCIDAL PRODUCTS REGULATION - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Assigning duties to competent authority/ies which would carry out regulatory, coordination and co-operation measures.
1.2	Devise memoranda of understanding for various competent authorities that will work together to implement the Regulation. Ensure appropriate coordination, efficiency and, where relevant, ensure compliance with the deadlines in the Regulation.
1.3	Organise stakeholder meetings to facilitate exchange of information, to ensure their participation in preparatory work and to identify user needs.
1.4	Assess capacity building needs to implement the Regulation.
1.5	Coordinate activities with Union Authorisations for certain biocidal products and work with the Biocidal Product Register
1.6	Establish a helpdesk
1.7	Ensure Poison Control service in line with Article 45 of the CLP Regulation (EC) 1272/2008
2	Regulation
2.1	The competent authority shall establish a procedure for applying, issuing and authorising the placing on the market and use of biocidal products and the active substances from which they are composed (this procedure should also include the simplified authorisation procedure).
2.2	Take the necessary steps and establish structures to ensure and monitor the proper use of biocidal products. Proper use shall involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary and appropriate precautionary steps are taken

2.3	Establish a procedure providing for the exceptional use of unauthorised products in accordance with the Regulation.
2.4	Establish a system for the classification, labelling and packaging of biocidal products including the requirements to provide safety data sheets when required by the Regulation, taking into account the provisions of the REACH Regulation and the CLP Regulation setting out provisions on safety data sheets.
2.5	Maintain a database to be updated at regular intervals, on the status of authorised biocidal products.
2.6	Ensure timely mutual recognition
2.7	Take measures to ensure compliance with the new obligation to share data involving vertebrate animal to minimise animal testing as far as possible
2.8	Lay down the provisions on penalties applicable to infringement of the provisions of this Regulation and take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.
2.9	Authorisation holders must ensure that biocidal products are classified, packaged and labelled in accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements
3	Training and Capacity Building
3.1	Prepare and publish guidance on the duties and the role of the different stakeholders. Provide safety guides for the use of biocidal products and active substances.
4	Monitoring
4.1	<p>Take the following monitoring measures to ensure compliance with the Regulation:</p> <ul style="list-style-type: none"> • implementing an effective inspection and enforcement system to secure compliance; • monitoring biocidal products that have been placed on the market to ensure that this is carried out in accordance the provisions of the Directive and the Regulation; • reviewing modifications and cancellations of authorisations; • ensuring commercial confidentiality and data protection; • monitoring compliance with Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products • reviewing the information in the database on the status of the authorisation of biocidal products, assessing details of applications that are refused, modified, renewed or cancelled.
5	Reporting

5.1	Provide information at regular intervals on a national level and set up an infrastructure to handle demands upon request by the public or public authorities, whether national or from other Member States.
5.2	Ensure that every five years, starting from 1 September 2015, a report is submitted to the Commission a report on the implementation of this Regulation. These must be submitted by 30 June of the relevant year and shall cover the period until 31 December of the year preceding their submission.
5.3	The Competent Authority should take necessary measures to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use.
5.4	Ensure that the authorisation holder notifies each competent authority that has granted a national authorisation for a biocidal product family of each product within the biocidal product family at least 30 days before placing it on the market.
5.5	Notify national provisions on penalties in case of infringements of the Regulation to the Commission and notify without delay any subsequent amendment affecting them.
5.6	Inform the Commission of the names and addresses of the designated competent authorities and, where they exist, helpdesk. Member States shall, without undue delay, inform the Commission of any changes to the names and addresses of the competent authorities or helpdesk.

3.2. Phasing Considerations

Candidate countries are likely to already possess a system for the placing on the market and use of biocidal products and active substances. However, the designated competent authority and the users may need a substantial amount of time not only to implement and apply Regulation (EU) No 528/2012 but also to ensure the necessary capacity building both logistically and in terms of human resources. The major tasks involved that are likely to be time-consuming are: to set up the necessary administrative system to process applications for authorisations and to ensure better co-ordination at the national and EU level. Whilst the nature of the Regulation itself involves many stakeholders even amongst public authorities, consideration should be given to having one authority to regulate and monitor compliance and to be responsible for national authorisation, processing applications for mutual recognition, parallel trade permits and amendments and extensions of existing approvals as well as for the co-ordination and reporting to the Commission and for the liaising with the ECHA. All competent authorities must train their personnel with respect to procedures and best practices for interfacing with stakeholders as regards the provisions of the Regulation on data sharing and grounds for restricting the sharing of certain confidential information.

4. IMPLEMENTATION GUIDANCE

4.1. General

Legal issues that need to be addressed, given the nature of the obligations of the Regulation, include: principles of confidentiality, the mutual recognition of biocidal products approved in other Member States, conditions under which to allow the refusal of an application for the placing on the market of biocidal products, the obligation to share certain data (especially in relation to animal testing) and co-ordination between the public authorities involved. The training of officers in enforcement is essential both for compliance purposes and good governance.

The legal framework of the Regulation (EU) No 528/2012 has introduced the following novelties:

- Expanded Scope including treated articles, food contact materials, in-situ generated biocidal products
- Detailed product authorization procedure regarding biocidal products – National Authorisation and Mutual Recognition vs. Union Authorisation.
- Exclusion criteria regarding active substances of very high concern.
- Substitution regarding biocidal products containing active substances of high concern.
- Provision regarding biocidal products presenting low risk or concern.
- Provision relating to Nanomaterials.
- Significant role of the ECHA, Biocidal Products Committee, and ECHA Board of Appeals in the active substance approval process, inter-party disputes regarding data access, Peer-review, Establishment of Article 95 list of active substance suppliers.
- Changes to product-types (PTs)
- New data use and sharing requirements to prevent unnecessary testing on vertebrate animals.
- Strengthened data compensation provisions
- Partial harmonisation of fees payable for active substance approval and product authorization applications.
- Disclosure of Information on ECHA Website (Art. 66 (3)),
- Register of Biocidal Products established
- Data entry by IUCLID
- Introduction of penalty legislation in case of non-compliance
- Member State must set up helpdesks
- Application of Article 45 of the CLP Regulation on poison control, now extended to biocidal products

Regulation (EU) No 528/2012 introduces some transitional provisions. Examples of these include:

- Authorized products under the Biocidal Products Directive remain on market until authorization expiry/cancellation (subject to the Biocidal Products Regulation from 1 September 2013)
- Biocidal products not expressly considered as such under Biocidal Products Directive (in situ products, treated articles with a primary biocidal function etc.) may stay on market until product authorization decision provided that the application for substance approval was submitted by 1 September 2016.
- Treated articles may until the date of a decision concerning the approval for the relevant product type of the active substances contained in the biocidal products, continue to be placed on the market if the application for such approval is submitted before 1 September 2016.
- The new Union Authorisation (Art. 42, of the Biocidal Products Regulation) provide for the following phase-in provisions:

From 1 September 2013:

- PT 1: Human hygiene
- PT 3: Veterinary hygiene
- PT 4: Food and feed area
- PT 5: Drinking water
- PT 18: Insecticides, acaricides and products to control arthropods
- PT 19: Repellents and attractants
- Biocidal Products with new active substances

From 1 January 2017:

- PT 2: Disinfectants and algacides not intended for direct app to H/A
- PT 6: Preservatives for products during storage (In-can)
- PT 13: Working or cutting fluid preservatives

From 1 January 2020: All other PTs except:

- PT 14: Rodenticides
- PT 15: Avicides
- PT 17: Piscicides
- PT 20: Control of other vertebrates
- PT 21: Antifouling products

The ECHA Guidance on biocides legislation describes how to fulfil the information requirements set by the Regulation (EU) 528/2012) and how to perform the required assessments. It also explains the guiding principles for the evaluation of the applications to be performed by the authorities.

The guidance on biocides legislation is available at the ECHA website: <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation>

The list below gives the guidance documents and provides a summary of the development to date.

- Volume I Identity/physico-chemical properties/analytical methodology
 - Part A Information Requirements (2014). This Guidance describes the information requirements for active substances and biocidal products in accordance with the Title 1 of Annex II and III of the Regulation (EU) 528/2012.
 - Part B Assessment. This Guidance is currently being developed.
 - Part C Evaluation. This Guidance is currently being developed.
- Volume II Efficacy
 - Part A Information Requirements (2014). This Guidance describes the information requirements for active substances and biocidal products in accordance with the Title 1 of Annex II and III of the Regulation (EU) 528/2012.
 - Part B Assessment. This Guidance is currently being developed.
 - Part C Evaluation. This Guidance is currently being developed.
- Volume III Human Health
 - Part A Information Requirements (2014). This Guidance describes the information requirements for active substances and biocidal products in accordance with the Title 1 of Annex II and III of the Regulation (EU) 528/2012.
 - Part B Assessment (2015). This Guidance provides technical advice on how to perform the hazard and exposure assessment and risk characterisation for biocidal active substances and products with respect to human health risk assessment. The Guidance on Exposure Assessment (Chapter 3) should be read together with the Biocides Human Health Exposure Methodology Document available at the following link <http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure>.
 - Part C Evaluation. This Guidance is currently being developed.
- Volume IV Environment
 - Part A Information Requirements (2014). This Guidance describes the information requirements for active substances and biocidal products in accordance with the Title 1 of Annex II and III of the Regulation (EU) 528/2012.
 - Part B Risk Assessment (active substances) (2015). This Guidance provides technical advice on how to perform the hazard and exposure assessment and risk characterisation for biocidal active substances with respect to environmental risk assessment.
 - Part C Evaluation. This Guidance is currently being developed.
- Volume V Specific Guidance
 - Guidance on applications for technical equivalence (2013). This Guidance informs potential applicants about their obligations resulting from the provisions of Article 54 of the Regulation (EU) 528/2012: when they need to apply for an assessment of technical equivalence and on the procedural steps in making that application. The Guidance also informs potential applicants about the assessment conducted by the Agency and the approach used for assessing the technical equivalence of the alternative source of an active substance versus its reference source.

- Guidance on active substance suppliers (2014). This Guidance describes the obligations under Article 95 of the Regulation (EU) 528/2012 and explains the regulatory consequences.
- Guidance on micro-organisms (2015). This Guidance provides technical advice on the information requirements, the hazard and exposure assessment, the risk characterisation and the evaluation of the active substances and biocidal products in accordance with Annex II, Title 2 and Annex III, Title 2 of the Regulation (EU) 528/2012 for micro-organisms.
- Guidance on data sharing (2012).

The ECHA has also published in 2014 Practical guide on Biocidal Products Regulation providing practical information on Biocidal Products Regulation requirements and best practice on how to fulfil them. The document is available at: <http://echa.europa.eu/practical-guides/bpr-practical-guides>

4.2. Planning and Administration

- One of the key initial obligations of the Candidate Countries is to establish competent authorities having a sufficient number of suitably qualified and experienced personnel to ensure efficient and effective implementation of their key tasks. This involves overall scoping of capacities and where needed reinforcement of staff and experts as well as to ensure sufficient financial resources and coordination mechanisms to carry out their obligations, especially the authorisation and mutual recognition processes, within the time limits given. In addition, advice needs to be provided, in the form of guidance notes, where both larger companies and SMEs are targeted. The competent authority may establish a national helpdesk which can provide targeted advice and information giving support. The helpdesk established under the REACH Regulation can also cover the Biocidal Products Regulation.
- A dedicated IT platform, the Register for Biocidal Products (R4BP), will be used for submitting applications, exchanging data and information between the applicant, ECHA, Member State competent authorities and the European Commission. It will also document decisions and help to disseminate information to the public. More about this Register on: <http://echa.europa.eu/support/dossier-submission-tools/r4bp>
- Introduce the institutional structures to be able to administer the simplified authorisation procedure for low-risk substances, applying to biocidal products containing Annex I actives are eligible for a simplified authorization procedure if all of the following conditions are met:
 - all active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex;
 - the biocidal product does not contain any substance(s) of concern;
 - the biocidal product does not contain any nanomaterials;
 - the biocidal product is sufficiently effective; and
 - the handling of the biocidal product and its intended use do not require personal protective equipment.

4.3. Regulation

- The definitions of the Regulation must be carefully transposed and abided by, in order to secure compliance. The possible derogations should also be faithfully applied so as not give rise to possible barriers to trade.
- The Biocidal Products Regulation is based on three major criteria that are identified:
 - establish at the EU level a positive list of active substances which may be used in biocidal products
 - the authorisation and placing on the market for biocidal products within Member States
 - mutual recognition of authorisation within the EU
- Application for authorisation shall be made by, or on behalf, of the person who will be responsible for the first placing on the market of a biocidal product in a particular Member State and the application shall be made to the competent authority of that Member State. Every applicant is required to have a permanent office within the EU.
- The Regulation will phase out the use of (through application of exclusion criteria):
 - Substances classified as 1A or 1B CMRs under the CLP (Art. 5(1))
 - Substances considered endocrine disruptors (Art. 5(1))
 - PBTs/vPvBs (Art. 5(1))
 - Provisionally Cat. 2 CMR (Art. 5(3))
- The derogation to the exclusion criteria (Article 5) only allows the approval of the active substance if:
 - There is negligible exposure to humans under realistic worst case conditions of use;
 - There is proof that the active substance is essential to prevent or control a serious danger to human health, animal health or to the environment; or
 - Excluding the substance would have a disproportionate negative impacts for society when compared to the risk to human health, animal health or the environment arising from the use of the substance; or
- The Regulation introduces the notion of technical equivalence, which means similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the
 - manufacturing process and/or manufacturing
 - location, compared to the substance of the reference
 - source in respect of which the initial riskassessment was carried out.
- Special attention must be given to determine the circumstances under which unauthorised substances shall be allowed as these may not go beyond the circumstances prescribed by the Regulation.
- The Regulation also provide for the possibility to apply for a Union Authorisation, which applies in the whole EU. The European Commission grants such authorisation and such authorised products can

be placed on the market across the EU without any need to apply for separate national authorisations or the mutual recognition process. Applications for a Community authorisation will be submitted to the European Chemicals Agency (ECHA) and to a competent authority of the applicant's choice. The competent authority will evaluate the application and send its conclusions to ECHA for an opinion. On the basis of an ECHA opinion, the Commission will then decide whether a Union authorisation can be granted, and if so under which conditions. A Union authorisation issued by the Commission is valid throughout the Union unless otherwise specified. It confers the same rights and obligations in each Member State as a national authorisation. For those categories of biocidal products referred to in Article 42(1), the applicant may apply for Union authorisation as an alternative to applying for a national authorisation and mutual recognition. Industry can choose to obtain Union Authorisation if, amongst other things:

- the BP has ‘similar conditions of use across Union’;
 - actives substances does not meet the exclusion criteria under Article 5 (e.g. CMRs 1A/1B, etc);
 - the product falls within certain PTs i.e. NOT under PT14, 15, 17, 20 or 21
- Certain data involving vertebrate animal tests has to be shared to minimise animal testing as far as possible Vertebrate tests. A certain compensation can be taken out.
 - The new Regulation also sets up the Biocidal Products Committee (BPC), which prepares the opinions of ECHA related to several BPR processes, which are being considered by the Commission when taking the final decisions through a regulatory committee procedure. The BPC became operational from the application date of the BPR of 1 September 2013. Each Member State appoints one member to the BPR for a renewable term of three years. They may also appoint an alternate member. More information about this committee is available at ECHA website: <http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee>.
 - Provision should also be made in legal instruments to establish when requests for applications may be refused such as when they are manifestly unreasonable or likely to be used and availed of for commercial purposes.
 - In case it is considered inappropriate to include certain measures in a legal instrument because of their predominantly administrative nature, it is recommended that memoranda of understanding be drawn up to ensure smooth and uniform implementation given the large number of public authorities that may be involved.
 - With respect to charges, Article 80 of the Regulation provides that:
 - fees shall be set at such a level as to ensure that the revenue derived from the fees is, in principle, sufficient to cover the cost of the services delivered and shall not exceed what is necessary to cover those costs;
 - partial reimbursement of the fee if the applicant fails to submit the information requested within the specified time limit;
 - the specific needs of SMEs shall be taken into account, as appropriate, including the possibility of splitting payments into several instalments and phases;
 - the structure and amount of fees shall take into account whether information has been submitted jointly or separately;

- in duly justified circumstances, and where it is accepted by the Agency or the competent authority, the whole fee or a part of it may be waived;

Please note that the structure and amount of the fees payable to the European Chemicals Agency, as well as the conditions for payment have been established by Commission Implementing Regulation (EU) 5645/2013.

- Candidate countries have to take measures on Food contact materials or articles containing biocidal substances. In Annex V of the Biocidal Products Regulation there are various product-types relevant to Food Contact:
 - Product-type 4: disinfectants – food and feed area: products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food/feed (including drinking water) for humans or animals and products used to impregnate materials which may enter into contact with food
 - Product-type 7: film preservatives, i.e. products used for the preservation of films or coatings by control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects, such as, plastics, sealants, binders, papers etc
 - Product-type 9: Fibre, leather, rubber and polymerized materials preservatives, i.e. products used for the preservation of fibrous or polymerized materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration (includes biocidal products which antagonise the settlement of micro-organisms on the surface of materials and thereafter hamper or prevent the development of odour and/or offer other kinds of benefits)
 - Product-type 12: Slimicides: products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g., on wood and paper pulp

The Biocidal Products Regulation has been fully operational only since 1 September 2013. This means that limited experience has been gained to date with the current legislation.

However, in March 2016 the Commission has presented to the Council and the European Parliament a report on how the Regulation contributes to the sustainable use of biocidal products. This report also reflects on the need to introduce additional measures, in particular for professional users, in view of reducing the risks posed to human health, animal health and the environment by biocidal products.

The report has identified measures to be pursued both by the Commission and the Member States:

- focus and strengthen efforts on the review programme of existing active substances to ensure it is completed at the latest by end 2024;
- ensure that once active substances are approved, product authorisations are granted, amended or cancelled within 3 years;
- invest additional resources on enforcement activities;

- benefit from the legislative tools available, in particular by closely following the developments of BREFs that can be relevant for biocidal products used in industrial processes;
- encourage communication and awareness raising campaigns to inform end- users, through websites, in-store leaflets or videos, quick response codes on biocidal products, etc.;
- encourage the development and implementation of standards (e.g. under CEN) that could contribute to the sustainable use of biocidal products;
- welcome research initiatives on the sustainable use of biocides and alternatives to biocidal products.

4.4. **Monitoring**

The primary competent authority for implementing this Regulation may be the ministry of health or the ministry for the environment or an agency for environment protection, which shall be the regulator responsible for monitoring compliance and enforcement. Some Member States have established a health and safety authority (UK)²⁷⁶ (HR)²⁷⁷ or a standardisation authority (MT) as competent authority. An independent committee, the Biocides Consultative Committee advises the competent authority in the UK when the latter addresses the assessment of active substances and the approval of biocidal products. This is an independent committee made up of scientific experts and lay members who will represent the interests of consumers, workers and the environment. In Malta, a similar advisory body also represents other stakeholders in the public sector from the ministries of trade, agriculture, spatial planning, transportation, statistics and resources. Ultimately, only one competent authority should be responsible for co-ordination at the national and EU level. Since the Regulation provides for mutual recognition of authorised products, an applicant from one Member State, upon submitting an application and paying the necessary fees to the competent authority of another Member State, should also obtain an authorisation provided that any necessary data has been supplied and any conditions on the active substance approval are met and are in accordance with the Regulation.

4.5. **Enforcement**

As regards enforcement, candidate countries should strengthen enforcement activities in order to ensure that no product is illegally placed on their market and that biocidal products are properly labelled and used.

The Regulation requires that the Member States lay down national provisions on penalties applicable to infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

²⁷⁶ Health and Safety Executive <http://www.hse.gov.uk/biocides/index.htm>

²⁷⁷ Department for chemicals and biocidal products in Directorate for Sanitary Inspection as a part of Ministry of Health.

5. COSTS

The costs for the implementation of the Biocidal Products Regulation are divided between the Member States and their competent authorities and the relevant industry - producers, suppliers and users of the Biocidal Products. The extended scope of the Regulation results in greater costs to the industry in particular. The costs for competent authority are mainly those associated with the initial set up and the running costs for the designated competent authorities, e.g. the hiring of staff, experts, the furnishing of the authority with the necessary infrastructure and coordination mechanisms. Where a helpdesk is set up this will also be financed by the Member States and its operation which includes providing of advice and dissemination of information and guidance. Costs will also be incurred for preparing legislation to ensure efficient, proportionate and dissuasive penalties.

Regarding the costs for certain of the functions of the competent authorities, in particular the national authorisations, authorisation reviews, parallel trade permits etc. These will be off-set through taking out administrative fees paid by the applicant. These fees are now more harmonised, through the Regulation, which means that the variation in the fee structures from one Member State to another has been reduced considerably. Industry also has to pay certain fees for a Union Authorisation, to be determined by a separate implementing measure.

Other notable costs for industry is those associated with the overarching incentive to substitute the use of certain, harmful biocidal products with less harmful. The wider scope of the Regulation also covers biocidal products in food contact materials which extends the costs to a wider industrial sector.

The costs for animal testing (on vertebrates) are however, reduced through the new obligation in the Regulation to share certain data with a view to reduce the number of animal experiments. Although the company sharing the data may ask for compensation, the overall costs for the industry in regard to animal testing is expected to be decreased.

THE REGULATION ON PERSISTENT ORGANIC POLLUTANTS

Official Title: Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (*OJ L 158, 30.4.2004*) as amended by Regulation (EC) No 1195/2006²⁷⁸, Regulation (EC) No 172/2007²⁷⁹, Regulation (EC) No 323/2007²⁸⁰, Regulation (EC) No 304/2009²⁸¹, Regulation (EU) No 756/2010²⁸², Regulation (EU) No 757/2010²⁸³, Regulation (EU) 519/2012²⁸⁴, Regulation (EU) 1342/2014²⁸⁵ and Regulation (EU) 2015/2030^{286,287}

Council Decision 259/2004/EC of 19 February 2004 concerning the conclusion, on behalf of the European Community, of the Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutant

²⁷⁸ Council Regulation (EC) No 1195/2006 of 18 July 2006 amending Annex IV to Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants (*OJ L 217, 8.8.2006*)

²⁷⁹ Council Regulation (EC) No 172/2007 of 16 February 2007 amending Annex V to Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants (*OJ L 55, 23.2.2007*)

²⁸⁰ Commission Regulation (EC) No 323/2007 of 26 March 2007 amending Annex V to Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants and amending Directive 79/117/EEC (*OJ L 85, 27.3.2007*)

²⁸¹ Commission Regulation (EC) No 304/2009 of 14 April 2009 amending Annexes IV and V to Regulation (EC) No 850/2004 of the European Parliament and of the Council as regards the treatment of waste containing persistent organic pollutants in thermal and metallurgical production processes (*OJ L 96, 15.4.2009*)

²⁸² Commission Regulation (EU) No 756/2010 of 24 August 2010 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes IV and V (*OJ L 223, 25.8.2010*)

²⁸³ Commission Regulation (EU) No 757/2010 of 24 August 2010 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes I and III (*OJ L 223, 25.8.2010*)

²⁸⁴ Commission Regulation (EU) No 519/2012 of 19 June 2012 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annex I, (*OJ L 159, 20.6.2012*)

²⁸⁵ Commission Regulation (EU) No 1342/2014 of 17 December 2014 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes IV and V (*OJ L 363, 18.12.2014*)

²⁸⁶ Commission Regulation (EU) 2015/2030 of 13 November 2015 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annex I (*OJ L 298, 14.11.2015*)

²⁸⁷ Also note the recent amendments adopted in 2016, but not included in the current edition, namely Commission Regulation (EU) 2016/293 of 1 March 2016 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annex I (*OJ L 55, 2.3.2016*) and Commission Regulation (EU) 2016/460 of 30 March 2016 amending Annexes IV and V to Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants (*OJ L 80, 31.3.2016*)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Persistent organic pollutants (POPs) are chemical substances that persist in the environment, bio accumulate through the food web, and pose a risk of causing adverse effects to human health and the environment. This group of priority pollutants consists of pesticides (such as DDT), industrial chemicals (such as polychlorinated biphenyls, PCBs) and unintentional by-products of industrial processes (such as dioxins and furans).

At international level, two main legal instruments regulate the reduction, elimination of the production, use and releases of these substances:

- [The Protocol to the regional UNECE Convention on Long-Range Transboundary Air Pollution \(CLRTAP\) on POPs, opened for signatures in June 1998 and entered into force on 23 October 2003](#)
- [The global Stockholm Convention on POPs, opened for signatures in May 2001 and entered into force on 17 May 2004](#)

These instruments establish strict international regimes for initial lists of POPs (16 in the UNECE Protocol and 12 in the Stockholm Convention). Both instruments also contain provisions for including additional chemicals into these lists. They lay down the following control measures:

- Prohibition or severe restriction of the production and use of intentionally produced POPs
- Restrictions on export and import of the intentionally produced POPs (Stockholm Convention)
- Provisions on the safe handling of stockpiles (Stockholm Convention)
- Provisions on the environmentally sound disposal of wastes containing POPs
- Provisions on the reduction of emissions of unintentionally produced POPs (e.g. dioxins and furans)
- New substances added to the Stockholm Convention and to the POP Protocol

The EU ratified the Protocol on 30 April 2004 and the Stockholm Convention on 16 November 2004.

- Council Decision 259/2004/EC of 19 February 2004 concerning the conclusion, on behalf of the European Community, of the Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants
- Council Decision concerning the conclusion, on behalf of the European Community, of the Stockholm Convention on Persistent Organic Pollutants

The EU adopted Regulation (EC) No 850/2004 to ensure effective implementation of these two environmental agreements. To a certain extent the Regulation goes further than the international agreements emphasising the aim to eliminate the production and use of the internationally recognised POPs.

The Regulation contains provisions regarding

- production, placing on the market and use of chemicals,
- management of stockpiles and wastes,
- measures to reduce unintentional releases of POPs
- setting up of national emission inventories for unintentionally produced POPs,
- developing national implementation plans (NIPs);

- establish monitoring and information exchange mechanisms;
- annual reporting on the actual production and use of POPs and triennial reporting on the implementation of the remaining provisions of the Regulation.

Both international agreements on POPs include provisions for adding further substances that exhibit the characteristics of POPs to the technical Annexes. The Commission, together with the Member States, is promoting and supporting action to identify further POP candidates and initiate international action on their control. Hence, the POP Regulation has been amended several times:

- Council Regulation (EC) No 1195/2006 amending Annex IV . This concerns changes to the list of substances subject to waste management provisions set out in article 7
- Council Regulation (EC) No 172/2007 and Commission Regulation (EC) No 323/2007 amending Annex V. This concerns changes to Part 2 Wastes and operations to which Article 7(4)(b) applies
- Commission Regulation (EC) No 323/2007 which concerns an additional entry in Part 2 of Annex V: 'Pre-treatment operations prior to permanent storage pursuant to this part of this Annex may be performed, provided that a substance listed in Annex IV that is isolated from the waste during the pre-treatment is subsequently disposed of in accordance with Part 1 of this Annex. In addition, repackaging and temporary storage operations may be performed prior to such pre-treatment or prior to permanent storage pursuant to this part of this Annex
- Commission Regulation (EC) No 304/2009 amending Annexes IV and V
 - The limit is calculated as PCDD and PCDF according to the indicated toxic equivalency factors (TEFs):
 - Part 1 is changed by adding an additional explanation concerning 'R1 Use principally as a fuel or other means to generate energy, excluding waste containing PCBs' regarding the conditions under which R4 Recycling/reclamation of metals and metal compounds can take place. Also it clarifies that where only part of a product or waste, such as waste equipment, contains or is contaminated with persistent organic pollutants, it shall be separated and then disposed of in accordance with the requirements of this Regulation.
 - In Part 2, footnote 6 now reads: The limit is calculated as PCDD and PCDF according to the following toxic equivalency factors (TEFs) with additional table of TEFs.
- Commission Regulation (EU) No 756/2010 amending Annexes IV and V:
 - List of substances subject to waste management provisions set out in Article 7
 - This concerns changes to Part 2 Wastes and operations to which Article 7(4)(b) applies
- Commission Regulation (EU) No 757/2010 amending Annexes I and III
 - Adding new substances to Part A — Substances listed in the Convention and in the Protocol as well as substances listed only in the Convention, reflecting outcomes in COP4, where it was decided to list eight of the substances in Annex A (elimination) to the Convention. The PFOS should be listed together with the other eight substances in Annex I to Regulation (EC) No 850/2004.

Especially the amendments in Regulation 756/2010 and 757/2010 implement the international agreement reached at the 4th Conference of the Parties (COP) to the Stockholm Convention in 2009, which also entered

into force on the same date. The new dangerous chemicals added to the EU Regulation on POPs have already been subject to prohibition or severe restrictions in the EU. With the new amendments certain restrictions go further than previously was the case in order to comply with the new international commitments

The new chemicals listed are: 4 types of polybromodiphenyl ether (PBDEs), alpha hexachlorocyclohexane, beta hexachlorocyclohexane, perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride and pentachlorobenzene. The original POPs were mainly pesticides but certain of the new substances have been widely used in consumer products, such as perfluorooctane sulfonic acid (PFOS) which is used for example in metal plating and fire fighting foams but also in stain repellents.

- Commission Regulation (EU) No 519/2012 amending Annex I
 - Adding three new substances: hexachlorobutadiene, polychlorinated naphthalenes and short-chain chlorinated paraffins to Annex I, Part B in accordance with the Decisions taken by the CLRTAP.
 - Amending Part A of Annex I in order to include endosulfan.

- Commission Regulation (EU) No 1342/2014

This Regulation replaces Annexes IV and V to Regulation (EC) 850/2004, in order to update those Annexes. Annex IV lays down the list of substances subject to waste management provisions, whilst Annex V lays down the list of substances subject to restrictions. These amendments are in accordance with the updates to the Stockholm Convention on Persistent Organic Pollutants and apply from 18 June 2015

- Commission Regulation (EU) 2015/2030

This Regulation, amending Annex I, defines the prohibition criteria of short-chain chlorinated paraffins (SCCPs) in substances and mixtures:

- The production, placing on the market and use of substances or preparations containing SCCPs in concentrations lower than 1 % by weight shall continue to be allowed.

However, the amendment also introduces a new requirement regarding articles that will be applicable to consumer products. The new restriction states:

- Articles containing SCCPs in concentrations equal to or greater than 0.15 % by weight shall be prohibited.

This restriction entered into force on 4 December 2015.

Although not covered by the current review please note that Annexes I, IV and V were subject to amendments in 2016²⁸⁸. Thus, Regulation (EU) 2016/293 amends Annex I by adding hexabromocyclododecane (HBCDD) to the list of substances subject to prohibitions, whereas Regulation (EU) 2016/460 amends Annex IV and V accordingly.

For more information on POPs refer to DG ENV, chemical unit's website: http://ec.europa.eu/environment/archives/pops/index_en.htmhttp://ec.europa.eu/environment/chemicals/international_conventions/index_en.htm

(see also below under implementation guidance for more references to guidance and studies).

²⁸⁸ This fourth edition and update of the Handbook covers the period 1 January 2012 until 1 January 2016.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Designate an authority (or authorities) to be responsible for implementing the notification and information procedures laid down in the Regulation and inform the Commission about this designation (Art. 15).
- Devise the national implementation plan, in consultation with the public, and drawing upon the experience and available information from the Commission and the Member States. The national implementation plan should also take into account the EU implementation plan, as need be. (Art. 8)
- Ensure that release inventories for the substances listed in Annex III into air, water and land are drawn up and maintained in accordance with their obligations under the Convention and the Protocol. (Art. 6(1))
- Develop an action plan, as a part of the national implementation plan, which includes measures to require and promote the use of substitute or modified materials, products and process to prevent the formation and release of substances listed in Annex III (Art. 6(2)). Such measures include, upon considering proposals to construct new facilities or modifying existing ones, giving priority consideration to processes, techniques or practices that do not lead to the formation and releases of substances listed in Annex III (this shall take into account BAT requirements under IED (2010/75/EU))
- Decide on exemptions from the general ban from mixing waste with substances listed in Annex IV, e.g. in cases where the content of Annex IV substances in the waste is below the concentration limits set out in Annex IV or in cases where competent authority allows certain exemptions on environmental grounds and ensuring that BAT is used in destruction or transformation. (Art. 7(2), (4))
- Establish, in close cooperation, with the Commission and other Member States, appropriate programmes and mechanisms, consistent with the state of the art, for the regular provision of comparable monitoring data on the presence of dioxins, furans and PCBs as identified in Annex III in the environment. Such programmes and mechanisms must be in line with the principles and new developments under the Protocol and the Convention. (Art. 9)
- Take measures to facilitate information exchange within the EU and with third countries, particularly focusing on the reduction, minimization or elimination of the production, use and release of POPs and to their alternatives, comprising data on the risks and socio-economic costs involved. These measures shall comprise awareness programmes addressing environmental and health concerns, especially targeting policy and decision makers, vulnerable groups, ensuring public access to environmental information (in line with procedures set out in Directive 2003/4/EC) and training of workers and scientific, technical and managerial personnel. (Art. 10)
- Plan measures for the cooperation with the Commission and the other Member States in providing technical and financial assistance to developing countries and transitional countries to help them comply with their obligations under the POPs Convention. Determine whether to involve NGOs in such technical assistance. (Art. 11)

2.2. Regulation

- Ensure compliance with the waste management principles in Art. 7:
 - that all producers and holders of waste shall undertake all reasonable efforts to avoid contamination of this waste with substances listed in Annex IV.
 - Where waste consist of, contain or is contaminated by any substance listed in Annex IV this waste is promptly disposed of or recovered, which may mean isolating it from remaining waste, in accordance with Annex V, part 1 in such a way as to completely destroy or transform POPs so that the remaining waste and releases do not exhibit the characteristics of POPs. Decide on exemptions from this where the content of Annex IV substances in the waste is below the concentration limits set out in Annex IV or in cases where competent authority allows certain exemptions on environmental grounds and ensuring that BAT is used in destruction or transformation. (Art. 7(2), (4))
 - Waste management takes into account particular rules set out in the Industrial Emissions Directive (2010/75/EU) and Directive 96/59/EC PCB/PCT (Art. 7(2))
 - ensure that in the process of disposal and recovery operations no POPs set out in Annex IV is recovered, recycled, reclaimed or re-used (Art. 7(3)).
- Ensure that holders of a stockpile, consisting of or containing any banned substance listed in Annex I or Annex II manage that stockpile as waste in accordance with Article 7. The holder of a stockpile greater than 50 kg, consisting of or containing any substance listed in Annex I or Annex II, and the use of which is permitted, must provide detailed information to the competent authority and ensure that it is managed in a safe, efficient and environmentally sound manner. (Art. 5)
- The holder of a stockpile greater than 50 kg, consisting of or containing any substance listed in Annex I or Annex II, and the use of which is permitted, must provide detailed information to the competent authority and ensure that it is managed in a safe, efficient and environmentally sound manner.
- Ensure that the use and management of notified stockpiles is monitored by a competent authority (Art. 5(3))
- Introduce a complete ban on the production, placing on the market and use of substances listed in Annex I, whether on their own, in preparations or as constituents of articles. (Art. 3(1))
- Ensure that the production, placing on the market and use of substances listed in Annex II, whether on their own, in preparations or as constituents of articles, is limited to the restricted uses set out in Annex II. (Art. 3(2))
- Only allow exemptions from the above control measures as set out in Article 4 and detailed in the relevant amendments to the POPs Regulation. Note that Article 4 provides exemptions for
 - a substance used for laboratory-scale research or as a reference standard;
 - a substance occurring as an unintentional trace contaminant in substances, preparations or articles.
 - substances occurring as a constituent of articles produced or already in use before or on the date of entry into force of this Regulation;

- allowing production and use of a substance listed in Part A of Annex I or in Part A of Annex II as a closed-system site-limited intermediate until the deadline specified in the relevant Annex under the conditions set out in Art. 4(3).

2.3. Information and Reporting

- Ensure early and effective consultation with the public in the drawing up of the national implementation plan. (Art. 8(1))
- Communicate the action plan, comprised in the national implementation plan, on measures to identify, characterize, minimise and totally phase out the total releases of Annex III substance, to both the Commission and the other Member States. (Art. 6(2))
- The holder of a stockpile greater than 50 kg, consisting of or containing any substance listed in Annex I or Annex II, and the use of which is permitted, must provide detailed information to the competent authority of the Member State in which the stockpile is established with information concerning the nature and size of that stockpile. Such information shall be provided annually until the deadline specified in Annex I or II for restricted use. (Art. 5(2))
- Report to the Commission on:
 - the designation of competent authorities (Art. 15);
 - Implementation national provisions introducing penalties as well as subsequent modifications the national implementation plan to the Commission (Art. 8(2))
 - The application of the Regulation, including infringement cases and penalties. This reporting shall take place every three years and using the reporting template of the Commission (Art. 12(1))
 - statistical data on the actual or estimated total production and placing on the market of any substance listed in Annex I or II. Such data must be submitted annually, using the reporting template of the Commission. (Art. 12(2));
 - summary information compiled from the notifications, concerning stockpiles, received pursuant to Article 5(2); summary information compiled from the release inventories drawn up pursuant to Article 6(1); and summary information on the presence of dioxins, furans and PCBs as identified in Annex III in the environment, as compiled pursuant to Article 9. This reporting shall take place every three years, using the reporting template of the Commission (Art. 12(3));
 - cases where listed substances occurring a constituent of articles produced or used already before or on date of entry into force of this Regulation (Art. 4(2))
- Immediately notify the Secretariat of the Convention, as well as the Commission and to the other Member States in case of decisions to grant exemption under Art. 4(3) allowing temporary production and use of restricted substances listed in Part A of Annex I or in Part A of Annex II, as a closed-system site-limited intermediate. This notification has to provide details on:
 - actual or estimated total production and use of the substance concerned;
 - the nature of the closed-system site-limited process, specifying the amount of any non-transformed and unintentional trace contamination by any persistent organic pollutant starting material in the final product. (Art. 4(3))
- Ensure cooperation with the Commission and the Member States in exchanging information within the EU and with third countries relevant to the obligations under the Convention and in particular

information on reduction, minimization or elimination of the production, use and release of POPs, also providing information on risks and socio-economic costs for alternative substances (Art. 10)

2.4. Additional Legal Instruments

EU legislation that should be taken into consideration in the implementation of this Regulation is presented below.

Directly relevant legislation includes:

- REACH Regulation (EC) No. 1907/2006: contains provisions specifying how substances should be assessed with regard to their POP characteristics. Under REACH, the production and use of substances exhibiting POP characteristics can be prevented and new POP candidates can be identified
- Council Directive 96/59/EC on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT). This Directive aims to completely dispose of PCBs and equipment containing PCBs as soon as possible and equipment with PCB volumes of more than 5 litres before the end of 2010. It also sets requirements for the environmentally sound disposal of PCBs.
- Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals: the export of all substances listed in Annexes A and B of the Stockholm Convention except PFOS is banned. The export of PFOS is currently still possible, but only on condition that the importing country consents to the import of that chemical.
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures. Classification and labelling inventory set up by the CLP Regulation make available relevant information that can be used to identify new potential POP candidates and also provides classification and labelling on several POPs.
- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. This Regulation aims to promote substitution of substances exhibiting POP or PBT characteristics in biocidal products for less hazardous ones and allows the use of POP or PBT substances in biocidal products only if there are no alternatives available.
- Industrial Emissions Directive (2010/75/EU): lays down control measures to reduce emissions of unintentionally produced POPs by covering the major industrial stationary sources of these POPs and covers all waste incineration facilities that are a very important source of POPs by-products. Sets emission limit values for air, discharges of waste water for dioxins and furans .
- Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. It prevents chemicals exhibiting POP characteristics from being used in plant protection products.

Other related legislation includes:

- Waste Directive (2008/98/EC). The classification of waste as hazardous waste should be based, inter alia, on the Union legislation on chemicals, in particular concerning the classification of preparations as hazardous, including concentration limit values used for that purpose

- RoHS Directive 2011/65/EU. Prohibits PBDE and other hazardous substances in electrical and electronic equipment.
- WEEE Directive 2012/19/EU. Provisions on waste containing hazardous substances, e.g. PCB (PCBs/PCTs containing capacitors), mandatory segregation of PCB- containing components.
- ELV Directive 2000/53/EC. Due to the segregation of hazardous components from the vehicle, the releases of unintentional POPs from shredder plants are decreased.
- Landfil Directive (1999/31/EC). Hazardous waste for landfills needs a prior treatment.
- EU Ecolabel Regulation (EC) 66/2010. Criteria of product categories laid down in Commission decisions may cover POPs e.g. in textile floor covering for trace contamination with POP pesticides. A product cannot obtain an ecolabel if it contains a PBT/vPvB substance.
- Seveso III Directive 2012/18/EU regulates prevention, preparedness and response to major- accidents involving dangerous substances
- Water Framework Directive 2000/60/EC. Persistent hydrocarbons and persistent and bioaccumulable organic toxic substances indicated as main pollutants under Annex VIII. Several POPs included in Annex X (list of Priority Substances (PS), for which Environmental Quality Standards are set and there is a monitoring and reporting obligation; most of the POPS in the PS list are also Priority Hazardous Substances, for which there is an objective to phase out discharges, emissions and losses.
- Marine Strategy Framework Directive 2008/56/EC. Synthetic compounds identified as priority substances under directive 2000/60/EC which are relevant for the marine environment.
- Drinking Water Directive 98/83/EC. Standards for the most common substances (so- called parameters), among them polycyclic aromatic hydrocarbons, and. pesticides (aldrin, dieldrin, heptachlor and heptachlor epoxide).
- Access to Environmental Information (Directive 2003/4/EC). This Directive guarantees the right of access to environmental information held by or for public authorities. With regards to emissions, no request can be refused. Thus, this Directive is a powerful instrument to gather emission data, also on POPs and can be used supplementary to the E-PRTR Regulation.
- Regulation on Pollutant Release and Transfer Register ((EC) No 166/2006). It aims to enhance public access to environmental information. The E-PRTR includes additional source categories (e.g. diffuse sources), additional pollutants and stricter threshold levels for a number of pollutants (including POPs)
- Environmental Crimes Directive (2008/99/EC)

3. IMPLEMENTATION

3.1. Key tasks

The key tasks involved in implementing this Regulation are summarised in the checklist below.

3.2. Phasing Considerations

Table 8. Checklist with Key Implementation Tasks

REGULATION ON POPs - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Ratify the POPs Convention if not already done.
1.2	Designate an authority (or authorities) to be responsible for implementing the notification and information procedures laid down in the Regulation and inform the Commission about this designation
1.3	Devise the national implementation plan and the ancillary action plan reflecting the input of the public and stakeholders. Carry out this work in the context of a general information campaign involving all relevant authorities, the actors using or generating POPs as part of their activities, NGOs and other interested stakeholders.
1.4	Plan the implementation of the Regulation and the division of responsibilities between the relevant public authorities.
1.5	Plan the measures of the national implementation plan, focusing on the requirement and promotion to using substitute or modified materials, products and processes to prevent the formation and release of substances listed in Annex III
1.6	Set up procedures for ensuring that in the context of assessing new applications for IED permits or other authorisations for new or modified facilities, specific attention is given to the possibility to use processes, techniques or practices which does not lead to the formation and release of substances listed in Annex III
1.7	In addition to the national implementation plan and the release inventory and monitoring programme consider other appropriate programmes and mechanisms for monitoring the presence of POPs (e.g. dioxins, furans and PCBs) in the environment. Such programmes have to be coordinated with the POPs Secretariat, the Commission and the other Member States

1.8	Set up release inventories for the substances listed in Annex III into air, water and land are drawn up and maintained this inventory.
1.9	Establish monitoring and information exchange mechanisms: <ul style="list-style-type: none"> • monitoring stockpiling and compliance with provisions of the Regulation • facilitate information exchange within the EU and with third countries and for cooperating with the Commission and the other Member States in provision of technical and financial assistance to developing countries
1.10	Training of staff of competent authority and capacity building with relevant authorities and also in NGO which may be entrusted with some implementation tasks (technical support)
1.11	Produce guidance documents
2	Regulation
2.1	Take the necessary measures to comply with ban and restrictions on the production, placing on the market and use of listed POPs (Annex I and II), whether on their own, in preparations or as constituents of articles. These measures must also ensure reduction of all unintentional releases of POPs
2.2	Ensure compliance with the provisions on managing of stockpiles and wastes that may be contaminated with POPs ensuring as a first choice all separation of POPs contaminated waste and materials with other waste categories, ensuring that such waste is not being recycled or reused but safely destructed
2.3	Ensure that the use and management of notified stockpiles is monitored by a competent authority (Art. 5(3))
2.4	Ensure that the production, placing on the market and use of substances listed in Annex II, whether on their own, in preparations or as constituents of articles, is limited to the restricted uses set out in Annex II.
3	Information and Reporting
3.1	Adopt the measures and systems for: <ul style="list-style-type: none"> • Public consultation (e.g. on national implementation plan) • Information exchange • Reporting towards the Commission and the other Member States
3.2	Immediately notify the Secretariat of the Convention, as well as the Commission and other Member States in case of decisions to grant exemption under Art. 4(3) allowing temporary production and use of restricted substances listed in Part A of Annex I or in Part A of Annex II, as a closed-system site-limited intermediate

3.3	<p>Report to the Commission on:</p> <ul style="list-style-type: none"> • the designation of competent authorities (Art. 15); • Implementation of national provisions introducing penalties as well as subsequent modifications the national implementation plan to teh Commission (Art. 8(2)) • The application of the Regulation, including infringement cases and penalties. This reporting shall take place every three years and using the reporting template of the Commission (Art. 12(1)) • statistical data on the actual or estimated total production and placing on the market of any substance listed in Annex I or II. Such data must be submitted annually, using the reporting template of the Commission. (Art. 12(2)); • summary information compiled from the notifications, concerning stockpiles, received pursuant to Article 5(2); summary information compiled from the release inventories drawn up pursuant to Article 6(1); and summary information on the presence of dioxins, furans and PCBs as identified in Annex III in the environment, as compiled pursuant to Article 9. This reporting shall take place every three years, using the reporting template of the Commission (Art. 12(3)); • cases where listed substances occurring a constituent of articles produced or used already before or on date of entry into force of this Regulation (Art. 4(2))
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4. IMPLEMENTATION GUIDANCE

A number of reports, guidance documents and information notes have been developed at EU level to assist the Member States and candidate countries in their implementation efforts. For instance, the Commission has to produce a report every three years on the application of this Regulation and integrate it with the information already available in the context of the E-PRTR (Regulation (EC) No 166/2006) and CORINAIR Emission Inventory of EMEP (Cooperative Programme for Monitoring and Evaluation of the Long-Range Transmission of Air Pollutants in Europe). This report includes information on the use of derogations as referred to in Article 7(4). In June 2014 the Commission prepared the second Union's Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants²⁸⁹ showing the concrete actions and measures related to the POPs listed in the Convention.

The Union Implementation Plan aims to:

- review the existing Union level measures related to POPs;
- assess their efficiency and sufficiency in meeting the obligations of the Stockholm Convention;
- identify needs for further Union level measures;
- establish a plan for implementing the further measures;
- identify and strengthen links and potential synergies between POPs management and other environmental policies and other policy fields; and
- increase awareness on POPs and their control measures.

Useful information sources:

- Dioxin Strategy (2010)²⁹⁰
- The Stockholm Convention homepage²⁹¹
- Layman's guide to the Convention²⁹²
- UNEP's POPs Programme²⁹³

²⁸⁹ Commission Staff Working Document Union's Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants Accompanying the document Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions on the review and update of the first European Community Implementation Plan in accordance with Article 8(4) of Regulation No 850/2004 on persistent organic pollutants (SWD/2014/0172 final)

²⁹⁰ COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE, On the implementation of the Community Strategy for dioxins, furans, and polychlorinated biphenyls (COM(2001)593) – Third progress report* COM/2010/0562 final

²⁹¹ <http://chm.pops.int/default.aspx>

²⁹² United Nations Environment Programme (UNEP) Chemicals, „Ridding the World of POPs: A guide to the Stockholm Convention on Persistent Organic Pollutants, 2005. Available at:

http://www.pops.int/documents/guidance/beg_guide.pdf

²⁹³

<http://www.unep.org/chemicalsandwaste/>

- Council Decision concerning the conclusion, on behalf of the EU, of the Stockholm Convention on Persistent Organic Pollutants
- Report of the "Study on waste related issues of newly listed POPs and candidate POPs" (2010)²⁹⁴
- Information note on Regulation (EC) No 850/2004²⁹⁵
- The European Union and the Stockholm Convention Implementing Measures on Persistent Organic Pollutants²⁹⁶
- Toolkit for Identification and Quantification of Releases of Dioxins, Furans and Other Unintentional POPs (January 2013)²⁹⁷

In addition to the guidance and documentation prepared at EU level, candidate countries are advised to draw benefit from a number of general observations and good practice suggestions for applying the Regulation are presented below based upon the collective experience of Member States.

4.1. Planning

- The competent authority/ies will vary depending on the administrative structure within the country concerned, but may include government departments or agencies with responsibility for the chemical industry, trade and customs control. If more than one competent authority is established, it must be made clear who is responsible for which tasks.

Each Party to the Stockholm Convention - individual states as well the EU as a regional economic integration organisation - has to establish an Implementation Plan to show the concrete action that will be taken against the POPs listed in the Convention. The EU's first Implementation Plan, which complements the national plans of the EU Member States, was adopted on 9 March 2007. The second European Union Implementation Plan on Persistent Organic Pollutants was adopted in June 2014. The second Implementation Plan addressed the inclusion of a number of new POPs into the Stockholm Convention and the UNECE CLRTAP POP Protocol, the technical and legislative progress made in the area as well as the findings of the Commission Report COM (2010) 514 on the application of the Regulation (EC) 850/2004 on persistent organic pollutants. The overall purpose of the plan is not only to fulfil the legal obligations of the EU's international obligations and EU law but also to take stock of actions underway and to lay down a strategy and action plan for further EU measures related to POPs and in particular to the Stockholm Convention. The latest EU Implementation Plan lists 26 actions.

²⁹⁴Consortium „Expert Team to Support Waste Implementation Interim Report“, *Study on waste related issues of newly listed POPs and candidate POPs, Service Contract for the European Commission*, No ENV.G.4/FRA/2007/0066, 2010. Available at: http://ec.europa.eu/environment/waste/studies/pdf/pops_summary_report.pdf

²⁹⁵

http://ec.europa.eu/environment/archives/pops/pdf/pops_infonote.pdf

²⁹⁶ http://europa.eu/environment/chemicals/international_conventions/pdf/convention_stockholm.pdf

²⁹⁷ <http://toolkit.pops.int>

- Candidate countries' governments have to develop and implement strategies for identifying stockpiles and products and articles containing POPs. Once identified, these stockpiles need to be managed in a safe, efficient and environmentally sound manner.
- In efforts concerning release inventories and programmes and plans to identify and assess POPs in the environment, candidate countries could consult the Standardised Toolkit for Identification and Quantification of Dioxin and Furan Releases, which ensures a harmonised framework for the release inventories required under the Stockholm Convention

Examples of Practice in Member States

Romania:

Romania ratified the Stockholm Convention on Persistent Organic Pollutants by Law no 261/2004, and made sustained efforts for the implementation of the obligations assumed through ratification. In this sense the first step was the development of the National Implementation Plan for Stockholm Convention with GEF and UNIDO support. The National Implementation Plan was adopted by the Governmental Decision no 1497/2008.

Through TAIEX and Twinning Project systems some activities were developed with the aim to share information related to the various implementation issues such as: reporting requirements, national implementation plans, methodologies of the inventories elaboration, modalities of disposal and recovery of the waste consisting of, containing or contaminated by POPs, measures to reduce, minimise or eliminate the production, use and release of persistent organic pollutants, effect of POPs over the human health and environment.

At regional level, in 2009, Romania, with UNIDO support, officially launched the "Regional BAT and BEP Forum for Central and Eastern Europe, Caucasus, and Central Asia (CEECCA) to Promote Strategies to Reduce or Eliminate Unintentionally Produced POPs from Industry". For 2 years period Romania had the Chairmanship of the Forum being assisted by two Co-chairs, Armenia and Sweden.

The Forum is focused on providing technical assistance to developing countries and countries with economies in transition in order to fully enable implementing the BAT/BEP related provisions, mentioned in the Article 5 of the Stockholm Convention on persistent organic pollutants.

Since 2007, when Romania became a Member State to the European Union also the provisions of Regulation (EC) no 850/2004 on persistent organic pollutants were applied at national level. In order to create the infrastructure for the implementation of Regulation provisions was adopted the Governmental Decision no 561/2008 on establishment of measures for the implementation of Regulation (EC) no 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/CEE.

Examples from a Member State: National Implementation Plan

Sweden:

An updated National Implementation Plan (NIP) for the Stockholm Convention was presented to the Government in May 2012 by the Swedish Environmental Protection Agency in collaboration with KemI and the Swedish Agency for Marine and Water Management. In preparing this report, the three agencies have consulted a broad range of stakeholders from other agencies, industry organisations, academia, civil society and environmental non-governmental organisations in Swedish society. The report describes Swedish legislation, on chemicals in general and POPs in particular, as well as measures that Sweden has taken to protect the Swedish population and the Swedish environment from POPs, so as to comply with the Convention obligations.

Country Baseline: The most acute problem related to “old” POPs in Sweden today is that levels of dioxins and dioxin-like PCBs in fatty fish from the Baltic Sea are unacceptably high and constitute a risk to human health.

Implementation of the basic obligations (intentionally produced): Sweden considers that it has fulfilled its obligations under the Convention with regard to the production, placing on the market, use, import and export of all the substances in Annexes A and B. Concerning the additional POP pesticides listed under the Convention, these were all banned in Sweden as long ago as the 1970s and 1980s.

PCBs in sealants and flooring: The 2007 Ordinance on PCBs etc. requires compulsory inventories of PCB sealants and flooring materials and remediation/decontamination of sealants and flooring containing more than 500 ppm (mg/kg) PCB by 30 June 2016. Results indicate that the Swedish inventory and cleanup of PCBs in buildings has generally worked well.

PCBs in electrical and electronic equipment: All equipment (above 5 dm³) with PCB levels higher than 500 ppm has been decontaminated. Most equipment with levels of 50–500 ppm has been decontaminated. Most equipment within the range of 2–50 ppm has been decontaminated due to stricter regulation in Sweden.

PFOS: Sweden had imports of PFOS for use in the metal industry totalling about 200 kilograms in 2010. No use in this sector is allowed after 26 August 2015. The industrial use of PFOS as mist suppressants for non-decorative hard chromium (VI) plating in Sweden is not what can be described as closed-loop.

HCB: During market surveillance activities in 2010 and 2011 HCB was found in fireworks available on the Swedish market. Border and market surveillance therefore remains necessary. Cases of noncompliance will be reported to the European Commission.

Stockpiles, wastes and articles in use: There are no known stockpiles of POP wastes in Sweden. Nor does Sweden have any storage of POP wastes, apart from temporary storage before disposal. The installed amounts in Sweden of PFOS in PFOS-treated leather furniture and carpets made of synthetic fibres are not known. Before further action is taken to reduce releases of PFOS in waste management, more knowledge on installed amounts is needed.

Identified needs for further action to reduce releases are:

- Improved self-monitoring: operators need to show more clearly their emissions and the loads they give rise to. Data that reflect entire process cycles, including disruptions, and provide information about this variation need to be collected. In this respect, operator self-monitoring needs to be improved. It is currently under investigation whether ash samples from different industrial processes should be included in the national environmental monitoring programme.
- To increase representativeness, continuous sampling methods should be further improved and applied, as such sampling makes it possible to monitor how and to what extent process variations affect the formation of POPs. A goal has been set in the Swedish national waste plan that waste incineration plants should have continuous sampling of emissions of dioxins and furans. The relevant stakeholders should work to improve measurements from Swedish waste incineration plants and authorities should provide guidance and awareness-raising and follow-up of this goal. Continuous sampling could also be set as a condition in permits issued for waste incineration plants.
- Study of Swedish destruction capacity for POPs waste: Swedish capacity for destruction of hazardous waste through incineration is generally very good. To ensure that POPs waste is treated in accordance with Article 6.1d of the Stockholm Convention, Sweden will initiate a study focusing on emissions to air and the POP content of ashes and slags.
- Take measures to ensure that landfilling of residues containing POP flame retardants (shredder light fraction) will stop. Sweden has had a national ban on landfilling of organic waste for more than seven years (Ordinance on the Landfilling of Waste (2001:512)). Most organic waste is consequently incinerated, and only a very small residue is still landfilled.

Source: Swedish NIP available at:

<https://www.naturvardsverket.se/Documents/publikationer6400/978-91-620-6498-3.pdf?pid=3806>

4.2. Regulation

Covered POPs:

- initial 12 POPs: in 2001, twelve POPs have been recognised as causing adverse effects on human health or the environment and these can be placed in three categories:
 - Pesticides: aldrin, chlordane, DDT, dieldrin, endrin, heptachlor, hexachlorobenzene, mirex, toxaphene.
 - Industrial chemicals: hexachlorobenzene, polychlorinated biphenyls (PCBs).
 - By-products: hexachlorobenzene; polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans (PCDD/PCDF), and PCBs.
- The new POPs are the substances that were listed in the Stockholm Convention at the 4th, 5th and 6th Conference of the Parties (COP) to the Stockholm Convention held in May 2009, in April 2011 and in May 2013, respectively, and in the POP Protocol at the 27th meeting of the Executive Body of LRTAP Convention held in December 2009 and that were not listed in any of these instruments before. Thus, the new POPs are tetra-, penta-, hexa-, and hepta-BDE (Polybrominated diphenylethers; PBDEs), Pentachlorobenzene (PeCB), PFOS (including salts) and PFOSF, endosulfan, short-chained chlorinated paraffins (SCCPs), hexachloro- butadiene (HCBD) HBCDD and polychlorinated naphthalenes (PCNs). With the exception of HBCDD, these substances have been included in the POP Regulation.
- General and specific exemptions concerning the listed substances are limited to a minimum.
- The Regulation is built on the principle of substitution and in certain cases imposes stricter control measures than those resulting from the Protocol and the Convention. When new chemicals and pesticides are assessed, EU member states and the Commission are required to consider the criteria for POP substances described in Annex D to the Stockholm Convention. Substances that fulfil the criteria are to be phased out or severely restricted. This is closely connected to chemical-related work on REACH in the EU.
- As most of the listed the POPs are no longer in use, there are hardly any direct consequences of the Regulation on the chemicals industry and operators dealing with marketing of chemicals. However, new substances with POPs characteristics may be developed and introduced onto the market. Those should be identified through the legislation for new chemicals or for biocidal products and pesticides. Due to the lack of knowledge about existing substances, there may also be POPs-like substances on the market that have not yet been recognised. With the EU chemicals policy REACH, the management of all POPs-like chemicals has been improved and more POPs are likely to be identified through the registration requirement for existing substances. Under REACH, POPs-like substances will require authorisation or will be restricted.
- The Regulation and the POPs Convention requires waste containing POPs to be handled, collected, transported and stored in an environmentally sound manner. Their toxic content needs to be destroyed. The Convention does not allow recovery, recycling, reclamation, direct reuse or alternative uses of POPs, and it prohibits their improper transport across international boundaries.

- The Convention and the POPs Regulation (cf. Art 4 (1) (b)) generally exempt "substances occurring as an unintentional trace contaminant in substances, preparations or articles". This notion is not applied in other pieces of EU chemicals legislation, which instead set fixed values below which a substance is not considered restricted. A fixed threshold facilitates uniform enforcement and control and provides legal certainty to economic operators. The amending Regulation of 2010 fixed thresholds as an interpretation of what is to be understood by an unintentional trace contaminant. The concrete threshold must be based on the specific properties of the restricted substance. The original 12 substances in the Convention were mainly pesticides while the COP4 decisions contain substances used in consumer products. An interpretation was therefore needed. The thresholds are an interpretation of the Convention that fits into an EU law context.
- Take into account the interrelationship between REACH Regulation and the POPs Regulation. However, the amendment of POPs Regulation extending it to cover pentaBDE and PFOS, have led to an amendment of REACH Annex XVII, which previously also listed these substances. Hence, in this regard, candidate countries should exclusively focus on substances listed in POPs Regulation for the POPs restricting scheme. However, for commercial octaBDE these will de facto be prohibited as it contains BDE-congeners meeting the POP criteria, e.g. heptaBDE. However, the specific octaBDE congener does not meet the POPs criteria in its own right. OctaBDE will continue to stay in REACH Annex XVII as it meets the PBT criteria.
- The PBDEs are listed in the POPs Regulation using the same approach as in REACH Annex XVII, i.e. using the chemical formula.
- The Convention and the POPs Regulation use the term "prohibition" of POP substances listed in their respective Annex I (or A). In some cases, a POP substance can be present in an article, even if not intended. A special provision has been inserted that allows the presences of "unintentional trace contaminants" (UTC). Taking into account that the majority of the listed substances are plant protection products for which the provision is of less relevance it is logical to assume that it probably more was intended to address problems with unintentional releases. For example dioxin can be present in the ambient environment and thus can contaminate a given product.
- All remaining stockpiles for which no use is permitted shall be managed as hazardous waste. Export of POP stockpiles has already been restricted under the PIC Regulation.
- Control measures aimed at minimising releases of unintentional POPs rely on the existing EU legislation on, inter alia, pollution control of industrial installations and waste incineration. However, the Regulation obliges Member States to draw up and maintain comprehensive release inventories for dioxins, furans, PCBs and polyaromatic hydrocarbons (PAH) and to communicate their national action plans on measures to minimise total releases of these substances. The action plan shall also include measures to promote the development of substitute or modified materials, products and processes to prevent the formation and releases of POPs.
- Producers and holders of waste are obliged to undertake measures to avoid contamination of waste with POP substances. Otherwise the control measures on waste follow closely those of the Stockholm Convention: Recovery of POP substances is banned and the waste should be managed in a way that ensures the destruction or irreversible transformation of the POP content. By way of derogation and in case such waste management operations are not environmentally preferable, Member States may allow certain other operations, with stringent conditions, e.g. permanent storage of demolition waste contaminated with PCBs.

4.3. Information and Reporting

- Article 12 of the Regulation requires annual reporting by Member States on the actual production and use of POPs, and triennial reporting on the implementation of other provisions of the Regulation ("Article 12 Reports").
- Stockpiles greater than 50 kg meant for permitted uses (e.g. as a reference standard or for certain uses of lindane during the phase out period) shall be notified to the competent authority and managed in a safe, efficient and environmentally sound manner.

5. COSTS

The costs of implementing this Regulation are mainly concerned with setting up the system to monitor compliance with ban and restricted use in POPs or POPs acting substances. Since most of the regulated chemicals are already being phased out a substantial part of the efforts concern the identification and assessment of new, replacing substances to ensure that these do not have POPs resembling properties. The main costs for the public sector is setting up and running of procedures and systems for notification, monitoring and reporting. Some of the tasks could be coordinated or integrated with those carried out by the competent authority for implementing the REACH Regulation. Also systems already established as a Party to the Stockholm Convention should rather be expanded and built upon rather to create new structures or bodies. The costs for industry is mainly to research for the identification of replacements.

THE REGULATION ON THE EXPORT AND IMPORT OF HAZARDOUS CHEMICALS

Official Title: Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (OJ L 201 27.7.2012)

Amended by:

Commission Delegated Regulation (EU) No 1078/2014 of 7 August 2014 amending Annex I to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals Text with EEA relevance (OJ L 297, 15.10.2014)

Commission Delegated Regulation (EU) 2015/2229 of 29 September 2015 amending Annex I to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals (OJ L 317, 3.12.2015)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Regulation (EU) No 649/2012 of the European Parliament and the Council of 4 July 2012 concerning the export and import of hazardous chemicals regulates the import and export of certain hazardous chemicals and requires industry to notify their intention to export these chemicals. This Regulation applies to banned or severely restricted chemicals listed in Annex I, containing industrial chemicals and pesticides, including biocides. The Regulation also applies to chemicals that are banned for export as listed in Annex V and to all chemicals when exported regarding their packaging and labelling, which must comply with relevant EU legislation.

Chemicals found in drugs, radioactive materials, wastes, chemical weapons, food and food additives, feeding stuffs, genetically modified organisms, and pharmaceuticals (except disinfectants, insecticides and parasiticides) are regulated by other EU legislation and therefore excluded from the scope of this Regulation.

Furthermore, the Regulation does not apply to chemicals exported or imported for research or analysis provided that the quantities are unlikely to affect human health or the environment and do not exceed ten kilograms from each exporter to each importing country per calendar year.

The Regulation (EU) 649/2012 places obligations on companies who wish to export these chemicals to non-EU countries. The export of such chemicals is subject to two types of requirements: export notification and explicit consent where the latter requirement applies only in certain cases.

The Regulation also places obligations on importers of chemicals that are either banned or severely restricted by EU legislation or subject to the prior informed consent (PIC) procedure under the Rotterdam Convention. However, it should be noted that import of chemical substances is mostly covered by other EU legislation such as for example the REACH Regulation (EC) 1907/2006 or Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

As already mentioned above, the Regulation (EU) 649/2012 implements within the European Union, the Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade. The European Union (EU) ratified the Convention on 20 December 2002 and fully implemented its provisions through a series of regulations that were developed over time, namely Regulation (EC) No 304/2003 replaced by the Regulation (EC) No 689/2008 replaced by the latest legal measure Regulation (EU) No 649/2012. To achieve a higher level of protection of human health and the environment the EU decided to include a number of additional provisions into Regulation (EU) 649/2012 on export and import of hazardous chemicals that go beyond the Convention requirements. The requirements for export notification and for explicit consent are extended to all countries rather than applying only to those countries that are Party to the Convention. Furthermore, an export notification for chemicals listed in Annex I to the Regulation is required irrespective of their intended use in the importing country.

In sum, the three main aims of Regulation (EU) 649/2012 are:

- to implement the Rotterdam Convention on the prior approval by the importing country of international shipments of certain hazardous chemicals and pesticides;
- to promote shared responsibility and co-operation on controlling and monitoring the international transport of dangerous chemicals; and
- to contribute to a more environmentally friendly use of such chemicals.

The Regulation applies as of 1 March 2014 placing some new tasks to the ECHA. Thus, from this date ECHA is responsible for some administrative and technical tasks related to the new Regulation. The Agency's main task is to process and send export notifications to the importing countries outside the EU, and keep a database of the export notifications forwarded to and the explicit consents given by the importing countries. Under the previous legislation, these tasks were the responsibility of the European Commission's Joint Research Centre (JRC).

The Regulation has six annexes:

- Annex I comprises three parts (Part 1 listing chemicals subject to export notification procedure referred to in Art. 8); Part 2 listing chemicals qualifying for PIC notification referred to in Art. 11; and Part 3 listing chemicals subject to the PIC procedure under the Rotterdam Convention) (relevant to Arts. 13 and 14).
- Annex II on export notification setting out the information required pursuant to Article 8.
- Annex III on information to be supplied to the Commission by the designated national authorities of the Member States in accordance with Article 10
- Annex IV concerns notification of the Secretariat of the Convention of a banned or severely restricted chemical, setting out information requirements for notifications (relevant to Article 11 of the Regulation)
- Annex V lists chemicals and products subject to an export ban (relevant to Art. 15 of the Regulation). Part 1 refers to persistent organic pollutants (POPs) as listed in Annexes A and B to the Stockholm Convention on POPs, whereas Part 2 refers to chemicals other than persistent organic pollutants as listed in Annexes A and B to the Stockholm Convention on POPs according to the provisions thereof.
- Annex VI: List of Parties to the Convention requiring information concerning transit movements of chemicals subject to the PIC procedure (referred to in Art. 16 of the Regulation)

According to Article 23 (1) of the Regulation, at least once a year the Commission is required to review, on the basis of the development in EU law and under the Convention, the list of chemicals in Annex I to the PIC Regulation. To amend Annex I, the Commission adopts a delegated act that adds further chemicals to or changes existing entries in this Annex. The power to adopt delegated acts was conferred to the Commission by the European Parliament and the Council for a period of five years (starting from 1 March 2014). In this context two delegated acts have been adopted, namely:

- Commission Delegated Regulation (EU) No 1078/2014 of 7 August 2014 amending Annex I to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals, and
- Commission Delegated Regulation (EU) 2015/2229 of 29 September 2015 amending Annex I to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Designate an authority (or authorities) to be responsible for implementing the notification and information procedures laid down in the Regulation and inform the Commission about this designation (Art. 4).
- Designate authorities, especially customs authorities, responsible for controlling the import and export of chemicals listed in Annex I (Art. 18).
- Ensure that all chemicals listed in Annex I are handled and traded according to the provisions of the Regulation.
- Ensure that the lists of chemicals listed in Part 1 (subject to export notification), Part 2 (subject to export notification and qualifying for the PIC notification procedure) and Part 3 (chemicals subject to the PIC procedure) are made available to the public in electronic format (Art. 7(3)).
- Consider whether to establish a system obliging exporters to pay an administrative fee for each export notification given and for each request for explicit consent (Art. 8(8))

2.2. Regulation

- Ensure that exporters of chemicals comply with their obligations under the Regulation:
 - Ensure that chemicals and articles listed in Annex V, which are prohibited in the EU, are not being exported (Art. 15(2)), unless such chemicals fall under the provisions of Article 2(3);
 - Duly notifying exports to parties or other countries of chemicals listed in Parts 1 to 3 of Annex I to the competent authority, including:
 - ensure that Part 1 chemicals have to be notified to the designated national authority of the Member State in which the exporter is established at least 35 days prior to the first export of any chemical (either as substance itself or in mixture). Thereafter the exporter must notify his DNA of the first export of the chemical each calendar year no later than 35 days before the export takes place. (Art. 8). The export notification is not needed if the importing party has made an official consent or non-consent to the secretariat or made a waiver to the notification requirement.
 - Ensure that no later than 35 days before the first export of any article containing in unreacted form a chemical listed in Part 2 or 3 and the first export in each subsequent calendar year is notified to the designated national authority (Art. 15(1)), unless conditions for waiver are fulfilled.
 - Ensure that Parts 2 and 3 chemicals can only be exported if the exporter has obtained an explicit consent to the import through the designated national authorities of the country where the

exporter is established and in the country of import. Part 3 chemicals cannot be exported unless the latest circular issued by the secretariat indicates such a consent. (Art. 14(6))

- Respect the import responses of importing countries in relation to PIC chemicals listed in Part 3 of Annex I. (Art. 14(4))
 - Ensure that there is no exporting of any chemical later than six months before the expiry date. In the case of pesticides, ensure that the size and packaging of containers is such as to minimise risks of creating obsolete stocks. (Art. 14(10) and 14(11))
 - Include the relevant reference identification number (RIN) in the customs declaration for the export. (Art. 19(1))
 - Indicate the respective CUS number and Combined Nomenclature Code on the customs declaration.
 - Provide their DNA any information required by an importing Party to the Convention no later than 30 days before the first transit movement of chemical listed in Part 3 takes place no later than eight days before each subsequent transit movement. (Art. 16)
 - Ensure that they annually submit, to the designated national authority of its Member State, information on the quantity of the chemical shipped to each convention party or other country during the preceding year, along with a list of the names and addresses of each importer. This information must reach the authority during the first quarter of each year (Art. 9(1));
 - Notify importing parties about chemicals listed in Annex I, including articles containing chemicals listed in Parts 2 and 3 of Annex I;
 - Ensure that all exported hazardous chemicals and mixtures are packaged, labelled and controlled in accordance with EU legislation, especially Regulation (EC) No 1272/2008, Regulation (EC) 1907/2006, Regulation (EU) 528/2012 or any other relevant EU legislation (Art. 17(1)). Where appropriate, label should contain expiry and production date (Art. 17(2)).
 - Ensure that the information on the label and on the safety data sheet (SDS) is given in the official language(s) or in one or more principal languages of the importing country. (Art.17 (4))
 - Provide an SDS to each importer (Art. 17(3))
 - Provide on request the importing countries with available additional information on exported chemicals. (Art. 8(7))
 - Submit to the DNA an annual report for the preceding year on exported quantities of chemicals listed in Annex I. The report is due before 31 March each year. (Art. 10)
 - Provide all relevant available information to the Commission upon request within 60 days of the request in case where chemical qualifies for PIC notification, but information is insufficient to meet the requirements of Annex IV (Art. 11(4))
- Ensure that each importer complies with its obligations:
 - submit the information about the quantities imported into the EU. (Art. 10)
 - provide any additional information as requested by the Commission. (Art. 11(4))

- Ensure that the designated national authority complies with its obligations under the Regulation, including:
 - checking the notifications and their compliance with Annex II and forwarding the notification to the Agency (Art. 8(2));
 - deciding on possible waivers to the export notification requirement and to allow immediate exports of chemicals in cases where a delay in transportation could endanger public health or the environment in the importing or other country (Art. 8(5));
 - immediately forwarding notifications to the Agency and any ancillary information received where the designated authority receives any export notification directly or indirectly from relevant authorities from parties or other countries (Art. 9(2)).
 - Requesting explicit consents from the DNA/appropriate authority of the importing country for exports of chemicals listed in Parts 2 and 3 of Annex I. In case of export of Annex I Part 2 chemicals to OECD countries, deciding in consultation with the Commission whether the requirement for explicit consent may be waived on the basis of the chemical being licensed, registered or authorised in the OECD country. (Art. 14 (6))
 - Consulting the Commission and taking decisions on granting of the waivers for export of chemicals listed in Parts 2 and 3 of Annex I in cases where no response has been received within 60 days of a request for explicit consent. (Art. 14 (7))
 - Forwarding export notifications received from third countries to Agency. (Art. 9 (2))
 - For PIC chemicals, where relevant, informing the Commission of national regulatory actions so that this information can be taken into account in EU import decisions (Art. 13 (2)) and making available EU import decisions to those concerned within their competence (Art. 13 (5)).
 - Forwarding to those concerned within its jurisdiction the information on chemicals and on decisions of importing parties regarding import conditions applicable to those chemicals. (Art. 14 (3) in conjunction with Article 14 (1))
 - Handling of special RIN requests.
- Where a Member State takes final regulatory action FRA to ban or severely restrict a chemical, the DNA provides the Commission with sufficient information to allow it to consult the other Member States. The submitting Member State is also obliged to consider any comments received from other Member States before informing the Commission whether an FRA notification should be forwarded to the Secretariat or whether the information should instead be forwarded under the information exchange provisions. (Art. 11 (8))
- Establish effective, proportionate and dissuasive penalties applicable in the event of infringements of the provisions of the Regulation and take all necessary steps to ensure correct implementation. The Commission must be notified about these penalties and also in case of modifications to these sanctions (Art. 28).
- Ensure that amendments to Annexes I, II and V of the Regulation are reflected in national law on a timely basis.

2.3. Information and Reporting

- Facilitate the exchange of scientific, technical, economic and legal information (including toxicological and safety information) regarding chemicals under the Regulation. (Art. 20)
- Cooperate in promoting technical assistance. (Art. 21)
- Deal with confidential information as requested and in accordance with Article 20, especially regarding which information is to be regarded as confidential.
- Regularly send information to the Commission on the operation of the various procedures (Art. 22), including activities controlling compliance of exporters (Art. 18 (1))
- Provide the Agency with a annual report with aggregated information on trade in chemicals listed in Annex I in accordance with Annex III (Art. 10(3)).
- Specific obligations of the DNA:
 - On request, provide importing countries with additional information related to exported chemicals. (Art. 8 (7))
 - On request, assist the Commission in compiling additional information with respect to final regulatory action 'FRA' notifications (Art. 11(6))
 - Advise and assist importing countries, upon request, in obtaining additional information to help them make an import response for PIC chemicals (Art. 14 (5))
 - Forward to the Commission (with a copy to ECHA) any information required by an importing Party to the Convention that has been provided by the exporter concerned prior to each transit movement of a chemical listed in Part 3 of Annex I. (Art. 16 (3))

2.4. Additional Legal Instruments

EU legislation that should be taken into consideration in the implementation of this Regulation includes:

- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products
- Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC
- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures
- Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury

- Directive 2003/4/EC on access to environmental information

3. IMPLEMENTATION

3.1. Key tasks

The key tasks involved in implementing this Regulation are summarised in the checklist below.

The key tasks are arranged under subheadings and organised in chronological order of implementation wherever possible.

Table 9. Checklist with Key Implementation Tasks

REGULATION ON THE EXPORT AND IMPORT OF HAZARDOUS CHEMICALS - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate a competent authority to take responsibility for the notification and information measures required for the import and export of chemicals requiring prior informed consent.
1.2	Designate authorities, especially customs authorities, responsible for controlling the import and export of chemicals listed in Annex I
2	Regulation
2.1	Do not export chemicals and products listed in Annex V, which are prohibited in the EU.
2.2	Establish procedures and protocols to ensure that the competent authority complies with its obligations under the Regulation, including: <ul style="list-style-type: none">• receiving notification of a proposed first export of a substance subject to notification at least 35 days before the intended export;• approve and forward the export notification to ECHA at least 25 days before the intended export;• providing the necessary information to the Commission on transit movements to parties of the convention that require information on transit movements of chemicals subject to the PIC procedure;• reporting to the Commission;• taking appropriate actions in response to reactions from the country of destination;• amending and implementing the revised Annexes on a timely basis, in particular Annex I;• ensuring that dangerous substances for export to third countries comply with EU labelling and packaging requirements; and

	<ul style="list-style-type: none"> • monitoring compliance with the provisions of the Regulation.
2.3	Ensure that the export of chemicals whose use is prohibited within the EU for the protection of human health or the environment, listed in Annex V, is prohibited.
3	Obligations to the exporters
3.1	Develop and provide guidance to exporters on their obligations under the Regulation, including: <ul style="list-style-type: none"> • the packaging and labelling of chemicals in accordance with EU requirements; • complying with the import decisions of countries of destination; and • notifying competent authorities of the proposed first export of chemicals subject to notification to third countries.
4	Information and Reporting
4.1	Co-operate with the Commission in evaluating the risks posed by certain chemicals.
4.2	Provide the Commission with a yearly report with aggregated information in accordance with Annex III.
4.3	Report to the Commission on: <ul style="list-style-type: none"> • designation of competent authorities; • notifications received relating to exports of chemicals; • information on the operation of the notification system; • national legislation to ban or severely restrict a chemical; • penalties applicable in the event of infringements; • the procedural operations, including the functioning of customs controls, • occurrences of infringements, penalties and remedial action.

3.2. Phasing Considerations

This Regulation cannot be fully implemented until appropriate systems for classifying chemicals are in place. Its implementation should therefore be carried out in parallel with Regulation (EC) No 1272/2008 on classification, labelling and packaging of dangerous substances and the REACH Regulation (No 1907/2006).

Some regulatory control of chemical import and export may already exist in candidate countries, especially those that are already participating in the international PIC procedure.

4. IMPLEMENTATION GUIDANCE

A number of general observations and good practice suggestions for applying the Regulation are presented below based upon the collective experience of Member States.

Furthermore, the Guidance document to facilitate the implementation of the PIC Regulation (Regulation (EU) No 649/2012) by describing good practice on how to fulfil the obligations has been developed with the participation of the European Commission, Designated National Authorities for the PIC Regulation and accredited stakeholders, including industry. The Document is available at: <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-pic>

To improve the procedure and provide the stakeholders with all the necessary information the IT tool - ePIC has been established and maintained by ECHA to ensure that requirements under the Regulation (EU) 649/2012 are supported by appropriate IT systems. ePIC has three independent interfaces, one dedicated to industry users, one to authority users (ECHA, DNAs and the Commission) and one for customs officers. It allows information to be securely exchanged between industry users, authority users and customs users. With the release of ePIC 1.1 on 8 January 2015, industry users will be able to generate and submit these reports to their relevant Designated National Authorities. In the new version of ePIC, for most users a draft version of the reports is automatically generated and pre-filled by ePIC – to the extent possible- with the data available in the system. Once the reports have been finalised, they can be sent to the Designated National Authorities for aggregation on country level. ePIC User Manual for Industry (2015) is available at: http://echa.europa.eu/documents/10162/21731237/epic_usm_industry_en.pdf

4.1. Planning

- Member States must designate one or more national authorities (DNA) to act on its behalf with regard to the performance of the administrative functions required by this Convention. The DNAs serve as the focal point in the respective country for the dissemination of information concerning the provisions of the Convention to the relevant government departments, as well as to other partners such as exporting and importing industries and customs, and to the Commission. Member States are also responsible for control and enforcement matters. They are required to report on their activities in this regard. Given the highly technical nature of tasks allocated to DNAs under this Regulation, the Member States usually nominate institutions of governmental administration or agencies that already have experience and responsibilities for managing chemicals and/or pesticides at a national level.
- The Member States have to designate authorities such as customs offices to control imports and exports of chemicals listed in Annex I. They and the Commission shall co-ordinate their enforcement activities in relation to exporters. Member States will have to regularly report on such activities. Regulation (EU) 649/2012 provides for measures to assist customs control.
- The competent authority/ies will vary depending on the administrative structure within the country concerned, but may include government departments or agencies with responsibility for the chemical industry, trade and customs control. If more than one competent authority is established, it must be made clear who is responsible for which tasks.

Examples from a Member State – competent authorities

United Kingdom: The Export and Import of Dangerous Chemicals Regulations 2008 No 2108 established the Health and Safety Executive as the Designated National Authority for Great Britain..

Enforcement of PIC in Great Britain is carried out jointly by the Health and Safety Executive; HM Revenue and Customs and the UK Border Agency . The Health and Safety at Work etc Act 1974 and the Customs and Excise Management Act 1979 provide enforcing authorities with a range of tools to secure compliance with the law and to ensure a proportionate response to criminal offences. These may include the offer of information; and advice; a warning that duty-holder is failing to comply with the law; and prosecution (or report to the Procurator Fiscal with a view to prosecution in Scotland)

More information at: <http://www.hse.gov.uk/pic/index.htm>

Sweden: this Regulation is primarily dealt with by the National Chemicals Inspectorate (KEMI) and the Customs Department. KEMI inspects permits and provides advice to the Ministry of Environment. KEMI is the competent authority according to the Rotterdam Convention and participates in various Commission meetings. Sweden had a small chemical manufacturing industry and was reliant on the imports of chemicals for some years prior to accession to the EU. The country had developed a rigorous regulatory system early on and subscribed to the voluntary UNEP scheme in 1992, which included prior informed consent.

Consequently, the implementation of this Regulation had few implications for this Member State.

More information at:

<http://www.kemi.se/sv/Innehall/Lagar-och-andra-regler/EU-forordningar/Export-och-import-av-farliga-kemikalier/>

4.2. Regulation

- Once the competent authority has been designated, a procedure must be established for the notification of the export and import of dangerous chemicals

The export notification procedure consists of the following steps:

1) Submission of an export notification

The exporter creates and submits an export notification for a substance or mixture or article to his DNA via ePIC. A reference identification number (RIN) is issued as a result of this process

2) Processing by the DNA

The DNA checks the compliance of the submitted information with Annex II to the PIC Regulation (Export notification)

3) Processing by ECHA

ECHA also checks the export notification and, if it is the first yearly EU notification for that chemical, it is transmitted to the importing country (otherwise it is stored in ePIC) along with the confirmation of the receipt form and, if submitted by the exporter, a copy of the SDS for the chemical. The final notification is stored on ePIC and is available to the exporter and DNAs. If the RIN can be activated at this stage, its active period will be communicated in the message sent (directly by ePIC) to the exporter and to his DNA.

- An exporter must notify the competent authority (in its own country) of its intention to export certain dangerous chemicals to a third country for the first time. This notification must be done at least 35 days before the export is to take place. Certain information must be included in the notification and this is laid down in Annex II of the Regulation, together with a standard form that should be used. Once the DNA has confirmed that the draft notification is complete, the DNA must forward it to ECHA no later than 25 days before the expected date of export. After approval, ECHA transmits the final notification to the DNA or other appropriate authority of the importing country no later than 15 days before the first intended date of export (and thereafter no later than 15 days before the first export in any subsequent calendar year).
- The ECHA acts as the central authority for the PIC procedure. It notifies the competent bodies outside the EU of chemicals that are banned or severely restricted within the EU. On receipt of information about the export from the EU of a dangerous chemical, it assigns a reference number to the export, which is used also for each subsequent export of the same chemical from the EU to that third country.
- Once the ECHA has issued the reference number to the Member State's competent authority, and the third country has indicated that it will accept the substance, the export may take place. The reference number must be used for all subsequent exports of the substance to that country.
- All chemicals that are exported from the EU must be packaged and labelled in accordance with the CLP Regulation (EC) No 1272/2008) or other relevant Union legislation, unless requirements of the importing country indicate otherwise.

- A monitoring system should be established to ensure that the provisions of the Regulation are complied with. This may involve inspection of exports as they leave the country concerned as well as inspection of the records of known exporters of chemicals.
- In accordance with the decisions on the international PIC procedure, Annex I will be amended from time to time. These amendments will need to be implemented in national law and practice. They require minute attention to detail, given the number of substances, participating countries and their respective decisions related to consent status. These changes will also have to be notified to relevant firms and competent/customs authorities in advance of their entry into force so as to provide sufficient time for dealing with the revised lists.
- In general, the Commission will act as the central authority in respect of imports of substances to the EU. However, where a Member State receives a notification of an import it is required to forward the notification to the Commission together with any additional information provided, and to prohibit or restrict the import in accordance with the decision of the Commission.

4.3. Obligations of the Exporter

- An "exporter" includes the person holding the export contract, or in the absence of a contract, the person having the power to determine export of the chemical from the customs territory of the EU. In the case where the exporter is not established in the EU, the contracting Party established in the EU must fulfil the obligations of the exporter.
- As the Regulation is directly applicable for Member States (and candidate countries from day one of membership), guidance should be provided to exporters informing them of their obligations under the Regulation to ensure successful implementation. This should specify:
 - the information that must be included with a notification (as specified in Annex II of the Regulation);
 - to whom the notification must be sent;
 - guidance on what information is required to be included with the export;
 - information on the packaging and labelling required by the national legislation implementing CLP Regulation;
 - the content of the Annex I list;
 - details of how to make subsequent exports; and
 - information on the circumstances under which a new notification must be made.

It may be appropriate for a competent authority to operate a helpline to assist exporters in the completion of notifications. In addition, information could be provided to exporters on which substances destination countries will and will not accept. Guidance is available from FAO/UNEP guidance documents available at:

<http://www.pic.int/Implementation/ResourceKit/tabid/1064/language/en-US/Default.aspx>

4.4. Monitoring and Reporting

- Both the Member States and the Commission must monitor developments under the Regulation. The Member States and ECHA must regularly (every three years) send information on the operation of the various procedures to the Commission. These reports cover elements such as:
 - the number of export notifications handled,
 - the number of requests for explicit consent and their outcomes,
 - the nature and extent of controls/inspections, problems and infringements,
 - warnings and penalties issued,
 - other measures taken, etc.

Based on these submissions, the Commission in turn compiles a report, incorporating a synthesis of the information provided in the reports from Member States and ECHA. Such summary report on the overall functioning of the Regulation is then forwarded by the Commission to the European Parliament and to the Council.

5. COSTS

Statutory import/export control system already exists in some countries. The additional costs to the regulatory authority to collect the information required by this Regulation and to control the movement of chemicals is unlikely to be very large, particularly if the country already subscribes to similar schemes such as the UNEP or OECD schemes. Also candidate countries may establish a system obliging exporters to pay an administrative fee for each export notification given and for each request for explicit consent. The costs to industry will be limited to administrative costs.

REGULATION ON REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (REACH)

Official Title: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006)

Amended by:

Council Regulation (EC) No 1354/2007 of 15 November 2007 adapting Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), by reason of the accession of Bulgaria and Romania (OJ L 304, 22.11.2007)

Commission Regulation (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V (OJ L 268, 9.10.2008)

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008)

Commission Regulation (EC) No 134/2009 of 16 February 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XI (OJ L 46, 17.2.2009)

Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (OJ L 164, 26.6.2009)

Commission Regulation (EU) No 276/2010 of 31 March 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (dichloromethane, lamp oils and grill lighter fluids and organostannic compounds) (OJ L 86, 1.4.2010)

Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 133, 31.5.2010)

Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (‘REACH’) (OJ L 44, 18.2.2011)

Commission Regulation (EU) No 207/2011 of 2 March 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of

Chemicals (REACH) as regards Annex XVII (Diphenylether, pentabromo derivative and PFOS) (OJ L 58, 3.3.2011)

Commission Regulation (EU) No 252/2011 of 15 March 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex I (OJ L 69, 16.3.2011)

Commission Regulation (EU) No 253/2011 of 15 March 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XIII (OJ L 69, 16.3.2011)

Commission Regulation (EU) No 366/2011 of 14 April 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Acrylamide) (OJ L 101, 15.4.2011)

Commission Regulation (EU) No 494/2011 of 20 May 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium) (OJ L 134, 21.5.2011)

Commission Regulation (EU) No 109/2012 of 9 February 2012 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (CMR substances) (OJ L 37, 19. 2. 2012)

Commission Regulation (EU) No 125/2012 of 14 February 2012 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH') (OJ L 41, 15. 2. 2012)

Commission Regulation (EU) No 412/2012 of 15 May 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 128, 16. 5. 2012)

Commission Regulation (EU) No 835/2012 of 18 September 2012 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (Cadmium) (OJ L 252, 19. 9. 2012)

Commission Regulation (EU) No 836/2012 of 18 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards lead (OJ L 252, 19. 9. 2012)

Commission Regulation (EU) No 847/2012 of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards mercury (OJ L 253, 20. 9. 2012)

Commission Regulation (EU) No 126/2013 of 13 February 2013 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 43, 14. 2, 2013)

Council Regulation (EU) No 348/2013 of 17 April 2013 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 108, 18. 4 2013)

Council Regulation (EU) No 517/2013 of 13 May 2013 adapting certain regulations and decisions in the fields of free movement of goods, freedom of movement for persons, company law, competition policy, agriculture, food safety, veterinary and phytosanitary policy, transport policy, energy, taxation, statistics, trans-European networks, judiciary and fundamental rights, justice, freedom and security, environment, customs union, external relations, foreign, security and defence policy and institutions, by reason of the accession of the Republic of Croatia (OJ L 158, 10. 6. 2013)

Commission Regulation (EU) No 1272/2013 of 6 December 2013 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards polycyclic aromatic hydrocarbons (OJ L 328, 7.12. 2013)

Commission Regulation (EU) No 301/2014 of 25 March 2014 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards chromium VI compounds (OJ L 90, 26. 3. 2014)

Commission Regulation (EU) No 317/2014 of 27 March 2014 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (CMR substances) (OJ L 93, 28. 3. 2014)

Commission Regulation (EU) No 474/2014 of 8 May 2014 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH') as regards 1,4-dichlorobenzene (OJ L 136, 9. 5. 2014)

Commission Regulation (EU) No 895/2014 of 14 August 2014 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 244, 19. 8. 2014)

Commission Regulation (EU) 2015/282 of 20 February 2015 amending Annexes VIII, IX and X to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards the Extended One-Generation Reproductive Toxicity Study (OJ L 50 21. 2. 2015)

Commission Regulation (EU) 2015/326 of 2 March 2015 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards polycyclic aromatic hydrocarbons and phthalates (OJ L 58, 3. 3. 2015)

Commission Regulation (EU) 2015/628 of 22 April 2015 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH') as regards lead and its compounds (OJ L 104, 23. 4. 2015)

Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 132, 29. 5. 2015)

Commission Regulation (EU) 2015/1494 of 4 September 2015 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards benzene (OJ L 233, 5. 9. 2015)

Implementing legislation:

Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 107, 17.4.2008), amended by: Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013 (OJ L 79, 21.3.2013) and Commission Implementing Regulation (EU) 2015/864 of June 2015 (OJ L 139, 5.6.2015)

Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008), amended by: Commission Regulation (EC) 761/2009 of 23 July 2009 (OJ L 220, 24.8.2009), Commission Regulation (EU) 1152/2010 of 8 december 2020 (OJ L 324, 9.12.2010), Commission Regulation (EU) 640/2012 of 6 July 2012 (OJ L 193,

20.7.2012), Commission Regulation (EU) 260/2014 of 24 January 2014 (OJ L 81, 19.3.2014), Commission Regulation (EU) 900/2014 of 15 July 2014 (OJ L 247, 21.8.2014)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

The REACH (registration, evaluation, authorisation and restriction of chemicals) Regulation provides a comprehensive legislative framework for chemicals manufacture and use in Europe. It shifts from public authorities to the industry the responsibility for ensuring that chemicals produced, imported, sold and used in the EU are safe. Hence, the burden of proof is placed on companies. To comply with the Regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU. They have to demonstrate to ECHA how the substance can be safely used, and they must communicate the risk management measures to the users. If the risks cannot be managed, authorities can restrict the use of substances in different ways. In the long run, the most hazardous substances should be substituted with less dangerous ones.

REACH is designed to ensure a high level of protection of human health and the environment, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. This Regulation is a key element of the EU's commitment towards the implementation plan adopted at the 2002 World Summit on sustainable development which aims to ensure that, by 2020, chemicals are produced and used in ways that lead to minimisation of significant adverse effects on human health and the environment.

The REACH applies to all chemical substances: manufactured, imported, sold, used on their own, in mixtures or in products (not only substances used in industrial processes but also in our day-to-day life, for example in cleaning products and paints as well as in articles such as clothes, furniture and electrical appliances). However, it does not apply to certain groups of substances (e.g. those that are radioactive or under customs supervision) or to waste, as these are already extensively regulated under other legislation.

REACH establishes a systematic registration of substances. The registration should document safe use of substances, by including information on the hazards of the substance enabling registrants to classify and label them and identifying risk management measures, and communicate this information down the supply chain. The registration of substances under REACH basically does not distinguish between new and existing substances. Without registration, substances cannot be manufactured or imported into the EU. Two registration deadlines for substances placed on the market above 1000 tonnes and 100 tonnes per company per year have already passed in 2010 and 2013, respectively. The last REACH registration deadline of 31 May 2018 concerns substances that are manufactured in or imported into the EU above one tonne per company per year. For substances above 10 tonnes, registrants must perform a chemical safety assessment to identify if additional risk reduction measures are required.

ECHA and the Member States evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment. Evaluation under REACH focuses on three different areas: (a) examination of testing proposals submitted by registrants, (b) compliance check of the dossiers submitted by registrants and (c) substance evaluation.

Restrictions under REACH are designed to control risks not adequately controlled by industry. With respect to health and environment, the authorisation process aims to ensure that risks from Substances of Very High concern (SVHC) are controlled and that those substances are progressively replaced by suitable alternatives where these are economically and technically viable.

In addition, REACH sets out a number of detailed obligations aiming to reduce animal testing and provides incentives for the use and development of alternative methods for hazard assessment.

In 2008, two implementing legislative acts have been adopted:

- Commission Regulation (EC) No 440/2008 laying down test methods. The Commission reviews periodically these test methods with a view to replacing, reducing or refining testing on vertebrate animals (referring to the objectives and principles (3Rs) in Directive on the protection of animals used for scientific purposes (2010/63/EU). Subsequently, Regulation 440/2008 has been amended by Regulations (EC) 761/2009 (EU) 1152/2010, (EU) 640/2012, (EU) 260/2014 and (EU) 900/2014.
- Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency. The Regulation lays down the amounts, and rules for payment, of the fees and charges levied by the European Chemicals Agency. It provides for different fees for different types of submissions and actions, and provide for reductions for medium, small and micro enterprises (who can benefit from reductions of 30%, 60% and 90% respectively), as well as, in the case of REACH fees, for joint submissions of information. Moreover, no fees are due for registrations for substances in the 1-10 tonne range where all the information required by Annex VII to REACH is provided. The regulation has been amended by Commission Implementing Regulation (EU) No 254/2013 and Commission Implementing Regulation (EU) 2015/864.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Appoint a competent authority (authorities) responsible for performing the tasks allotted to it (them) under this Regulation, such as performing substance evaluation of registered substances, installing a system for inspection and for controlling compliance with the Regulation. These authorities shall be properly coordinated and have as one of their tasks to provide the general public information about risks connected with the use of substances (Arts 121-123)
- Establishing a system of effective, dissuasive and proportionate penalties for infringements of the provisions of the Regulation (Art. 126)
- Establishing a national helpdesk to provide advice to SMEs or other interested parties; and cooperating with the European Commission (EC), the European Chemicals Agency (ECHA) and competent authorities of other Member States in the implementation of the Regulation. (Art. 124)
- Oversee links with other legislation introducing restrictions on the use of substances, such as the RoHS Directive (2011/65/EU), Batteries Directive (2006/66/EC), POPs Regulation ((EC) 850/2004) and Waste Directive (2008/98/EC).

2.2. Regulation

- Ensure that manufactures and importers do not manufacture, import or place on the market substances individually, in mixtures or in products, unless:
 - they have been registered in accordance with the specified criteria and procedures (Title II: Arts. 5-24).
 - if additionally required, they have been granted an authorisation (Title VII: Arts. 56-66).
- Ensure that a substance on its own, in mixtures or in articles, for which Annex XVII contains a restriction, is not manufactured, placed on the market or used unless it complies with the conditions of that restriction (Title VIII: Art. 67).
- Ensure that manufactures, importers, downstream users and distributors comply with their obligations to communicate relevant information up and down the supply chain (Title IV: Arts. 31-36).
- Ensure compliance with the requirements on classification, packaging and labelling as introduced by the CLP Regulation, which also means several changes to the information in the Safety Data Sheets set out in Annex II.
- Ensure that the test methods laid down in Council Regulation (EC) No 440/2008, as amended are complied with. Also in general, comply with the principles of replacing, reducing or refining testing on

vertebrate animals (referring to the objectives and principles (3Rs) in Directive 2010/63/EU on the protection of animals used for scientific purposes.

2.3. Information and Reporting

- Competent authorities have to provide the general information about the risks involved with hazardous substances and engage in stakeholder consultations (Art. 123)
- Competent authorities shall submit electronically to the Chemicals Agency any available information that they hold on substances registered in accordance with Article 12(1) whose dossiers do not contain the full information referred to in Annex VII, in particular whether enforcement or monitoring activities have identified suspicions of risk. The competent authority shall update this information as appropriate. (Art. 124)
- Report to the Commission on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement (results of the official inspections, monitoring carried out, the penalties provided) (Arts. 117 and 127).
- Report to the ECHA on conclusions as to whether or how information obtained by substance evaluation should be used (Art. 48).
- Report to the general public on risks deriving from substances in order to protect human health and the environment (Art. 123).
- Besides the ongoing reports, Member States must notify the Commission of provisions on applicable penalties for the infringement of the provisions of the Regulation. The Commission must also be notified without delay of any subsequent amendments affecting these provisions (Art. 126).

2.4. Additional Legal Instruments

The following legislation should be taken into consideration when implementing and applying this Regulation:

- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures
- Directive 2010/63/EU on the protection of animals used for scientific purposes
- Council Directive 87/217/EEC on the prevention and reduction of environmental pollution by asbestos
- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products
- Regulation (EC) No 850/2004 on persistent organic pollutants
- Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals

- Regulation (EC) No 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury
- Industrial Emissions Directive (2010/75/EU)
- Seveso III Directive (2012/18/EU)
- Batteries Directive (2006/66/EC)
- RoHS Directive (2011/65/EU)
- Waste Directive (2008/98/EC)

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Regulation are summarised in the checklist below. They are arranged under subheadings and organised according to their priority in chronological order of implementation whenever possible.

Table 10. Checklist with Key Implementation Tasks

REACH REGULATION - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate a competent authority (Art. 121).
1.2	Establish an infrastructure to ensure access by the competent authority or authorities to the tools and databases of the ECHA.
1.3	Build up capacity for participating in the different committees (Art. 85), management board (Art. 79) and forum (Art. 86).
1.4	Take into account provisions of the CLP Regulation, in terms of using the GHS in classification, packaging and labelling of substances and mixtures which also concerns the compilation of safety data sheets. Make sure that all parties concerned are well informed.
1.5	Ensure that all relevant parties, particularly producers and importers are aware of the applicable fees and charges levied by the Chemical Agency set out in Regulation (EC) No 340/2008 Also a proportion of the fees and charges collected under this Regulation shall be transferred to the competent authorities of the Member States, where they are directly involved, such as finalising an evaluation procedure for a substance
1.6	Ensure integrated approach in complying with legislation also covering some of the substances listed as components or constituents in articles, e.g. mercury in batteries and the use of certain substances in electrical and electronic equipment. Hence, careful consideration is required to legislation such as Waste Directive 2008/98/EC, RoHS Directive 2011/65/EU and the POPs Regulation (EC) 850/2004.
1.7	Establish a national helpdesk providing information to manufacturers, importers and distributors to ensure that they understand the requirements of the Regulation (Art. 124).
1.8	Establish a mechanism to ensure that all substances manufactured or imported from outside the EU are registered (Art. 125).

1.9	Establish a system of applicable penalties applicable for infringement of the provisions of this Regulation (Art. 126).
2	Regulation and Monitoring
2.1	Establish an effective system for the inspection and enforcement of the implementation of this Regulation (Art. 125)
2.2	Establish a procedure for carrying out substance evaluation (Title VI: Arts. 44-49).
2.3	Ensure application of the provisions introduced by Regulation 1272/2008 on CLP for classification of substances
2.4	Ensure the the rules for safety data sheets of the GHS, introduced by the CLP Regulation, is applied which allow for the threefold mechanism of classification, labelling and safety data sheets to fulfil its role through interaction of its component parts:
2.5	Comply with the user restrictions, e.g. those set out in Annex XIV. Note that this Annex was amended by Regulations (EC) No 143/2011, (EU) 348/2013 and (EU) 895/2014.
2.6	Ensure application of the amended provisions of Annex XIII (established by Commission Regulation (EU) No 253/2011) on criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances. Registrations of substances and updates under REACH Regulation may be submitted in accordance with the Annex to this Regulation as from 19 March 2011 and shall comply with this Regulation from 19 March 2013.
2.7	Ensure compliance with the test methods set out in Council Regulation (EC) No 440/2008, as amended. Ensure compliance with Directive 2010/63/EU on the protection of animals used for scientific purposes. REACH Regulation also sets out the principle of replacing, reducing or refining testing on vertebrate animals (3Rs). Whenever possible testing on animals should be avoided and use should be made of available, existing test results or use other test methods not involving vertebrate animals.
2.8	Establish procedures and criteria for maintaining industrial and commercial secrecy.
3	Reporting
3.1	Report to the Commission on: <ul style="list-style-type: none"> • the operation of this Regulation in their respective territories, including sections on evaluation and enforcement; • provisions on applicable penalties for the infringement of the provisions of the Regulation. The Commission must also be notified without delay of any subsequent amendments affecting these provisions
3.2	Competent authorities shall submit electronically to the Chemicals Agency any available information that they hold on substances registered in accordance with Article 12(1) whose dossiers do not contain the full

	information referred to in Annex VII, in particular whether enforcement or monitoring activities have identified suspicions of risk. The competent authority shall update this information as appropriate.
3.3	Report to the ECHA on conclusions as to whether or how information obtained by substance evaluation should be used
3.4	Report to the general public on risks deriving from substances in order to protect human health and the environment

3.2. Phasing Consideration

The REACH Regulation is a key Regulation in the control of chemical hazards. It is likely to take a substantial amount of time to implement the Regulation because of its potential effect on a range of stakeholders. The main aims of this Regulation are to improve the protection of human health and the environment from the risks that can be posed by chemicals. This Regulation places greater responsibility on industry to manage the risks that chemicals may pose to human health and the environment. There will be a need to co-ordinate this legislation between the relevant ministry departments.

4. IMPLEMENTATION GUIDANCE

This Regulation plays a vital role in the protection of human health and the environment from chemical hazards. It should also enhance the competitiveness of the EU chemicals industry, a key sector in the economy of the EU, and should ensure the free circulation of substances on the EU internal market. It was adopted under Article 95 of the treaty establishing the European Union.

Some industrial sectors are partly exempted from the provisions of the Regulation because they are covered by provisions in other EU legislation, for example sectors manufacturing medicinal products or food.

Implementation of the Regulation requires a system that:

- ensures that all substances manufactured, imported and used are registered;
- establishes safety procedures to minimise the likelihood of a hazard becoming a risk; and
- ensures the communication of information regarding the safe handling of chemicals up and down the supply chain.

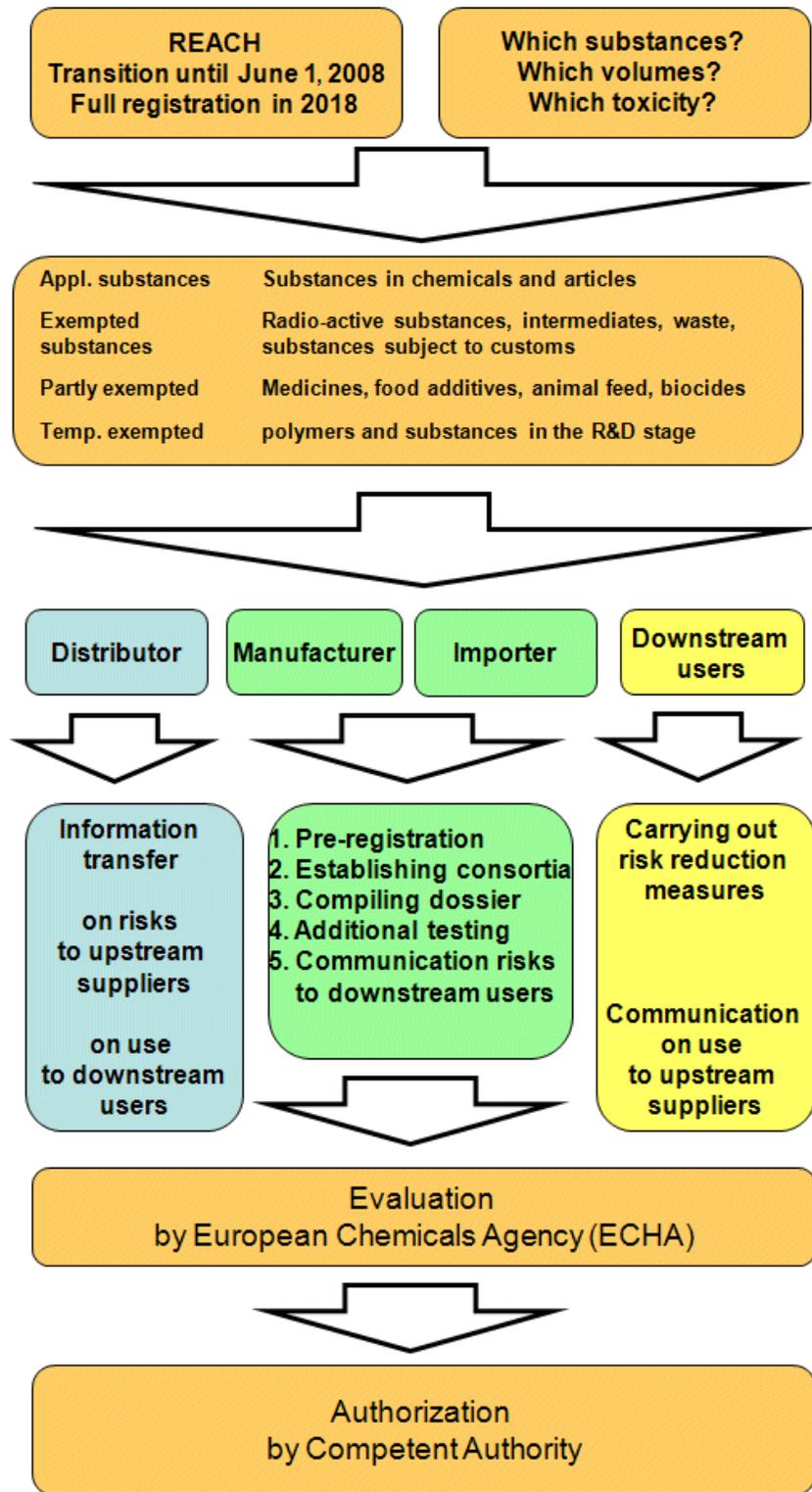
The Regulation is very complex and has potential effects on many different industrial branches.

As soon as a competent authority has been designated it is important for all involved staff (committee members, designated inspectors, helpdesk staff etc.) to acquire a good knowledge and understanding of the provisions of this Regulation. In order to establish a national helpdesk for industry and to ensure co-operation with other Member States and the ECHA there will be a high demand for experts on this Regulation and in related fields (e.g. toxicology, chemistry/substance identification).

A number of guidance documents and other informative materials have been produced at EU level. The great number of Guidance Documents are available on the website of the ECHA <http://echa.europa.eu/guidance-documents/guidance-on-reach>. The objective of these documents is to facilitate the implementation of REACH by describing good practice on how to fulfil the obligations.

Also CNRS and PRC, has with the support of the Commission created a portal on REACH Regulation, which contains elaborate descriptions of the obligations arising under REACH which are also referred to below under manufacturer, importer and user obligations. This guidance, which mainly addresses professional users of chemicals and people involved in prevention can be obtained at: <http://www.prc.cnrs-gif.fr/reach/en/home.html>

Source: CNRS and PRC REACH website: <http://www.prc.cnrs-gif.fr/reach/en/home.html>



Examples from a potential candidate country

Turkey: A consortium of InfoMil, RPS and Grontmij have in close cooperation with the Undersecretariat for Foreign Trade (UFT), the Istanbul Mineral and Metals Exporters Associations (İMMİB) and the Department of Chemicals Management of the Ministry of Environment and Forestry (MoEF), carried out awareness raising on REACH and CLP Regulations for Turkish chemical industry and building up of regional industrial helpdesks. The consortium UFT is the coordinator institution for the implementation of Customs Union and Association Council Decisions that focus on free movement of goods. İMMİB is an affiliated body of UFT. MoEF is the national competent authority for the harmonization of REACH and CLP Regulations.

The project is a government to government (G2G) project, financed by the Dutch Agency for International Business and Cooperation (EVD) for the Ministry of Infrastructure and Environment (IM).

The overall objective is to enhance capacity in public, semi-public and trade organizations to provide practical support to the chemical sector on the implementation of the REACH and CLP Regulations and raising awareness of the REACH and CLP Regulations.

As a general approach, the involvement of foreign experts in the training programme was the most intensive during the first activities in the project. Their involvement will decrease with time and the trained Turkish trainers will take over the role of the foreign experts "as much as possible and as soon as possible". At the end of the project, a core group of trainers will have been formed with competence in the key parts of the REACH and CLP Regulation.

The following project results are anticipated to be achieved:

- Establish a network of Industry helpdesks on the REACH and CLP regulations in regions where the chemical sector is clustered (Istanbul, Kocaeli, Izmir, Ankara, Bursa, Konya, Mersin).
- Raising informative capabilities of regional helpdesks' representatives to provide practical support to the chemical sector on the implementation of companies' obligations under the REACH and CLP Regulations.
- Development of an awareness raising and information programme to ensure that Turkish Chemical Sector is informed on the REACH and CLP Regulation.

Beneficiary institutions

- Directorate General for Export Undersecretariat of the Prime Ministry for Foreign Trade (UFT)
- Chemicals Management Department, General Directorate for Environmental Management, Ministry of Environment and Forestry (MoEF).

Stakeholders

- Export Promotion Centre of Turkey (IGEME)
- Istanbul Mineral and Metals Exporters' Associations (IMMIB) (Turkish Industry Helpdesk)
- Turkish Chemical Manufacturers Association (TKSD)
- The Union of Chambers and Commodity Exchanges of Turkey (TOBB)
- Center for Small and Medium Sized Enterprises Development Organization (KOSGEB)

Duration of the project: 18 months, 2010-2011.

For further information please contact InfoMil:

<http://rwsenvironment.eu/countries/turkey/awareness-raising/>

4.1. Planning

- The competent authority has to ensure harmonious application of the REACH in conjunction with the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (EU) No 1272/2008/EC which entered into force on 20 January 2009. The CLP Regulation will replace the Dangerous Substances Directive (67/548/EEC) as of 30 November 2010 and the Dangerous Preparations Directive (1999/45/EC) as of 31 May 2015 and amended REACH Regulation. The CLP Regulation includes the necessary amendments made to REACH and certain REACH provisions are transferred to it:
 - obligation for companies to classify their substances and mixtures themselves and to notify the classifications;
 - a harmonised list of substances classified at EU level will be drawn up;
 - a classification and labelling inventory, made up of all notifications and harmonised classifications referred to above, will be established.

The Regulation follows the GHS terminology: the term “substance” is kept but “preparation” is replaced by “mixture”; the term “category of danger” is replaced by “hazard class”. Hazard class means the nature of the physical, health or environmental hazard. Certain hazard classes may comprise differentiations; other classes may include hazard categories. The CLP Regulation defines 28 hazard classes: 16 physical hazard classes, 10 health hazard classes, one environmental hazard class and an additional class for substances hazardous for the ozone layer. Classes based on physico-chemical properties are different from the current categories of danger. They are built on classes defined in the international legislation concerning the transport of dangerous goods. Certain classes are therefore not known by the European users. On the other hand, the health hazards are similar to the hazards defined by the current system even if they are organized and allocated differently inside the hazard classes. The Regulation is based on the Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter referred to as "the GHS") that has been developed in the UN context. The CLP Regulation should ensure through accompanying substances with safety information a high level of protection of human health and the environment as well as the free movement of chemical substances, mixtures and certain specific articles, while enhancing competitiveness and innovation. The CLP Regulation requires companies to classify, label and package appropriately their hazardous chemicals before placing them on the market.

- The REACH Regulation gives greater responsibility to the industry to manage the risks from chemicals and to provide safety information on the substances. Manufacturers and importers will be required to gather and assess information on the properties of their chemical substances and on the exposure from their use, which will allow their safe handling, and to register their chemical substances by submitting registration dossiers to the European Chemicals Agency (ECHA) in Helsinki. The Regulation also calls for the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified. Non-phase-in (new) substances will have to be registered prior to manufacture or import into the EU. For phase-in (existing) substances a staggered registration procedure with three deadlines (1 December 2010, 1 June 2013 and 1 June 2018) has been established.

- The choice of a competent authority will require care, since the many government bodies will have a legitimate interest in the Regulation. For example, a body concerned with health and worker safety may be considered to be the most appropriate, but it is essential that mechanisms for involving other departments and receiving input from them, particularly those with a remit for environmental protection, are established. Where more than one competent authority is appointed tasks must be clearly allocated — for example, carrying out substance evaluation, maintaining the national helpdesk and communicating with the Commission and the ECHA. Training or recruitment may be required to ensure that the competent authority/ies is adequately equipped to complete the substance evaluation required or to provide support for SMEs.
- The Regulation has a potential impact on many stakeholders, and, as a result, great care must be taken to consult widely. For example, the stakeholders involved include not only companies and their workers and their representatives, but also environmental bodies, accident control authorities, emergency services, and a wide range of NGOs and government departments. This large number of interested parties reflects the importance of chemical substances in everyday life.
- Governments may benefit from consultation with the Commission, the ECHA, international organisations concerned with chemicals such as the OECD, and other national governments through, for example, the exchange of information, the discussion of best practices, or the pooling of common resources.

Examples of Competent Authorities in Member States

Germany: In Germany, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety has the legal competence for this Regulation. The Federal Institute for Occupational Safety and Health (BAUA) has been appointed as the competent authority responsible for implementation and enforcement of the Regulation. Subsequent examination/evaluation of data is performed jointly with the Federal Environmental Agency (UBA), the Federal Institute for Risk

Assessment (BfR), the Federal Institute for Materials Research and Testing (BAM) and the Safety and Health of Chemical and Biological Working Substances Department of the Federal Institute for Occupational Safety and Health. The authorities of the federal states are responsible for inspections.

Poland: the Ministry of Health has the legal competence in relation to this Regulation. The Bureau for Chemical Substances and Preparations (affiliated to the Ministry of Health) has been appointed as competent authority. This is an institution of Polish governmental administration, founded in the first half of 2001. The bureau was established after the adaptation of Polish legislation on chemicals control to the relevant Community regulations. The bureau is also responsible for the organisation of a system for inspections. Inspections are performed by different regional inspectorates (mainly sanitary inspectorates).

Austria: the competent authority responsible for the implementation and enforcement of the Regulation is the Ministry for Agriculture, Forestry, Environment and Water Management. The ministry is responsible for establishing the legal basis for the enforcement and control of the implementation of this Regulation and lays down the provisions on penalties applicable for infringements of the provisions of the Regulation in co-ordination with other ministries and involved stakeholders. For special tasks, such as substance evaluation, running the national helpdesk or sending experts to meetings, the competent authority mandates the Umweltbundesamt (Environmental Agency), which acts in some fields of chemical legislation on behalf of the competent authority. The authorities of the nine Austrian federal states are responsible for inspections.

Slovenia: the National Chemicals Bureau under the Ministry of Health has been appointed as the competent authority. The National Chemicals Bureau is competent for the preparation, implementation and supervision of implementation of legislation relating to chemicals. The Chemicals Bureau also co-ordinates the monitoring of the sale and use of chemicals and performs inspections.

4.2. Regulation and Monitoring

- In general, the REACH Regulation does not affect companies outside the EU, but their exports to the EU may be concerned by REACH. The importers established in the EU are primarily responsible for registering imported substances. In this respect the EU importers are relying on their non-EU exporter's information about the imported chemicals. Detailed information about chemical composition of preparations or about chemical identity(ies) of substances may for many non-EU exporters be considered as confidential business information which they do not want to disclose to EU importers. The exporting company outside the EU may appoint an only representative (OR) being a legal entity in the EU to fulfil the REACH tasks of an importer in the EU and being responsible for the registration obligations on behalf of the EU importers. In consequence, the identified EU importers are regarded as downstream users of the OR and do not have to register the same substance. For that reason, the OR needs to keep record of the listed importers including the imported volumes per importer and will be responsible for the information flow downstream by way of classifying and labelling the substance or mixture and providing safety data sheets for the professional users downstream. The foreign company cannot be part of the Substance Information Exchange Forum (SIEF), but most companies are setting up consortia as an effective manner of organising co-operation between participants of a SIEF, in which a non-EU company may participate.
- The Regulation requires the registration of each substance manufactured or imported in the EU. In order to register a substance, the manufacturer or importer sends a dossier electronically to the ECHA, which carries out a dossier evaluation including a compliance check of all submitted dossiers. A considerable number of the submitted dossiers have to be evaluated with respect to possible dangerous properties of high concern of substances. The so-called substance evaluation has to be done by the Member States. Information obtained from this evaluation process should be considered for identifying substances of very high concern, restriction and harmonised classification and labelling procedures and other similar procedures. A mechanism for carrying out this evaluation process and the possible following processes including co-operation with the ECHA must be established. Trained and experienced staff will be needed to handle these tasks.
- Guidance has been developed over the past few years for industry and for the authorities in order to ensure the smooth implementation of this Regulation. A number of guidance documents were drafted and discussed within projects led by the European Commission services, involving stakeholders from industry, Member States and non-governmental organisations. These guidance documents are available at the: <http://echa.europa.eu/support/guidance>.
- In addition, ECHA has prepared several other practical guides providing practical information on REACH and CLP requirements and best practice on how to fulfil them, which are available at: <http://echa.europa.eu/practical-guides>
- A national helpdesk must be established in each Member State to provide further practical advice to industry (especially for SMEs) on how to fulfil their obligations under this Regulation.
- An effective system for inspection and for the enforcement of the implementation of this Regulation has to be established. It has to be ensured that all substances manufactured, imported and used within the EU are registered and have an authorisation if required and that there is no infringement of the provisions on restrictions on the marketing and use of certain dangerous substances.

- There are also requirements relating to the provision of safety data sheets. These contain information for the user on the safe handling of the substance during storage, transport and disposal, as well as information on hazards, fire-fighting, first aid, accidental release measures and toxicological and ecotoxicological properties. Once again, a system of compliance monitoring will be required in order to ensure that data sheets are both provided and accurate.
- In addition, an adequate system of penalties for non-compliance will be required to provide an incentive for manufacturers and importers to meet the requirements of the Regulation.

4.3. Obligations for manufacturer, importer, or downstream user of chemicals or distributor

REACH focuses on all manufacturers and downstream users of chemicals as well as importers and distributors who have any dealings with chemical products. Under REACH, a company may play various roles depending on the types of substances it uses, and its participation in the life cycle of the substances. It may be a manufacturer or importer of one chemical, while for another chemical it may also be a downstream user. In short, REACH comprises the following steps:

- Pre-registration and exchange of information
- Registration of substances
- Evaluation by the relevant authorities.
- Authorization by the relevant authorities

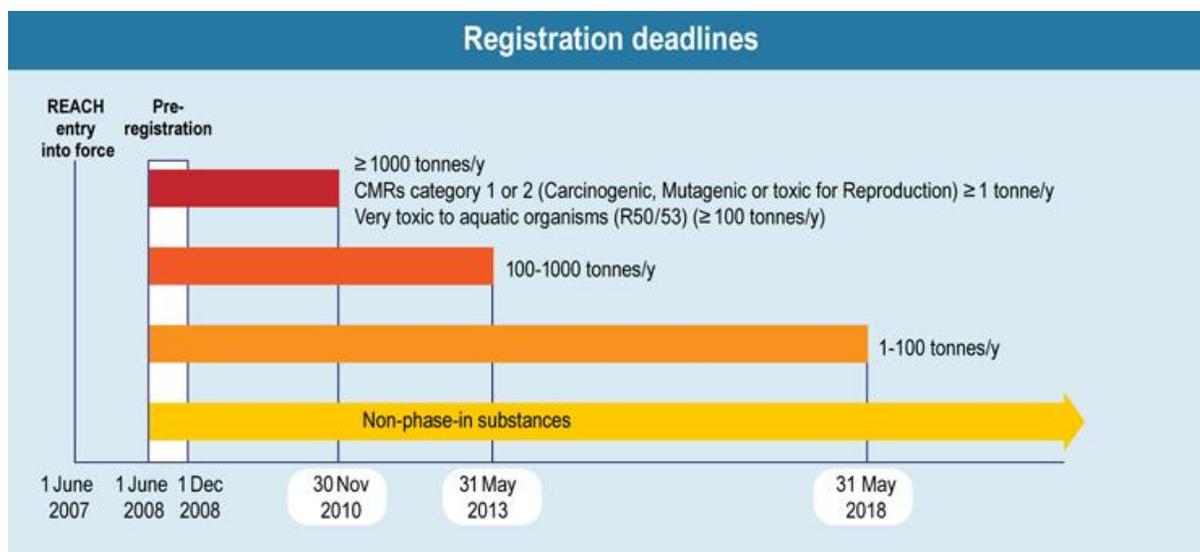
REACH requirements are stricter on manufacturers and importers than on downstream users and distributors:

- Manufacturers and importers intending to place substances (or substances in a mixture) on the EU-market are required to collect data on physical-chemical, toxicological and ecotoxicological properties in order to participate in the required registration process. The amount of data will depend on the anticipated or actual annual production or import volume, the characteristics of the substance involved, and the substances' intended use, as well as the extent to which, and in what way, people or the environment may be exposed to those substances.
- Downstream users and distributors are obliged to communicate information on use and exposure risks to producers/importers and must pass information on risks to health and environment in the supply chain, and to take actions in implementing risk reduction measures.
- All industry actors must respect restrictions and authorisation rules and they can apply for if they wish to use substances of very high concern. Companies dealing with chemicals may have more than one role under REACH, even for a single given substance.

4.3.1. Obligations of Manufacturers and Importers

Substances registration

- REACH requires manufacturers and importers to submit to the European Chemicals Agency (ECHA) a registration dossier containing: a technical dossier including data on the substance and, for substances in quantities of 10 tonnes or more per year per registrant, a chemical safety report assessing how risks to human health and the environment can be controlled. The registration obligations apply to substances manufactured or imported in quantities of 1 tonne or more per year and manufacturer/importer. Generally, they apply to all individual chemical substances on their own or in preparations. They apply to substances in articles, if the substance is intended to be released during normal use. Some substances are completely excluded from REACH and therefore from registration, e.g. radioactive substances and waste. Other substances are specifically exempted from registration where other equivalent legislation applies (substances used in medicinal products, in food or feeding stuff). Certain substances or uses of substances are regarded as being registered, and therefore no registration is required for these substances for these uses (e.g. active substances in biocidal products, active substances in plant protection products, substances notified as new substances in the previous system (Directive 67/548/EEC), under specific tonnage conditions). Isolated intermediates and substances manufactured or imported for the purposes of research and development have tailored provisions within the REACH legislation, including registration, as long as they are used in specified conditions.
- Registration deadlines: substances falling under the scope of the REACH Regulation and not exempted from the registration obligation must be registered before they can be manufactured or imported into the European Union. However, there is a special transition regime for substances which were already being manufactured or imported, under certain conditions, before the entry into force of REACH on 1 June 2007. Such substances are called “phase-in substances”, because they are being subjected to the registration system in different phases over time, rather than immediately in one go. A precondition to benefit from the registration postponement is that the “phase-in substance” is being pre-registered between 1 June 2008 and 1 December 2008. “Non-phase-in substances” or “phase-in substances” which have not been pre-registered, must be registered before manufacture or import starting from 1 June 2008.
- The Agency will perform a simple electronic completeness check at the dossier submission stage. The quality of the information submitted may be checked afterwards in the evaluation process.



Source: http://www.prc.cnrs-gif.fr/reach/en/registration_obligation.html

Substance identification

- For identification and naming in REACH, substances are divided into two main groups:
 - “Well defined substances”: substances with a defined qualitative and quantitative composition.
 - “UVCB substances”: substances of Unknown or Variable composition, Complex reaction products or Biological materials. When a registration is required for a “well defined substance”, it shall include the substance chemical composition, the chemical identity and the content of each constituent in the substance. For some types of substances, the chemical composition alone is not enough for characterisation and some additional physical parameters about the chemical structure have to be added to the substance identification. “UVCB substances” require other types of information for their identification in addition to what is known about their chemical composition.

When registration is required for an UVCB substance, manufacturers/importers shall include the name, the origin or source of the substance and the most relevant steps taken during processing.

- Manufacturers and importers have to determine if their respective substances may be regarded as „equal substances”. The identification of equal substances is important in data sharing which allows for limited substance testing and is based on proper substance identification.
- Manufacturers and importers may also apply the possibility under Annex XI, which allows for evaluating chemicals not on a one-by-one basis but by grouping chemicals in categories. The use of a category approach will mean that it is possible to identify properties which are common to at least some members of the category. The approach also provides a basis to identify possible trends in properties across the category. As a result, it is possible to extend the use of measured data to similar

untested chemicals. Reliable estimates that are adequate for classification and labelling and/or risk assessment can therefore be made without further testing

Information requirements relating to registration

- Under REACH, registrants are obliged to collect all available relevant information on the intrinsic properties of a substance to be registered, regardless of the quantity manufactured or imported. However, the type and quantity of information that is required as a minimum to meet the obligations of the REACH Regulation depends on the quantity that is manufactured or imported into the European Union. Annexes VII to X of REACH specify the minimum data requirements for a given substance according to its tonnage
- Information on the manufacture (if within the European Union), use, handling and disposal of the substance (i.e. covering its whole life cycle) or of articles containing the substance, should be gathered to obtain insight into populations and compartments exposed, as well as the nature of the exposures, i.e. route, frequency and duration (Annex VI of REACH, sections 3 and 5 and, for substances in quantities between 1 and 10 tonnes per year per registrant, Annex VI, section 6).
- All existing data on the intrinsic properties of the substance to be registered should be gathered, irrespective of tonnage: human data, testing data (physico-chemical data, in vitro and in vivo data) and non-testing data (data obtained with predictive tools). Exposure data should also be collected to obtain insight into populations and compartments exposed, as well as the nature of the exposures, i.e. route, frequency and duration.
- An assessment must be made of the adequacy of the available information for arriving at conclusions on hazard assessment, i.e.: determine if the substance has to be classified, if yes define the classification and labeling and where substances are in greater amounts than 10 tonnes per year, it has to be determined if the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) as well as identifying dose descriptor(s).
- Testing on vertebrate animals should always be the last resort.

Data sharing and joint submission of information

- Registration requires the submission of relevant and available data on intrinsic properties of substances and exposure scenarios and, when not available, the generation of data including testing. Specific mechanisms and procedures have been introduced in REACH to enable companies to share existing data before submitting a registration: the data sharing and the joint submission.
- A system is established to help potential registrants find others with whom they can share data and costs: the pre-registration and the Substance Information Exchange Fora (SIEFs). The process in place to initiate the data sharing or these substances is generally referred to as the “inquiry process”. It is essentially a three-step process whereby: 1) the potential registrant must ask ECHA prior to registration if the same substance has already been registered; 2) ECHA facilitates contact between the previous

registrant(s) and the potential registrant(s) and/or other potential registrants, if any; 3) data sharing is organized between previous registrant(s) and/or potential registrants including for new tests to be potentially conducted.

- REACH registrants are required to jointly submit information on the hazardous properties of the substance (studies and proposals for testing) and its classification and labelling and can, if they agree, also jointly submit the Chemical Safety Report (for substances ≥ 10 tonnes per year per registrant) and/or the guidance on safe use.

Chemical safety assessment

- Chemical safety assessment comprises of hazard assessment, exposure assessment and risk characterization.
 - Hazard assessment is the first step of the chemical safety assessment (CSA) comprising 1) Information gathering and evaluation; 2) hazard identification; classification and labelling; derivation of threshold levels; and PBT and vPvB assessment;
 - The exposure assessment consists of estimating the dose (or concentration) of the [substance](#) to which humans and the environment may be exposed. It concerns all the life-cycle of the substance, from the [manufacture](#) to the different identified [uses](#). It entails two clear steps: 1) Generation of exposure scenario(s) (ES) or of relevant use and exposure categories and 2) Exposure estimation. For substances [placed on the market](#), the relevant exposure scenario(s) and a summary of the exposure estimation shall be included in an annex to the [safety data sheet](#) (SDS). There is a [standard format](#) for the exposure scenario(s) annexed to the SDS.
 - The exposure assessment consists of estimating the dose (or concentration) of the substance to which humans and the environment may be exposed. It concerns all the life-cycle of the substance, from the manufacture to the different identified uses. It entails two clear steps:
 - Generation of exposure scenario(s) (ES) or of relevant use and exposure categories.
 - Exposure estimation.
 - For substances placed on the market, the relevant exposure scenario(s) and a summary of the exposure estimation shall be included in an annex to the safety data sheet (SDS). There is a standard format for the exposure scenario(s) annexed to the SDS.

Notification obligations for articles:

If an article contains a substance of very high concern ($\geq 0.1\%$ w/w) which has been placed on the candidate list for authorisation there is an obligation to notify the Agency. This requirement applies if the substance is present in the article produced or placed on the EU market in quantities of 1 tonne or more a year and exposure to humans or the environment cannot be excluded. The obligation will apply from 1 June 2011 at the earliest (or six months from the date the substance has been placed on the candidate list, in case the substance has not been on the list before 1 December 2010).

Information in the supply chain:

When a chemical safety assessment is performed (substances placed on the market in quantities ≥ 10 tonnes per year by a manufacturer or importer), [exposure scenarios](#) must be developed for dangerous substances and PBT/vPvB_substances. These exposure scenarios shall be placed in an annex to the Safety Data Sheet. The exposure scenarios contain a description of the risk management measures which the manufacturer or importer has implemented and recommends downstream user to implement. For this purpose, manufacturers or importers must assess all uses that are identified to them by their downstream users. If they decide not to support a particular use, they must justify this and notify the Agency and their downstream user.

Producers or importers of articles containing a substance of very high concern ($\geq 0.1\%$ w/w) which has been placed on the candidate list (<http://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles>) for authorisation must supply sufficient information to allow safe use of those articles to industrial and professional users. To consumers this information must be provided on request. In addition, the same information obligations as for manufacturers and importers of substances apply in analogy for substances in articles intended to be released.

Substances subject to authorisation:

An authorisation is required for uses and placing on the market of substances included in Annex XIV of the REACH Regulation. An authorisation can be requested by manufacturers, importers or downstream users on their own or in collaboration with other actors in the supply chain. Importers of articles are not required to apply for authorisation even if the article contains a substance included in Annex XIV.

Applicants for authorisation have to demonstrate that the risks from their uses are adequately controlled or that the socio-economic benefits outweigh the risks, in cases where there are no suitable alternative substances or processes.

Substances subject to restriction:

Manufacturers and importers and their customers must comply with the restrictions listed in Annex XVII of the REACH Regulation.

4.3.2. Downstream user obligations

Obligations relating to use of substances

1. Registration

Downstream users must not use and place on the market any substances which are not registered if registration is required. This means that the products used and put on the market may contain only substances which:

- are manufactured/imported by the manufacturer or the importer in amounts below 1 tonne per year, or
- are exempted from REACH or specifically from registration, or which
- have been (or are going to be) pre-registered and have a later registration deadline, or
- registered

This applies to substances on their own, those in mixtures and those which are intended to be released from articles under normal or reasonably foreseeable conditions of use. In practise, the downstream user should make sure that his supplier is aware of REACH. If the supplier is a distributor or another downstream user, he has to pass this request to the next actor up the supply chain.

Downstream users of substances generally do not have registration obligations, although individuals or companies that also manufacture, import or produce substances in articles may in exceptional circumstances be subject to the usual registration obligations. However, to get the relevant information, downstream users have the right to make their uses known to their suppliers, so that the suppliers can include these uses in their chemical safety assessments as “identified” uses or pass the request up the supply chain. In doing so, they provide sufficient information to allow their supplier to prepare an exposure scenario. Downstream users can give brief general descriptions of uses that can be used as a minimum to identify such uses to the supplier. They can also provide an exposure scenario (see: <http://echa.europa.eu/regulations/reach/downstream-users/exposure-scenarios> or <http://echa.europa.eu/support/practical-examples-of-exposure-scenarios>) describing their use to the supplier. The manufacturer is not obliged to supply a substance for a use that he considers he cannot support.

Downstream users must prepare their own chemical safety reports (including the development of exposure scenarios) for uses outside the conditions described in an exposure scenario included in the Safety Data Sheets supplied to them as soon as they use at least 1 tonne per year. This provision enables downstream users to keep their use(s) confidential from their supplier if they should wish to do so.

2. Notification

Substances used for the purposes of product and process orientated research and development (PPORD) may receive exemption from registration if they are notified to the European Chemicals Agency. This exemption applies for 5 years and may be extended for up to a further 5 years (10 years in the case of medicinal products or substances not put on the market) upon request. Such exemptions must be justified by the programme of research and development. The exemption applies only to the quantity of substance being used for the purposes of PPORD by the manufacturer or importer himself or in cooperation with a limited number of listed customers. A downstream user of a substance, who is listed as one of the selected customers with whom the manufacturer or importer cooperates in a PPORD notification has to use the substance for the purpose of PPORD and within any conditions set by the Agency and communicated to him by his supplier.

Another type of notification concerns some substances of very high concern present in articles. If a substance is identified for eventual inclusion in Annex XIV of REACH (list of substances subject to authorisation) and

is present in quantities totalling over one tonne per year in all articles manufactured by the producer, in a concentration of above 0.1% weight by weight – if not already registered for that use – the substance must be notified. To avoid any break in the supply chain due to the lack of notification (or registration), the downstream user should make sure that the producer of articles up his supply chain complies with REACH.

3. Authorisation

The use of some substances may be subject to an authorisation requirement. This will be indicated by the supplier, either in the section 15 of the safety data sheet or as part of information given when a safety data sheet is not required. Downstream users may also check the following lists published by the Agency: the list of candidate substances for eventual inclusion in annexe XIV of REACH (substances subject to authorisation), the recommendations for substances to be included in annexe XIV (first recommendations by 1 June 2009) and Annex XIV itself when available.

A downstream user may use a substance subject to an authorisation, provided that his use is in accordance with the conditions of a granted authorisation to an actor up his supply chain. He must report to the Agency at the latest 3 months after first receiving an authorised substance as such or in mixture. If his use is not covered by such an authorisation, and he wants to continue it, the downstream user will have to apply himself for an authorisation for his own use and if relevant, for his customers' use.

If no application for authorisation is made, the downstream user must stop using – including its incorporation into an article – the substance by the sunset date specified in Annex XIV and the substance as such or in a mixture must not be supplied to his customers after this date.

A substance listed in Annex XIV may be used for uses which are exempted from authorisation. A downstream user has thus to check whether his use is exempted or not. If it is exempted, he can continue his use without an authorisation. Nevertheless, he has to implement the conditions of use and risk management measures communicated by his supplier.

4. Substances subject to restrictions

Under REACH, restrictions may limit the use of a substance. If restrictions apply to a substance, either on its own or in a mixture or article, the downstream user may only continue to use or place it on the market if he complies with these restrictions. The supplier must include information on whether a substance he supplies is subject to restrictions in section 15 of the safety data sheet. If a safety data sheet is not required, the supplier is required to provide information on any substances subject to restrictions.

In some cases, the restriction may take the form of an outright ban on the use of the substance, in which case the downstream user will no longer be able to use it (the date of prohibition is specified in annexe XVII of REACH). In other cases, specific uses may be prohibited or other conditions applied, to control the risks of the substance. As for authorisations, the downstream user has to check whether his use is exempted from a restriction or not.

Obligations relating to Safety Data Sheets

- REACH and CLP Regulations have created a new regulatory framework in Europe and there is greater international consistency with adoption of the Global Harmonisation System (GHS) for classification and labelling throughout most of the World. Note that GHS refers to the ‘Safety Data Sheet’ or SDS and the word ‘Material’ is not required – therefore, in theory, even US ‘Material Safety Data Sheets’ will be SDS without the ‘M’ in future. Annex II of REACH describes the requirements for SDS preparation and dictates when an SDS is needed, the language, formatting etc. CLP Regulation (EC) 1272/2008 covers the details on how to classify a substance or mixture and also covers labelling requirements.
- User obligations regarding SDS: under REACH, downstream users must respect use conditions and risk management measures recommended by the manufacturers and the importers. As soon as a safety data sheet (SDS) is received, the user of a hazardous substance or mixture must check 1) the compliance with the described use and respect of the exposure scenario(s), 2) the respect of the risk management measures, and 3) the compliance with a granted authorisation or restriction. If the uses are covered, the user has 12 months to implement the measures communicated in the extended SDS starting from its receipt. If the uses are not covered, the user has 12 months to carry out his own chemical safety assessment (CSA) and to implement the related exposure scenarios. Steps involved:
 - Checking that the intended use of the substance corresponds to use described in the section 1.2 of the SDS. If it is an extended SDS with one or more exposure scenarios, the compliance of the use with one of the described exposure scenario must also be checked.
 - Control that the actual conditions of use match the conditions of safe use described in the exposure scenarios. If the intended use is not covered in the SDS and in the exposure scenarios or if the actual conditions of use do not comply with the risk management measures, the user must take action. He may either: ask the supplier to amend the chemical safety report (CSR) and to develop a new exposure scenario to make the use an identified use (see Duty to communicate); adapt his activity: he can change his use into an identified one, improve the use conditions to respect the risk management measures or try to substitute the substance with a less hazardous one; look for another supplier providing a scenario covering his use or ready to develop a new scenario; make his own chemical safety report in accordance with Annex XII of REACH. The user generates then an exposure scenario covering his use. He must attach this scenario to his own SDS and notify ECHA for his use.
 - The third check involves the substances subject to authorisation or concerned by use restrictions. The section 15 of the SDS enables the user to know if he is involved by such measures. If it is the case, he must check that his use complies with a granted authorisation or respects the restrictions fixed for the substance.
 - Development of the Extended Safety Data Sheet (e-SDS) - REACH Annex II revision: A Safety Data Sheet (SDS) needs to be supplied with hazardous substances and mixtures and made available for the supply of mixtures containing hazardous substances above thresholds of concern. Between now and 2018, as REACH phase-in substances are registered, there will be a transition to the extended SDS (eSDS) that incorporates descriptions of uses and the risk management measures (RMM) considered necessary as a result of the Chemical Safety

Assessment / Report (CSA / CSR). These descriptions of use and RMM are known as the Exposure Scenario (ES).

- All substances and other mixtures should be classified and labelled according to the CLP Regulation from 1 June 2015 and corresponding SDSs complying either with the Annex to Regulation (EU) 2015/830 or, if the transitional provision applies (if an SDS had been provided to a recipient before 1 June 2015), with Annex I or II to Regulation (EU) No 453/2010 must be provided when they are supplied until 1 June 2017.
- After 1 June 2017 only SDSs in accordance with the Annex to Regulation (EU) 2015/830 will be allowed for both substances and mixtures.

Obligations relating to Communication Duties

- A downstream user of a substance or a mixture is required to communicate to his immediate supplier new information on hazardous properties, regardless of the uses concerned. ‘New’ information means information that is not communicated to the downstream user by his supplier and that is not available in public data bases or literature. It may relate either to substances or to preparations. However there is no precise definition in REACH of what constitutes new information. Examples of new information may be observations on acute human health effects at workplaces or results of tests carried out by the downstream user.
- There are no specific deadlines for communicating information on hazards upstream. The downstream user should do so as soon as he becomes aware that, compared to the information received from his supplier, he has new information.
- The downstream user is required to report to the European Chemicals Agency if his classification of a substance is different to that of his supplier. The reason for differences in classification may be the use of new data or a different interpretation of existing data.
- A downstream user must communicate to his supplier information that might call into question the appropriateness of the risk management measures recommended in a safety data sheet supplied to him (recommendations for identified uses only). The downstream user needs to provide sufficient information to justify why he considers that the recommendations are not appropriate. If he regards the measures as ineffective or overprotective, he needs to indicate why this is the case, perhaps with reference to his own operational conditions and the results of his risk assessments.
- Any professional customer has the right to make a use known in writing to his immediate supplier of a substance or mixture, with the aim of making this an identified use. This is particularly important for substances or preparations which are supplied with exposure scenario(s). In these cases, if the immediate supplier is a downstream user, he may decide to identify the use and to prepare a downstream user chemical safety report for it or he may pass the request to the next actor up the supply chain.
- Any downstream user must provide his customers with information on hazards, safe conditions of use and appropriate risk management advice for substances on their own, in preparations or in articles. In some cases, when the downstream user formulates a mixture and put it on the market, this may require

him to consolidate or develop exposure scenario(s). For customers who are end-users, the formulator may choose to merge and consolidate the exposure scenarios received from his supplier(s) – and covering all or some of substances in the mixture – into new exposure scenario(s) for the mixture rather than just forwarding them. When merging the exposure scenarios received from his supplier(s), the formulator has to select the ones of relevance for the uses of his mixture.

4.4. **Reporting**

- The Regulation requires Member States to report to the Commission and the ECHA on aspects of implementation.
- Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories. This report shall include, in relation to enforcement, the results of official inspections, and information concerning the monitoring carried out, the penalties provided, and other measures taken concerning the control of compliance (Arts. 117 and 127).
- Competent authorities must inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment. This activity has to be carried out in co-ordination with other Member States and the ECHA according to a guidance provided by the ECHA.

5. COSTS

The main costs to governments of implementing this Regulation comprise costs of establishing the implementation systems, the day-to-day costs of maintaining them, the employment of trained staff, and the payments to specialist advisors/consultants for carrying out substance evaluation, for running the national helpdesk and attending committee meetings and for special events.

Minor costs should also be taken into account for establishing and maintaining the IT infrastructure in order to have a secure connection to the ECHA IT system, which is necessary for the exchange of data between Member States and the ECHA, and for establishing measures to ensure the confidentiality of this data.

The implementation costs to be borne by industry are very much higher than those borne by governments. As this Regulation shifts the responsibility for risk assessment for manufactured, imported and used substances to industry, the workload for companies required to register substances will be very high. Besides the costs of the staff involved, companies will need to pay for studies and tests as well as the registration fee(s). Depending on the manufactured or imported amount, and on the number of companies that have to register the same substance, the costs will differ considerably for different substances. The Regulation foresees the establishment of so-called substance information exchange forums (SIEFs) in order to share information on existing data, to avoid additional testing on animals, and to save costs. It is possible for companies registering the same substance to make a joint submission (Art. 11). Registrants using this possibility can also benefit from a reduced registration fee.

For other actors in the supply chain of substances there will be a greater need for handling information on the substances, which will result in some additional costs for companies not involved in the registration procedure.

Table 11. Checklist of the Types of Cost Incurred to Implement the Regulation

Checklist of the Types of Cost Incurred to Implement the Regulation
<p>Initial set-up costs:</p> <ul style="list-style-type: none">• establishment of competent authority(ies);• building capacity for national helpdesks and substance evaluation (including further actions);• building capacity and expertise for co-operation with the ECHA and other Member States;• establishment of a system of penalties;• training of staff and inspectors;• initial guidance documents for key actors, i.e. producers, importers and users of substances and mixtures.
<p>Ongoing costs:</p> <ul style="list-style-type: none">• attendance at meetings with Chemicals Agency and between competent authorities;

- carrying out substance evaluations and further actions;
- coordinate tasks and responsibilities with other relevant authorities.

REGULATION ON CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES

Official Title: Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures

Amended by:

Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 235, 5.9.2009)

Commission Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 83, 30.3.2011)

Commission Regulation (EU) No 618/2012 of 10 July 2012 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 179, 11.7.2012)

Commission Regulation (EU) No 487/2013 of 8 May 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 149, 1.6.2013)

Commission Regulation (EU) No 758/2013 of 7 August 2013 correcting Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 216, 10.8.2013)

Commission Regulation (EU) No 944/2013 of 2 October 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures Text with EEA relevance (OJ L 261, 3.10.2013)

Commission Regulation (EU) No 605/2014 of 5 June 2014 amending, for the purposes of introducing hazard and precautionary statements in the Croatian language and its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 167, 6.6.2014)

Commission Regulation (EU) No 1297/2014 of 5 December 2014 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 350, 6.12.2014)

Commission Regulation (EU) No 2015/1221 of 24 July 2015 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 197, 25.7.2015)

Implementing legislation

Commission Regulation (EU) No 440/2010 of 21 May 2010 on the fees payable to the European Chemicals Agency pursuant to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 126, 22.5.2010)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

Regulation (EC) No 1272/2008 (hereinafter referred to as the CLP Regulation) adapts the existing system for the classification of chemical substances and mixtures, under Directive 67/548/EEC and 1999/45/EC to the United Nations Globally Harmonised System (GHS). Under this international system, chemical substances and mixtures are classified according to their hazardous properties, and the pictogram and other notices which must appear on the label are determined. The rules introduced by the GHS are integrated in this Regulation which has replaced Directives 67/548/EEC and 1999/45/EC on the classification, labelling and packaging of chemical substances and mixtures as of 1 June 2015.

This Regulation harmonises requirements concerning the classification, labelling and packaging of chemical substances and mixtures in line with the international system approved by the United Nations. This harmonisation enhances protection of health and the environment, and improves the free circulation of chemical substances and mixtures.

Enterprises must classify, label and pack their substances and mixtures in line with the provisions of this Regulation before putting them on the market.

The Regulation covers chemical substances and mixtures which are composed of two chemical substances or more. It excludes a number of substances or activities involving dangerous substances, which are covered by other EU legislation, e.g. radioactive substances and mixtures (Directive 96/29/Euratom), substances subject to customs supervision which are in temporary storage, in a free zone or free warehouse with a view to re-exportation or still in transit; non-isolated intermediates (substances which are manufactured in order to be chemically transformed into another substance); substances and mixtures for scientific research and development which are not placed on the market; waste; medicinal products (Directive 2001/82/EC); cosmetic products (Council Directive 76/768/EEC); some medical devices; food; and the transport of dangerous goods.

Classification

The classification of chemical substances and mixtures is based on categories which take into account the degree of hazard and the specific nature of the hazardous properties. Substances and mixtures are classified in specific categories and hazard classes: (i) physicochemical hazard (e.g. flammable liquid); (ii) health hazard (e.g. acute toxicity); (iii) environmental hazard (e.g. for the ozone layer). Annex I lays down the criteria for the classification and labelling of hazardous substances and mixtures.

The Annexes of the Regulation also include the list of hazard statements, the list of precautionary statements, pictograms for each hazard class and the lists of classifications and labelling harmonised at EU level.

Labelling

Labelling must mention:

- the name of the substance or mixture and/or an identification number;
- the name, address and telephone number of the supplier;
- the nominal quantity of the substance or mixture.

If applicable, labelling must include:

- hazard pictograms (see Annex V of the Regulation);
- the signal words “Danger” or “Warning”;
- hazard statements such as “Fire or projection hazard”, “Fatal if swallowed”, etc. (see Annex III of the Regulation);
- precautionary statements such as “Keep only in original container”, “Protect from moisture”, “Keep out of reach of children”, etc. (see Annex IV of the Regulation);
- supplemental information, for example on physical properties or health hazards (see Annex II of the Regulation).

Packaging

Packaging containing hazardous substances or mixtures shall comply with the following requirements:

- packaging must prevent any of the contents escaping;
- packaging must be made of materials which are resistant if they come into contact with the contents;
- packaging must be strong and solid;
- packaging must have sealable fastenings.

In some cases, child-resistant fastenings and tactile warnings are required.

At the latest one month after having placed a substance on the market, the manufacturer or importer shall notify the Agency of information concerning its identity, the identity of the substance, hazard classes, concentration limits, etc. All this information shall be included in an inventory of classification and labelling that the Agency shall update on a regular basis.

The Regulation facilitates the harmonisation procedure for the classification and labelling of substances, as Member States, or even manufacturers, importers or downstream users, can submit a proposal for the harmonised classification and labelling of substances, containing the information set out in Annex VI, Part 1 of this Regulation to the European Chemicals Agency. Generally, only substances satisfying the classification criteria for Category 1 respiratory sensitisation, mutagenicity, carcinogenicity or reproductive toxicity, or active ingredients in pesticides or biocidal products will be subject to such harmonisation, but other substances may be subject thereto if a necessity for harmonisation is demonstrated.

Commission Regulation (EU) No 440/2010 was adopted on 21 May 2010 to establish the fees payable to the European Chemicals Agency pursuant to the CLP Regulation. The Agency will take out fees for proposals for harmonized classification and labeling of a substance. Article 5 stipulates the condition for reduced fees, for instance for SMEs, in accordance with Annex II

The CLP Regulation has been amended a few times due to adaptation to technical progress:

Commission Regulation (EU) 790/2009 amending Part 3 of Annex VI to Regulation (EC) No. 1272/2008, which lays down two lists of harmonized classification and labelling of hazardous substances.

Commission Regulation (EU) No 286/2011 includes various scientific-technical changes to the Annexes to the CLP Regulation. Many of them are based on the 3rd revision of the UN GHS. The changes relate, inter alia, to the labelling provisions, new sub-categories for respiratory and skin sensitisation, the revision of the

classification criteria for long-term hazards (chronic toxicity) to the aquatic environment and the hazard class for substances and mixtures hazardous to the ozone layer.

Commission Regulation (EU) No 618/2012 lays down several amendments to the Annex to Regulation (EC) No. 1272/2008 as regards the entries relating to certain substances and mixtures, their classification and labelling conditions.

Commission Regulation (EU) No 487/2013 lays down several amendments to the Annex to Regulation (EC) No. 1272/2008 as regards the entries relating to certain substances and mixtures, their classification and labelling conditions.

Council Regulation (EU) No 517/2013 adapts certain regulations and decisions in the fields of free movement of goods, freedom of movement for persons, company law, competition policy, agriculture, food safety, veterinary and phytosanitary policy, transport policy, energy, taxation, statistics, trans-European networks, judiciary and fundamental rights, justice, freedom and security, environment, customs union, external relations, foreign, security and defence policy and institutions, by reason of the accession of the Republic of Croatia

Commission Regulation (EU) No 758/2013 lays down some corrections to Part 3 of Annex VI to Regulation (EC) No. 1272/2008 as regards the classification, labelling and packaging of certain substances and mixtures.

Commission Regulation (EU) 944/2013 brings the CLP Regulation into line with the 5th revised edition of the UN Globally Harmonised System (GHS). Adaptations regarding the list of precautionary statements in Annex IV to the CLP Regulation apply in respect of substances from 1 December 2014 and in respect of mixtures from 1 June 2015. Those regarding the list of harmonised classification and labelling of hazardous substances apply from 1 January 2015 for nearly all entries.

Commission Regulation (EU) 605/2014 amends for the purposes of introducing hazard and precautionary statements in the Croatian language and its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

Commission Regulation (EU) No 1297/2014 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. The amended harmonised classifications shall apply for substances and mixtures from 1 January 2017 although they may be used before that date on a voluntary basis.

Commission Regulation (EU) 2015/1221 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. The amended harmonised classifications shall apply for substances and mixtures from 1 January 2017 although they may be used before that date on a voluntary basis.

This Regulation supplements the REACH system for registration, assessment, authorisation and restrictions concerning chemical substances (REACH Regulation (EC) 1907/2006).

CLP implements the Globally Harmonised System (GHS) of Classification and Labelling of Chemicals into the European Union. Development of the GHS began following the 1992 Rio de Janeiro UN Conference on Environment and Development with the aim of providing a consistent, harmonised system for the identification and communication of hazards about chemicals, so as to enable their safe use, transport and disposal. The first edition of the GHS was eventually published in 2002 and since then, the GHS has been

updated, revised and improved every two years as needs arise and experience is gained in its implementation. The latest 6th Edition of the GHS was published in 2015. More information about GHS can be found on the UNECE website: http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

Whereas GHS is based upon a “building block” approach, allowing countries to select those elements they believe to be most relevant, in the EU, only those building blocks that most closely match the DSD and DPD system have been incorporated into CLP Regulation. This may result in different classifications for some products in the EU compared to other parts of the world. Through CLP, the EU seeks to retain some of the benefits from the 40 years of experience with the DSD and DPD, which may result in further differences between the way that GHS is implemented in CLP and the way it is being implemented in other countries. CLP includes some additional classification elements from the DSD and DPD which are not yet included in the GHS. These additional requirements are sometimes referred to as the “EU Leftovers”.

The main similarities between GHS and CLP include:

- they cover approximately the same hazards of a substance or mixture
- they use similar or equivalent classification criteria, and
- they communicate these hazards through the provision of information on labels and safety data sheets

Main differences between two systems:

- there are some terminology changes, e.g. ‘mixture’ instead of ‘preparation’
- some new hazard classes and categories are introduced
- some classification criteria are different or use different cut-offs
- mixtures are handled differently
- some labelling elements are changed

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Appoint a competent authority(ies) responsible for proposals for harmonized classification and labelling and appoint enforcement authorities responsible for ensuring efficient enforcement of the provisions of the obligations under the Regulation. Establish mechanisms and procedures for cooperation between these authorities. (Art. 43)
- Establish a national helpdesk to provide advice to manufacturers, importers, distributors, downstream users and any other interested parties on their respective responsibilities and obligations under this Regulation. (Art. 44)
- Appoint a body/bodies responsible for receiving information from importers and downstream users placing mixtures on the market, in particular where relevant for planning and implementing preventative and curative measures. These should particularly focus on emergency health response. This information includes chemical composition of mixtures which are classified as hazardous. Ensure that this body respect provisions of confidentiality regarding the information received and that this data is only used for the purpose of formulating preventive and curative measures and for carrying out an analysis where further risk management measures are required. (Art. 45)
- Devise measures and control mechanisms to ensure that substances and mixtures are not placed on the market unless they have classified, labeled and packaged pursuant to this Regulation and that non-compliance is sanctioned with effective, proportionate and dissuasive penalties. (Arts. 46-47)
- At EU level and in the relevant UN forum, promote the harmonisation of the criteria for classification and labelling of persistent, bio accumulative and toxic (PBT) and very persistent and very bio accumulative (vPvB) substances. (Art. 53(2))

2.2. Regulation

- Ensure that no substances or mixtures are put on the market unless classification has been carried out in accordance with Articles 4-16 of CLP Regulation:
 - Manufacturers, importers and downstream users classify substances or mixtures pursuant to Title II before placing them on the market
 - A substance or mixture fulfilling criteria regarding physical, health or environmental hazards, referring to Parts 2-5 of Annex is considered hazardous and should be classified in relation to the respective hazard class. Classification shall take into account exposure route and nature of the effects. (Art. 3)
 - Manufacturers, producers of articles and importers classify substances not placed on the market in pursuant to Title II where CLP Regulation require registration (Articles 6, 7(1) or (5), 17 or 18) or notification (Articles 7(2) or 9)
 - Where a substance is subject to harmonised classification and labelling in accordance with Title V through an entry in Part 3 of Annex VI, it is classified in accordance with that entry. Where the substance also falls within one or more hazard classes or differentiations not covered by an entry in Part 3 of Annex VI, classification under Title II shall be carried out for those hazard classes or differentiations. (Art. 4(1),(2), (3))
 - Where a substances or mixture is classified as hazardous, suppliers have to label and package it in accordance with Title III and IV. (Art. 4(4))
 - Ensure that distributors and downstream users may use the classification derived by an actor in the supply chain if composition remains unchanged. Here distributors may use the classification derived by an actor in the supply chain (in pursuance with Title II). (Art. 4(5), (6))
- Ensure that no articles referred to in section 2.1 of Annex I are being placed on the market unless they are classified, labeled and packaged accordingly (Art. 4(8))
- Ensure that manufacturers, importers and downstream users comply with the hazard classification and hazard information evaluation requirements and procedures set out in Title II including:
 - Identification and examination of information to determine whether a substance or mixture entails a physical, health or environmental hazard referred to in Annex I, considering methods referred to in Art. 8(3), epidemiological data, information generated pursuant to Annex XI of REACH Regulation, new scientific information and international chemical information. This information has to be validated pursuant to Chapter 2 of Title II. Specific requirements apply to mixtures with carcinogenic, germ cell mutagenic or reproductive toxic substances, or where the biodegradation or bioaccumulation properties in the hazard class hazardous to the aquatic environment are evaluated. (Art. 5, 6);
 - If need be, in case of insufficient available information, generate new information for substance and mixture pursuant to Art. 8 with a view to determine whether a substances or a mixture entails a health or environmental hazard set out in Annex I or entail physical hazards referred to in Part 2 of Annex I. Such new information may comprise new tests pursuant to Annex XI to the REACH Regulation, applying the methods referred to in Art. 13(3) of REACH Regulation

- or Art. 13(4) regarding new ecotoxicological or toxicological tests or pursuant to international recognized and validated scientific principles and methods. Also specific methods for tests for physical hazards to be carried out from 1 January 2014. (Art. 8);
- Evaluate the information through applying the criteria for each hazard class or differentiation set out in Parts 2-5 of Annex I. When certain test methods have been applied, the tests methods employed have to be compared with those indicated in Article 8(3). Where criteria cannot be applied directly to the identified information, the evaluation should involve expert judgment and in certain cases of scarce information bridging principles have to be applied. (Art. 9);
 - Assigning concentration limits and M-factors for the classification set out in Article 10. M-factors have to be established for substances classified as hazardous to the aquatic environment, acute category 1 or chronic category 1. M-factors or concentration limits shall not be assigned for harmonized hazard classes or differentiations for substances included in Part 3 of Annex VI. In setting these the manufacturer, importer and downstream users must take into account limits and factors included already in the Classification and Labelling Inventory. (Art. 10);
 - Take into account cut-off values relating to cases where a substance contains another substance which is classified as hazardous and are above the values set out in section 1.1.2.2 of Annex I (Art. 11);
 - Taking additional measures set out in Article 12 and 13 if the evaluation undertaken pursuant to Article 9 and 12 so require. For instance, where the evaluation shows that the hazards associated with the substance or mixture meet the criteria for classification in one or more hazard classes or differentiation in Parts 2-5 of Annex I, these must be classified in relation to the relevant hazard classes or differentiations by assigning hazard categories and hazard statements;
 - Applying specific rules for the classification of mixtures relating to the reaction with certain agents or with other substances in the mixture and also determining cases where mixture does not need to be classified for explosive, oxidizing or flammable properties. (Art. 14);
- Ensure that manufacturers, importers and downstream users take all possible steps to review and reevaluate the classification of substances and mixtures, unless there is valid scientific justification for not changing the classification. Re-evaluation of the classification is necessary in case of:
 - new scientific or technical information that may affect the classification;
 - where there is a change to a mixture, such as the composition of the initial concentration of hazardous constituents, adding new constituents in concentrations above the cut-off value (Art. 15)
 - Ensure that no substances, mixtures or articles containing thereof are placed on the market unless labelling is in accordance with Title III (Articles 17-34) regarding the content of the label, its format and other information to ensure adequate identification of the substances or mixture and possible derogations in specific cases. This information must be provided in the official language of the Member States where it is placed on the market. Articles 17-34 govern issues such as:
 - The information on the label must include:
 - identification of supplier, quantity of substances or mixture (Art. 17),
 - label product identifiers, e.g. for substances, in the order or ranking 1) name and identification number as it appears in Part 3 of Annex VI, 2) in the classification and labelling inventory, 3) the

- number provided by the CAS, 4) the name in the IUPAC Nomenclature. For mixtures, Art. 18(3) applies (e.g. trade name, identity of all substances of the mixture) (Art. 18),
- hazard pictograms pursuant to section 1.2.1 of Annex I and in Annex V (Art. 19);
 - signal words for hazard classes in Parts 2-5 of Annex I (Art. 20);
 - hazard statements for hazard classes in Parts 2-5 of Annex I, or for substances included in Part 3 of Annex VI, complying with the wording set out in Annex III (Art. 21);
 - precautionary statements for hazard classes in Parts 2-5 of Annex I, or for substances included in Part 1 of Annex VI, complying with the wording set out in Part 2 of Annex IV (Art. 22)
- Derogations from labelling requirements can only be granted on the basis of Art. 23 for which labelling must comply with section 1.3 of Annex I (concerns certain pressure vessels such as gas containers, metals in massive form and explosives) and on the basis of Art. 29, where the packaging is in a shape or of a size making it impossible to meet all the requirements set out in Art. 31 (Art. 23);
 - Conditions for using an alternative chemical name on ground of intellectual property rights, which first must be approved by the ECHA, using the format referred to in Article 111 of the REACH Regulation and otherwise the procedure set out in REACH regarding review, fees, withdrawal, making information publicly available over the Internet (Art. 24);
 - Supplemental information on the label in certain case where substances or mixtures are classified as hazardous. Such statements must be in accordance with sections 1.1 and 1.2 of Annex II and Part 2 of Annex III or in accordance with Part 4 of Annex II and Part 3 of Annex III where a substance or mixture falls within scope of Plant Protection Regulation (EC) 1107/2009. No statements must be used which are misleading and contradictory to classification (Art. 25);
 - The precedence and order of displaying hazard pictograms and precautionary statements to guarantee clarity but avoid duplications. The statements shall for substances or mixtures supplied to the general public inform about disposal forms (Art. 26 and 28);
 - Obligation to display all hazard statements (Art. 27)
 - Updating of information on labels in case of change to the classification and labelling, especially where the new hazard is more severe, requiring additional labelling elements. Such update shall be made as soon as possible if new hazards are presented and in other cases within 18 months (Art. 30);
 - General rules for the application of labels in terms of how they are affixed to the surfaces of the packaging, placement, coloring and presentation. In terms of shape, colour and the size of hazard pictograms these should be in accordance with section 1.2.1 of Annex I. Location of information on the label shall be in accordance with Article 32, in terms of grouping information such as pictograms, statements and signal words. (Arts. 31-32);
 - Specific labelling rules for out packaging, inner packaging and single packaging, which aims at ensuring consistency also with rules on the transport of dangerous goods. Intermediate and inner packaging shall at least meet the requirements of the CLP Regulation. Single packages shall meet labelling rules on the transport of dangerous goods and the CLP Regulation (Art. 33)
- Ensure that no substances or mixture classified as hazardous are put on the market unless the packaging complies with the specifics of Article 35, e.g.

- the packaging is designed and constructed so that its contents cannot escape;
 - the materials constituting the packaging and fastenings shall not be susceptible to damage by the contents, or liable to form hazardous compounds with the contents;
 - the packaging and fastenings shall be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;
 - packaging fitted with replaceable fastening devices shall be designed so that it can be refastened repeatedly without the contents escaping;
 - packaging supplied to the general public must not be misleading for the consumer or attract attention of children and have certain properties to be child-resistant, bear warning information and comply with transport regulation.
- Resort to the procedure for harmonization of classification and labelling of substances set out in Arts. 36- 38 in the cases listed below. A proposal for harmonized classification and labelling can be submitted to the ECHA by the competent authority, a manufacturer, importer or downstream user. A proposal must be in the format set out in Part 2 of Annex VI with information set out in Part 1 of Annex VI taking into account relevant provisions in Annex I to the REACH Regulation, such as in compliance with the format B of the Chemical Safety Report and is subject to the fees established pursuant to the REACH Regulation.
 - a substance fulfills the criteria set out in Annex I, i.e. for (a) respiratory sensitisation, category 1 (Annex I, section 3.4); (b) germ cell mutagenicity, category 1A, 1B or 2 (Annex I, section 3.5); (c) carcinogenicity, category 1A, 1B or 2 (Annex I, section 3.6); and (d) reproductive toxicity, category 1A, 1B or 2 (Annex I, section 3.7);
 - Substance being an active substance in the meaning of Directive 91/414/EEC²⁹⁸ or Directive 98/8/EC²⁹⁹ (e.g. biocides) – subject to Art. 37(1), (4), (5) and (6) ;
 - Substances added to Annex VI on a case-by-case basis if action at EU level is deemed necessary (Art. 36)

Manufacturers, importers and downstream users having new information which may lead to a change of the harmonized classification and labelling elements of a substance listed in Part 3 of Annex VI must submit a proposal to the competent authority (Art. 36-37)

- Do not restrict the placing on the market of substances that comply with the Regulation, for reasons relating to notification, classification, packaging or labelling, unless the restriction is temporary and is imposed in accordance with specified conditions (so-called safeguard clause, in cases where Member States have grounds to believe that a substance or a mixture, constitute a serious risk to human health or the environment due to its classification, labelling or packaging. Such safeguard clauses have to comply with the applicable procedure meaning informing the Commission, the Chemicals Agency and the Member States and comply with the Commission Decision as to whether the measure can be

²⁹⁸ Repealed by the Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market

²⁹⁹ Repealed by the Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

maintained and for how long. Member States have to submit a proposal to the Chemicals Agency for harmonized classification and labelling. (Arts. 51, 52, CLP Regulation).

- Prohibit the advertisement of substances belonging to categories of dangerous substances without reference to the category and ensure that for a mixture classified as hazardous or covered by Art. 25(6) which may be bought by private consumers without first having seen the label, the advertisement mention the type of hazard indicated on the label. Also consult the provisions in Directive 2011/83/EU governing distance sales (Art. 48).
- Ensure that the wordings mixture(s) are used and not preparation(s) as was the case under Directive 1999/45/EC. (CLP Regulation and Regulation 1336/2008)
- Ensure compliance with changes to part 3 of Annex VI (table 3.1 and 3.2 from which several entries in Annex I, II, III, IV, V are deleted), introduced by Regulation (EC) No 790/2009, which are applicable as from 1 December 2010.
- Ensure that for the purpose of testing necessary under this Regulation, testing on animals is only carried out where there are no other alternatives and that under no circumstances are humans or non-human primates used. However, Member States can use data from clinical studies involving humans. (Art. 7)
- Take the necessary measures, including maintaining a system of official controls, to ensure that substances and mixtures are not placed on the market, unless they have been classified, labelled, notified and packaged in accordance with this Regulation. (Art. 46(1))
- Ensure that non-compliance with the provisions of the Regulation is subject to effective, proportionate and dissuasive penalties. (Art. 47)

2.3. Information and Reporting

- Ensure that any manufacturer or importer of substances subject to registration under REACH Regulation and substances or mixtures that must be classified as hazardous and are placed on the market notify the ECHA information to be included in the Classification and Labelling Inventory. Information to be notified is set out in Art. 40 and include identity of the notifier placing the substance on the market or of the substances that need REACH registration, classification, information on insufficient data for classification, specific concentration limits or M-factors, the label elements.
 - This notification must be submitted within one month after placing the substance on the market;
 - Note that this information does not have to be submitted under CLP Regulation if it has already been notified under REACH Regulation as part of registration. (Arts. 39-40);
 - This data has to be notified again whenever there is a change of classification and labelling following the review procedure (Art. 15);
 - In case of different entries for one and the same substance notifiers and registrants must agree on the entry to be included in the inventory. (Arts. 39-41)
- Ensure that suppliers maintain information for at least 10 years after the substances or mixture was last supplied by the supplier and coordinate this record keeping together with the provisions under Article 36 of REACH Regulation. Such information must be available to the competent authority or the enforcement authorities upon request. In certain cases, such as in case of cessation of the activities, this duty is taken over by another third party. This information may in certain cases already be available under notification requirement (Art. 40, CLP) or as part of registration under REACH Regulation. (Art. 49)
- Member States introducing safeguard clause must immediately inform the Commission, the Agency and the Member States giving the reasons for its decision. The Member States must also in case of the Commission granting a temporary authorization for safeguard clause, submit a proposal to the Agency for harmonised classification and labelling, within three months of the date of the Commission decision. (Art. 52 and 37, CLP Regulation)
- Submit a report to the European Chemicals Agency every five years by 1 July on the results of the official controls, and other enforcement measures taken. The first report was due on 20 January 2012. (Art. 46(2)),
- Notify the Commission about the national provisions on penalties and inform it every time changes are made to these provisions. (Art. 47)

2.4. Additional Legal Instruments

The CLP Regulation is a key Regulation affecting legislation not only in the chemical sector but in other sectors as well, such as transport sector, waste management sector, and the occupational health and safety sector. The below list can be useful as a point of departure in the overall assessment of the knock-on effect of the CLP Regulation on other national provisions. For instance, there are approximately 20 downstream Directives and Regulations which rely on the classification of substances and mixtures under the CLP. If a product changes classification, there may be impacts for the supplier from this additional legislation

Chemical legislation

- Directive 2010/63/EU on the protection of animals used for scientific purposes
- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products
- Regulation (EC) No 850/2004 on persistent organic pollutants
- Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals
- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Regulation (EC) No 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury

Other environmental legislation

- Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC
- Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
- Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC
- Directive 2008/98/EC on waste

Health and Safety

- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Regulation are summarised in the checklist below. The key tasks are arranged under sub-headings and organised in chronological order of implementation wherever possible.

Table 12. Checklist with Key Implementation Tasks

CLP REGULATION - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Appoint a competent authority responsible for proposals for harmonized classification and labelling and appoint enforcement authorities responsible for ensuring efficient enforcement of the provisions of the obligations under the Regulation. Establish mechanisms and procedures for cooperation between these authorities.
1.2	Establish a national helpdesk to provide advice to manufacturers, importers, distributors, downstream users
1.3	Appoint a body/bodies responsible for receiving information from importers and downstream users placing mixtures on the market, in particular where relevant for planning and implementing preventative and curative measures. Ensure that the received information is treated confidentially and diligently only for the purpose for which it was received.
1.4	Early stakeholder involvement and awareness raising.
1.5	Provide information to competent authorities as well as to industry and other relevant third parties. For instance, information shall be given regarding <ul style="list-style-type: none"> • the functions and role of the competent and enforcement authorities, • the classification and labelling inventory (database), operated by the European Chemicals Agency, which contains data relating to notifications under the CLP Regulation and registrations under REACH; • the functions of the European Chemicals Agency, and how it aims to provide industry and competent authorities with technical and scientific guidance and tools to comply with the CLP Regulation. • Under which grounds the European Chemical Agency can refuse access to information (e.g. Art 118 of the REACH Regulation)
1.6	Inform suppliers about the possibility to submit requests for using an alternative chemical name for a substance to protect the confidential nature of business and intellectual property rights. Such requests

	should be sent to the ECHA (in case of mixture being classified and labelled pursuant to the CLP Regulation)
1.7	Check the knock on effect of the CLP Regulation on other national provisions. There are approximately 20 downstream Directives and Regulations which rely on the classification of substances and mixtures under the DSD/DPD, and hence CLP. If a product changes classification, there may be impacts for the supplier from this additional legislation
2	Regulation
2.1	Ensure that manufacturers, importers and users apply the provisions on classification, labelling and packaging of substances and mixtures
2.2	Ensure that all substances and mixtures are reclassified according to the CLP Regulation, using the Translation Table and inform the manufacturers, importers or users on available guidance on the self-classification, review of classification and the harmonized classification.
2.3	Ensure that procedures exist for validation of information used for classification and re-classification
2.4	Ensure that manufacturers, importers and downstream users notify substances, mixtures and articles containing such. This obligation has to be coordinated with the obligation to register under the REACH Regulation which can result in duplication of data submitted. In case of inconsistency between the entries for one and the same substance, manufacturer, importers and downstream users have to agree on one classification.
2.5	Ensure that the relevant parties comply with the notification requirements and that they are duly informed about the considerable greater scope of substances, mixtures and articles containing such having to be notified then under the registration scope under REACH Regulation.
2.6	Establish a mechanism to ensure that all substances and mixtures are packaged and labelled in accordance with the CLP Regulation, taking into account the changes to risk phrasing, the 9 pictograms etc. Note the possibility to use certain derogations to labelling requirements concerning certain pressure vessels, explosives and for packages which format and size makes it impossible to comply with all the packaging requirements.
2.7	Establish a mechanism to ensure that manufacturers, importers and distributors provide safety data sheets, taking into account the changes to the SDS introduced by the GHS and CLP Regulation, especially the e-SDS. For requirements on SDS manufacturers, importers and downstream users have to pay attention to requirements under the REACH Regulation.
2.8	Provide information and guidance to manufacturers, importers and distributors to ensure they understand the requirements of the Regulation. Note that the ECHA has developed a number of guidance documents to be consulted. Also there are ample consultancy services which have provided brief guidance documents to provide a departing point in understanding the differences between the old and new system and the precise obligations involved.

2.9	Establish guidance and criteria regarding the obligations and applicable procedure for placing temporary restrictions on substances, such as having resort to the safeguard clause on grounds of protection of human health or the environment
2.10	Monitor that advertisements mention the hazard categories for substances and mixtures to ensure that professional and private buyers are fully informed about the various hazards and risks involved.
2.11	<p>Ensure that manufacturers, importers and users take their responsibilities under the CLP Regulation, taking into account the following key stages:</p> <ul style="list-style-type: none"> • Identifying their role under CLP <p>The term “manufacturer” has a specific meaning in both REACH and CLP, and is used for the person making a substance. Formulators who mix substances are considered to be downstream users. Whilst both manufacturers and downstream users have obligations to properly classify and label their products, manufacturers of substances also have some additional obligations, in particular an obligation to notify ECHA of the classification and labelling for their substance(s).</p> <ul style="list-style-type: none"> • Identifying the products that need reclassification <p>Most companies will already have developed a detailed inventory of their products for the purposes of REACH, and this document will provide a good starting point for identifying those products in need of reclassification. Note that changes in the classification criteria, and particularly in the way that mixtures are assessed, may mean that some products not currently classified as hazardous will become hazardous under the new approach. It is also important to consider products manufactured or imported below the 1 tonne threshold.</p> <ul style="list-style-type: none"> • Deciding on the approach for reclassifying <p>Companies will need to decide who will carry out the reclassification, and what resources may be needed to do this. Where this is done in house, resource and expertise have to be acquired. Software tools used may need upgrading to have them fully cover the new requirements. Where companies rely on external consultant, it is necessary to ensure that they have the adequate skills, experiences and resources.</p> <ul style="list-style-type: none"> • Deciding when to implement the new classifications <p>CLP imposes deadlines for reclassification, of 1 Dec 2010 for substances and 1 June 2015 for mixtures. However, many products will be in the supply chain for a long time. The timing should be opportune to ensure that deadlines are kept on one side but that there is sufficient time to educate sales force and customers of the upcoming changes before reclassification is carried out.</p> <p>Downstream users (formulator) also need to decide whether to wait until the component ingredients in the mixture used have been reclassified by their supplier. Users are advised to contact suppliers to find out what their plans are, and whether they anticipate any changes in the classification of their products under CLP</p> <ul style="list-style-type: none"> • Consider any knock-on effects <p>If any of the manufacturers’ products change classification, it may be necessary to change the packaging or take into account other impacts, such as regarding worker protection, limitations of quantities of the product stored and waste management and disposal requirements.</p>

2.13	Ensure that manufacturers do not abuse the possibilities for withholding certain information on chemicals, using alternative chemical names in classification and on SDS. Such exceptions should only be allowed on grounds of intellectual property rights and be reasonable.
2.14	Ensure that manufacturers, importers and downstream users resort to harmonized classification in certain cases and that it is harmonized with provisions under the REACH Regulation. Ensure that for proposals for harmonized classification and labeling of a substance, the relevant fee is paid to the Chemicals Agency in the currency and payment method indicated in Commission Regulation (EU) No 440/2010. Reductions are possible, e.g. for SMEs.
2.15	Ensure that testing on animals (with the exception of non-human primates which are completely banned for testing) is reduced and replaced with other means and where animal testing is the only alternative ensure that principles (3Rs) in the Directive on the protection of animals used for scientific purposes (2010/63/EU) is used.
2.16	Maintain a system of official controls, such as inspections and other measures to make sure that substances and mixtures are not placed on the market, unless they have been classified, labelled, notified and packaged in accordance with this Regulation.
2.17	Ensure that non-compliance with the provisions of the Regulation is subject to effective, proportionate and dissuasive penalties.
3	Reporting
3.1	Submit a report to the European Chemicals Agency every five years by 1 July on the results of the official controls, and other enforcement measures taken.
3.2	Notify the Commission about the national provisions on penalties and inform it every time changes are made to these provisions.
3.3	Member States introducing safeguard clause must immediately inform the Commission, the Agency and the Member States giving the reasons for its decision. The Member States must also in case of the Commission granting a temporary authorization for safeguard clause, submit a proposal to the Agency for harmonised classification and labelling, within three months of the date of the Commission decision. (Art. 52 and 37, CLP Regulation)
3.4	Ensure that any manufacturer or importer of substances subject to registration under REACH Regulation and substances or mixtures that must be classified as hazardous and are placed on the market notify the ECHA information to be included in the Classification and Labelling Inventory. Information to be notified is set out in Art. 40 and include identity of the notifier placing the substance on the market or of the substances that need REACH registration, classification, information on insufficient data for classification, specific concentration limits or M-factors, the label elements.
3.5	Ensure that suppliers maintain information for at least 10 years after the substances or mixture was last supplied by the supplier and coordinate this record keeping together with the provisions under Article 36 of REACH Regulation. Such information must be available to competent authority or the enforcement authorities upon request. In certain cases, such as in case of cessation of the activities, this

	duty is taken over by another third party. This information may in certain cases already be available under notification requirement (Art. 40, CLP) or as part of registration under REACH Regulation.
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3.2. Phasing considerations

The CLP Regulation applies directly in all member states. This means, firstly, member states do not need to transpose the Regulation in national legislation. Secondly, member states will need to repeal national legislation that implements the existing classification and labelling system. Also, as the CLP Regulation is direct acting on all Member States, there is no longer a need for a separate national publication and the Approved Supply List has therefore been discontinued with immediate effect.

On its entry into force on 20 January 2009, the CLP Regulation repealed in full Annex I of the Dangerous Substances Directive. However, as the agreed harmonised classifications and accompanying labelling requirements are still needed throughout the transitional period of the CLP Regulation to allow suppliers to classify preparations (mixtures), the list was immediately re-enacted in Table 3.2 of Part 3 of Annex VI to the CLP Regulation. Table 3.2 includes all the harmonised classifications that appeared in the Approved Supply List up to and including the 30th and 31st Adaptations to Technical Progress (ATP) of the Dangerous Substances Directive. The 30th and 31st ATPs were incorporated into the 1st ATP to the CLP Regulation, published on 5 September 2009 as Commission Regulation (EC) No 790/2009.

The application of the Regulation is likely to demand significant resources because its potential effect on a range of stakeholders are considerable. Lengthy consultation and information procedures may be a principal constraint on implementation. As well, there are health and safety, consumer protection, trading standards and cross-border issues in play. There will be a need to coordinate this legislation with a number of other Ministry Departments.

The provisions of the CLP has been phased in between 2010 and 2015, according to the following transitional schedule

Substances

1st December 2010 – 1st June 2015	Suppliers must classify substances according to both CHIP and CLP. They must label and package according to CLP.
1st June 2015 onwards	Suppliers must classify, label and package according to CLP.

Mixtures

20th January 2009 – 1st June 2015	<p>Suppliers must classify preparations according to CHIP, and may continue to label and package them according to regulations 6 to 11 of CHIP. However they may as an alternative choose to classify, label and package mixtures according to CLP. In this case, they must continue to classify in addition under regulation 4 of CHIP, but the requirements on labelling and packaging in regulations 6 to 11 of CHIP no longer apply</p>
1st June 2015 onwards	<p>Suppliers must classify, label and package according to CLP. There are certain limited circumstances where these transitional arrangements for substances and preparations can be extended. The re-labelling and re-packaging of substances and mixtures which are already in the supply chain ('on the shelves') on the above compliance dates, may be postponed until 1 December 2012 and 1 June 2017 respectively.</p>

4. IMPLEMENTATION GUIDANCE

4.1. Planning

- The CLP Regulation:
 - applies the terminology, evaluation principles and criteria of the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS);
 - ensures consistency with the legislation on the transport of dangerous goods;
 - includes the provisions on the classification & labelling inventory from Regulation (EC) No 1907/2006 (REACH Regulation);
 - defines a transitional period during which companies need to come into line with the new Regulation; and
 - maintains the concept of "dangerous", to avoid changing the scope of REACH and other EU legislation.
- The CLP Regulation relates to substances and mixtures irrespective of the tonnage manufactured or imported into the European Union. It is directly applicable to:
 - manufacturers and importers of substances, or mixtures,
 - distributors,
 - retailers and
 - users of chemicals.

It is also relevant to producers or importers of certain specific articles. Several guidance documents facilitating implementation on the CLP have been prepared by the ECHA to help industry to apply these new rules.

The guidance documents are available at the following link:
<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp>

- Some industrial sectors are exempted from the provisions of the Regulation because they are covered by provisions in other EU legislation, for example, radioactive equipment, medicinal products and cosmetics. Transport matters and substances supplied in small quantities are also exempt.
- Resources of member states' authorities will continue to be focused on substances of the highest concern, mainly substances classified for carcinogenicity, germ cell mutagenicity or reproductive toxicity (categories 1A or 1B according to GHS), respiratory sensitisation or for other effects on a case-by-case basis. Such classifications will continue to be harmonised and entered into Annex VI.
- CLP Regulation is the implementation of the UNO GHS in the European Union. The rules on classification, labelling and packaging are based on the 4th revision of the GHS. CLP additionally takes onboard some features and procedures from the previous EU system of classification and labelling, represented by the Dangerous Substances Directive (DSD) and the Dangerous Preparations Directive

(DPD) that are not part of GHS. Therefore, CLP is similar to, but not identical to the way in which GHS is introduced into the legal framework of countries outside the EU (differences may exist between implementations in individual non-EU countries).

Every country intending to apply this system leans on the document of GHS UNECE to adapt it in its own regulation. Thanks to the modular approach every country can select which modules have to be implemented. Thus some danger categories are not in force in the EU and some others are specific.

- The choice of competent authority(ies) responsible for proposals for harmonized classification and labelling and appointment of enforcement authorities responsible for ensuring efficient enforcement of the obligations under the Regulation will have to be carefully considered. Especially, several government bodies may have a legitimate interest in the CLP Regulation. For example, a body concerned with health or worker safety may be considered to be the most appropriate, but it is essential that mechanisms for involving other departments and receiving input from them, particularly those with a remit for environmental protection, are established. Where more than one competent authority is appointed tasks must be clearly allocated. It is worthwhile to investigate to what extent the competent authority(ies) responsible for REACH Regulation also can be responsible for the CLP Regulation, which will result in a comprehensive institutional framework, enhanced transparency and cost-efficiency. However, the competent authority and the enforcement authority should be kept separate due to principles of division of powers and ensure that there are no conflicts of interest. The enforcement authority has to be furnished with sufficient powers and resources to be able to efficiently follow up on the implementation of the CLP also taking into account related tasks under REACH Regulation and possibly also under other directly related EU provisions. Training or recruitment may be required to ensure that the competent authority/ies is adequately equipped to complete the risk assessments required.
- Since several authorities will be involved in implementing the CLP Regulation, it is essential to establish mechanisms and procedures for cooperation between these authorities.
- The national helpdesk to be established to provide advice to manufacturers, importers, distributors, downstream users and other interested parties regarding the obligations under the Regulation, has to be furnished with sufficient resources and expertise to be able to answer to complex queries. These national helpdesks are also likely to come into account with the European Chemical Agency and thus needs staff with relevant competence and expertise. The national helpdesk may be combined or closely linked to the helpdesk required under REACH Regulation. This will facilitate a one-stop-shop approach.
- The body/bodies responsible for receiving information from importers and downstream users placing mixtures on the market must have staff, sufficiently trained and having recourse to guidance on their concrete tasks in terms of formulating preventative and curative measures. The staff needs to understand the links with measures taken under the Seveso III Directive and under other civil protection legislation, responding to emergency situations. It is important that the importers and users have confidence in the body and data collecting system and that the received information is treated confidentially and not used for other non-relevant purposes.
- There are approximately 20 downstream Directives and Regulations which rely on the classification of substances and mixtures under the CLP. If a product changes classification, there may be impacts for the supplier from this additional legislation. This might include sites becoming subject to Seveso III Directive provisions, or moving from lower to top tier status; protective equipment requirements and

working practices; impacts on disposal of waste products, etc. Hence, the candidate countries have to carefully assess the knock-on effect of the new system on current legislative framework and plan for appropriate legislative changes and provision of information to the affected parties.

- The Regulation has a potential impact on many stakeholders, and as a result great care must be taken to consult widely. For example, the stakeholders involved include not only companies and their workers, together with their representatives, but also environmental bodies, accident control authorities, emergency services, and wide range of NGOs and government departments. This large number of interested parties reflects the importance of chemical substances in everyday life.
- Governments may benefit from consultation with the Commission, the European Chemicals Agency, international agencies concerned with chemicals such as the OECD, UN, and other national governments by, for example, the exchange of information, discussion of best practices, access to test results, or pooling of common resources.
- An adequate system of penalties for non-compliance will be required to provide an incentive for manufacturers and importers to meet the requirements of the Regulation.
- Regarding the restrictions on animal testing for the purpose of assessing substances under this Regulation, candidate countries should first try obtain data from other available sources, e.g. from other Member States, data from clinical studies etc. Under the Directive on the protection of animals used for scientific purposes (2010/63/EU) databases have been established with available data.

Examples from a Member State:

Germany: On 20 January 2009 the EC Regulation 1272/2008 concerning the classification, labelling and packaging of substances and mixtures came into force. As regards the implementation of this Regulation in the authorisation procedure for plant protection products and the listing procedure for plant resistance improvers and adjuvants the BVL (*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit*) has published details in the notification 09/02/18 of 12 August 2009 in the Federal Gazette (Volume 132, 4 Sept. 2009, p 3126). The BVL will proceed as follows regarding classification and labelling:

- From 1 December 2009, the labelling of the active substance(s) with regard to toxicology will be stated as an additional piece of information for all plant protection products (= mixtures), plant strengtheners and adjuvants in the notifications of authorisation, approval and listing according to Regulation (EC) No 1272/2008 since this information can be provided by the Federal Institute for Risk Assessment.
- When submitting an application as from December 2009, information on the classification and labelling of all hazardous ingredients which are present in a plant protection product with a concentration as a rule greater than or equal to 0.1 % should be provided if possible according to Regulation (EC) No 1272/2008 (e.g. using a safety data sheet according to Regulation (EC) No 1907/2006 (REACH)). This information is compulsory when submitting an application on or after 1 December 2010. Experience in the derivation of plant protection product labelling gained by the assessment authorities with this information should become part of a workshop for applicants and is to take place in 2010 at the BVL.
- For all applications submitted as from 1 December 2009 the labelling of the plant protection product according to (EC) No 1272/2008 will be stated in addition in the authorisation certificate.

Beginning with 1 January 2015 all remaining authorisations and listings up to 1 June 2015 will officially be changed.

If an authorisation holder wishes to change to the new system after 1 December 2009, but before 1 June 2015, he can do this by writing to the BVL (no particular form is required). Following evaluation, which may involve the Federal Institute for Risk Assessment and the Federal Environment Agency, the BVL will issue a notification of amendment.

Examples from a Member State:

Malta:

In Malta the CLP Regulation was implemented through Legal Notice 214 of 2009 under the Product Safety Act. LN 214 of 2009 states that the penalties applicable for infringement of the provisions of Regulation (EC) No. 1272/2008 shall be those provided for in Part IV of the Product Safety Act.

4.2. Regulation

Note that the CLP Regulation is legally binding across the Member States. It is directly applicable to all industrial sectors.

4.2.1. Classification

- From 1 June 2015, mixtures must be classified, labelled and packaged, before placing on the market, in accordance with CLP only. However, mixtures already classified, labelled and packaged in accordance with Directive 1999/45/EC and placed on the market before 1 June 2015 will only have to be re-labelled and re-packaged at the latest by 1 June 2017.
- Self-classification: in most of the cases, suppliers need to decide on the classification of a substance or mixture. This is called self-classification. There are normally four basic steps to self-classify a substance or a mixture:
 - Collection of available information
 - Evaluation of the adequacy and reliability of the information
 - Review of the information against the classification criteria
 - Decision on classification
- Annex VII of CLP Regulation sets out a ‘Translation’ Table, which can be used to ‘convert’ classifications made under the previous Dangerous Substances Directive to the new classifications made by applying the CLP criteria. Where there is no direct one-to-one equivalent, the Annex has assigned the least severe classification and places a duty on the supplier to decide if a more severe classification is needed. This annex is intended to be used by those substances and mixtures that have already been self-classified under the existing European legislation, and where the hazard categories identified are equivalent. The European Commission intends the table to help suppliers/importers of substances and mixtures fulfill their obligations under the new Regulation without having to reclassify, as long as the chemical has already been classified under the existing system. If a supplier/importer chooses not to use the table they must fully re-evaluate the substance or mixture using the criteria in the Regulation. The classifications from the previous directives have been turned into CLP classifications. Suppliers may use these translations if the following conditions are met:
 - A substance was classified according to the Dangerous Substance Directive before 1 December 2010 or a mixture is classified according to the Dangerous Preparations Directive before 1 June 2015.
 - There are no further data available for the substance or mixture for the considered hazard class.

Guidance on the Application of the CLP Criteria³⁰⁰ provides guidance on the use of these translation tables.

³⁰⁰ Available at the following link: <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp>

- If required by REACH, manufacturers and importers also need to classify substances which are not placed on the market, such as on-site isolated intermediates, transported intermediates or substances for product and process-orientated research and development (PPORD).
- Review of classifications: Manufacturers, importers and downstream users need to follow new scientific or technical developments and estimate whether a re-evaluation of the classification of the substance or mixture they place on the market should be done.
- Harmonised classification and labelling. In some cases, the decision on the classification of a chemical is taken at EU level. It is mandatory for the suppliers of the respective substance or mixture to apply this harmonised classification and labelling. This process often concerns the most hazardous substances, e.g. carcinogenic, mutagenic, and toxic for reproduction or respiratory sensitisers. All previously harmonised substances classifications under the previous legislation (Dangerous Substances Directive) have been converted into CLP harmonised classifications. Member States, manufacturers, importers and downstream users may ask for the classification and labelling of a substance to be harmonised. Proposals can only be submitted for substances, and not for mixtures. Under Article 37(4) of the CLP Regulation, proposals for new harmonised classifications will be considered by the Risk Assessment Committee set up under the REACH Regulation. All the agreed harmonised classifications can be found at the web site for the European Commission's Joint Research Centre.
- Active substances contained in plant protection or biocidal products will have to be classified according to the CLP criteria. In contrast to other substances supplied and used in the industrial supply chain, all hazard classifications of these substances will normally be harmonised at the EU level. The harmonised classifications appear both in Tables 3.1 and 3.2 of Annex VI to CLP. However, where new information is available which may lead to a change of the harmonised classification, the procedure for harmonisation of classification and labelling of substances shall apply in accordance with Articles 36 (2) and 37 (1), (4),(5) and (6).
- The CLP Regulation creates a Classification and Labelling Inventory. The Classification & Labelling (C&L) Inventory is a database which contains classification and labelling information on substances notified under Regulation (EC) No 1272/2008 (the CLP Regulation) and registered under Regulation (EC) No 1907/2006 (the REACH Regulation). The following information is published according to CLP (Article 42):
 - the name in the IUPAC Nomenclature for substances classified with certain hazard classes or categories set out in Article 119(1)(a), without prejudice to Article 119(2)(f) and (g) of REACH
 - the name of the substance as given in EINECS, if applicable, and other numerical identifiers as appropriate and available
 - the classification and labelling of the substance
 - all notifications for any published substance are included in the Inventory. This includes notifications for non-classified substances. It will also contain the list of legally binding harmonised classifications (Annex VI to the CLP Regulation). It is established and maintained by ECHA.
- Related guidance to understand the inventory is available at website of ECHA <http://echa.europa.eu/regulations/clp/cl-inventory>

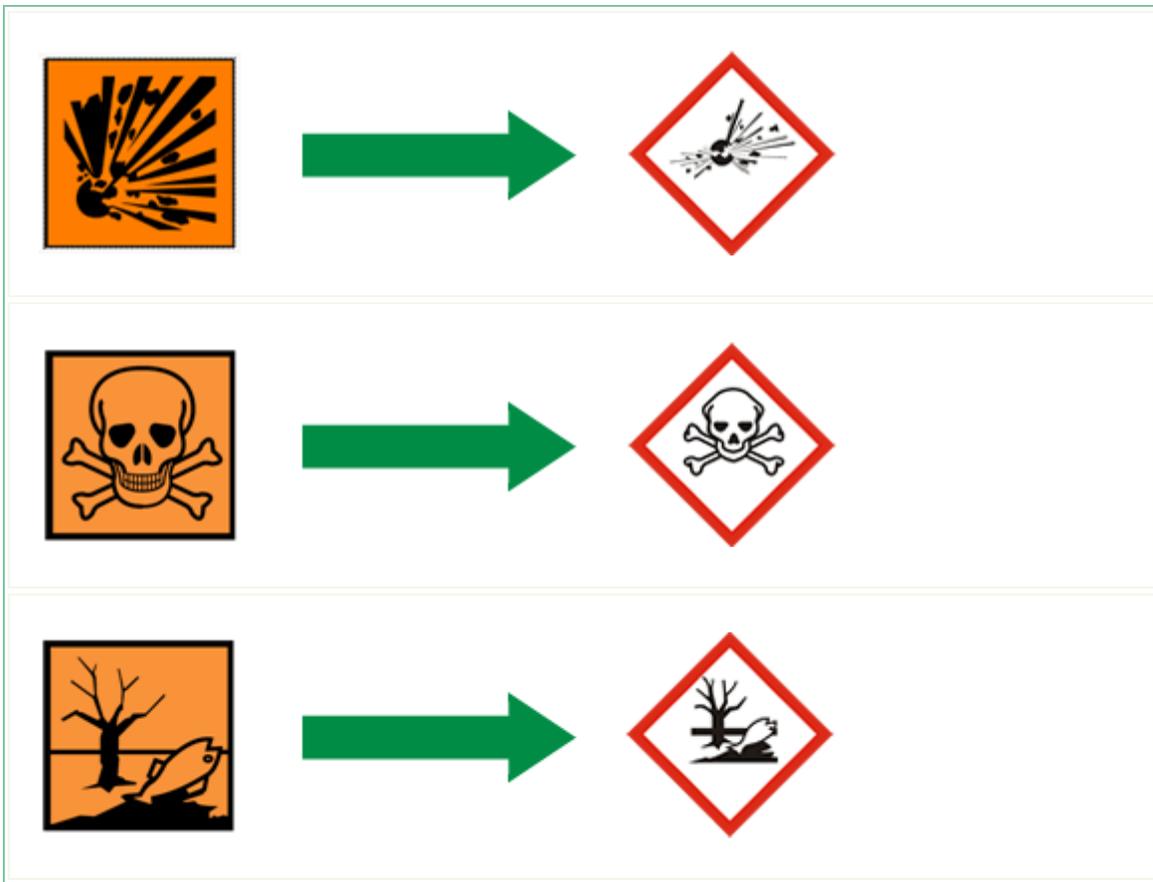
These include:

- Practical guide 7: How to Notify Substances to the Classification & Labelling Inventory, available at: http://echa.europa.eu/documents/10162/13643/pg_7_clp_notif_en.pdf
- Introductory Guidance on the CLP Regulation,
- Guidance on the Application of the CLP Criteria

Two latter guidance are available at: <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp>

4.2.2. Labelling

- Suppliers must label a substance or mixture contained in packaging according to CLP before placing it on the market either when a substance is classified as hazardous or a mixture contains one or more substances classified as hazardous above a certain threshold. This label must include:
 - The name, address and telephone number of the supplier
 - The nominal quantity of a substance or mixture in the packages made available to the general public (unless this quantity is specified elsewhere on the package)
 - Product identifiers
 - Where applicable, hazard pictograms, signal words, hazard statements, precautionary statements and supplemental information required by other legislation.
- A number of labelling elements have changed under the CLP. There are new pictograms; the descriptive Indications of Danger, such as “Flammable” and “Harmful” are replaced by the simpler Signal Words “Danger” and “Warning”; and Risk and Safety Phrases are replaced by Hazard Statements and Precautionary Statements. In many cases these new phrases are very similar to the old phrases, but there are also many new phrases, particularly for the Precautionary Statements. Following the GHS and CLP criteria, many substances and mixtures will be assigned a large number of Precautionary (P) statements –often 20-30 or even more if the product has several hazards. The CLP Regulation recommends that normally no more than six P statements should appear on the label. Selection of these P Statements may be a complex process for some products, as there is currently no guidance on the use of each individual Statement, as there was for the Safety (S) Phrases. There are minimum sizes for labels and pictograms. Additional information required by, for example, the BPD or VOC legislation is considered to be ‘supplemental information’ for the purposes of labelling. For multilingual labels, the hazard and precautionary statements need to be kept together for each language.
- A new design for the existing hazard symbols



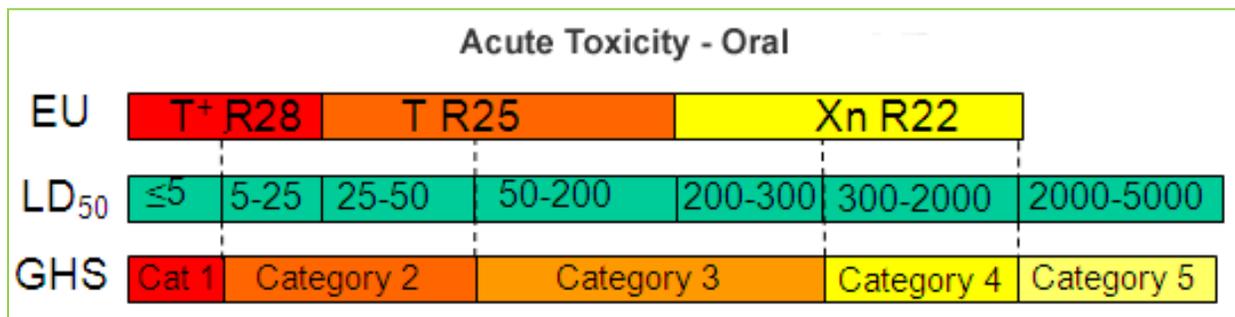
- In total 9 pictograms including 3 new harmonised hazard warning symbols for labels,
 - Physical hazards: explosive, flammable, oxidizing, gases under pressure
 - Health hazards: corrosive, acute toxic, irritant, chronic toxic
 - Environmental hazards: ecotoxic

The new hazard pictograms, as well as pictograms applicable under transport legislation, can be downloaded from the UN website: <http://live.unece.org/trans/danger/publi/ghs/pictograms.html>



- Hazard class are divided in three categories:
 - Physical hazards, from 2.1 to 2.16, characterising risks due to physico-chemicals properties. For example: 2.1 Explosives, 2.6 Flammable liquid, 2.15 Organic peroxide;
 - Health hazards, from 3.1 to 3.10. For example: 3.2 Skin corrosion, 3.7 Toxic to reproduction;
 - Environment hazard: 4.1 Hazardous to the aquatic environment (acute and chronic).
- According to the hazard class it belongs to, hazard categories have different symbols:
 - letters: in hazard class 2.15 organic peroxide is the category A Heating may cause an explosion.
 - figures: in hazard class 2.1 Explosives is the category 1.1 Explosive, mass explosion hazard.
 - figures and letters: in hazard class 3.3 Eye damages/Irritation is the category 2B Causes eye irritation.
- Hazard statements are the combination of a hazard class and a hazard category. It should be symbolized by H. Example: H240 Heating may cause an explosion for Organic peroxide (2.15) category A. This codification is still under discussion and might be amended. Hazard statements are symbolized with the followings codes:
 - P1XX for General statements
 - P2XX for prevention statements.
 - P3XX for Response statements.
 - P4XX for Storage statements.
 - P5XX for Disposal statements

New scientific criteria to assess hazardous properties of chemicals: the diagram below demonstrates there are differences between the definitions for 'acute toxicity - oral' under the existing system compared to the new GHS criteria.



- New precautionary statements for labels, for example:
 - P102 - Keep out of reach of children
 - P271 - Use only outdoors or in well-ventilated area
 - P410 - Protect from sunlight
- A number of challenges will be faced in the design of new labels. The new pictograms, which are diamond shaped, rather than rectangular, will take up more space on the labels, as it is difficult to make text flow around them. It is also possible for products to attract up to 5 or 6 hazard pictograms, compared to a maximum of 4 under the DSD and DPD. Furthermore, many of the new hazard and precautionary statements are longer than the old risk and safety phrases, again requiring more space on the label. These issues are expected to particularly challenge suppliers trying to maintain the readability of labels for small packages, and also packages with multi-lingual labels.
- CLP provides certain exemptions for substances and mixtures contained in packaging that is small (typically less than 125ml) or is otherwise difficult to label. The exemptions allow the supplier to omit the hazard and/or precautionary statements or the pictograms from the label elements normally required under CLP.
- If substances or mixtures are supplied to the general public, then child-resistant fastenings and/or tactile warnings of danger have to be attached to their packaging in case these substances or mixtures display certain hazards or if the packaging contains methanol or dichloromethane.
- As a general rule, the labelling or marking in accordance with transport legislation is sufficient when the outer packaging of a hazardous substance is subject to both the transport and the CLP rules. The CLP labelling does not need to appear. When a hazard pictogram required by CLP relates to the same hazard as in the rules for the transport of dangerous goods, the CLP pictogram does not need to appear on the outer packaging.
- Hazard pictograms shall be in the shape of a square set at a point. They shall have a black symbol on a white background with a red frame sufficiently wide to be clearly visible. Each hazard pictogram shall

cover at least one fifteenth of the surface area of the harmonised label and the minimum area shall not be less than 1 cm².

- A mechanism will be required for ensuring that these packaging and labelling requirements are met. This could be achieved at the same time as installations are inspected for other environmental or health and safety purposes, or could be achieved by a specific inspection. Packaging and labeling could also be inspected in the market place.
- Suppliers who are concerned about disclosing the full composition of a mixture, on the label or in the safety data sheet, can request the use of an alternative chemical name for a substance to protect the confidential nature of their business. Until 1 June 2015, suppliers should submit their requests to ECHA or to a Competent Authority depending on whether the mixture is classified and labelled according to CLP or the previous legislation (Dangerous Preparations Directive). An alternative chemical name can be approved in these cases: 1) when the substance does not have a EU workplace exposure limit, 2) the use of the alternative name meets the need to provide enough information to take necessary health and safety precautions at the workplace and that the risks from handling the mixture can be controlled, and 3) the substance is classified only in certain hazard classes.

4.2.3. Notification

- The classification and labelling of any registered or hazardous substance for sale must be notified to the ECHA for inclusion in the classification and labelling inventory that the agency regularly updates.
- Notification is required by Manufacturers and Importers of substances. The definitions of Manufacturer and Importer under CLP are the same as for REACH.
- Downstream users who purchase all their raw materials within the EU do not need to submit any notifications, as this should already have been done by a company further up the supply chain.
- Non-EU companies should not submit notifications. They should provide the necessary data to their customers who are the importers. If, for confidentiality reasons, the non-EU company does not want to share this information with all of its customers, it can ask one of its customers to submit on behalf of a group of importers. Where an Only Representative (OR) has been appointed, then the non-EU company can use them to submit the notification. However, ORs have no legal role or obligations under CLP. EU guidance suggests the non-EU company supplies the OR with a sample of the product, so that they become responsible for import and are therefore entitled to submit a notification.
- Notification is required for:
 - All substances subject to REACH Registration, whether they are hazardous or not. This includes isolated intermediates. Substances contained in articles and subject to registration under REACH Article 7 also need to be notified;
 - Hazardous substances which are placed on the market, in quantities of less than 1 tonne per year. There is no minimum quantity threshold for notification, so notification will be required even if only a few grams are supplied;
 - Hazardous substances present in mixtures placed on the market, where the amount of the hazardous substance in the mixture is above the concentration limits specified in either CLP

(CHIP in the UK) and which results in the classification of the mixture as hazardous. A useful table of these concentration limits is provided at the end of Practical Guide 7: How to notify substances to the classification and labelling inventory. Importers of mixtures which are classified as hazardous will therefore need to obtain sufficient information from their suppliers to understand which components of the mixture are hazardous and above the relevant concentration limits.

- Placing on the market is defined as making a substance available either commercially or free of charge. For Importers, introducing a substance into the territory of the EU is also considered placing on the market, so notification is required even if the substance is imported for their own use.
- Where a substance has been given a harmonised classification (i.e. in Annex VI of CLP), companies are still required to submit a notification for that substance, however, in this case the task is simplified as they must use the harmonised classification. Companies may however, identify additional hazards for a harmonised substance that has not been covered by the harmonised classification.
- Notification is not required if the substance has already been registered, and the registration dossier includes the classification according to both the DSD and CLP. Where a NONS dossier has been transferred into REACH then the registrant will need to update their dossier with the CLP classification as soon as possible. Where a NONS dossier has not been transferred into REACH, e.g. because the tonnage is less than 1 tonne per year, then a notification will still be required.
- Substances in the finished state and intended for the final user or for uses for which there is specific legislation in place, e.g. radioactive materials, medicinal products, cosmetic products and food and feeding stuffs are exempted from the requirement to notify. Substances for R&D may also be exempted provided they are not placed on the market and are used under controlled conditions. Companies wishing to take advantage of this exemption need to take care however with the definition of not placing on the market. Transfer of the substance between two different laboratories in a company is considered to be placing on the market if the two laboratories are part of different legal entities.
- Since the initial deadline for notification has passed, notifications for new substances that are manufactured or imported for the first time should be made within one month of placing the substance on the market.

4.2.4. Safety Data Sheets

- There are also requirements relating to the provision of safety data sheets. These contain information for the user on the safe handling of the substance during storage, transport and disposal and information on hazards, firefighting, first aid, accidental release measures and toxicological and ecotoxicological properties. Once again a system of compliance monitoring will be required to ensure that data sheets are both provided and accurate.
- Once the product is relabelled in accordance with CLP, the new classification, including the label elements, will need to be included in section 2 of the SDS. The CLP classifications of significant components will also need to be included in section 3. Any change in the classification will also need to be reflected in the information provided in other sections of the SDS. These classifications should be consistent with the new Classification and Labelling Inventory.

4.2.5. Technical Guidance

- The European Chemicals Agency (ECHA) oversees the CLP Regulation at European level and is responsible for providing suitable guidance for chemical suppliers and others who may have an interest in how the Regulation is intended to be applied. ECHA has produced several guidance documents available at: <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp>.

These include:

- *Introductory Guidance on CLP (2015)* provides guidance on basic features and procedures laid down in the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
 - *Guidance on the Application of the CLP Criteria (2015)* provides detailed guidance on the application of the CLP criteria for physical, health and environmental hazards.
 - *Guidance on CLH dossiers (2014)* provides guidance for Member State Competent Authorities and for manufacturers, importers and downstream users (DU) on how to compile and submit a proposal for harmonised classification and labelling of a substance. It also explains which procedure a corresponding dossier will undergo once it has been submitted.
 - *Guidance on substance identification (2014)* describes how to name and identify a substance under REACH and CLP.
 - *Guidance on labelling and packaging (2011)* provides guidance on how to label and package substances and mixtures in accordance with the CLP Regulation.
- In addition, ECHA has prepared several other practical guides providing practical information on REACH and CLP requirements and best practice on how to fulfil them, which are available at: <http://echa.europa.eu/practical-guides>
 - The competent authorities should strive to work closely together with the European Commission, trade associations, industry and other stakeholders to develop guidance and help educate those affected.

4.2.6. Information and Reporting

- Under REACH and CLP Regulations chemical companies must submit to ECHA various key information about the substances that they manufacture, import or (in some cases) use. This includes information on the hazard properties of the substance, on the classification and labelling, and includes also their assessment of the potential risk presented by the substances, where required. This information is submitted to ECHA for several purposes, including establishing a centralised database which makes this information available to the public and to the authorities (ECHA, Commission, Member State Competent Authorities and Enforcement Authorities).
- Under transitional measures (Art. 136(1) and 136(2) of REACH), manufacturers and importers must submit outstanding data on existing priority substances that the European Commission has requested from them directly to the Member State Competent Authority (MSCA) in charge.

5. COSTS

The main costs to governments of implementing this Regulation comprise costs of establishing the implementation systems, the day-to-day costs of maintaining them, the employment of trained staff, and the payments to specialist advisors/consultants for carrying out substance evaluation, for running the national helpdesk and attending committee meetings and for special events.

For the regulatory authority, the costs are those of establishing the implementation systems, the day to day costs of maintaining it and managing notifications.

The implementation costs to be borne by industry are very much higher than those borne by governments. In industry, the manufacturers of new substances will bear major costs arising from the self-classification, review of classifications and harmonized classification. Other costs will arise from the new labelling requirements, involving new pictograms, risk phrases etc. Also, more emphasis will have to be given to compliance checks, involving packaging and labelling controls, as the existing requirements in Candidate Countries are harmonised with those within the EU.

Table 13. Checklist of the Types of Cost Incurred to Implement the Regulation

Checklist of the Types of Cost Incurred to Implement the Regulation
<p>Initial set-up costs:</p> <ul style="list-style-type: none">• Developing initial implementing/application strategy also to assess implications moving from current system to GHS/CLP approach which also may involve certain „Knock-on” effects effecting obligations under other occupational health and safety, environmental and transport legislation;• Establishment of competent authority(ies), help desks and the initial help of external experts or consultants (mainly cost for the government);• Building capacity for national helpdesks and substance evaluation (costs for the government);• Establishment of a system of inspections and penalties (cost for the government, which partly can be offset by administrative fees for inspections and of course through the levying of fines);• Training of staff and inspectors (mainly for the government).
<p>Ongoing costs:</p> <ul style="list-style-type: none">• Mechanisms for cooperation with ECHA, the Commission and competent authorities of other Member States (both for industry and governments);• Self-classification, review of classifications, harmonised classifications (mainly for the industry);• Notifications (mainly for industry)• Labelling and packaging of substances, mixtures and articles containing such (for industry)• Training of staff and hiring of external experts (both for government and for industry).

THE DIRECTIVE ON THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES

Official Title: Directive 2010/63/EU of the European Parliament and of the Council of the 22 September 2010 on the protection of animals used for scientific purposes

Implementing legislation

Commission Implementing Decision 2012/707/EU of 14 November 2012 establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes (OJ L 320/33, 17.11.2012)

Commission Implementing Decision 2014/11/EU of 20 December 2013 correcting Annex II to Implementing Decision 2012/707/EU establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes (OJ L 10, 15.1.2014)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

In 1986 the Council adopted Directive 86/609/EEC in order to eliminate disparities between laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes. Since the adoption of that Directive, further disparities between Member States had emerged and some Member States had adopted more stringent provisions on animals used for scientific purposes, while others only applied the minimum requirements laid down in Directive 86/609/EEC. Directive 2010/63/EU was adopted setting out more detailed rules in order to reduce such disparities by approximating the rules applicable in that area but also to reflect new scientific knowledge in respect of factors influencing animal welfare as well as the capacity of animals to sense and express pain, suffering, distress and lasting harm.

The Directive applies to animals used for one of a number of specified purposes, including basic and applied research, the efficacy and safety testing of drugs, foodstuffs and other substances or products and those used for the purposes of higher education and training. An animal procedure must not be performed if the aim can also be achieved by an alternative method which does not entail the use of an animal. The Directive specifies standards for accommodation and care of animals, welfare requirements for the avoidance of pain or stress, and the humane treatment of animals at the end of a procedure. Establishments using animals, as well as breeding and supplying establishments, must be authorised by the competent authority. The Member States must ensure that these establishments are run in compliance with the terms of the Directive. No testing can be performed without an authorisation on the basis of a favorable project evaluation including harm benefit assessment.

Some of the main elements of 2010 Directive can be summarised as:

- Mandatory authorisation and project evaluation for all applications to use animals, including evaluation that the 3Rs (Replacement, Reduction and Refinement of the use of animals) are fully applied.
- Establishment of Union Reference Laboratory at the JRC to promote the development, validation and use of alternative methods, not only in toxicology, but now also in the areas of basic and applied research, and to promote dialogue on the 3Rs between legislators, regulators and all relevant stakeholders.
- A requirement that Member States contribute to the development and validation of alternative approaches, promote 3Rs at a national level and assist the Commission in identifying and nominating suitable laboratories to participate in validation studies.
- Systematic prospective severity classification of procedures on animals with detailed statistical reporting on actual occurred severities.
- A ban on the use of great apes, with limited opportunities to lift it.
- Periodic 3R-oriented thematic reviews by the Commission, paying specific attention to technological developments and new scientific and animal welfare knowledge.

The Directive is implementing the commitments under the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes, to which EU is a party. Decision 1999/575/EC concerns the conclusion by the EU of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes. On 15 June 2006, the Fourth Multilateral Consultation of Parties to the European Convention for the protection of vertebrate animals used for

experimental and other scientific purposes adopted a revised Appendix A to that Convention, which set out guidelines for the accommodation and care of experimental animals. Commission incorporated those guidelines in a Commission Recommendation of 2007/526/EC. However, it is important to note that main part of these guidelines is now introduced as compulsory standards through Annex III of Directive 2010/63/EU. Furthermore, the Directive sets out far more stringent standards and controls on the care and use of animals for scientific purposes than those contained in the Convention.

Animal welfare is a value of the Union that is enshrined in Article 13 of the Treaty on the Functioning of the European Union (TFEU).

Directive represents an important step towards achieving the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so focusing on the Three “Rs” (Replacement, Reduction and Refinement of the use of animals). To that end, it seeks to facilitate and promote the advancement of alternative approaches. It also seeks to ensure a high level of protection for animals that still need to be used in procedures. The Directive prohibits new, more progressive legislation if not already in place and thus harmonises but also freezes the 28 Member States at a relatively high level. This Directive will be reviewed regularly in light of evolving science and animal-protection measures.

Member States had to adopt and publish, by 10 November 2012, the laws, regulations and administrative provisions necessary to comply with this Directive and apply these provisions as from 1 January 2013. Art. 64 of the Directive lays down some transitional arrangements for projects approved prior to 1 January 2013 not extending beyond 2018.

In 2012 the Commission Implementing Decision 2012/707/EU was adopted, which sets out a common format for submitting information on the use of animals for scientific purposes as referred to in paragraphs 1, 2, and 3 of Article 54 of Directive 2010/63/EU. The new system will allow the Commission to assess effectiveness of the implementation of the legislation and help ensure consistency in its application. The first data under the new statistical reporting format was collected at national level from 1 January 2014. Since its adoption, the Commission together with Member States and all key stakeholders have developed a number of consensus Guidance Documents to facilitate implementation of the Directive. More information on the use of animals for scientific purposes, the Guidance Documents (available in all community languages under "Publications"), the new implementing Decision, reports on "The Development, Validation and Legal Acceptance of Alternative Methods to Animal Tests in the Field of Cosmetics and a list of Member States' competent authorities on can be obtained at: http://ec.europa.eu/environment/chemicals/lab_animals/index_en.htm

Finally, it is important to note the relevance of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, REACH Regulation (EC) No 1907/2006 and the CLP Regulation (EC) No 1272/2008 all introducing data sharing obligation to minimize the need for experiments with vertebrates.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Designate one or more competent authorities responsible for the implementation of this Directive, which does not have to be public authorities provided that they have sufficient expertise and infrastructure and there is no conflict of interest. (Art. 59(1))
- Designate a national authority serving as a contact point (Art. 59(2)).
- Determine whether to keep more stringent requirements than those set out in the Directive provided that they were in place already in force on 9 November 2010 (Art. 2)
- Adopt and publish, by 10 November 2012, the laws, regulations and administrative provisions necessary to comply with this Directive and apply these provisions as from 1 January 2013 (Art. 61(1)).
- Introduce the necessary binding rules on penalties to ensure that the provisions of the Directive are fully implemented. The penalties shall be effective, proportionate and dissuasive. (Art. 60)
- Take the necessary steps to ensure compliance with the transitional arrangements for projects which have been approved before 1 January 2013, which have a maximum duration not extending beyond 1 January 2018. Such projects do not have to apply Arts. 36-45 of the new Directive but rather the provisions of the previous Directive (86/609/EEC) apply. For projects approved before 1 January 2013 which have a longer duration than 1 January 2018, these have to acquire a project authorization by 1 January 2018. (Art. 64)
- Set up a system of prior authorisation of user, breeding and supplying establishments. (Arts. 36-44) including compliance with regard to requirements for personnel, their education, training and competence. In addition, a system has to be set up for dealing with project authorisations set out in Arts. 40, 42 and 44
- Set up an inspection system to be administered by the competent authorities to ensure that regular inspections are carried out of all breeders, suppliers and users to verify compliance with the Directive. The measures involved include:
 - Carry out an initial risk analysis, taking into account criteria in Art. 34(2), to establish the frequency of inspections for the various establishments, taking into account the minimum criteria laid down in Art. 34. For instance breeders, suppliers and users of non-human primates have to be inspected annually;
 - Determine the proportionate of routine and non-routine inspections;
 - Setting up a recording system to ensure that records of all inspections are kept for five years;
 - Establish a procedure for assisting Commission in its control of the operation of national inspections (Arts. 34 and 35)
- Establish procedures to ensure mutual recognition of data from other Member States that are generated by procedures recognised by the legislation of the Union. (Art. 46)

- Establish a system whereby procedures are classified as ‘non-recovery’, ‘mild’, ‘moderate’, or ‘severe’ on a case- by-case basis using the assignment criteria set out in Annex VIII (Art. 15)
- Take measures to contribute to the development of alternative approaches (not involving animal testing or fewer animals or with less painful procedures) and to support research in the field. For this purpose, Member States have to:
 - assist the Commission in identifying and nominating suitable specialised and qualified laboratories to carry out such validation studies;
 - promote alternative approaches and ensure wide dissemination of information regarding such approaches
 - nominate a single contact point to provide advice on the suitability of alternative approaches to be subject to the validation procedure, (Art. 47)
- Establish a national committee for the protection of animals used for scientific purposes, which will advise the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice. (Art. 49)
- Set up a procedure for making decisions on using the safeguard clauses in Article 55 regarding using non-human primates for purposes referred to in Article 8(1)(a)(i) or to use procedures involving long-term severe pain, suffering or distress. This may be on grounds referred to in Art. 55(1) (2) such as preservation of species or in relation to an unexpected outbreak of a life-threatening condition in human beings. Such measures must first be subject to prior notification to the Commission, which (within 30 days) may approve or deny the request. (Art. 55)

2.2. Regulation

- Ensure that all breeders, suppliers and users authorized by the competent authority and that they fully comply with the requirements of the Directive. This authorisation may be granted for a limited period. Where there are significant changes to the establishment, the authorisation must be renewed. The authorisation must specify the persons responsible for overseeing implementation of the Directive. (Art. 20)
- Ensure that the appropriate measures are taken, including suspending or withdrawing authorisation in case breeders, suppliers and users are in case of non-compliance with the Directive. (Art. 21)
- Ensure that establishments fulfil the requirements in Arts. 22-29:
 - That the installations and equipment are of a design, construction and using methods suitable for the type of animals housed and the procedures to be performed, taking into account requirements in Annex III (Art. 22);
 - Ensure that the establishments have sufficient staff and that they have the appropriate education and training, taking into account Annex V and meeting the minimum requirements, as published

- by the competent authority. They shall have received scientific instruction relevant to the work undertaken and have specific knowledge of the species concerned. (Art. 23);
- That each establishment has one or several persons on site responsible for overseeing the animal welfare and care and that all staff dealing with animals have access to species specific information and they are adequately educated, trained and competent, that animals are not subject to unnecessary suffering and that projects follow the project authorisation (Art. 24);
 - That there is at least one veterinarian with expertise in laboratory animal medicine having advisory duties designated for the establishment (Art. 25);
 - That each breeder, supplier and user sets up an animal welfare body, involving the person involved in welfare and care and involve other scientific members and the designated veterinarian, where applicable. This body shall carry out tasks such as advising staff on animal welfare and establish and review internal operation process in terms of monitoring, reporting as well as following the development and results of the projects (Arts. 26 and 27);
 - That breeders using non-human primates have a strategy for increasing proportion of animals used which are offspring of those bred in captivity (Art. 28);
 - Adopting a rehoming scheme or programme of rehabilitation for wild animals (Art. 29)
- Ensure that all projects are subject to prior authorisation and evaluation set out in Arts. 36-40 such as:
 - Performing a project evaluation, demonstrating that the project is justified on educational or scientific grounds or as mandated by law, that the use of animals is justified and project is designed to have the most humane procedures possible. The evaluation shall for instance include an evaluation of objectives and an assessment of compliance with principle of replacement, reduction and refinement, assessment of procedure classification and a harm-benefit analysis (Art- 38);
 - First obtaining a project authorisation a favourable project evaluation from the competent authority (Art. 36)
 - Ensuring that the project is fully carried out pursuant to the authorisation,
 - The project application must contain a project proposal, a non-technical summary and information listed in Annex VI (Art. 37);
 - That certain projects are subject to a retrospective assessment carried out by the competent authority at the end of the project to assess whether objectives of project have been achieved, the harm inflicted on animals and the number of animals used and the severity of procedures, Retrospective assessment is mandatory for projects using non-humane primates. (Art. 39);
 - That the project authorisation is limited to maximum of five years and only cover procedures which have been subject to evaluation and classification and which specify the user of the project, the persons responsible for compliance with authorisation. (Art. 40);
 - Ensure that projects approved after 1 January 2013 fully complies with the provisions of the Directive. (Art. 64)
 - In the evaluation of applications for authorization of using animals in experiments, take into account the principle of replacement, reduction and refinement set out in Art. 4, meaning that where possible

projects shall not involve using animals if there are equally satisfactory methods not involving animals and always try to minimize the pain, suffering and distress of animals. (Art. 4)

- Prohibit experiments using endangered species listed in Annex A to Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade, unless justified under Art. 5 (b)(i), (c) or (e) of Art. 5 of this Directive and there is scientific justification for using Annex A species (Art. 7).
- As a principle not allow use of non-human primates in procedures, only allowed if conditions in Article 8 are fulfilled (Art. 8)
- Ensure that wild animals are used for experiments only if other animals would not suffice for the aims of the experiment. If wild animals are used, ensure that their capture is carried out by a competent person using humane methods (Art. 9).
- Ensure that stray animals of domestic species are not used in experiments, unless competent authority grants an exemption (Art. 11).
- Ensure that dogs, cats and non-human primates are provided with a unique identification mark, in the least painful manner, before they are weaned or as soon as they are taken into an establishment (Art. 32).
- Ensure that experimental animals are provided with appropriate housing, freedom of movement, food, water and care, that they can satisfy their physiological and ethological needs to a maximum and that their environmental conditions are checked daily by a competent person, arrangements are made to ensure that any avoidable pain, suffering or distress is discovered and eliminated as quickly as possible. The care and accommodation must meet the requirements in Annex III, applicable as from the dates specified (Art. 33).
- Ensure that procedures are in principle avoided if there are alternative options not involving animals. Where they are unavoidable that have to be in compliance with Chapter III (Arts. 12-19) which include:
 - Ensuring that procedures are carried out in the user's establishment and are carried out for a specific project (Art. 12)
 - Choosing a procedure which minimises the number of animals used, use animals with the lowest capacity to experience pain, suffering, distress, cause the least pain, suffering or distress while being the most likely to provide satisfactory results. Death as the end-point of a procedure shall be avoided as far as possible and where unavoidable limit number of affected animals and their suffering. (Art. 13);
 - Ensure that animals set out in Annex I may only be used in procedures where they have been bred for such use, observing the specific requirements as regards the use of non-human primates, which will be applicable from the dates indicated in Annex II (Art. 10)
 - Avoid unnecessary pain, suffering and distress and minimise severe pain by using appropriate anaesthesia methods (Art. 14)
 - Ensure the procedure is classified as 'non-recovery', 'mild', 'moderate', or 'severe' on a case-by-case basis using the assignment criteria set out in Annex VIII (Art. 15)

- Ensuring that the reuse of animals already used in a procedure complies with conditions in Art. 16 and that animals are not used more than once in experiments entailing severe pain, distress or equivalent suffering;
 - The procedure shall end where no further observations can be made. A veterinarian or other competent person shall decide whether to keep an animal alive or not, but shall be killed if it is likely to remain in moderate or severe pain, suffering or distress. (Art. 17);
 - Promote the sharing of organs and tissues of animals killed (Art. 18);
 - Rehome or return the animals to a suitable habitat or husbandry system where conditions in Art. 19 are met, ensuring good animal well-being and no danger to public health or the environment. (Art. 19)
- Ensure that animals are killed in the establishment of a breeder, supplier or user (unless field study), by a competent person, with minimum pain, suffering and distress. Ensure that the method of killing for animals covered in that Annex is used unless the competent authorities have granted an exemption under grounds set out in Art. 6(4). (Art. 6)
 - Subject to the use of the safeguard clause in Article 55(3), ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated (Art. 15(2))
 - Recognise the validity of data generated by experiments carried out in other Member States, unless further testing is necessary to protect public health and safety (Art. 46).

2.3. Information and Reporting

- Report to the Commission on:
 - the laws, regulations and administrative provisions implementing the provisions of the Directive. (Art. 61(1)).
 - the binding rules on penalties for non-compliance. (Art. 60)
 - implementing provisions, focusing on Articles 10(1), 26, 28, 34, 38, 39, 43 and 46, using the common reporting format established by the Commission. First report is due on 10 November 2018 and after that every five years. (Art. 54(1))
 - statistical information using the format established by the Commission. First time for this submission is 10 November 2015 and every year thereafter (Art. 54(2)).
 - exemptions granted under Art. 6(4)(a). Such information has to be submitted at annual intervals, providing sufficient information using the common format established by the Commission (Art. 54(4))
- Details of a national authority serving as contact point for the purposes of this (Art. 59(2)).
 - Ensure that where the contact person referred to in Article 24(1) and Art. 25 ensuring compliance with the Directive, changes, this is notified to the competent authority. (Art. 20(4)).

- A Member State which has adopted a provisional measure in accordance with paragraph 1, 2 or 3 shall immediately inform the Commission and the other Member States thereof, giving reasons for its decision and submitting evidence of the situation as described in paragraphs 1, 2 and 3 on which the provisional measure is based. (Art. 55(4))
- Ensure that Member States and the relevant establishments keep records:
 - Ensure that establishments keep all the relevant documentation including project authorisations and the result of the project evaluation for at least 3 years from the date of expiry of the project and be made available to the authority. Projects which undergo retroactive assessment shall keep this information at least until the assessment is completed (Art. 45)
 - Member States have to keep records of inspections for at least five years and keep these available for the Commission (Art. 34(5));
 - Ensure that all breeders, suppliers and users keep „animal records”, at least for five years and making this information available to the competent authority, of at least the following:

the number and the species of animals bred, acquired, supplied, used in procedures, set-free or rehomed;

the origin of the animals, including whether they are bred for use in procedures;

the dates on which the animals are acquired, supplied, released or rehomed;

from whom the animals are acquired;

the name and address of the recipient of animals;

the number and species of animals which died or were killed in each establishment. For animals that have died, the cause of death shall, when known, be noted; and

in the case of users, the projects in which animals are used. (Art. 30)

- Ensure that all breeders, suppliers and users of dogs, cats and non-human primates keep an individual history file for each animal. This file shall be established at birth and be kept at least for three years after the death or rehoming of the animal and making this information available to the competent authority. This information shall include:
 - identity;
 - place and date of birth, when available;
 - whether it is bred for use in procedures; and
 - in the case of a non-human primate, whether it is the offspring of non-human primates that have been bred in captivity. (Art. 31)
- Ensure that advice and decisions given by the animal-welfare body referred to in Article 27 are kept for at least three years and made available to the competent authority (Art. 27(2))
- Ensure that establishments notify the competent authority of any changes of the person or persons responsible for implementing the Directive (Art. 20(4))

2.4. Additional Legal Instruments

- Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP)

- Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances

These two directives, together with the Animal Experiments Directive, establish a system of harmonised test methodologies and quality standards that allow the mutual recognition of test results.

- Council Decision 1999/575/EC of 23 March 1998 concerning the conclusion by the Community of the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, the EU has become party to the Council of Europe Convention ETS.
- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products
- REACH Regulation (EC) No 1907/2006
- CLP Regulation (EC) No 1272/2008

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the checklist below. The key tasks are arranged under subheadings and organised in chronological order of implementation wherever possible.

Table 14. Checklist with Key Implementation Tasks

DIRECTIVE ON THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Appoint a competent authority and national contact point and supply it with necessary human, financial and technical resources.
1.2	Establish a national committee
1.3	Wide consultation with stakeholders involving relevant authorities, breeders, suppliers, users, scientific organs, animal protection organisations also with a view to discuss alternative options
1.4	Set up an authorisation and registration system for establishments using, breeding or supplying animals for experimental purposes.
1.5	Set up a system of authorisation for projects, taking into account requirements on project evaluation, retrospective assessments
1.6	Establish a data collection system regarding the use of animals in experiments and publish the statistical information annually.
1.7	Set up procedures to ensure that persons designing projects, carry out procedures on animals (including killing of animals) and caring for them are adequately trained and have demonstrated competence to perform experiments on animals or to care for animals used for scientific purposes, and that animal welfare bodies are set up in each establishment to advise staff on care and welfare and application of the Three Rs (to Replace, Reduce and Refine the use of animals for scientific purposes)
1.8	Establish a system whereby procedures are classified as ‘non-recovery’, ‘mild’, ‘moderate’, or ‘severe’ on a case- by-case basis using the assignment criteria set out in Annex VIII
1.9	Develop guidance for the competent authorities and for the establishments concerned (e.g. breeders, suppliers and users), detailing their obligations and overall objectives of the Directive)

1.10	Plan the phasing in of the space allowances for housing of animals set out in Annex III taking effect 1.1.2017.
1.11	Establish the procedures for reporting towards the competent authority and towards the Commission
2	Regulation
2.1	Inspect and authorise establishments that breed, supply or use animals.
2.2	Ensure authorisation of projects integrating a systematic, case by case project evaluation carried out by competent authority.
2.3	Ensure that projects approved after 1 January 2013 fully complies with the provisions of the Directive. For projects approved prior to this date, such projects do not have to apply Arts. 36-45 of the new Directive but rather the provisions of the previous Directive (86/609/EEC) apply. For projects approved before 1 January 2013 which have a longer duration than 1 January 2018, these have to acquire a project authorization by 1 January 2018. (Art. 64)
2.4	Publish non-technical project summaries and ensure that commercially sensitive information is not published.
2.5	Set up an inspection system to verify that establishments are run in compliance with the terms of the Directive based on risk analysis including annual inspection that are both announced and unannounced.
2.6	Make sure establishments meet the relevant requirements with stricter requirements concerning the use of non-human primates, which include certain programmes and plans.
2.7	Establish a system of statistical data collection and ensure publication of annual statistical data in line with Commission Implementing Decisions 2012/707/EU.
3	Reporting
3.1	Report to the Commission on: <ul style="list-style-type: none"> • the laws, regulations and administrative provisions implementing the provisions of the Directive; <ul style="list-style-type: none"> – the binding rules on penalties for non-compliance. – implementing provisions, focusing on Articles 10(1), 26, 28, 34, 38, 39, 43 and 46, using the common reporting format established by the Commission. First report is due on 10 November 2018 and after that every five years. – statistical information using the format established by the Commission. Such information has to be submitted annually. – Exemptions granted under Art. 6(4)(a). Such information has to be submitted at annual intervals.

	<ul style="list-style-type: none"> • details of a national authority serving as contact point for the purposes of this as well as changes to this person • the taking of a provisional measure, which shall be immediately reported both to the Commission and the other Member States
3.2	<p>Ensure that Member States and the relevant establishments keep records:</p> <ul style="list-style-type: none"> • Ensure that establishments keep all the relevant documentation including project authorisations and the result of the project evaluation for at least 3 years from the date of expiry of the project) • Member States have to keep records of inspections for at least five years and keep these available for the Commission (Art. 34(5)); • Ensure that all breeders, suppliers and users keep „animal records”, at least for five years and making this information available to the competent authority, of at least the following: • Ensure that all breeders, suppliers and users of dogs, cats and non-human primates keep an individual history file for each animal. This file shall be established at birth and be kept at least for three years after the death or rehoming • Ensure that establishments notify the competent authority of any changes of the person or persons responsible for implementing the Directive (Art. 20(4))

3.2. Phasing Considerations

Experience within Member States suggests that the most demanding and time-consuming tasks associated with implementing this Directive are:

- transposing the requirements of the Directive into national legislation and policy due to possible extensive discussions among the public;
- the preparation of an authorisation system for animal use;
- instituting an authority responsible for monitoring user, breeding and supplying establishments; and
- the collection of statistical data according to the harmonised format including assurance of data quality and timeliness.

These tasks should, therefore, be planned to commence during the initial phase of implementation.

During the whole transposition process, it should be borne in mind that legislation on animal use is a very controversial and politically sensitive issue. The government should be prepared for strong intervention by animal rights groups. Moreover, the public is likely to follow the legislation process very closely. Therefore, a well-reflected communications and public participation policy should be developed during the legislative process.

Also note the transitional arrangements for projects approved prior to 1 January 2013 and not extending beyond 1 January 2018, which do not have to apply Arts. 36-45 of the new Directive but rather the provisions of the

previous Directive (86/609/EEC) apply. For projects approved before 1 January 2013 which have a longer duration than 1 January 2018, these have to acquire a project authorization by 1 January 2018.

4. IMPLEMENTATION GUIDANCE

The Directive aims to abolish trade barriers between EU Member States arising from the different legal requirements for the treatment of animals used for experimental purposes. Furthermore,

The Directive is designed to limit the use of animals in scientific experiments to a minimum. In cases where there are no suitable alternatives, animal experiments must be conducted so that the animal's pain, suffering and distress during the experiment is minimised as much as possible.

Member States must introduce an authorisation or registration system for all establishments using, breeding or supplying animals for experimental purposes. As pointed out above, the Directive requires a systematic authorisation and evaluation of all projects using animals. These establishments must be subject to inspections to ensure compliance with the requirements of the Directive. Member States and the Commission should contribute to the development and validation of alternative techniques that involve fewer animals or entail less painful procedures. This is also an approach supported by the Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, which provides for data sharing requirements to reduce the need for procedures involving vertebrates.

Implementation of the specific requirements of this Directive will be influenced by the present status, needs and conditions concerning animal experiments in each candidate country. However, drawing upon the collective experience of the Member States, a number of general observations and good practice suggestions for implementing this Directive are presented below.

The National Contact Points of the Member States responsible for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes and the Commission met on 6-7 October 2011 to reach consensus and guidance on application of selected provisions with a view to finding a common approach throughout the EU. The below are texts from this guidance document, which can be obtained at: http://ec.europa.eu/environment/chemicals/lab_animals/interpretation_en.htm

Article 3 - Definitions for a procedure and project

A **project** means a programme of work having a defined

scientific objective and involving one or more procedures. Projects can vary in size and complexity, for example, from the work of a single scientist consisting of a single blood harvest procedure in a single species, to an entire department's drug discovery programme, which involves many scientists, multiple complex procedures and a wide range of species.

Procedure means any *use*, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering or distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle according to good veterinary practice. Within a project, procedures will be performed to meet a defined scientific purpose. Procedures may be simple or complex depending on the purpose. The purpose may be achieved by using a single step procedure (for example withdrawal of blood), but much more commonly requires a number of steps used in combination to achieve a single outcome, and which requires the use of the same animal (for example antibody production would generally require a number of antigen injections to stimulate antibody production, and a number of blood samples to achieve the desired outcome).

Examples of Procedures

A single subcutaneous injection of a test substance may be given in a pharmaceutical project to attain the objective of understanding the drug distribution within the body tissues. The animal is then killed by a method listed in Annex IV.

This project comprises of one procedure (the injection of the test substance) which may cause the animal pain, suffering, distress or lasting harm. In contrast, a procedure to assess the effect of the test substance on blood pressure using telemetry would require a number of separate technical steps to be carried out to meet this single scientific purpose (multi – step procedure). The animal would need to be anaesthetised, blood pressure transducer implanted and, following a suitable recovery period, administered the test substance by subcutaneous injection. The animal is then killed by a method listed in Annex IV. In this example three steps namely anaesthesia, surgical implantation of blood pressure transducer and injection of the test substance) need to be used in combination to meet the single scientific purpose of understanding the effects of the substance on blood pressure.

Article 16 - Use, re-use and continued use

Use

The “use” of an animal within a project extends from the time the procedure (or first procedure/technique in a series) is applied to it, to the time when the observations, or the collection of data (or other products) for a particular scientific purpose (usually a single experiment or test), are completed.

Re-use

“Re-use” is a term to indicate the subsequent use of an animal which has already completed a procedure (or series of procedures/techniques) for a particular scientific purpose.

Continued Use

This is a term not included in the Directive, but can be used to describe the situation when the single “use” of an animal extends over more than one project or across different procedures within the same project. This arrangement can simplify project applications and avoid undue repetition.

Example 1 - Re-use

Purpose 1: to obtain sheep blood to make diagnostic plates for bacteriology.

Purpose 2: to determine the effect on blood parameters in sheep of a test dietary supplement, which may have adverse effects.

First use

A sheep is used on the first procedure to obtain a blood sample for use in preparation of diagnostic plates.

Second use

The same animal is then used on a second unrelated project to study the metabolism of a dietary supplement, blood samples are taken for analysis and other non-invasive measurements are made.

4.1. Planning

- Identify and nominate the competent authorities, contact points etc. If it is judged that a non-public body might be more efficient in fulfilling the obligations of the competent authority and it has sufficient expertise and resources and does not have a conflict of interest, candidate countries should consider appointing this body. A national committee has to be set up for the protection of animals used for scientific purposes. It shall advise the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice. This committee should consult with the main stakeholders including animal welfare protection groups.
- A number of steps are required to ensure efficient authorisation, evaluation and inspection procedures. Candidate countries are advised to consult the existing Member States and their designated contact points.
- Ensure wide stakeholder consultation prior to the implementation of the provisions of the Directive. This consultation should involve all major stakeholders such as industry, biomedical scientists, consumer organisations and animal-welfare groups. Such consultation will certainly ensure a more efficient, timely and coordinated implementation. In this consultation, the use of alternative approaches should be emphasised and efforts made at national and EU level on this.
- The Directive on the use of animals for scientific purposes introduces several novelties such as more detailed and stringent procedures for animal testing. It also requires a more pro-active approach in finding alternative approaches, meaning procedures not involving animals or to a more limited and humane extent. To this end, the Union Reference Laboratory has been established which has as its main task to coordinate and promote the development and use of alternative approaches. This Laboratory also acts as a general focal point for exchange of information also between legislators, regulators and relevant stakeholders (industry, biomedical scientists, consumer organisations and animal-welfare groups. Any measures on development and promoting alternative approaches at national level should be coordinated with the Union Reference Laboratory to acquire best practices, obtain useful information and for effective stakeholder consultation.

Examples from a Member State:

United Kingdom: In the UK, a detailed impact assessment was undertaken with the lead of the Home Office cooperating with the Department of Health, Social Services and Public Safety Northern Ireland (DHSSPSNI). Stated as objectives of the implementing policy: ” The principal policy objective is to comply with UK Treaty obligations to transpose the provisions of Directive 2010/63/EU into UK legislation fully and appropriately. Additional objectives are to do so adopting measures which are proportionate; provide for efficient and effective regulation and appropriate standards of animal welfare and protection; promote the use of alternatives to animal use; avoid unnecessary administrative and regulatory burdens; and support the success, sustainability and competitiveness of the UK research and science base. UK opted for transposing the Directive retaining the current higher UK standards and requirements, where appropriate, as allowed under Article 2 of Directive 2010/63/EU.

In this impact assessment the Home Office checked impact on:

- Statutory equality duties
- Economic impacts (i.e. competition, small firms)
- Environmental impacts (i.e. greenhouse gas assessment, wider environmental issues Social impacts (i.e. health and well-being Health, human rights, justice system, rural proofing) and sustainable development

As UK opted for the most stringent option (to maintain higher stricter standards) the Home Office concluded that the main risk is that the UK adopts a framework that places the UK science-base at a competitive disadvantage because other Member States adopt compliant, but less stringent, measures. Home Office proposed to reduce this risk by maintaining an active dialogue with the Commission and other Member States to coordinate our approach with theirs and promote harmonisation.

Source: „UK implementation of European Directive 2010/63/EU on the protection of animals used for scientific purposes”

<http://www.homeoffice.gov.uk/publications/about-us/consultations/transposition-protection-animals/protection-animals-scientific-ia?view=Binary>

4.2. Regulation

- Ensure that procedures and sufficient guidance is established to ensure that staff of the relevant competent authorities and the relevant establishments (especially the users) understand their record keeping obligations, comprising project relevant documentation (Article 45), the animal records and the individual history files dogs, cats and non-human primates.
- In relation to notification/authorisation of experiments, most laboratories in the Member States have internal ethics committees that review, provide opinions on or sanction proposed work.
- In relation to Article 33 on housing and caring requirements prepare a plan for ensuring compliance with the new requirements on housing area and the number of animals per area as set out in Annex III. Some requirements are only applicable as from 2017 but candidate countries should aim at earlier implementation where possible.
- Article 20 requires that all breeders, suppliers and users are authorised by and registered with the competent authority. Authorisation is dependent on compliance with the requirements of the Directive. The authorisation must specify the person responsible for compliance and the persons referred to in Articles 24(1) and 25. Significant changes in the structure or functions of the establishment will require re-authorisation and changes to named persons must be notified to the competent authority. Authorisation will be of corporate users, breeders and suppliers rather than establishments. It is assumed this will require existing certificates of designation to be reissued on the revised basis.
- Article 23 requires that each breeder, supplier and user has sufficient staff on site and that they have been adequately educated and trained before carrying out procedures on animals; designing procedures and projects; taking care of animals; or killing animals. Those designing procedures and projects must have received instruction in a scientific discipline relevant to the work being undertaken and have species-specific knowledge. Staff carrying out procedures on animals, designing procedures and projects and taking care of animals must be supervised until they have demonstrated the requisite competence. Member States can choose to ensure these requirements are met either through a system of authorisation or by other means. This provides an opportunity to simplify the current personal licensing system or to transfer responsibility for the control of individuals applying procedures to animals from central government to designated establishments. The Directive requires that Member States publish their minimum requirements with regard to education and training, based on the elements listed in Annex V. Member States must also publish their minimum requirements for obtaining, maintaining and demonstrating requisite competence.
- Article 39 creates a requirement for the retrospective assessment of all projects using non-human primates and projects involving procedures classified as "severe" and allows Member States the option of requiring retrospective assessment of projects involving 'moderate' procedures (to be decided on a case by case basis). In several Member States, there are currently no legislative requirements for projects to be retrospectively assessed. However, in some countries like the UK, a kind of retrospective assessment is undertaken for the 75% projects that are renewed on expiry (approximately 375 of the 500 or so project licences issued each year). Under the Directive, retrospective assessment may only be required for fewer than 20% of projects (100 per year). Countries with these more stringent requirements can of course maintain these standards.

4.3. Reporting

- The reporting duty has been strengthened significantly in the Directive on the protection of animals used for scientific purposes as well as the provisions on record keeping and notification duty. Candidate countries are advised to consult the practices of the existing Member States in the adoption of reporting and record keeping systems. These systems should be normally in an electronic format, be easy to administer, comply with relevant Commission guidance and established templates and promote transparency.

4.4. Technical guidance

The European Commission oversees the implementation of this Directive at European level and is responsible for providing suitable guidance for researchers, animal technologists and caretakers, members of animal welfare bodies, designated veterinarians, competent authorities and others who may have an interest in how the Directive is intended to be applied. Therefore, together with all key stakeholders, the Commission has developed a wide range of guidance material, intended to help all players in their different roles to apply Directive's principles correctly.

Guidance on Animal Welfare Bodies and National Committees

Guidance on how to set up an effective Animal Welfare Body within an establishment and how National Committees in Member States can support their functioning as well as advise authorities to ensure coherent approach to project evaluation. The document provides guidance on how to fulfil the requirements under Articles 26, 27 and 49 of Directive 2010/63/EU on the protection of animals used for scientific purposes.

Education and Training Guidance

This guidance document includes the principles and criteria for a modular, outcome-based education and training framework. It discusses supervision and competence assessment, as well as continued professional development. These provide the basis for the development of a mutual recognition of training courses across countries. The guidance document also contains general principles for the use of live animals in education and training.

Inspection and Enforcement Guidance

Guidance on how to approach inspection and enforcement under the Directive. The guidance document shows how an effective inspection programme can be a reassurance to all involved in the care and use of animals.

Guidance on Evaluation and Retrospective Assessment

A guidance document on how to establish an effective, efficient and consistent project evaluation process including harm-benefit assessment and the retrospective assessment of projects.

Guidance on Severity Assessment Framework

Guidance on how to consider severity during project planning and in prospective severity classification, ensure consistent monitoring and report the actual severity after an experiment, including many examples from different areas.

Guidance documents are available at the following link

http://ec.europa.eu/environment/chemicals/lab_animals/pubs_guidance_en.htm

5. COSTS

The implementation of this Directive will entail costs for the European Commission, the Member States, science/academia, industry and private testing laboratories.

The creation of an authorisation and control system for all establishments related to animal experiments can generate high costs for the Member States, in particular if they have not had any, or only a less developed, control system regarding the treatment and use of animals in experiments. The main expenditures are expected to emerge from the permitting, monitoring, and investigative work required under the Directive. The employment of additional staff, in particular of specialists qualified in the area of veterinary medicine, is probably the most important cost driver for the Member States. Part of the costs might be recovered from businesses through fees for permits, investigations and inspections.

The establishments covered by this Directive are forced to make investments in order to meet the directive's requirements for the accommodation and care of animals. The costs for a modernisation programme can vary enormously, depending on the current condition of the animal facilities. It is anticipated that industry, together with academic and scientific institutions, will have to bear some (or all) of the additional costs for experiments involving animals under this Directive. Some of the costs incurred on the government and competent authorities, particularly in relation to the authorisation of establishments and projects and the inspections and reporting can be partially covered by administrative fees (must be transparent and not prohibitive).

Table 15. Checklist of the Types of Cost Incurred to Implement the Directive

Checklist of the Types of Cost Incurred to Implement the Directive
<p>Initial set-up costs:</p> <ol style="list-style-type: none">1. Set-up costs for the government or competent authority<ul style="list-style-type: none">• designate a competent authority; (for the government)• establish a data collection system regarding data related to authorisations or data that need to be submitted to the Commission)• set up an authorisation system and licensing procedures (for the government)• set up a control system with routine and non-routine inspections including procedures to cooperate in case of Commission's control inspections;• training and recruitment of inspectors (for the public sector)2. Set-up costs for establishments (private sector)<ul style="list-style-type: none">• training and recruitment of a person responsible for ensuring animal welfare throughout procedures, scientific and veterinary staff;• establishing various plans and programmes linked to the projects and procedures, such as rehoming plans.• establish a data collection system for animal records and individual history files, decisions of animal welfare committee

Transitional costs (particularly for existing Member States:

1. Transitional costs for establishments:
 - to adopt new care and accommodation standards
 - to renew certificates of designation;
 - to adopt new humane killing methods.
2. Transitional costs for the government:
 - to prepare training guidelines;
 - a code of practice for humane killing

Ongoing costs:

1. Ongoing costs for the government
 - collecting data for reporting to the Commission;
 - monitoring compliance with standards (mainly for the government except for certain provisions of self-monitoring);
 - issuing of permits and registration of establishments (mainly for the government);
 - retrospective assessment of projects;
 - setting up and running the local systems of controls on individuals
 - compilation of statistical information (government).
2. Ongoing costs for the establishments
 - monitoring compliance with standards (mainly for the government except for certain provisions of self-monitoring);
 - monitoring compliance with standards

Examples from a Member State:

United Kingdom: The impact assessment of implementing the new directive estimated the costs to:

1. Transitional costs (establishments):
 - to adopt new care and accommodation standards (£16 million - £3.2m per annum 2012-2016);
 - to renew certificates of designation (£0.02m);
 - to adopt new humane killing methods (£0.2m).
2. Transitional costs (government):
 - to prepare training guidelines (£0.03m);
 - a code of practice for humane killing (£0.03m).
3. Annual average running costs of retrospective assessment of projects (£0.1m).
4. Total costs of setting up and running the local systems of controls on individuals £21.4m of which £3.3m transitional costs and £2.4m annual average cost.

Source: „UK implementation of European Directive 2010/63/EU on the protection of animals used for scientific purposes” Impact assessment (2011)

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/157917/protection-animals-scientific-ia.pdf

THE DIRECTIVE ON THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES

Official Title: Directive 2010/63/EU of the European Parliament and of the Council of the 22 September 2010 on the protection of animals used for scientific purposes

Implementing legislation

Commission Implementing Decision 2012/707/EU of 14 November 2012 establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes (OJ L 320/33, 17.11.2012)

Commission Implementing Decision 2014/11/EU of 20 December 2013 correcting Annex II to Implementing Decision 2012/707/EU establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes (OJ L 10, 15.1.2014)

1. SUMMARY OF MAIN AIMS AND PROVISIONS

In 1986 the Council adopted Directive 86/609/EEC in order to eliminate disparities between laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes. Since the adoption of that Directive, further disparities between Member States had emerged and some Member States had adopted more stringent provisions on animals used for scientific purposes, while others only applied the minimum requirements laid down in Directive 86/609/EEC. Directive 2010/63/EU was adopted setting out more detailed rules in order to reduce such disparities by approximating the rules applicable in that area but also to reflect new scientific knowledge in respect of factors influencing animal welfare as well as the capacity of animals to sense and express pain, suffering, distress and lasting harm.

The Directive applies to animals used for one of a number of specified purposes, including basic and applied research, the efficacy and safety testing of drugs, foodstuffs and other substances or products and those used for the purposes of higher education and training. An animal procedure must not be performed if the aim can also be achieved by an alternative method which does not entail the use of an animal. The Directive specifies standards for accommodation and care of animals, welfare requirements for the avoidance of pain or stress, and the humane treatment of animals at the end of a procedure. Establishments using animals, as well as breeding and supplying establishments, must be authorised by the competent authority. The Member States must ensure that these establishments are run in compliance with the terms of the Directive. No testing can be performed without an authorisation on the basis of a favorable project evaluation including harm benefit assessment.

Some of the main elements of 2010 Directive can be summarised as:

- Mandatory authorisation and project evaluation for all applications to use animals, including evaluation that the 3Rs (Replacement, Reduction and Refinement of the use of animals) are fully applied.
- Establishment of Union Reference Laboratory at the JRC to promote the development, validation and use of alternative methods, not only in toxicology, but now also in the areas of basic and applied research, and to promote dialogue on the 3Rs between legislators, regulators and all relevant stakeholders.
- A requirement that Member States contribute to the development and validation of alternative approaches, promote 3Rs at a national level and assist the Commission in identifying and nominating suitable laboratories to participate in validation studies.
- Systematic prospective severity classification of procedures on animals with detailed statistical reporting on actual occurred severities.
- A ban on the use of great apes, with limited opportunities to lift it.
- Periodic 3R-oriented thematic reviews by the Commission, paying specific attention to technological developments and new scientific and animal welfare knowledge.

The Directive is implementing the commitments under the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes, to which EU is a party. Decision 1999/575/EC concerns the conclusion by the EU of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes. On 15 June 2006, the Fourth Multilateral Consultation of Parties to the European Convention for the protection of vertebrate animals used for

experimental and other scientific purposes adopted a revised Appendix A to that Convention, which set out guidelines for the accommodation and care of experimental animals. Commission incorporated those guidelines in a Commission Recommendation of 2007/526/EC. However, it is important to note that main part of these guidelines is now introduced as compulsory standards through Annex III of Directive 2010/63/EU. Furthermore, the Directive sets out far more stringent standards and controls on the care and use of animals for scientific purposes than those contained in the Convention.

Animal welfare is a value of the Union that is enshrined in Article 13 of the Treaty on the Functioning of the European Union (TFEU).

Directive represents an important step towards achieving the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so focusing on the Three “Rs” (Replacement, Reduction and Refinement of the use of animals). To that end, it seeks to facilitate and promote the advancement of alternative approaches. It also seeks to ensure a high level of protection for animals that still need to be used in procedures. The Directive prohibits new, more progressive legislation if not already in place and thus harmonises but also freezes the 28 Member States at a relatively high level. This Directive will be reviewed regularly in light of evolving science and animal-protection measures.

Member States had to adopt and publish, by 10 November 2012, the laws, regulations and administrative provisions necessary to comply with this Directive and apply these provisions as from 1 January 2013. Art. 64 of the Directive lays down some transitional arrangements for projects approved prior to 1 January 2013 not extending beyond 2018.

In 2012 the Commission Implementing Decision 2012/707/EU was adopted, which sets out a common format for submitting information on the use of animals for scientific purposes as referred to in paragraphs 1, 2, and 3 of Article 54 of Directive 2010/63/EU. The new system will allow the Commission to assess effectiveness of the implementation of the legislation and help ensure consistency in its application. The first data under the new statistical reporting format was collected at national level from 1 January 2014. Since its adoption, the Commission together with Member States and all key stakeholders have developed a number of consensus Guidance Documents to facilitate implementation of the Directive. More information on the use of animals for scientific purposes, the Guidance Documents (available in all community languages under "Publications"), the new implementing Decision, reports on "The Development, Validation and Legal Acceptance of Alternative Methods to Animal Tests in the Field of Cosmetics and a list of Member States' competent authorities on can be obtained at: http://ec.europa.eu/environment/chemicals/lab_animals/index_en.htm

Finally, it is important to note the relevance of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, REACH Regulation (EC) No 1907/2006 and the CLP Regulation (EC) No 1272/2008 all introducing data sharing obligation to minimize the need for experiments with vertebrates.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Designate one or more competent authorities responsible for the implementation of this Directive, which does not have to be public authorities provided that they have sufficient expertise and infrastructure and there is no conflict of interest. (Art. 59(1))
- Designate a national authority serving as a contact point ((Art. 59(2)).
- Determine whether to keep more stringent requirements than those set out in the Directive provided that they were in place already in force on 9 November 2010 (Art. 2)
- Adopt and publish, by 10 November 2012, the laws, regulations and administrative provisions necessary to comply with this Directive and apply these provisions as from 1 January 2013 (Art. 61(1)).
- Introduce the necessary binding rules on penalties to ensure that the provisions of the Directive are fully implemented. The penalties shall be effective, proportionate and dissuasive. (Art. 60)
- Take the necessary steps to ensure compliance with the transitional arrangements for projects which have been approved before 1 January 2013, which have a maximum duration not extending beyond 1 January 2018. Such projects do not have to apply Arts. 36-45 of the new Directive but rather the provisions of the previous Directive (86/609/EEC) apply. For projects approved before 1 January 2013 which have a longer duration than 1 January 2018, these have to acquire a project authorization by 1 January 2018. (Art. 64)
- Set up a system of prior authorisation of user, breeding and supplying establishments. (Arts. 36-44) including compliance with regard to requirements for personnel, their education, training and competence. In addition, a system has to be set up for dealing with project authorisations set out in Arts. 40, 42 and 44
- Set up an inspection system to be administered by the competent authorities to ensure that regular inspections are carried out of all breeders, suppliers and users to verify compliance with the Directive. The measures involved include:
 - Carry out an initial risk analysis, taking into account criteria in Art. 34(2), to establish the frequency of inspections for the various establishments, taking into account the minimum criteria laid down in Art. 34. For instance breeders, suppliers and users of non-human primates have to be inspected annually;
 - Determine the proportionate of routine and non-routine inspections;
 - Setting up a recording system to ensure that records of all inspections are kept for five years;
 - Establish a procedure for assisting Commission in its control of the operation of national inspections (Arts. 34 and 35)
- Establish procedures to ensure mutual recognition of data from other Member States that are generated by procedures recognised by the legislation of the Union. (Art. 46)

- Establish a system whereby procedures are classified as ‘non-recovery’, ‘mild’, ‘moderate’, or ‘severe’ on a case- by-case basis using the assignment criteria set out in Annex VIII (Art. 15)
- Take measures to contribute to the development of alternative approaches (not involving animal testing or fewer animals or with less painful procedures) and to support research in the field. For this purpose, Member States have to:
 - assist the Commission in identifying and nominating suitable specialised and qualified laboratories to carry out such validation studies;
 - promote alternative approaches and ensure wide dissemination of information regarding such approaches
 - nominate a single contact point to provide advice on the suitability of alternative approaches to be subject to the validation procedure, (Art. 47)
- Establish a national committee for the protection of animals used for scientific purposes, which will advise the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice. (Art. 49)
- Set up a procedure for making decisions on using the safeguard clauses in Article 55 regarding using non-human primates for purposes referred to in Article 8(1)(a)(i) or to use procedures involving long-term severe pain, suffering or distress. This may be on grounds referred to in Art. 55(1) (2) such as preservation of species or in relation to an unexpected outbreak of a life-threatening condition in human beings. Such measures must first be subject to prior notification to the Commission, which (within 30 days) may approve or deny the request. (Art. 55)

2.2. Regulation

- Ensure that all breeders, suppliers and users authorized by the competent authority and that they fully comply with the requirements of the Directive. This authorisation may be granted for a limited period. Where there are significant changes to the establishment, the authorisation must be renewed. The authorisation must specify the persons responsible for overseeing implementation of the Directive. (Art. 20)
- Ensure that the appropriate measures are taken, including suspending or withdrawing authorisation in case breeders, suppliers and users are in case of non-compliance with the Directive. (Art. 21)
- Ensure that establishments fulfil the requirements in Arts. 22-29:
 - That the installations and equipment are of a design, construction and using methods suitable for the type of animals housed and the procedures to be performed, taking into account requirements in Annex III (Art. 22);
 - Ensure that the establishments have sufficient staff and that they have the appropriate education and training, taking into account Annex V and meeting the minimum requirements, as published

- by the competent authority. They shall have received scientific instruction relevant to the work undertaken and have specific knowledge of the species concerned. (Art. 23);
- That each establishment has one or several persons on site responsible for overseeing the animal welfare and care and that all staff dealing with animals have access to species specific information and they are adequately educated, trained and competent, that animals are not subject to unnecessary suffering and that projects follow the project authorisation (Art. 24);
 - That there is at least one veterinarian with expertise in laboratory animal medicine having advisory duties designated for the establishment (Art. 25);
 - That each breeder, supplier and user sets up an animal welfare body, involving the person involved in welfare and care and involve other scientific members and the designated veterinarian, where applicable. This body shall carry out tasks such as advising staff on animal welfare and establish and review internal operation process in terms of monitoring, reporting as well as following the development and results of the projects (Arts. 26 and 27);
 - That breeders using non-human primates have a strategy for increasing proportion of animals used which are offspring of those bred in captivity (Art. 28);
 - Adopting a rehoming scheme or programme of rehabilitation for wild animals (Art. 29)
- Ensure that all projects are subject to prior authorisation and evaluation set out in Arts. 36-40 such as:
 - Performing a project evaluation, demonstrating that the project is justified on educational or scientific grounds or as mandated by law, that the use of animals is justified and project is designed to have the most humane procedures possible. The evaluation shall for instance include an evaluation of objectives and an assessment of compliance with principle of replacement, reduction and refinement, assessment of procedure classification and a harm-benefit analysis (Art- 38);
 - First obtaining a project authorisation a favourable project evaluation from the competent authority (Art. 36)
 - Ensuring that the project is fully carried out pursuant to the authorisation,
 - The project application must contain a project proposal, a non-technical summary and information listed in Annex VI (Art. 37);
 - That certain projects are subject to a retrospective assessment carried out by the competent authority at the end of the project to assess whether objectives of project have been achieved, the harm inflicted on animals and the number of animals used and the severity of procedures, Retrospective assessment is mandatory for projects using non-humane primates. (Art. 39);
 - That the project authorisation is limited to maximum of five years and only cover procedures which have been subject to evaluation and classification and which specify the user of the project, the persons responsible for compliance with authorisation. (Art. 40);
 - Ensure that projects approved after 1 January 2013 fully complies with the provisions of the Directive. (Art. 64)
 - In the evaluation of applications for authorization of using animals in experiments, take into account the principle of replacement, reduction and refinement set out in Art. 4, meaning that where possible

projects shall not involve using animals if there are equally satisfactory methods not involving animals and always try to minimize the pain, suffering and distress of animals. (Art. 4)

- Prohibit experiments using endangered species listed in Annex A to Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating trade, unless justified under Art. 5 (b)(i), (c) or (e) of Art. 5 of this Directive and there is scientific justification for using Annex A species (Art. 7).
- As a principle not allow use of non-human primates in procedures, only allowed if conditions in Article 8 are fulfilled (Art. 8)
- Ensure that wild animals are used for experiments only if other animals would not suffice for the aims of the experiment. If wild animals are used, ensure that their capture is carried out by a competent person using humane methods (Art. 9).
- Ensure that stray animals of domestic species are not used in experiments, unless competent authority grants an exemption (Art. 11).
- Ensure that dogs, cats and non-human primates are provided with a unique identification mark, in the least painful manner, before they are weaned or as soon as they are taken into an establishment (Art. 32).
- Ensure that experimental animals are provided with appropriate housing, freedom of movement, food, water and care, that they can satisfy their physiological and ethological needs to a maximum and that their environmental conditions are checked daily by a competent person, arrangements are made to ensure that any avoidable pain, suffering or distress is discovered and eliminated as quickly as possible. The care and accommodation must meet the requirements in Annex III, applicable as from the dates specified (Art. 33).
- Ensure that procedures are in principle avoided if there are alternative options not involving animals. Where they are unavoidable that have to be in compliance with Chapter III (Arts. 12-19) which include:
 - Ensuring that procedures are carried out in the user's establishment and are carried out for a specific project (Art. 12)
 - Choosing a procedure which minimises the number of animals used, use animals with the lowest capacity to experience pain, suffering, distress, cause the least pain, suffering or distress while being the most likely to provide satisfactory results. Death as the end-point of a procedures shall be avoided as far as possible and where unavoidable limit number of affected animals and their suffering. (Art. 13);
 - Ensure that animals set out in Annex I may only be used in procedures where they have been bred for such use, observing the specific requirements as regards the use of non-human primates, which will be applicable from the dates indicated in Annex II (Art. 10)
 - Avoid unnecessary pain, suffering and distress and minimise severe pain by using appropriate anaesthesia methods (Art. 14)
 - Ensure the procedure is classified as 'non-recovery', 'mild', 'moderate', or 'severe' on a case- by-case basis using the assignment criteria set out in Annex VIII (Art. 15)

- Ensuring that the reuse of animals already used in a procedure complies with conditions in Art. 16 and that animals are not used more than once in experiments entailing severe pain, distress or equivalent suffering;
 - The procedure shall end where no further observations can be made. A veterinarian or other competent person shall decide whether to keep an animal alive or not, but shall be killed if it is likely to remain in moderate or severe pain, suffering or distress. (Art. 17);
 - Promote the sharing of organs and tissues of animals killed (Art. 18);
 - Rehome or return the animals to a suitable habitat or husbandry system where conditions in Art. 19 are met, ensuring good animal well-being and no danger to public health or the environment. (Art. 19)
- Ensure that animals are killed in the establishment of a breeder, supplier or user (unless field study), by a competent person, with minimum pain, suffering and distress. Ensure that the method of killing for animals covered in that Annex is used unless the competent authorities have granted an exemption under grounds set out in Art. 6(4)). (Art. 6)
 - Subject to the use of the safeguard clause in Article 55(3), ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated (Art. 15(2))
 - Recognise the validity of data generated by experiments carried out in other Member States, unless further testing is necessary to protect public health and safety (Art. 46).

2.3. Information and Reporting

- Report to the Commission on:
 - the laws, regulations and administrative provisions implementing the provisions of the Directive. (Art. 61(1)).
 - the binding rules on penalties for non-compliance. (Art. 60)
 - implementing provisions, focusing on Articles 10(1), 26, 28, 34, 38, 39, 43 and 46, using the common reporting format established by the Commission. First report is due on 10 November 2018 and after that every five years. (Art. 54(1))
 - statistical information using the format established by the Commission. First time for this submission is 10 November 2015 and every year thereafter (Art. 54(2)).
 - exemptions granted under Art. 6(4)(a). Such information has to be submitted at annual intervals, providing sufficient information using the common format established by the Commission (Art. 54(4))
- Details of a national authority serving as contact point for the purposes of this (Art. 59(2)).
 - Ensure that where the contact person referred to in Article 24(1) and Art. 25 ensuring compliance with the Directive, changes, this is notified to the competent authority. (Art. 20(4)).

- A Member State which has adopted a provisional measure in accordance with paragraph 1, 2 or 3 shall immediately inform the Commission and the other Member States thereof, giving reasons for its decision and submitting evidence of the situation as described in paragraphs 1, 2 and 3 on which the provisional measure is based. (Art. 55(4))
- Ensure that Member States and the relevant establishments keep records:
 - Ensure that establishments keep all the relevant documentation including project authorisations and the result of the project evaluation for at least 3 years from the date of expiry of the project and be made available to the authority. Projects which undergo retroactive assessment shall keep this information at least until the assessment is completed (Art. 45)
 - Member States have to keep records of inspections for at least five years and keep these available for the Commission (Art. 34(5));
 - Ensure that all breeders, suppliers and users keep „animal records”, at least for five years and making this information available to the competent authority, of at least the following:
 - the number and the species of animals bred, acquired, supplied, used in procedures, set-free or rehomed;
 - the origin of the animals, including whether they are bred for use in procedures;
 - the dates on which the animals are acquired, supplied, released or rehomed;
 - from whom the animals are acquired;
 - the name and address of the recipient of animals;
 - the number and species of animals which died or were killed in each establishment. For animals that have died, the cause of death shall, when known, be noted; and
 - in the case of users, the projects in which animals are used. (Art. 30)
 - Ensure that all breeders, suppliers and users of dogs, cats and non-human primates keep an individual history file for each animal. This file shall be established at birth and be kept at least for three years after the death or rehoming of the animal and making this information available to the competent authority. This information shall include:
 - identity;
 - place and date of birth, when available;
 - whether it is bred for use in procedures; and
 - in the case of a non-human primate, whether it is the offspring of non-human primates that have been bred in captivity. (Art. 31)
 - Ensure that advice and decisions given by the animal-welfare body referred to in Article 27 are kept for at least three years and made available to the competent authority (Art. 27(2))
- Ensure that establishments notify the competent authority of any changes of the person or persons responsible for implementing the Directive (Art. 20(4))

2.4. Additional Legal Instruments

- Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP)
- Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances

These two directives, together with the Animal Experiments Directive, establish a system of harmonised test methodologies and quality standards that allow the mutual recognition of test results.

- Council Decision 1999/575/EC of 23 March 1998 concerning the conclusion by the Community of the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, the EU has become party to the Council of Europe Convention ETS.
- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products
- REACH Regulation (EC) No 1907/2006
- CLP Regulation (EC) No 1272/2008

3. IMPLEMENTATION

3.1. Key Tasks

The key tasks involved in implementing this Directive are summarised in the checklist below. The key tasks are arranged under subheadings and organised in chronological order of implementation wherever possible.

Table 16. Checklist with Key Implementation Tasks

DIRECTIVE ON THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Appoint a competent authority and national contact point and supply it with necessary human, financial and technical resources.
1.2	Establish a national committee
1.3	Wide consultation with stakeholders involving relevant authorities, breeders, suppliers, users, scientific organs, animal protection organisations also with a view to discuss alternative options
1.4	Set up an authorisation and registration system for establishments using, breeding or supplying animals for experimental purposes.
1.5	Set up a system of authorisation for projects, taking into account requirements on project evaluation, retrospective assessments
1.6	Establish a data collection system regarding the use of animals in experiments and publish the statistical information annually.
1.7	Set up procedures to ensure that persons designing projects, carry out procedures on animals (including killing of animals) and caring for them are adequately trained and have demonstrated competence to perform experiments on animals or to care for animals used for scientific purposes, and that animal welfare bodies are set up in each establishment to advise staff on care and welfare and application of the Three Rs (to Replace, Reduce and Refine the use of animals for scientific purposes)
1.8	Establish a system whereby procedures are classified as ‘non-recovery’, ‘mild’, ‘moderate’, or ‘severe’ on a case- by-case basis using the assignment criteria set out in Annex VIII
1.9	Develop guidance for the competent authorities and for the establishments concerned (e.g. breeders, suppliers and users), detailing their obligations and overall objectives of the Directive)

1.10	Plan the phasing in of the space allowances for housing of animals set out in Annex III taking effect 1.1.2017.
1.11	Establish the procedures for reporting towards the competent authority and towards the Commission
2	Regulation
2.1	Inspect and authorise establishments that breed, supply or use animals.
2.2	Ensure authorisation of projects integrating a systematic, case by case project evaluation carried out by competent authority.
2.3	Ensure that projects approved after 1 January 2013 fully complies with the provisions of the Directive. For projects approved prior to this date, such projects do not have to apply Arts. 36-45 of the new Directive but rather the provisions of the previous Directive (86/609/EEC) apply. For projects approved before 1 January 2013 which have a longer duration than 1 January 2018, these have to acquire a project authorization by 1 January 2018. (Art. 64)
2.4	Publish non-technical project summaries and ensure that commercially sensitive information is not published.
2.5	Set up an inspection system to verify that establishments are run in compliance with the terms of the Directive based on risk analysis including annual inspection that are both announced and unannounced.
2.6	Make sure establishments meet the relevant requirements with stricter requirements concerning the use of non-human primates, which include certain programmes and plans.
2.7	Establish a system of statistical data collection and ensure publication of annual statistical data in line with Commission Implementing Decisions 2012/707/EU.
3	Reporting
3.1	Report to the Commission on: <ul style="list-style-type: none"> • the laws, regulations and administrative provisions implementing the provisions of the Directive; <ul style="list-style-type: none"> – the binding rules on penalties for non-compliance. – implementing provisions, focusing on Articles 10(1), 26, 28, 34, 38, 39, 43 and 46, using the common reporting format established by the Commission. First report is due on 10 November 2018 and after that every five years. – statistical information using the format established by the Commission. Such information has to be submitted annually. – Exemptions granted under Art. 6(4)(a). Such information has to be submitted at annual intervals.

	<ul style="list-style-type: none"> • details of a national authority serving as contact point for the purposes of this as well as changes to this person • the taking of a provisional measure, which shall be immediately reported both to the Commission and the other Member States
3.2	<p>Ensure that Member States and the relevant establishments keep records:</p> <ul style="list-style-type: none"> • Ensure that establishments keep all the relevant documentation including project authorisations and the result of the project evaluation for at least 3 years from the date of expiry of the project) • Member States have to keep records of inspections for at least five years and keep these available for the Commission (Art. 34(5)); • Ensure that all breeders, suppliers and users keep „animal records”, at least for five years and making this information available to the competent authority, of at least the following: • Ensure that all breeders, suppliers and users of dogs, cats and non-human primates keep an individual history file for each animal. This file shall be established at birth and be kept at least for three years after the death or rehoming • Ensure that establishments notify the competent authority of any changes of the person or persons responsible for implementing the Directive (Art. 20(4))

3.2. Phasing Considerations

Experience within Member States suggests that the most demanding and time-consuming tasks associated with implementing this Directive are:

- transposing the requirements of the Directive into national legislation and policy due to possible extensive discussions among the public;
- the preparation of an authorisation system for animal use;
- instituting an authority responsible for monitoring user, breeding and supplying establishments; and
- the collection of statistical data according to the harmonised format including assurance of data quality and timeliness.

These tasks should, therefore, be planned to commence during the initial phase of implementation.

During the whole transposition process, it should be borne in mind that legislation on animal use is a very controversial and politically sensitive issue. The government should be prepared for strong intervention by animal rights groups. Moreover, the public is likely to follow the legislation process very closely. Therefore, a well-reflected communications and public participation policy should be developed during the legislative process.

Also note the transitional arrangements for projects approved prior to 1 January 2013 and not extending beyond 1 January 2018, which do not have to apply Arts. 36-45 of the new Directive but rather the provisions of the previous Directive (86/609/EEC) apply. For projects approved before 1 January 2013 which have a longer duration than 1 January 2018, these have to acquire a project authorization by 1 January 2018.

4. IMPLEMENTATION GUIDANCE

The Directive aims to abolish trade barriers between EU Member States arising from the different legal requirements for the treatment of animals used for experimental purposes. Furthermore,

The Directive is designed to limit the use of animals in scientific experiments to a minimum. In cases where there are no suitable alternatives, animal experiments must be conducted so that the animal's pain, suffering and distress during the experiment is minimised as much as possible.

Member States must introduce an authorisation or registration system for all establishments using, breeding or supplying animals for experimental purposes. As pointed out above, the Directive requires a systematic authorisation and evaluation of all projects using animals. These establishments must be subject to inspections to ensure compliance with the requirements of the Directive. Member States and the Commission should contribute to the development and validation of alternative techniques that involve fewer animals or entail less painful procedures. This is also an approach supported by the Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, which provides for data sharing requirements to reduce the need for procedures involving vertebrates.

Implementation of the specific requirements of this Directive will be influenced by the present status, needs and conditions concerning animal experiments in each candidate country. However, drawing upon the collective experience of the Member States, a number of general observations and good practice suggestions for implementing this Directive are presented below.

The National Contact Points of the Member States responsible for the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes and the Commission met on 6-7 October 2011 to reach consensus and guidance on application of selected provisions with a view to finding a common approach throughout the EU. The below are texts from this guidance document, which can be obtained at: http://ec.europa.eu/environment/chemicals/lab_animals/interpretation_en.htm

Article 3 - Definitions for a procedure and project

A **project** means a programme of work having a defined

scientific objective and involving one or more procedures. Projects can vary in size and complexity, for example, from the work of a single scientist consisting of a single blood harvest procedure in a single species, to an entire department's drug discovery programme, which involves many scientists, multiple complex procedures and a wide range of species.

Procedure means any *use*, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of pain, suffering or distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle according to good veterinary practice. Within a project, procedures will be performed to meet a defined scientific purpose. Procedures may be simple or complex depending on the purpose. The purpose may be achieved by using a single step procedure (for example withdrawal of blood), but much more commonly requires a number of steps used in combination to achieve a single outcome, and which requires the use of the same animal (for example antibody production would generally require a number of antigen injections to stimulate antibody production, and a number of blood samples to achieve the desired outcome).

Examples of Procedures

A single subcutaneous injection of a test substance may be given in a pharmaceutical project to attain the objective of understanding the drug distribution within the body tissues. The animal is then killed by a method listed in Annex IV.

This project comprises of one procedure (the injection of the test substance) which may cause the animal pain, suffering, distress or lasting harm. In contrast, a procedure to assess the effect of the test substance on blood pressure using telemetry would require a number of separate technical steps to be carried out to meet this single scientific purpose (multi – step procedure). The animal would need to be anaesthetised, blood pressure transducer implanted and, following a suitable recovery period, administered the test substance by subcutaneous injection. The animal is then killed by a method listed in Annex IV. In this example three steps namely anaesthesia, surgical implantation of blood pressure transducer and injection of the test substance) need to be used in combination to meet the single scientific purpose of understanding the effects of the substance on blood pressure..

Article 16 - Use, re-use and continued use

Use

The “use” of an animal within a project extends from the time the procedure (or first procedure/technique in a series) is applied to it, to the time when the observations, or the collection of data (or other products) for a particular scientific purpose (usually a single experiment or test), are completed.

Re-use

“Re-use” is a term to indicate the subsequent use of an animal which has already completed a procedure (or series of procedures/techniques) for a particular scientific purpose.

Continued Use

This is a term not included in the Directive, but can be used to describe the situation when the single “use” of an animal extends over more than one project or across different procedures within the same project. This arrangement can simplify project applications and avoid undue repetition.

Example 1 - Re-use

Purpose 1: to obtain sheep blood to make diagnostic plates for bacteriology.

Purpose 2: to determine the effect on blood parameters in sheep of a test dietary supplement, which may have adverse effects.

First use

A sheep is used on the first procedure to obtain a blood sample for use in preparation of diagnostic plates.

Second use

The same animal is then used on a second unrelated project to study the metabolism of a dietary supplement, blood samples are taken for analysis and other non-invasive measurements are made.

4.1. Planning

- Identify and nominate the competent authorities, contact points etc. If it is judged that a non-public body might be more efficient in fulfilling the obligations of the competent authority and it has sufficient expertise and resources and does not have a conflict of interest, candidate countries should consider appointing this body. A national committee has to be set up for the protection of animals used for scientific purposes. It shall advise the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice. This committee should consult with the main stakeholders including animal welfare protection groups.
- A number of steps are required to ensure efficient authorisation, evaluation and inspection procedures. Candidate countries are advised to consult the existing Member States and their designated contact points.
- Ensure wide stakeholder consultation prior to the implementation of the provisions of the Directive. This consultation should involve all major stakeholders such as industry, biomedical scientists, consumer organisations and animal-welfare groups. Such consultation will certainly ensure a more efficient, timely and coordinated implementation. In this consultation, the use of alternative approaches should be emphasised and efforts made at national and EU level on this.
- The Directive on the use of animals for scientific purposes introduces several novelties such as more detailed and stringent procedures for animal testing. It also requires a more pro-active approach in finding alternative approaches, meaning procedures not involving animals or to a more limited and humane extent. To this end, the Union Reference Laboratory has been established which has as its main task to coordinate and promote the development and use of alternative approaches. This Laboratory also acts as a general focal point for exchange of information also between legislators, regulators and relevant stakeholders (industry, biomedical scientists, consumer organisations and animal-welfare groups. Any measures on development and promoting alternative approaches at national level should be coordinated with the Union Reference Laboratory to acquire best practices, obtain useful information and for effective stakeholder consultation.

Examples from a Member State:

United Kingdom: In the UK, a detailed impact assessment was undertaken with the lead of the Home Office cooperating with the Department of Health, Social Services and Public Safety Northern Ireland (DHSSPSNI). Stated as objectives of the implementing policy: ” The principal policy objective is to comply with UK Treaty obligations to transpose the provisions of Directive 2010/63/EU into UK legislation fully and appropriately. Additional objectives are to do so adopting measures which are proportionate; provide for efficient and effective regulation and appropriate standards of animal welfare and protection; promote the use of alternatives to animal use; avoid unnecessary administrative and regulatory burdens; and support the success, sustainability and competitiveness of the UK research and science base. UK opted for transposing the Directive retaining the current higher UK standards and requirements, where appropriate, as allowed under Article 2 of Directive 2010/63/EU.

In this impact assessment the Home Office checked impact on:

- Statutory equality duties
- Economic impacts (i.e. competition, small firms)
- Environmental impacts (i.e. greenhouse gas assessment, wider environmental issues Social impacts (i.e. health and well-being Health, human rights, justice system, rural proofing) and sustainable development

As UK opted for the most stringent option (to maintain higher stricter standards) the Home Office concluded that the main risk is that the UK adopts a framework that places the UK science-base at a competitive disadvantage because other Member States adopt compliant, but less stringent, measures. Home Office proposed to reduce this risk by maintaining an active dialogue with the Commission and other Member States to coordinate our approach with theirs and promote harmonisation.

Source: „*UK implementation of European Directive 2010/63/EU on the protection of animals used for scientific purposes*”

<http://www.homeoffice.gov.uk/publications/about-us/consultations/transposition-protection-animals/protection-animals-scientific-ia?view=Binary>

4.2. Regulation

- Ensure that procedures and sufficient guidance is established to ensure that staff of the relevant competent authorities and the relevant establishments (especially the users) understand their record keeping obligations, comprising project relevant documentation (Article 45), the animal records and the individual history files dogs, cats and non-human primates.
- In relation to notification/authorisation of experiments, most laboratories in the Member States have internal ethics committees that review, provide opinions on or sanction proposed work.
- In relation to Article 33 on housing and caring requirements prepare a plan for ensuring compliance with the new requirements on housing area and the number of animals per area as set out in Annex III. Some requirements are only applicable as from 2017 but candidate countries should aim at earlier implementation where possible.
- Article 20 requires that all breeders, suppliers and users are authorised by and registered with the competent authority. Authorisation is dependent on compliance with the requirements of the Directive. The authorisation must specify the person responsible for compliance and the persons referred to in Articles 24(1) and 25. Significant changes in the structure or functions of the establishment will require re-authorisation and changes to named persons must be notified to the competent authority. Authorisation will be of corporate users, breeders and suppliers rather than establishments. It is assumed this will require existing certificates of designation to be reissued on the revised basis.
- Article 23 requires that each breeder, supplier and user has sufficient staff on site and that they have been adequately educated and trained before carrying out procedures on animals; designing procedures and projects; taking care of animals; or killing animals. Those designing procedures and projects must have received instruction in a scientific discipline relevant to the work being undertaken and have species-specific knowledge. Staff carrying out procedures on animals, designing procedures and projects and taking care of animals must be supervised until they have demonstrated the requisite competence. Member States can choose to ensure these requirements are met either through a system of authorisation or by other means. This provides an opportunity to simplify the current personal licensing system or to transfer responsibility for the control of individuals applying procedures to animals from central government to designated establishments. The Directive requires that Member States publish their minimum requirements with regard to education and training, based on the elements listed in Annex V. Member States must also publish their minimum requirements for obtaining, maintaining and demonstrating requisite competence.
- Article 39 creates a requirement for the retrospective assessment of all projects using non-human primates and projects involving procedures classified as "severe" and allows Member States the option of requiring retrospective assessment of projects involving 'moderate' procedures (to be decided on a case by case basis). In several Member States, there are currently no legislative requirements for projects to be retrospectively assessed. However, in some countries like the UK, a kind of retrospective assessment is undertaken for the 75% projects that are renewed on expiry (approximately 375 of the 500 or so project licences issued each year). Under the Directive, retrospective assessment may only be required for fewer than 20% of projects (100 per year). Countries with these more stringent requirements can of course maintain these standards.

4.3. Reporting

- The reporting duty has been strengthened significantly in the Directive on the protection of animals used for scientific purposes as well as the provisions on record keeping and notification duty. Candidate countries are advised to consult the practices of the existing Member States in the adoption of reporting and record keeping systems. These systems should be normally in an electronic format, be easy to administer, comply with relevant Commission guidance and established templates and promote transparency.

4.4. Technical guidance

The European Commission oversees the implementation of this Directive at European level and is responsible for providing suitable guidance for researchers, animal technologists and caretakers, members of animal welfare bodies, designated veterinarians, competent authorities and others who may have an interest in how the Directive is intended to be applied. Therefore, together with all key stakeholders, the Commission has developed a wide range of guidance material, intended to help all players in their different roles to apply Directive's principles correctly.

Guidance on Animal Welfare Bodies and National Committees

Guidance on how to set up an effective Animal Welfare Body within an establishment and how National Committees in Member States can support their functioning as well as advise authorities to ensure coherent approach to project evaluation. The document provide guidance on how to fulfil the requirements under Articles 26, 27 and 49 of Directive 2010/63/EU on the protection of animals used for scientific purposes.

Education and Training Guidance

This guidance document includes the principles and criteria for a modular, outcome-based education and training framework. It discusses supervision and competence assessment, as well as continued professional development. These provide the basis for the development of a mutual recognition of training courses across countries. The guidance document also contains general principles for the use of live animals in education and training.

Inspection and Enforcement Guidance

Guidance on how to approach inspection and enforcement under the Directive. The guidance document shows how an effective inspection programme can be a reassurance to all involved in the care and use of animals.

Guidance on Evaluation and Retrospective Assessment

A guidance document on how to establish an effective, efficient and consistent project evaluation process including harm-benefit assessment and the retrospective assessment of projects.

Guidance on Severity Assessment Framework

Guidance on how to consider severity during project planning and in prospective severity classification, ensure consistent monitoring and report the actual severity after an experiment, including many examples from different areas.

Guidance documents are available at the following link

http://ec.europa.eu/environment/chemicals/lab_animals/pubs_guidance_en.htm

5. COSTS

The implementation of this Directive will entail costs for the European Commission, the Member States, science/academia, industry and private testing laboratories.

The creation of an authorisation and control system for all establishments related to animal experiments can generate high costs for the Member States, in particular if they have not had any, or only a less developed, control system regarding the treatment and use of animals in experiments. The main expenditures are expected to emerge from the permitting, monitoring, and investigative work required under the Directive. The employment of additional staff, in particular of specialists qualified in the area of veterinary medicine, is probably the most important cost driver for the Member States. Part of the costs might be recovered from businesses through fees for permits, investigations and inspections.

The establishments covered by this Directive are forced to make investments in order to meet the directive's requirements for the accommodation and care of animals. The costs for a modernisation programme can vary enormously, depending on the current condition of the animal facilities. It is anticipated that industry, together with academic and scientific institutions, will have to bear some (or all) of the additional costs for experiments involving animals under this Directive. Some of the costs incurred on the government and competent authorities, particularly in relation to the authorisation of establishments and projects and the inspections and reporting can be partially covered by administrative fees (must be transparent and not prohibitive).

Table 17. Checklist of the Types of Cost Incurred to Implement the Directive

Checklist of the Types of Cost Incurred to Implement the Directive
<p>Initial set-up costs:</p> <p>3. Set-up costs for the government or competent authority</p> <ul style="list-style-type: none">• designate a competent authority; (for the government)• establish a data collection system regarding data related to authorisations or data that need to be submitted to the Commission)• set up an authorisation system and licensing procedures (for the government)• set up a control system with routine and non-routine inspections including procedures to cooperate in case of Commission's control inspections;• training and recruitment of inspectors (for the public sector) <p>4. Set-up costs for establishments (private sector)</p> <ul style="list-style-type: none">• training and recruitment of a person responsible for ensuring animal welfare throughout procedures, scientific and veterinary staff;• establishing various plans and programmes linked to the projects and procedures, such as rehoming plans.• establish a data collection system for animal records and individual history files, decisions of animal welfare committee

Transitional costs (particularly for existing Member States:

3. Transitional costs for establishments:
 - to adopt new care and accommodation standards
 - to renew certificates of designation;
 - to adopt new humane killing methods.
4. Transitional costs for the government:
 - to prepare training guidelines;
 - a code of practice for humane killing

Ongoing costs:

3. Ongoing costs for the government
 - collecting data for reporting to the Commission;
 - monitoring compliance with standards (mainly for the government except for certain provisions of self-monitoring);
 - issuing of permits and registration of establishments (mainly for the government);
 - retrospective assessment of projects;
 - setting up and running the local systems of controls on individuals
 - compilation of statistical information (government).
4. Ongoing costs for the establishments
 - monitoring compliance with standards (mainly for the government except for certain provisions of self-monitoring);
 - monitoring compliance with standards

Examples from a Member State:

United Kingdom: The impact assessment of implementing the new directive estimated the costs to:

5. Transitional costs (establishments):
 - to adopt new care and accommodation standards (£16 million - £3.2m per annum 2012-2016);
 - to renew certificates of designation (£0.02m);
 - to adopt new humane killing methods (£0.2m).
6. Transitional costs (government):
 - to prepare training guidelines (£0.03m);
 - a code of practice for humane killing (£0.03m).
7. Annual average running costs of retrospective assessment of projects (£0.1m).
8. Total costs of setting up and running the local systems of controls on individuals £21.4m of which £3.3m transitional costs and £2.4m annual average cost.

Source: „UK implementation of European Directive 2010/63/EU on the protection of animals used for scientific purposes” Impact assessment (2011)

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/157917/protection-animals-scientific-ia.pdf

REGULATION ON THE BANNING OF EXPORTS OF MERCURY AND SAFE STORAGE OF MERCURY

Official Title: Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury

1. SUMMARY OF MAIN AIMS AND PROVISIONS

This Regulation, which entered into force on 4 December 2008, has two principle objectives:

- Establishing and EU ban on all exports of metallic mercury and certain mercury compounds and mixtures from 15 March 2011. The ban on exports of mercury from the European Union (EU) shall contribute to reducing the global mercury supply, and, indirectly, to limiting the emissions of this heavy metal, which is extremely toxic to the environment.
- Characterising as waste and ensuring the safe storage of significant quantities of mercury used in or produced by certain industrial activities, also applicable as from 15 March 2011.

1. The ban

This Regulation bans the exports of metallic mercury and certain mercury compounds and mixtures originating from the EU. The ban is to apply from 15 March 2011 to exports of:

- metallic mercury (Hg);
- cinnabar ore;
- mercury chloride (Hg₂Cl₂);
- mercury oxide (HgO);
- mixtures of metallic mercury with other substances with a mercury concentration of at least 95 % weight by weight.

2. Mercury storage

From 15 March 2011, mercury produced by certain industrial activities are considered as waste and have to be stored in a way that is safe for human health and the environment. The industrial activities concerned are:

- the chlor-alkali industry;
- the cleaning of natural gas
- non-ferrous smelting and mining operations; and
- the extraction of cinnabar ore in the European Union.

Metallic mercury from these sources is considered waste and can be stored:

temporarily or permanently in an underground salt-mine adapted for the purpose or in deep underground, hard rock formations; or even temporarily in above-ground facilities specifically dedicated for that purpose prior to its final disposal.

This option constitutes a derogation from the provisions of Directive 1999/31/EC, which prohibit the disposal of liquid waste in landfills (metallic mercury is liquid at normal temperature and pressure).

Regarding the storage certain assessments and authorisation procedures have to be complied with:

- Safety assessment:

The safety assessment for the temporary storage of mercury is carried out in accordance with Decision 2003/33/EC establishing criteria and procedures for the acceptance of waste at landfills. This assessment shall ensure that the particular risks arising from the nature and long-term properties of the metallic mercury and its containment are covered.

- Storage permit

The permit which is granted to mercury storage sites shall include requirements for regular visual inspections of the containers and the installation of appropriate vapour detection equipment to detect any leak.

Member States had to submit to the Commission a copy of any permit issued for a facility designated to store mercury, as well as information on the application and market effects of this Regulation in their territory by 1 July 2012.

In addition to the above, the Regulation foresees an exchange of information between the Member States and the industries concerned regarding the possibility of:

- extending the export ban to other mercury compounds, to mixtures with a lower mercury content and to products containing mercury (thermometers, barometers and sphygmomanometers);
- an import ban of metallic mercury, mercury compounds and products containing mercury;
- extending the storage obligation to metallic mercury from other sources;
- time limits concerning temporary storage of metallic mercury.

The ban on exports and the safe storage of surplus mercury are essential elements of the EU strategy concerning mercury adopted in 2005³⁰¹. This strategy aims to combat pollution caused by mercury in the EU and the world. It includes 20 actions which aim to reduce mercury emissions, limit supply and demand and protect against exposure, particularly to methylmercury present in fish. The Regulation also interrelates with Environmental Quality Standards Directive 2008/105/EC, which lays down limit values for mercury emission standards in the EU's aquatic environment.

Measures taken at EU level must be seen as part of a global effort to reduce the risk of exposure to mercury, in particular in the framework of the Mercury Programme under the United Nations Environment Programme. In this context, the Minamata Convention on Mercury was signed in 2013 and opened for ratification. The objective of the Convention is to protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds and it sets out a range of measures to meet that objective. These include measures to control the supply and trade of mercury, including setting limitations on certain specific sources of mercury such as primary mining, and to control mercury-added products and manufacturing processes in which mercury or mercury compounds are used, as well as artisanal and small scale gold mining. The text of the Convention includes separate articles on emissions and releases of mercury, with controls directed at reducing levels of mercury while allowing flexibility to accommodate national development plans. In addition, it contains measures on the environmentally sound interim storage of mercury and on mercury wastes, as well as contaminated sites. Provision is made in the text for financial and technical support to developing countries and countries with economies in transition, and a financial mechanism for the provision of adequate, predictable and timely financial resources is defined.

³⁰¹ Communication from the Commission of 28 January 2005, "Community Strategy concerning Mercury" [COM(2005) 20 final- Not published in the Official Journal].

Recently the Commission adopted a ratification package that will allow the EU to ratify the Convention once the legislative process is concluded.

The package consists of two proposals:

- New Regulation on Mercury repealing and replacing Regulation (EC) 1102/2008, and
- Council Decision concerning the conclusion on behalf of the EU of the Minamata Convention on Mercury

The Regulation will amend current EU legislation by:

- repealing Regulation (EC) 1102/2008, while maintaining its substantive provisions that ban mercury exports and regulate waste mercury disposal;
- prohibiting within the EU any future new uses of mercury in products and industry, unless significant environmental and health benefits are demonstrated and there are no mercury-free alternatives;
- addressing the issue of dental amalgam, by restricting its use to the encapsulated form and by demanding the use of separators by dentists;
- bringing certain additional adjustments to current EU law, necessary to allow the EU to ratify the Convention;
- simplifying certain EU law provisions on mercury.

2. PRINCIPAL OBLIGATIONS OF MEMBER STATES

2.1. Planning

- Strive to participate in or keep abreast of events for exchange of information that may be organised by the Commission under Art. 8, focusing on the need to extend the export ban to further mercury compounds, an import ban, extending the storage obligation to mercury from additional sources, change to time limits for the temporary storage.

2.2. Regulation

- Ensure that the export of metallic mercury (Hg, CAS RN 7439-97-6), cinnabar ore, mercury (I) chloride (Hg_2Cl_2 , CAS RN 10112-91-1), mercury (II) oxide (HgO , CAS RN 21908-53-2) and mixtures of metallic mercury with other substances, including alloys of mercury, with a mercury concentration of at least 95 % weight by weight is banned from 15 March 2011, except where mercury compounds are exported for research and development, medical or analysis purposes. (Art. 1)
- Ensure (as from 15 March 2011) there is no mixing of metallic mercury with other substances for the purpose of export of metallic mercury. (Art. 1)
- Ensure (as from 15 March 2011) that the following are considered waste and are disposed of in accordance with Directive 2008/98/EC on waste in a way that is safe for human health and the environment:
 - metallic mercury that is no longer used in the chlor-alkali industry;
 - metallic mercury gained from the cleaning of natural gas;
 - metallic mercury gained from non-ferrous mining and smelting operations; and
 - metallic mercury extracted from cinnabar ore in the EU (Art. 2)
- Ensure that storage of metallic mercury considered waste is allowed, provided that it receives a prior permit, that the mercury is contained safely and provisions of Directive 1999/31/EC and Decision 2003/33/EC apply:
 - temporarily storage for more than one year or permanently storage (disposal operations D 15 or D 12 respectively, as defined in Annex I of Directive 2008/98/EC) in salt mines adapted for the disposal of metallic mercury, or in deep underground, hard rock formations providing a level of safety and confinement equivalent to that of those salt mines; or
 - temporarily storage (disposal operation D 15, as defined in Annex II A of Directive 2006/12/EC) for more than one year in above-ground facilities dedicated to and equipped for the temporary storage of metallic mercury. Ensure that this latter storage complies with

provisions of Seveso III Directive (2012/12/EU). For this above-ground storage the criteria set out in section 2.4 of the Annex to Decision 2003/33/EC shall not apply. (Art. 3)

- Ensure that the safety assessment, carried out in accordance with Decision 2003/33/EC, for the disposal of metallic mercury according to Article 3 of this Regulation, must take into account the particular risks arising from the nature and long-term properties of the metallic mercury and its containment. (Art. 4(1))
- Ensure that the permit referred to in Articles 8 and 9 of Directive 1999/31/EC for underground or above-ground storage facilities (Article 3(1)(a) and (b)) of this Regulation include requirements for regular visual inspections of the containers and the installation of appropriate vapour detection equipment to detect any leak. (Art. 4(2))
- Any final disposal operation (disposal operation D 12, as defined in Annex I of Directive 2008/98/EC) concerning metallic mercury shall only be permitted after the date at which the amendment of Annexes I, II and III of Directive 1999/31/EC has been adopted. (Art. 4)
- Take all measures to ensure compliance with the Regulation and establish effective, proportionate and dissuasive penalties applicable to infringements of its provisions. (Art. 7)

2.3. Information and Reporting

- Notify the provisions on penalties to the Commission and immediately notify in case of change of these provisions. (Art. 7)
- Submit to the Commission a copy of any permit issued for a facility designated to store metallic mercury temporarily or permanently (disposal operations D 15 or D 12), accompanied by the respective safety assessment pursuant to Article 4(1) of this Regulation. (Art. 5)
- Ensure that the Commission is informed on the application and market effects of this Regulation in their respective territories but supply this data earlier if so requested by the Commission. (Art. 5(2))
- Ensure that importers, exporters and operators of activities send to the Commission and to the competent authorities the following data:
 - volumes, prices, originating country and destination country as well as the intended use of metallic mercury entering the EU;
 - volumes, originating country and destination country of metallic mercury considered as waste that is traded crossborder within the EU. (Art. 6)
- Ensure that the companies concerned in the chlor-alkali industry send the following data related to the decommissioning of mercury in a given year to the Commission and the competent authorities of the Member States concerned:
 - best estimate of total amount of mercury still in use in chlor-alkali cell;
 - total amount of mercury stored in the facility;

- amount of waste mercury sent to individual temporary or permanent storage facilities, location and contact details of these facilities. This information has to be sent each year by 31 May (Art. 6(1), (3))
- Ensure that the companies concerned in the industry sectors that gain mercury from the cleaning of natural gas or as a by-product from non-ferrous mining and smelting operations send the following data related to mercury gained in a given year to the Commission and the competent authorities of the Member States concerned:
 - amount of mercury gained;
 - amount of mercury sent to individual temporary or permanent storage facilities as well as location and contact details of these facilities. This information shall be sent each year by 31 May (Art. 6(2), (3))

2.4. Additional Legal Instruments

EU legislation that should be taken into consideration in the implementation of this Regulation includes:

- REACH Regulation (EC) No. 1907/2006
- CLP Regulation (EC) No 1272/2008
- Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals
- Landfill Directive (1999/31/EC).

3. IMPLEMENTATION

3.1. Key tasks

The key tasks involved in implementing this Regulation are summarised in the checklist below.

Table 18. Checklist with Key Implementation Tasks

REGULATION ON THE BAN ON EXPORT OF METALLIC MERCURY - KEY IMPLEMENTATION TASKS	
1	Planning
1.1	Designate a competent authority to monitor compliance with obligations under the Regulation
1.2	Public awareness and public consultation on problems associated with a large global mercury supply and the need to reduce this supply by introducing an EU ban on mercury exports.
1.3	Coordination with measures on global mercury reduction taken at international level;
1.4	Assess the situation as regard metallic mercury in the country, in terms of quantities produced and amounts that can be qualified as waste for which safe storage has be ascertained.
1.5	Devise the procedure for storage safety assessments. The assessment must be carried out in accordance with Decision 2003/33/EC establishing criteria and procedures for the acceptance of waste at landfills. This assessment shall ensure that the particular risks arising from the nature and long-term properties of the metallic mercury and its containment are covered.
1.6	Devise the procedure for storage permitting, permit reviews and updates, taking into account requirements under IED.
1.7	Define measures needed to ensure compliance with the Regulation and establish effective, proportionate and dissuasive penalties applicable to infringements of its provisions.
1.8	Provide technical instructions on the safety assessment, carried out in accordance with Decision 2003/33/EC, for the disposal of metallic mercury and ensure that the assesement adequately addresses the particular risks arising from the nature and long-term propertiesof the metallic mercury and its containment
1.9	Coordinate with competent authorities for Landfill Directive (and the IED) to ensure that the permit issued under Articles 8 and 9 of Directive 1999/31/EC for underground or above-ground storage facilities comprise requirement on regular visual inspections of the containers and the installation of appropriate vapour detection equipment to detect any leak

1.10	Provide for a system of regular inspections of the storage place, including visual inspection of the containers and the installation of appropriate vapour detection equipment to detect any leak.
1.11	Prepare guidance for implementing authorities and relevant industries (chlor-alkali industry, cleaning of natural gas, non-ferrous mining and smelting operations and cinnabar ore operations) to inform about the obligations under the Regulation and that mercury which is no longer used in the industrial operations or are residues from operations are considered waste and must be disposed of in accordance with the requirements of the Regulation.
1.12	Training and guidance for customs authorities ensuring proper instructions of how to deal with shipments suspected to contain mercury
2	Regulation and Monitoring
2.1	As from 15 March 2011 not allow any exports of metallic mercury and certain mercury compounds and mixtures (i.e. metallic mercury (Hg); cinnabar ore; mercury chloride (Hg ₂ Cl ₂); mercury oxide (HgO); and mixtures of metallic mercury with other substances with a mercury concentration of at least 95 % weight by weight.
2.2	As from 15 March 2011, ensure the safe storage of this metal used in or produced by certain industrial activities (the chlor-alkali industry; the cleaning of natural gas, non-ferrous smelting and mining operations; and the extraction of cinnabar ore)
2.3	Ensure that no operator stores mercury without first obtaining a storage permit. Provide for a system of regular inspections of the storage place, including visual inspection of the containers and the installation of appropriate vapour detection equipment to detect any leak.
2.4	Ensure that operators of storage facilities for mercury install appropriate vapour detection equipment to detect any leak and that there is self-monitoring of this regularly.
2.5	For the temporary and permanent storage, such as storage in salt mines or in deep underground or temporary storage in above-ground facilities suitable for temporary storage of mercury ensure compliance with the provisions under Landfill Directive (1999/31/EC) and Decision 2003/33/EC.
2.6	Ensure the temporary storage (disposal operation D15, as defined in Annex I of Directive 2008/98/EC) for more than one year in above-ground facilities dedicated to and equipped for the temporary storage of metallic mercury. Ensure that this latter storage complies with provisions of Seveso III Directive (2012/18/EU) in terms of containing risks, which involves drawing up certain safety procedures and an internal emergency plan.
2.7	Ensure that metallic mercury is not mixed with other substances for the purpose of export of metallic mercury.
2.8	Ensure that the below is considered waste and must be disposed of in accordance with Directive 2008/98/EC on waste in a way that is safe for human health and the environment: <ul style="list-style-type: none"> • metallic mercury that is no longer used in the chlor-alkali industry;

	<ul style="list-style-type: none"> • metallic mercury gained from the cleaning of natural gas; • metallic mercury gained from non-ferrous mining and smelting operations; • metallic mercury extracted from cinnabar ore in the EU
2.9	Ensure that the temporary or permanent storage underground or temporary storage above ground is not carried out prior to obtaining a permit under Directive 1999/31/EC on landfills and that the assessment under Decision 2003/33 has been carried out and that the permit contains requirements on regular visual inspections of the containers and the installation of appropriate vapour detection equipment.
3	Reporting
3.1	Compilation of statistical information (government)
3.2	Member States shall submit to the Commission a copy of any permit issued for a facility designated to store mercury, as well as information on the application and market effects of this Regulation in their territory by 1 July 2012.
3.3	Notify the provisions on penalties to the Commission (by 4 December 2009) and immediately notify it in case of change of these provisions. (Art. 7)
3.4	Submit to the Commission a copy of any permit issued for a facility designated to store metallic mercury temporarily or permanently (disposal operations D 15 or D 12), accompanied by the respective safety assessment pursuant to Article 4(1) of this Regulation.
3.5	Ensure that by 1 July 2012, the Commission is informed on the application and market effects of this Regulation in their respective territories but supply this data earlier if so requested by the Commission.
3.6	By 1 July 2012, importers, exporters and operators of activities send to the Commission and to the competent authorities the required data (e.g. volumes, prices, countries involved)
3.7	Ensure that by 31 May of each year the companies concerned in the chlor-alkali industry, industry sectors that gain mercury from the cleaning of natural gas or as a by-product from non-ferrous mining and smelting operations send the required data related to the decommissioning of mercury in a given year to the Commission and the competent authorities of the Member States concerned (e.g. on amount of mercury used, gained, sent to individual temporary or permanent storage facilities)
3.8	Ensure that by 31 May of each year the companies concerned in the chlor-alkali industry, industry sectors that gain mercury from the cleaning of natural gas or as a by-product from non-ferrous mining and smelting operations send the required data related to the decommissioning of mercury in a given year to the Commission and the competent authorities of the Member States concerned (e.g. on amount of mercury used, gained, sent to individual temporary or permanent storage facilities)

3.2. Phasing Considerations

This Regulation cannot be fully implemented until appropriate systems for the banning and safe storage of metallic mercury have been ensured. The ban and the requirements for obtaining a storage permit to comply with the other requirements on safe temporary or long-term storage apply to the Member States as from 2011. Given the efforts also at the international level to address the problems with large supplies of mercury, it is not likely that the EU will grant any transitional periods for enforcing the ban and storage requirements. Hence, the candidate countries should take the necessary measures to prepare for complying fully with the Regulation on the date of EU accession. In the meantime, they should participate actively in various international and EU forums discussing the mercury issues including the various technical aspects to mercury storage.

The key phases in the implementation are:

1. Preparatory phase with initial stakeholder involvement, identification of mercury sources and amounts at national level. The initial assessments and analysis will also explore which activities and actors will be impacted and how as well as the financial implications for the stakeholders. These measures will eventually lead to an overall implementation plan
2. Devise the necessary institutional and legal structures for implementing the Regulation, including systems for permitting, inspection and reporting, which involves setting up national authorities, possibly a help desk, training of staff, issuing of guidance documents
3. Start implementing the permitting and monitoring system and ensure that all affected actors comply with the Regulation.

4. IMPLEMENTATION GUIDANCE

A number of general observations and good practice suggestions for applying the Regulation are presented below based upon the collective experience of Member States.

4.1. Planning

- The competent authority/ies will vary depending on the administrative structure within the country concerned, but may include government departments or agencies with responsibility for the chemical industry, trade and customs control.
- Develop full understanding of the scope and extent of the ban. The commodity codes for the affected mercury:
 - 2805 40 00 - metallic mercury
 - Ex 2617 90 00 - cinnabar
 - Ex 2620 60 - slag, ash and residues containing arsenic, mercury, thallium, or their mixtures, of a kind used for extraction or arsenic or those metals for the manufacture of their chemical compounds
 - Ex 2843 90 10 - amalgams
 - Ex 2852 00 00 - compounds, inorganic or organic, of mercury excluding amalgams
 - Ex 2853 00 90 - other (amalgams)
- The export ban does not include products containing mercury such as thermometers, barometers, batteries, dental amalgam, low energy light bulbs (compact fluorescent lights), computer or television screens. Customs declarations for permitted exports for medical purposes should be accompanied by a letter from the third country importer stating that he or she is a legally recognised medical practitioner or works for a pharmaceutical company meeting the appropriate registration requirements in the import country. Regarding customs declarations for permitted exports for research and development and analysis purposes these should be accompanied by a letter from the 3rd country importer saying that any scientific experimentation, analysis or chemical research will be carried out under controlled conditions in a volume less than 1 tonne per year.

Examples from a Member State: competent authorities

United Kingdom: DEFRA introduced the Mercury Export and Data (Enforcement) Regulations 2010 (SI 2010 No. 265) to assign national enforcement responsibilities and powers, as policy on environmental matters is devolved. The lead enforcement authorities for implementing the ban are the three UK environment agencies, namely:

- Environment Agency for England and Wales (EA);
- Scottish Environmental Protection Agency (SEPA);
- Northern Ireland Environment Agency (NIEA).

UKBA (UK Border Agency) will respond to requests from HMRC or any of the environment agencies to detain any suspect consignments. The environment agencies will deal with physical examination, seizure and disposal of the controlled goods and any other things with them. Their responsibilities will include the investigation of any false claims in customs export declarations that goods qualify for permitted exemptions to the mercury export ban or are not subject to the ban.

Examples from a Member State

Romania: As from 2005, even before EU accession, Romania became active in the negotiation process regarding the European strategy for the metallic mercury management. Initially, Romania began collecting information in order to have a database on import, export, storage and metallic mercury production or devices that contain metallic mercury. As a next step, Romania reported annually this national data.

Romania was also active at the negotiations for the EU Regulation 1102/2008. At the national level workshops and bilateral meetings were organised, having as principal task to discuss how to fulfil the EU obligation at the national level. Also, in collaboration with the EC was organized a TAIEX regarding the management of metallic mercury. At the national level Romania is studying the opportunity to store the metallic mercury in their own salt mines or, store it in other EU state. Romania is studying also, from the financial point of view, the retrofitting process for the installation that still use metallic mercury in their processes and will start a program for collecting and recycling the devices that contain metallic mercury.

Sweden: The Swedish mercury strategy aims to reduce mercury levels in the environment to natural background levels and to be able to eat fish from Swedish lakes without any concerns about health risks. Its key objectives are:

Reducing mercury emissions from point sources as far as possible

Phasing out the use of mercury in products and processes

Collecting and treat mercury already in use

No recycling of mercury

Final disposal of mercury waste

Export ban on mercury and mercury compounds

Enhancing international cooperation

Source: <https://www.naturvardsverket.se/Documents/publikationer6400/978-91-620-8691-6.pdf?pid=10261>

Examples from a Member State

Denmark: Mercury has been a prioritised substance in Danish pollution abatement for several decades. Due to its well documented adverse environmental characteristics, mercury and its compounds are among the most regulated hazardous substances both nationally in Denmark, in the EU and in international conventions. This is also reflected by the fact that mercury is among the few substances which are, or are soon to be, regulated globally. Denmark and other Nordic countries have been among the main promoters behind the formation of strict regulation of mercury and its compounds in the EU and globally. Mercury pollution to all environmental media is targeted by legislation, yet with most emphasis on the atmospheric releases due to mercury's ability for long-range transport.

Denmark's ban on the marketing, import and export of mercury covers most intentional mercury uses, with exemptions for a number of mercury applications, partly such for which alternatives are not fully matured on the market (for example energy-saving lamps) and partly a number of uses for which exemptions are made in order to not impair trade among EU Member states. In the EU context, mercury is however also severely restricted, and with the dedicated focus of the Community mercury strategy, remaining intentional mercury uses may be further restricted as adequate alternatives for these are matured and accepted.

As regards other mercury source categories, mercury releases are also regulated to a varying extent. Waste incineration is regulated with an air emission limit in the Industrial Emissions Directive, and otherwise indirectly via facility-specific environmental permits which may also target releases to other media. Mercury releases to the atmosphere from coal combustion is addressed in Danish regulation indirectly only, in the form of a guideline on air emissions in environmental permits, which is to be considered in facility-specific environmental permits. Based on available emission estimates, atmospheric emissions from these major sources have been reduced heavily over the last decades. Mercury-specific filter types exist however, which have the capacity to reduce air emissions further. These are applied on many (but not all) of the Danish waste incineration plants, but not on any Danish coal fired power plants. Neither mercury, nor any mercury compounds are manufactured in Denmark. Manufacturing of metallic mercury in the EU is now limited to recycling of mercury, as all other EU sources of supply have been banned.

The Danish consumption of mercury declined by 90% already in the period 1993-2001 due to a prioritised strategy from Denmark's side. Restrictions on certain mercury uses were introduced even before the first general mercury ban in 1994. At the same time, a change in technology occurred from manual, mercury-filled instruments to mercury-free digital solutions with more functionalities, which also helped reduce the consumption.

A search for mercury and mercury compounds in the Danish Product Register, which register mixtures aimed at professional users in Denmark, did only show the use of elemental mercury and 4 mercury compounds, and in amounts in the range of a few kilograms per year. Similarly, a search in the Nordic chemicals database SPIN only gave few hits. This is in accordance with the absence of mercury compounds registered under REACH for the EU.

Source: Danish Ministry of Environment, Environmental Protection Agency: Survey of mercury and mercury compounds, Part of the LOUS-review Environmental Project No. 1544, 2014 <http://www2.mst.dk/Udgiv/publications/2014/01/978-87-93026-98-8.pdf>

4.2. Technical Specifications

- Apply the relevant EC Criteria for underground disposal as set out in Council Decision 2003/33/EC of 19 Dec 2002 establishing criteria and procedures for the acceptance of waste at landfills
 - A site-specific safety assessment as defined in Annex A

- Importance of geological barrier
- Ultimate objective of underground storage = Isolation of wastes from the biosphere
- Wastes + geological barrier + cavities + engineered structures + technical aspects must fulfil the corresponding requirements
- The site-specific assessment of risk requires the identification of:
 - The hazard (deposited wastes)
 - The receptors (biosphere and possibly groundwater)
 - The pathways by which substances from the wastes may reach the biosphere
 - The assessment of impact of substances that may reach the biosphere
- An integrated performance assessment analysis normally includes:
 - Geological assessment
 - Geomechanical assessment
 - Hydrogeological assessment
 - Geochemical assessment
 - Biosphere impact assessment
 - Assessment of the operational phase
 - Long-term assessment
 - Assessment of the impact of all the surface facilities at the site

Examples from a Member State

Sweden

Sweden is recognised as having the most far-reaching approach to mercury waste. Sweden has a national environmental goal and legislation stating that the use of mercury shall be phased out. In addition, mercury waste shall be deposited in final storage underground to eliminate emissions and to isolate mercury from the biosphere.

Since 1 August 2005 Sweden implemented an ordinance regarding mercury in waste (Waste Ordinance 2001:1063), which states: Waste that contains at least 0.1 percent by weight mercury and is not in a permanent landfill had to be placed in deep underground disposal by 1 January 2015 at the latest. It was not allowed to dispose of mercury waste before 1 January 2015 in a way that prevents terminal storage in bedrock.

Germany

Germany is the main importing country of mercury containing waste and the only country importing mercury containing waste for permanent storage (D12).

According to the German legislation hazardous waste is only allowed to be deposited in salt rock due to the lack of hard rock formations fulfilling the requirements of safe long-term storage. The Ordinance on the simplification of waste disposal regulations came into force on 16 July 2009. This regulation takes into consideration Regulation (EC) No 1102/2008 as regards the long-term storage of mercury. Following the regulation, the long-term storage of metallic mercury is possible in landfill class III (above ground) and landfill class IV (underground storage). The class IV landfills have been recently introduced for the purpose of mercury storage in Germany. Liquid wastes are forbidden in long-term storage. An exception is made for the long-term storage of liquid mercury. With regard to above-ground storage (landfill class III), the landfill has to be dedicated for the storage of mercury and needs to be operationally and technically equipped for this purpose. In the case of underground storage (landfill class IV) the landfill has to be adapted for the purpose of disposing of metallic mercury and this has to be taken into particular consideration in the site-specific safety assessment. Wastes accepted into long-term storage facilities need to have a written certification granting the planned recovery or disposal operation

Source: *European Commission - Final report: Requirements for facilities and acceptance criteria for the disposal of metallic mercury prepared by BiPRO GmbH (16.04.2010), Reference number: 07.0307/2009/530302/ETU/G.2.2, 16.04.2010, available at: http://ec.europa.eu/environment/chemicals/mercury/pdf/bipro_study20100416.pdf*

5. COSTS

The costs of implementing this regulation will be shared between the public and private sector. The public sector is expected to cover costs associated with ensuring the permitting, monitoring and inspections of the activities covered. Some of these costs such as the permitting and inspections can be partly offset with an administrative fee.

The costs for industry mainly concern those that either use or generate mercury as part of their products or processes. These sectors will, as a minimum, face costs for ensuring safe storage of mercury. However, these sectors will also in the longer-term be required to look into alternatives to avoid or at least reduce the use and generation of mercury in the activities. Hence, costs for research and development and innovation is also expected.

Table 19. Checklist of the Types of Cost Incurred to Implement the Directive

Checklist of the Types of Cost Incurred to Implement the Directive
<p>Initial set-up costs:</p> <p>Set-up costs for the government or competent authority</p> <ul style="list-style-type: none"> • designate a competent authority; • stakeholder engagement and public awareness of the urgent need to reduce the global mercury supply and ensure export ban from EU to other countries and to ensure safe storage. Consult with stakeholders, especially on the siting of underground and above-ground storage facilities • assess possible storage facilities • establish an initial inventory and data collection system regarding mercury data • set up a permitting system under Landfill Directive (1999/31/EC) (for the government) • set up a control system with periodic visual inspections; • training and recruitment of staff and inspectors <p>Set-up costs for establishments (private sector)</p> <ul style="list-style-type: none"> • ensure disposal of mercury from the various industrial sectors (e.g. chlor-alkali industry, cleaning of natural gas, non-ferrous mining and smelting operations and cinnabar ore operations) • training and recruitment of a person responsible for maintaining safe mercury storage; • assess the storage possibilities on site of industrial establishments • establish a data collection system for reporting on amounts collected and stored to the competent authorities and the Commission
<p>Capital investments:</p>

For private sector: Invest in BAT for safe mercury storage ensuring that the containers and the methods and the safety devices are appropriate for the temporary or longer-term storage of mercury

Ongoing costs:

Ongoing costs for the government

- collecting data for reporting to the Commission;
- monitoring compliance with ban and safe storage requirements;
- issuing of storage permit, reviewing and updating of existing permits;
- coordination with measures on global mercury reduction taken at international level;
- Visual inspections of storage facilities
- compilation of statistical information (government)
- Training and guidance for customs authorities ensuring proper instructions of how to deal with shipments suspected to contain mercury

Ongoing costs for the establishments

- monitoring compliance with standards;
- ensure that metallic mercury waste is safely stored.

NOISE

Section 9

1. INTRODUCTION AND OVERVIEW	1509
1.1. EU Policy.....	1509
1.2. EU Legal Instruments.....	1510
1.2.1. Motor Vehicles.....	1510
1.2.2. Aircraft	1513
1.2.3. Railways.....	1514
1.2.4. Industrial noise.....	1514
1.2.5. Outdoor Equipment	1514
1.2.6. Household Appliances.....	1515
1.2.7. The Directive on Environmental Noise.....	1515
1.3. Future Developments	1515
1.3.1. Policy Documents	1515
1.3.2. Framework for Noise Policy	1516
2.1. Introduction.....	1517
2.2. Strategy Development.....	1517
2.2.1. Key Stages.....	1517
2.2.2. Stage 1 - Review and analyse existing situation	1518
2.2.3. Stage 2 - Identify significant problems and deficiencies associated with existing systems for controlling noise emissions	1519
2.2.4. Stage 3 - Definition and Analysis of Strategic Objectives	1519
2.2.5. Stage 4 - Identify and Evaluate Options for Achieving Objectives	1519
2.2.6. Stage 5 - Strategy Formulation	1520
2.2.7. Stage 6 - Strategy Implementation Plan.....	1520
3. INSTITUTIONS AND RELEVANT PARTIES.....	1522
3.1. Stakeholders.....	1522
3.2. National Government Institutions	1522
3.3. Competent Authorities	1522
3.4. Regional and Local Government.....	1524
3.5. Private Sector Involvement.....	1524
3.6. Communication and Consultation.....	1524
4. TECHNICAL ISSUES	1526
4.1. Relationship between Standards set in EU Directives and Voluntary Standards	1526
4.2. Noise Measurement Methods.....	1527
5. REGULATION AND ENFORCEMENT.....	1528

5.1.	Overview.....	1528
5.2.	Type-Approval and Type-Examination.....	1528
5.2.1.	Motor Vehicles.....	1528
5.2.2.	Outdoor Equipment.....	1529
5.3.	Noise Certification and Registration Requirements.....	1529
5.3.1.	Railway vehicles.....	1529
5.3.2.	Aircrafts.....	1530
5.4.	Monitoring, Inspection and Enforcement.....	1530
5.5.	Data Collection and Reporting.....	1533
6.	PRIORITIES AND TIMING.....	1534
7.	ECONOMIC AND FINANCIAL ISSUES.....	1535
7.1.	Introduction.....	1535
7.2.	Cost Elements.....	1535
7.2.1.	General Issues.....	1535
7.2.2.	Public Costs.....	1536
7.2.3.	Private Costs.....	1536
8.	SUMMARY OF KEY ISSUES.....	1537

NOISE - OVERVIEW

1. INTRODUCTION AND OVERVIEW

This section of the Handbook deals with EU legislation in the noise sector. This section contains a general overview and summary of the most important noise legislation targeting noise from transport sources (i.e.: road and non-road vehicles, trains and aircrafts), non-mobile sources (e.g. household machinery and outdoor equipment), as well as environmental noise. The introduction is followed by one specific fiche on the Environmental Noise Directive (2002/49/EC).

1.1. EU Policy

Environmental noise pollution is, in the EU noise policy context, defined as the noise caused by traffic, and industrial activities. Noise pollution has a number of adverse health effects, including impaired hearing, sleep and mental disorders, high blood pressure and is considered to be a significant environmental health problem in Europe. It is estimated that millions of people in the EU suffer from noise levels that scientists and health experts consider unacceptable. Furthermore, the effects of exposure to noise impact EU economies. They lead to a loss of productivity of workers whose health and well-being are affected by noise, put a burden on health care systems and cause a substantial depreciation of real-estate value. EU policy on environmental noise initially had a different priority compared to other environmental sectors because solutions were often considered best handed at the national or local levels. EU intervention in noise policy was mainly based on internal market objectives: setting harmonized noise limits and mandatory technical standards for motor vehicles, trains, aircrafts, household appliances, outdoor equipment and other noise-generating products. With increasing knowledge of the health impacts of noise, EU noise policy and legislation took a wider approach with the adoption in 2002 of the Environmental Noise Directive (2002/49/EC), which is a main instrument to identify noise pollution levels in EU and to trigger the necessary action at Member State level. This directive is concerned with the assessment and management of environmental noise caused by means of transport and industrial activity.

In its 7th Environment Action Programme, the European Union committed to significantly decrease noise pollution in the Union, moving closer to levels recommended by the World Health Organisation, by 2020. This will require, in particular: implementing and updating Union noise policy aligned with the latest scientific knowledge, measures to reduce noise at source, including improvements in city design.

The Commission published in 2011 a first implementation report³⁰², summarising the implementation progress to date and describing ways forward to improve implementation and enhance effectiveness of EU's environmental noise policy.

³⁰² COM(2011) 321 final of 1 June 2011

1.2. EU Legal Instruments

1.2.1. Motor Vehicles

Two legal acts are related to type-approval procedures for motor vehicles and motorcycles, with respect to noise emissions. The EU legislation on road traffic noise set limits on permitted sound levels for the vehicles, their exhaust systems, silencers and tyres, together with requirements for measurement and testing:

Directive 70/157/EEC³⁰³ introduces limits on sound levels of road vehicles, and specifies procedures for measuring sound levels of exhaust systems and silencers. This Directive is repealed with effect from 1 July 2027, by the Regulation (EU) No 540/2014 of the European Parliament and of the Council of 16 April 2014 on the sound level of motor vehicles and of replacement silencing systems, and amending Directive 2007/46/EC and repealing Directive 70/157/EEC. The new Regulation has introduced changes related to:

- New test method – a new test method that better reflects current driving behaviour will be introduced. This method, developed by the Economic Commission for Europe of the United Nations (UNECE) has already been used in the EU for monitoring purposes over the last three years.
- Lower limit values - for motor vehicles, the limit values will be lowered in two steps of 2 decibel A-weighting (dB(A)) each. For heavy-duty vehicles, the reduction will be 1 dB(A) for the first step and 2 dB(A) for the second step. The first step is foreseen to apply 7 years after the proposal's publication date in the Official Journal. The second step will follow 4 years later.
- Additional sound emission provisions (ASEP) – these will be included in the type-approval procedure and the existing exemptions for certain vehicle types will be revised. ASEP are preventive requirements intended to cover driving conditions in real traffic outside the type-approval driving cycle. This measure aims to ensure that the noise of a vehicle under street driving conditions does not significantly differ from when the vehicle is tested.
- Minimum noise - a specific Annex on the minimum noise ('Approaching Vehicle Audible Systems') of electric and hybrid electric vehicles has been proposed. These requirements should ensure that only adequate sound generating devices are used in vehicles.
- Noise labelling - to foster competition, some requirements on noise labelling at the dealership were introduced. Manufacturers will ensure that the sound level of each vehicle is displayed during its sale.
- Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles. The Regulation establishes the administrative and technical requirements for the type-approval of all new vehicles, systems, components and separate technical units.
- Commission Delegated Regulation (EU) No 134/2014 of 16 December 2013 supplementing Regulation (EU) No 168/2013 of the European Parliament and of the Council with regard to environmental and propulsion unit performance requirements and amending Annex V thereof

³⁰³ Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles, as amended by Directives 73/350/EEC, 77/212/EEC, 81/33/EEC, 84/372/EEC, 84/424/EEC, 87/354/EEC, 89/491/EEC, 92/97/EEC, 96/20/EC, 1999/101/EC and 2007/34/EC

- Directive 2001/43/EC, amending Council Directive 92/23/EEC, relating to tyres for motor vehicles and their trailers and to their fitting introduces limits on the noise generated where tyre meets road. These limits differentiate between vehicle type and tyre width (5 classes) and will be enforced by including tyre noise tests in EC type-approval certificate requirements, which must be met for any tyre to be placed on the EU market.

Key Concepts

Strategic Noise Maps: Directive 2002/49/EC seeks to establish a common basis for addressing noise problems across the EU. Member States are required to appoint competent authorities to draw up "strategic noise maps" for major roads, railways, airports and agglomerations using harmonised noise indicators, with the public to be informed and consulted about noise exposure, its effects and the measures being considered to address noise. Competent authorities are then to draw up action plans to reduce noise where necessary and to maintain environmental noise quality where it is good.

Noise Emission Limits: Noise emission limits are set for motor vehicles (including motorcycles), trains and aircraft, and incorporated in legal instruments. The various Directives provide that Member States may not set more stringent noise levels than those contained in the Directives. Technical and scientific advice on standards may be obtained from technical research and other government institutes, scientific advisors or independent consultants.

Type-Approval of Motor Vehicles: Motor vehicles (including motorcycles) are required to be type-approved, i.e. before a new production series is allowed on the market, the series must be examined to make sure that it conforms with certain specifications regarding safety and emissions characteristics for vehicles. There is a common European Whole Vehicle Type Approval system, which applies to all road vehicles and as well to off-road vehicles. National type approval is no longer allowed in EU Member States. The European Whole Vehicle Type-Approval is based on several dozen separate EU Directives. Noise requirements make up only one small part of the requirements for type-approval. Furthermore, while many other characteristics of motor vehicles will be checked later in the life of the vehicle (through first inspections of individual vehicles, periodic vehicle inspections at pre-determined occasions, and roadside spot-checks), noise emissions are only controlled through the type-approval process.

Outdoor Equipment: Under Directive 2000/14/EC relating to noise emissions in the environment from equipment for use outdoors (as amended by Directive 2005/88/EC and Regulation (EC) 219/2009), covering a wide range of outdoor equipment, manufacturers can choose between different options for verification of compliance with noise requirements. The options range from self-certification to the verification of units by a notified body to the use of quality assurance systems. Where manufacturers elect to self-certify or use quality assurance systems, the directive provides for monitoring and surveillance of the process by notified bodies.

Rail noise:

1. Interoperability of the Trans-European high-speed rail system

- Directive 2008/57/EC on the interoperability of the rail system within the Community
- Commission Regulation (EU) No 1304/2014 of 26 November 2014 on the technical specification for interoperability relating to the subsystem 'rolling stock — noise' amending Decision 2008/232/EC and repealing Decision 2011/229/EU

2. Noise-differentiated track access charges (NDTAC)

- Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area (recast) foresees an optional introduction of noise-differentiated track access charges.
- Commission Implementing Regulation (EU) 2015/429 of 13 March 2015 setting out the modalities to be followed for the application of the charging for the cost of noise effects. It harmonises the charging principles and thus encourages more Member States to introduce noise charging, which would provide more incentives for the sector to retrofit.

The NDTAC is an economic incentive for retrofitting freight wagons with composite brake blocks. The replacement of cast iron brake blocks with innovative composite brake blocks is deemed to be the most efficient way of significantly reducing the noise generated by freight wagons in the short term. Using these blocks can reduce noise levels by up to 10 dB, which means halving them in terms of human perception.

3. Connecting Europe Facility (CEF)

- Regulation (EU) No 1316/2013 of the European Parliament and of the Council of 11 December 2013 establishing the Connecting Europe Facility, amending Regulation (EU) No 913/2010 and repealing Regulations (EC) No 680/2007 and (EC) No 67/2010. Through establishing the CEF it allows 20 % of co-funding for the eligible costs of retrofitting existing freight wagons with composite brake blocks. The EU assistance is distributed through calls, running from 2014 until 2020; the first call 'noise' took place in 2014, the next one will be launched in 2016/2017.

Environmental Assessment: Environmental assessment is a procedure to ensure that the environmental implications of decisions, including noise pollution where appropriate, are taken into account before the decisions are made. Two types of procedure are provided for in EU legislation:

- Strategic Environmental Assessment: SEA Directive (2001/42/EC), which aims at ensuring that the environmental consequences of certain plans and programmes are identified and assessed during their preparation and before their adoption. To that end, environmental assessments must be carried out, in which the likely significant effects on the environment of implementing the plans or programmes under consideration, and reasonable alternatives taking into account the objectives and the geographical scope of these plans or programmes, are identified, described and evaluated. While noise pollution is not explicitly referred to in the SEA Directive, the 'likely significant effects on the environment' to be addressed include effects on 'human health'.
- Environmental Impact Assessment: Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment (Environmental Impact Assessment - EIA). The EIA procedure ensures that environmental consequences of certain projects, including noise, must be identified and assessed before authorisation is given.

Shared Responsibility: Shared responsibility refers to a principle incorporating new ways of working with the market, involving citizens, enterprises and other stakeholders, in order to induce necessary changes in both production and public and private consumption patterns that have a negative influence on the state of, and trends in, the environment. In effect, this approach considers that only by replacing the command-and-control approach with an approach based on shared responsibility between the various actors can commitment to agreed measures be achieved. The Commission green paper on future noise policy³⁰⁴ of November 1996 was the first

³⁰⁴ (COM(96) 540)

step in the development of a noise policy with the aim that no person should be exposed to noise levels, which endanger health and quality of life. This paper called for the application of the principle of shared responsibility in the noise sector.

Standards: Requirements related to product characteristics or procedures can be either legally defined or set in voluntary standards developed by national or international standardisation bodies. Laws can also reference standards developed by standardisation bodies, thus making them legally binding. The technical standards applied in the noise Directives constitute a mix. The annexes to some Directives contain specific noise measurement methods, while others make a reference to external documents like those of the International Civil Aviation Organisation, or allow implementing states to create their own standards.

1.2.2. Aircraft

One Directive and three Regulation limit noise emissions from aircrafts, and their operation, by reference to the Convention on International Civil Aviation. The operation of the civil subsonic aeroplanes is limited in line with the International Civil Aviation Organisation (ICAO) standards through banning of noisiest aircraft from European airports. The step forward in reducing noise pollution is adoption of the Regulation (EU) No 598/2014 of the European Parliament and of the Council of 16 April 2014 on the establishment of rules and procedures with regard to the introduction of noise-related operating restrictions at Union airports within a Balanced Approach and repealing Directive 2002/30/EC establishing new aviation noise rules pursuant to the ICAO's guidelines on Balanced Approach. This approach consists of four key elements: reducing noise levels at source through deployment of modern aircraft, managing the land around airports in a sustainable way, adapting operational procedures to reduce the noise impact on the ground, and, if required, introducing operating restrictions such as bans on night flights. The latter is used only after consideration of other elements of the balanced approach.

Beside the Regulation (EU) 598/2014 the legislative framework comprises:

- Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC
- Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations
- Directive 2006/93/EC of the European Parliament and of the Council of 12 December 2006 on the regulation of the operation of aeroplanes covered by Part II, Chapter 3, Volume 1 of Annex 16 to the Convention on International Civil Aviation, second edition (1988) (codified version)

1.2.3. Railways

EU noise legislation also covers noise from railways. Most of the noise-restricting measures will be the responsibility of the countries rather than the private sector, since many railway systems are still owned and operated by the state. The legislative framework comprises:

- Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community (Recast)
- Commission Regulation (EU) No 1304/2014 of 26 November 2014 on the technical specification for interoperability relating to the subsystem ‘rolling stock — noise’ amending Decision 2008/232/EC and repealing Decision 2011/229/EU
- Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area (recast)
- Commission Implementing Regulation (EU) 2015/429 of 13 March 2015 setting out the modalities to be followed for the application of the charging for the cost of noise effects
- Regulation (EU) No 1316/2013 of the European Parliament and of the Council of 11 December 2013 establishing the Connecting Europe Facility, amending Regulation (EU) No 913/2010 and repealing Regulations (EC) No 680/2007 and (EC) No 67/2010

On 22 December 2015 the Commission services have adopted a commission Staff Working Document (SWD) on rail freight noise reduction³⁰⁵. This document provides a review of existing measures aimed at effective reduction of rail noise of freight wagons and an analysis of additional possible solutions that might be considered in the years to come.

1.2.4. Industrial noise

No specific legislation foresees limits on industrial noise, but Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control), although mainly dealing with outdoor emissions legislation, allows Member States competent authorities to regulate noise levels through legislation or integrated permits.

1.2.5. Outdoor Equipment

Directive 2000/14/EC relating to noise emissions in the environment from equipment for use outdoors (as amended by Directive 2005/88/EC) aims to simplify pre-existing legislation covering outdoor equipment. The Directive consolidates nine noise Directives and extends their scope to cover 63 types of machinery (categorised as 57 items). The principal feature of the directive is the requirement that all equipment types be labelled for their guaranteed maximum noise level. In addition, the directive imposes noise emission limits for 22 types of equipment listed and harmonises methods of noise measurement. The directive sets out a range of options for conformity assessment. Manufacturers may choose from self-certification, unit verification and full quality

³⁰⁵ <http://ec.europa.eu/transport/modes/rail/doc/2016-01-05-cswc-rail-noise-reduction.pdf>

assurance systems. Unit verification and the checking and surveillance of self- certification and full quality assurance systems are to be carried out by independent bodies appointed by Member States and notified to the Commission ("notified bodies"). The directive establishes a procedure for the collection of noise emission data, information which will serve as the basis for devising economic incentives and eco-label awards. Responsibility for collecting the data will rest with the certification bodies, which will be required to send the Commission a copy of their test reports.

1.2.6. Household Appliances

The fourth category comprises one directive on noise emissions from household appliances, specifying voluntary requirements for labelling. Directive 2009/125/EC³⁰⁶ establishes a framework for setting ecodesign requirements for energy-using products. In its implementation provisions for different products and specific standards and procedures for measurements related to them are set. In this context also noise from household appliances is addressed.

Finally, Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC relates to recreational craft and poses noise limits to these.

1.2.7. The Directive on Environmental Noise

Directive 2002/49/EC of 25 June 2002 aims to provide a common basis for tackling noise problems across the EU. It requires Member States to appoint competent authorities to draw up strategic noise maps for major roads, railways, airports and agglomerations using harmonised noise indicators. In line with the provisions of the Aarhus Convention, Directive 2003/35/EC providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC and Directive 2003/4/EC on public access to environmental information and repealing Council Directive 90/313/EEC, the Directive requires the public to be informed and consulted about noise exposure, its effects and the measures being considered to address noise. Although the Directive does not set any limit values or prescribe measures to be adopted, it requires competent authorities to draw up action plans to reduce noise where necessary and to maintain environmental noise quality where it is good. The Directive has been amended in 2015 by Commission Directive (EU) 2015/996 of 19 May 2015 establishing common noise assessment methods according to Directive 2002/49/EC of the European Parliament and of the Council.

1.3. Future Developments

1.3.1. Policy Documents

Environmental noise, caused by traffic and by industrial and recreational activities is a common and persistent local environmental problem in Europe, and the source of an increasing number of complaints from the public.

³⁰⁶ Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products

The Seventh EU Environment Action Programme 'Living well within the limits of our planet' (7th EAP), which entered into force in 2014, will be guiding European environment policy until 2020. In order to give more long-term direction, it sets out a vision beyond that, of where it wants the Union to be by 2050. The 7th EAP continues the effort, begun with the 5th and 6th EAPs, to address noise pollution in a wider context.

One objective of the 7th EAP is to significantly decrease noise pollution in the Union, moving closer to WHO recommended levels. Measures envisaged to meet the target set for 2020 consists of implementing an updating Union noise policy aligned with the latest scientific knowledge, measures to reduce noise at source, including improvements in city design.

1.3.2. Framework for Noise Policy

The purpose of the EU noise policy is to provide a coherent and co-ordinated approach to noise abatement efforts EU-wide (objectives to be enhanced and taken further pursuant to the 7th EAP). In its green paper on future noise policy, the Commission indicated that changes in overall approach are required to address a wider array of noise concerns, to determine how much noise from certain sources should be reduced; the level at which action should be taken; and the optimal measures or combinations of instruments to achieve an eco-efficient approach.

The green paper further indicated that there is a need for better co-operation across the EU to improve data collection and the comparability of information, and to improve the exchange of experience on noise abatement between Member States. It further suggested that the existing "command and control" compliance methods used for this and other pollution abatement efforts, should be replaced with a system of shared responsibility that brings all stakeholders to the table to agree upon the most effective course of action to reduce noise emissions.

Recognising that noise problems are generally viewed as local in nature, it is argued in the green paper that much of the machinery and equipment that constitutes the source of noise problems is not of local origin. As a consequence, effective action depends on co-ordinated policies at the local, national and EU level.

Directive 2002/49/EC on environmental noise is an important part of the effort to establish an overall noise policy. In addition, the Commission has created an EU noise expert network (whose mission is to assist the Commission in the development of its noise policy) and is providing financial support to a number of different noise-related studies and research projects.

2. DEVELOPMENT OF A SECTORAL STRATEGY AND IMPLEMENTATION PLAN

2.1. Introduction

As with other environmental sectors, efforts to approximate EU noise requirements are best commenced with the development of strategies for managing noise (frameworks or "blueprints" that stipulate what actions will be taken, by whom and by when) and plans for implementing the strategies (containing the details of how these actions will be undertaken).

The essential steps and decisions that need to be addressed in order to comply with current EU policies and legislation limiting noise emissions are outlined below. Strategies for managing noise in a broader context beyond the existing Directives are also considered, taking into account the proposed expansion of EU policies and Directives in this sector. The strategies have been developed mainly to address national government responsibilities for planning, overseeing and controlling the type-approvals and testing of vehicles, machinery and products identified in the Directives. Many of the principles and techniques described herein will also be useful for consideration by local government authorities and private entities involved in regulating noise emissions.

The development of a noise sector strategy will be driven both by the requirements of the EU acquis, and also by national conditions and priorities. The integration of these two aspects is crucial to ensure a balanced strategy that responds both to EU environmental legislation and to national priorities and associated demands.

2.2. Strategy Development

2.2.1. Key Stages

In developing a noise strategy, taking into account the focus in the development of EU noise policy, supplemented by the 7th EAP, and the Directive 2002/49/EC on environmental noise, candidate countries should consider noise policy in an integrated context, focusing not only on source-specific noise emission limits as set in EC legislation, but also more broadly on the reduction of the number of people exposed to environmental noise.

The main steps involved in strategy development are summarised in the box below.

Steps to Developing a Noise Strategy

Review and analyse existing national policies and procedures controlling noise emissions and exposure.

Identify significant problems and deficiencies associated with existing systems for controlling noise emissions and reducing noise exposure.

Define strategic objectives for noise abatement efforts (e.g.: number of people exposed).

Identify and assess the options available for achieving strategic objectives.

Formulate an integrated noise management strategy based on the preferred option. Prepare a detailed strategy implementation plan.

The main considerations for each of these stages are outlined below.

2.2.2. Stage 1 - Review and analyse existing situation

The purpose of this initial step is to gather all relevant information concerning noise exposure and noise emissions, especially focusing on the source areas covered by the EU Directives (motor vehicles, aircrafts, outdoor equipment, and household appliances).

- Nature and Scale of Noise-Related Problems
 - Identify the major sources of noise emissions, usually roads, railways and aircrafts, eventually including information on equipment and activities that produce noise at volumes deemed to have harmful effects on human health.
 - Identify the number of people exposed to environmental noise, using common noise indicators and methods as defined in Directive 2002/49/EC.
 - Compile information on the production, import and export of motor vehicles, aircrafts, outdoor equipment and household appliances that are specifically addressed in current EU law.
- Institutional Arrangements, Legislation and Enforcement
 - Review current national and local laws and regulations relating to environmental noise and/or that set noise limits for specific sources or otherwise limit activities because of the noise emitted.
 - Identify and detail all legal requirements that pertain to type approvals and certification of products in the source areas covered.
 - Review institutional arrangements for implementing and ensuring compliance with legal requirements to assess their effectiveness.
- Public Perception and Attitudes
 - Research public attitudes on noise and identify incidences of specific complaints over noise problems. Focus in greatest detail on the source categories of the current EU legislation, and also on transport and industrial noise.
 - Verify if the citizens and the public authorities are aware of the type and dimension of the problem (noise is the second environmental health problem, just after particulate matter, but most of times not know or understood).

2.2.3. Stage 2 - Identify significant problems and deficiencies associated with existing systems for controlling noise emissions

Having reviewed and analysed the existing situation, including public/consumer concerns, the next step will be to identify and define clearly the current problems and deficiencies associated with existing noise control efforts.

2.2.4. Stage 3 - Definition and Analysis of Strategic Objectives

In developing a noise strategy, candidate countries should consider noise policy in an integrated context, focusing not only on source specific noise emission limits as set in EU legislation, but also more broadly on the reduction of the number of people exposed to environmental noise.

Strategic objectives for national noise policies could include:

- setting a timeframe for meeting EU policies and legislation;
- ensuring that all (targeted) products manufactured, used or exported from the country are type-approved and meet EU and international noise standards;
- developing a legal and regulatory framework that is specific enough to meet current EU noise requirements yet flexible enough to incorporate further requirements as they are established;
- establishing a noise monitoring programme (i.e. ensuring that competent authorities are ready to produce noise maps) that can identify and monitor persistent noise problems, preferably aligned with the requirements of Directive 2002/49/EC to avoid duplication;
- establishing and progressively implementing a national noise policy in order to reduce noise where necessary and maintain environmental noise quality where it is good.

2.2.5. Stage 4 - Identify and Evaluate Options for Achieving Objectives

This stage involves identifying, evaluating and comparing different options or alternatives for achieving objectives. In evaluating the options several threshold decisions need to be considered.

A Noise Framework Abatement Law or Source-Specific Legislation.

In light of Directive 2002/49/EC on the assessment and management of environmental noise, candidate countries should adopt legislation aimed at monitoring, controlling and reducing environmental noise as well as focusing on source-specific noise emissions.

Institutional Development

The path taken in terms of legal transposition will affect the choices available in terms of institutional arrangements. Candidate countries need to designate competent authorities. They can choose to appoint either one competent authority, with responsibility for all noise Directives, or to appoint separate competent authorities for the different Directives. In the latter case, the competent authority could cover related types of Directives as well (i.e. labelling of noise emissions and energy consumption of household appliances). In this context, the structure of competent authorities in charge of producing noise maps and action plans needs to be set up and ensured that they are well linked.

Domestic or International Type-Approval

Candidate countries will need to decide how to deal with type-approval of motor vehicles.

Facilities issuing type-approvals for motor vehicles can either be established in the country itself, or the country can rely on services provided in other countries. Since in-country type-approval is not required for motor vehicles, countries can also choose to slowly build up their domestic capability to issue type-approval certification.

Public or Private Implementation

Both type-approval and inspection activities can be carried out by public entities or by private sector entities. Facilities responsible for type-approval have been privatised in some EU Member States, as have facilities that regularly check that the standards are maintained. The tasks can also be carried out as public-private partnerships.

Countries also have to decide how much of the monitoring and enforcement work they take on (i.e. pot checks), and to what degree noise emissions standards are made self-enforcing. For example, companies may be required to apply for type-approval in order that their products are allowed on the market. The standards can then be considered self-enforcing, if no further checks are undertaken.

2.2.6. Stage 5 - Strategy Formulation

Strategy formulation is the end result of the previous series of stages. It is the culmination of the options discussion and selection process, and should result in a government decision to move forward based on the preferred options. The strategy should be included as part of the country's NPAA efforts, and should go through the necessary consultation and approval procedures to be declared official policy.

2.2.7. Stage 6 - Strategy Implementation Plan

After development of the noise sector strategy, the next step in the approximation process is to prepare implementation plans. Unlike the strategy itself, which is typically aimed at a very wide audience, the implementation plan is primarily intended for use by those charged with executing the strategy. It therefore needs to elaborate in considerable detail all the tasks and activities that must be undertaken in order to realise the various objectives, proposals and programmes contained in the strategy.

It is suggested that the document comprising the strategy implementation plan should generally contain, as a minimum, the elements presented in the box below.

It should also be borne in mind that completion of strategy and implementation plans for noise represents only the first step in an on-going process. It is therefore vital that both the strategy and implementation plan are continually monitored and regularly reviewed to ensure that the various objectives, measures and underlying assumptions are still valid/appropriate, and that the time scale for achieving the overall goal of the strategy is still realistic.

Suggested Minimum Contents of an Implementation Plan for Noise

- 1) Identification of the authorities/agencies responsible for implementation (including transposition of EU Directives into national law).
- 2) Identification and definition of all the key tasks and activities required in order to implement the adopted strategy.
- 3) The sequence, timing and linkages of key tasks and activities. Key implementation decision points and milestones. Detailed timetables for implementation.
- 4) Detailed estimates of the resources required and related costs, especially for noise maps and action plans.
- 5) Cash flow projections for the overall plan and for all plan sub-components.
- 6) A detailed financing plan.
- 7) Supporting data and explanatory text, as required e.g. identifying and detailing the allocation of responsibilities for key implementation tasks; the indicators of achievement to be used; and potential obstacles to successful implementation.

3. INSTITUTIONS AND RELEVANT PARTIES

3.1. Stakeholders

Development of a noise sector strategy and its implementation will require the involvement of a number of stakeholders (institutions within the environmental administration, other agencies within the state administration, the private sector affected by the Directives, and NGOs). In addition, the public must be granted opportunities to participate and influence the process of noise regulation. A plan should be created for involving stakeholders both during the strategy formulation stage and then as the policy is implemented.

The principal stakeholders, and their role in the process of developing and implementing a noise sector strategy that achieves compliance with EU policies and legislation, is outlined below. It is important to keep in mind that the scope of the policy (i.e. whether to include also Regulations on additional products or activities other than those currently regulated through EU legislation), will have a direct effect on the number of stakeholders.

3.2. National Government Institutions

Noise policy is often characterised by fragmented responsibility, with several national government institutions involved and prominent roles for local government (through local nuisance ordinances). National government institutions will need to be tasked with overall responsibility to establish the overall noise policy reflecting relevant EU Directives. If a comprehensive approach is taken, including setting noise limit values, then a single institution should be tasked with the policy setting role — typically the environment ministry.

In terms of meeting current EU requirements, the main institutions involved will be those that regulate product access to the market, including transportation, trade (customs), industry, environment and welfare/labour (occupational health and safety).

3.3. Competent Authorities

Competent authorities should be in charge of day-to-day policy matters and implementation.

They are typically subordinate institutions within the ministry with overall responsibility for developing and implementing noise policy and legislation, (e.g. the civil aviation department within the ministry of transport for aircrafts). The competent authority has various tasks, including:

- developing draft legislation and amendments for the Directives setting noise emission limits and procedures;
- appointing and accrediting bodies to carry out strategic noise maps, action plans, noise measurements, unit verification (outdoor equipment), type-approvals (vehicles) and certification (for aircrafts, railway vehicles and motorcycles) and to carry out checks where manufacturers self-certify and surveillance where full quality assurance systems are adopted (outdoor equipment); and

- preparing reports which the Member States are required to submit to the European Commission.

The designation of competent authorities will be driven by the decision on how comprehensive the noise policy will be. The practical implementation of market access EU Directives is focused on product testing and approvals and states taking this approach will need to consider where current responsibility resides for type-approvals and safety certification for these products. Many other considerations beyond noise will need to be addressed, including mobile source emissions (vehicles), electrical systems and wiring (appliances, machinery), collision impact safety features (vehicles), child safety features (appliances, vehicles), etc.

Table 1. Principal Stakeholders and Their Roles in Noise Abatement

Principal Stakeholders and Their Roles in Noise Abatement	
Stakeholders	Roles
Central government, in particular one or more of the ministries responsible for health, welfare/labour, industry, environment, transport and trade (customs)	Overall responsibility for policy development and planning. Responsibility for compliance with EU noise requirements. Responsibility for various aspects of noise policy implementation, including ensuring the safety of the workforce using noisy machinery, and ensuring that imported products are certified as being type approved.
Competent authorities (typically subordinated institutions within the ministries, or accredited private institutions)	Responsible for the practical aspects of noise policy implementation including: drawing up strategic noise maps and action plans, appointing and supervising notified bodies (for aircrafts, railways and outdoor equipment), accrediting bodies to carry out type approvals, keeping up to date with international developments in noise policy, providing information (guidance) to industry on how to comply with legal requirements and standards, and informing consumers of their rights.
Regional and Local Government	Ensuring that local noise ordinances are developed (or revised) in harmony with national noise policy. Playing an important role in Strategic Noise Mapping and Noise Action Planning. Implementing noise abatement actions
Industry, including producers and importers of motor vehicles, outdoor equipment and household appliances, and aviation companies	Responsible for seeking type approvals for new products, and certification that equipment placed on the market or in use (aircrafts) meet the EU and the international noise standards
NGOs	Representing the public interest, especially relating to noise and consumer products.
Public and consumers	Directly affected by noise issues within the workplace, in proximity to noisy activities (airports, highways, urban construction sites), and as a result of purchasing appliances.

3.4. **Regional and Local Government**

Regional and local authorities often play a major role in noise abatement, through local zoning and land planning requirements and in developing local nuisance laws that restrict noisy activities (site specific and time specific). Such authorities are also likely to be involved in the drawing up of strategic noise maps and action plans pursuant to Directive 2002/49/EC on the assessment and management of environmental noise (and therefore to be part of the "competent authorities"). Involvement of local authorities in the discussions on a balanced approach is seen as an important factor in reducing aircraft noise and limiting the annoyance for people living near airports.

3.5. **Private Sector Involvement**

Implementing the existing EU Directives for noise will require the direct participation of producers and importers to ensure that type approvals have been obtained, and that the vehicles and equipment produced meet type-approved limits.

The Directive on Outdoor Equipment opens opportunities for greater private sector participation through the option of conformity assessment based on approved quality assurance programmes. Competent authorities may also choose to include the private sector in the type testing, approval and spot check procedures. The involvement of the private sector in this way may be useful as a means to utilise expertise and equipment that may not be available from within the government. However, the use of private testing facilities will also require additional oversight on the part of the competent authority to make sure that the private institutions are carrying out their activities impartially and according to the law. This should include the development of an accreditation procedure that ensures that these institutions satisfy the minimum criteria set out in Annex IX to the Directive.

If the established noise policy includes the setting of noise limits that are not currently included in EU law, then there is more need to actually develop noise standards. In this case, additional private sector consultations will likely be required, including advisory boards with private sector participation.

3.6. **Communication and Consultation**

Initially, noise Directives did not specify a given set of consultation procedures, other than the requirement to report to the European Commission on actions taken to implement the Directives. However, consultation procedures are now expressly required by Directive 2002/49/EC on the assessment and management of environmental noise. An effective noise policy that is compliant with this Directive will therefore need to include various consultation procedures.

In addition, candidate countries should plan to establish a formal public notice and comment procedure that enables interested parties to comment on laws, regulations and implementing decrees prior to enactment. This formal procedure should include the requirement that the state (in this case the ministry responsible for developing noise policy) documents and provides written response to comments submitted.

The general public, NGOs and industry utilising noise-limited equipment should also be informed about developments in the noise sector. Notice should be given of pending actions, and the public should be able to comment. The public will be more directly affected by and is likely to become more involved with policies focusing on environmental noise levels and urban planning targeted at abating environmental noise. Brochures and reports explaining concepts and the current situation are important public information tools.

4. TECHNICAL ISSUES

The general purpose of technical standards is to establish minimum technical requirements for the quality of certain goods or resources, and/or their operation and performance. Within EU Member States, EU technical standards specified in Directives or Regulations take precedence over all other standards and national standards need to reflect and complement any relevant EU standards.

Several EU noise Directives specify noise emission limits and noise measurement methods.

Detailed noise measurement procedures are set out for aircrafts, railway vehicles, motor vehicles and outdoor equipment. The methods are revised and up-dated by the competent Agencies, Commission Services and Committees established under the framework Directives covering type-approval and type-examination for motor vehicles, and for outdoor equipment. These noise measurement standards are usually based on, and in line with, voluntary ISO (International Standardisation Organisation) standards. National transposition measures can sometimes include a direct reference to the relevant ISO or similar standards, making them legally binding. The Directive on Outdoor Equipment refers directly to ISO standards, and when producers of the equipment choose the mode of enforcement, they may choose to fully implement a quality assurance system based on ISO standards, and (although that system will be subject to monitoring and surveillance by a notified body) they will be exempt from other verification procedures regarding noise emissions.

The noise measurement methods specified for aircrafts are adopted directly from the Convention on International Civil Aviation. The standards have been developed by the International Civil Aviation Organisation (ICAO).

The noise measurement methods for railway noise are specified in the Technical Specification for Interoperability and are set either within the Regulations, either within EN standards.

The Directive related to noise emissions from household appliances does not include emission limit values or noise measurement methods. When a national implementing action is taken, Member States should refer to the harmonised standards developed by the European Standardisation Committee (CEN), where such standards exist.

4.1. Relationship between Standards set in EU Directives and Voluntary Standards

At the international level, voluntary standards are developed by the International Organisation for Standardisation (ISO), which is a non-governmental, world-wide federation of national standards bodies from 130 countries. Industry-wide standardisation takes place when a majority of products or services conform to the same standards, which facilitates trade and technology transfer.

In the EU, national standards bodies co-operate through the European standardisation organisation, the CEN (Comité Européen de Normalisation). There are other standardisation organisations as well, focusing on specific products/processes, such as CENELEC (the European Electrotechnical Standardisation Organisation). The objective of CEN is to promote, create and harmonise European standards and to remove technical barriers to the internal market. The standards developed are voluntary, but some may go on to be

adopted by the EU as the technical basis for Directives or Regulations. States may also opt to make reference to standards in their laws, thereby making them legally binding. Both national standards (either nationally developed or international standards translated into the national language) or international standards can be referred to in national law.

4.2. Noise Measurement Methods

The limit values set out for motor vehicles cover seven types of motor vehicles and their silencers, and range from 74 dB(A) (passenger vehicles) to 80 dB(A) (certain goods vehicles). The Directives apply to any motor vehicle intended for use on the road, having at least four wheels and a maximum design speed exceeding 25 km/h. Vehicles that run on rails, agricultural and forestry tractors, and all mobile machinery are not covered by the Directive. Motorcycles are required to observe a 75 to 80 dB(A) limit. Sound levels have been progressively reduced.

Regulation (EC) No 216/2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency (EASA), as amended by Commission Regulation (EU) No 2016/4 defines the "essential requirements for environmental protection" and requires that products, parts and appliances shall comply with the requirements contained in Annex 16 to the Convention on International Civil Aviation (Chicago Convention). Annex 16 to the Chicago Convention gives a detailed test procedure for aircraft flying under three flight regimes and sets ground-level noise limits. The limits are in terms of the effective perceived noise level (EPNL) measured in EPNdB and are dependent on the weight of the aircraft. The heavier the aircraft the higher the noise limit, within certain overall constraints. All the necessary details of the test method are included in Annex 16 and no further standards are required.

Noise measurement methods are also set for railway vehicles, which as said are mainly defined in the Technical Specifications for Interoperability. The basic parameters for this TSI were adopted by Commission Regulation (EU) No 1304/2014.

In terms of outdoor equipment, specific noise limit values are set for a range of equipment under Directive 2000/14/EC (as amended). The Directive also harmonises methods for the measurement of noise emissions. Labelling, but no noise limits, will be required for 41 types of equipment regulated under the new Directive.

Directive 2002/49/EC on the assessment and management of environmental noise requires harmonised noise indicators based on ISO 1996-2: 1987 to be used for noise evaluation.

If performing noise measurements, ISO 1996-1:2003 and ISO 1996-2:2007 are to be used.

While performing noise mapping, it requires using a set of four different noise assessment methods, referred to in the Annex II to Directive 2002/49/EC. The common EU methods for calculating exposure to different noise levels have been established by Commission Directive (EU) 2015/996 of 19 May 2015 establishing common noise assessment methods according to Directive 2002/49/EC of the European Parliament and of the Council.

5. REGULATION AND ENFORCEMENT

5.1. Overview

After competent authorities and notified bodies have been designated and standards set, practical measures must be taken to implement the noise Directives. In this context, type- approval (for motor vehicles) and unit verification (for outdoor equipment) procedures and facilities need to be instituted, as do monitoring, enforcement, and reporting functions. Producers of outdoor equipment may also opt to use a quality assurance system (subject to monitoring and surveillance by an appropriate body). Noise certification requirements for aircrafts need to be implemented, and measures taken to ensure that information provided regarding noise emissions from household appliances is correct.

The following section focuses on type-approval and type-examination procedures, and briefly discusses noise certification of airplanes. The section serves to illustrate that noise requirements are closely integrated with other technical requirements of machines, and that noise regulation and enforcement can never be considered or planned in a vacuum. More detail is provided regarding type-approval of motor vehicles, since these procedures are the most developed at EU level.

5.2. Type-Approval and Type-Examination

5.2.1. Motor Vehicles

The testing of noise emissions from vehicles, motorcycles and exhaust systems is required under EU type-approval procedures.

Type-approval in general is a procedure whereby a manufacturer can obtain certification from a competent authority that the product meets the requirements of a certain directive. Thus whole vehicle type-approval is the procedure whereby a manufacturer can obtain certification from a competent authority that the complete vehicle meets the requirements of the type-approval framework directive 2007/46/EC. Under the type-approval regime, before being put on the market, the vehicle type is tested by national technical service in accordance with the legislation and the national approval authority delivers the approval ("CE certificate) on the basis of these tests. The EU type-approval system is based on the principles of third-party approvals and mutual recognitions of such approvals.

Conformity of Production

The principle of the type-approval framework directive is that the competent authority that grants a type-approval for a vehicle, system, component or technical unit is, and remains, responsible for ensuring the conformity of production during the whole period of validity of the approval in question. One aspect of conformity is that of noise emissions conforming to the level of emissions allowed and specified in the type-approval. The Member State is required to assess conformity of production measures in two stages. Before granting approval the competent authority must verify that adequate arrangements for ensuring conformity of production have been taken by the applicant. After having granted type-approval, the competent authority must

verify that the conformity of production arrangements of the manufacturer continues to be adequate. This verification may be carried out at the level of the manufacturers' technical equipment and control programmes, but may also be extended to the actual testing of selected production samples through spot checks.

Registration, permit to sale or entry into service

Under the terms of Article 26 of Directive 2007/46/EC, each Member State shall register and permit the sale or entry into service of new vehicles on grounds relating to their construction and functioning if, and only if, they are accompanied by a valid certificate of conformity, which is, in effect, a statement by the manufacturer that the vehicle conforms to the relevant type-approval. Member States cannot refuse to register vehicles for use on their roads if they comply with a properly issued certificate of conformity. Conformity with the noise emission requirements are only one component of what is required for registration or permit for sale and entry into service.

5.2.2. Outdoor Equipment

Manufacturers of outdoor equipment can choose between three different options for ensuring conformity of production under the Directive on Outdoor Equipment. These are self-certification; implementing a full quality assurance programme; and unit verification, a modified version of current type-examination procedures that includes noise emissions testing. Unit verification procedures are similar to type-approval procedures. Outdoor equipment must have undergone conformity of production procedures before they are allowed on the market (individual equipment must be labelled appropriately and furnished with an EC declaration of conformity). Self-certification is necessary for outdoor equipment for which only noise labelling and an EC declaration of conformity is required. In all cases, a copy of the declaration should be sent to the Commission.

In addition to carrying out unit verifications, the authorities or institutions designated as notified bodies will be responsible for periodic (and where necessary) random checking of self-certification and for the approval, monitoring and surveillance of systems of full quality assurance that are put in place by manufacturers.

5.3. Noise Certification and Registration Requirements

5.3.1. Railway vehicles

The TSI Noise introduces limit values for the noise emitted by individual vehicles and is therefore an important instrument for reducing environmental noise levels in Europe. By gradually introducing lower limit levels in the TSI Noise, the supply industry is put under pressure to develop quieter products. Besides the aspect of noise reduction, the TSI Noise is intended to promote interoperability. All new mainline trains in Europe have to conform to technical specifications for interoperability. The assessment of conformity is performed by a notified body. The process requires that all new and upgraded trains and infrastructure on the trans-European network comply with technical specifications for interoperability. Compliance is shown through EC certificates of verification, which are provided by notified bodies.

EU PROJECT ACOUTRAIN

ACOUTRAIN will simplify and improve the acoustic certification process of new rolling stock. Today the need for conformity assessment for a new vehicle according to the Technical Specification for Interoperability on Noise represents a significant element of both cost and time to market due to the need to carry out expensive and time consuming tests.

The goal of the project is to speed up product authorisation by introducing elements of virtual testing while retaining the same degree of reliability and accuracy. A successful simplification of the TSI conformity assessment process would result in a strengthening of the competitiveness of the European railway sector. This will be ready for inclusion in the next “full revision” of the TSI Noise, planned in 2013.

The R&D work program will be implemented with the following structure:

- Establishment of procedures for a virtual certification of acoustic performances of freight and passenger trains;
- An improvement and harmonization of the rolling noise characterization process;
- Establishment of methodologies to measure other noises sources;
- A methodology to validate global tools for pass-by noise and standstill noise predictions so that they can be used as part of future certification;
- A validation of the procedure range for the virtual noise certification.

More information about this project is available at: <http://acoutrain.eu/>

5.3.2. Aircrafts

The EU noise Directives require that noise emissions from aircrafts operating in the EU are regulated. This legal requirement is implemented through noise certification requirements for registration and operation in Member State airports. Member States have the option to create their own systems of certification and registration. In practice, these systems follow the Convention on International Civil Aviation. Every aircraft designed and manufactured in Europe requires EASA certification. The EASA approved noise levels are the basis against which national authorities issue individual noise certificates.

5.4. Monitoring, Inspection and Enforcement

Monitoring, inspection and enforcement are intended to give practical effect to ensure that legal requirements and mandatory standards are being complied with. The monitoring, inspection and enforcement tasks in the noise sector are related to ensuring that noise emissions, at the time of manufacture and entry into market of a product, are in compliance with the specifications of the relevant Directives. (In the case of aircrafts, the registration requirement, and the operation in Member State airports, triggers the noise Directives. These actions take place not only at the time of production or first registration, but also when aircrafts are bought and sold, or apply to enter new airports.)

The following are key monitoring, inspection and enforcement tasks in the noise sector:

- The competent authority/ies must ensure that products put on the market comply with the noise Directives. They must register and permit the sale and use of motor vehicles only if they have a valid certificate issued by the manufacturer as the holder of the type- approval/examination or other validation of conformity of production. The competent authority is advised to have a register of all types of products covered, which are produced in the country or imported. Registration should be conditional on proper certification. Similarly, outdoor equipment covered by Directive 2000/14/EC should not be placed on the market unless it bears the requisite markings and is accompanied by an EC declaration of conformity. Where such markings and the declaration are present, the equipment must be assumed to be compliant with the directive.
- Noise measurement methods defined in the relevant directive must be used. Only certified or accredited testing laboratories should be allowed to perform the tests. National accreditation authorities are likely to be involved in accrediting laboratories for making noise measurements.
- Motor vehicles placed on the market are furnished with certificates of conformity, or other documents stating conformity with the type approved. Periodic verification inspections through spot checks may be required to reinforce the self-certification procedure or the certificate of conformity, confirming compliance of production to the type-approved. Similarly, where the conformity of outdoor equipment is self-certified, periodic checks (and in some cases, random checks) are required. Where manufacturers rely on a system of full quality assurance, that system should also be monitored and inspected by an appropriate body.
- In order to ensure that products imported into the country meet required noise limits, it will be important for customs authorities to verify that products have received the necessary type-approval/examination. If the products have not received type-examination, or the situation is unclear, the competent authority (in the capacity of being responsible for registering products for the market) should be notified. The competent authority would then authorise investigations and tests in accordance with provisions for type- approval/examination, and the product would either be approved for the market or rejected. The importer would be responsible for the expenses incurred.
- If equipment is found not to meet type-examination certification standards, the certificate holder must be required to rectify production within a specified time period (during which certification can be suspended). Certification can be withdrawn or suspended as deemed necessary by the approval body. A system of fines and enforcement procedures must be defined to ensure that sub-standard equipment is prohibited from the market.
- Product manufacturers/importers should have recourse to an appeals process (against decisions by the competent authority/approved body).

The essential features of an effective monitoring, inspection and enforcement regime are:

- legally well-defined inspection and enforcement powers, and corresponding sanctions;
- sufficient, appropriately qualified and motivated human resources;
- sufficient and appropriate technical resources (equipment, etc.);
- clear, properly documented operational systems and procedures; and
- comprehensive systems for storing, recording and retrieving data and information.

Without these elements, it is difficult, if not impossible, to give effect to established policies, legislation and standards governing product related noise emissions.

5.5. Data Collection and Reporting

An obligation exists in most Directives to report to the Commission on progress in implementation and the level of compliance achieved. There are also provisions for informing the public about household appliance noise levels, informing and consulting the public on noise exposure and its effects, and informing other Member States about technical issues. Specific reporting requirements relate to:

- provisions of national law adopted in the field of each Directive;
- technical measures adopted to comply with Directives;
- authorities designated to undertake approvals under provisions of Directives, and the equipment approved by them.

Concerning the Environmental Noise Directive, a complex set of strict reporting deadlines is to be met, including 7 sets of reported data. Also the Commission has set up a database of information on strategic noise maps in order to facilitate the compilation of the report referred to in Article 11 and other technical and informative work. Data about environmental noise levels should therefore be collected, collated or reported by the Member States in accordance with comparable criteria, using harmonised indicators and evaluation methods, as well as criteria for the alignment of noise-mapping set at EU level.

The original reporting requirements in some other Directives have been modified by Directive 91/692/EEC on standardising and rationalising reports on the implementation of directives relating to the environment. According to Directive 91/692/EEC, reporting shall take place every three years in the form of sectoral reports done on the basis of an outline or questionnaire provided by the Commission.

6. PRIORITIES AND TIMING

Priorities and timing will be driven first and foremost by the objectives and options selected during strategy formulation. It is likely that for candidate countries the practical issues of transposing and implementing the EU noise Directives will drive prioritisation and timing. Prioritisation and timing among the four source categories and individual Directives will depend in part on the level of current regulatory activity in these areas in each country.

7. ECONOMIC AND FINANCIAL ISSUES

7.1. Introduction

The main costs imposed upon government by the Directives in the noise sector will be:

- establishing the authorities responsible for overseeing the agreed noise emission levels;
- drawing up "strategic noise maps";
- preparing and implementing noise reduction action plans;
- setting up laboratories or other institutions carrying out measurements, calculations or verifications needed concerning type-approval, type-examination, noise mapping. These costs will be borne primarily by the competent authorities, even if the services are contracted to private laboratories. Costs for the establishment and operations of public and private laboratories may be partially off-set through fees paid by equipment and vehicle manufacturers and importers. Candidate countries may also choose to utilise the type- approval and examination facilities of other Member States, and thereby delay, or reduce the costs of setting up domestic facilities.

The main costs imposed upon producers and consumers are compliance with emission limits and technical requirements under the Directives. These costs will be borne by the producers of vehicles, aircraft and equipment (industry) or by consumers (households, motorists etc). Laboratory fees related to type-approval may also be borne by product producers.

The costs for government may be significant, depending on existing institutional arrangements and the presence of measurement and laboratory facilities for testing, examination and type- approval. The costs for producers and consumers will depend on the extent to which producers will need to modify equipment to meet the new noise standards. It is assumed that a portion of these costs will be passed on to consumers.

7.2. Cost Elements

7.2.1. General Issues

Most of the noise Directives (those on vehicles and outdoor equipment) concern type- approval/conformity assessment of industrial products with respect to their sound level. Candidate countries can, to a large extent, minimise costs associated with type- approval/conformity assessment procedures.

A Member State does not necessarily need to provide actual EU type-approval services itself, because manufacturers can apply for type-approval in another Member State. In such cases, national type-approval may be granted to EU type-approved industrial products on the basis of the importer's certificate of conformity (based on EU type-approval issued by another Member State).

For domestic industrial products covered by the Directives, it might be preferable to perform tests for national/EU type-approval to verify compliance with the noise Directives. Testing services for noise emissions

from manufacturing products can be performed at any accredited technical organisation offering such testing services. These facilities can be situated in any Member State. The responsibility to acquire such test results is borne by the manufacturer. Therefore, the state does not necessarily need to offer such a service nationally. However, where self-certification or full quality assurance systems are applied, the state is required to conduct monitoring and surveillance of the process by notified bodies. Conformity requirements for outdoor equipment can also be achieved by industry through quality assurance programmes. When noise issues are embedded in a more comprehensive quality assurance programme, the costs related to noise standards can be reduced.

7.2.2. Public Costs

The institutional cost item consists of costs related to the establishment or expansion of type-approval facilities and institutions. The costs here are likely to be moderate, as such facilities and institutions already exist, and since such approval procedures can take place in any Member State, i.e. candidate countries do not necessarily have to establish their own procedures. Further, probably moderate, costs may be incurred where verification processes are needed for the monitoring and surveillance of self-certification and full quality assurance systems. Additional costs will be incurred in order to put in place systems for the preparation of noise maps and action plans to address the problem of noise pollution.

The enforcement of the Directives requires increased staffing and training at the type-approval/examination authorities and at the facilities performing tests. More staff are needed for performing periodical checks of industrial products in use, for spot checks, and for inspections to verify the conformity of production (if the industrial products covered are being produced in the Member State), and as regards verification where self-certification or full quality assurance systems are applied. These costs are very nation specific, as they depend on local wage levels, as well as on the scale of testing activities. The testing activities depend on the volume and diversity of the industrial products covered by the noise Directives that are being introduced and tested.

7.2.3. Private Costs

National producers could encounter additional costs when adjusting their production processes to the new noise limits, and establishing in-house noise testing facilities. If the increase in production costs is passed over to the consumer, sales reductions can result. However, if the domestic producers want to export to the EU, it is likely that they will have to conform to these requirements anyway. Therefore, these costs cannot be viewed entirely as accession-related costs.

On the other hand, consumers in the candidate countries could face such price increases already before their countries join the EU (for example, in the case of imported vehicles, when the effect of the noise directive implemented in Western Europe has already been embodied in the price). As noise reductions for the type of vehicles covered by the noise Directives is generally achieved as part of the integrated design and construction of the vehicles, it is very difficult to distinguish costs directly associated with the noise Directives.

8. SUMMARY OF KEY ISSUES

In order to minimise the administrative burden and associated costs of implementing legislation in this sector, candidate countries should endeavour to focus their efforts and actions on addressing those issues and requirements that are fundamental to EU approximation in this sector, in particular by ensuring that:

- a strategy and detailed plan/s for the future management of noise emissions from motor vehicles, aircrafts, outdoor equipment, and household appliances are prepared and implemented;
- a strategy for the assessment and management of environmental noise using noise mapping techniques and the drafting and implementation of action plans, including providing for the information and the participation of the public, is adopted;
- arrangements are put in place for the effective involvement and participation of all relevant bodies and interest groups that have a significant role/function to perform in relation to noise emissions;
- appropriate competent authorities and approved bodies are designated or established, and their respective duties, functions and powers are clearly defined;
- sufficient human and technical resources are allocated to allow all key functions and tasks to be performed properly, especially those relating to regulation and enforcement;
- the resources and expertise of the private sector are mobilised and utilised in appropriate ways.

A series of checklists of the key questions that should be considered in preparing and implementing such a strategy/ies are present in the tables below.

Table 2. Noise Sector General Activities

Function	Action required
Policy development and approximation planning	Assign responsible authority (ies) for approximation of noise sector Directives
	Develop gap assessment tables comparing EU noise directive requirements with country laws, regulations and standards
	Decide on legal approach to sector Directives (e.g. establishing a noise framework law, developing laws based on the four equipment types or creating a law for each directive, establishing the preferred mix of laws and implementing regulations)
	Assess the institutional requirements to implement the EU noise Directives, and compare to existing institutional framework.
	Decide on preferred institutional approach for noise approximation. This includes the decision on whether to have the environmental ministry and/or other ministries oversee all or parts of the regulatory programme for noise. Other ministries involved typically include health, welfare/labour, industry, transport or environment.
	Develop an action plan for bridging legal gaps and meeting institutional requirements
	Consider cost and financing implications of implementing legal and institutional changes
	Develop a finance plan to meet cost requirements

	Obtain necessary approvals for action plan through cabinet of ministers (and possibly parliament).
	Provide public notice of planned course of action to implement regulatory programme for noise.

Table 3. Noise Directives Concerning Motor Vehicles

Function	Action required
Legal transposition/ implementation	Develop and implement legislation specifying methods for measuring sound levels, setting noise limits, and setting requirements for exhaust systems and silencers.
Institutional development	Designate competent authority.
Policy and planning	Institute national type-approval system, or, alternatively, establish procedure relying on type-approvals issued in other states.
Policy and planning	Establish application procedures for vehicle producers to obtain type-approval certificates for motor vehicles and exhaust systems
Technical standards and laboratory analysis	Identify and accredit facilities capable of performing noise measurements.
Monitoring, surveillance and enforcement	Ensure that the competent authority registers and permits the sale of or entry into service of new vehicles only if they are accompanied by a valid certificate of conformity, which is a statement by the manufacturer that the vehicle conforms to the relevant type-approval.
	Institute procedures to verify conformity of production (with noise limit certification). Measures to verify conformity can be taken at the point of production.
	Establish monitoring system to verify conformity, including spot-checks of vehicles on the market. A decision needs to be made on the authority responsible for carrying out spot checks — typically the traffic inspectorate, environmental administration/inspection and/or the customs authority (regarding imported vehicles).
	Establish penalty procedures for vehicle producers and importers of vehicles not in compliance with noise requirements (not in conformity with the type- approval).
Finance	As part of the overall finance plan for the noise sector, develop a finance plan for meeting the requirements of the vehicle-related noise Directives, especially relating to costs of type-approval and spot checks of the conformity of production.
Reporting and public information	Set up information collection, review and dissemination procedures, to include compliance information to vehicle producers, wholesalers and retailers, general information to the public, and reporting to the Commission

Table 4. Noise Emissions From Airplanes

Function	Action required
Legal transposition/ implementation	Develop and enact legislation and implementing regulations setting noise limits for aircrafts, based on standards specified by the International Civil Aviation Organisation. Legislation should specify test methods (in accordance with Annex 16 of the Convention on International Civil Aviation). Specify exemptions to the law, and indicate recognition of certification documents from other Member States.
Institutional development	Designate a competent authority ultimately responsible for granting noise certification, controlling that registered aircrafts have the requisite noise certification, and that aircrafts applying to enter national airports fulfil the noise requirements.
	Designate authority/ies responsible for registration, for noise certification of aircrafts,, and for approval of the operation of aeroplanes in Member State territory (if different from the competent authority). Designate authority/ies responsible for the imposition of operating restrictions and an independent body to hear appeals (when required) against decisions to impose such restrictions.
	Certify laboratories/testing facilities to perform noise certification tests. Ensure that certified institutions are independent of vested interests.
Policy and planning	Ensure that noise standards are included in aircraft registration requirements. Aircrafts that do not comply with the Directives cannot be reregistered.
	Consider implementing a noise reduction and abatement programme as part of air traffic planning using noise maps and action plans.
Technical standards and laboratory analysis	Ensure that technical noise standards and testing methodologies are based on ICAO specifications. (Initial laboratory analysis is the responsibility of the manufacturer.)
Monitoring, surveillance and enforcement	Establish a system for granting noise certificates to aircrafts, and for granting approval for the operation of aircrafts in the territory of the Member State. Establish a system for imposing noise-related operating restrictions at airports.
	Ensure that foreign aircraft in violation of set standards are prohibited from operating in the Member State.
	Condition aircraft registration on certification (thus streamlining the implementation of certification procedures).
	Consider installing and using noise measurement equipment at airports for either continuous or spot-check noise monitoring at take-off and landing, to verify that the noise certification information of aeroplanes using the airport is correct.
	Develop a penalty protocol for effective enforcement of the directive
Finance	Develop financing plan and decide on financing methods (public/private).
Reporting and public information	Set up information collection, review and dissemination procedures, to include compliance information to aircraft producers, airlines and air service companies, general information to and consultation with the public, and reporting to the Commission.

Table 5. Permissible Noise Emissions: Outdoor Equipment

Function	Action required
Legal transposition/ implementation	Identify institutional authority responsible for the national transposition of the directive.
	Establish an inter-ministerial process for input into the transposition process.
	Based on gap analyses, establish new and amended laws and regulations for the harmonisation of national laws with the EU Directives
	Enact legal provisions and guidelines for national certification of conformity (with noise limits for outdoor equipment).
	Enact legal provisions and issue guidelines for a noise emissions labelling programme for outdoor equipment.
	Establish legal provisions for test procedures, and establish an enforcement system (i.e. spot checks and fines).
Institutional development	Designate competent authority responsible for overseeing the noise abatement programme, as well as an audit system, for outdoor equipment.
	Designate notified body/ies (under the supervision of the competent authority) to be responsible for managing unit verification and for overseeing self-certification and systems of full quality assurance.
Policy and planning	Institute appropriate conformity assessment procedures covering outdoor equipment.
	Establish and oversee a system of regulatory controls, to ensure that equipment that complies with the requirements of the directive has access to the Member State market, while equipment that does not comply with the provisions of the Directives is excluded from the market.
	Establish more stringent noise emission limits in designated sensitive areas.
Technical standards and laboratory analysis	Develop noise emission standards for 22 types of outdoor equipment.
	Specify uniform test methods.
	Certify and periodically review certification of testing laboratories, (public or private, existing or newly created).
Monitoring, surveillance and enforcement	Develop and maintain a register of all outdoor equipment produced in the country or imported.
	Ensure that only conformity-assessed equipment, furnished with a valid certificate issued by the manufacturer, is registered for sale and use.
	Ensure that outdoor equipment requiring labelling of noise emissions has met the requirements.
	Develop and institute a system of enforcement procedures (e.g. fines, certification suspension or withdrawal) to ensure that equipment in violation of the noise emission limits is removed and prohibited from the market.
	Initiate compliance schedules against producers of equipment not in compliance, specifying time period to achieve compliance (during which certification is suspended).
	Undertake periodic verification inspections (e.g. once every two years) to confirm that outdoor equipment manufactured in the country conforms to requirements.
	Establish appeals procedures for equipment manufacturers/importers to have certification and penalty decisions reviewed.
	Institute periodic performance reviews of the authorised certifying bodies.
Finance	Decide on financing methods (public/private) and identify sources of financing.
Reporting and public information	Provide opportunities for industry interests to comment on proposed legislation, standards and testing methods, and on possible incentives for meeting uniformity in testing methods.
	Provide opportunity for public input through notice of pending action and public comment procedures.
	Report to the Commission as required.

Table 6. Noise Emissions from Household Appliances

Function	Action required
Legal transposition/ implementation	Develop, enact and implement legislation specifying the provision of information regarding noise emissions from household appliances.
	Enact legislation through implementing regulations, which should specify statistical methods, test methods and procedures (national standards are accepted).
Institutional development	Designate a competent authority that will, in turn, if necessary authorise an approved body responsible for implementation.
Policy and planning	Decide on whether to include a labelling programme for noise levels of household appliances (voluntary).
	Decide on how to integrate the provision of information regarding noise with other labelling requirements for household appliances. Such labelling can, for example, be included as part of the mandatory label on energy consumption of household appliances.
Technical standards and laboratory analysis	Issue technical standards for testing
	Accredit laboratories for making required tests.
Monitoring, surveillance and enforcement	Standardise label formats, and create a system for monitoring the accuracy of the information provided by producers/importers on product labels.
	Establish a system of penalties for producers/importers providing false information on product labels
Finance	Decide on financing methods (public/private) and identify sources of financing.
Reporting and public information	Set up information collection, review and dissemination procedures, to include compliance information to producers, wholesalers and retailers of household appliances, general information to the public, and reporting to the Commission.

Table 7. The Assessment and Management of Environmental Noise

Function	Action required
Legal transposition/ implementation	Develop, enact and implement legislation for the drawing up of noise maps, the provision to the public of information on environmental noise and the development of action plans with the active involvement of the public.
	Legislation should use harmonised noise mapping methods, but existing methods of assessment may be used until common methods are adopted by the Commission provided that they are equivalent to the interim recommended methods mentioned in the directive).
Institutional development	Designate a competent national authority that will be responsible for collecting noise maps and action plans, and eventually local authorities that will be responsible for making noise maps and action plans.
Policy and planning	Identify agglomerations, major roads, railways and airports that are subject to the provisions of the directive.
Technical standards and laboratory analysis	<ul style="list-style-type: none"> • Use harmonised noise indicators for noise mapping. • Create a system for adapting data and obtaining required values based on existing assessment methods.

Finance	Decide on financing methods and identify sources of financing.
Monitoring, surveillance and enforcement	<ul style="list-style-type: none"> • Monitor the drawing up and review of noise maps and action plans. • Monitor and enforce compliance with measures imposed in action plans.
Reporting and public information	<ul style="list-style-type: none"> • Communicate responsible bodies for the reporting of the data. • Communicate to the Commission details of the agglomerations, major roads, railways and airports covered by the directive. • Communicate noise limits in place. • Report noise maps every five years. • Report action plans every five years. • Ensure operation of public consultation and notice procedures.

LIST OF ACRONYMS

Annex 1

LIST OF ACRONYMS FOR MEMBER STATES

AT	Austria
BE	Belgium
BG	Bulgaria
HR	Croatia
CY	Cyprus
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
EL	Greece
FI	Finland
FR	France
HU	Hungary
IE	Ireland
IT	Italy
LV	Latvia
LT	Lithuania
LU	Luxembourg
MT	Malta
NL	Netherlands
PL	Poland
PT	Portugal
RO	Romania
SK	Slovakia

SI	Slovenia
ES	Spain
SE	Sweden
UK	United Kingdom

Acronyms

AP	Acidification Potential
AQD	Ambient Air Quality Directive
BAT	Best Available Techniques
BATNEEC	Best Available Techniques Not Entailing Excessive Cost
BREFs	BAT Reference Documents
CA	Competent Authority
CCS	Capture Carbon Storage
CDM	Clean Development Mechanisms
CERs	Certified Emission Reductions
CEECs	Central and Eastern European Countries
CEN	Comité Européen de Normalisation
CENELEC	The European Electrotechnical Standardisation Organisation
CITL	Community Independent Transaction Log
CJEU	Court of Justice of the European Union
CLP	Classification, Labelling and Packaging
CO₂	Carbon Dioxide
CSA	Chemical Safety Assessment
COP	Conference of the Parties
EAP	Environmental Action Programme
EBTP	European Biofuels Technology Platform
ECCP	European Climate Change Programme
ECHA	European Chemicals Agency
EIA	Environmental Impact Assessment
EIPPC	European IPPC Bureau
ELV	End-of-Life Vehicles (Directive 2000/53/EC)
ELVs	Emission Limit Values
EMAS	Community Eco-management and Audit Scheme
EMEP	1979 Convention on Long-Range Transboundary Air Pollution on the long-term financing of the co-operative programme for the monitoring and evaluation of the long-range transmission of air pollutants in Europe
EPER	European Pollutant Emission Register
EQS	Environmental Quality Standards
ERUs	Emissions Reduction Units
EUEB	Ecolabelling Board
EU	European Union
EU ETS	European Union Emissions Trading Scheme
EUTL	European Union Transaction Log
FAO	Food and Agricultural Organisation of the United Nations
F-GASEs	Fluorinated Gases
GMO	Genetically Modified Organism

GLP	Good Laboratory Practices
GES	Good Environmental Status
GHGs	Greenhouse Gases
GHS	Global Harmonized System
GWP	Global Warming Potential
HCFC	Hydrochlorofluorocarbons
HFC	Hydro-fluorocarbons
HARMO	Harmonisation within Atmospheric Dispersion Modelling for Regulatory Purposes
IAS	Invasive Alien Species
IED	Industrial Emissions Directive (2010/75/EU)
IMPEL	European Union Network for the Implementation and Enforcement of Environmental Law
INSPIRE	Infrastructure for Spatial Information in the European Community
ISO	International Standardisation Organisation
JI	Joint Implementation
JRC	Joint Research Center
LCP	Large Combustion Plants
LRTAP	1979 Convention on Long-Range Transboundary Air Pollution
MCP	Medium Combustion Plants
MEP	Marine Eutrophication Potential
MSFD	Marine Strategy Framework Directive
MW	Megawatts
NACE	Nomenclature générale des activités économiques dans les Communautés Européennes
NEC	National Emission Ceiling
NO_x	Nitrogen Oxides
ODS	Ozone Depleting Substances
PAH	Polycyclic Aromatic Hydrocarbons
PCB	Polychlorinated Biphenyls
PCT	Polychlorinatedterphenyls
PIC	Prior Informed Consent
PM_{2.5} and PM₁₀	Particulate Matters
POCP	Photochemical Ozone Creation Potential
POPs	Persistent Organic Pollutants
PRTR	Pollutant Release and Transfer Register
PVC	Polyvinyl Chloride
PVR	Petrol Vapour Recovery
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical Substances
RoHS	Restriction of Hazardous Substances
RBMP	River Basin Management Plan
SACs	Special Areas of Conservation
SCCP	Short-chained Chlorinated Paraffins
SDS	Safety Data Sheets
SEA	Strategic Environmental Assessment

SMEs	Small and Medium Sized Enterprises
SO2	Sulphur Dioxides
SPAs	Special Protection Areas
TFEU	Treaty on the Functioning of the European Union
UNEP	United Nations Environment Programme
UNFCCC	United Nations Framework Convention on Climate Change
VOCs	Volatile Organic Compounds
WEEE	Waste Electronic and Electrical Equipment
WFD	Water Framework Directive
WHO	World Health Organisation
WISE	Water Information System for Europe

**LIST OF
ENVIRONMENTAL
ACQUIS**

Annex 2

LIST OF ENVIRONMENTAL ACQUIS COVERED IN THIS HANDBOOK

		Sector/Directive/Regulation/Other
		HORIZONTAL
1	Directive 2011/92/EU <i>EIA</i>	Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment Amended by Directive 2014/52/EU
2	Directive 2001/42/EC <i>SEA</i>	Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment
3	Directive 2003/4/EC <i>Access to information</i>	Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC
4	Directive 2003/35/EC <i>Public Participation</i>	Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC
5	Directive 2004/35/EC <i>Environmental Liability</i>	Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage Amended by Directives 2006/21/EC, 2009/31/EC and 2013/30/EU
6	Directive 2007/2/EC <i>INSPIRE</i>	Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE)
7	Directive 2008/99/EC <i>Environmental crime</i>	Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law
		AIR QUALITY

8	Directive 2008/50/EC <i>Ambient Air Quality</i>	Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe Amended by: Commission Directive (EU) 2015/1480
9	Decision 2011/850/EU <i>Reciprocal exchange of information and reporting</i>	2011/850/EU: Commission Implementing Decision of 12 December 2011 laying down rules for Directives 2004/107/EC and 2008/50/EC of the European Parliament and of the Council as regards the reciprocal exchange of information and reporting on ambient air quality
10	Directive 2004/107/EC <i>Heavy Metals</i>	Directive 2004/107/EC of the European Parliament and of the Council of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air Amended by: Regulation (EC) No 219/2009 and Commission Directive (EU) 2015/1480
11	Directive 2001/81/EC <i>National Emissions Ceilings</i>	Directive 2001/81/EC of the European Parliament and of the Council of 23 October 2001 on national emission ceilings for certain atmospheric pollutants Amended by Council Directives 2006/105/EC, 2013/17/EU and Regulation (EC) 219/2009
12	Directive (EU) 2016/802 <i>Sulphur Content in Liquid Fuels</i>	Directive (EU) 2016/802 of the European Parliament and of the Council of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels
13	Directive 94/63/EC <i>VOCs petrol</i>	European Parliament and Council Directive 94/63/EC of 20 December 1994 on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations Amended by Regulations (EC) 1882/2003 and (EC) 1137/2008
14	Directive 2009/126/EC <i>Stage II VOCs petrol</i>	European Parliament and Council Directive 2009/126/EC of 21 October 2009 on Stage II petrol vapour recovery during refuelling of motor vehicles at service stations Amended by: Commission Directive 2014/99/EU
15	Directive 97/68/EC <i>Emissions from non-road mobile machinery</i>	European Parliament and Council Directive 97/68/EC on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery Amended by: Directives 2001/63/EC, 2002/88/EC, 2004/26/EC, 2006/105/EC, 2010/26/EU, 2011/88/EU, 2012/46/EU and Regulation (EC) No 596/2009

16	<p>Regulation 595/2009 Regulation 582/2011 <i>Type-approval of heavy duty motor vehicles and engines</i></p>	<p>Regulation (EC) No 595/2009 of the European Parliament and of the Council of 18 June 2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC</p> <p>Amended by: Commission Regulations (EU) No 582/2011 and (EU) No 133/2014</p>
17	<p>Regulation (EC) No 715/2007 <i>Type approval for light passenger and commercial vehicles</i></p>	<p>Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type-approval of vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information,</p> <p>Amended by Commission Regulations (EC) No 692/2008, (EU) No 566/2011, (EU) No 459/2012 and Regulation (EC) No 595/2009</p>
18	<p>Decision 86/277/EEC <i>Monitoring and evaluation of air pollutants in Europe</i></p>	<p>Council Decision 86/277/EEC on the conclusion of the protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on long-term financing of the co-operative programme for monitoring and evaluation of the long-range transmission of air pollutants in Europe (EMEP)</p>
		WASTE MANAGEMENT
19	<p>Directive 2008/98/EC <i>Waste Framework</i></p> <p>2007/151/EC: Commission Decision <i>Questionnaire for waste report</i></p>	<p>Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste</p> <p>Amended by: Commission Regulation (EU) No 1357/2014 and Commission Directive (EU) 2015/1127</p> <p>2007/151/EC: Commission Decision of 6 March 2007 amending Decisions 94/741/EC and 97/622/EC as regards the questionnaires for the report on the implementation of Directive 2006/12/EC of the European Parliament and of the Council on waste and on the implementation of Council Directive 91/689/EEC on hazardous waste</p> <p>Commission Implementing Decision of 18.4.2012 C(2012) 2384 final establishing a questionnaire for Member States reports on the implementation of Directive 2008/98/EC of the European Parliament and of the Council on waste</p>

20	Directive 86/278/EEC <i>Sewage Sludge</i>	<p>Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture</p> <p>As amended by Directive 91/692/EEC, Regulation (EC) 807/2003 and (EC) 219/2009</p>
21	Directive 2006/66/EC <i>Batteries</i>	<p>Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC</p> <p>Amended by: Directives 2008/12/EC, 2008/103/EC and 2013/56/EU</p> <p>Implementing legislation: Commission Decisions 2008/763/EC, 2009/851/EC Commission Regulations (EU) No 1103/2010 and (EU) 493/2012</p>
22	Directive 94/62/EC <i>Packaging</i>	<p>European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste</p> <p>Amended by Regulations (EC) 1882/2003 and (EC) 219/2009 and Directives 2004/12/EC, 2005/20/EC, 2013/2/EU and (EU) 2015/720</p>
23	Directive 96/59/EC <i>PCB/PCT</i>	<p>Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT) as amended by Regulation (EC) 596/2009</p>
24	Directive 2000/53/EC <i>ELVs</i>	<p>Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles</p> <p>Amended by: Directives 2008/33/EC and 2008/112/EC</p> <p>Implementing legislation: Commission Directives (EU) 2016/774, 2013/28/EU, 2011/37/EU and Commission Decisions 2010/115/EC, 2008/689/EC, 2005/673/EC, 2005/438/EC, 2005/437/EC, 2002/525/EC</p>
25	Directive 2011/65/EU <i>RoHS</i>	<p>Directive 2011/65/EC of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment</p> <p>Amended by: Commission Delegated Directives (EU) 2016/585, (EU) 2015/863, (EU) 2015/573, (EU) 2015/574, eight Commission Delegated Directives 2014/69/EU to 2014/76/EU, sixteen Commission Delegated Directives 2014/1/EU to 2014/16/EU and two Commission Delegated Directives 2012/50/EU and 2012/51/EU</p>

26	Directive 2012/19/EU WEEE	Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)
27	Directive 1999/31/EC <i>Landfill</i>	Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste Amended by Regulations (EC) 1882/2003 and (EC) 1137/2008 and Council Directive 2011/97/EU
28	Decision 2003/33/EC <i>Landfill</i>	Council Decision 2003/33/EC of 19 December 2002 establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to the Directive 1999/31/EC
29	Regulation (EC) 1013/2006 <i>Shipments of Waste</i>	Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste Amended by: Regulations (EC) 1379/2007, (EC) 669/2008, (EC) 219/2009, (EU) No 413/2010, (EU) No 664/2011, (EU) No 135/2012, (EU) No 255/2013, (EU) No 1257/2013, (EU) No 660/2014, (EU) No 1234/2014, (EU) 2015/2002 and Directive 2009/31/EC
30	Regulation (EC) No. 1418/2007 <i>Export and recovery of certain wastes</i>	Commission Regulation (EC) No. 1418/2007 of 29 November 2007 concerning the export and recovery of certain waste listed in Annex III or IIIA to Regulation (EC) No. 1013/2006 to certain countries to which the OECD Decision on the control of transboundary movements of waste does not apply Amended by: Regulations (EC) No 740/2008, (EC) No 967/2009, (EU) No 837/2010, (EU) No 661/2011, (EU) No 674/2012, (EU) No 57/2013, (EU) No 519/2013, (EU) No 733/2014
31	Directive 2006/21/EC <i>Mining Waste</i>	Directive 2006/21/EC of the European Parliament and of the Council of 15 March 2006 on the management of waste from extractive industries and amending Directive 2004/35/EC Amended by Regulation (EC) 596/2009 Implementing legislation: Amended by Commission Decisions 2009/335/EC, 2009/337/EC, 2009/358/EC, 2009/359/EC and 2009/360/EC
32	Regulation (EU) No 1257/2013 <i>Ship Recycling</i>	Regulation (EU) No 1257/2013 of the European Parliament and of the Council of 20 November 2013 on ship recycling and amending Regulation (EC) No 1013/2006 and Directive 2009/16/EC

		WATER QUALITY
33	<p>Directive 2000/60 /EC <i>Water Framework</i></p> <p>Directive 2009/90/EC <i>Technical specifications for monitoring</i></p>	<p>Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy</p> <p>Amended by: Decision 2455/2001/EC and Directives 2008/32/EC, 2008/105/EC, 2009/31/EC, 2013/39/EU, 2013/64/EU, 2014/101/EU</p> <p>Commission Directive 2009/90/EC of 31 July 2009 laying down, pursuant to Directive 2000/60/EC of the European Parliament and of the Council, technical specifications for chemical analysis and monitoring of water status</p>
34	<p>Directive 91/271/EEC <i>UWWT</i></p>	<p>Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment</p> <p>Amended by Directive 98/15/EC and Regulation (EC) 1882/2003 and Regulation (EC) 1137/2008</p>
35	<p>Decision 2014/431/EU <i>UWWT</i></p>	<p>Commission Implementing Decision 2014/431/EU of 26 June 2014 concerning formats for reporting on the national programmes for the implementation of Council Directive 91/271/EEC</p>
36	<p>Directive 2008/56/EC <i>Marine Strategy</i></p> <p>Decision 2010/477/EC <i>Standards on good environmental status</i></p>	<p>Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for Community action in the field of marine environmental policy (Marine Strategy Framework Directive)</p> <p>Commission Decision 2010/477/EC of 1 September 2010 on criteria and methodological standards on good environmental status of marine waters</p>
37	<p>Directive 98/83/EC <i>Drinking Water</i></p>	<p>Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption</p> <p>Amended by Regulations (EC) 1882/2003 and (EC) 596/2009 2009 and Commission Directive (EU) 2015/1787</p>
38	<p>Directive 91/676/EEC <i>Nitrates</i></p>	<p>Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources as amended by Regulations (EC) 1882/2003 and (EC) 1137/2008</p>

39	2006/7/EC <i>Bathing Water</i>	Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality and repealing Directive 76/160/EEC Amended by Regulation (EC) 596/2009 and Council Directive 2013/64/EU
40	Directive 2006/118/EC <i>Groundwater</i>	Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration Amended by: Commission Directive 2014/80/EU
41	Directive 2008/105/EC <i>Water Quality Standards</i>	Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council Amended by Directive 2013/39/EU
42	Directive 2007/60/EC <i>Floods</i>	Directive 2007/60/EC of the European Parliament and of the Council of 23 October 2007 on the assessment and management of flood risks
		NATURE PROTECTION
43	Directive 2009/147/EEC <i>Wild Birds</i>	Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (codified version of Directive 79/406/EEC and its amendments) Amended by: Council Directive 2013/17/EU
44	Directive 92/43/EEC <i>Habitats</i>	Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora Amended by: Directives 97/62/EC, 2006/105/EC. 2013/17/EU and Regulation (EC) No 1882/2003
45	Directive 1999/22/EC <i>Zoo</i>	Council Directive 1999/22/EC of 29 March 1999 relating to the keeping of wild animals in zoos
46	Regulation (EEC) 3254/91 <i>Leghold Traps</i>	Council Regulation (EEC) No 3254/91 of 4 November 1991 prohibiting the use of leghold traps in the Community and the introduction into the Community of pelts and manufactured goods of certain wild animal species originating in countries which catch them by means of leghold traps or trapping methods which do not meet international humane trapping standards

47	Regulation (EC) 338/97 <i>CITES</i>	Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein Amended by Regulations: (EC) No 938/97, (EC) No 2307/97, (EC) No 2214/98, (EC) No 1476/1999, (EC) No 2724/2000, (EC) No 1579/2001, (EC) No 2476/2001, (EC) No 1497/2003, (EC) No 1882/2003, (EC) No 834/2004, (EC) No 1332/2005, (EC) No 318/2008, (EC) No 407/2009, (EC) No 398/2009, (EU) No 709/2010, (EU) No 101/2012, (EU) No 1158/2012, (EU) No 750/2013, (EU) No 1320/2014
48	Regulation (EC) 865/06 <i>CITES</i>	Commission Regulation (EC) No 865/2006 laying down detailed rules concerning the implementation of Council Regulation (EC) No. 338/97 Amended by Regulations (EC) No 100/2008(OJ L 31, 5.2.2008), (EC) No 791/2012 (OJ L 242, 7.9.2012), (EU) No 1283/2013 (OJ L 332, 11.12.2013), (EU) No 2015/870 (OJ L 142, 6.6. 2015) and Commission Implementing Regulations (EU No 792/2012, (EU) 2015/57
49	Regulation (EU) No 1143/2014 <i>LAS</i>	Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species
50	Regulation (EU) 2016/1141 <i>LAS</i>	Commission Implementing Regulation (EU) 2016/1141 of 13 July 2016 adopting a list of invasive alien species of Union concern pursuant to Regulation (EU) No 1143/2014 of the European Parliament and of the Council
51	Regulation (EU) No 995/2010 <i>EUTR</i>	Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market
52	Regulation (EC) No 2173/2005 <i>FLEGT</i>	Council Regulation (EC) No 2173/2005 of 20 December 2005 on the establishment of a FLEGT licensing scheme for imports of timber into the European Community Amended by: Regulation (EU) No 657/2014
		INDUSTRIAL POLLUTION CONTROL
55	Directive 2010/75/EU <i>IED</i>	Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control

56	Directive (EU) 2015/2193 <i>MCP</i>	Directive (EU) 2015/2193 of the European Parliament and the Council of 25 November 2015 on the limitation of emissions of certain pollutants into the air from medium combustion plants
57	Directive 2012/18/EU <i>Seveso III</i>	Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC
58	Directive 2004/42/EC <i>VOC Paints</i>	Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC Amended by: Directives 2008/112/EC, 2010/79/EU and Regulation (EC) no 1137/2008
59	Regulation (EC) No 66/2010 <i>Eco-label</i>	Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel
60	Regulation (EC) No 1221/2009 <i>EMAS</i> <i>Decision 2011/832/EU global guidance</i>	Regulation (EC) No 1221/2009 of the European parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No. 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC 2011/832/EU: Commission Decision of 7 December 2011 concerning a guide on EU corporate registration, third country and global registration under Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)
61	Regulation (EC) No 166/2006 <i>European Pollutant Release and Transfer Register</i>	Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC and amended by Regulation (EC) 596/2009
		CHEMICALS
62	Directive 2010/63/EU	Directive 2010/63/EU of the European Parliament and of the Council of the 22 September 2010 on the protection of animals used for scientific purposes

	<i>Protection of animals used for scientific purposes</i>	
63	Directive 87/217/EEC <i>Asbestos</i>	Council Directive 87/217/EEC of 19 March 1987 on the prevention and reduction of environmental pollution by asbestos as amended by Directive 91/692/EEC and Regulation (EC) 807/2003
65	Regulation (EU) No 528/2012 <i>Biocidal Products</i>	Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products Amended by: Regulation (EU) No 334/2014 and Commission Delegated Regulations (EU) No 837/2013 and (EU) No 736/2013
65	Regulation (EC) No 850/2004 <i>Persistent Organic Pollutants</i>	Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC Amended by: amended by Regulation (EC) No 1195/2006, Regulation (EC) No 172/2007, Regulation (EC) No 323/2007, Regulation (EC) No 304/2009, Regulation (EU) No 756/2010, Regulation (EU) No 757/2010, Regulation (EU) 519/2012, Regulation (EU) 1342/2014 and Regulation (EU) 2015/2030
66	Regulation (EU) No 649/2012 <i>Export Import</i>	Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals Amended by: Commission Delegated Regulations (EU) No 1078/2014 and (EU) 2015/2229
67	Regulation (EC) No 1907/2006 <i>REACH</i>	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC As amended by: Council Regulation (EC) No 1354/2007, (EC) No 440/2008, Regulation (EC) No 1272/2008 and Commission Regulations: (EC) No 340/2008, (EC) No 134/2009, (EC) No 552/2009, (EU) No 366/2011, (EC) No 761/2009, (EU) No 276/2010, (EU) No 453/2010, (EU) No 1152/2010, (EU) No 143/2011, (EU) No 207/2011, (EU) No 252/2011, (EU) No 253/2011, (EU) No 366/2011, (EU) No 494/2011, (EU) No 109/2012, (EU) No 125/2012, (EU) No 412/2012, (EU) No 835/2012, (EU) No 836/2012, (EU) No 847/2012, (EU) No 126/2013, (EU) No 348/2013, (EU) No

		517/2013, (EU) No 1272/2013, (EU) No 301/2014, (EU) No 317/2014, (EU) No 474/2014, (EU) No 895/2014, (EU) 2015/282, (EU) 2015/326, (EU) 2015/628, (EU) 2015/830, (EU) 2015/1494
68	Regulation (EC) No 1272/2008 <i>CLP</i>	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) 1907/2006 Amended by: Commission Regulations (EC) No 790/2009, (EU) No 286/2011, (EU) No 618/2012, (EU) No 487/2013, (EU) No 758/2013, (EU) No 944/2013, (EU) No 605/2014, (EU) No 1297/2014, (EU) No 2015/1221
69	Regulation (EC) No 1102/2008 <i>Metallic Mercury</i>	Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury
		NOISE
70	Directive 2002/49/EC <i>Environmental Noise</i>	Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise Amended by Regulation (EC) 1137/2008 and Commission Directive (EU) 2015/996

**LIST OF CASES IN
THE COURT OF
JUSTICE**

Annex 3

LIST OF CASES IN THE COURT OF JUSTICE OF THE EUROPEAN UNION RELEVANT TO THE ENVIRONMENTAL POLICY AREA

(1 JANUARY 2012-31 DECEMBER 2014)

- Draft -

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
MULTIPLE GROUNDS				
<p><i>Directive 75/442/EC</i></p> <p><i>Directive 2001/42/EC</i></p> <p>Waste Framework and SEA</p>	<p>Case C-225/13</p> <p>Judgment of the Court (Second Chamber) of 9 April 2014</p> <p>Reference for a preliminary ruling: Conseil d'État - Belgium</p> <p>ECLI:EU:C:2014:245</p>	<p>Ville d'Ottignies-Louvain-la-Neuve and Others v Région wallonne</p>	<p>This request for a preliminary ruling concerns the interpretation of Council Directive 75/442/EEC of 15 July 1975 on waste (OJ 1975 L 194, p. 39), as amended by Commission Decision 96/350/EC of 24 May 1996 (OJ 1996 L 135, p. 32; 'Directive 75/442'), and Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment (OJ 2001 L 197, p. 30).</p> <p>The request has been made in proceedings between the town of Ottignies-Louvain-la-Neuve and Messrs Tillieut, Gregoire and Lacroix and the Région wallonne (Region of Wallonia), concerning a permit applied for by Shanks SA to operate and condition a site intended for waste disposal.</p>	<p>Article 7(1) of Council Directive 75/442/EEC of 15 July 1975 on waste, as amended by Commission Decision 96/350/EC of 24 May 1996, must be interpreted as meaning that a national legislative provision, such as that at issue in the main proceedings, which provides that, in derogation from the rule that no landfills may be authorised except on the sites provided for in the waste management plan required by that article, landfills authorised before that waste management plan entered into force may, after such entry into force, be granted new permits in respect of the plots covered by the authorisation, does not constitute a 'waste management plan' within the meaning of that provision of Directive 2001/42, as amended by Decision 96/350.</p> <p>Article 8 of Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste, as amended by Council Directive 2011/97/EU of</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				5 December 2011, does not, however, preclude such a national legislative provision which may be based on Article 14 of that directive and apply to landfills which have been granted a permit or which are already in operation at the date of the transposition thereof, provided that the other conditions set out in Article 14 are met, which it is for the referring court to ascertain.
<p><i>Directive 85/337/EEC</i> <i>Directive 2003/35/EC</i></p> <p><i>EIA and Public Participation</i></p>	<p>Case C-72/12</p> <p>Judgment of the Court (Second Chamber) of 7 November 2013.</p> <p>Request for a preliminary ruling</p> <p>ECLI:EU:C:2013:712</p>	<p>Gemeinde Altrip and Others v Land Rheinland-Pfalz.</p>	<p>This request for a preliminary ruling concerns the interpretation of Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC (OJ 2003 L 156, p. 17) and of Article 10a of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment (OJ 1985 L 175, p. 40), as amended by Directive 2003/35 ('Directive 85/337').</p> <p>The request has been made in proceedings between the Gemeinde Altrip (municipality of Altrip), the civil-law company Gebrüder Hört GbR and Mr Schneider, and the Land Rheinland-Pfalz (Rhineland-Palatinate) concerning a decision approving plans to construct a flood</p>	<p>1. <i>By providing that it was to be transposed into national law by 25 June 2005 at the latest, Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC, which inserted Article 10a into Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, must be interpreted as meaning that the rules of national law adopted for the purposes of transposing that article into national law were intended also to apply to administrative development consent</i></p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			retention scheme covering over 320 hectares of a former Rhine floodplain.	<p><i>procedures initiated before 25 June 2005 when the latter resulted in the granting of consent after that date.</i></p> <ol style="list-style-type: none"> 2. <i>Article 10a</i> of Directive 85/337, as amended by Directive 2003/35, must be interpreted as precluding the Member States from limiting the applicability of the provisions transposing that article to cases in which the legality of a decision is challenged on the ground that no environmental impact assessment was carried out, while not extending that applicability to cases in which such an assessment was carried out but was irregular. 3. Subparagraph (b) of Article 10a of Directive 85/337, as amended by Directive 2003/35, must be interpreted as not precluding national courts from refusing to recognise impairment of a right within the meaning of that article if it is established that it is conceivable, having regard to the circumstances of the case, that the contested decision would not have been different without the procedural defect invoked by the applicant. None the less, that will be the case only if the court of law or body hearing the action does not in any way make the burden of proof fall on the applicant and

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>makes its ruling, where appropriate, on the basis of the evidence provided by the developer or the competent authorities and, more generally, on the basis of all the documents submitted to it, taking into account, inter alia, the seriousness of the defect invoked and ascertaining, in particular, whether that defect has deprived the public concerned of one of the guarantees introduced with a view to allowing that public to have access to information and to be empowered to participate in decision-making, in accordance with the objectives of Directive 85/337.</p>
<p><i>Directive 85/337/EEC</i> <i>Directive 1999/31/EC</i></p> <p>EIA and Landfill</p>	<p>Case C-121/11</p> <p>Judgment of the Court (Third Chamber) of 19 April 2012</p> <p>Reference for a preliminary ruling: Conseil d'État - Belgium</p> <p>ECLI:EU:C:2012:225</p>	<p>Pro-Braine ASBL and Others v Commune de Braine-le-Château.</p>	<p>This reference for a preliminary ruling concerns the interpretation of Article 14(b) of Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (OJ 1999 L 182, p. 1) and of Article 1(2) of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment (OJ 1985 L 175, p. 40), as amended by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 (OJ 2003 L 156, p. 17) ('Directive 85/337').</p> <p>The reference has been made in proceedings between Pro-Braine ASBL and Others ('Pro-Braine') and</p>	<p>The definitive decision relating to the carrying on of operations at an existing landfill site, taken on the basis of a conditioning plan, pursuant to Article 14(b) of Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste, does not constitute a 'consent' within the meaning of Article 1(2) of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, as amended by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003, unless that decision authorises a change to or</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			the local authority of Braine-le-Château concerning Pro-Braine's action for the annulment of the decision authorising the carrying on of operations at the 'Cour-au-Bois Nord' landfill site until the end of the existing authorisation period, that is, 27 December 2009, repealing the previous conditions of operation and imposing new conditions of operation.	extension of that installation or site, through works or interventions involving alterations to its physical aspect, which may have significant adverse effects on the environment within the meaning of point 13 of Annex II to Directive 85/337, and thus constitute a 'project' within the meaning of Article 1(2) of that Directive.
<p><i>Directive 85/337/EEC</i></p> <p><i>Directive 96/61/EC</i></p> <p>EIA and IPPC</p>	<p>Case C-260/11</p> <p>Judgment of the Court (Fourth Chamber) of 11 April 2013.</p> <p>Reference for a preliminary ruling: Supreme Court of the United Kingdom - United Kingdom.</p> <p>ECLI:EU:C:2013:221</p>	<p>The Queen, on the application of David Edwards and Lilian Pallikaropoulos v Environment Agency and Others.</p>	<p>This request for a preliminary ruling concerns the interpretation of the fifth paragraph of Article 10a of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment (OJ 1985 L 175, p. 40) and the fifth paragraph of Article 15a of Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control (OJ 1996 L 257, p. 26), as amended by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 (OJ 2003 L 156, p. 17) ('Directive 85/337' and 'Directive 96/61', respectively).</p> <p>The request has been made in proceedings between, on the one hand, Mr Edwards and Ms Pallikaropoulos and, on the other, the Environment Agency, the First Secretary of State and the Secretary of State for Environment, Food and Rural Affairs concerning a permit issued by the Environment Agency for the operation of a cement works. The request</p>	<p>The requirement, under the fifth paragraph of Article 10a of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment and the fifth paragraph of Article 15a of Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control, as amended by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003, that judicial proceedings should not be prohibitively expensive means that the persons covered by those provisions should not be prevented from seeking, or pursuing a claim for, a review by the courts that falls within the scope of those articles by reason of the financial burden that might arise as a result. Where a national court is called upon to make an order for costs against a member of the public who is an unsuccessful claimant in an environmental dispute or, more generally, where it is</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			<p>concerns the conformity with European Union law of the decision of the House of Lords ordering Ms Pallikaropoulos, whose appeal had been dismissed as unfounded, to pay the costs of the opposing parties.</p>	<p>required – as courts in the United Kingdom may be – to state its views, at an earlier stage of the proceedings, on a possible capping of the costs for which the unsuccessful party may be liable, it must satisfy itself that that requirement has been complied with, taking into account both the interest of the person wishing to defend his rights and the public interest in the protection of the environment.</p> <p>In the context of that assessment, the national court cannot act solely on the basis of that claimant’s financial situation but must also carry out an objective analysis of the amount of the costs. It may also take into account the situation of the parties concerned, whether the claimant has a reasonable prospect of success, the importance of what is at stake for the claimant and for the protection of the environment, the complexity of the relevant law and procedure, the potentially frivolous nature of the claim at its various stages, and the existence of a national legal aid scheme or a costs protection regime.</p> <p>By contrast, the fact that a claimant has not been deterred, in practice, from asserting his claim is not of itself sufficient to establish that the proceedings are not prohibitively expensive for him.</p> <p>Lastly, that assessment cannot be conducted according to different criteria depending on whether it is carried out at the conclusion of first-</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				instance proceedings, an appeal or a second appeal.
<p><i>Directive 85/337/EEC</i> <i>Directive 92/43/EEC</i> <i>Council Decision 2005/370/EC</i></p> <p>EIA and Habitats</p> <p>Aarhus Convention</p>	<p>Case C-182/10</p> <p>Judgment of the Court (Fourth Chamber) of 16 February 2012</p> <p>Reference for a preliminary ruling: Cour constitutionnelle - Belgium.</p> <p>ECLI:EU:C:2012:82</p>	<p>Marie-Noëlle Solvay and Others v Région wallonne.</p>	<p>This reference for a preliminary ruling concerns the interpretation of Articles 2, 3, 6 and 9 of the Convention on access to information, public participation in decision-making and access to justice in environmental matters, concluded on 25 June 1998 and approved on behalf of the European Community by Council Decision 2005/370/EC of 17 February 2005 (OJ 2005 L 124, p. 1) ('the Aarhus Convention'), Articles 1, 9 and 10a of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment (OJ 1985 L 175, p. 40), as amended by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 (OJ 2003 L 156, p. 17) ('Directive 85/337'), and Article 6(3) and (4) of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ 1992 L 206, p. 7, 'the Habitats Directive').</p> <p>The reference has been made in proceedings brought by persons residing near Liège-Bierset and Brussels South Charleroi airports and the Brussels-Charleroi railway against the Région wallonne (Region of Wallonia) concerning development consents for works relating to those airports and railway.</p>	<p>1. For the interpretation of Articles 2(2) and 9(4) of the Convention on access to information, public participation in decision-making and access to justice in environmental matters, concluded on 25 June 1998 and approved on behalf of the European Community by Council Decision 2005/370/EC of 17 February 2005, it is permissible to take the Implementation Guide for that Convention into consideration, but that Guide has no binding force and does not have the normative effect of the provisions of that Convention.</p> <p>2. Article 2(2) of the Convention on access to information, public participation in decision-making and access to justice in environmental matters and Article 1(5) of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, as amended by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003, must be interpreted as meaning that only projects the details of</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>which have been adopted by a specific legislative act, in such a way that the objectives of the Convention and the directive have been achieved by the legislative process, are excluded from the scope of those instruments. It is for the national court to verify that those two conditions have been satisfied, taking account both of the content of the legislative act adopted and of the entire legislative process which led to its adoption, in particular the preparatory documents and parliamentary debates. In that regard, a legislative act which does no more than simply ‘ratify’ a pre-existing administrative act, by merely referring to overriding reasons in the public interest without a substantive legislative process enabling those conditions to be fulfilled having first been commenced, cannot be regarded as a specific act of legislation within the meaning of the latter provision and is therefore not sufficient to exclude a project from the scope of that Convention and that directive as amended.</p> <p>3. Articles 3(9) and 9(2) to (4) of the Convention on access to information, public participation in decision-making</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>and access to justice in environmental matters and Article 10a of Directive 85/337, as amended by Directive 2003/35, must be interpreted as meaning that:</p> <ul style="list-style-type: none"> • when a project falling within the scope of those provisions is adopted by a legislative act, the question whether that legislative act satisfies the conditions laid down in Article 1(5) of that directive as amended must be capable of being submitted, under the national procedural rules, to a court of law or an independent and impartial body established by law, and • if no review procedure of the nature and scope set out above were available in respect of such an act, any national court before which an action falling within its jurisdiction is brought would have the task of carrying out the review described in the previous indent and, as the case may be, drawing the necessary conclusions by disapplying that legislative act. <p>4. Article 6(9) of the Convention on access to information, public</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>participation in decision-making and access to justice in environmental matters and Article 9(1) of Directive 85/337, as amended by Directive 2003/35, must be interpreted as not requiring that the decision should itself contain the reasons for the competent authority's decision that it was necessary. However, if an interested party so requests, the competent authority is obliged to communicate to him the reasons for that decision or the relevant information and documents in response to the request made.</p> <p>5. Article 6(3) of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora must be interpreted as not allowing a national authority, even if it is a legislative authority, to authorise a plan or project without having ascertained that it will not adversely affect the integrity of the site concerned.</p> <p>6. Article 6(4) of Directive 92/43 must be interpreted as meaning that the creation of infrastructure intended to accommodate a management centre cannot be regarded as an imperative reason of overriding</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				public interest, such reasons including those of a social or economic nature, within the meaning of that provision, capable of justifying the implementation of a plan or project that will adversely affect the integrity of the site concerned.
<p><i>Directive 2000/60/EC</i> <i>Directive 85/337/EEC</i> <i>Directive 92/43/EEC</i></p> <p>WFD, EIA and Habitats</p>	<p>Case C-43/10</p> <p>Judgment of the Court (Grand Chamber) of 11 September 2012.</p> <p>Reference for a preliminary ruling: Symvoulion tis Epikrateias - Greece.</p> <p>ECLI:EU:C:2012:560</p>	<p>Nomarchiaki Aftodioikisi Aitolokarnanias and Others v Ypourgos Perivallontos, Chorotaxias kai Dimosion ergon and Others.</p>	<p>This reference for a preliminary ruling concerns the interpretation of Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ 2000 L 327, p. 1), of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment (OJ 1985 L 175, p. 40), as amended by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 (OJ 2003 L 156, p. 17) ('Directive 85/337'), of Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment (OJ 2001 L 197, p. 30) and of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ 1992 L 206, p. 7).</p> <p>The reference has been made in legal proceedings brought by the</p>	<p>1. Articles 13(6) and 24(1) of Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy must be interpreted as respectively fixing 22 December 2009 as the date of expiry of the period allowed to Member States for the publication of river basin management plans and 22 December 2003 as the date of expiry of the maximum period available to the Member States for the transposition of that directive, in particular Articles 3 to 6, 9, 13 and 15 thereof.</p> <p>2. Directive 2000/60 must be interpreted as meaning that:</p> <ul style="list-style-type: none"> • it does not preclude, in principle, a provision of national law whereby consent is given, prior to 22 December 2009, to a transfer of water from one river basin to another or

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			<p>Nomarchiaki Aftodioikisi Aitoloakarnanias (Prefectural Authority of Aitoloakarnania) and other legal persons against the Ipourgos Perivallontos, Khorotaxias kai Dimosion Ergon (Minister for the Environment, Regional Planning and Public Works) and other ministers, seeking the annulment of measures relating to the project for the partial diversion of the upper waters of the river Acheloos (Western Greece) to the river Pinios, in Thessaly.</p>	<p>from one river basin district to another where the managements plans for the river basin districts concerned were not yet adopted by the competent national authorities;</p> <ul style="list-style-type: none"> • such a transfer must not be such as seriously to jeopardise the realisation of the objectives laid down by that directive; • however, to the extent that that transfer is liable to have adverse effects on water of the kind stated in Article 4(7) of that directive, consent may be given to it, at the very least if the conditions set out in Article 4(7)(a) to (d) are satisfied, and • the fact that it is impossible for the receiving river basin or river basin district to meet from its own water resources its needs in terms of drinking water, electricity production or irrigation is not a sine qua non for such a transfer of water to be compatible with that directive provided that the conditions listed above are satisfied. <p>3. The fact that a national parliament approves</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>management plans for river basins, such as the plans at issue in the main proceedings, where no procedure for public information, consultation or participation has been implemented does not fall within the scope of Article 14 of Directive 2000/60, and in particular the scope of Article 14(1) thereof.</p> <p>4. Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, as amended by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003, and in particular Article 1(5) thereof, must be interpreted as not precluding legislation such as Law 3481/2006, adopted by the Greek Parliament on 2 August 2006, which approves a project for the partial diversion of the waters of a river such as that at issue in the main proceedings on the basis of an environmental impact assessment for that project which had served as the basis for an administrative decision adopted on the conclusion of a procedure which complied with the obligations in terms of public information and</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>participation laid down by that directive, even where that decision was annulled by court order, provided that that legislation constitutes a specific legislative act, so that the objectives of that directive can be achieved through the legislative process. It is for the national court to determine whether those two conditions have been complied with.</p> <p>5. A project for the partial diversion of the waters of a river, such as that at issue in the main proceedings, is not to be regarded as a plan or programme falling within the scope of Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment.</p> <p>6. The areas which were listed in the national list of sites of Community importance transmitted to the European Commission pursuant to the second subparagraph of Article 4(1) of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora and were then included in the list of SCIs adopted by Commission</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>Decision 2006/613/EC of 19 July 2006 adopting, pursuant to Council Directive 92/43/EEC, the list of sites of Community importance for the Mediterranean biogeographical region were entitled, after notification of Decision 2006/613 to the Member State concerned, to the protection of that directive before that decision was published. In particular, after that notification, the Member State concerned also had to take the protective measures laid down in Article 6(2) to (4) of the directive.</p> <p>7. Directive 92/43, and in particular Article 6(3) and (4) thereof, must be interpreted as precluding development consent being given to a project for the diversion of water which is not directly connected with or necessary to the conservation of a special protection area, but likely to have a significant effect on that special protection area, in the absence of information or of reliable and updated data concerning the birds in that area.</p> <p>8. Directive 92/43, and in particular Article 6(4) thereof, must be interpreted as meaning that grounds linked, on the one</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>hand, to irrigation and, on the other, to the supply of drinking water, relied on in support of a project for the diversion of water, may constitute imperative reasons of overriding public interest capable of justifying the implementation of a project which adversely affects the integrity of the sites concerned. Where such a project adversely affects the integrity of a site of Community importance hosting a priority natural habitat type and/or a priority species, its implementation may, in principle, be justified by grounds linked with the supply of drinking water. In some circumstances, it might be justified by reference to beneficial consequences of primary importance which irrigation has for the environment. On the other hand, irrigation cannot, in principle, qualify as a consideration relating to human health and public safety, justifying the implementation of a project such as that at issue in the main proceedings.</p> <p>9. Under Directive 92/43, and in particular the first sentence of the first subparagraph of Article 6(4) thereof, for the purposes of determining the</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>adequacy of compensatory measures account should be taken of the extent of the diversion of water and the scale of the works involved in that diversion.</p> <p>10. Directive 92/43, and in particular the first subparagraph of Article 6(4) thereof, interpreted in the light of the objective of sustainable development, as enshrined in Article 6 EC, permits, in relation to sites which are part of the Natura 2000 network, the conversion of a natural fluvial ecosystem into a largely man-made fluvial and lacustrine ecosystem provided that the conditions referred to in that provision of the directive are satisfied.</p>
<p><i>Directive 85/337/EEC</i> <i>Directive 96/61/EC</i> <i>Decision 2005/370/EC</i></p> <p>Aarhus Convention</p> <p>EIA and IPPC</p>	<p>Case C-416/10</p> <p>Judgment of the Court (Grand Chamber) of 15 January 2013</p> <p>Reference for a preliminary ruling: Najvyšší súd Slovenskej republiky - Slovakia.</p> <p>ECLI:EU:C:2013:8</p>	<p>Jozef Križan and Others v Slovenská inšpekcia životného prostredia</p>	<p>This request for a preliminary ruling concerns the interpretation of the Convention on access to information, public participation in decision-making and access to justice in environmental matters, signed in Aarhus on 25 June 1998 and approved on behalf of the European Community by Council Decision 2005/370/EC of 17 February 2005 (OJ 2005 L 124, p. 1) ('the Aarhus Convention'), of Articles 191(1) and (2) TFEU and 267 TFEU, of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment (OJ 1985</p>	<p>1. Article 267 TFEU must be interpreted as meaning that a national court, such as the referring court, is obliged to make, of its own motion, a request for a preliminary ruling to the Court of Justice of the European Union even though it is ruling on a referral back to it after its first decision was set aside by the constitutional court of the Member State concerned and even though a national rule obliges it to resolve the dispute by following the legal opinion of that latter court.</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			<p>L 175, p. 40), as amended by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 (OJ 2003 L 156, p. 17) ('Directive 85/337'), and of Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control (OJ 1996 L 257, p. 26), as amended by Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 (OJ 2006 L 33, p. 1) ('Directive 96/61').</p> <p>This request has been made in proceedings between, on the one hand, Mr Križan and 43 other appellants, natural persons, residents of the town of Pezinok, as well as Mesto Pezinok (town of Pezinok), and, on the other, the Slovenská inšpekcia životného prostredia (Slovak Environment Inspection; 'the inšpekcia') concerning the lawfulness of decisions of the administrative authority authorising the construction and operation by Ekologická skládka as ('Ekologická skládka'), the intervener in the main proceedings, of a landfill site for waste.</p>	<p>2. Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control, as amended by Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006, must be interpreted as meaning that it:</p> <ul style="list-style-type: none"> • requires that the public concerned have access to an urban planning decision, such as that at issue in the main proceedings, from the beginning of the authorisation procedure for the installation concerned, • does not allow the competent national authorities to refuse the public concerned access to such a decision by relying on the protection of the confidentiality of commercial or industrial information where such confidentiality is provided for by national or European Union law to protect a legitimate economic interest, and • does not preclude the possibility of rectifying, during the administrative procedure at second instance, an unjustified refusal to make available to the public concerned an

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>urban planning decision, such as that at issue in the main proceedings, during the administrative procedure at first instance, provided that all options and solutions remain possible and that regularisation at that stage of the procedure still allows that public effectively to influence the outcome of the decision-making process, this being a matter for the national court to determine.</p> <p>3. Article 15a of Directive 96/61, as amended by Regulation No 166/2006, must be interpreted as meaning that members of the public concerned must be able, in the context of the action provided for by that provision, to ask the court or competent independent and impartial body established by law to order interim measures such as temporarily to suspend the application of a permit, within the meaning of Article 4 of that directive, pending the final decision.</p> <p>4. A decision of a national court, taken in the context of national proceedings implementing the obligations resulting from Article 15a of Directive 96/61, as amended by Regulation</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				No 166/2006, and from Article 9(2) and (4) of the Convention on access to information, public participation in decision-making and access to justice in environmental matters, signed in Aarhus on 25 June 1998 and approved on behalf of the European Community by Council Decision 2005/370/EC of 17 February 2005, which annuls a permit granted in infringement of the provisions of that directive is not capable, in itself, of constituting an unjustified interference with the developer's right to property enshrined in Article 17 of the Charter of Fundamental Rights of the European Union.
<i>Directive 2001/42/EC</i> <i>Directive 91/676/EEC</i> SEA and Nitrates	Case C-41/11 Judgment of the Court (Grand Chamber) of 28 February 2012 Reference for a preliminary ruling: Conseil d'État - Belgium. ECLI:EU:C:2012:103	Inter-Environnement Wallonie ASBL and Terre wallonne ASBL v Région wallonne.	This reference for a preliminary ruling concerns the circumstances in which a 'plan' or 'programme' within the meaning of Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment (OJ 2001 L 197, p. 30), which has not been the subject of an environmental assessment as required by that directive, may provisionally be kept in force. The reference has been made in the course of proceedings brought by Inter-Environnement Wallonie ASBL ('Inter-Environnement Wallonie') and Terre wallonne ASBL ('Terre	When a national court has before it, on the basis of its national law, an action for annulment of a national measure constituting a 'plan' or 'programme' within the meaning of Directive 2001/42 on the assessment of the effects of certain plans and programmes on the environment and it finds that the 'plan' or 'programme' was adopted in breach of the obligation laid down by that directive to carry out a prior environmental assessment, that court is obliged to take all the general or particular measures provided for by its national law in order to remedy the failure to carry out such an assessment, including the possible suspension or

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			<p>wallonne’) against Région wallonne (the Region of Wallonia) for annulment of the order of the Walloon Government of 15 February 2007 amending Book II of the Environment Code, which forms the Water Code, as regards the sustainable management of nitrogen in agriculture (<i>Moniteur belge</i> of 7 March 2007, p. 11118) (‘the contested order’).</p>	<p>annulment of the contested ‘plan’ or ‘programme’.</p> <p>However, having regard to the specific circumstances of the case before it, the referring court may, exceptionally, be authorised to make use of its national provision empowering it to maintain certain effects of an annulled national measure in so far as:</p> <ul style="list-style-type: none"> • that national measure is a measure which correctly transposes Directive 91/676 concerning the protection of waters against pollution caused by nitrates from agricultural sources; • the adoption and entry into force of the new national measure containing the action programme within the meaning of Article 5 of that directive do not enable the adverse effects on the environment resulting from the annulment of the contested measure to be avoided; • annulment of the contested measure would result in a legal vacuum in relation to the transposition of Directive 91/676 which would be more harmful to the environment, in the sense that the annulment would result in a lower level of protection of waters against pollution caused by nitrates from agricultural sources and

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				would thereby run specifically counter to the fundamental objective of that directive; and <ul style="list-style-type: none"> the effects of such a measure are exceptionally maintained only so long as is strictly necessary for the adoption of the measures making it possible to remedy the irregularity found.
<p><i>Directive 2001/42/EC</i></p> <p><i>Directive 92/43/EEC</i></p> <p>SEA and Habitats</p>	<p>Case C-177/11</p> <p>Judgment of the Court (Eighth Chamber) of 21 June 2012</p> <p>Reference for a preliminary ruling: Symvoulio tis Epikrateias - Greece. ECLI:EU:C:2012:378</p>	<p>Sylogos Ellinon Poleodomon kai Chorotakton v Ypourgos Perivallontos, Chorotaxias & Dimosion Ergon and Others</p>	<p>The reference for a preliminary ruling concerns the interpretation of Article 3(2)(b) of Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment (OJ 2001 L 197, p. 30) (the ‘SEA Directive’, ‘SEA’ standing for ‘strategic environmental assessment’).</p> <p>The reference has been made in the course of proceedings before the Simvoulio tis Epikrateias (Greek Council of State) by the association Sillogos Ellinon Poleodomon kai Khorotakton (Greek Association of Urban and Regional Planners, ‘the applicant’), the seat of which is in Athens, seeking annulment of Ministerial Decision No 107017 of 28 August 2006 transposing the SEA Directive into Greek law (YPEXODE/EYPE/oik. 107017/28-8-2006; ‘the Ministerial Decision of 28 August 2006’), adopted jointly by Ipourgos Perivallontos, Khorotaxias kai Dimosion Ergon (Minister for the</p>	<p>1. Article 3(2)(b) of Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment must be interpreted as meaning that the obligation to make a particular plan subject to an environmental assessment depends on the preconditions requiring an assessment under Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, as amended by Council Directive 2006/105/EC of 20 November 2006, including the condition that the plan may have a significant effect on the site concerned, being met in respect of that plan. The examination carried out to determine whether that latter condition is fulfilled is necessarily limited to the question as to whether it</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			Environment, Regional Planning and Public Works), Ipourgos Ikonomias kai Ikonomikon (Minister for Economic Affairs and Finance) and Ipourgos Esoterikon, Dimosias Diikisis kai Apokentrosis (Minister for the Interior, Public Administration and Decentralisation).	can be excluded, on the basis of objective information, that that plan or project will have a significant effect on the site concerned.
<p><i>Directive 2000/60/EC</i> <i>Directive 85/337/EEC</i> <i>Directive 2001/42/EC</i> <i>Directive 92/43/EEC</i></p> <p>WFD, EIA, SEA and Habitats</p>	<p>Case C-43/10. Judgment of the Court (Grand Chamber) of 11 September 2012. Reference for a preliminary ruling: Symvoulion tis Epikrateias - Greece. ECLI:EU:C:2012:560</p>	<p>Nomarchiaki Aftodioikisi Aitolokarnanias and Others v Ypourgos Perivallontos, Chorotaxias kai Dimosion ergon and Others.</p>	<p>This reference for a preliminary ruling concerns the interpretation of Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ 2000 L 327, p. 1), of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment (OJ 1985 L 175, p. 40), as amended by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 (OJ 2003 L 156, p. 17) ('Directive 85/337'), of Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment (OJ 2001 L 197, p. 30) and of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ 1992 L 206, p. 7).</p> <p>2 The reference has been made in legal proceedings brought by the Nomarchiaki Aftodioikisi</p>	<p>Articles 13(6) and 24(1) of Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy must be interpreted as respectively fixing 22 December 2009 as the date of expiry of the period allowed to Member States for the publication of river basin management plans and 22 December 2003 as the date of expiry of the maximum period available to the Member States for the transposition of that directive, in particular Articles 3 to 6, 9, 13 and 15 thereof.</p> <p>2. Directive 2000/60 must be interpreted as meaning that:</p> <ul style="list-style-type: none"> • it does not preclude, in principle, a provision of national law whereby consent is given, prior to 22 December 2009, to a transfer of water from one river basin to another or from one river basin district to another where the managements plans for the river basin districts concerned

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			<p>Aitoloakarnanias (Prefectural Authority of Aitoloakarnania) and other legal persons against the Ipourgos Perivallontos, Khorotaxias kai Dimosion Ergon (Minister for the Environment, Regional Planning and Public Works) and other ministers, seeking the annulment of measures relating to the project for the partial diversion of the upper waters of the river Acheloos (Western Greece) to the river Pinios, in Thessaly.</p>	<p>were not yet adopted by the competent national authorities;</p> <ul style="list-style-type: none"> • such a transfer must not be such as seriously to jeopardise the realisation of the objectives laid down by that directive; • however, to the extent that that transfer is liable to have adverse effects on water of the kind stated in Article 4(7) of that directive, consent may be given to it, at the very least if the conditions set out in Article 4(7)(a) to (d) are satisfied, and • the fact that it is impossible for the receiving river basin or river basin district to meet from its own water resources its needs in terms of drinking water, electricity production or irrigation is not a sine qua non for such a transfer of water to be compatible with that directive provided that the conditions listed above are satisfied. <p>3. The fact that a national parliament approves management plans for river basins, such as the plans at issue in the main proceedings, where no procedure for public information, consultation or participation has been implemented does not fall within the scope of Article 14 of Directive 2000/60, and in</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>particular the scope of Article 14(1) thereof.</p> <p>4. Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, as amended by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003, and in particular Article 1(5) thereof, must be interpreted as not precluding legislation such as Law 3481/2006, adopted by the Greek Parliament on 2 August 2006, which approves a project for the partial diversion of the waters of a river such as that at issue in the main proceedings on the basis of an environmental impact assessment for that project which had served as the basis for an administrative decision adopted on the conclusion of a procedure which complied with the obligations in terms of public information and participation laid down by that directive, even where that decision was annulled by court order, provided that that legislation constitutes a specific legislative act, so that the objectives of that directive can be achieved through the legislative process. It is for the</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>national court to determine whether those two conditions have been complied with.</p> <p>5. A project for the partial diversion of the waters of a river, such as that at issue in the main proceedings, is not to be regarded as a plan or programme falling within the scope of Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment.</p> <p>6. The areas which were listed in the national list of sites of Community importance transmitted to the European Commission pursuant to the second subparagraph of Article 4(1) of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora and were then included in the list of SCIs adopted by Commission Decision 2006/613/EC of 19 July 2006 adopting, pursuant to Council Directive 92/43/EEC, the list of sites of Community importance for the Mediterranean biogeographical region were entitled, after notification of Decision 2006/613 to the Member State</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>concerned, to the protection of that directive before that decision was published. In particular, after that notification, the Member State concerned also had to take the protective measures laid down in Article 6(2) to (4) of the directive.</p> <p>7. Directive 92/43, and in particular Article 6(3) and (4) thereof, must be interpreted as precluding development consent being given to a project for the diversion of water which is not directly connected with or necessary to the conservation of a special protection area, but likely to have a significant effect on that special protection area, in the absence of information or of reliable and updated data concerning the birds in that area.</p> <p>8. Directive 92/43, and in particular Article 6(4) thereof, must be interpreted as meaning that grounds linked, on the one hand, to irrigation and, on the other, to the supply of drinking water, relied on in support of a project for the diversion of water, may constitute imperative reasons of overriding public interest capable of justifying the implementation of a project</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>which adversely affects the integrity of the sites concerned. Where such a project adversely affects the integrity of a site of Community importance hosting a priority natural habitat type and/or a priority species, its implementation may, in principle, be justified by grounds linked with the supply of drinking water. In some circumstances, it might be justified by reference to beneficial consequences of primary importance which irrigation has for the environment. On the other hand, irrigation cannot, in principle, qualify as a consideration relating to human health and public safety, justifying the implementation of a project such as that at issue in the main proceedings.</p> <p>9. Under Directive 92/43, and in particular the first sentence of the first subparagraph of Article 6(4) thereof, for the purposes of determining the adequacy of compensatory measures account should be taken of the extent of the diversion of water and the scale of the works involved in that diversion.</p> <p>10. Directive 92/43, and in particular the first subparagraph of Article 6(4) thereof,</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				interpreted in the light of the objective of sustainable development, as enshrined in Article 6 EC, permits, in relation to sites which are part of the Natura 2000 network, the conversion of a natural fluvial ecosystem into a largely man-made fluvial and lacustrine ecosystem provided that the conditions referred to in that provision of the directive are satisfied.
<p>TFEU Directive 2008/98/EC Regulation (EC) 1013/2006</p> <p>Waste framework and Shipment of waste</p>	<p>Case C-292/12</p> <p>Judgment of the Court (Fifth Chamber) of 12 December 2013.</p> <p>Reference for a preliminary ruling: Tartu Ringkonnakohus - Estonia</p> <p>ECLI:EU:C:2013:820</p>	<p>Ragn-Sells AS v Sillamäe Linnavalitsus.</p>	<p>This request for a preliminary ruling concerns the interpretation of Articles 35 TFEU, 49 TFEU, 56 TFEU, the competition rules of the FEU Treaty and Article 16(3) of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ 2008 L 312, p. 3).</p> <p>The request has been made in proceedings between Ragn-Sells AS ('Ragn-Sells') and Sillamäe Linnavalitsus (Municipality of Sillamäe) concerning certain contract documents drawn up by that municipality in the course of a procedure for awarding a service concession for the collection and transport of waste produced on its territory.</p>	<p>The provisions of Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste, read in conjunction with Article 16 of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, must be interpreted as:</p> <ul style="list-style-type: none"> • permitting a local authority to require the undertaking responsible for the collection of waste on its territory to transport mixed municipal waste collected from private households and, as applicable, from other producers, to the nearest appropriate treatment facility established in the same Member State as that authority; • not permitting a local authority to require the undertaking responsible for the collection of waste on its territory to

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				transport industrial and building waste produced on its territory to the nearest appropriate treatment facility established in the same Member State as that authority, where that waste is intended for recovery, if the producers of that waste are themselves required to deliver the waste either to that undertaking or directly to that facility.
<p><i>Directive 2008/98/EC Regulation (EC) No 1907/2006</i></p> <p>Waste Framework and REACH</p>	<p>Case C-358/11</p> <p>Judgment of the Court (Second Chamber) of 7 March 2013</p> <p>Reference for a preliminary ruling: Korkein hallinto-oikeus - Finland</p> <p>ECLI:EU:C:2013:142</p>	<p>Lapin elinkeino-, liikenne- ja ympäristökeskuksen liikenne ja infrastruktuuri - vastuualue v Lapin luonnonsuojelupiiri ry</p>	<p>This request for a preliminary ruling concerns the interpretation of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ 2008 L 312, p. 3) and of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1 and corrigendum OJ 2007 L 136, p. 3), in its version resulting from Commission Regulation (EC) No 552/2009 of</p>	<ol style="list-style-type: none"> 1. European Union law does not, as a matter of principle, exclude the possibility that waste regarded as hazardous may cease to be waste within the meaning of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives if a recovery operation enables it to be made usable without endangering human health and without harming the environment and, also, if it is not found that the holder of the object at issue discards it or intends or is required to discard it within the meaning of Article 3(1) of that directive, this being a matter for the referring court to ascertain. 2. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			<p>22 June 2009 (OJ 2009 L 164, p. 7) ('the REACH Regulation').</p> <p>The request has been made in proceedings between Lapin elinkeino-, liikenne- ja ympäristökeskuksen liikenne ja infrastruktuuri –vastualue ('transport and infrastructure section' of the Lapland Centre for Economic Development, Transport and Environmental Responsibility; the 'liikenne ja infrasruktuuri – vastualue') and the Lapin luonnonsuojelupiiri ry (Lapland Nature Protection Association) concerning repair works to a track made up of duckboards whose infrastructure consists of old wooden telecommunications poles treated with a solution known as 'CCA' (copper-chromium-arsenic) ('CCA solution').</p>	<p>Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, in the version resulting from Commission Regulation (EC) No 552/2009 of 22 June 2009, in particular Annex XVII thereto, in so far as it authorises the use, subject to certain conditions, of wood treated with a 'CCA' (copper-chromium-arsenic) solution, must be interpreted as meaning that, in circumstances such as those in the main proceedings, it is relevant for the purpose of determining whether such wood may cease to be waste because, if those conditions were fulfilled, its holder would not be required to discard it within the meaning of Article 3(1) of Directive 2008/98.</p> <p>3. Articles 67 and 128 of Regulation No 1907/2006, in the version resulting from Regulation No 552/2009, must</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>be interpreted as meaning that European Union law harmonises the requirements relating to the manufacture, placing on the market or use of a substance such as that relating to arsenic compounds which is the subject of a restriction under Annex XVII to that regulation.</p> <p>4. Annex XVII, point 19(4)(b), to Regulation No 1907/2006, in the version resulting from Regulation No 552/2009, which lists the applications for which, by way of derogation, wood treated with a 'CCA' (copper-chromium-arsenic) solution may be used, must be interpreted as meaning that the list in that provision is exhaustive in character and that, therefore, that derogation cannot be applied to cases other than those referred to therein. It is for the referring court to determine whether, in circumstances such as those at issue in the main proceedings, the use of the telecommunications poles concerned as an underlay for duckboards does in fact come within the scope of the applications listed in that provision.</p> <p>5. The provisions of Annex XVII, point 19(4)(d), second indent,</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				to Regulation No 1907/2006, in the version resulting from Regulation No 552/2009, according to which wood treated with a 'CCA' (copper-chromium-arsenic) solution must not be used in any application where there is a risk of repeated skin contact, must be interpreted as meaning that the prohibition at issue must apply in any situation which, in all likelihood, will involve repeated skin contact with the treated wood, such likelihood having to be inferred from the specific conditions of normal use of the application to which that wood has been put, this being a matter for the referring court to ascertain.
HORIZONTAL				
<i>Directive 85/337/EEC</i> EIA	Case C-244/12 Judgment of the Court (Fifth Chamber) of 21 March 2013 Reference for a preliminary ruling: Verwaltungsgerichtshof - Austria	Salzburger Flughafen GmbH v Umweltsenat	This request for a preliminary ruling concerns the interpretation of the relevant provisions of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment (OJ 1985 L 175, p. 40), as amended by Council Directive 97/11/EC of 3 March 1997 (OJ 1997 L 73, p. 5) ('Directive 85/337'). The request has been made in proceedings between Salzburger Flughafen GmbH ('Salzburger Flughafen') and the Umweltsenat (Administrative Chamber for	1. Articles 2(1) and 4(2)(b) and (3) of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, as amended by Council Directive 97/11/EC of 3 March 1997, preclude national legislation which makes projects which change the infrastructure of an airport and fall within the scope of Annex II to that directive subject to an environmental impact assessment only if those projects are likely to increase

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			Environmental Matters) concerning the obligation to subject certain projects which expand the infrastructure of the airport of Salzburg (Austria) to an environmental impact assessment.	<p>the number of aircraft movements by at least 20 000 per year.</p> <p>2. When a Member State, pursuant to Article 4(2)(b) of Directive 85/337, as amended by Directive 97/11, with regard to projects falling within the scope of Annex II thereto, establishes a threshold which is incompatible with the obligations laid down in Articles 2(1) and 4(3) of that directive, the provisions of Articles 2(1) and 4(2)(a) and (3) of the directive have direct effect, which means that the competent national authorities must ensure that it is first examined whether the projects concerned are likely to have significant effects on the environment and, if so, that an assessment of those effects is then undertaken.</p>
<p><i>Directive 85/337/EEC</i></p> <p>EIA</p>	<p>Case C-420/11</p> <p>Judgment of the Court (Fourth Chamber) of 14 March 2013</p> <p>Reference for a preliminary ruling: Oberster Gerichtshof - Austria</p> <p>ECLI:EU:C:2013:166</p>	<p>Jutta Leth v Republik Österreich and Land Niederösterreich</p>	<p>This request for a preliminary ruling concerns the interpretation of Article 3 of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment (OJ 1985 L 175, p. 40), as amended by Council Directive 97/11/EC of 3 March 1997 (OJ 1997 L 73, p. 5) and by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 (OJ 2003 L 156, p. 17) ('Directive 85/337').</p>	<p>Article 3 of Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, as amended by Council Directive 97/11/EC of 3 March 1997 and by Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003, must be interpreted as meaning that the environmental impact assessment, as provided for in that article, does not include the assessment of the effects</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			<p>The request has been made in the course of proceedings between Ms Leth, on the one hand, and Republik Österreich (Republic of Austria) and <i>Land</i> Niederösterreich (State of Lower Austria), on the other, regarding her application for (i) compensation for the pecuniary damage which she claims to have sustained as a result of the decrease in the value of her home following the extension of Vienna-Schwechat airport (Austria) and (ii) a declaration that the defendants in the main proceedings will be liable for any future damage.</p>	<p>which the project under examination has on the value of material assets. However, pecuniary damage, in so far as it is the direct economic consequence of the effects on the environment of a public or private project, is covered by the objective of protection pursued by Directive 85/337.</p> <p>The fact that an environmental impact assessment has not been carried out, in breach of the requirements of that directive, does not, in principle, by itself, according to European Union law, and without prejudice to rules of national law which are less restrictive as regards State liability, confer on an individual a right to compensation for purely pecuniary damage caused by the decrease in the value of his property as a result of the environmental effects of that project. However, it is for the national court to determine whether the requirements of European Union law applicable to the right to compensation, including the existence of a direct causal link between the breach alleged and the damage sustained, have been satisfied.</p>
<p><i>Directive</i> 2001/42/EC</p> <p>SEA</p>	<p>Case C-463/11</p> <p>Judgment of the Court (Fourth Chamber) of 18 April 2013</p> <p>Reference for a preliminary ruling: Verwaltungsgerichtshof</p>	L v M	<p>This request for a preliminary ruling concerns the interpretation of Articles 3(4) and (5) of Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and</p>	<p>Article 3(5) of Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment, read in conjunction with Article 3(4)</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
	Baden-Württemberg - Germany ECLI:EU:C:2013:247		programmes on the environment (OJ 2001 L 197, p. 30; ‘the directive’). The request has been made in the course of proceedings between L and M, a municipality, concerning the legal validity of a building plan prepared by M without an environmental assessment, as required by the directive, having been carried out.	thereof, must be interpreted as precluding national legislation such as that at issue in the main proceedings, pursuant to which breach of a qualitative condition, imposed by the implementing provision of that directive to exempt the adoption of a particular type of building plan from an environmental assessment under that directive, is irrelevant to the legal validity of that plan.
Directive 2003/4/EC Environmental Information	Case C-204/09. Judgment of the Court (Grand Chamber) of 14 February 2012. Reference for a preliminary ruling: Bundesverwaltungsgericht - Germany. ECLI:EU:C:2012:71	Flachglas Torgau GmbH v Bundesrepublik Deutschland.	This reference for a preliminary ruling concerns the interpretation of Articles 2 and 4 of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ 2003 L 41, p. 26). The reference has been made in proceedings between Flachglas Torgau GmbH (‘Flachglas Torgau’) and the Federal Republic of Germany concerning the rejection by the latter of Flachglas Torgau’s request for access to information relating to the Law on the national allocation plan for greenhouse gas emission licences in the allocation period 2005-2007 (Gesetz über den nationalen Zuteilungsplan für Treibhausgas Emissionsberechtigungen in der Zuteilungsperiode 2005 bis 2007) (‘Zuteilungsgesetz 2007’).	1. The first sentence of the second subparagraph of Article 2(2) of Directive 2003/4 on public access to environmental information and repealing Directive 90/313 must be interpreted as meaning that the option given to Member States by that provision of not regarding bodies or institutions acting in a legislative capacity as public authorities may be applied to ministries to the extent that they participate in the legislative process, in particular by tabling draft laws or giving opinions, and that option is not subject to the conditions set out in the second sentence of the second subparagraph of Article 2(2) of that directive.(see para. 51, operative part 1) 2. The first sentence of the second subparagraph of Article 2(2) of Directive 2003/4 on public

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>access to environmental information and repealing Directive 90/313 must be interpreted as meaning that the option given to Member States by that provision of not regarding bodies or institutions acting in a legislative capacity as public authorities can no longer be exercised when the legislative process in question has ended. (see para. 58, operative part 2)</p> <p>3. Indent (a) of the first subparagraph of Article 4(2) of Directive 2003/4 on public access to environmental information and repealing Directive 90/313 must be interpreted as meaning that the condition that the confidentiality of the proceedings of public authorities must be provided for by law can be regarded as fulfilled by the existence, in the national law of the Member State concerned, of a rule which provides, generally, that the confidentiality of the proceedings of public authorities is a ground for refusing access to environmental information held by those authorities, in so far as national law clearly defines the concept of 'proceedings', which it is for the national court to</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				determine.
Directive 2003/4/EC Environmental Information	Case C-515/11 Judgment of the Court (Second Chamber) of 18 July 2013 Reference for a preliminary ruling: Verwaltungsgericht Berlin - Germany ECLI:EU:C:2013:523	Deutsche Umwelthilfe eV v Bundesrepublik Deutschland	This request for a preliminary ruling concerns the interpretation of the first sentence of the second subparagraph of Article 2(2) of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ 2003 L 41, p. 26). The request has been made in proceedings between Deutsche Umwelthilfe eV and the Bundesrepublik Deutschland concerning the former's request for access to information held by the Bundesministerium für Wirtschaft und Technologie (Ministry of Economic Affairs and Technology) in the Ministry's correspondence with representatives of the German automotive industry during the consultation which preceded the adoption of legislation on energy consumption labelling.	The first sentence of the second subparagraph of Article 2(2) of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC must be interpreted as meaning that the option given to Member States by that provision of not regarding 'bodies or institutions acting in a ... legislative capacity' as public authorities, required to allow access to the environmental information which they hold, may not be applied to ministries when they prepare and adopt normative regulations which are of a lower rank than a law.
Directive 2003/4/EC Environmental Information	Case C-279/12 Judgment of the Court (Grand Chamber) of 19 December 2013 Reference for a preliminary ruling: Upper Tribunal (Administrative Appeals Chamber) - United Kingdom. ECLI:EU:C:2013:853	Fish Legal and Emily Shirley v Information Commissioner and Others	This request for a preliminary ruling concerns the interpretation of Article 2(2) of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ 2003 L 41, p. 26). The request has been made in proceedings between, on the one hand, Fish Legal and Mrs Shirley and, on the other, the Information Commissioner and United Utilities Water plc,	1. In order to determine whether entities such as United Utilities Water plc, Yorkshire Water Services Ltd and Southern Water Services Ltd can be classified as legal persons which perform 'public administrative functions' under national law, within the meaning of Article 2(2)(b) of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			Yorkshire Water Services Ltd and Southern Water Services Ltd ('the water companies concerned') relating to the refusal by those companies of requests made by Fish Legal and Mrs Shirley for access to certain information relating to sewerage and water supply.	<p>environmental information and repealing Council Directive 90/313/EEC, it should be examined whether those entities are vested, under the national law which is applicable to them, with special powers beyond those which result from the normal rules applicable in relations between persons governed by private law.</p> <p>2. Undertakings, such as United Utilities Water plc, Yorkshire Water Services Ltd and Southern Water Services Ltd, which provide public services relating to the environment are under the control of a body or person falling within Article 2(2)(a) or (b) of Directive 2003/4, and should therefore be classified as 'public authorities' by virtue of Article 2(2)(c) of that directive, if they do not determine in a genuinely autonomous manner the way in which they provide those services since a public authority covered by Article 2(2)(a) or (b) of the directive is in a position to exert decisive influence on their action in the environmental field.</p> <p>3. Article 2(2)(b) of Directive 2003/4 must be interpreted as meaning that a person falling within that provision constitutes a public authority in</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				respect of all the environmental information which it holds. Commercial companies, such as United Utilities Water plc, Yorkshire Water Services Ltd and Southern Water Services Ltd, which are capable of being a public authority by virtue of Article 2(2)(c) of the directive only in so far as, when they provide public services in the environmental field, they are under the control of a body or person falling within Article 2(2)(a) or (b) of the directive are not required to provide environmental information if it is not disputed that the information does not relate to the provision of such services.
AIR QUALITY				
<i>Directive 2008/50/EC</i> Ambient Air Quality	Case C-404/13 Judgment of the Court (Second Chamber) of 19 November 2014 Reference for a preliminary ruling: Supreme Court of the United Kingdom - United Kingdom	The Queen, on the application of ClientEarth v The Secretary of State for the Environment, Food and Rural Affairs	This request for a preliminary ruling concerns the interpretation of Articles 4 TEU and 19 TEU and Articles 13, 22, 23 and 30 of Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ 2008 L 152, p. 1). The request has been made in proceedings between ClientEarth, a non-governmental organisation interested in protection of the environment, and the Secretary of State for the Environment, Food and Rural Affairs, concerning that organisation's request for revision of	1. Article 22(1) of Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe must be interpreted as meaning that, in order to be able to postpone by a maximum of five years the deadline specified by the directive for achieving conformity with the limit values for nitrogen dioxide specified in Annex XI thereto, a Member State is required to make an application for postponement and to establish an air quality plan when it is

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			the air quality plans drawn up by the United Kingdom of Great Britain and Northern Ireland under Directive 2008/50 for certain of its zones and agglomerations.	<p>objectively apparent, having regard to existing data, and notwithstanding the implementation by that Member State of appropriate pollution abatement measures, that conformity with those values cannot be achieved in a given zone or agglomeration by the specified deadline. Directive 2008/50 does not contain any exception to the obligation flowing from Article 22(1).</p> <p>2. Where it is apparent that conformity with the limit values for nitrogen dioxide established in Annex XI to Directive 2008/50 cannot be achieved in a given zone or agglomeration of a Member State by 1 January 2010, the date specified in that annex, and that Member State has not applied for postponement of that deadline under Article 22(1) of Directive 2008/50, the fact that an air quality plan which complies with the second subparagraph of Article 23(1) of the directive has been drawn up, does not, in itself, permit the view to be taken that that Member State has nevertheless met its obligations under Article 13 of the directive.</p> <p>3. Where a Member State has failed to comply with the requirements of the second</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				subparagraph of Article 13(1) of Directive 2008/50 and has not applied for a postponement of the deadline as provided for by Article 22 of the directive, it is for the national court having jurisdiction, should a case be brought before it, to take, with regard to the national authority, any necessary measure, such as an order in the appropriate terms, so that the authority establishes the plan required by the directive in accordance with the conditions laid down by the latter.
<i>Directive 1999/32/EC</i> <i>Sulphur content in liquid fuels</i>	Case C-537/11 Judgment of the Court (Fourth Chamber) of 23 January 2014 Reference for a preliminary ruling: Tribunale di Genova - Italy ECLI:EU:C:2014:19	Mattia Manzi and Compagnia Naviera Orchestra v Capitaneria di Porto di Genova.	This request for a preliminary ruling concerns the interpretation of Article 2(3g) and 4a(4) of Council Directive 1999/32/EC of 26 April 1999 relating to a reduction in the sulphur content of certain liquid fuels and amending Directive 93/12/EEC (OJ 1999 L 121, p. 13), as amended by Directive 2005/33/EC of the European Parliament and of the Council of 6 July 2005 (OJ 2005 L 191, p. 59) ('Directive 1999/32'). The request has been made in proceedings between Mr Manzi and the Compagnia Naviera Orchestra against the Capitaneria di Porto di Genova (Genoa Port Authority) concerning the administrative penalty order made against them for failing to comply with the maximum sulphur content in marine fuels.	1. A cruise ship, such as that at issue in the main proceedings, falls within the scope of Article 4a(4) of Council Directive 1999/32/EC of 26 April 1999 relating to a reduction in the sulphur content of certain liquid fuels and amending Directive 93/12/EEC, as amended by Directive 2005/33/EC of the European Parliament and of the Council of 6 July 2005 with regard to the criterion of 'regular services', as laid down in Article 2(3g) thereof, provided that it operates cruises, with or without intermediate calls, finishing in the port of departure or another port, provided that those cruises are organised at a particular

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>frequency, on specific dates and, in principle, at specified departure and arrival times, with interested persons being able to choose freely between the various cruises offered, which is a matter for the referring court to ascertain.</p> <p>2. The validity of Article 4a(4) of Directive 1999/32, as amended by Directive 2005/33, cannot be examined in the light of the general principle of international law <i>pacta sunt servanda</i> or the principle of cooperation in good faith enshrined in the first subparagraph of Article 4(3) TEU on the ground that that provision of the directive may lead to an infringement of Annex VI to the International Convention for the Prevention of Pollution from Ships, signed in London on 2 November 1973, as supplemented by the Protocol of 17 February 1978 and thereby oblige the Member States party to the Protocol of 1997 amending the International Convention of 1973 for the Prevention of Pollution from Ships, as amended by the Protocol of 1978 relating thereto, signed in London on 26 September 1997, to infringe their obligations</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				with respect to the other contracting parties thereto. 3. It is not for the Court to rule on the impact of Annex VI on the scope of Article 4a(4) of Directive 1999/32.
WASTE MANAGEMENT				
<i>Directive</i> 75/442/EEC Waste Framework	Case C-113/12 Judgment of the Court (Fourth Chamber) of 3 October 2013 Reference for a preliminary ruling: Supreme Court - Ireland ECLI:EU:C:2013:627	Donal Brady v Environmental Protection Agency	This request for a preliminary ruling concerns the interpretation of Council Directive 75/442/EEC of 15 July 1975 on waste (OJ 1975 L 194, p. 39), as amended by Commission Decision 96/350/EC of 24 May 1996 (OJ 1996 L 135, p. 32) ('Directive 75/442'). The request has been made in proceedings between Mr Brady and the Environmental Protection Agency ('the EPA') concerning certain conditions attached to a license to increase the size of a piggery issued by that authority to Mr Brady.	1. The first subparagraph of Article 1(a) of Council Directive 75/442/EEC of 15 July 1975 on waste, as amended by Commission Decision 96/350/EC of 24 May 1996, must be interpreted as meaning that slurry produced in an intensive pig farm and stored pending delivery to farmers in order to be used by them as fertiliser on their land constitutes not 'waste' within the meaning of that provision but a by-product when that producer intends to market the slurry on terms economically advantageous to himself in a subsequent process, provided that such reuse is not a mere possibility but a certainty, without any further processing prior to reuse and as part of the continuing process of production. It is for the national courts to determine, taking account of all the relevant circumstances obtaining in the situations before them, whether those various criteria are satisfied.

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>2. European Union law does not preclude the burden of proving that the criteria for finding that a substance such as the slurry produced, stored and transferred in circumstances such as those of the main proceedings constitutes a by-product are met from resting on the producer of that slurry, provided that this does not result in the effectiveness of European Union law, and in particular of Directive 75/442, as amended by Decision 96/350, being undermined and that compliance with the obligations flowing from European Union law is ensured, in particular the obligation not to make subject to the provisions of that directive substances which, on application of those criteria, must, under the Court's case-law, be regarded as by-products to which the directive does not apply.</p> <p>3. Article 2(1)(b)(iii) of Directive 75/442, as amended by Decision 96/350, must be interpreted as meaning that, where Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources has</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				<p>not been transposed into the law of a Member State, livestock effluent produced while operating a pig farm located in that Member State cannot be considered to be, by virtue of the existence of the latter directive, ‘covered by other legislation’ within the meaning of that provision.</p> <p>4. In a situation where slurry produced and held by a pig farm is to be classified as ‘waste’ within the meaning of the first subparagraph of Article 1(a) of Directive 75/442, as amended by Decision 96/350:</p> <ul style="list-style-type: none"> • Article 8 of that directive must be interpreted as precluding the holder from being authorised, under any conditions, to transfer that waste to a farmer who uses it as fertiliser on his land if it transpires that that farmer neither possesses the permit referred to in Article 10 of the directive nor is exempted from the requirement to possess such a permit and registered in accordance with Article 11 of the directive; and • 3Articles 8, 10 and 11 of the directive, read together, must be interpreted as

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				precluding the transfer of that waste by the holder to a farmer who uses it as fertiliser on his land, and who possesses a permit as referred to in Article 10 or is exempted from the requirement to possess such a permit and is registered in accordance with Article 11, from being subject to the condition that the holder assumes liability for compliance by that other farmer with the rules that are to apply to the recovery operations carried out by the latter by virtue of European Union law concerning the management of waste and fertilisers.
<i>Directive 2008/98/EC</i> Waste Framework	Case C-551/13 Judgment of the Court (Sixth Chamber) of 18 December 2014 Reference for a preliminary ruling: Commissione Tributaria Provinciale di Cagliari - Italy	Società Edilizia Turistica Alberghiera Residenziale (SETAR) SpA v Comune di Quartu S. Elena	This request for a preliminary ruling concerns the interpretation of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ 2003 L 312, p. 3). The request has been made in proceedings between Società Edilizia Turistica Alberghiera Residenziale (SETAR) SpA ('SETAR'), proprietor of a hotel complex in the locality of S'Oru e Mari (Italy) in the Comune di Quartu S. Elena, concerning SETAR's refusal to pay the municipal tax for the disposal of solid urban waste (tassa per	EU law and Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives must be interpreted as precluding national legislation, such as that at issue in the main proceedings, which transposes into national law a provision of that directive, but the entry into force of which is deferred pending the adoption of a subsequent internal measure, if that entry into force takes place after the end of the transposition period prescribed by the directive.

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			lo smaltimento dei rifiuti solidi urbani; 'the TARSU').	Article 15(1) of Directive 2008/98, read in conjunction with Articles 4 and 13 of that directive, must be interpreted as not precluding national legislation under which no provision is made permitting a waste producer or waste holder to dispose of that waste independently and accordingly to be exempted from liability for payment of a municipal tax for the disposal of waste, provided that that legislation meets the requirements entailed by the principle of proportionality.
<i>Directive 1999/31/EC</i> <i>Landfill</i>	Case C-97/11 Judgment of the Court (Fourth Chamber) of 24 May 2012 Reference for a preliminary ruling: Commissione Tributaria Provinciale di Palermo - Italy ECLI:EU:C:2012:306	Amia SpA v Provincia Regionale di Palermo.	This reference for a preliminary ruling concerns the question whether, in the light of the judgment in Case C-172/08 <i>Pontina Ambiente</i> [2010] ECR I-1175, the referring court must refrain from applying the national provisions which it considers to be contrary to Article 10 of Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (OJ 1999 L 182, p. 1), as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ 2003 L 284, p. 1, 'Directive 1999/31'), as well as Articles 1 to 3 of Directive 2000/35/EC of the European Parliament and of the Council of 29 June 2000 on combating late payment in commercial transactions (OJ 2000 L 200, p. 35). The reference has been made in proceedings between Amia SpA, in liquidation ('Amia'), and the Provincia Regionale di Palermo (regional	In circumstances such as those in the main proceedings: <ul style="list-style-type: none">It is for the referring court, first, before disapplying the relevant provisions of Law No 549 of 28 December 1995 on measures to rationalise public finances, to establish whether, taking into consideration the whole body of domestic law, both substantive and procedural, there is no possibility of reaching an interpretation of its national law with which to resolve the case in the main proceedings in a manner consistent with the wording and purpose of Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste, as amended by Regulation (EC) No 1882/2003 of the European Parliament and

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			province of Palermo) concerning a demand for payment of a special levy on the disposal of solid waste in landfill.	<p>of the Council of 29 September 2003, and Directive 2000/35/EC of the European Parliament and of the Council of 29 June 2000 on combating late payment in commercial transactions;</p> <ul style="list-style-type: none"> • If such an interpretation is not possible, it is for the referring court to disapply, in the main proceedings, any national provision contrary to Article 10 of Directive 1999/31 as amended by Regulation No 1882/2003 and Articles 1 to 3 of Directive 2000/35.
NATURE PROTECTION				
<p><i>Directive 92/43/EEC</i></p> <p>Habitats</p>	<p>Case C-258/11</p> <p>Judgment of the Court (Third Chamber) of 11 April 2013</p> <p>Reference for a preliminary ruling: Supreme Court – Ireland</p> <p>ECLI:EU:C:2013:220</p>	<p>Peter Sweetman and Others v An Bord Pleanála.</p>	<p>This request for a preliminary ruling concerns the interpretation of Article 6 of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ 1992 L 206, p. 7; ‘the Habitats Directive’).</p> <p>The request has been made in proceedings between (i) Mr Sweetman, Ireland, the Attorney General and the Minister for the Environment, Heritage and Local Government and (ii) An Bord Pleanála (the Irish Planning Board), supported by Galway County Council and Galway City Council, concerning An Bord Pleanála’s decision to grant development consent for the N6 Galway City Outer Bypass road scheme.</p>	<p>Article 6(3) of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora must be interpreted as meaning that a plan or project not directly connected with or necessary to the management of a site will adversely affect the integrity of that site if it is liable to prevent the lasting preservation of the constitutive characteristics of the site that are connected to the presence of a priority natural habitat whose conservation was the objective justifying the designation of the site in the list of sites of Community importance, in accordance with the directive. The precautionary principle should be applied for the purposes of that appraisal.</p>

Legislation affected	Case no.	Parties	Conclusion	Summary
<p><i>Directive 92/43/EEC</i></p> <p>Habitats</p>	<p>Case C-301/12</p> <p>Judgment of the Court (Second Chamber) of 3 April 2014</p> <p>Reference for a preliminary ruling: Consiglio di Stato – Italy</p> <p>ECLI:EU:C:2014:214</p>	<p>Cascina Tre Pini Ss v Ministero dell’Ambiente e della Tutela del Territorio e del Mare and Others</p>	<p>This request for a preliminary ruling concerns the interpretation of Articles 9 and 11 of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ 1992 L 206, p. 7), as amended by the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (OJ 2003 L 236, p. 33; ‘the Habitats Directive’).</p> <p>The request has been made in proceedings between Cascina Tre Pini Ss (‘Cascina’), a company incorporated under Italian law, and the Ministero dell’Ambiente e della Tutela del Territorio e del Mare (Ministry of the Environment and the Protection of the Land and the Sea; ‘the Ministero’), the Regione Lombardia (Region of Lombardy), the Presidenza del Consiglio dei Ministri (Office of the Prime Minister), the Consorzio Parco Lombardo della Valle del Ticino (Lombardy Association of the Ticino Valley Park) and the Comune di Somma Lombardo (municipality of Somma Lombardo) concerning the procedure for review of the status of site of Community importance (‘SCI’)</p>	<p>1. Articles 4(1), 9 and 11 of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, as amended by the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded, must be interpreted as meaning that the competent authorities of the Member States are required to propose to the European Commission the declassification of a site on the list of sites of Community importance, where those authorities have received a request from the owner of land included in that site, alleging an environmental degradation of the site, provided that that request is based on the fact that, despite compliance with the provisions of Article 6(2) to (4) of that directive, that site can definitively no longer contribute to the conservation of natural habitats and of the wild fauna and flora or the setting up of the Natura 2000 network.</p> <p>2. Articles 4(1), 9 and 11 of Directive 92/43, as amended by the Act concerning the conditions of</p>

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
			of a site including a plot of land of which Cascina is the owner.	accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded, must be interpreted as not precluding national legislation under which a power is conferred on the regional and local authorities alone to propose the adaptation of the list of the sites of Community importance, but not on the State, even to act in lieu of the regional or local authorities in the event that they fail to act, provided that that allocation of power does not prevent the proper application of the provisions of that directive.
<i>Directive 92/43/EEC</i> <i>Habitats</i>	Case C-521/12 Judgment of the Court (Second Chamber) of 15 May 2014 Reference for a preliminary ruling: Raad van State – Netherlands ECLI:EU:C:2014:330	T. C. Briels and Others v Minister van Infrastructuur en Milieu	This request for a preliminary ruling concerns the interpretation of Article 6(3) and (4) of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ 1992 L 206, p. 7) ('the Habitats Directive'). The request has been made in proceedings between T.C. Briels and Others and the Minister van Infrastructuur en Milieu (Minister for Infrastructure and the Environment, 'the Minister') concerning the project for widening the A2 's-Hertogenbosch-Eindhoven motorway (together, 'the A2 motorway project').	Article 6(3) of Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora must be interpreted as meaning that a plan or project not directly connected with or necessary to the management of a site of Community importance, which has negative implications for a type of natural habitat present thereon and which provides for the creation of an area of equal or greater size of the same natural habitat type within the same site, has an effect on the integrity of that site. Such measures can be categorised as

<i>Legislation affected</i>	<i>Case no.</i>	<i>Parties</i>	<i>Conclusion</i>	<i>Summary</i>
				'compensatory measures' within the meaning of Article 6(4) only if the conditions laid down therein are satisfied.
<i>Regulation (EC) No 338/97</i> CITES	Case C-532/13 Judgment of the Court (Second Chamber) of 4 September 2014 Reference for a preliminary ruling: Fővárosi Közigazgatási és munkaügyi bíróság - Hungary	Sofia Zoo v Országos Környezetvédelmi, Természetvédelmi és Vízügyi Főfelügyelőség	This request for a preliminary ruling concerns the interpretation of Article 11(2)(a) and (b) of Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (OJ 1997 L 61, p. 1). The request has been made in proceedings between Sofia Zoo (Bulgaria) and the Országos Környezetvédelmi, Természetvédelmi és Vízügyi Főfelügyelőség (Inspectorate General of the State for the conservation of the environment and nature and for the administration of water) (Hungary) ('the Inspectorate General'), concerning the latter's decision to order the confiscation of 17 specimens of wild animals originating from Tanzania.	Article 11(2)(a) and (b) of Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein must be interpreted as meaning that an import permit which does not comply with the conditions laid down in that regulation must be considered void only in respect of the specimens actually affected by the ground of invalidity of that import permit, those specimens then being the only ones which may be seized and possibly confiscated by the competent authority of the Member State where they are situated.

