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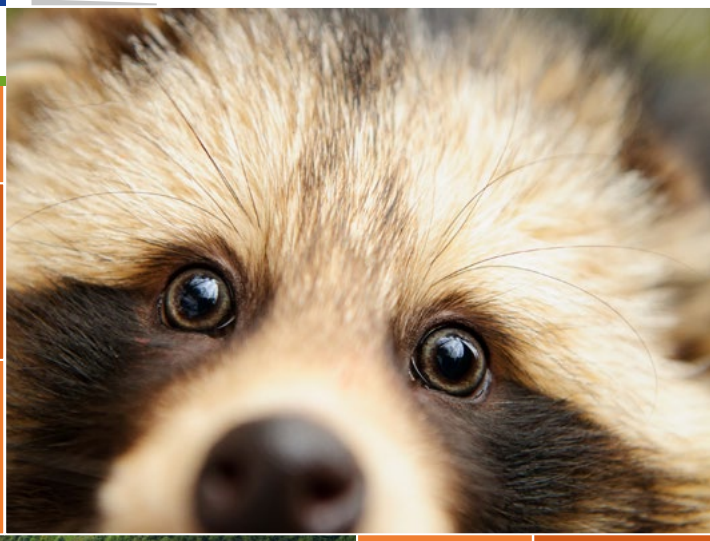

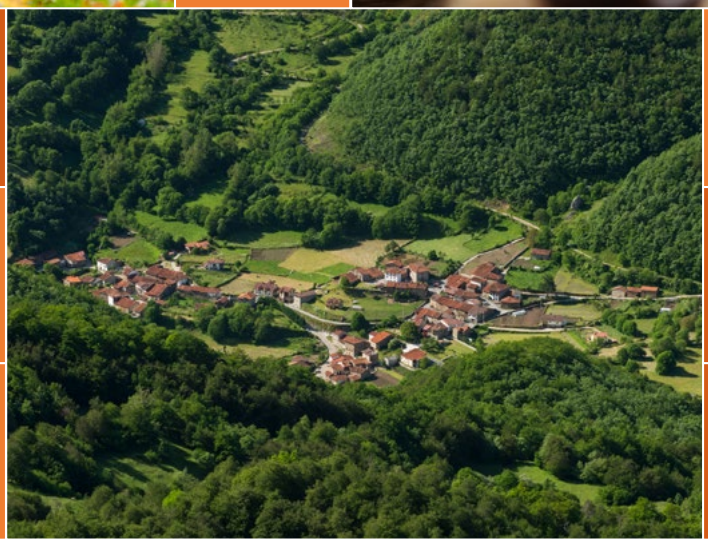

DG Health and Food Safety

OVERVIEW REPORT

Rabies Eradication in the EU

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Health and food audits and analysis

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OVERVIEW REPORT
ON A SERIES OF AUDITS AND FACT-FINDING MISSIONS CARRIED OUT IN MEMBER STATES AND NON-EU COUNTRIES FROM 2012 TO 2016 IN ORDER TO EVALUATE THE IMPLEMENTATION OF RABIES ERADICATION PROGRAMMES

Executive Summary

The European Union (EU) co-finances major vaccination programmes for rabies eradication in wildlife which aim to minimize the risk of citizens and domestic animals being infected by rabies. The target for approved rabies eradication programmes is to eliminate wildlife rabies from the EU by 2020. Rabies eradication has already been successful in most areas but further efforts are still needed in certain countries, in particular in areas close to the eastern borders of the EU. This overview report, based on audits and other activities by the Commission services, presents the main issues of importance for the successful elimination of wildlife rabies and highlights identified good practices.

Procedures for planning, approval and implementation of oral vaccination programmes are well established for many years and there is close cooperation between the Commission services and Member States. Agreed systems for rabies surveillance, aerial bait distribution, monitoring of bait distribution and fox population immunity are applied by Member States, albeit with varying success. Although distribution of high quality vaccine baits twice per year is the key element of the eradication programmes, campaigns are sometimes delayed or omitted for administrative reasons. Member States regularly delegate vaccine bait distribution to contracted operators, sometimes with insufficient official controls during storage and distribution, which reduces their ability to take timely corrective action where needed.

After vaccine bait distribution, samples from foxes are tested to demonstrate that the vaccine has reached the target fox/raccoon dog population. Such samples are sometimes too few, of poor quality, and often unevenly distributed, and laboratory methods for detection of rabies antibodies in wild animals vary among and within countries. This makes it difficult for some Member States to demonstrate that the oral vaccination campaigns have protected a sufficient proportion of foxes in the whole vaccination zone and also makes it complicated to compare progress between Member States. The sampling worked best where the central competent authority was actively involved throughout the year and had legally regulated cooperation with hunters' associations.

The marked reduction of reported wildlife rabies cases in Member States is the most important proof that rabies eradication is progressing according to plan in most areas. Robust and representative data from several years' of rabies surveillance are essential to demonstrate freedom from rabies. However, it has proven challenging to reach and maintain sufficient numbers of "indicator animals" tested for the presence of rabies, particularly in areas where rabies eradication has been successful and there have been few or no rabies cases in recent years.

As recommended in recent Commission guidelines, epidemiological experts in Member States should be used by competent authorities to evaluate if sampling is representative, test results reliable, and vaccination campaigns effective. Epidemiological analyses are crucial to inform decisions by the competent authorities on whether to increase or decrease vaccination areas, and could help explain the remaining "hot spots" where wildlife rabies has remained in spite of years of oral vaccination campaigns. Such critical analyses by epidemiological experts would certainly help the Commission to verify that co-funded rabies eradication programmes are efficiently implemented everywhere.

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ABBREVIATIONS USED IN THIS REPORT

Abbreviation	Explanation
DG SANTE	Directorate General for Health and Food Safety of the European Commission
EU	European Union
ORV	Oral rabies vaccination

1 INTRODUCTION

Rabies is a fatal viral disease in the vast majority of unvaccinated humans and other mammals, once symptoms are present. Treatment is possible if given soon after the suspected contact with rabies virus. The virus is mainly transmitted via bites or other contact with saliva or blood, it moves along the nerves and symptoms occur once it has reached the brain. In the European Union (EU), where mass vaccination of cats and dogs has helped eliminate dog rabies, the disease is still circulating in wildlife in certain areas. Although rabies can be found in many wild species the fox is the only known reservoir for rabies in Europe, i.e. able to maintain and spread the virus, whilst raccoon dogs are important virus transmitters. This is why these two species are the target species for vaccination campaigns. The target set by the European Commission is to eliminate wildlife rabies from the EU by 2020.

While injectable vaccines against rabies have been successfully used for prevention of rabies in humans and domestic animals since Pasteur's discovery in 1885, it is only with the development of oral vaccines, based on weakened (attenuated) live virus, in the 1970s' that successful control of rabies in a wild animal population became feasible.

Switzerland was the first European country to start oral rabies vaccination (ORV) of foxes in 1978 and was joined in the 1980s' by France, Belgium, the Netherlands, Luxembourg, Germany, Austria, and Italy. In 1989, the European Commission introduced the first financial contribution for ORV of wildlife in EU Member States, gradually extending the geographical coverage to all affected Member States. Such EU co-funded campaigns have contributed to the very positive trend towards elimination of rabies from the EU: Between 2010 and 2015, rabies cases reported in wildlife dropped from 710 cases in eight countries to 100 cases in four countries. The total number of reported rabies cases in animals (excluding cases in bats and imported cases) dropped from 1552 cases in nine countries in 2010 to 128 cases in four countries in 2015.

2 METHODOLOGY AND OBJECTIVE

Annex 1 comprises a full list of EU legislation providing the audit criteria for the audits in this report.

Between April 2012 and May 2016, the Commission services carried out audits in Poland, Bulgaria, Romania and Hungary to verify the implementation of the co-funded ORV programmes (see **Annex II**). The approved rabies eradication programmes for Latvia, Lithuania, Poland and Hungary, as appropriate, also include ORV campaigns in buffer zones on the territories of Belarus and Ukraine. Therefore fact-finding visits together with technical experts from Member States were carried out to Ukraine and Belarus, in agreement with the national competent authorities. For more comprehensive information please consult the published audit reports here: http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

Annex III provides a list of Commission documents, scientific reports and international standards of relevance for rabies eradication, which were taken into account during the audits and fact-finding visits.

More comprehensive and technical findings from the audits and fact-finding missions are described in **Annex V**.

3 BACKGROUND

3.1 CO-FUNDING AND AUDITS OF RABIES ERADICATION PROGRAMMES

In the last five years the annual contribution from the EU for rabies eradication in wildlife (foxes and raccoon dogs) has varied between 20 and 27 million euro, which represents around 16% of the total contributions to national animal disease and eradication programmes. Ninety percent of the EU funding for rabies eradication is spent on oral vaccination (purchase and distribution from aeroplanes), whilst the remainder is co-funding costs for sampling and testing in order to monitor and control the efficacy of vaccinations. In 2015, the EU co-funded ORV campaigns in Finland, Estonia, Latvia, Lithuania, Poland, Hungary, Romania, Bulgaria, Slovakia, Slovenia, Croatia, Italy, and Greece, either because of the presence of wildlife rabies in the country or because of the risk of re-introduction.

Rabies-infected animals wandering in from neighbouring non-EU countries can make elimination of rabies more difficult in Member States that share borders with countries with wildlife rabies. In recent years the EU has therefore, as part of approved Member State programmes, funded oral rabies vaccination of wildlife in buffer zones on the territories of non-EU countries. In 2015, five approved Member State programmes included ORV in buffer zones along EU borders on the territories of the Russian Federation, Belarus and Ukraine. For these activities, the EU funded 100% of the eligible costs for purchase and distribution of ORV baits. From 2016 the EU can also co-finance the testing costs for monitoring samples, provided these laboratory tests are carried out in a Member State. Although included in Figure 1, ORV campaigns in the Western Balkan countries within the framework of the EU Instrument for Pre-Accession Assistance are not evaluated in this report.

Over the past fifteen years, the Commission services have carried out 23 audits and fact-finding visits evaluating the implementation of approved rabies eradication programmes. The audit reports have been published as previously described under section 2.

3.2 GEOGRAPHICAL COVERAGE OF ORAL RABIES VACCINATION AND PROGRESS OF ERADICATION

Annex IV provides maps of rabies in wildlife and in domestic animals, as well as areas that were subject to ORV campaigns (not only financed by the EU) in the years 2000, 2005, 2010, and 2015.

Figure 1 provides a more detailed map over the approximate areas covered by ORV and the different sources of financing in 2015.

Figure 1: ORV in 2015 in the EU and on the territories near EU borders in non-EU countries. IPA refers to Instrument for Pre-accession Assistance.

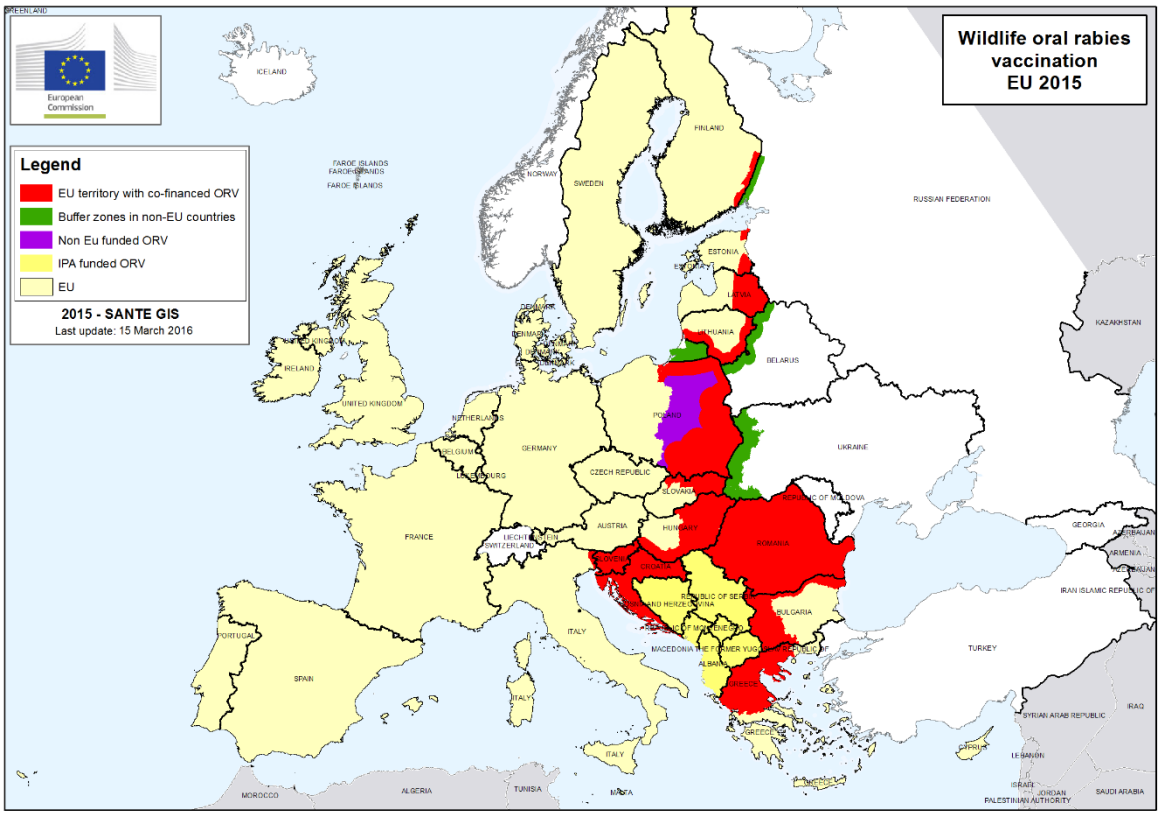
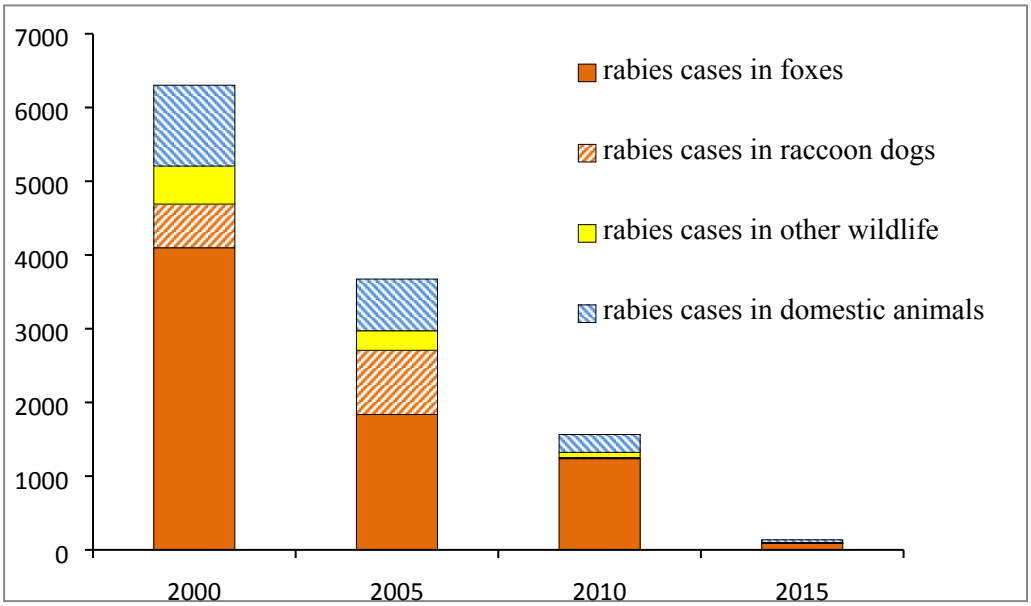


Figure 2 summarises rabies cases in foxes, raccoon dogs, other wildlife, and domestic animals reported to "Rabies - Bulletin – Europe"[1] from the current EU Member States. Among the current 28 Member States, four reported cases of wildlife rabies in 2015, whilst 15 years earlier 13 of these countries experienced wildlife rabies. As the rabies cases in wildlife declined, so did the rabies cases in domestic animals.

[1] Detailed data about rabies outbreaks and oral rabies vaccination are available on the website of "Rabies - Bulletin – Europe", Rabies Information System of the WHO Collaboration Centre for Rabies Surveillance and Research: http://www.who-rabies-bulletin.org/Queries/Default.Aspx

Figure 2: Rabies cases in the 28 current (2016) EU Member States



Additional information about rabies cases in humans and animals can be found in the annual EU summary reports on zoonoses, zoonotic agents and food-borne outbreaks, published here: http://www.efsa.europa.eu/en/publications. Please note that each of the EU summary reports deals only with data from countries that were EU Member States during the reporting year and Iceland, Norway and Switzerland, whereas Figure 2 above takes into account data also from the countries which were not yet EU Member States in 2000, 2005 and 2010 so that each bar includes data from the 28 countries that are currently EU Member States.

4 SUMMARY OF THE MAIN CONCLUSIONS FROM AUDITS AND FACT-FINDING VISITS

4.1 VACCINE BAIT PROCUREMENT, QUALITY CONTROL AND STORAGE

Although the specific procedures vary, contracts with vaccine suppliers and distribution companies are signed following public procurement processes in all four Member States, in line with EU rules. In some Member States, complaints/appeals against tender procedures (sometimes at regional level), delays in awarding national budgetary means for the procurement of vaccine, and other administrative problems delayed or prevented the implementation of ORV campaigns. One-year contracts, combined with national budgetary procedures out of the control of veterinary services, increase the risk that vaccination campaigns are missed or delayed to a suboptimal time of year, which is likely to slow down the elimination of wildlife rabies.

The sometimes limited official controls on vaccine storage conditions show that Member States might place too high a level of trust in private operators' own checks on the maintenance of appropriate temperatures during storage and transport of vaccine baits. When combined with a lack of titre testing at the end of the storage period, the competent authority cannot verify the quality of the oral rabies vaccine baits that are to be distributed. Unless the minimum acceptable vaccine titres are verified, not only on arrival but also after storage,

costly aerial distribution may take place of vaccine baits that fail to meet the minimum requirements and therefore might be less effective.

In some cases procurement took place at regional levels, with regional differences in tender specifications and contracts, many separate authorities planning and organising controls on quality and storage of vaccine baits. This lead to differences in timing of campaigns and vaccine distribution patterns, and made it more difficult to implement coordinated vaccination campaigns.

Good practices observed

- When official controls reveal that bait storage temperatures have temporarily been too high, additional vaccine titre tests are carried out on the batches to check if the vaccine quality has been affected.
- Centralised, multi-year procurement procedures for vaccine baits and bait distribution save time and resources and minimise the risk of unnecessary delays of vaccination campaigns.
- The risk of distributing non-compliant vaccine baits is reduced through routine testing of vaccine titres in all batches at the end of the storage period but before aerial distribution.
- Testing that the vaccine potency remains the same in the baits after exposure to the actual environmental conditions (for at least seven days) after aerial distribution provides the authorities with supporting evidence that the vaccine baits taken by the foxes were of a quality able to stimulate an immune response.

4.2 DISTRIBUTION OF VACCINE BAITS AND RELATED OFFICIAL CONTROLS

Vaccine baits are dropped from aeroplanes and Member States had contracted private operators for this task. When contracts were organised at regional levels many different flight companies were involved in the distribution and many regional/local authorities gave instructions to their contractors and carried out controls. This makes national coordination of ORV campaigns more difficult and may lead to differences in instructions, implementation and controls between regional campaigns.

Two of the four Member States had implemented two ORV campaigns each year as planned in the approved rabies eradication programmes for 2010-2015. When ORV campaigns took place they generally covered the whole areas that had been defined in the approved programmes.

Vaccine baits need to be distributed at pre-determined spatial intervals to reach as many target animals as possible. Member States met or exceeded the recommended density of 20 vaccine baits/km^2 when calculated as a national average, based on the total number of baits distributed and the total area covered. However, more detailed data are needed to verify that the distance between baits is correct everywhere. Since 2015, the Commission therefore

requires that electronic data from flight lines and bait drop locations from recording devices in the planes are checked by the authorities on a daily basis. It had been more complicated for the competent authorities to establish such control systems than expected by the Commission, and day-to-day verification of proper vaccine bait distribution via electronic files was not effective at the time of these audits.

Some Member States had sufficient controls on the flight lines to take corrective action during the campaign if the area coverage was incorrect. In other cases, the contracted operators are given the full responsibility for planning and implementing the aerial distribution of vaccine baits. When official controls of flight and bait drop data are carried out only after the end of a campaign, any deficiencies in the distribution are detected too late for the competent authority to initiate timely corrective actions. Should corrective actions be necessary, i.e. redistribution of baits over certain areas, such actions are likely to be severely delayed due to a need to re-negotiate contracts for vaccine bait procurement and distribution.

Good practices observed

- Procedures in place for additional emergency vaccination in areas where rabies is detected unexpectedly, as well as for increasing bait density in such areas in the following campaign.
- Flight lines rotated 90 degrees between campaigns to improve the geographical coverage.
- Timely official controls on aerial distribution to make it possible for the competent authority to order flight operators to take corrective actions (where necessary) within 24 hours.

4.3 MONITORING OF BAIT CONTACT AND FOX POPULATION IMMUNITY

To monitor the effectiveness and progress of ORV, Member States take samples from hunted foxes to check whether these have eaten the bait (and thus, the vaccine) and if they have developed immunity against rabies virus. The target is to sample 4 foxes/100 km^2, evenly distributed over the vaccination area. Without active interventions and supervision from central level, the monitoring programme does not always receive high priority by regional offices and hunting associations. This may lead to under-implementation of the sampling, patchy sample distribution, and sometimes incorrect sampling, which are all factors that reduce the reliability of the monitoring results. When Member States fail to collect and analyse representative samples the test results do not provide sufficient information to evaluate the effectiveness of the ORV campaigns.

Table 1 shows how the Member States have reached the overall sampling targets in recent years and the colours (red, amber and green) indicate how close the sample numbers are to the target figure. The representativeness, e.g. spatial distribution and age distribution, of the sampling has not been factored into the colour coding.

Table 1: National data reported to the Commission for the years 2013, 2014 and 2015.

	Monitoring: Number of foxes /100 km² in the vaccination zone (target=4)		
	2013	2014	2015
Bulgaria	0.43 foxes 0.25 golden jackals	0.28 foxes 0.1 golden jackals	2.25 foxes 0.77 golden jackals
Hungary	4	4	>4
Poland	>4	>4	>4
Romania	1.6	2.5	3.9

The vaccine baits include a marker (tetracycline) that makes it possible to test in the laboratory if an animal has licked or chewed on the bait (bait contact). Monitoring samples are tested for tetracycline in teeth/bone using a standardised test method and provide comparable data to verify bait uptake and distribution over time.

Foxes infected by rabies virus are not expected to live long enough to develop antibodies. Therefore the presence of antibodies can be used as evidence of vaccination. The proportion of sampled foxes tested for antibodies generally improved between 2013 and 2014, although sample quality remains problematic. National laboratories use different antibody tests methods and test different types of body fluids. Consequently, the estimates of population immunity may be suitable for monitoring progress and differences within the country provided that the sampling is representative, but are not suitable for comparisons between Member States. Furthermore, if test methods vary among regional laboratories it is difficult for the central authority to monitor the effectiveness of vaccination within the country.

As summer is not the normal fox hunting season, most of the samples are collected between November and March. This is not likely to have a negative effect on the ability of competent authorities to assess the progress of the rabies elimination, provided that the age determination of the foxes is reliable. Tetracycline remains in the teeth and bones so only data that can be linked to young foxes will demonstrate bait uptake specifically from the most recent campaigns. Adult animals could have been in contact with baits and been vaccinated in previous campaigns, but young foxes have only been exposed to one or two campaigns. It is therefore important to include sufficient number of young foxes and to include age data when evaluating test results in order to assess if the most recent campaigns have been successful. Audits showed that hunters sometimes received incorrect instructions about the age of foxes to be shot. Laboratory methods to determine the age of the foxes are generally more reliable than field assessments. The lack of reliable age data in some Member States makes it difficult for the competent authorities to assess the effectiveness of the ORV campaigns.

Table 2 shows the results of the monitoring of bait contact and population immunity at national level, as reported by the competent authorities. The audits showed that the proportions of foxes that had been in contact with baits and the proportions where antibodies

were detected sometimes varied substantially between different geographical areas within a Member State. The results also illustrate the different estimates of population immunity obtained when using different analytical methods, here referred to as methods A and B.

Table 2: National data reported to the Commission for the years 2013, 2014 and 2015.

	Bait contact (T= tested foxes) and % positive test results						**Antibodies to rabies virus (T=tested foxes) and % positive test results**					
	2013		**2014**		**2015**		**2013**		**2014**		**2015**	
	T	% +	T	% +	T	% +	T	% +	T	% +	T	% +
Bulgaria	253	**75**	753	**60**	1236	**65**	133	**41***	479	**37***	894	**43***
Hungary	1757	**71**	2510	**69**	2931	**75**	856	**25***	2085	**35***	2403	**44***
Poland	21547	**86**	16756	**88**	13284	**89**	17049	**75#**	6561 6383	**76#** **43***	10117	**54***
Romania	3196	**24**	5385	**55**	7482	**74**	2947	**22***	5048	**31***	6418	**28***

*** analysed by method A; # analysed by method B**

Where sufficient data were available they showed, as expected, that the proportions of young (less than one year old) foxes that had been in contact with baits and developed antibodies were lower than those seen in older animals.

The approved vaccination and monitoring programmes focus on foxes. The inclusion of raccoon dogs (the other reservoir species) in the monitoring of bait uptake and immunity is allowed but very few, if any, raccoon dogs had been tested in these four Member States. Rabies has been detected in raccoon dogs in Poland and Romania, and in three other Member States that are not included in this overview report.

Member States have expressed concern about an observed increase in numbers and geographical distribution of golden jackals and the effect these animals could potentially have on competition about vaccine baits and spread of rabies. A limited number of golden jackals have been tested for tetracycline and antibodies to rabies virus in Bulgaria. Results from 2013, 2014 and 2015 indicated bait uptake at the same level as in foxes but a lower proportion of animals with detected antibodies than in foxes.

Good practices observed

- Instructions to hunters to assist veterinary services – which they are obliged to do under national law. This facilitates representative sampling and reaching target numbers.
- The whole fox carcass is brought to local veterinary services/laboratories, where official veterinarians are responsible for extracting and preparing appropriate samples and for submitting these to the analysing laboratory. This increases the number of samples, particularly for antibody testing, and reduces the proportion of poor quality samples

submitted for analysis.

- Effective monitoring of sampling and sample distribution during the year, which makes it possible, where necessary, for authorities to take timely corrective actions to increase or adjust the sampling in order to reach the targets in the programme.

4.4 RABIES SURVEILLANCE

A reduction of rabies cases is the most important indicator that the eradication programme is successful. The reliability of this assessment depends on the effectiveness of the surveillance. All Member States have well-functioning systems in place for investigations of wild and domestic animals showing signs of rabies, and for immediately informing human health authorities at local level of such suspicions. In addition, rabies surveillance should include other "target animals", such as wild animals found dead and domestic animals found dead on pastures where they could have been in contact with infected wild animals.

Rabies surveillance in target animals depends on the ability of competent authorities to engage hunters, farmers and other persons spending time in fox habitats in the surveillance. In spite of regular awareness campaigns, this is particularly problematic in countries or regions with few or no rabies cases in recent years, and in areas outside the ORV zones. This illustrates the challenges of maintaining the necessary vigilance and awareness among farmers and people spending time in nature, whilst at the same time reassuring the public and authorities that the fox vaccination campaigns are successful.

Member States applied very different measures regarding wildlife when rabies cases in wildlife were detected in a previously "rabies free" area. A lack of active surveillance when wildlife rabies has been detected in a previously "rabies free" area may lead to a failure to identify a "hot spot" with multiple rabies cases and give a false sense of security. This may lead to a failure to take an informed decision on whether to implement an emergency ORV campaign before the next planned campaign, or lead to emergency ORV being implemented on too small an area. In both cases, further spread of rabies in the local wildlife population will be facilitated.

In the absence of effective passive surveillance on the whole territory of the Member State, rabies testing of foxes shot under the vaccination monitoring programme increases the chances of detecting rabies cases. However, rabies test results from the vaccination monitoring programme are not sufficient to confirm the absence of rabies.

Good practices observed

- Increased local hunting and rabies testing of all shot foxes when rabies in wildlife is detected in a previously "rabies-free" area. This helps determine the extent of the rabies incursion and facilitates informed decisions on emergency vaccination.

4.5 LABORATORIES

All testing laboratories use relevant methods for rabies diagnosis and for monitoring of bait uptake and antibodies. Methods to diagnose rabies are mostly included in the scope of accreditation. Furthermore, the reliability of test results for rabies diagnosis, tetracycline detection, and age determination in national reference laboratories can be assessed by competent authorities through the results from inter-laboratory comparative tests organised and evaluated by the EU reference laboratory for rabies.

Rabies virus strains detected in animals were typed to check if the rabies cases had been caused by the rabies virus included in the vaccine or by wild-type rabies virus. No indications of vaccine-type virus had been found in the four Member States. The occasional delay in submitting virus from all rabies cases for typing reduces the chances for early detection of potential problems with the virus strain in a vaccine and would delay actions to suspend its use.

Titre determination of rabies virus in vaccine batches once the vaccine had been purchased was sometimes carried out in other national laboratories than the national reference laboratory. Such laboratories are not obliged to take part in inter-laboratory comparative tests organised by the EU reference laboratory for rabies. This makes it difficult for the competent authorities to verify the reliability of the quality tests carried out on vaccine baits.

Neither the EU reference laboratory for rabies, nor any of the national reference laboratories had organised any inter-laboratory comparative tests for antibody detection in wildlife samples[2]. Thus, the reliability of test results for antibody detection has been difficult to assess, especially when methods are not included in the scope of accreditation in the laboratory.

Good practices observed

- Laboratory technicians in regional laboratories receive training in the national reference laboratory, and the relevant method validation files from the control laboratories must be approved by the national reference laboratory, before a control laboratory could take part in testing under the rabies eradication programme. These procedures support harmonisation of test methods, which facilitates the interpretation of results.
- The national reference laboratory organises regular inter-laboratory comparative tests for rabies diagnosis for control laboratories, which makes it possible for the authorities to verify the reliability of diagnostic tests for rabies virus.

[2] As mentioned under point 8, the first inter-laboratory comparative test for detection of antibodies to rabies virus in sera from foxes was organised during the winter 2016/2017.

4.6 ANALYSIS OF THE EFFECTIVENESS AND PROGRESS OF RABIES ERADICATION

Comprehensive epidemiological analyses, as recommended in the Guidelines issued by the Commission (see Annex IV), had not been carried out in any of the four Member States at the time of the audits. The units responsible for planning and reporting to the Commission were often evaluating the progress of rabies eradication without access to epidemiological experts and analytical tools.

When most of the monitoring results are obtained from very few locations within the vaccination zone the results are not representative enough for an assessment of the overall effectiveness of the ORV. The annual summaries presented by Member States to the Standing Committee on Plants, Animals, Food and Feed; Section Animal Health & Welfare do not show if there has been such clustered sampling. Nor do they always show if there are major differences in monitoring results between regions or if the competent authority has linked such differences to difficulties in rabies eradication.

Clustered or insufficient sampling is sometimes repeated year after year, often combined with a lack of antibody tests from many of the sampled animals. This makes it difficult for the Member State and the Commission to evaluate in detail the effectiveness of the ORV, and makes it difficult to take informed decisions on extending or decreasing the vaccination areas. It may also result in inadequate data collection for a declaration of freedom from rabies at the end of the programme.

Good practices observed

- Breakdown of surveillance and monitoring data by hunting ground to form the basis for specialised epidemiological analyses.
- An assessment of rabies surveillance and monitoring results using basic epidemiological mapping tools can reveal spatial gaps in sampling and test results and identify priority areas for improvements regarding monitoring and surveillance in subsequent years.

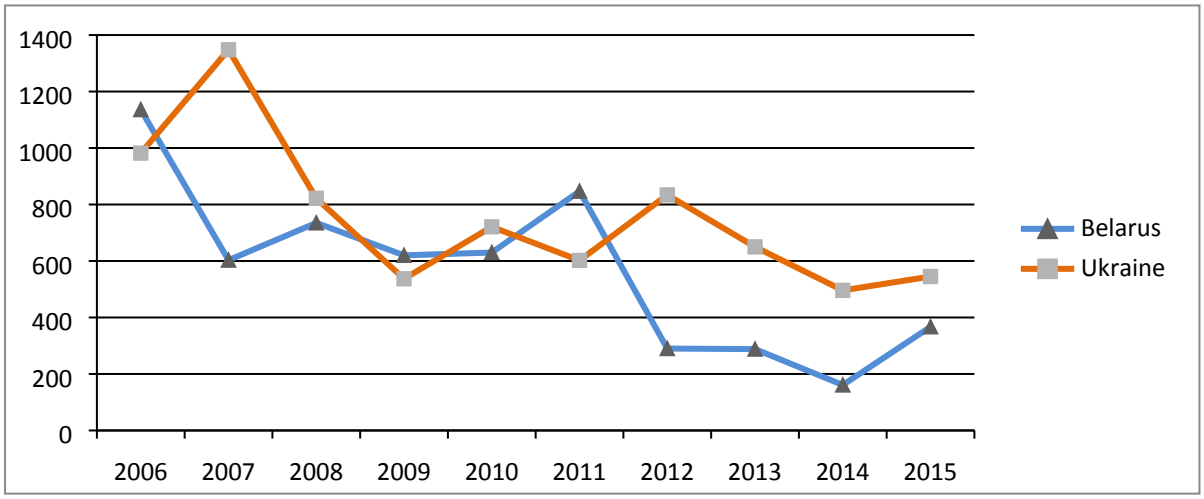
5 ORAL RABIES VACCINATION PROGRAMMES IN NON-EU COUNTRIES

5.1 PLANNING AND IMPLEMENTATION OF ORV CAMPAIGNS IN NON-EU COUNTRIES

The EU has co-financed ORV programmes, as parts of approved Member State programmes, in Belarus since 2011 and in Ukraine since 2012. The aim is to create a buffer zone where rabies cases in wildlife are kept at a minimum through regular ORV campaigns on the eastern side of EU borders, in order to reduce the risk that rabies infected wild animals cross the borders into EU territory. The EU is financing 100% of the costs for vaccine purchase and distribution in these zones. Both countries have organised two ORV campaigns each year, except in 2015 when one country failed to implement the spring campaign. In 2010-2016 the EU financed ORV campaigns in the Kaliningrad region of the Russian Federation, which resulted in the eradication of rabies from this region.

Figure 3 illustrates the cases of wildlife rabies in the past ten years, as reported by Ukraine to "Rabies - Bulletin – Europe", and as presented by Belarus during the fact finding visit. Both countries have implemented local or regional ORV programmes in the past, but not with the aim of systematically eliminating wildlife rabies from their territories.

Figure 3: Rabies cases in wildlife in Belarus and Ukraine (whole territory)



The financial contributions from the EU are based on eradication plans that are agreed with the relevant Member States and approved as part of their rabies eradication programmes. Once the financial decisions have been taken in the EU, formal contracts are drawn up between the non-EU country and the relevant Member States. These Member States are responsible for verifying the implementation of the ORV campaigns abroad before transferring the payment, and include reports from these ORV campaigns in their regular reports to the Commission. As illustrated in **Table 3**, Belarus and Ukraine each receive funding for their ORV programmes through two or three Member States. These Member States are each responsible for the ORV campaign in a specified geographical part of the buffer zones.

Table 3: Member States' rabies eradication programmes that include ORV campaigns in Belarus or Ukraine

Countries	Belarus	Ukraine
Latvia	yes	-
Lithuania	yes	-
Poland	Included in Polish programme, not yet implemented	yes
Hungary	-	yes

The formal procedures for signing contracts between Ukraine/Belarus and the relevant Member States are time-consuming. Recently, political and administrative changes in one of these countries had led to delays in signing the contracts with Member States and operators,

resulting in the omission of the spring campaign. By 2016 Poland and Belarus had not yet signed any contract, in spite of ORV in Belarus being part of the approved programme for Poland for several years. This has left a substantial gap in the buffer zone on the territory of Belarus, where no measures have been taken to reduce the risk of rabies incursion into the EU.

Although competent authorities in the two non-EU countries engage with the Commission services and Member States, direct contacts between the relevant technical experts in Member States and their colleagues in Belarus and Ukraine are difficult due to administrative protocols and sometimes language barriers. The fact-finding visits allowed these technical experts from Member States to meet, sometimes for the first time, their colleagues in the non-EU countries and to discuss (with the help of Commission interpreters) many practical aspects of planning, implementation, and reporting of the ORV programmes.

Vaccine bait procurement, ORV campaigns, and monitoring of vaccine bait contact and population immunity are carried out according to the same principles as in Member States. The vaccine baits used in the ORV campaigns are produced outside the EU. Comprehensive quality control results are required by both competent authorities, there are official controls on storage temperatures, and titre tests are repeated before distribution. As in Member States, the results are sometimes not available until after the ORV campaign. Rabies surveillance is effective in both countries and the level of public awareness is high.

Both competent authorities lacked sufficient data from the operators to verify that the vaccine baits had been distributed over the agreed areas and with the correct bait densities. Electronic data collection for flight lines and vaccine bait drop locations, as required by the Commission from 2015, was not yet working.

5.2 MONITORING THE EFFECTIVENESS OF ORV CAMPAIGNS IN NON-EU COUNTRIES

In one of the non-EU countries, hunters are obliged to submit all foxes shot for rabies testing and the number of foxes sampled for monitoring met the targets in the approved programme although there was substantial variation between regions. Overall, the monitoring results indicate that the proportions of foxes in contact with baits and vaccinated had increased year by year. However, the proportions of the sampled foxes that were tested for antibodies had decreased over the years and varied between regions, which reduced the representativeness of the serological results.

In the other non-EU country in 2015, insufficient numbers of foxes had been sampled and only a small fraction of the sampled foxes had been tested for antibodies, which prevents a reliable assessment of the effectiveness of the recent ORV campaigns.

These countries submit the results from surveillance and monitoring to the Member States: each Member State receives data only for the part of the buffer zone included in their approved programme and forwards these, without further epidemiological analysis, to the Commission as part of the report for the national programme in the Member State.

6 OVERALL CONCLUSION ON RABIES ERADICATION IN THE EU

Rabies eradication in Member States has been successful in most areas, as illustrated in Annex IV. In order to reach the Commission's target to eliminate rabies from wildlife in the EU by 2020, further efforts are still needed in certain countries, particularly in areas close to the eastern borders of the EU.

Procedures for planning, EU approval and implementation of ORV programmes are well established. Agreed systems for rabies surveillance, aerial bait distribution, monitoring of bait distribution and fox population immunity are applied by Member States, albeit with varying success. Although aerial distribution of high quality vaccine baits is the key element of the eradication programmes, campaigns are sometimes delayed or omitted for administrative reasons. Member States regularly delegate distribution to contracted operators, sometimes with very limited official controls during storage and distribution which reduced their ability to take timely corrective actions if needed. Systems for geolocation registration of flights and bait locations intended to facilitate and improve official controls were introduced in 2015 but the systems for daily official checks of such data were still being set up.

Reliable monitoring of whether the distributed vaccine baits have reached and induced immunity in the target population needs to be based on representative sampling and reliable test methods. Whilst samples for testing of bait uptake are relatively easy to obtain, reaching target sample numbers for antibody testing is proving more difficult and sampling is often clustered. This makes it difficult for some Member States to demonstrate that the ORV campaigns have induced adequate population immunity in the whole vaccination territory. The monitoring worked best in the Member State where the central competent authority was actively involved throughout the year and had legally regulated cooperation with hunters' associations.

It has proven difficult to reach and maintain sufficient numbers of "indicator animals" tested for rabies surveillance, particularly in areas where eradication has been successful and there have been few or no rabies cases in recent years. Robust surveillance data from several years are essential for demonstrating freedom from rabies in the future. However, the limited data available indicate that rabies eradication is progressing according to plan in most areas.

The general lack of analyses by epidemiological experts in Member States, of the representativeness of test results and the effectiveness of the ORV campaigns, undermines informed decisions on extending or decreasing the vaccination area. Such analyses could also help explain the remaining "hot spots" where wildlife rabies has remained in spite of years of ORV campaigns. This lack of critical analyses carried out by Member States makes it more difficult for the Commission to assess if the rabies eradication programmes have been efficiently implemented.

The implementation of ORV campaigns, monitoring and surveillance in the buffer zones in the two non-EU countries follows the same principles as in Member States and suffers similar problems: insufficient monitoring data and official controls to demonstrate that the rabies vaccine has reached, and resulted in immunity, in the target population. There is also a gap in

the buffer zone along the border between Poland and Belarus. Although competent authorities in the two non-EU countries are actively involved in creating a buffer zone where rabies cases are kept to a minimum, close cooperation between technical experts in the EU and their colleagues in the non-EU countries is hampered by administrative barriers and sometimes language problems. This makes it difficult for the responsible Member States to assist the non-EU countries, and to detect and address difficulties or inconsistencies. In addition, the fact that ORV plans and results are channelled through more than one Member State for each non-EU country makes it complicated for the Commission to obtain an overview of the implementation, effectiveness and efficiency of the ORV campaigns in these non-EU countries.

7 MATTERS FOR CONSIDERATION BY MEMBER STATES

Careful registration of flight lines and vaccine bait locations and official monitoring by trained official staff during an ongoing campaign is vital for timely detection of irregularities and implementation of effective corrective actions.

The declared temperature stability of the ORV baits and the climatic conditions during each campaign can be taken into account when determining the level of post-distribution testing needed. The information from field testing can be used to assess if the distributed baits were likely to have been effective for long enough (at least 7 days) after distribution. Such checks are particularly relevant when campaigns are carried out under climatic conditions that exceed or are close to the declared temperature stability limits of the vaccine baits.

Competent authorities need to focus on maintaining vigilance and effective passive surveillance on the whole territory of a Member State, also when the risk of encountering rabid animals is considered by the public to be small due to the success of the ORV campaigns.

Regular evaluations by epidemiological expertise, of all data related to sampling as well as results from monitoring and surveillance can support strategic decisions by providing the competent authority with critical evaluations on the reliability of data and the progress of rabies eradication. Such evaluations can also assist the Commission in assessing the (cost-) effectiveness of the ORV campaigns, as well as support proper data collection for future declarations of freedom from rabies.

Country-specific recommendations are included in each audit report.

8 ACTION TAKEN OR PLANNED BY THE COMMISSION SERVICES

EU Member States

Guidelines to design an EU co-financed programme on eradication and control of rabies (SANTE/10201/2015rev1) were made available in 2015.

The Commission services have carried out short visits to certain Member States during vaccine bait distribution.

The Commission has:

- increased the financial support for the delivery of wild animals to be tested. This support is even more reinforced if the animals are delivered in the framework of passive rabies surveillance. From 2016, golden jackals can be included, where relevant, in the EU co-financed monitoring of bait contact and immunity;
- requested that the EU reference laboratory organises inter-laboratory comparative tests for detection of antibodies in samples from wildlife. The first such test was organised at the end of 2016;
- fixed three different maximum amounts for vaccine purchase reimbursement depending on the vaccine used to decrease the costs and hence ensure the long-term sustainability of the campaigns;
- issued several recommendations to one Member State to launch a centralised call for tender to purchase vaccines with the aim of reducing costs and hence ensure the long-term sustainability of the campaigns;
- requested Member States to include in their final report the raw geographical data concerning flight tracks and bait distribution. This data is assessed randomly by the Commission services to verify that the campaign was conducted properly.

In addition to formal audits by the Commission services, the Rabies Subgroup of the EU Task Force on the Eradication of Animal Diseases has carried out assessments of the rabies situation in Bulgaria (2011), Poland (2012), Hungary (2015), and other countries, and indicated areas for improvement. Their reports have been published here: http://ec.europa.eu/dgs/health_food-safety/funding/cff/animal_health/vet_progs_en.htm

Non-EU countries

Two meetings were organised where Member States and certain non-EU countries, including Ukraine, Russian federation and Belarus (beginning of 2016) and the Western Balkans (at the end of 2015), were brought together to discuss planning and implementation of EU co-financed ORV campaigns outside EU borders.

On-site training has been organised for certain non-EU countries during a vaccination campaign to improve planning and control of aerial bait distribution. In addition, technical

assistance has been provided to one non-EU country on how to assess, on a daily basis, the electronic data from vaccine bait distribution.

The EU reference laboratory has verified the titres of the vaccines to be used in one non-EU country for the autumn campaign 2016.

The Commission intends to adjust the procedures for notification of financial contributions related to ORV campaigns in non-EU countries in order to facilitate the signing of ORV contracts between these countries and the relevant Member States.

The testing costs for monitoring and surveillance samples sourced from buffer zones in non-EU countries are now consider as eligible and reimbursable at 100%, provided these laboratory tests are carried out in a Member State.

In Ukraine, the EU has started to fund, through the Polish and Hungarian rabies eradication programmes, an expanded buffer zone from 2016 of 100-120 km depth from the EU border. Previously, the depth of the buffer zone was 50-70 km.

From 2016, the EU has allocated funds to implement rabies vaccination in Moldova, linked to the Romanian rabies eradication programme.

In 2017, two seminars on rabies eradication are planned in border regions under the Better Training for Safer Food initiative.

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 652/2014	OJ L 189, 27.06.2014, p. 1-32	Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC
Dec. 2008/341/EC	OJ L 115, 29.4.2008, p. 44-46	2008/341/EC: Commission Decision of 25 April 2008 laying down Community criteria for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses
Dec. 2008/425/EC	OJ L 159, 18.6.2008, p. 1-45	2008/425/EC: Commission Decision of 25 April 2008 laying down standard requirements for the submission by Member States of national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses for Community financing

Dec. 2008/897/EC	OJ L 322, 2.12.2008, p. 39-49	2008/897/EC: Commission Decision of 28 November 2008 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2009 and following years
Dec. 2008/940/EC	OJ L 335, 13.12.2008, p. 61-90	2008/940/EC: Commission Decision of 21 October 2008 laying down standard reporting requirements for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses co-financed by the Community
Dec. 2009/470/EC	OJ L 155, 18.6.2009, p. 30-45	2009/470/EC: Council Decision of 25 May 2009 on expenditure in the veterinary field (Codified version)
Dec. 2009/560/EC	OJ L 194, 25.7.2009, p. 56-59	2009/560/EC: Commission Decision of 22 July 2009 approving certain amended programmes for the eradication and monitoring of animal diseases and zoonoses for the year 2009 and amending Decision 2008/897/EC as regards the Community's financial contribution to certain Member States for programmes approved by that Decision
Dec. 2009/858/EC	OJ L 314, 1.12.2009, p. 75-78	2009/858/EC: Commission Decision of 27 November 2009 approving certain amended programmes for the eradication and monitoring of animal diseases and zoonoses for the year 2009 and amending Decision 2008/897/EC as regards the reallocation of the Community's financial contribution to certain Member States for programmes approved by that Decision and by Decision 2009/560/EC
Dec. 2009/883/EC	OJ L 317, 3.12.2009, p. 36–45	2009/883/EC: Commission Decision of 26 November 2009 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2010 and following years

Dec. 2010/712/EU	OJ L 309, 25.11.2010, p. 18-30	2010/712/EU: Commission Decision of 23 November 2010 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2011 and following years
Dec. 2010/732/EU	OJ L 315, 1.12.2010, p. 43-47	2010/732/EU: Commission Decision of 30 November 2010 approving certain amended programmes for the eradication and monitoring of animal diseases and zoonoses for the year 2010 and amending Decision 2009/883/EC as regards the financial contribution by the Union for programmes approved by that Decision
Dec. 2011/416/EU	OJ L 185, 15.7.2011, p. 77-78	2011/416/EU: Commission Implementing Decision of 14 July 2011 approving certain amended programmes for the eradication and monitoring of animal diseases and zoonoses for the year 2011 and amending Decision 2010/712/EU as regards the financial contribution from the Union for certain programmes approved by that Decision
Dec. 2011/807/EU	OJ L 322, 6.12.2011, p. 11-22	2011/807/EU: Commission Implementing Decision of 30 November 2011 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2012 and following years
Dec. 2012/761/EU	OJ L336, 8.12.2012, p.83-93	2012/761/EU: Commission Implementing Decision of 30 November 2012 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2013

Dec. 2013/722/EU	OJ L 328, 7.12.2013, p. 101-117	2013/722/EU: Commission Implementing Decision of 29 November 2013 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2014 and the following years
Dec. 2014/288/EU	OJ L 147, 17.5.2014, p. 88-113	2014/288/EU: Commission Implementing Decision of 12 May 2014 as regards the standard reporting requirements for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses co-financed by the Union and repealing Decision 2008/940/EC

ANNEX II TO OVERVIEW REPORT DG(SANTE)/2016-8980

LIST OF AUDITS AND FACT-FINDING MISSIONS

Country	Date of Audit	Date of study visit	SANTE ref. no.
Poland	16-20 April 2012		2012-6391
Bulgaria	6-12 April 2014		2014-7057
Romania	18-23 January 2015		2015-7623
Hungary	1-6 February 2015		2015-7624
Ukraine		10-15 April 2016	2016-8777
Belarus		22-27 May 2016	2016-8775

Annex III to overview report DG(SANTE)/2016-8980
Commission documents, Scientific reports and international standards

Commission documents

- The financial contributions for rabies eradication in 2015 are set in a Grant Decision approving national programmes. This information is outlined in points 11(11) and 11(12) in Working Document SANCO/12531/2014 rev 2 "Outcome of the evaluation procedure of eradication, control and surveillance programmes submitted by Member States for Union financial contributions for 2015 and following years: final list of the programmes selected and final amount allocated to each programme" https://ec.europa.eu/food/sites/food/files/animals/docs/diseases_wd_12531_2014_rev2_paff_13-01-2015_en.pdf

- Commission Implementing Decision of 16.10.2014 on the adoption of the financing decision for the year 2015 for the implementation of Union co-funded programmes for the eradication, control and surveillance of animal diseases and zoonoses. https://ec.europa.eu/food/sites/food/files/safety/docs/cff_animal_vet-progs_fin-dec-2015_diseases_7437-2014.pdf

- The objectives and expected outcomes are further explained in Commission Guidelines for the Union co-funded programmes of eradication, control and surveillance of animal diseases and zoonoses for the years 2015-2017(Working Document SANCO/10181 Rev2) available here: https://ec.europa.eu/food/sites/food/files/safety/docs/cff_animal_vet-progs_wd-10181-2014-rev2.pdf

- The financial contributions for rabies eradication in 2016 are set in a Grant Decision approving national programmes. This information is outlined in points A.10(3) and B.2. in Working Document SANTE/12114/2015 rev 2 "Outcome of the evaluation procedure of eradication, control and surveillance programmes submitted by Member States for Union financial contributions for 2016 and following years: final list of the programmes selected and final amount allocated to each programme" https://ec.europa.eu/food/sites/food/files/safety/docs/cff_animal_vet-progs_working_doc_12114_rev2_2016.pdf

- **SANTE Guidelines:** Guidelines to design an EU co-financed programme on eradication and control of rabies (SANTE/10201/2015rev1), published here: https://ec.europa.eu/food/sites/food/files/safety/docs/cff_animal_vet-progs_guidance_rabies.pdf

- In January 2015, the Commission informed Member States with approved rabies eradication programmes that from 2015 the competent authority implementing co-financed rabies vaccination must:
    - require for the contractor for aerial distribution to use a system that electronically records the geographical position of release for each bait, and to deliver the data to the authorities on a daily basis, together with the flight tracks recorded during distribution (In case the territory covered in Member State or third country is smaller than 20,000 square kilometres per campaign the daily control of flight tracks was considered sufficient);
    - analyse the data and verify the sufficient dispersal of baits in all the appropriate areas;
    - include the conclusion of the analysis by the Member State's competent authority of the flight track data and, if relevant, of the bait dropping data in the intermediate and final reports submitted to the Commission
    - include in the reports the corresponding data files (flight tracks and dropping data) for each campaign for targeted and random control carried out by the Commission;
    - ensure, where relevant, that quality controls on rabies vaccine baits (maintenance of the cold chain and at least virus titre testing of each batch) are carried out by competent authorities also for the part of an approved programme that is implemented in a non-EU country.

Scientific reports and international standards

- **The 2002 Scientific Report**
  The oral vaccination of foxes against rabies. Report of the Scientific Committee on Animal Health and Animal Welfare of the European Commission. Adopted on 23 October 2002.

- **The 2010 Scientific Report**
  Cliquet F, Freuling C, Smreczak M, Van der Poel WHM, Horton D, Fooks AR, Robardet E, Picard-Meyer E, Müller T., 2010. Development of harmonised schemes for monitoring and reporting of rabies in animals in the European Union. EFSA Supporting Publication 2010; 7(7):EN-67, 60 pp.
  http://www.efsa.europa.eu/en/supporting/pub/67e.htm
  This report comprises *inter alia* guidance for sampling of wild animal populations.

- **The 2013 WHO report**
  World Health Organisation (WHO) Expert Consultation on Rabies - second report. WHO technical report series No. 982. ISBN 978 92 4 069094 3 (PDF). Chapter 10 Prevention and control of rabies in wild animals.
  http://apps.who.int/iris/bitstream/10665/85346/1/9789240690943_eng.pdf?ua=1

- **The 2015 Scientific Report**

  EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), 2015. Scientific opinion – Update on oral vaccination of foxes and raccoon dogs against rabies. EFSA Journal 2015;13(7):4164, 70 pp.
  http://www.efsa.europa.eu/en/efsajournal/pub/4164

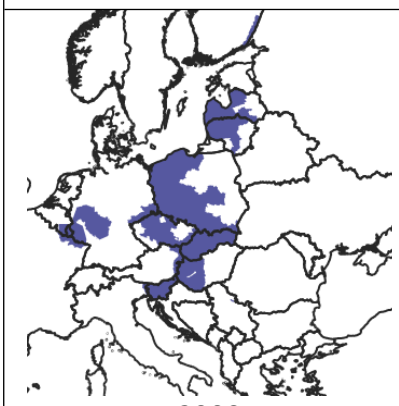
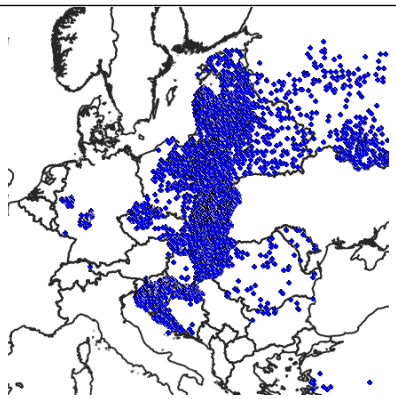
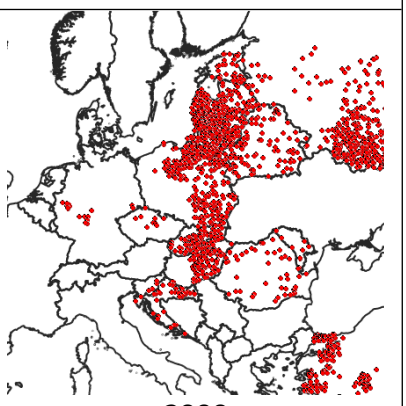
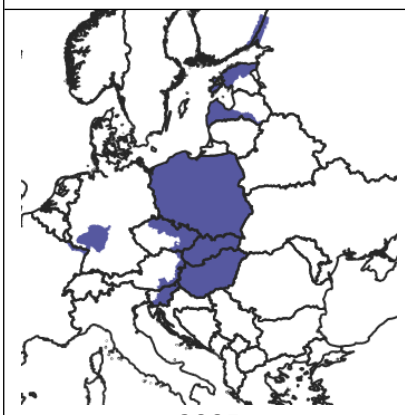
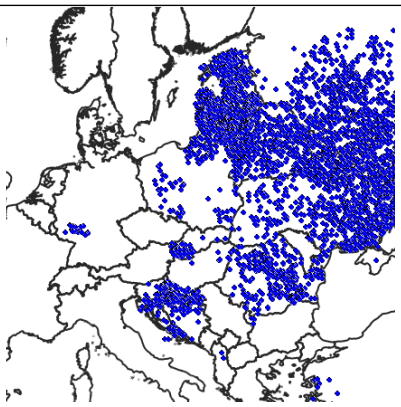
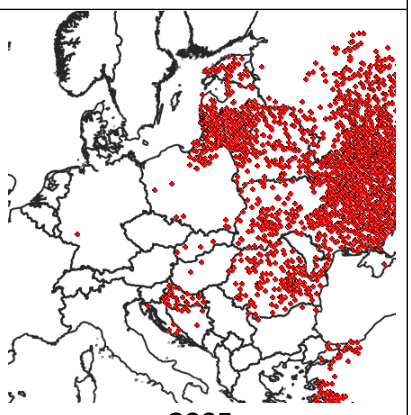
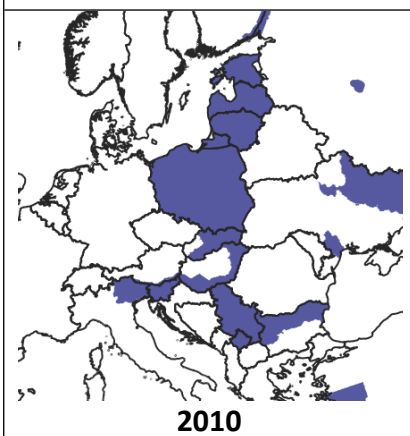
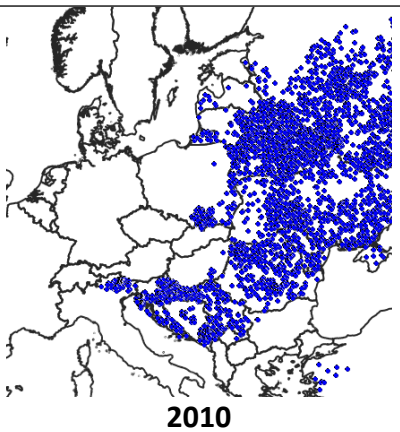
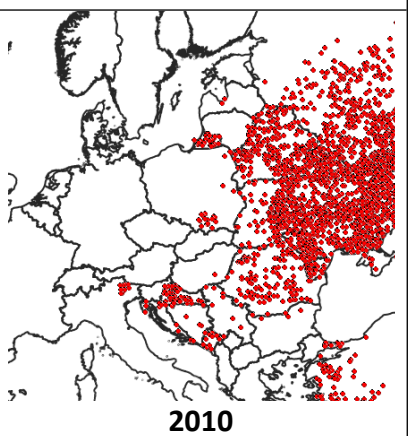
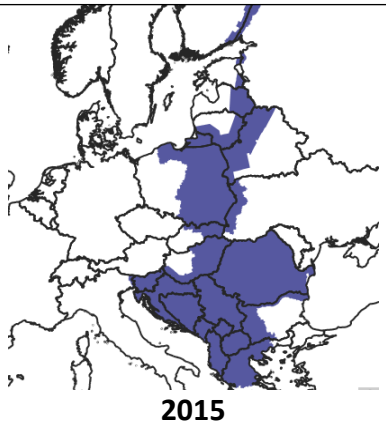
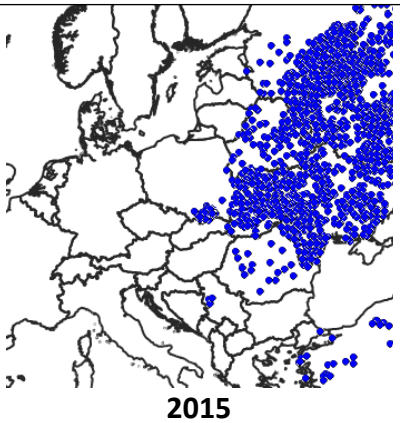
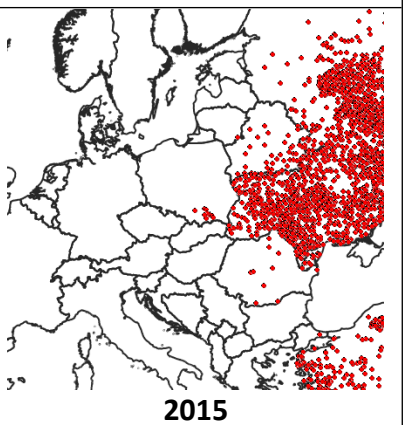
  In 2015 at the request of the European Commission, the Scientific Panel on Animal Health and Welfare of the European Food Safety Authority (EFSA) presented this scientific opinion which was an update of a report from 2002 by the Scientific Committee on Animal Health and Animal Welfare providing scientific guidance on oral vaccination of foxes against rabies.

- **World Organisation for Animal Health (OIE):**

  Terrestrial Animal Health Code (2016); Chapter 8.13 "Infection with rabies virus"
  http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_rabies.htm

  Manual of Diagnostic tests and Vaccines for Terrestrial Animals (2016); Chapter 2.1.17 "Rabies (infection with rabies virus)"
  http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/2.01.17_RABIES.pdf

ANNEX IV to overview report DG(SANTE)/2016-8980: Oral rabies vaccination areas and rabies cases in wildlife (except bats) and domestic animals 2000, 2005, 2010, and 2015.

Oral rabies vaccination	Rabies in wildlife	Rabies in domestic animals
 2000	 2000	 2000
 2005	 2005	 2005
 2010	 2010	 2010
 2015	 2015	 2015

Maps and data extracted from Rabies - Bulletin – Europe, Rabies Information System of the WHO Collaboration Centre for Rabies Surveillance and Research (http://www.who-rabies-bulletin.org/Queries/Default.Aspx)

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ABBREVIATIONS AND DEFINITIONS USED IN ANNEX V

Abbreviation	Explanation
ELISA	Enzyme-linked immunosorbent assay
EU	European Union
EUR	Euro
EURL	EU Reference Laboratory (for rabies)
FAT	Fluorescent antibody test
RFFIT	Rapid fluorescent focus inhibition test
ORV	Oral rabies vaccination

1 BACKGROUND

1.1 RABIES ERADICATION PROGRAMMES IN THE EU

1.1.1 Co-funding and audits of rabies eradication programmes

Ninety percent of the EU funding for rabies eradication is spent on oral vaccination (purchase and distribution), whilst the remainder is co-funding costs for sampling and testing in order to monitor and control the efficacy of vaccinations. In 2015, the EU co-funded ORV campaigns in Finland, Estonia, Latvia, Lithuania, Poland, Hungary, Romania, Bulgaria, Slovakia, Slovenia, Croatia, Italy, and Greece. For one of these Member States the financial contribution from the EU was 50% of the eligible costs, whilst financial contributions of 75% of the eligible costs were allocated to the other 12 Member States. The total financial contribution was not to exceed 25,236,000 EUR and a ceiling contribution was defined for each Member State.

Wild animals do not recognise national borders so rabies-infected animals wandering in from neighbouring non-EU countries make elimination of wildlife rabies more difficult close to EU borders with countries with wildlife rabies. In recent years, the EU has therefore funded ORV of wildlife in buffer zones on the territories of non-EU countries as part of approved Member State programmes. For 2015, five approved Member State programmes included ORV in buffer zones along EU borders, on the territories of the Russian Federation, Belarus and Ukraine. For these activities, the EU funded 100% of the eligible costs for purchase and distribution of ORV baits. From 2016, the EU can also co-finance the testing costs for monitoring samples, provided these tests are carried out in a Member State. The maximum financial contribution for these parts of the Member State programmes was not to exceed 4,677,000 EUR in 2015.

In addition, the EU is co-funding ORV programmes in six countries or territories in the Western Balkans through the EU Instrument for Pre-Accession Assistance.

Over the past fifteen years, the Commission services have carried out 23 audits and fact-finding missions evaluating the implementation of approved rabies eradication programmes. The audit reports have been published as described under section 2.

1.1.2 Geographical coverage of oral rabies vaccination and progress of eradication

Annex IV provides maps of rabies in wildlife and in domestic animals, as well as areas that were subject to ORV campaigns (not only financed by the EU) in the years 2000, 2005, 2010, and 2015.

Figure 1 provides a more detailed map over the approximate areas covered by ORV and the different sources of financing in 2015.

Figure 2 summarises rabies cases in foxes, raccoon dogs, other wildlife, and domestic animals reported to "Rabies - Bulletin – Europe"[1] from EU Member States in 2016. Among

the current 28 Member States, four reported cases of wildlife rabies in 2015, whilst 15 years earlier 13 of these countries experienced wildlife rabies. As the rabies cases in wildlife declined, so did the rabies cases in domestic animals. The total number of reported rabies cases in animals (excluding cases in bats and imported cases) dropped from 1552 cases in nine countries in 2010 to 128 cases in four countries in 2015.

Figure 1: ORV in 2015 in the EU and on the territories near EU borders in non-EU countries. IPA refers to Instrument for Pre-accession Assistance.

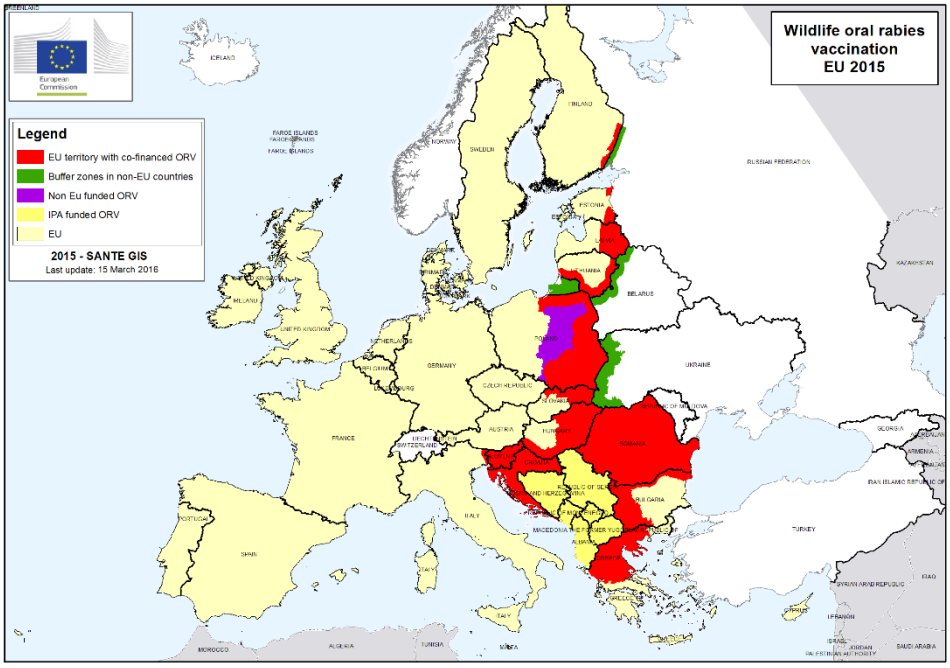
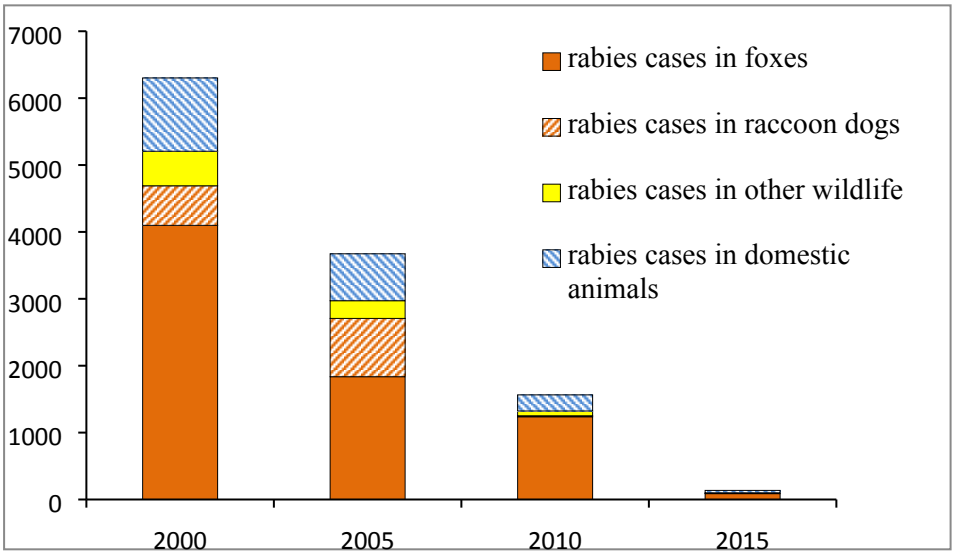


Figure 2: Rabies cases in the 28 current (2016) EU Member States



[1] Detailed data about rabies outbreaks and oral rabies vaccination are available on the website of "Rabies - Bulletin – Europe", Rabies Information System of the WHO Collaboration Centre for Rabies Surveillance and Research: http://www.who-rabies-bulletin.org/Queries/Default.Aspx

Additional information about rabies cases in humans and animals can be found in the annual EU summary reports on zoonoses, zoonotic agents and food-borne outbreaks, published here: http://www.efsa.europa.eu/en/publications. Please note that each report deals only with data from countries that were EU Member States during the reporting years, and Iceland, Norway and Switzerland, whereas Figure 2 above takes into account data from countries which were not yet EU Member States.

1.2 VACCINATING WILD ANIMALS AGAINST RABIES

The most important tool when eliminating rabies from wildlife populations in the EU is vaccination of foxes, which are the species considered to be reservoirs for rabies in the EU, and raccoon dogs, which are important rabies transmitters. A fox or raccoon dog gets vaccinated when ingesting rabies vaccine, packaged in a capsule hidden inside a tasty bait casing (together they are referred to as vaccine bait). The vaccine in the bait stimulates antibody production, leading to immunity, when it comes in contact with lymphatic tissues in the mouth and throat. The report from the World Health Organisation (WHO) second expert consultation on rabies in 2013 (hereafter referred to as the 2013 WHO Report) states that rabies vaccine baits are usually consumed within a week so the bait casing needs to protect the vaccine capsule for at least seven days under local weather conditions.

The descriptions in the following text will only mention foxes, although the same principles apply for raccoon dogs.

The 2002 Report "The oral vaccination of foxes against rabies" of the Scientific Committee on Animal Health and Animal Welfare (hereafter referred to as the 2002 Scientific Report, see Annex III), and the 2015 "Scientific opinion – Update on oral vaccination of foxes and raccoon dogs against rabies" by the Animal Health and Animal Welfare panel of the European Food Safety Authority (EFSA) (hereafter referred to as the 2015 Scientific Report, see Annex III), recommend that the virus titre is tested in all vaccine batches before and during vaccination campaigns. Different brands of ORV vaccine baits vary with regard to the required storage conditions, and resistance of the casing and vaccine to rainfall or high temperatures. If vaccine baits are distributed at sub-zero temperatures the vaccine capsule inside the casing may remain frozen until eaten, which can reduce the vaccination effect. ORV campaigns need to be carried out under climatic conditions that do not harm the type of vaccine baits chosen by the Member State.

Biannual ORV campaigns (spring and autumn) are applied in the EU to reach as many animals as possible, especially the cubs born each year in spring. ORV programmes stretch over several years. Once a large enough proportion of the fox population is protected through vaccination, rabies virus can no longer circulate. No EU-wide targets have been set for the sero-prevalence (proportion of animals with antibodies) fox population. The 2013 WHO Report states that "the level of herd immunity required varies with the transmission dynamics of the disease in particular target species and populations and with local conditions".

Vaccine baits are dropped at regular intervals from aircrafts, and sometimes distributed by hand in "no-fly" areas. The 2002 Scientific Report recommends densities of 18-20 and 20-30 vaccine baits per square kilometre for low and high fox densities, whilst the 2015 Scientific Report states that in routine ORV campaigns the bait density should not be less than 20 baits/ km^2. The reports recommend that the flight lines should be no more than 500 m apart in order to achieve an even distribution and reach as many foxes as possible. Higher bait density should be considered in areas with particularly large fox populations as well as for "emergency vaccination" in areas where rabies persists or has been reintroduced.

Competent authorities are expected to check during the ORV campaigns, that the bait distribution is as described in the approved programme. This is to be done by daily checks of electronic data on flight lines and bait drop locations recorded by devices installed in the aeroplanes. If incorrect bait distribution is spotted the authorities must take immediate action to correct it.

The rabies cases in wildlife are normally reduced dramatically already after a few years of ORV campaigns, but to finally eliminate wildlife rabies usually takes many years. In addition, ORV campaigns and careful rabies surveillance need to continue for at least two years after the last rabies cases were detected before a territory can be considered free from wildlife rabies.

The general principles for rabies control in wild animals are further described in Chapter 10 of the 2013 WHO report.

1.3 Evaluating the level of protection in a wild animal population

In 2005, the WHO published its first expert consultation on rabies. This report stated that a minimum of four target animals (foxes and raccoon dogs) per 100 km^2 should be investigated each year for contact with baits, vaccination status, and rabies incidence to monitor the efficacy of the oral vaccination programme. The same recommendation has since been repeated in several scientific studies and reports. The EU is co-funding test costs for up to four foxes/raccoon dogs per 100 km^2 in the vaccinated areas, and this number is set as a target in most of the approved rabies eradication plans.

1.3.1 Contact with baits

The palatable substances in the vaccine bait casing which covers the vaccine capsule are mixed with a marker substance. The rabies vaccine baits used in the EU contain tetracycline as the marker substance. This substance leaves a life-long trace line in bones and teeth, which can be detected in the laboratory microscope as a fluorescent signal on the cut surface of a tooth or jaw bone. The age of the fox can be determined on the same sample. Following training and repeated inter-laboratory comparisons organised by the EU reference laboratory (EURL) for rabies most national reference laboratories can reliably carry out the tetracycline test while some have problems determining the age of the youngest foxes. Detection of tetracycline traces in teeth or bone indicates that the animal has licked or chewed vaccine baits (bait contact). Although evidence that the animal has been in contact with baits is no

proof of vaccination, such information is useful for checking if the bait distribution system has managed to reach the target wildlife population. Since tetracycline traces remain for life the bait contact could have happened years ago in older animals. If the ages of the tested animals is determined, which can be done on the same jaw samples, it is possible to see if tetracycline is detected also in young animals, which would verify that the most recent vaccination campaign(s) have reached their target populations.

1.3.2 Vaccination status

In order to demonstrate that an animal has actually been vaccinated against rabies (by ingesting the vaccine inside the bait) antibodies to rabies virus must be detected in serum or body fluids. Very few animals are expected to survive rabies long enough to produce antibodies, so antibodies indicate that the animal has been vaccinated. Publications of epidemiological modelling and case studies suggest that if 60-70% of the foxes in an area are protected following vaccination it might be possible to eliminate rabies from foxes within a few years. If a smaller proportion of the foxes develop immunity after ORV campaigns, more campaigns are normally needed before rabies is eliminated. Different detection methods for antibodies do not always give the same results for the same sample, so such test results only provide a rough estimate of the population immunity. There are examples where wildlife rabies has been eliminated rapidly even when the test results indicated that only a limited proportion of the foxes had detectable antibodies.

Different laboratory methods can be used to detect antibodies against rabies virus. Certain methods, referred to as virus neutralisation tests (e.g. the fluorescent antibody virus neutralisation (FAVN) test, and rapid fluorescent focus inhibition test (RFFIT)) make use of cell cultures and live rabies virus, which requires highly trained staff and laboratories that are designed to protect staff when handling live rabies virus.

Different types of enzyme-linked immunosorbent assay (ELISA) tests are commercially available for detection of antibodies to rabies virus. ELISA tests do not require live virus or cell cultures, are sometimes not as affected by poor quality samples, and are better suited for testing large numbers of samples. Virus neutralisation tests and ELISA do not necessarily give the same results since the methods are based on different principles, and differences between ELISA methods may also lead to different test results on the same sample.

The 2015 Scientific Report states that considering the different tests in use for the ORV programmes, and the different ELISAs that are commercially available with various levels of reliability, proficiency tests should be regularly organised with field samples received for monitoring in order to assess the performance (in terms of analytical specificity and sensitivity) of existing methods used in the laboratories.

1.3.3 Detection of rabies cases

Rabies cases can only be confirmed in laboratories, by demonstrating rabies virus in the brain and brain stem of infected animals. It is therefore not possible to test living animals for the presence of rabies virus.

There are several laboratory methods for detecting rabies virus in tissues from dead animals, as described in Chapter 2.1.17 of Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2016, of the World Organisation for Animal Health (OIE). The 2015 Scientific Report states that rabies surveillance should be based on laboratory tests, using standards prescribed by the OIE.

The EFSA supporting publication "Development of harmonised schemes for monitoring and reporting of rabies in animals in the European Union" (hereafter referred to as the 2010 Scientific Report, see Annex III) states that the best chance to find rabies cases in wild animals is by sampling and testing so called indicator animals. This means testing animals for rabies if i) humans might have been exposed (contact with animal saliva or blood), ii) the animals display abnormal behaviours which could be symptoms of rabies iii) the animals have been killed in traffic, or iv) the animals are found dead (in countries with rabies). This is often referred to as a passive surveillance programme. In parallel to the passive surveillance in wildlife, all domestic animals suspected of having rabies (or similar neurological diseases) should be tested for rabies. This applies also to domestic animals found dead during grazing in countries with rabies.

No standardised target sample numbers can be determined for passive surveillance, for obvious reasons. High public awareness to ensure that indicator animals are reported to the authorities and swift responses from the authorities to ensure these cases are tested for rabies are crucial factors for effective passive surveillance.

Healthy looking foxes are shot in ORV areas during hunting and tested for the purpose of monitoring bait uptake and antibodies (see 4.4.2). Although these animals are often tested also for rabies, the 2010 Scientific Report clearly states that these animals are not indicator animals and consequently rabies test results from these two categories must not be mixed when the effectiveness of an ORV programme is evaluated.

The 2010 and 2002 Scientific Reports recommend that rabies virus from all wildlife cases in areas where attenuated rabies virus vaccines (e.g. ORV vaccines) are used, should be typed in order to distinguish between vaccine strains and field rabies strains. Such analyses may also provide useful information about links between outbreaks.

1.3.4 Assessing the effectiveness of an oral rabies vaccination campaign

A reduction of the number of rabies cases is the most important sign that an ORV programme is effective - provided that passive surveillance is continuous, sufficient numbers of indicator animals are tested for rabies, and that these animals originate from all relevant geographical areas. The most important tool to reduce the number of rabies cases as quickly as possible is to carry out two correct ORV campaigns per year. Monitoring of all components of the ORV campaigns is necessary to verify that they were carried out correctly or to detect any shortcomings early so that corrections can be made immediately.

Monitoring bait contact through tetracycline detection is a good way to verify that bait distribution has reached the target animal population – provided that the results are correlated

to the age of the sampled animals and that sampling is representative and evenly distributed over the vaccinated areas.

Monitoring what proportion of the tested animals have antibodies to rabies virus can verify if the vaccine baits have induced protection in the target animal population – provided that the performance of the test method is known, results are correlated to the age of the sampled animals and that sampling is representative and evenly distributed over the vaccinated areas. Provided that the same test method is used for the whole country year after year, the results can be used to assess the progress of fox population immunity. Comparing antibody test results and tetracycline test results in the same animals can provide indications on the reliability of test results and indicate potential problems with vaccine quality under field conditions.

Section 3.2 of the Guidelines to design an EU co-financed programme on eradication and control of rabies (SANTE/10201/2015rev1), hereafter referred to as the SANTE Guidelines, (see Annex III), provides guidance on the necessary components of a system for epidemiological analyses of all data from a ORV programme and recommends that such analyses are carried out by epidemiological units with adequate expertise.

If measures for prevention of rabies are in place and no cases of rabies have been confirmed in the country during two years in spite of ongoing disease surveillance, and certain other conditions are met, a country may be considered as rabies free under the specific terms of Article 8.13.3 of Chapter 8.13 ("Infection with rabies virus") of the Terrestrial Animal Health Code of the World Animal Health Organisation (OIE, 10/6/2016).

2 OVERVIEW OF MAIN FINDINGS AND CONCLUSIONS

In addition to the descriptions that are provided in audit reports and reported to international organisations, the audited Member States regularly present the results from rabies eradication programmes to the Commission and the other Member States in the Standing Committee on Plants, Animals, Food and Feed; Section Animal Health & Welfare. The presentations can be found on the Commission website:

http://ec.europa.eu/food/animals/health/regulatory_committee/presentations_en.htm#20160913

2.1 PROCUREMENT, QUALITY CONTROL AND STORAGE

2.1.1 Procurement

The models for public procurement of ORV vaccine baits and aerial bait distribution differed among the Member States visited. However, all models included formal tender procedures, formal contracts, verification of the accompanying documents, and testing of the vaccine titres in each batch. Some contracts were signed at central level and covered both supply and distribution of vaccine baits for 3-4 year periods. Others were split between separate tenders/contracts for vaccine baits and distribution, sometimes handled by each regional

authority involved in the programme. The regional model had led to differences between regions with regard to tender specifications, timing of campaigns and vaccines used.

All Member States visited procured rabies vaccine baits (containing attenuated live rabies virus) that had been manufactured, tested and originally approved for release on the market in an EU Member State in accordance with EU and national rules, including the legally binding procedures stipulated in the European Pharmacopoeia monograph ("Rabies vaccine (live, oral) for foxes and raccoon dogs")[2].

2.1.2 Vaccine and bait quality

Whilst all Member States carried out titre tests on all batches to verify the virus content on arrival into storage, other tests schemes were limited (Table 1).

Table 1: Tests carried out to verify the vaccine titre in ORV baits

Vaccine titre tests:	Each batch on arrival	After storage, before ORV distribution	After 10 days exposure to environmental conditions during ORV distribution	Remaining in storage after ORV campaign
Member States (n=4)	All	1	1	1

Some Member States routinely started ORV campaigns before batch test results had been obtained. The authorities explained that, should test results be non-compliant, vaccination would be repeated where the non-compliant batch had been distributed. This would require renewed negotiations with vaccine suppliers and distributors, a delayed ORV campaign, and would lead to high additional costs. No such situations had occurred in the audited Member States.

2.1.3 Storage of vaccine baits

In all four Member States, the contractors for vaccine supply and/or aerial vaccine bait distribution were responsible for correct storage and transport of vaccine baits from delivery into the country until aerial distribution took place. The two brands of vaccine baits used by those Member States both require storage at temperatures no higher than -20°C. The competent authorities largely trusted the temperature control systems operated by the contractors, and official controls on storage conditions were often infrequent and sometimes poorly documented.

Vaccine baits remaining in the aircraft(s) at the end of one day's flights were sometimes brought back into the freezer to be used the following day. Officials stated that the baits would still be frozen when taken out of the aircraft but there were no documented checks to support these statements. A representative of one vaccine manufacturer stated that overnight storage in fridge temperature would be better than re-freezing if the vaccine baits were fully

[2] Available for purchase from the Council of Europe: https://www.edqm.eu/en/european-pharmacopoeia-8th-edition-1563.html

or partially thawed, but no specific instructions had been provided with the vaccine or by the competent authority.

Conclusions on procurement, quality control and storage

Although the detailed procedures vary between Member States, contracts with vaccine suppliers and distribution companies were signed following a public procurement process in all four Member States, in line with EU rules. However, one-year contracts, combined with national budgetary procedures out of the control of veterinary authorities, increase the risk that vaccination campaigns are missed or delayed to a suboptimal time of year, which is likely to slow down the elimination of wildlife rabies.

The weaknesses observed with regard to official controls on vaccine storage conditions show that Member States might place too high a level of trust in private operators to ensure that the vaccine baits are not damaged by inappropriate temperatures during storage or transport. When combined with a lack of titre testing at the end of the storage period, the competent authority is unable to verify the quality of the oral rabies vaccine baits distributed in the campaign.

Unless the minimum acceptable vaccine titres are verified, not only on arrival but also after storage, (EU co-funded) distribution costs and valuable time might be wasted on distribution of vaccine baits that fail to meet the minimum requirements and therefore might be less effective.

Good practices observed

When official controls reveal that bait storage temperatures have temporarily been too high additional vaccine titre tests are carried out on the batches to ensure that the vaccine quality has not been affected.

Centralised, multi-year procurement procedures for vaccine baits and bait distribution save time and resources and minimise the risk of unnecessary delays of vaccination campaigns.

The risk of distributing non-compliant vaccine baits is reduced through routine testing of vaccine titres in all batches at the end of the storage period but before aerial distribution.

Testing that the vaccine potency remains the same in the baits after exposure to the actual environmental conditions (for at least seven days) after aerial distribution provides the authorities with supporting evidence that the vaccine baits taken by the foxes were of a quality able to stimulate an immune response.

2.2 DISTRIBUTION OF VACCINE BAITS AND RELATED OFFICIAL CONTROLS

2.2.1 Implementation of ORV campaigns

Two of the four Member States had implemented two ORV campaigns each year in accordance with the approved rabies eradication programmes for 2010-2015. In the other Member States, complaints/appeals against tender procedures (sometimes at regional level), delays in awarding national budgetary means for the procurement of vaccine, and other administrative problems had sometimes delayed or prevented the implementation of ORV campaigns. When ORV took place, it generally covered the whole areas that had been defined in the approved programmes.

Table 2: The number of ORV campaigns actually implemented between 2010 and 2015. In the table, "2" indicates that both the spring and the autumn campaigns were implemented

	2010	**2011**	**2012**	**2013**	**2014**	**2015**
Bulgaria	Spring	Spring	2	2	2	2
Hungary	2	2	2	2	2	2
Poland	2	2	2	2	2	2
Romania	n/a	Spring	none	(2) *	Autumn	2

* incorrect distribution

2.2.2 Bait distribution and official controls

All four Member States had contracted private operators for the distribution of vaccine baits. The contracts specify *inter alia* storage conditions for vaccine baits, areas to be covered, the bait density to be achieved, the timing of campaigns, and when and how information should be provided to the competent authority. Most contracts included an obligation to inform the public about campaigns and warning them not to touch the baits. In some cases the competent authority issued such information and warnings.

In most of the Member States contracts were signed at central level with a single operator. A contract might include both vaccine bait supply and distribution, or only distribution while vaccine baits were procured separately by the competent authority. The contracted operators were responsible for both planning and implementing flight routes under the direct or indirect supervision of the competent authorities. One operator holding a contract with a central competent authority had subcontracted the practical implementation of storage, storage quality control, aerial distribution, and record keeping to other operators.

In one Member State contracts were drawn up and signed at regional levels, resulting in many different flight companies being involved in the distribution, each receiving instructions from a different regional authority, including timing and flight routes, and each regional authority procuring and supplying vaccine baits to their contracted flight operators.

The number of vaccine baits required, the total area to be covered, the distances between flight lines, and the density of baits are specified in the approved programmes. When settlements and water surfaces are excluded during implementation but not in the programme, the resulting bait density on land will be higher because all vaccine baits are usually distributed.

All Member States met or exceeded the recommended density of 20 vaccine baits/km^2 as recommended in the 2015 Scientific Report. In one case the competent authority and the contractor had agreed to rotate the flight lines by 90 degrees between campaigns to improve the geographical coverage. However, two Member States implemented flight lines that were 1000 metres apart, instead of 500 as recommended in the 2015 Scientific Report. Both these Member States had experienced increases in rabies cases or reintroduction of rabies in certain areas and had reacted by applying flight lines with 500 metres distance and densities of 30-66 vaccine baits/km^2 in these particular areas. Some Member States had increased the bait density in such areas of concern in the following campaign, whilst in one Member State no emergency measures were implemented when a similar, unexpected incursion was detected.

Not all competent authorities had systems in place, or appropriate equipment and competence to record and analyse electronic flight and bait drop data through global positioning systems (GPS) on a daily basis. This requirement was introduced by the Commission during this audit series. Where such systems had been (recently) introduced none of the competent authorities managed to analyse data on a daily basis, to achieve effective supervision during the campaign, due to weaknesses in technical equipment and limited practical experience. Consequently, incorrect distribution was sometimes only detected when the files were submitted to the Commission after the campaign.

The level of official control and supervision over aerial vaccine bait distribution varied widely among Member States:

- *from* full delegation of routing and day-to-day planning to the contracted operator, *to* detailed flight routes provided to the contractor by the competent authority.
- *from* one announced official visit at the airfield for each campaign, *to* official veterinarians being present and keeping detailed records at the airfield every day during the campaign.
- *from* electronic records made available to the competent authority weeks after the end of the campaign, *to* electronic records of flight lines and bait drops provided to the competent authority daily.
- *from* competent authority checks on electronic distribution data only after the end of the distribution campaign, *to* detection of incorrect flight lines within 24 hours and immediate corrective actions by the competent authority.

Only a small proportion of the vaccine baits are distributed by hand, either by official staff or by contracted/subcontracted persons with knowledge about fox habitats. The sites for manual spread are agreed with the competent authorities who also receive reports of the (approximate) bait locations after the campaigns. Vaccine baits are distributed manually in

areas where aerial distribution is impossible (e.g. no-fly zones around power plants and certain industrial sites) and in green areas close to settlements if these are known fox habitats or sometimes if rabies has been detected in the vicinity.

Conclusions on distribution of vaccine baits and related official controls

It had been more complicated for the competent authorities to establish systems for daily checks of electronic data, over flight lines and bait drop locations, than expected by the Commission. Therefore the day-to-day verification of proper vaccine bait distribution via electronic files was not effective at the time of these audits.

Some Member States have sufficient controls on the flight lines to take corrective action during the campaign. However, where the contracted operators are given the full responsibility for planning and implementing the aerial distribution of vaccine baits and official controls of flight and bait drop data are carried out only after the end of a campaign, any deficiencies in the distribution are detected too late for the competent authority to initiate timely corrective actions. Should corrective actions be necessary, i.e. redistribution of baits over certain areas, such actions are likely to be severely delayed due to a need to re-negotiate contracts for vaccine baits and distribution.

Good practices observed

Procedures in place for additional emergency vaccination in areas where unexpected incursions of rabies is detected, as well as for implementation of higher bait density in that area in the following campaign.

Flight lines turned 90 degrees between campaigns to improve the geographical coverage.

Timely official controls of flight lines make it possible for the competent authority to order corrective actions by operators (where necessary) within 24 hours.

2.3 MONITORING OF BAIT CONTACT AND FOX POPULATION IMMUNITY

2.3.1 Sampling of foxes for the monitoring programme

Two Member States routinely met the sampling target of 4 foxes /100 km^2 in the vaccinated territory, and had little variation between regions. In both cases, sampling was actively monitored; time was spent on information campaigns and meetings with hunters and in one of these Member States hunters were legally obliged to carry out sampling ordered by the competent authority.

Two Member States did not check the progress of sampling during the year from central level, and under-implementation was regularly noticed at the end of the sampling year. In one of these, a legal obligation for hunters to collect samples was introduced recently and was followed by a marked increase in sample numbers. In these two Member States there was a marked difference in implementation between regions, which had not been addressed by the

competent authorities. That regional office had staff with knowledge and interest in both hunting and rabies eradication and had established good cooperation with the local hunters and managed to meet the regional sampling target, whilst other regions collected no or very few samples.

Plans issued by the competent authorities for sampling to monitor bait uptake and population immunity (the proportion of foxes that have detectable antibodies to rabies virus) usually envisage sampling during three-four months starting one month after the end of each ORV campaign. Limited sampling takes place between the spring and the autumn campaigns, as the summer is not the normal fox hunting season, so in reality most of the samples for the monitoring are collected between November and March. Hunters who provide samples receive a fixed compensation per animal, as specified in the approved eradication programmes. The local competent authorities play an important role in the programmes. They, sometimes in cooperation with the contractor for aerial distribution, are usually responsible for issuing sampling instructions and sampling equipment, for direct contact with the hunters, for receiving samples or foxes, for sending samples to laboratories, and for monitoring the progress of sampling.

In two Member States the age of a shot fox was determined by the hunter through visual inspection, whilst the age of foxes was determined in laboratories by examining sections of teeth in the other two Member States. Hunters sometimes received different instructions in different regions, on whether or not young foxes should be included, and how/if the age of the animals should be assessed and documented in the field.

Where the whole fox carcase was brought in to veterinary authorities or laboratories for sampling, serum or body fluids could be safely extracted for antibody testing from most of the animals. However, where hunters were required to bring only the heads and blood samples from shot foxes to the sample collection points, blood samples were not taken from many foxes and the sample quality was often poor. In some cases, hunters were used to collecting fox heads for rabies surveillance, and continued to do so, but did not want to handle the animals further for blood sampling. In those situations, very few samples were analysed for antibodies to rabies virus.

2.3.2 Vaccine bait contact and fox population immunity

Most of the foxes collected for the monitoring programme are tested for vaccine bait contact, whilst fewer are tested for antibodies to rabies virus. Tables 3 and 4 describe national monitoring results for 2013, 2014 and 2015, based on data in the annual presentations made by Member States in the Standing Committee on Plants, Animals, Food and Feed[3]. In 2015, the two Member States which failed to reach the target numbers for the monitoring programme at the time of the audits reported marked improvements compared to the data for 2013 and 2014. Table 3 shows how the Member States have reached the overall sampling

[3] The presentations by the audited Member States of the results from rabies eradication can be found on the Commission website:
http://ec.europa.eu/food/animals/health/regulatory_committee/presentations_en.htm#20160913

targets in recent years and the colours (red, amber and green) indicate how close the sample numbers are to the target figure. Although the audits showed that the sampling sometimes varied substantially between different geographical areas within a Member State, the representativeness of the sampling, e.g. spatial distribution and age distribution, has not been factored into the colour coding.

Table 3: National data reported to the Commission for the years 2013, 2014 and 2015.

	Monitoring: foxes /100 km² in the vaccination zone (target=4)		
	2013	**2014**	**2015**
Bulgaria	0.43 foxes 0.25 golden jackals	0.28 foxes 0.1 golden jackals	2.25 foxes 0.77 golden jackals
Hungary	4	4	>4
Poland	>4	>4	>4
Romania	1.6	2.5	3.9

Table 4 shows the results of the monitoring of bait contact and population immunity. This table shows national data. However, the audits showed that the proportions of foxes that had been in contact with baits and the proportions where antibodies were detected sometimes varied substantially between different geographical areas within a Member State. When two different methods were used during the same sampling year (Poland 2014), results of samples tested by ELISA indicated lower population immunity than the samples (50%) tested by RFFIT the same year and the year before, which is likely to be an effect of the choice of test method.

Table 4: National data reported to the Commission for the years 2013, 2014 and 2015.

	Bait contact (T= tested foxes) and % positive test results						**Antibodies to rabies virus (T=tested foxes) and % positive test results**					
	2013		**2014**		**2015**		**2013**		**2014**		**2015**	
	T	% +	T	% +	T	% +	T	% +	T	% +	T	% +
Bulgaria	253	**75**	753	**60**	1236	**65**	133	**41***	479	**37***	894	**43***
Hungary	1757	**71**	2510	**69**	2931	**75**	856	**25***	2085	**35***	2403	**44***
Poland	21547	**86**	16756	**88**	13284	**89**	17049	**75#**	6561 6383	**76#** **43***	10117	**54***

Romania	3196	**24**	5385	**55**	7482	**74**	2947	**22***	5048	**31***	6418	**28***

* analysed by ELISA; # analysed by RFFIT

Where sufficient data were available they showed, as expected, that the proportions of young (less than one year old) foxes that had been in contact with baits and developed antibodies were lower than those seen in older animals.

2.3.3 Other wildlife species included in the monitoring

The approved vaccination and monitoring programmes focus on foxes. Although inclusion of raccoon dogs in the monitoring is allowed very few, if any, raccoon dogs had been tested in these four Member States. Rabies has been detected in raccoon dogs in Poland and Romania, and in three other Member States that are not included in this overview report.

Member States have expressed concern about an observed increase in numbers and geographical distribution of golden jackals and the effect these animals could potentially have on competition about vaccine baits and spread of rabies. A limited number of golden jackals have been tested for tetracycline and antibodies to rabies virus in Bulgaria. Results from 2013, 2014 and 2015 indicated bait uptake at the same level as in foxes but a substantially lower sero-prevalence than in foxes.

Conclusions on monitoring of bait contact and fox population immunity

Without active interventions and supervision from central level, the monitoring programme does not always receive high priority by regional offices or hunting associations, This may lead to under-implementation of the sampling, patchy sample distribution, and sometimes incorrect sampling, which are all factors that reduce the reliability of the monitoring results The clustered sampling during winter months is not likely to have a negative effect on the ability of competent authorities to assess the progress of the rabies elimination, provided that the age determination of the foxes is reliable.

Most monitoring samples are tested for tetracycline using a standardised test method and provide comparable data to verify bait uptake and distribution over time. However, tetracycline remains in the teeth so only data that can be linked to young foxes will demonstrate bait uptake specifically from the most recent campaigns. The lack of reliable age data in some Member States makes it difficult for the competent authorities to assess the effectiveness of the ORV campaigns.

The proportion of monitoring samples tested for antibodies generally improved between 2013 and 2014, although sample quality remains problematic. When Member States fail to achieve representative geographical sample distributions the results from antibody testing do not provide sufficient information to estimate population immunity. When laboratories use different antibody tests methods and test different matrices, the estimates of population immunity may be suitable for monitoring progress and differences within the country but are unsuitable for comparisons between Member States. Furthermore, if test methods vary among

regional laboratories it is difficult for the central authority to monitor the effectiveness of vaccination within the country.

Good practices observed

Instructions to hunters to assist veterinary services – which they are obliged to do under national law. This facilitates representative sampling and reaching target numbers.

The whole fox carcass is brought to local veterinary services/laboratories, where official veterinarians are responsible for extracting and preparing appropriate samples and for submitting these to the analysing laboratory. This increases the number of samples, particularly for antibody testing, and reduces the proportion of poor quality samples submitted for analysis.

Effective monitoring of sampling and sample distribution during the year, which makes it possible, where necessary, for authorities to take timely corrective actions to increase or adjust the sampling in order to reach the targets in the plan.

2.4 RABIES SURVEILLANCE

2.4.1 Animals tested for rabies

All Member States had well-functioning systems in place for investigations of rabies suspect animals among domestic animals and for immediately informing human health authorities at local level of the suspicion. However, the definition of a rabies suspect domestic animal varied among regions and between Member States. Rabies testing of domestic animals found dead on pastures was not always done, whilst in one region all stray dogs were considered as rabies risks and were therefore euthanized and rabies tested.

Passive surveillance in wild animals depends on the ability of competent authorities to engage hunters, farmers and other persons spending time in fox habitats in the surveillance. In spite of regular awareness campaigns, this is particularly problematic in countries or regions with few or no rabies cases in recent years, and in areas outside the ORV zones. In one Member State, public awareness and the number of foxes submitted under the passive surveillance increased substantially when rabies reoccurred in the country.

Whilst some Member States have good passive surveillance programmes and receive high numbers of wild target animals for rabies testing other Member States receive very few wild animals for rabies testing under the passive surveillance programme, unless they have been killed due to aggressive or abnormal behaviour close to humans or domestic animals. Rabies test results from animals found dead or killed by cars are rare in these Member States, but this may also be a consequence of imprecise report data supplied from hunters to laboratories or incomplete case records provided to the competent authorities.

Almost all foxes shot for monitoring purposes (see 2.3.1.) are tested for rabies virus before any testing starts for tetracycline and antibodies. Although these foxes are not indicator animals (the preferred population for rabies surveillance) rabies cases are sometimes found among them. In one Member State with weak passive surveillance in wild animals, two out of the three rabies positive foxes identified in recent years were found in the monitoring programme.

2.4.2 Measures when rabies has been detected in wildlife

All Member States had varying routines in place for situations where rabies cases were identified in or near humans or domestic animals. Such measures could include a census of all susceptible domestic animals, movement restrictions, epidemiological investigations, vaccinations of livestock and pets, culling of in-contact unvaccinated animals, and isolation of in-contact vaccinated animals. Sometimes manual bait distribution took place around villages close to wildlife rabies cases.

Member States applied very different measures regarding wildlife when rabies cases in wildlife were detected in a previously "rabies free" area. Whilst one Member State ordered immediate active rabies surveillance through hunting and testing in the area in order to establish the extent of the rabies incursion, another Member State took measures to protect humans and domestic animals but did not carry out any active wildlife rabies surveillance in the area where a rabid fox had been detected.

Conclusions on rabies surveillance

Although symptomatic wild and domestic animals are identified and submitted for rabies testing, passive surveillance of other indicator animals is sometimes weak, in particular when rabies is no longer considered a real risk due to successful ORV campaigns. This illustrates the challenges of maintaining the necessary vigilance through stakeholder involvement and awareness, while reassuring the public that the fox vaccination campaigns are successful.

The lack of active surveillance when wildlife rabies has been detected in a previously "rabies free" area may lead to a failure to identify a "hot spot" with multiple rabies cases and give a false sense of security. This may lead to a failure to take an informed decision on implementing an emergency ORV campaign before the next planned campaign, or lead to emergency ORV being implemented on too small an area. In both cases, further spread of rabies in the local wildlife population will be facilitated.

In the absence of effective passive surveillance on the whole territory of the Member State, testing of foxes shot under the monitoring programme increases the chances of detecting rabies cases. However, rabies test results from the vaccination monitoring programme are not sufficient to confirm the absence of rabies under OIE standards.

Good practices observed

Increased local hunting and rabies testing of all shot foxes when rabies in wildlife is detected in a previously "rabies-free" area. This helps determine the extent of the rabies incursion and facilitates informed decisions on emergency vaccination.

2.5 LABORATORIES

2.5.1 Laboratory network

Detailed assessments of the capabilities of testing laboratories were not included in this audit series. Diagnostic and monitoring tests are sometimes carried out in numerous regional or local laboratories and sometimes only in one central laboratory. Most of the laboratories involved in testing samples for rabies diagnosis and monitoring of ORV were accredited. Whilst test methods for rabies diagnosis, such as fluorescent antibody test (FAT), were included in the scopes of accreditation in the vast majority of the testing laboratories, the methods for antibody detection and tetracycline detection were not always included in the scopes.

Sampling procedures and laboratory test procedures for detection of rabies virus are well established in countries where rabies is a current or recent problem and results are produced promptly, particularly when there has been human exposure. The laboratories in the four Member States all primarily used FAT, which is fast and can provide a reliable diagnosis of rabies in 98-100% of cases according to the OIE manual. This method is referred to as the "gold standard" for rabies diagnosis. Other complementary test methods were often available and were used particularly for cases where there had been human exposure and the FAT test was negative.

The test methods used for detection of antibodies to rabies virus were presented in Table 4. Different test methods are used among, and sometimes within, Member States. According to published product specifications, the different ELISA methods used by the laboratories apply different cut-off levels of antibodies to determine if the result is positive or negative. In addition, results from RFFIT and ELISA methods are not directly comparable. In two Member States the majority of samples for antibody detection were tested by laboratories where the relevant methods were not included in the scopes of accreditation.

Tests for tetracycline in teeth/bone and age determination of foxes are routinely carried out using methods which have been described and evaluated by the EURL.

2.5.2 The role of the national reference laboratory

The EURL regularly organises inter-laboratory comparative tests for national reference laboratories on rabies diagnosis (including FAT). It has also organised three tests on tetracycline and age determination in tooth samples from foxes and one for titration of live rabies virus (in vaccine). The evaluation of test results is shared with all national reference laboratories at the annual meetings and in evaluation reports for each round of tests. The national reference laboratories presented mostly satisfactory results from inter-laboratory

tests, although one had not yet participated in any inter-laboratory test for tetracycline and age determination at the time of the audit.

Neither the EURL nor any of the national reference laboratories have organised any inter-laboratory comparative tests for antibody detection in wildlife samples[4].

Tests related to the assessment of vaccine titres once the vaccine baits have been purchased are sometimes carried out by other national institutes, not linked to the national reference laboratory. In such cases the Member State laboratories had either not participated in the inter-laboratory comparative test organised by the EURL in 2011 or not submitted the results to the EURL. In the latter case, the results had been unsatisfactory but the laboratory had not requested any assistance from the EURL or taken other documented actions to improve the test method.

When several laboratories were involved, national reference laboratories had organised inter-laboratory comparative tests for rabies diagnosis. In one Member State the national reference laboratory trained all technical staff involved in regional laboratories and approved method validations before the laboratory could take part in testing under the rabies eradication programme. In the Member State where also antibody and tetracycline tests were carried out in several laboratories, annual inter-laboratory tests had been organised by one of the regional laboratories, but participation was not mandatory and the national reference laboratory had neither participated nor been informed of the results.

In addition to testing samples, two national reference laboratories were actively involved in the annual planning of the ORV campaign. One of these laboratories had the main responsibility for monitoring the sampling during the year and held monthly meetings with the responsible local authorities. Another national reference laboratory monitored the sample submissions against the annual plan but these data remained in the laboratory and were not used by the central authority, even though no other verification took place during the year.

Rabies virus from animals diagnosed with rabies were typed to check if the cases had been caused by the rabies virus included in the ORV vaccine or by wild type rabies virus. No indications of vaccine-type virus had been found in the four Member States. However, where typing methods were not available in the national reference laboratory there was a substantial delay in submitting samples to a laboratory in another Member State. If the tests had revealed spread of a vaccine virus, further investigations and actions to prevent spread would have been severely delayed.

Conclusions on laboratories

All testing laboratories use relevant methods for rabies diagnosis and for monitoring of bait uptake and antibodies. Methods to diagnose rabies are mostly included in the scope of accreditation and the reliability of test results for rabies diagnosis, tetracycline detection, and age determination in national reference laboratories can be further verified by competent

[4] The first inter-laboratory comparative test for detection of antibodies to rabies virus in sera from foxes was organised by the EURL during the winter 2016/2017.

authorities through the results from regular inter-laboratory comparative tests organised and evaluated by the EURL. However, the failure to submit virus from all rabies cases for typing reduces the chances for early detection of potential problems with the attenuation of the virus strain in a vaccine.

The reliability of test results for antibody detection is more difficult for the competent authority and the EURL to assess due to the lack of inter-laboratory comparative tests, especially when methods are not included in the scope of accreditation in the laboratory.

Good practices observed

Laboratory technicians in regional laboratories receive training in the national reference laboratory, and the relevant method validation files from the control laboratories must be approved by the national reference laboratory, before a control laboratory could take part in testing under the rabies eradication programme. These procedures support harmonisation of test methods.

The national reference laboratory organises regular inter-laboratory comparative tests for rabies diagnosis for control laboratories, which makes it possible for the authorities to verify the reliability of diagnostic tests for rabies virus.

2.6 ANALYSIS OF THE EFFECTIVENESS AND PROGRESS OF RABIES ERADICATION

Comprehensive epidemiological analyses, as recommended in the SANTE Guidelines, had not been carried out in any of the four Member States at the time of the audits. However, one Member State had collated data from different sources, broken down to hunting area level in preparation for an epidemiological evaluation of the effectiveness of implemented emergency measures.

Most competent authorities carried out analyses of the progress of rabies eradication in the units responsible for planning and reporting to the Commission, without specialised epidemiological experts and analytical tools. Through such evaluations, two competent authorities had noted regional differences in monitoring results and had issued improved sampling instructions, which addressed problems regarding fox age distribution and sample storage in certain areas. One of these Member States assessed the implementation using hunting grounds as the smallest area, in addition to the much larger regions.

In the other two Member States there was little evidence that regional differences in monitoring results had been analysed by the competent authorities to find possible reasons for these differences and take corrective action. One of the latter Member States subsequently initiated monthly supervision of sampling and test results during 2015. An evaluation report, based on epidemiological spatial mapping tools, was submitted to the Commission in response to a recommendation in the audit report. The evaluation report demonstrated under-implementation, identified gaps in sampling, showed major differences in test results and

passive surveillance among regions, and included a list of improvements to be implemented by the competent authority.

In some Member States, results from monitoring and rabies surveillance are summarized at the end of the year without being broken down by local areas such as hunting grounds. In such cases clustered sampling is not spotted by the central competent authority and no assessment can be made of the representativeness of the test results.

The annual summaries presented by Member States to the Standing Committee on Plants, Animals, Food and Feed; Section Animal Health & Welfare, do not show if there has been clustered sampling. Nor do they always show if there have been major differences in monitoring results between regions or if the competent authority has linked such differences to difficulties in rabies eradication.

Conclusion on analysis of the effectiveness and progress of rabies eradication

When most of the monitoring results are obtained from very few locations within the vaccination zone the results are not representative enough for an assessment of the overall effectiveness of the ORV campaigns.

Systems for specialised epidemiological analyses, as recommended in the SANTE Guidelines were not in place in the Member States at the time of the audits. The lack of analyses by epidemiological experts in Member States of the representativeness of test results and of the effectiveness of the ORV campaigns, makes it difficult for the Commission to assess if the rabies eradication programmes are effective and efficient.

Clustered or limited sampling is sometimes repeated year after year, often combined with a lack of antibody tests from many of the sampled animals. This makes it difficult for the Member State and the Commission to evaluate in detail the effectiveness of the ORV, undermines informed decisions on extending or decreasing the vaccination zone, and may result in inadequate data collection for eventually declaring freedom from rabies at the end of the eradication programme.

Good practices observed

Breakdown of surveillance and monitoring data by hunting ground to form the basis for specialised epidemiological analyses.

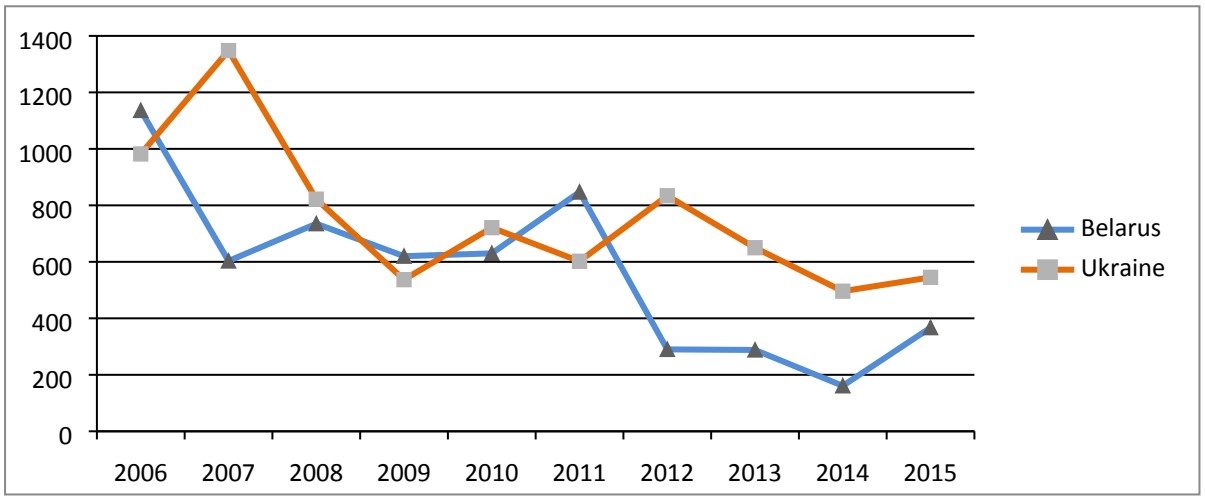
An assessment of rabies surveillance and monitoring results using basic epidemiological mapping tools can reveal spatial gaps in sampling and test results and identify priority areas for improvements regarding monitoring and surveillance in subsequent years.

2.7 ORAL RABIES VACCINATION PROGRAMMES IN NON-EU COUNTRIES

2.7.1 Planning and implementation of ORV campaigns in non-EU countries

Figure 3 illustrates the cases of wildlife rabies in the past ten years, as reported by Ukraine to "Rabies - Bulletin – Europe", and as presented by Belarus to the Commission team during the fact finding visit. Both countries have implemented local or regional ORV programmes in the past, but not with the aim of systematically eliminating wildlife rabies from their territories.

Figure 3: Rabies cases in wildlife in Belarus and Ukraine (whole territory)



EU co-financed ORV programmes have been in place in Belarus since 2011 and in Ukraine since 2012. The aim is to create a buffer zone on the eastern side of EU borders, where rabies cases in wildlife are kept at a minimum through regular ORV campaigns, in order to reduce the risk that rabies infected wild animals cross the borders into EU territory. Both countries have organised two ORV campaigns per year, except in 2015 when one country failed to implement the spring campaign. In 2010-2016 the EU financed ORV campaigns in the Kaliningrad region of the Russian Federation, which resulted in the eradication of rabies from this region.

The financial contributions to Ukraine and Belarus are based on eradication plans that are agreed with the relevant Member States and approved as part of their rabies eradication programmes. Once the financial decisions have been taken in the EU, formal contracts are drawn up between the non-EU country and the relevant Member States. These Member States are responsible for verifying the implementation of the ORV campaigns abroad before transferring the payment, and include reports from these ORV campaigns in their regular reports to the Commission. As illustrated in Table 3, Belarus and Ukraine each receive funding for their ORV programmes through two or three Member States. These Member States are each responsible for the ORV campaign in a specified geographical part of the buffer zones.

Table 3: Member States' rabies eradication programmes that include ORV campaigns in Belarus or Ukraine

Countries	Belarus	Ukraine
Latvia	yes	-
Lithuania	yes	-
Poland	Included in Polish programme, not yet implemented	yes
Hungary	-	yes

The formal procedures for signing contracts between Ukraine/Belarus and the relevant Member States are time-consuming. Recently, political and administrative changes in one of the non-EU countries had led to delays in signing the contracts with Member States and operators, resulting in the omission of the spring campaign. Ways of improving the situation for 2017 were discussed. No contract has been signed between Poland and Belarus, in spite of ORV in Belarus being part of the approved programme for Poland for several years. This leaves a substantial gap in the buffer zone on the territory of Belarus where no measures have been taken to reduce the risk of rabies incursion into the EU.

Although competent authorities in the two non-EU countries engage with the Commission and Member States, direct contacts between the relevant technical experts in Member States and their colleagues in Belarus and Ukraine are difficult due to administrative procedures and sometimes language barriers. During the fact-finding visits, technical experts from Member States met, sometimes for the first time, their colleagues in the non-EU countries and discussed, with the help of Commission interpreters, many practical aspects of planning, implementation, and reporting of the ORV programmes.

Vaccine bait procurement, ORV campaigns, and monitoring of vaccine bait contact and population immunity are carried out according to the same principles as in Member States. The vaccine baits are produced outside the EU. Comprehensive quality control results are required by both competent authorities, there are official controls on storage temperatures and titre tests are repeated before distribution. As in Member States, the results are sometimes not available until after the ORV campaign. Rabies surveillance is effective in both countries and the level of public awareness is high.

The competent authorities lacked sufficient data from the operators to verify that the vaccine baits had been distributed over the agreed areas and with the correct bait densities. Furthermore, electronic data collection for flight lines and vaccine bait drop locations, as required by the Commission from 2015, was not yet working.

2.7.2 Monitoring the effectiveness of ORV campaigns in non-EU countries

In Ukraine, the number of foxes sampled for monitoring met the targets in the approved plan. This was achieved through a requirement to submit all foxes shot by hunters for rabies testing. In the vaccination zone (involving three regions), all foxes that did not have rabies

were used for the monitoring of bait contact and population immunity until the total target number of samples had been met. There was substantial variation between regions. Overall, the monitoring results indicate that the proportions of foxes in contact with baits and vaccinated had increased year by year. In 2015, 52% of the tested foxes had been in contact with vaccine baits and 50% of the tested foxes had antibodies to rabies virus. However, the proportions of the sampled foxes that were tested for antibodies had decreased over the years and varied between regions, which reduced the representativeness of the results.

In Belarus, less than half of the target numbers of foxes were sampled and tested for bait contact each year. In 2015, 46% of the tested foxes had been in contact with vaccine baits and 39% of the tested foxes had antibodies to rabies virus. However, only a small fraction of the sampled foxes had been tested for antibodies, which prevents a reliable assessment of the effectiveness of the recent ORV campaigns.

Results from surveillance and monitoring are submitted to the Member States. Each Member State receives data only for the part of the buffer zone included in their approved programme. The Member States forward these data to the Commission as part of the report for the national programme, without further epidemiological analysis. The fact that results are channelled through two Member States for each non-EU country makes it complicated to obtain an overview of the implementation, effectiveness and efficiency of the ORV programme in each country.

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