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Directorate F - Food and Veterinary Office

DG(SANTE) 2015-7623 - MR

FINAL REPORT OF AN AUDIT CARRIED OUT IN ROMANIA FROM 19 JANUARY 2015 TO 23 JANUARY 2015 IN ORDER TO EVALUATE THE IMPLEMENTATION OF THE RABIES ERADICATION PROGRAMME

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Romania carried out between 19 and 23 January 2015, as part of the FVO audit programme for 2015. The general objective of the audit was to evaluate whether, the programmes for eradication of rabies in Romania for the years 2013, 2014 and 2015 (the first month), approved by Commission Implementing Decisions 2012/761/EU, and 2013/722/EU, have been implemented effectively and if the competent authority has sufficient data to demonstrate that the rabies eradication is progressing according to the objectives of the programmes.

The audit included follow-up of actions taken by the competent authorities in response to the recommendations of the previous FVO audit report (DG(SANCO)2012-6392).

After the failure in implementation of 2013 programme, the programme for eradication of rabies in Romania in 2014 was not implemented as foreseen; only one out of two planned vaccination campaigns was carried out. The unexecuted spring campaign in 2014 represents a lost opportunity to maintain and further increase immunity in the population of foxes, and thereby unnecessary waste of some resources that have already been committed to vaccination of foxes in previous years. The new multiannual contract for supply and aerial distribution of rabies vaccine baits addresses this issue and provides an assurance of uninterrupted continuation of the eradication programme for the 2014-2017 period.

The adequate pre-distribution quality checks on vaccine batches in 2014 ensure the quality of the vaccine used. But certain weaknesses in the control practices, in particular regarding the maintenance of the cold chain for baits, still exist.

Both aerial and manual distributions of vaccine baits in the autumn campaign 2014 were well-organised and well supervised, therefore suitable to achieve the objectives of the programme.

Monitoring of the vaccine uptake and population immunity in 2013-2014 was inadequate. Improvement seen after the autumn campaign 2014 and at the beginning of 2015 should provide sufficient information to demonstrate that rabies eradication is progressing according to the objectives of the programmes. However current on-going supervision from central level is insufficient to ensure that the targets for sampling will be met in all counties.

The level of passive surveillance is poor in several counties and makes it difficult to reliably assess the true rabies epidemiological situation. In addition, the surveillance data collected lack a sufficient level of details to identify potential risks to the overall success of the eradication programme.

The public awareness of the risks and typical symptoms of rabies and the actions taken to control the risk of spread to humans and domestic animals are appropriate but the period of isolation of animals in contact which is too short. Only small proportion of known dogs was vaccinated against rabies in 2014/2015, increasing the risk of a higher incidence of rabies, particularly in the young dog population.

For monitoring and surveillance the laboratories provide reliable and timely results.

A superficial and insufficient analysis of the effectiveness and progress of the rabies

eradication is seriously compromised by the unrepresentative and poor quality data that are available to the CCA.

The report makes recommendations to the competent authorities aimed at addressing areas in which further improvements are required.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
CA	Competent Authority
CCA	Central Competent Authority
DG(SANCO)	Health and Consumers Directorate General
DG(SANTE)	Health and Food Safety Directorate General
EC	European Community
ELISA	Enzyme Linked Immuno-Sorbent Assay
EU	European Union
FVO	Food and Veterinary Office
FAT	Fluorescent antibody test
GPS	Global Positioning System
ISO	International Organisation for Standardisation
NRL	National Reference Laboratory
NSVFSA	National Sanitary Veterinary and Food Safety Authority

1 INTRODUCTION

This audit took place in Romania from 19 to 23 January 2015 and was undertaken as part of the planned audit programme of the Food and Veterinary Office (FVO). The audit team comprised two auditors from the FVO and one national expert from a Member State of the European Union (EU). The team was accompanied throughout the audit by representatives of the National Sanitary Veterinary and Food Safety Authority (NSVFSA) which is the Central Competent Authority (CCA) for the scope of this audit.

2 OBJECTIVES

The objective of the audit was to evaluate whether the programmes for eradication of rabies in Romania for the years 2013, 2014 and 2015 (the first month), approved by Commission Implementing Decisions 2012/761/EU and 2013/722/EU, have been implemented effectively and if the competent authority has sufficient data to demonstrate that rabies eradication is progressing according to the objectives of the programmes.

The scope of the audit covered relevant areas of the approved programmes, in particular, assessments of whether:

i) the quality controls on baits and bait storage and distribution are adequate;
ii) the distribution of baits (aerial and manual) is suitable to achieve the objectives;
iii) the monitoring of vaccine uptake and population immunity is adequate;
iv) the passive/active rabies surveillance is effective and used also to verify that no rabies cases have been caused by vaccine strains;
v) the laboratories are providing reliable and timely results;
vi) the Competent Authority (CA) has analysed the effectiveness and progress of the rabies eradication.

MEETINGS / VISITS		no.	COMMENTS
Competent Authorities	Central	1	Opening and closing meeting
	Regional	2	
Laboratories		3	National reference laboratory for rabies, two county laboratories
Hunting association premises		1	

3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation and, in particular:

- Article 45 of 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 and

- Article 37 of Regulation (EC) No 652/2014 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.

Annex I comprises a full list of EU legislation providing the audit criteria for this audit. The annex refers, where relevant, to the last amended version.

4 BACKGROUND

In addition to the legal requirements in EU legislation, the following scientific reports and European Commission documents provide guidance which is taken into account in the framework of this audit:

- At the request of the Commission, the Scientific Committee on Animal Health and Animal Welfare issued a report in 2002 (hereafter referred to as the 2002 Scientific Report) providing scientific guidance on the oral vaccination of foxes against rabies. This report is available here: http://ec.europa.eu/food/fs/sc/scah/out80_en.pdf.

- The scientific report "Development of harmonised schemes for monitoring and reporting of rabies in animals in the European Union", which was submitted to the European Food Safety Authority in 2010, comprises inter alia guidance for sampling of the wild animal population. This report has been published here: http://www.efsa.europa.eu/en/supporting/pub/67e.htm.

- Points 5 and 6 of the Annex to 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, set out the objectives and expected outcomes of national veterinary programmes from 2015 (C(2014)7437 final). These objectives and expected outcomes are further explained in Commission Guidelines for the European Union co-funded programmes of eradication, control and surveillance of animal diseases and zoonoses for the years 2015-2017 (Working Document SANCO/10181 Rev2). Both documents are available here: http://ec.europa.eu/food/animal/diseases/index_en.htm

From 1987, rabies cases in Romania have been notified to the Rabies Bulletin Europe. Between 1987 and 1999 between 23 and 77 rabies cases per year were reported, 44.60% of which were detected in wild animals. Between 2000 and 2014 the number of rabies cases reported increased and ranged from 95 up to 1089 (in 2008), 73.49% of which were detected in wild animals.
Prior to the accession to the EU, vaccination of foxes in Romania was organised on county basis with distribution of vaccine baits by hand in cooperation with the hunters' organisations. Rabies eradication programmes in Romania (with aerial distribution of vaccine baits) have been approved since 2007 by the European Commission. However, implementation of the rabies eradication plan in foxes started only in 2011. Two campaigns were carried out in 2011, in 16 out of the 41 counties of the country. No aerial distribution was carried out in 2012, due to a dispute between the CA and the contractor. The dispute was resolved early 2013 and both the spring and autumn campaigns were implemented. In 2014, a

new tender was organised, but due to the later finish of this tender (June 2014), instead of two campaigns only one, in autumn 2014, was carried out[1].

Table 1: Rabies cases (excluding cases in bats) and vaccination campaigns:

Animal species		2008	2009	2010	2011	2012	2013	2014
Wild animals	foxes	883	396	321	234	305	286	95
	other	23	12	17	10	13	18	7
Domestic animals	dogs	79	35	49	41	52	41	11
	cats	47	28	25	20	30	27	6
	other	57	44	57	37	57	62	42
Vaccination campaigns	spring				x*	only manual distribution of vaccine baits	x	
	autumn				x*		x	x

*(in 16 out of 41 Counties)

The previous FVO audit report (DG(SANCO)2012-6392) on rabies eradication is available on the European Commission website: http://ec.europa.eu/food/fvo/index_en.cfm. Six out of nine recommendations from that report remain open in the follow-up module of the Country Profile for Romania (DG(SANCO)2013-6842), which has been published here: http://ec.europa.eu/food/fvo/country_profiles/details.cfm?co_id=RO.

During the on-the-spot visit by the Commission services in October 2013 (when the campaign was on-going) the set-up, implementation and on-site official supervision of the aerial vaccination campaigns by the contractor were found unsatisfactory as vaccine was distributed only in the areas around the airfields and the automatic bait release machines were adjusted to drop baits at the maximum possible rate so that all the baits loaded on the aircraft were released over a very short time. This led to an extremely high density of vaccine in very limited areas of Romania, while the vast majority of the territory was not covered with vaccination at all. This resulted in upholding co-financing (Commission Implementing Decision of 27.10.2014 on a financial contribution from the Union for the expenditure incurred by Romania in 2013 for the financing of a programme for the eradication of rabies C(2014) 8172).

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

Legal requirements

[1] In their response to the draft report the CA noted that in 2014 they organized a new tender for the period 2014-2017. After the 2013 vaccination campaign, where certain deficiencies were detected, the CCA redesigned technical specifications for vaccination campaigns (requesting service provider to apply certain requirements that would not allow conducting the vaccination program in inappropriate conditions). Therefore and due to the fact that a new procurement procedure for such a complex program takes at least 90 days to be completed (if there is no appeal), procedure for awarding the contract ended in June 2014 and the campaign in spring 2014 was not carried out due to inappropriate temperature conditions.

Articles 3 to 8 of Regulation No 882/2004.

Findings

1. The national legislation in place provides the CA with sufficient competencies and powers to implement the programme for eradication of rabies:

- Government Decision No 55/2008 amended by Government Decision No 751/2012 approves and provides funding for the strategic programme for the supervision, control and eradication of rabies in foxes. It provides the CCA with the legal power to fully implement the programme for eradication of rabies approved by the European Commission, enabling vaccination in all 41 counties. The amendment mentioned gives flexibility for the dates of the vaccination campaign.
- By Order No 359 dated of 7 May 2014, the CA has for the first time a power to enforce the sampling carried out by the hunters under the monitoring of the efficacy of a vaccination campaign in foxes.
- Service note No 28702 dated of 02.10.2014 includes specifications for both manual and aerial distribution of vaccine baits. This Service note lays down the specific tasks and responsibilities of different CAs, as well as laboratories and institutes involved.

2. In line with Article 4 of Regulation (EC) No 882/2004, there are designated CAs for all the task related to the rabies eradication programme:

- The NSVFSA is the CCA. It draws up the programme, assures funds for its implementation and it is responsible for the supervision and coordination of the activities of other bodies involved. Following a tender procedure (finished in June 2014), the CCA signed a four-year contract for the 2014-2017 period with a vaccine consortium for supply and aerial distribution of rabies vaccine baits.
- Forty-two County Sanitary Veterinary and Food Safety Directorates supervise implementation the programme at county level, including organisation of surveillance for rabies, manual distribution of vaccine baits, and training of personnel carrying out manual distribution of vaccine baits.
- There is a National reference laboratory for rabies (NRL) within the Institute for Diagnosis and Animal Health. It coordinates diagnostic activities in 40 county laboratories, the training of laboratory staff, and liaises with the European Union Reference Laboratory. In cooperation with the epidemiological office within this Institute, they draw up epidemiological reports.
- The Institute for Control of Veterinary Biological Products and Medicines assesses, authorise and tests the vaccines used in the eradication programme.
- The technical commission established by Order No 264/2014 is responsible for monitoring vaccine bait transport, their storage and distribution (both by hand and aerial). It consists of representatives of the CCA, the Institute for Control of Veterinary Biological Products and Medicines, the NRL and representatives of County Sanitary Veterinary and Food Safety Directorates.
- The Ministry of Environment and Forests supervises the Private Hunting Associations. Within it, the National Administration of Forests regulates hunting by establishing hunting quota based on census of animals.
- The Associations of Hunters and Fishermen of Romania and the Private Hunting Associations, among other tasks, monitor the density of fox population, and carry out hunting of foxes in order to monitor the effectiveness of the vaccination programme.

There are 2,103 hunting grounds administered by the National Administration of Forests, Associations of Hunters and Fishermen and by private administrators.

3. Staff performing official controls receives appropriate training enabling them to undertake their duty competently in line with Article 6 of Regulation (EC) No 882/2004:

- The CCA held a specific training course in October 2013 on rabies eradication. It covered details of aerial and manual distribution of vaccine baits, sampling, and applying mapping tools. The course comprised theory and a practical exercise (a short rabies simulation exercise to work through all stages which should be followed in positive cases and in vaccination campaign of foxes) and at least one official veterinarian from every County Sanitary Veterinary and Food Safety Directorate, staff from the NRL and officials from the central level took part. The audit team saw evidence that the participants spread the information acquired through cascade training sessions to veterinary practitioners, official staff and hunters involved in monitoring of rabies at county level. A list of attendees and presentations for the course were presented to the audit team.

4. Prior to the 2014 aerial distribution, the CCA instructed the contractor on areas above which the aerial distribution vaccination should and should not be performed. The audit team noted that when, in particular at the beginning of aerial distribution, the CCA detected deficiencies in the aerial distribution (e.g. vaccine baits dropped above water surfaces or settlements), additional and targeted training was provided to the pilots and operators, organised directly at the airfield.

5. In the last quarter of 2013, all County Sanitary Veterinary and Food Safety Directorates were audited on the implementation of the rabies eradication programme for the period January 2012 to November 2013 by their local audit departments (under the direction of the NSVFSA Technical Audit and Control Directorate). The recommendations of the audits related to deficiencies in documentation of the anti-rabic vaccination in dogs and cats, some deficiencies in documentation related to rabies cases, and underperformance in implementation of the sampling plan for monitoring the efficacy of the vaccination of foxes. In one County Sanitary Veterinary and Food Safety Directorate visited, two recommendations of the audit related to the rabies eradication programme (i.e. to urgently acquire equipment for catching and euthanasia of stray dogs and to provide rabies isolates from county laboratory to the NRL for genotyping) have been addressed. The CA stated that the implementation of corrective actions will be checked during the next routine audit.

6. On a monthly basis, the County Sanitary Veterinary and Food Safety Directorates provide the CCA data regarding implementation of the rabies eradication programme, e.g. the number of samples tested during the month, origin of sample and species tested, and the results of the tests. The monthly reports include also data on progress of the anti-rabic vaccination campaign in dogs and cats. The CCA closely monitors the measures taken by County offices in the case of rabies outbreak.

Conclusions on competent authorities

7. The national legal framework and the structure and organisation of the CA provide a solid basis for the implementation of activities of the rabies eradication programme

and their monitoring. The specific training provided to officials helps ensuring uniformity in their actions and controls. The training to the contractor and follow-up on their results had a significant role in the correct distribution of baits.

8. The existence of internal audits with systematic follow-up together with the CCA monitoring on rabies outbreaks improves the consistency and correctness of official activities.

5.2 ORAL VACCINATION OF FOXES

Legal requirements

Article 1 of Commission Decision 2008/425/EC; Article 16 of Commission Implementing Decisions 2012/761/EC (2013 programme), and Article 15 of Commission Implementing Decision 2013/722/EC (2014 programme); Articles 3(2)(b) and 4(1)(b) of Commission Decision 2008/940/EC (until 2014); Articles 3(2), 4(a)(iv) and 4(b) of Commission Implementing Decision 2014/288/EU (from 2015).

Findings

5.2.1 Vaccine, vaccine storage and quality controls

9. The vaccine used contains one of the strains recommended in the WHO, OIE and EU guidelines (SAD Bern strain) and it is produced in another EU country.

10. For the 2014 autumn campaign pre-distribution quality checks on vaccine batches were in place, and vaccine storage, transportation conditions and cold-chain requirements were adhered to:
    - The vaccine was directly transported from the manufacturer to the airfield in temperature controlled containers. At the time of delivery, the representatives of the technical commission carry out a check of vaccine baits in order to verify their compliance with contract criteria (an identity check of the consignment, physical check of the quantity and status of the vaccine baits, including their integrity and their storage temperature).
    - The samples from all 13 batches of vaccine delivered had been sent to the Institute for Control of Veterinary Biological Products and Medicines for detection of virus titre on delivery date (before distribution). Three batches have been retested because the storage conditions (temperature) were not respected. All results were compliant.
    - No samples were tested during the campaign to verify the stability of baits under the actual weather conditions, but baits remained only a few days in storage before their effective use.
    - The vaccine baits were stored under the responsibility of the aerial distribution contractor. They monitored the temperature inside each compartment of the containers, and record it every 15 minutes. A single temperature peak up to – 6^{o} C (for approx. 30 minutes) was recorded every day for "defrosting" process. The contractor had instructions from the CCA on what actions should be taken in the case of any deviations from temperature requirements.
    - Vaccine baits left over in the plane after the flights were checked by the official veterinarian. The CCA stated that due to low temperature during aerial

distribution all those vaccine baits were still frozen after landing and therefore returned back to the freezer container for use the following day. No temperature record was kept of this check.

11. The documentation kept was comprehensive, complete and included:
    - Delivery notes of vaccine from manufacturer (5,334,194 doses made up of 13 batch codes, distributed between nine airfields).
    - International bill of lading.
    - Declaration accompanying transport of vaccine with information, e.g. truck licence number, date and time departure, and quantity vaccine.
    - Manufacturers' certificate of analysis for individual batches of vaccine of their compliance with the approved specification laid down in the marketing authorisation.
    - The results for vaccine stability (after five days at 25º C). These tests were carried out in the NRL of the country of the vaccine producer, all with compliant results.
    - Results of titration of virus for every batch of vaccine.
    - Temperature records inside the container with the vaccine baits during transport.

5.2.2 Distribution of vaccine baits

12. In 2014 oral vaccination of foxes was planned in two vaccination campaigns, in spring and autumn. It was foreseen for a total area of 213,375 square kilometres, with manual and aerial distribution of vaccine baits. For aerial distribution the programme determined flight lines 500 metres apart and spreading 25 vaccine baits per square kilometre.

13. Distribution of vaccines did not take place as planned (spring campaign was not executed), but baits in autumn campaign were spread by aerial distribution in accordance with the recommendations in the 2002 Scientific Report:
    - The contractor for the aerial distribution of vaccine baits used 26 fixed-wing airplanes operating out of nine airfields. The contractor was responsible for the day-to-day planning and implementation of the vaccination campaign.
    - Vaccine distribution started on 06 October and finished on 27 November 2014.
    - 5,334,194 vaccine baits were distributed by aerial distribution and 75,400 baits by hand, as outlined in the plan for the autumn campaign (half of the baits planned for the whole year 2014).
    - Each plane used for distribution had a global positioning (GPS) device for flight route and another one - linked to the automatic device which drops the baits - recording location, time and altitude of bait drop. A video-recording system was set up on board each aircraft during the flights, filming dropping of the baits by automatic device. All flight routes were prepared in advance by the flight operator, and downloaded one route per plane per flight onto the flight route GPS. After each flight, the GPS data for actual flight routes and encrypted GPS data for bait drop locations were downloaded and sent daily to the CCA.

14. Manual distribution of the vaccine baits was planned in the areas where fox dens are located, with priority around settlements where rabies cases had been detected and in areas not covered by aerial vaccination but with known fox activities.
    In the two counties visited, the audit team noted that:

- The distribution was carried out in accordance with a distribution plan.
- The sites for vaccination were selected by the CA in cooperation with the hunting managers.
- The distribution was carried out by the official veterinarian accompanied by hunters. On average 12-13 baits were placed per den.
- The records, including distribution map, date and number of the vaccine baits used, were kept and were available to the audit team.

5.2.3 Supervision and official control of vaccine storage, quality and distribution

15. Official controls of vaccine storage were carried out in accordance with the CCA instructions but these instructions were incomplete:
    - The CCA informed the audit team that the representatives of the technical commission were permanently present at the airfield during vaccine distribution[2].
    - Temperature records regarding the bait storage conditions during 2014 campaign were checked by the technical commission (official veterinarian) once per day during vaccine distribution and the records of the official checks were available.
    - The audit team reviewed the instance when temperature records from the thermometers in the freezing container showed deviation from the established limit (a rise of temperature from -20^{o} C up to -1.2 ^{o} C due to a power cut). The deviation was noted by the contractor only after more than 24 hours and the CA was notified. During this 24 hours period, aerial distribution was not carried out. The batches stored inside this container were sampled and re-tested for virus titre in the Institute for Control of Veterinary Biological Products and Medicines. The test results were compliant with contract criteria.
    - The procedure in place did not define the frequency of official temperature controls, and the critical point (combination of raised temperature above limit with maximum allowed time) was not included either.

16. The review of the records of official controls for 2014 showed that the CA had an effective verification system in place to ensure that aerial bait distribution was carried out in accordance the programme:
    - A representative of the technical commission signed the daily records on aerial distribution and sent them to the CCA. The records included information on aircraft identification, number of baits loaded for each flight and number of baits distributed, take-off and landing time, and outside temperature. The number of baits not distributed (present on the board after landing) was also recorded.
    - Daily information was provided by the contractor, including details on flights performed, e.g. flight distance, length of flights, vaccine baits quantity in stock at the beginning and the end of each day, temperature records inside storage containers, and all logbooks and maintenance books of every pilot and airplane used.
    - The CCA monitored, in real time, the activities of the airplanes through an online connection between airplanes and their internet server. This could not be verified since the audit took place outside of the vaccination period.

[2] In their response to the draft report the CA noted that as regards the official controls for the vaccine storage the CA has all the tools necessary to check the storage temperature of the vaccine and give penalties to service provider as result of his non-compliances with requirements and when the vaccine is no longer suitable to be distributed.

- Based on data received daily (GPS position of aircraft and encrypted data regarding GPS position of vaccine baits distributed) and using geographic information system software (for mapping and decryption of data), the CCA carried out random checks to verify that bait drop positions overlaid with flight routes and the density of vaccine baits distributed were in accordance with the plan.
- Where the CCA detected deficiencies (e.g. instances where the aircrafts entered no-fly zone, or distances of 500 metres between flight lines were not observed) they informed the service provider by email and requested immediate corrective actions
- At the end of the campaign the service provider gave the CA all decrypted data regarding the dropping of vaccine baits. Those data were used for further verification (cross-checking) of correct implementation of vaccine baits distribution.

17. The audit team reviewed electronic data for three randomly selected flights (e.g. flight tracks, including date/time for selected waypoints, position of selected vaccine baits released including date/time data for each bait). The data confirmed the implementation of aerial distribution of vaccine baits as foreseen in the eradication programme:
    - Flight lines of 500 metres apart and the distance of maximum 80 m between locations of vaccine baits dropped guaranteed a density of distribution of at least 25 baits per square kilometre.
    - Only some minor anomalies occurred regarding frequency of bait dropping (in particular at the end of some flights) with minimal effect on the overall professionally executed aerial distribution.

18. In both counties visited, the manual distribution of the vaccine baits was carried out under the direct supervision of the official veterinarian and in accordance with the distribution plan approved by the county office.

Conclusions on oral vaccination of foxes

19. Due to the late resolution of the tender for vaccine distribution, the programme for eradication of rabies in Romania in 2014 was not implemented as foreseen; only one out of two planned vaccination campaigns was carried out.

20. The adequate pre-distribution quality checks on vaccine batches ensure the quality of the vaccine when it is distributed. The incomplete procedures in place to demonstrate maintenance of the cold chain for baits point to certain weaknesses in the control practices.

21. The effective verification system on daily and final bait drop data ensured that aerial bait distribution was carried out correctly. Aerial distribution of baits in autumn 2014 was professionally executed and well documented by the contractor. The distribution of baits (aerial and manual) is suitable to achieve the objectives of the programme.

5.3 MONITORING, AWARENESS AND SURVEILLANCE

The principles of detection of rabies and monitoring of vaccination in foxes are described in the 2002 and 2010 Scientific Reports. Briefly:

- Rabies cases are detected by demonstration of rabies virus in brain tissue of infected animals. The 2010 Scientific Report states that the best chances of finding rabies cases and to declare freedom from rabies are by sampling and testing indicator animals under a passive surveillance programme i.e. testing animals that display abnormal behaviour particularly if humans have been exposed (suspect cases), road-kills, and animals found dead.
- Detection of tetracycline in teeth or bone indicates that the fox has licked or chewed on the vaccine bait. In order to demonstrate that the fox 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. Whilst testing for tetracycline provides data on the distribution of vaccine baits, only antibody testing can demonstrate what proportion of the fox population has become protected against rabies. No animals infected with rabies are expected to survive long enough to produce antibodies, so antibodies indicate that the animal has been vaccinated.

Legal requirements

Article 1 of Commission Decision 2008/425/EC; Article 16 of Commission Implementing Decisions 2012/761/EC; Article 15 of Commission Implementing Decision 2013/722/EC; and from 2015 Articles 3(2) and 4(a)(iv) of Commission Implementing Decision 2014/288/EU.

Findings

5.3.1 Monitoring of bait uptake and population immunity

22. Monitoring is carried out on apparently healthy foxes shot by hunters. These animals are also used for active surveillance for rabies cases. In all files reviewed by the audit team, the whole carcass was sent to the laboratory for testing, which ensures the best possible sample quality.

23. The sampling starts at 45 days following each vaccination campaign and it lasts for 60 days. The sample numbers for monitoring of the vaccination campaigns are set by the CCA, broken down by counties and sent prior to the vaccination campaign to every County Sanitary Veterinary and Food Safety Directorate, i.e. twice per year.

24. Sampling of foxes to monitor vaccine uptake and fox population immunity was seriously under-implemented and unevenly geographically distributed in 2013-2014:
    - The following table summarises laboratory data for foxes sampled in calendar years 2013 and 2014

Year	Rabies cases	Number of foxes tested for			% tested foxes in contact with bait	% tested foxes vaccinated
		Rabies virus	Tetracycline	Antibodies		

2013	286*	2755*	1638	1387	15.32% (251)	9.95% (138)
2014	95*	2269*	2165	2022	27.67% (599)	28.04% (567)

For rabies* total numbers under active and passive surveillance

- In 2013 and 2014 none of the 41 counties met their target of number of planned samples - four foxes /100 Km^2 per year (representing approx. 8,500 foxes shot in Romania). Only 0.86 foxes / 100 Km^2 were tested for tetracycline and 0.73 foxes /100 Km^2 were tested for antibodies in 2013. In 2014 those figures slightly increased to 1.01 foxes / 100 Km^2 and 0.95 foxes /100 Km^2 respectively, but still were well below the targets.
- In 2014 the sampling for tetracycline varied between the counties, ranging from 0.1 up to 2.4 foxes /100 Km^2.
- In one county visited, out of 170 foxes tested for rabies virus, only 64 were tested for tetracycline and rabies antibodies under the monitoring scheme. By permitting to use only foxes shot within a 60 days sampling window, all other foxes shot during the year become ineligible for monitoring. The majority of foxes were shot to regulate fox population density and the carcases were sent directly to the rendering plant without laboratory examination.

25. There has been a significant improvement in sampling after the autumn campaign 2014 as a result of new CA legal powers to enforce sampling by the hunters and more active involvement of the CA:
    - The CCA set the target for sampling at approximately three foxes per 100 square kilometres (6 965 foxes)[3].
    - The sampling in counties had started in December 2014 or beginning of January 2015. The CCA stated that the sampling will finish by the end of February 2015 and then the results will be evaluated.
    - In counties visited, the implementation of the sampling plan after the autumn campaign 2014 was well organised and advanced. The CA informed all hunting managers about their responsibilities for implementation of the sampling plan, indicating the number of samples to be taken from each hunting ground. In on county at the time of the FVO visit (on 16th day out of 60 days sampling window), 48 samples out of 144 planned had been tested. The CA indicated that the sampling target will be met. In another county visited at the time of the FVO visit, out of 128 samples planned, 100 had already been taken (on 48th day out of 60 days monitoring window).

26. The procedures of age determination of the monitored foxes were not detailed enough and the determination was based on an insufficiently accurate method:

[3] In their response to the draft report the CA noted that for 2014 campaign they reached the target for sampling with a total of 3,826 foxes shot and tested for tetracycline and for antibodies by ELISA test. The target for sampling was 6965 foxes for both campaigns envisaged in 2014. In 2015 they intend to shoot planned number of foxes - 8535 (4 foxes/100 square kilometres) and complete their testing for evaluation of the effectiveness of vaccination in 2015. The same annual targets are planned for the whole period 2015-2017 (Romanian eligible area for the oral vaccination of foxes is 213,375 km2, so the total yearly number for shooting in 2 campaigns is 8375 foxes).

- No clear cut-off between the category of young foxes (cubs) and adults is set up by the CCA and thereby the age threshold in the counties visited varied between 12 and 15 months.
- The age determination only by visual inspection of carcases, in particular after autumn campaign, is not providing sufficiently reliable results. The young foxes are already 8-9 months old and grown up which makes visual age classification very difficult. The age has not been verified by more specific laboratory method.

5.3.2 Active/targeted surveillance

27. All foxes submitted to the laboratory under the vaccination monitoring programme, are tested for rabies virus before any other tests are carried out. The audit team noted that:
    - In 2014, 2,269 foxes have been examined for the rabies virus, including foxes tested under active and passive surveillance.
    - One of the national measures taken in the protection zone around rabies cases is to request additional samples of foxes for virus detection. In the two cases reviewed by the audit team, this measure was requested by the CA but not implemented by the hunters and no additional foxes were shot during the period while the measures were imposed (30 days).

5.3.3 Passive surveillance and awareness

28. Passive surveillance varies between the counties and is inadequate in several counties. The data available are not comprehensive enough to fully assess the effectiveness of passive surveillance:
    - Although requested by the audit team, the CCA did not provided data on the number of foxes tested and found positive for rabies virus broken down by type of surveillance (active; passive).
    - The numbers of suspect cases (tested under passive surveillance) were provided by the CCA per county and per calendar year, but no further details (e.g. numbers broken down by different category of indicator animals such as animals killed with clinical signs, found dead or road-kills), were available.
    - In 2014, 252 suspect samples were tested for rabies (mainly dogs, foxes, cats, bovines, and other species). The number of suspect cases varied between the counties. In six counties and Bucharest municipality no suspect case was reported. The low number of suspect cases were notified particularly in the counties along the southern border of Romania, as well as the very low number of total samples were tested for virus in this region[4].
    - Completed submission forms for laboratory analyses allow information collection on the health status of animals, respectively if an animal was found dead, shot,

[4] In their response to the draft report the CA noted that as regards to low level of passive surveillance they obtained information from the counties on the recent sharp declination of the mortality in foxes and they consider it as result of their successful immunization. In 2015 (until 11 June) only 13 rabies cases were reported in foxes (out of 20 rabies cases detected in all animal species). Regarding passive surveillance in domestic animals, all cases of mortality or suspect animals with clinical signs are kept under observation or were euthanized after the event and the samples were sent to the laboratory for examination.

[5] In their response to the draft report the CA noted that as regards the forms used for submission samples to laboratory the CA is in the process of analysing of the forms and their update.

was killed, or euthanized. However it does not provide clear guidance to the sampler to ensure completeness of forms in a harmonised way, e.g. it is no clear when the sampler should specify "shot" and when "killed" animals. The forms do not have a field to provide additional information needed to assess the effectiveness of passive surveillance and progress of the eradication programme, e.g. to distinguish between samples taken from stray and owned dogs[5]. Some data collected has not yet been used for any analyses.

29. Public and hunters are aware of the risk of rabies:
    - The CCA informed the audit team of awareness campaigns organised during 2013 and 2014. They included the distribution of leaflets and posters for which the contractor was responsible.
    - The audit team noted that:
        - Information on the rabies campaign is available on the NSVFSA website.
        - The hunters met during the on-the-spot visit were fully aware of the rabies vaccination campaigns and risk of rabies.

5.3.4 Suspect cases and measures taken when rabies has been confirmed

30. The CA took measures, in line with national requirements, when rabies is suspected and confirmed but the national requirement applied on contact animal with rabies case are not epidemiologically sound:
    - When rabies is confirmed in domestic or wild animals, specific control measures are applied, in accordance with the NSVFSA President Order No. 29/ 28.03. 2008 for the approval of a sanitary veterinary norm regarding general measures of prevention and control of rabies in domestic and wild animals. Measures applied include carrying out epidemiological enquiry, establishment of the protection and the surveillance area, and implementation of the control plan with deadlines and responsibilities. The audit team noted that emergency vaccination is carried out around the rabies cases and in 2013 emergency vaccination included 8,247 domestic animals, e.g. sheep, cows, goats, pigs and horses.
    - The audit team reviewed two rabies cases in 2013 and 2014 and noted that the measures taken were in line with the national legislation. The length of observation of animals (including those not vaccinated against rabies) which were in contact with a rabies case is 14 days, from the moment of contact. However, this 14 day period of isolation and observation of contact animals is insufficient to ascertain that such animals are not incubating rabies.

31. In 2014 vaccination against dogs and cats had not been implemented as planned in the approved programme and only small proportion of known dogs have been vaccinated/revaccinated:
    - Vaccination against rabies of domestic dogs and cats in Romania is compulsory. Each animal shall be vaccinated from the age of three months with yearly revaccination. The revaccination is organised in campaigns held at the end of the calendar year from October until the end of December.
    - The obligation to have the dog microchipped which entered into force in 2014, had a major negative impact on the numbers of dogs vaccinated in the anti-rabic vaccination campaign in 2014. The vaccination coverage dramatically decreased. At the end of 2014, out of 3,519,886 known dogs only 280,510 were vaccinated. Although the cost related to vaccination is provided by the state free of charge, the

cost related to microchipping is borne by the dog owner. The CAs visited, noted a low number of vaccinated dogs, acted upon the situation and took some measures to remedy the situation. In one county, the CA requested local authorities to financially support dog owners from public resources, in another county, the CA reminded local authorities to enforce legislation and sanction those owners whose dogs are not vaccinated. Due to the situation, the anti-rabic vaccination campaign in dogs and cats in 2014 was extended until the end of February 2015.

- The population of stray dogs is large in the cities but is not covered by the organised vaccination campaign. All stray dogs entering shelters are vaccinated against rabies. Some of these dogs remain in the shelter while others are re-homed.

5.3.5 Supervision of the monitoring and surveillance programmes

32. Supervision of the implementation of the monitoring and surveillance programmes is carried out at various levels and stages of their implementation but this supervision does not prevent the inconsistencies and discrepancies in data and overall underperformance of programmes:
    - Supervision is carried out by County Sanitary Veterinary and Food Safety Directorates and County Sanitary Veterinary and Food Safety Directorate laboratories. In both counties visited, the audit team noted that the numbers of samples provided by the hunters and tested are regularly checked and evaluated against the sampling plan. Copies of all test results are provided by the laboratory to the CA. The records of supervision were available to the audit team.
    - The NRL for rabies receives, on a monthly basis, the situation on the number of laboratory tests performed by the County Sanitary Veterinary and Food Safety Directorate laboratories. The data for some counties reviewed by the audit team showed some inconsistencies, in particular as regards a higher number of foxes tested for tetracycline or rabies antibodies than for virus detection. The discrepancies exist between the number of tests for tetracycline and rabies antibodies. The audit team noted that the NRL staff is aware of those inconsistencies and stated that they notified the CCA who has the power to enforce corrective actions.
    - The audit team noted that no on-going supervision of the sampling plan was carried out by the CCA. In 2013-2014 no corrective action was taken or initiated by the CCA during a sampling year to address under-implementation of the monitoring programme in counties with very few samples taken, or discrepancies noted in data provided by the laboratories.
    - The fitness of samples submitted for laboratory analyses is routinely checked but the age of foxes determined by the hunter is not verified in the laboratory with more specific method (based on the pattern of dentition and counting layers of dentine in canines) (for more see chapter 5.3.1)

5.3.6 Analysis of the effectiveness of the rabies eradication programme

33. The collection of data as well as their interpretation from the perspective of the progress of the programme implementation is performed by the experts of the NRL for rabies and by experts of the Epidemiology office within the Institute for Diagnosis and Animal Health.

34. On the basis of the data available, mainly those representing the laboratory results, first analysis of the effectiveness of the oral vaccination of foxes in Romania during the period 2011-2014 (first trimester) was elaborated in June 2014[6].

35. The main conclusions of this analysis are:
    - An increase in the immunization rate of foxes after the vaccination campaigns in 2011-2013 and a decrease in disease incidence in 2013.
    - After the vaccination campaigns in 2013, the results on the whole country showed a significant increase in the immunization rate in correlation with an increased percentage of the vaccine marker presence.

36. The audit team noted the absence of analysis of adequacy of sampling. No target levels for tetracycline and rabies antibody prevalence have been set up. No information was provided regarding efficacy of active and passive surveillance. GPS data on sample location has not yet been used to provide more detailed information on geographical distribution of samples and rabies cases. No detailed temporal and spatial analyses of rabies cases and monitoring have been done so far to address progress of the programme in individual counties.

Conclusions on monitoring, awareness and surveillance

37. The monitoring of vaccine uptake and population immunity in 2013-2014 was inadequate. The 60 days sampling window applied after vaccination campaign limits the possibility to increase the number of samples. However there has been a significant improvement in sampling after the autumn campaign 2014 as a result of new CA legal powers to enforce sampling by the hunters and more active involvement of the CA.

38. The supervision from central level during the monitoring period does not ensure that sampling targets will be met in all counties.

39. The age determination of the monitored foxes is not verified by laboratory method, which undermines the reliability of the age data used to assess the effectiveness of the autumn campaigns in particular.

40. Passive and active surveillance programmes for rabies are in place. However, the effectiveness, in particular of passive surveillance, varies between the counties and is inadequate in several counties. This means that surveillance results are not sufficient to reliably assess the rabies incidence in all regions. Furthermore, the surveillance data reported to central level are not detailed enough to allow the identification of potential risks to the overall success of the eradication programme.

41. The public have been made aware of the risks and typical symptoms of rabies. The actions taken to control the risk of spread to humans and domestic animals in the

[6] In their response to the draft report the CA noted that a comparative analysis of the effectiveness of rabies vaccination for 2013 and 2014 campaigns has been carried out. The analyses shows slight increase of seroprevalence in fox population in this period (from 28.35% in 2013 to 32,52% in 2014) and sharp increase of tetracycline detection in samples tested in 2014 (from 28.26% in 2013 to 71.25% in 2014).

vicinity of rabies cases in foxes are adequate but the period of isolation of animals in contact is too short. Furthermore, the implementation of the 2014 compulsory vaccination programme for dogs is seriously hampered by owner reluctance to bear the costs of the recently introduced compulsory microchipping and registration of their animals. This increases the risk of dog rabies, particularly in young unvaccinated dogs.

42. Monitoring since 2011 was insufficient to provide quality data to assess the effectiveness of the rabies programme. Provided that the oral vaccination and monitoring will be implemented in the future as it is after the 2014 autumn vaccination campaign, then the CA should have representative data to assess the progress.

5.4 LABORATORY NETWORK

Legal requirements

Article 4(2)(c), Article 12 and Article 33 of Regulation (EC) No 882/2004.

Findings

5.4.1 Diagnostic capability

43. The analysis methods used and official laboratories under the eradication programme fulfil the requirements of Articles 11 and 12 of of Regulation (EC) No 882/2004:
    - Initially all samples taken under the rabies programme are analysed for virus detection in 40 County Sanitary Veterinary and Food Safety Directorate laboratories. All those laboratories are accredited to carry out the Fluorescent Antibody Test (FAT) for rabies diagnosis.
    - FAT-negative samples taken under the vaccination monitoring programme are sent to the NRL, for tetracycline marker and antibodies detection by Enzyme-linked Immuno-sorbent Assay (ELISA). In addition, FAT-positive samples are sent to the NRL for confirmation, and typing and sequencing of rabies virus isolates.
    - The audit team noted that
        - All rabies positive samples have been forwarded to the NRL and subjected to genotyping to differentiate between wild rabies virus and vaccine strain as foreseen in the programme. At the time of the FVO audit, only wild strains had been identified with a high degree of genetic diversity (at least six lineages) - http://www.ncbi.nlm.nih.gov/pubmed/20178821.
        - The test methods, for detection of rabies virus (FAT), antibodies to rabies virus (ELISA) and the method for detection of the bait uptake marker, are included in the scope of accreditation of the NRL.
        - In 2011-2014 the NRL has successfully participated in several proficiency tests organised by the European Union Reference Laboratory for rabies with FAT, reverse transcription polymerase chain reaction, titration tests for vaccine virus, tetracycline detection and virus isolation on cell culture. Furthermore in 2012 the laboratory participated in a comparative study for ELISA test.

- The NRL organises annual proficiency tests for FAT for County Sanitary Veterinary and Food Safety Directorate laboratories. In cases where a laboratory fails to meet required standards, the performance in FAT is retested in an extra proficiency test run.

44. In the Institute for Control of Veterinary Biological Products and Medicines the audit team noted that every batch of vaccine used in a vaccination campaign of foxes is tested for virus titres. Although the method used is under the scope of accreditation, the result from the proficiency test organised by the EURL in 2011 was unsatisfactory. Since then the institute had not participated in any other proficiency test. Although recommended by the European Union Reference Laboratory, no further training was provided to the staff on this method.

5.4.2 Role of the NRL in the rabies eradication programme

45. The NRL is responsible for testing samples as described above. In addition, staff of the NRL maintains electronic data sheets listing the variables and results for the samples analysed under the rabies eradication programme by County Sanitary Veterinary and Food Safety Directorate laboratories.

46. The FVO team noted that:
    - The NRL had an active role in planning the eradication programme and in evaluating the effectiveness of the programme.
    - The electronic data maintained in the laboratory are suitable for on-going monitoring of the progress of sampling as well as for basic evaluations of the effectiveness of the vaccination campaign. However they lack the level of details required for deeper analysis of the surveillance programme (for more see point 55). In addition they have not been used yet for supervision of the implementation of sampling plan.

Conclusions on laboratory network

47. The laboratories (county and central) have the appropriate validated and accredited methods for detection of rabies and for monitoring of the vaccination programme. They provide reliable and timely results.

48. Although included in the scope of accreditation, the method used for titration of virus in vaccine baits has never been validated with a satisfactory result in international comparative tests. This makes it difficult for the CA to assess the reliability of these results.

5.5 FOLLOW-UP

49. The table below summarizes the follow-up to the relevant recommendations made in report DG(SANCO)2012-6392

No	Recommendation	Assessment
4	The CCA should ensure that the flight line distance should not exceed 500 m when using the aerial method of bait	Adressed. See findings No 16, 17.

	distribution, as per recommendation (19) of the 2002 SCAHAW report.	
5	The CCA should ensure that targets are met in all CSVFSDs in respect of shooting and sampling of foxes to assess the uptake of rabies vaccine bait and the development of protective immunity against rabies in the fox population, as per recommendation (1) of the 2002 SCAHAW report.	Not addressed. See findings No 24, 32 and recommendation No 2 of the current audit report.
6	The CCA should consider reviewing the set of measures to be applied to contact animals in case of outbreak of rabies and their documentation, in order to ensure that epidemiologically sound actions are applied to reduce the risk of spread of rabies to people or other animals as is the aim of the rabies eradication plan approved by Commission Implementing Decision 2011/807/EU.	Not addressed. See finding No 30 and recommendation No 5 of the current audit report.
7	The CCA should ensure that monitoring of the efficiency of oral vaccination campaigns, performed in accordance with recommendation (1) of the 2002 SCAHAW report, includes the collection, transmission and analysis of sufficient data for the assessment and possible adjustment of vaccination campaigns.	Not addressed. See finding No 26, 28, 32, 36 and recommendation No 3 of the current audit report.
8	In the frame of official controls on the reception and storage of vaccine, the CCA should have procedures in place to ensure that corrective actions are taken when needed, as required by Article 8 (3)(b) of Regulation (EC) No 882/2004.	Not addressed. See finding No 15 and recommendation No 1 of the current audit report.
9	In areas where attenuated rabies virus vaccines have been used, all rabies virus isolates should be typed, in order to distinguish between vaccine and field virus strains. in accordance with recommendation (4) of the 2002 SCAHAW report.	Adressed. See finding No 43.

6 OVERALL CONCLUSIONS

After the failure in implementation of 2013 programme, the programme for eradication of rabies in Romania in 2014 was not implemented as foreseen; only one out of two planned vaccination campaigns was carried out. The unexecuted spring campaign in 2014 represents a lost opportunity to maintain and further increase immunity in the population

of foxes, and thereby unnecessary waste of some resources that have already been committed to vaccination of foxes in previous years. The new multiannual contract for supply and aerial distribution of rabies vaccine baits addresses this issue and provides an assurance of uninterrupted continuation of the eradication programme for the 2014-2017 period.

The adequate pre-distribution quality checks on vaccine batches in 2014 ensure the quality of the vaccine used. But certain weaknesses in the control practices, in particular regarding the maintenance of the cold chain for baits, still exist.

Both aerial and manual distributions of vaccine baits in the autumn campaign 2014 were well-organised and well supervised, therefore suitable to achieve the objectives of the programme.

Monitoring of the vaccine uptake and population immunity in 2013-2014 was inadequate. Improvement seen after the autumn campaign 2014 and at the beginning of 2015 should provide sufficient information to demonstrate that rabies eradication is progressing according to the objectives of the programmes. However current on-going supervision from central level is insufficient to ensure that the targets for sampling will be met in all counties.

The level of passive surveillance is poor in several counties and makes it difficult to reliably assess the true rabies epidemiological situation. In addition, the surveillance data collected lack a sufficient level of details to identify potential risks to the overall success of the eradication programme.

The public awareness of the risks and typical symptoms of rabies and the actions taken to control the risk of spread to humans and domestic animals are appropriate but the period of isolation of animals in contact which is too short. Only small proportion of known dogs was vaccinated against rabies in 2014/2015, increasing the risk of a higher incidence of rabies, particularly in the young dog population.

The laboratories provide reliable and timely results.

A superficial and insufficient analysis of the effectiveness and progress of the rabies eradication is seriously compromised by the unrepresentative and poor quality data that available to the CCA.

7 CLOSING MEETING

A closing meeting was held on 23 January 2015 with representatives of the competent authorities. At this meeting, the main findings and preliminary conclusions of the audit were presented by the audit team.

8 RECOMMENDATIONS

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ("action plan"), within one month of receipt of the report, aimed at addressing the recommendations set out below.

No.	Recommendation
1.	Ensure that the comprehensive documented procedures are in place for official controls on the storage of vaccine to verify that cold-chain requirements are strictly adhered to and to take corrective actions when needed. Article 8(1) and (3) of Regulation (EC) No 882/2004. Recommendation based on conclusion No 20. Associated finding No 15.
2.	Ensure, through effective management of the programme, that the target sample numbers, as defined in the approved rabies eradication programme, are met for each of the tests (FAT, tetracycline, antibodies), in order to obtain sufficient data for the evaluation of the progress, efficiency and effectiveness of this programme. Article 15 of Commission Implementing Decision 2013/722/EC and Point 6(a) and (c) of the Annex to Commission Decision 2008/341/EC. Recommendation based on conclusions No 37, 38. Associated findings No 24 and No 32.
3.	Ensure that data obtained from the monitoring and surveillance programmes are regularly monitored and evaluated on the efficiency and effectiveness of the measures and that these evaluations are reported to the Commission. Data collected shall be complete, verified and detailed enough to allow comprehensive analysis. Points 6(c) and 7(a)(b) of the Annex to Commission Decision 2008/341/EC. Recommendation based on conclusions No 39, 42. Associated findings No 26, 28, 32 and No 36.
4.	Ensure that the surveillance programmes in place, to reliably assess the rabies incidence, are effective in all regions. Points 1(a) of Article 15 of Commission Implementing Decision 2013/722/EC. Recommendation based on conclusion No 40. Associated findings No 27 and No 28.
5.	Ensure the review of the set of measures to be applied to contact animals in case of outbreak of rabies; such measures shall be based on the available relevant scientific knowledge and include all the necessary precautions to secure rapid control of the disease and to reduce the risk of spread of rabies to people or other animals. Points 5(d)(e) of the Annex to Commission Decision 2008/341/EC. Recommendation based on conclusion No 41.

	Associated finding No 30.
6.	Ensure the effective implementation of a compulsory vaccination programme for dogs and cats against rabies, in order to reduce the risk of spread of rabies to domestic animals. Points 1(a) of Article 15 of Commission Implementing Decision 2013/722/EC. Recommendation based on conclusion No 41. Associated finding No 31.
7.	Ensure that all laboratories involved in the eradication programme deliver results at the required quality standards, including the laboratory for control of the virus titre in oral rabies vaccine. Points 5(f) of the Annex to Commission Decision 2008/341/EC. Recommendation based on conclusion No 48. Associated finding No 44.

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. 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. 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. 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. 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. 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
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. 2008/341/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