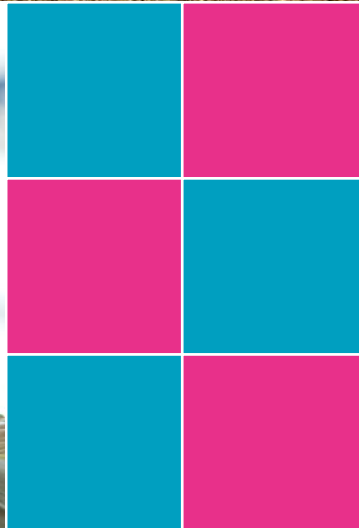
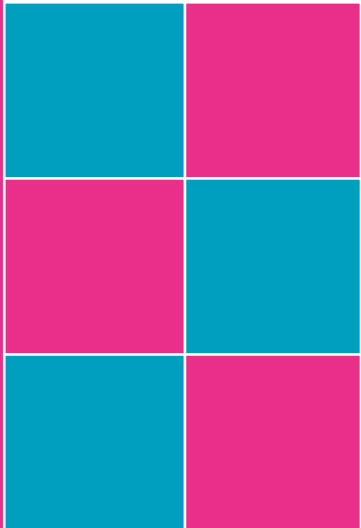
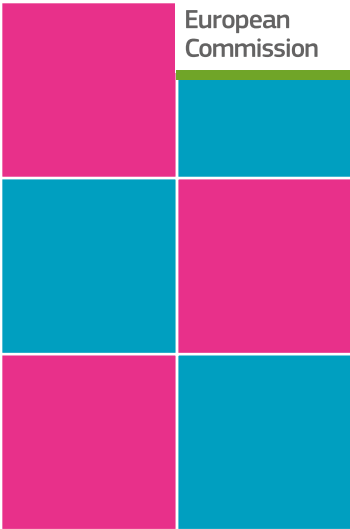




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DG Health and
Food Safety

INTERIM OVERVIEW REPORT

Antimicrobial Resistance Monitoring in Zoonotic and Commensal Bacteria

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2016-6239 - OR

INTERIM OVERVIEW REPORT
ON A SERIES OF AUDITS CARRIED OUT IN MEMBER STATES
IN 2015 AND 2016 IN ORDER TO
EVALUATE THE MONITORING AND REPORTING OF ANTIMICROBIAL
RESISTANCE IN ZONOTIC AND COMMENSAL BACTERIA IN CERTAIN FOOD-
PRODUCING ANIMAL POPULATIONS AND FOOD

Executive Summary

This interim report compiles the main findings and conclusions of the audits carried out in 8 Member States, as part of a wider DG Health and Food Safety on-going project, regarding the implementation of Decision 2013/652/EU on the monitoring and reporting of antimicrobial resistance (AMR) in zoonotic and commensal bacteria.

Overall, the report highlights that the active commitment of Member States has resulted in significant improvements in the design and implementation of most of the sampling and testing requirements. Whilst the present situation ensures that sample design largely follows the applicable requirements and can therefore provide comparable data within the European Union, some areas for improvement were noted. These refer notably to i) the gathering and testing of Salmonella isolates obtained by food business operators in the context of controls on hygiene slaughter, and ii) the even distribution of caecal sampling at slaughterhouses throughout the year.

The national laboratory networks performed mostly in a satisfactory manner. Some areas where improvements were still required concern i) the coordination role of the National Reference Laboratories, and ii) the appropriate use of the reference strains for the performance of the dilution method for antimicrobial susceptibility testing. The reporting of AMR data to the European Food Safety Authority (EFSA), although mainly in line with the applicable requirements, showed common weaknesses in the overall description of the implementation of the monitoring, which is important to ensure that the results are interpreted correctly.

In addition to noting the challenges faced by Member States, the report also highlights some of the many examples of good practice and working practices that go beyond what is required by the legislation.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AMR	Antimicrobial resistance
AST	Antimicrobial susceptibility testing
CLSI	Clinical and Laboratory Standards Institute
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ESBL	Extended-spectrum β -lactamases
EU	European Union
EURL	European Union Reference Laboratory
ISO	International Organization for Standardization
JACRA	Joint Interagency Antimicrobial Consumption and Resistance Analysis.
NRL	National Reference Laboratory
SNCP	<i>Salmonella</i> National Control Programme

1 Introduction and background

The problem: antimicrobial resistance (AMR)

Each year, drug resistant infections result in significant estimated patient deaths and cause substantial healthcare and productivity losses in the European Union (EU). The problem of AMR is increasing worldwide with an estimated 700 000 deaths per year globally. According to recent reports, if the current AMR situation is left unchecked, AMR deaths will overtake those from cancer by 2050 and the associated costs for the world economy would be 2-3% of gross domestic product per year ¹.

Quantifying the problem: AMR monitoring harmonisation

Reliable and comparable data are crucial to understand current and future AMR trends and to develop and evaluate strategies to fight AMR. Therefore, there is a general consensus among international organisations such as the World Health Organization (WHO), *Codex Alimentarius* and the World Organisation for Animal Health (OIE), that the methodology for AMR surveillance, including antimicrobial susceptibility testing (AST) methods and interpretative criteria, should be internationally harmonised as far as possible to facilitate comparability.

AMR monitoring in food producing animals and food in the EU

Directive 2003/99/EC of the European Parliament and of the Council on the monitoring of zoonoses and zoonotic agents ² requires Member States to ensure that monitoring provides comparable data on the occurrence of AMR.

Commission Implementing Decision 2013/652/EU, was enacted within the 2011-2016 Commission action plan against the rising threats of AMR. This Decision lays down detailed rules for the harmonised monitoring of the most relevant, from a public health perspective, combinations of bacterial species and food-producing animal populations/food. This harmonisation provides valuable comparable data that are compiled and trended by the European Food Safety Authority (EFSA) ³. The resulting information is used to perform wider analyses, such as the joint report on consumption of antimicrobials and AMR in animals, food and humans (JIACRA) ⁴, produced by the European Centre for Disease Prevention and Control (ECDC), EFSA and the European Medicines Agency (EMA), under a **One Health** approach.

Support available to Member States for the implementation of AMR monitoring

The European Commission supports Member States issuing yearly grant decisions for the coordinated control plan for AMR monitoring. The grants provide reimbursement of up to 50 % of the costs incurred by Member States in the performance of the tests within given limits. In addition, in order to facilitate harmonisation of the AMR monitoring, the EU Reference Laboratory (EURL) for AMR provides support for laboratory testing, and EFSA provides

¹ The Review on Antimicrobial Resistance: Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations [Last accessed April, 2017] https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

² References to all EU legal texts cited in this report are provided in Annex 1 and they refer, where applicable, to the last amended version.

³ The European Union summary report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food in 2014. EFSA Journal 2016;14(2):4380 [207 pp.]. Available online: www.efsa.europa.eu/efsajournal

⁴ ECDC/EFSA/EMA first joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals [Last accessed April 2017] - <http://ecdc.europa.eu/en/publications/publications/antimicrobial-resistance-jiacra-report.pdf>

technical support regarding sampling and reporting. Annex 2 lists the relevant EFSA guidance documents.

Commission oversight of the implementation of Decision 2013/652/EU

One of the measures supporting the 2011-2016 Commission action plan against the rising threats of AMR concerned the on-the-spot verification of the implementation of Decision 2013/652/EU. Within this framework, DG Health and Food Safety is carrying out a series of audits with the objectives of i) evaluating the implementation of these harmonised monitoring and reporting rules, and ii) gathering information on good practices and on the implementation of voluntary monitoring systems, including the identification of new initiatives to improve awareness and understanding of AMR. Eight such audits to different Member States were carried out during 2015 and 2016, with the series continuing in the coming years. These audits concentrated primarily on the evaluation of the AMR monitoring performed during 2014 and 2015. The 2016 monitoring data are due to be reported to EFSA by 31 May 2017. The eight audits are listed at Annex 4.

This interim report summarises the main findings and conclusions which have emerged from the audits, including challenges encountered by Member States. The report also provides examples of good practices that have helped Member States to achieve compliance with certain requirements which proved particularly challenging, and examples of national practices that go beyond what is required by the legislation and that are of added value in the context of AMR monitoring. It must be emphasised that these examples do not constitute an exhaustive account of the situations encountered during the audits. Further information can be found in the above-mentioned individual audit reports.

In addition to these audits, another measure supporting the 2011-2016 Commission action plan against the rising threats of AMR concerned the support to Member States in the implementation of the Commission guidelines on the prudent use of antimicrobials. This activity will be covered in another interim report (ref. DG(SANTE) 2016-6238) to be published during 2017.

Value of the results obtained: usage of the AMR data

AMR monitoring data are essential to develop and evaluate wider policies on the use of antimicrobials. Some competent authorities in the Member States visited, notably those in the Netherlands, Denmark and Germany, have developed AMR monitoring plans that can be taken as a good illustration of how to develop wider One Health AMR action plans, in which the monitoring data are trended, analysed and used to develop and evaluate specific policies to tackle AMR. As an example, the MARAN⁵ report from the Netherlands (monitoring of antimicrobial resistance and antibiotic usage in animals in the Netherlands) illustrates how AMR decreasing trends can be linked to antimicrobial reduction usage in certain animal populations.

⁵ Monitoring of antimicrobial resistance and antibiotic usage in animals in the Netherlands [Last accessed April, 2017]. [http://www.swab.nl/swab/cms3.nsf/uploads/4F5A0D8E6F0DD139C1257E6E0051833A/\\$FILE/NethmapMaran2015%20_webversie.pdf](http://www.swab.nl/swab/cms3.nsf/uploads/4F5A0D8E6F0DD139C1257E6E0051833A/$FILE/NethmapMaran2015%20_webversie.pdf)

2 Overview of main findings and conclusions

2.1 Sampling design and implementation

2.1.1 General requirements of Decision 2013/652/EU

What bacterial species must be monitored?

Salmonella spp. and *Campylobacter jejuni*, as they are important zoonotic agents.

Escherichia coli, an indicator commensal bacteria commonly isolated from animal intestinal content that can contaminate food and can transfer resistance genes to other bacteria⁶. The inclusion of this bacterium in the monitoring is due to the fact that *Salmonella* prevalence in Member States is decreasing, notably in poultry populations, and the number of available isolates has reduced significantly.

In addition, the monitoring includes *Salmonella* spp. and *E. coli*, from animal populations and meat sourced at retail, producing certain enzymes.

What are these enzymes and why are they important?

These enzymes are the following β -lactamases: extended-spectrum β -lactamases (ESBL), Amp C β -lactamases (AmpC) and carbapenemases. β -lactamases confer resistance to a variety of β -lactam antibiotics, including penicillin derivatives (penams), cephalosporins (cephems), monobactams, and carbapenems. Because of the clinical importance of these antibiotics, ESBL-, AmpC- and carbapenemases-producing bacteria pose substantial challenges to human health. For instance, many carbapenemases are able to break down almost all β -lactams, rendering bacteria extremely drug resistant⁷, which is a great concern as they could result in multidrug resistant infections in humans. In addition, the resistance genes are often located in mobile elements such as plasmids which are easily transferred between bacteria, and most of these bacteria strains also carry resistances to other drugs. Therefore, monitoring the occurrence of these β -lactamases-producing bacteria is fundamental for designing appropriate control measures.

When must Member States test isolates from different species and food?

Decision 2013/652/EU applied as of 1 January 2014, and required monitoring for poultry populations (laying hens, broilers and turkeys) and broiler meat in even years, and monitoring for fattening pigs, calves, and meat thereof in uneven years until 2020.

How many isolates have to be tested annually?

To ensure representativeness, there is a minimum number of isolates (170) to be tested for AMR for each combination of bacterial species and animal population. This minimum number can be halved (or even further reduced in specific cases), or the animal population may be excluded from testing, if the production volumes for a particular animal population fall below certain thresholds.

⁶ Technical specifications on the harmonised monitoring and reporting of antimicrobial resistance in *Salmonella*, *Campylobacter* and indicator *Escherichia coli* and *Enterococcus* spp. bacteria transmitted through food. EFSA Journal 2012;10(6):2742 [64 pp.]. Available online: www.efsa.europa.eu/efsajournal.

⁷ Scientific Opinion on the public health risks of bacterial strains producing extended-spectrum β -lactamases and/or AmpC β -lactamases in food and food-producing animals. EFSA Journal 2011;9(8):2322. [95 pp.]. Available online: www.efsa.europa.eu/efsajournal.

In addition, regarding ESBL-, AmpC- or carbapenemase-producing *E. coli*, and in order to gather prevalence data, there is a minimum number of 300 samples to be tested using selective media for each animal population and food category. Likewise, this minimum number can be halved or further reduced for production volumes below a certain threshold.

For ease of reference, Annex 3 summarises the requirements in table form.

2.1.2 Which *Salmonella* isolates have to be tested?

Salmonella isolates obtained from samples taken in mandatory schemes already in place before the introduction of Decision 2013/652/EU. Therefore, these samples are taken from:

- i. laying hens, broilers and turkeys at farm level in the framework of *Salmonella* National Control Programmes (SNCP) ⁸; and
- ii. samples from broiler, fattening turkey, pigs and bovine under 1 year of age carcasses taken at slaughterhouses for testing and verification of compliance of hygiene ⁹.

These isolates are meant to be obtained from the isolate collections already available. When a number of isolates higher than the minimum number is available, a selection has to be performed according to sampling dates and geographical origin.

2.1.2.1 Isolates obtained in the context of the SNCP

Most Member States had, to various degrees, adequate systems in place to gather isolates for AST testing from official and operator sampling.

One weakness frequently observed concerned the limited access to relevant information such as the details of the sampled flock sampled for the selection of the *Salmonella* isolates which would avoid the notification of isolates from repeated epidemiological units. Access to such information is important since isolates reported have to be obtained from different flocks, unless they belong to different serovars, in order to avoid duplications.

Good practice

- In Spain, the National Reference Laboratory (NRL) performing AST had access to the database where all isolates, obtained by official laboratories and private laboratories working for the operators, were systematically and timely recorded. This allowed the laboratory to perform an adequate selection and review periodically the number of available isolates.

2.1.2.2 Carcass isolates

One of the objectives of Regulation (EC) No 2073/2005 is to assess the hygiene of the slaughtering operations. To this effect, it requires that the operators take certain samples. Although official sampling in the context of this Regulation is not compulsory to verify

⁸ In accordance with Article 5 of Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of *Salmonella* and other specified food-borne zoonotic agents.

⁹ In accordance with Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.

hygiene at slaughter, most of the Member States audited performed it to different extents. Due to the relatively low prevalence of *Salmonella* in the EU, the isolates available from these official samples were generally not sufficient to achieve the minimum number required.

Article 6 of Directive 2003/99/EC empowers the competent authorities to gather isolates obtained from food business operators' samples for subsequent AST. Despite the fact that this Directive was transposed in all Member States visited, only two of them used this provision.

Obtaining these food business operator isolates has proven to be a challenge for the majority of Member States due to the following factors:

- The involvement of private laboratories that use (as allowed by Regulation (EC) No 2073/2005) rapid tests in many cases, which do not render an isolate. In addition, the laboratories are often located in a jurisdiction out of reach for the competent authority concerned.
- The absence of an overview detailing information on isolates obtained by food business operators and the origin of these isolates.
- The costs for the storage and transport of isolates (in order to submit them for AST) are often an issue for the food business operators and/or private laboratories working for them.

Good practice

- The competent authorities of Austria and Denmark were using national legislation to gather food business operators' *Salmonella* isolates obtained by private laboratories in the context of Regulation (EC) No 2073/2005, therefore enabling them to achieve the objectives of the AMR monitoring.

2.1.3 Besides Salmonella, what else do Member States have to test?

The sampling plan also has to encompass the following elements:

- Caecal content from broilers and fattening turkeys obtained at slaughter for the isolation of *C. jejuni*, indicator commensal *E. coli*, and ESBL-, AmpC- or carbapenemases-producing *E. coli*. Caecal content from pigs and fattening bovines under 1 year of age obtained at slaughter for isolation of indicator commensal *E. coli* and ESBL-, AmpC- or carbapenemases-producing *E. coli*. The collection of samples has to take place at slaughterhouses, which is the most cost effective approach ¹⁰.
- Poultry, pig and bovine fresh meat sampled at retail for isolation of ESBL-, AmpC- or carbapenemases-producing *E. coli*.

Sampling has to be performed in healthy animals, with sampled diseased animals reported separately.

¹⁰ Technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria. EFSA Journal 2014;12(5):3686 [33 pp.]. Available online: www.efsa.europa.eu/efsajournal.

2.1.3.1 Caecal samples

Achieving the minimum required number of isolates/samples

Achieving the minimum required number of samples/isolates is paramount to ensure data representativeness and allows comparability between Member States, and detects changes in AMR trends over time.

In the Member States visited, the sampling design covered the required number of samples to achieve the AMR monitoring objectives, with few exceptions. Some Member States established sampling targets beyond the requirements.

Inadequate supervision was the most important cause that contributed to a weak implementation of the sampling plans. This was mainly noted in the 2014 monitoring plans, since the competent authorities subsequently made several improvements in this respect, albeit to different extents. Supervision was weakened mainly by an inadequate exchange of information, during the sampling period, between different levels of the competent authority including laboratories, in order to react in a timely manner to situations that may hamper the achievement of sampling targets. To achieve the targets set by Decision 2013/652/EU, it is important that an overview of the samples taken, including the samples rejected by the laboratory and the isolates obtained is available to the responsible competent authority in order to increase sampling, if necessary.

Due to the low prevalence of *C. jejuni*, achieving the minimum required number of isolates proved to be a challenge, in particular in the turkey population, where only Germany gathered sufficient isolates in 2014. In two Member States, the prevalence of *C. coli* was higher than *C. jejuni* (which was as low as 7% in turkeys). In addition, a limited number of epidemiological units were generally available for this animal population. In broilers, the situation was different with 6 Member States out of 10 achieving the targets.

Good practices

- In Slovakia, the sampling officers recorded the samples taken on a web-based platform. In Romania monthly reporting from the regions to the central level took place. These procedures allowed the competent authorities to keep track, in a timely manner, of the level of implementation and to introduce corrective measures, if necessary, to achieve the set targets.
- In Austria, the competent authority established a colour code system to evaluate compliance with the sampling targets by the different sampling units. This, together with timely feedback, ensured completion of the sampling targets.

Even distribution of sampling throughout the year

An even distribution of samples over each month of the year ensures an adequate coverage of all the seasons, catering for the possibility of different antimicrobial treatments having been administered to the animals sampled.

One issue identified in most Member States visited was that the monitoring plan was not issued in time for it to be implemented throughout the entire year, resulting in coverage of only 5 months in the worst cases. The main reason related to administrative delays, often due to budget approvals.

In several Member States the sampling plan was not approved until the annual Commission Grant Decision was sent. The Grant Decision is sent to the Member States on an annual basis and establishes the maximum amount of samples and tests subject to financial assistance, as well as the monetary threshold.

Good practices

- In Hungary, the sampling plan covered the period until the next plan was issued in order to avoid the impact of administrative delays.
- In Germany, an early planning allowed all months of the year to be covered.

Selection of slaughterhouses

The slaughterhouses selected for sampling have to cover at least 60% of the domestic animal population targeted and, to ensure data representativeness, the sample allocation to each slaughterhouse has to be proportional to the volumes slaughtered. For this purpose, domestic population refers to those animals raised in the Member State concerned. The reason to target the sampling towards these animals, and exclude those dispatched from other Member States for direct slaughter, is to ensure that the data obtained relate only to the Member State concerned, therefore allowing full comparability with the data obtained in other Member States.

A key element for the correct design of the monitoring plan is that the competent authority avails of accurate data per slaughterhouse in a timely manner. Several Member States presented weaknesses in this area concerning issues such as data availability on bovines slaughtered under 1 year of age and animals imported for direct slaughter (which in some cases amounted to a significant number). These issues, together with an inadequate coordination where the plan was cascaded from central level to lower levels, jeopardised covering the minimum 60% of the targeted population and the proportional sampling allocation.

National practice going beyond the requirements

- In the Netherlands, the sample allocation to slaughterhouses processing bovines under 1 year of age took into consideration different production types such as white and rose veal, allowing the competent authority to have specific AMR data linked to these different production types.

Random sampling

Sampling days and sampling batches/carcasses must be selected randomly and only one sample per epidemiological unit per year can be taken. Random sampling is important to ensure data representativeness, allowing all epidemiological units the same chance of being sampled. The epidemiological unit for pigs and bovines under 1 year of age is the holding, whereas for poultry it is the flock.

Randomisation, in particular regarding the selection of sampling days, was a challenge for most Member States. Limitations in the availability of the sample delivery service significantly constrained the sampling dates. It is unusual for laboratories to work during week-ends, and therefore they do not accept samples on Fridays (and, in some cases, not even on Thursdays – see sampling delivery to laboratory section below). This limitation biased the monitoring not only in terms of sampling days, but also because many slaughterhouses process problematic animals at the end of the week's production on Fridays, meaning that these animals (which may be more likely to have been subjected to antimicrobial treatments) are excluded from sampling.

A challenge arising from the production structure in some Member States was the low amount of epidemiological units available for sampling for some populations such as turkeys and from some particular slaughterhouses. As a consequence, in some Member States the competent authorities had to cover over 60% of the targeted domestic population to avail of a sufficient number of samples and achieve the required number of isolates. This issue also had an effect in the sampling organisation, as a greater effort had to be made to cover more slaughterhouses and slaughter days.

Isolates that can be tested voluntarily

Member States may also voluntarily perform AST and report the results to EFSA for *C. coli* and *Enterococcus* (see Annex 3).

Enterococcus was tested and reported in one Member State, and *C. coli* in four Member States, to different extents. It has to be highlighted that the two Member States that reported a low prevalence of *C. jejuni* in poultry reported voluntarily *C. coli* isolates for the relevant animal populations.

National practices going beyond the requirements

The reporting system handled by EFSA also allows reporting AST from isolates from other bacteria/animal/food combination not covered by Decision 2013/652/EU, if gathered under the same conditions. All Member States reported AST information isolates belonging to this category (including *Salmonella*), ranging from few to several thousand isolates. This increased reporting, which is useful for informing the development and evaluation of national policies to fight AMR, was due to different reasons:

- an increased sampling frequency (yearly instead of every two years of the compulsory populations),
- the inclusion of additional populations such as dairy cows and ducks in the sampling plan,
- a higher number of isolates targeted (up to 300 in some cases) and,
- the use of molecular techniques in a large number of samples.

Sample delivery to the laboratory

One major challenge faced by Member States was to establish a reliable system to deliver samples to the laboratory. The EURL protocol that harmonises the isolation of ESBL- or Amp C-producing *E. coli* from caecal samples establishes that samples have to be tested within 48 hours of collection.

Important efforts were noted in this area, with Member States committing significant resources to ensure a timely delivery of samples. Most Member States were implementing the above specifications and, consequently, not testing samples outside of this 48-hour window. Two Member States aimed at being within the specifications, but they had a more flexible approach towards this issue and tested samples arriving at laboratories beyond 48 hours of collection. To ensure that samples were processed within the timeframe many laboratories did not accept samples on Fridays and not even on Thursdays (see random sampling section above).

Good practices

- Spain, Italy and Hungary used couriers and specifically assigned teams with their own transport, in order to ensure that samples were processed by the laboratory within 48 hours of collection.

2.1.3.2 Retail samples

Samples taken at retail also have to be representative, and should therefore be obtained using a randomised sampling approach. Representativeness can be achieved following EFSA 2014

Technical Specifications¹⁰ and sampling in geographical areas covering 80% of the national population. In addition, if 80% or more of the meat is supplied by supermarkets the competent authority can only take samples from these outlets. Other strategies that ensure representativeness could also be used; nevertheless, in order to get an unbiased picture of the consumer exposure, batches should never be preselected according to the origin of the meat.

The main sampling strategy followed by the Member States covered 80% of the national population and was concentrated in retail shops that supplied the majority of the meat to final consumers. The number of samples to be taken was largely achieved in all Member States, but a common weakness identified by the audits was that information regarding the lot (which is the epidemiological unit according to the EFSA 2014 Technical Specifications) was not recorded and/or cross checked to avoid testing samples from the same epidemiological units. The above-mentioned challenge of processing samples at the laboratory within 48 hours of collection also applied to retail samples.

2.2 Laboratories

The NRLs for AMR are required to perform the corresponding analyses, although the competent authority may decide to designate other laboratories for the performance of AST. These other laboratories have to be involved in a quality assurance system including proficiency testing (AST is not required to be covered by the scope of accreditation).

One of the key achievements of Decision 2013/652/EU has been the harmonisation of the laboratory testing methods used in order to ensure comparability of the AMR monitoring data. Member States must perform AST using the dilution methods described by the European Committee on AST and the Clinical and Laboratory Standards Institute (CLSI), accepted as ISO standard 20776-1:2006. The Decision also standardises both the epidemiological cut-off values (which are used to establish whether the isolate is resistant or not to a particular antimicrobial), and antimicrobial concentrations to be used for AST.

There are reference bacterial strains known to yield a given result (within a range) when tested for their susceptibility to different antimicrobials. The use of these reference strains is essential to ensure that the results obtained are reliable and therefore comparable. For this reason, the above-mentioned international standards require that reference strains are tested every day that the AST is performed or allow a less frequent use only when stringent conditions are met.

In order to establish and compare the proportion of samples containing ESBL-, or Amp C-, producing *E. coli* in different Member States the selective isolation of these bacteria from caecal and retail samples must be performed according to the corresponding EURL protocol. Member States may also perform the selective isolation of carbapenemases-producing *E. coli* using this protocol.

2.2.1 Laboratory organisation

In most Member States visited the testing was performed by a laboratory network comprising several laboratories, although in two Member States a single NRL was the sole laboratory performing this task.

In three Member States, the audits detected issues in the performance of the role of the NRLs, notably regarding the dissemination of information and their coordination obligations.

2.2.2 *Methods used, accreditation and comparability testing*

The audits found that the laboratories performing AST systematically used the prescribed dilution method with all the listed antimicrobials and interpreted the results using the epidemiological cut-off values and the concentration ranges set out by Decision 2013/652/EU.

All laboratories were ISO 17025 accredited by their national accreditation bodies. Whilst the relevant methods were not always under the scope of accreditation, they were under the quality system. Most of the laboratories operated with satisfactory quality control systems underpinning their performance, although in one Member State there were serious issues concerning compliance with ISO 17025 standards.

In addition, the difference encountered in performance correlated with the fact that the less performing laboratory networks started implementing the harmonised AST just after the introduction of Decision 2013/652/EU, whereas other networks had been performing these methods well before 2014. The situation has generally improved since 2014, as demonstrated by the comparative tests results organised by the EURL, with the majority of laboratories performing satisfactorily in these tests. In this regard, the EURL has played an important role providing support and expert advice in order to enhance AST harmonisation.

National practice going beyond the requirements

- Laboratories in the Netherlands and in Denmark extensively used molecular methods for the identification of particular resistance genes, which provided additional valuable information and served as a verification step of the phenotypical results rendered by the AST.

2.2.3 *Ensuring quality of AST*

The most significant issue identified during the audits, in terms of impact on the reliability of the results obtained, was the use of the reference strains according to the standards. In two Member States the reference strains were not used as required, for instance they were only used when performing proficiency tests. This reduced use of the reference strain was mainly linked to budget limitations.

A common issue identified in most Member States concerned the need to strengthen the procedures in place regarding the identification and actions to be taken in the context of out-of-range or implausible AST values. Furthermore, due to budget restrictions, in several Member States, these tests were not repeated or seldom repeated, if necessary, in order to verify the validity of some of these implausible results that were reported to EFSA.

Good practice

- In the Netherlands, two reference strains were tested in order to re-inforce the quality control of the AST.

2.2.4 ESBL-, AmpC- and carbapenemases-producing *E. coli* testing

Regarding testing for ESBL-, AmpC- or carbapenemases-producing *E. coli*, the Member States audited generally followed the EURL protocol, and the main issues identified concerned the insufficient validation of the selective media.

2.3 Assessment and reporting of AMR data

There are a number of requirements for the submission of AMR monitoring data to EFSA, which provides support to Member States for the harmonised reporting by means of organising regular meetings, and providing training, reporting manuals and data dictionaries. These requirements concern reporting through the EFSA data collection framework the results of the harmonised AMR monitoring in the form of raw isolate-based data. These data contain details on the sampling context and the results of the minimum inhibitory concentrations obtained for each combination of bacteria and antimicrobial. In addition, there is an obligation to submit a narrative with the overall description of the AMR plan, including the sampling strategy, laboratory methodology, control programmes and investigation of the results. This narrative is meant to allow an understanding of whether the strategies implemented support the comparability of the results obtained, and if they can identify implementation constraints, such as the existence of limited epidemiological units.

Thanks to the collaboration and support from EFSA, the quality of reporting of the 2015 data improved considerably in the Member States visited, in comparison with the first reporting year.

That said, a common issue identified in most of the Member States audited was the lack (or quite imprecise) reporting of the overall description of the implementation of the AMR monitoring plan. In some cases the underlying cause was a deficient communication between the officials in charge of the sampling design and implementation and the officials submitting the data to EFSA, which did not ensure that the information was available to the latter or that an adequate description was drafted.

Good practice

- Austria reported to a high standard the overall description of the implementation of the AMR monitoring plan.

National practices going beyond the requirements

- It was common for Member States to report AST data regarding non-mandatory isolates. In the cases of Denmark, Germany, the Netherlands and Spain the reported number amounted to a significant amount. This additional information is valuable to understand resistance patterns.

3 Overall conclusion

The report highlights that the active commitment of Member States has resulted in significant improvements in the design and implementation of most of the sampling and testing requirements. Whilst the present situation ensures that sample design largely follows the applicable requirements and can therefore provide comparable data within the EU, some areas for improvement were noted. These refer notably to i) the gathering and testing of *Salmonella* isolates obtained by food business operators in the context of controls on hygiene slaughter, and ii) the even coverage of caecal sampling at slaughterhouses throughout the year.

The national laboratory networks performed mostly in a satisfactory manner. Some areas where improvements were still required concern i) the coordination role of the NRLs, and ii) the appropriate use of the reference strains for the performance of the dilution method for antimicrobial susceptibility testing. The reporting of AMR data to EFSA, although mainly in line with the applicable requirements, showed common weaknesses in the overall description of the implementation of the monitoring, which is important to ensure that the results are interpreted correctly.

4 Matters for consideration by Member States

The individual audit reports (see Annex 4) have made targeted recommendations to the relevant competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place. Nevertheless, in light of the analyses of the information gathered so far, the points listed below may be considered by all the Member States for the design and implementation of their AMR monitoring plans, with a view of strengthening the reliability of the harmonised data submitted to EFSA.

1. Ensuring the timely availability of the necessary information such as slaughter volumes and the origin of isolates in order to support the planning of sampling and isolate selection. If applicable, timely information sharing with the local level is also important.
2. Ensuring an adequate coordination and information exchange within and between the competent authorities in charge of planning and sampling, as well as with the laboratories. The information exchange should include timely updates on the accomplishment of the sampling plan, in order to allow an adequate supervision and the subsequent necessary adjustments for achieving the set targets.
3. Developing clear and detailed procedures for sampling, covering areas such as sampling days and carcass/batch randomisation, transport and sample minimum requirements (e.g. packaging and delivery times to the laboratory). The procedures should address the

specific information to be included in the sampling form, which must always include the epidemiological unit.

4. Involving the laboratories in the design of the sampling plan, in order to factor in laboratory availability, so that it does not affect negatively the implementation of the sampling plan.
5. Ensuring that the reference strains are used in accordance with the relevant standards when performing the AST.
6. Verifying the completeness and plausibility of the data to be reported to EFSA and ensure that information to be included in the overall description of the implementation of the AMR monitoring is complete and available to the reporting officer in advance of the notification deadline.

5 Actions planned by the Commission services

The Commission services have already evaluated the preliminary results presented in this report and have initiated the following actions, which are aimed at assisting Member States in the implementation of the AMR monitoring and reporting in this area:

1. The European Commission has launched a European One Health action plan against AMR in which actions are planned to strengthen One Health surveillance and reporting of AMR and antimicrobial use and to benefit from the best evidence-based analysis and data. The action plan is available at the following link:
https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf
2. The preparatory work for a request for a Scientific Opinion to EFSA has already started. The Scientific Opinion will provide solid scientific advice to support amendments in Decision 2013/652/EU and, at the same time, it will help overcome key implementation barriers highlighted by this report.
3. The EURL has been requested to review the corresponding protocols, notably regarding a more flexible approach towards the 48-hour window between collection and testing of samples, without compromising the validity and comparability of the laboratory results.
4. The possibility to introduce changes in the financial support available to Member States is being evaluated. In this regard, the Commission is evaluating whether co-financing could be extended to areas such as the use of reference strains and the repetition of a certain number of tests when unusual or implausible results are obtained.

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Reg. 2160/2003	OJ L 325, 12.12.2003, p. 1-15	Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents
Dir. 2003/99/EC	OJ L 325, 12.12.2003, p. 31-40	Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC
Dec. 2013/652/EU	OJ L 303, 14.11.2013, p. 26-39	2013/652/EU: Commission Implementing Decision of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria
Dec. 2013/653/EU	OJ L 303, 14.11.2013, p. 40-47	2013/653/EU: Commission Implementing Decision of 12 November 2013 as regards a Union financial aid towards a coordinated control plan for antimicrobial resistance monitoring in zoonotic agents in 2014

ANNEX 2

EFSA Guidance Documents

EFSA. 2012 - Technical specifications on the harmonised monitoring and reporting of antimicrobial resistance in *Salmonella*, *Campylobacter* and indicator *Escherichia coli* and *Enterococcus* spp. bacteria transmitted through food.

In EFSA Journal. <http://www.efsa.europa.eu/en/efsajournal/pub/2742.htm>

EFSA. 2012 - Technical specifications for the analysis and reporting of data on antimicrobial resistance (AMR) in the European Union Summary Report.

In EFSA Journal. <http://www.efsa.europa.eu/en/efsajournal/pub/2587.htm>

EFSA. 2014 - Technical specifications on randomised sampling for harmonised monitoring of antimicrobial resistance in zoonotic and commensal bacteria.

In EFSA Journal. <http://www.efsa.europa.eu/en/efsajournal/pub/3686.htm>

EFSA. 2015 - Data dictionaries-guidelines for reporting data on zoonoses, antimicrobial resistance and food-borne outbreaks using the EFSA data models for the Data Collection Framework (DCF) to be used in 2015, for 2014 data.

In EFSA. <http://www.efsa.europa.eu/en/supporting/doc/776e.pdf>

EFSA. 2015 - Manual for reporting on antimicrobial resistance within the framework of Directive 2003/99/EC and Decision 2013/652/EU for information deriving from the year 2014.

In EFSA. <http://www.efsa.europa.eu/en/supporting/pub/771e.htm>

Annex 3 - Table 1: Combinations of bacterial species/food and food animal populations and number of isolates to be tested

Animal populations /Type of meat	Where to collect	Compulsory								Facultative			
		<i>Salmonella</i>		<i>Campylobacter Jejuni</i>		Indicator commensal <i>E. coli</i>		ESBL- orAmpC ^(g) - or Carbapenemases ^(h) - producing <i>E. Coli</i>		<i>Campylobacter Coli</i>		Indicator commensal enterococci	
		Samples to collect	no. Isolates ^(c)	Samples to collect	no. Isolates ^(c)	Samples to collect	no. Isolate ^(c)	Samples to collect	no. Samples ^(c)	Samples to collect	no. Isolates ^(c)	Samples to collect	no. Isolates ^(c)
Laying hens	Farm	boot swabs ^(a)	170 ^(d)	–	–	–	–	–	–	–	–	–	–
Broilers	Farm	boot swabs ^(a)	170 ^(d)	–	–	–	–	–	–	–	–	–	–
	Slaughterhouse	carcasses ^(b)	170 ^(d)	caecal spl.	170 ^(d)	caecal spl.	170 ^(d)	caecal spl.	300 ^(f)	caecal spl.	170 ^(d)	caecal spl.	170 ^(d)
	Retail	–	–	–	–	–	–	fresh meat	300 ^(f)	–	–	–	–
Fattening turkeys	Farm	boot swabs ^(a)	170 ^(d)	–	–	–	–	–	–	–	–	–	–
	Slaughterhouse	carcasses ^(b)	170 ^(d)	caecal sp. ^(e)	170 ^(d)	caecal sp. ^(e)	170 ^(d)	cecal sp. ^(e)	300 ^(f)	–	–	caecal spl. ^(e)	170 ^(d)
Fattening pigs	Slaughterhouse	carcasses ^(b)	170 ^(d)	–	–	–	–	–	–	–	–	–	–
		–	–	–	–	caecal spl.	170 ^(d)	caecal spl.	300 ^(f)	caecal spl.	170 ^(d)	caecal spl.	170 ^(d)
	Retail	–	–	–	–	–	–	meat	300 ^(f)	–	–	–	–
Calves under 1 year	Slaughterhouse	carcasses ^{(b)(e)}	170 ^(d)	–	–	caecal sp. ^(e)	170 ^(d)	caecal sp. ^(e)	300 ^(f)	–	–	caecal sp. ^(e)	170 ^(d)
Bovine meat	Retail	–	–	–	–	–	–	meat	300 ^(f)	–	–	–	–

(a): In the framework of the SNCP (Regulation (EC) No 2160/2003). If prevalence is low and fewer than 170 isolates are available, all isolates from national control programmes to be tested for AMR.

(b): In the framework of Regulation (EC) No 2073/2005.

(c): If MS production of meat < 100 000 Tonnes poultry and 100 000 Tonnes pig meat slaughtered, only 85 isolates are needed for each combination.

(d): One isolate per serovar per epidemiological unit per year.

(e): Only if MS production of meat > 10 000 Tonnes slaughter per year.

(f): If <100 000 T Poultry and pig meat or <50 000 T Bovine: 150 samples.

(g): Compulsory from 2015 on

(h): Voluntary

ANNEX 4 - DETAILS OF INDIVIDUAL DG HEALTH AND FOOD SAFETY AUDITS CONSIDERED FOR THIS INTERIM REPORT

Country	Dates of Audit	Reference No.
Denmark	15-22 September 2015	2015-7383
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3613		
Germany	10-20 November 2015	2015-7404
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3614		
Slovakia	8-16 March 2016	2016-8917
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3643		
Austria	14-22 April 2016	2016-8918
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3687		
Spain	5-16 September 2016	2016-8678
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3729		
Hungary	4-12 October 2016	2016-8676
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3728		
Netherlands	10-18 November 2016	2016-8919
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3776		
Romania	5-15 December 2016	2016-8677
http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3789		

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