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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

BULGARIA

FROM 07 TO 11 APRIL 2014

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 Bulgaria carried out between 7 and 11 April 2014, as part of the FVO audit programme for 2014. The general objective of the audit was to evaluate the implementation of measures contained in the programme for the eradication of rabies, approved by Commission Implementing Decision 2012/761/EU (2013 programme) and Commission Implementing Decision 2013/722/EU (2014 programme) and, in particular, to evaluate whether the programme for eradication of rabies has been implemented effectively and if the competent authority has sufficient data to demonstrate that the rabies eradication is progressing according to the objective of the programme. The audit included follow-up of actions taken by the competent authorities in response to the recommendations from a meeting of the Rabies Subgroup of the Commission's Task Force in Bulgaria in March 2011, and the recommendations of the previous FVO audit report (DG(SANCO)2010-8404).

Quality controls on rabies vaccine baits are adequate and the distribution of baits (aerial and manual) is suitable for achieving the objectives of the eradication programme. However, the competent authority is not prepared for the task of verifying that bait distribution is carried out correctly through daily checks of bait drop data, which will be provided from this year by the company responsible for aerial distribution as required by the Commission services.

The monitoring of vaccine uptake and fox population immunity is inadequate for an evaluation of the effectiveness of the programme. Sampling has been seriously under-implemented since the start of the vaccination campaigns in 2009 and the geographical coverage is patchy. The supervision of the sampling during the year is ineffective and is hampered by the reliance on the voluntary cooperation of private hunters, who frequently deliver incomplete samples, i.e. only fox heads which do not allow for antibody testing. The competent authority has failed to convince the hunters of the importance of this sampling and, although hunters have started to receive payments for samples, payments have been made for incomplete samples and no up-to-date information or instructions have been issued to hunters or to official veterinarians to ensure that complete samples are obtained.

Passive and active surveillance programmes for rabies are in place and the public have been made aware of the risks and typical symptoms of rabies. Adequate actions have been taken to control the risk for spread to humans and domestic animals in the vicinity of rabies cases in foxes. However, there are no procedures in place to investigate, by targeted active surveillance, if more foxes in the same area are infected. This is likely to lead to an under-estimation of the extent of an outbreak. Furthermore, the lack of results from detailed analysis of the rabies virus from the 2012 and 2014 cases undermines the epidemiological investigation of the possible origin of the infection. In addition, the passive surveillance focuses on clinically suspect cases, and the active surveillance is only carried out in areas covered by the vaccination campaign, so the results of this surveillance are not sufficient to reliably assess the rabies incidence nationwide.

The laboratory provides rapid reliable results for suspect cases, using a method to detect rabies which is in the scope of accreditation and validated in a comparative test organised by the EU-RL. Although included in the scope of accreditation, the method used for detection of antibodies to rabies virus, i.e. for assessing the effectiveness of the vaccination programme, has never been included in a comparative test and validation data for the test is not known by the laboratory, which makes it difficult for the competent authority to assess the reliability of the results.

The competent authority has not analysed the effectiveness or the progress of the rabies eradication in spite of the fact that sample data and test results collated by the laboratory are suitable both for day-to-day monitoring and for analysis of the overall effectiveness of the vaccination programme.

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
BFSA	Bulgarian Food Safety Agency
DG(SANCO)	Health and Consumers Directorate General
EC	European Community
ELISA	Enzyme Linked Immuno-Sorbent Assay
EU	European Union
EU-RL	European Union Reference Laboratory
FVO	Food and Veterinary Office
FAT	Fluorescent antibody test
ISO	International Organisation for Standardisation
MS	Member State
RFSA	Regional Food Safety Agency

1 Introduction

This audit took place in Bulgaria from 7 to 11 April 2014 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 European Union (EU) Member State (MS). The team was accompanied throughout the audit by representatives of the Bulgarian Food Safety Agency (BFSA) which is the central competent authority for the scope of this audit.

2 Objectives

The general objective of the audit was to evaluate the implementation of measures contained in the programme for the eradication of rabies, approved by Commission Implementing Decision 2012/761/EU (2013 programme) and Commission Implementing Decision 2013/722/EU (2014 programme) and, in particular, to evaluate whether the programme for eradication of rabies has been implemented effectively and if the competent authority has sufficient data to demonstrate that the rabies eradication is progressing according to the objective of the programme.

The specific objectives of this evaluation were assessments of whether i) the quality controls on baits were adequate, ii) the distribution of baits (aerial and manual) was suitable to achieve the objectives, iii) the monitoring of vaccine uptake and population immunity was adequate, iv) the passive/active rabies surveillance was effective, v) the laboratories were providing reliable and timely results and whether the competent authority had analysed the effectiveness and progress of the rabies eradication.

The audit included follow-up of actions taken by the competent authorities in response to the recommendations from a meeting of the Rabies Subgroup of the Commission's Task Force in Bulgaria in March 2011, and the recommendations of the previous FVO audit report (DG(SANCO)2010-8404), in particular Recommendation 2010-8404-01 in the follow-up module of the Country Profile (DG(SANCO)/2012/6413 Final), which recommended the competent authority to ensure that sufficient data are collected and analysed to monitor the efficacy of the vaccination campaign. Both reports are available on the Commission website: http://ec.europa.eu/food/fvo/index_en.cfm

The audit also verified how the competent authority had addressed the findings on the implementation of the 2013 eradication programme during the on-the-spot visit by the Commission services in October 2013.

In pursuit of this objective, the following sites were visited:

MEETINGS / VISITS		no.	COMMENTS
Competent Authorities	Central	2	Opening and closing meeting with the BFSA
	Regional	3	Regional Food Safety Directorate in Kyustendil, Blagoevgrad, Pazardzhik. Representatives of hunters and local official veterinarians present.
Laboratories		1	National Reference Laboratory for rabies

Other sites	2	Storage site for rabies vaccine baits, Sofia Lesnovo airfield (aerial distribution of baits)

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 27(9) of Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field.

Specific requirements in relation to the control of rabies are contained in a number of EU legal texts. Full legal references to EU legal acts quoted in this report are provided in Annex 1 and refer, where applicable, to the last amended version.

4 Background

Wildlife-mediated rabies was first detected in in the northern part of the country in 1974. No rabies cases in wildlife were detected in southern Bulgaria 1997-2006 but in 2007 the disease re-occurred in the south-west and spread to other southern and eastern regions in the following years.

The annual EU co-funded rabies eradication programme was first approved for the year 2009. The programme includes two oral vaccination campaigns (spring and autumn) for wildlife reservoirs as well as controls to monitor the efficacy of these campaigns. Two vaccination campaigns were carried out in 2009 but only one campaign, in spring, was carried out in 2010 and 2011. In 2012 and 2013 both the spring and the autumn campaigns were implemented.

The following table lists the rabies cases detected during 2008-2014 to date. The last row indicates the number of vaccination campaigns that year.

	Number of animals infected						
Animal species	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014** (1st quarter)
Wild animals	39	49	2	1*	1*	0	1**
Domestic animals	10	10	4	0	0	0	0
Vaccination campaigns	- -	*spring* *autumn*	*spring* -	*spring* -	*spring* *autumn*	*spring* *autumn*	*spring and autumn (planned)*

* fox detected in Kyustendil region

** fox detected in Blagoevgrad region

The previous FVO audit of the rabies eradication programme in Bulgaria was carried out in November 2010 (DG(SANCO)/2010-8404, hereafter referred to as the 2010 FVO report). The report concluded that an officially controlled system for aerial spread of vaccine baits was in place and appropriate actions were taken when rabies was detected. However, serious deficiencies were

noted with regard to the number of samples taken to monitor the efficacy of the programme and the results of those tests.
In March 2011 a meeting of the Rabies Subgroup of the Commission's Task Force (hereafter referred to as the 2011 Task Force) was held in Bulgaria. A report from their meeting, which focussed on the rabies situation and eradication in Bulgaria, has been published on the Commission website:
http://ec.europa.eu/food/animal/diseases/eradication/rb_rep1415032011_en.pdf

The 2011 Task Force made ten recommendations to the Bulgarian competent authorities: 1) to ensure uninterrupted vaccination campaigns, 2) to have flexible and reactive management of the programme, 3) to enhance the passive rabies surveillance by focussing on indicator animals (suspect, road-kills, found dead), 4) to maximise monitoring samples through education and information and cooperation with hunters, 5) to set up a national rabies database and give high priority to epidemiological analysis of surveillance and monitoring data, 6) to cooperate and coordinate with neighbouring countries, 7) to monitor virus titres in baits before and during campaigns, 8) to introduce manual bait distribution in larger areas where aerial distribution is not possible, 9) to expand the vaccination areas to altitudes above 1200 metres and 10) to organise training in tetracycline test analysis for the laboratory.

In addition to the legal requirements in EU legislation there are certain scientific reports with relevance to rabies control and eradication. 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. In addition, 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 wild animal populations (hereafter referred to as the 2010 Scientific Report). This report has been published here: http://www.efsa.europa.eu/en/supporting/pub/67e.htm.

5 Findings And Conclusions

5.1 Competent Authorities

5.1.1 Legal requirements

Articles 3 to 8 of Regulation No 882/2004 and points 6 and 7 of the Annex to Commission Decision 2008/341/EC.

5.1.2 National legislation

The main national legal instruments related to the rabies eradication programme are the Law on Veterinary Activity, Ordinance on the Prevention and Control of Rabies, Ordinance on the procedure for Notification and Registration of Contagious Diseases, and Ordinance on the Monitoring of Zoonoses for the Prevention, Control and Eradication of Animal Diseases.

The annual sampling programme for monitoring of the rabies vaccination programme is approved and disseminated to the regional competent authorities in the form of an Order of the Executive Director of the BFSA. Separate Orders of the Executive Director of the BFSA are issued in spring

and autumn for the release of vaccine bait from storage and the initiation of the vaccination campaign.

5.1.3 Chain of command and organisation of the eradication programme

As described in the Country profile for Bulgaria (DG(SANCO)/2013/6841, valid as of April 2014) the BFSA is the central competent authority for animal health controls, including the planning, implementation, supervision and evaluation of the rabies eradication programme. The annual plan for rabies eradication, which is submitted to the Commission for approval, is drawn up by the BFSA. Tasks related to rabies eradication are mainly carried out by two persons in BFSAs Animal Health, Welfare and Feed Control Directorate. The Veterinary Medicinal Products Directorate is responsible for issuing a licence for use for each batch of the oral rabies vaccine. In addition, the Risk Assessment Centre in the BFSA provides independent scientific assessments of risks *inter alia* related to animal health, including rabies.

The BFSA exchanges information about the rabies eradication programme with Ministry of Health, Ministry of Interior, Ministry of Environment and Waters, National Forestry Administration, local authorities, private veterinary practitioners, and the Union of Hunters and Anglers.

Following a tender procedure, the BFSA has signed a three-year contract with a vaccine consortium responsible for the supply and aerial spread of rabies vaccine baits 2012-2014. Although the airfields used are located in three different regions, the representatives of the vaccine consortium communicate directly with the BFSA.

A national rabies monitoring plan lists, for each regions covered by the vaccination programme, the number of animals from which samples are to be collected and submitted for analysis for rabies virus, the bait uptake marker (tetracycline) and antibodies to rabies virus. This monitoring plan is sent to the relevant Regional Food Safety Agencies (RFSA) at the beginning of each year. There are 28 RFSAs, 20 of these were involved in the 2013 vaccination programme and 22 are included in the 2014 programme. Each RFSA calculates the breakdown of samples per municipality and sends this plan to all relevant official veterinarians, who operate at municipal level. The actual killing and collection of foxes for the monitoring is done by private hunters.

Although the RFSAs are involved in awareness campaigns and contacts with hunters' associations, the local official veterinarians are responsible for organising the sampling of foxes by the local hunting teams.

The FVO team noted that:

- the Order of the Executive Director of the BFSA for sampling in 2014 had been issued 4 February, listing for each region the target number for samples to monitor the vaccination campaign and, for the first time, the target numbers for passive surveillance samples;

- neither the competent authorities nor the Union of Hunters and Anglers have any authority over the private hunters and cannot order them to deliver foxes for the surveillance and monitoring programmes;

- hunters interviewed stated that they had been told since 2011 that they would be paid for submitting foxes for testing. However, the first payments (corresponding to 5 Euro per fox) were made by the RFSAs in December 2013, for samples delivered during that calendar

year;

- the BFSA has decided to extend the 2014 vaccination area by 10,536 square kilometres (16%) compared to the area defined in the approved 2014 eradication programme and in the three-year contract with the vaccine consortium. This amendment to the contract had not yet been signed by 11 April;

- as of 11 April, the Order of the Executive Director of the BFSA initiating the vaccination campaign had not yet been issued because the competent authority was waiting for the vaccine quality test results from the EU reference laboratory. After the audit the competent authority informed the FVO that such results had been obtained on 15 April and the campaign was planned to commence on 23 April;

- the two RFSAs which had been added to the 2014 vaccination programme were first made aware of this when they noticed in the Order of the Executive Director of the BFSA for sampling, which had been sent to all RFSAs, that they were expected to collect samples for monitoring of the vaccination programme. They had not received any specific information or training on the procedures for vaccine distribution, how to raise awareness in the area, or how to organise the monitoring of the vaccination programme.

5.1.4 Conclusions on competent authorities

The BFSA has a clear chain of command to the level of the local official veterinarians; however the collection of foxes for surveillance and monitoring is done by private hunters on a voluntary basis. The BFSA had not provided any targeted information or training to the two RFSAs included for the first time in the vaccination area[1]. This is likely to reduce the chances that these two regions will meet the sampling targets for 2014.

5.2 Oral vaccination of Foxes

5.2.1 Legal requirements

Commission Decision 2008/341/EC; Commission Decision 2008/425/EC; Article 16 of Commission Implementing Decision 2012/761/EC (2013 programme); Article 15 of Commission Implementing Decision 2013/722/EC (2014 programme).

5.2.2 Vaccine, storage and quality controls

After delivery from the manufacturer in another MS, the vaccine is stored in two cold stores and will be transported to the three airfields in temperature controlled vehicles when the vaccination campaign begins. The BFSA appoints a regional commission, comprising three persons from the relevant RFSA, for each cold store.

The vaccine is delivered to a cold store and accepted by the director of the vaccine consortium. He then passes control of vaccine security and storage conditions over to the regional commission responsible for sampling the vaccine batches for titre control prior to use, monitoring cold store temperatures and supervising the storage and release of vaccine. When the vaccination campaign starts, all the vaccine is transported to a mobile freezer container at the airfield. There the vaccine is

1 In their response to the draft report the Competent Authority noted that veterinarians from the additionally included RFSAs had not been trained since the contract to vaccinate in the new areas had not yet been concluded.

kept and used under official control by official veterinarians who are present throughout the day whenever vaccine is distributed.

The FVO team visited the cold store in Sofia and noted that:

- five vaccine batches had been delivered to the vaccine consortium on 19.3.2014 and the handover document showed that the vaccine had been handed over to the competent authority on the same day. However, the BFSA did not appoint the regional commission in Sofia until the following day;

- the documentation relating to vaccine for the 2014 campaign included: vaccine consortium acceptance of vaccine from manufacturer (1 331000 doses made up of five batch codes, distributed between the two cold stores); manufacturer's certificate of analysis for individual batches of vaccine; transfer of two vaccine batches to the regional commission in Sofia;

- samples from five batches of vaccine had been sent to the EU reference laboratory for rabies (EU-RL) 24.3.2014;

- as in 2013, any vaccine doses returned from the last planes each day will be returned to the freezer for use the following day. The official veterinarian stated that the baits would still be frozen at that stage.

5.2.3 Distribution of vaccine baits

2014 will be the third year of aerial spread by the same contracted vaccine consortium, which is operating from three airfields in Bulgaria. Following an extension of the vaccination area in the south-west (along the border with Greece), the 2014 vaccination campaign will cover a total area of 77,086 square kilometres, using flight lines 500 metres apart and spreading 20 vaccine baits per square kilometre.

Each plane used for distribution is equipped with one global positioning (GPS) device for flight route and another GPS device (linked to the automatic device which is dropping the baits) recording location, time and altitude of bait drop. The flight operator, who has prepared all flight routes in advance, downloads one route per plane per flight onto the flight route GPS. After each flight, the GPS data for actual flight routes and bait drop locations will be downloaded and stored by the flight operator. The information will also be forwarded, via the vaccine consortium, to the BFSA the same evening or the following morning (depending on the finishing time for the last flight). The set-up, implementation and on-site official supervision of the aerial vaccination campaigns by the vaccine consortium was found satisfactory during the on-the-spot visit by the Commission services in October 2013 (when the campaign was on-going).

The BFSA has regular contacts with the veterinary services in neighbouring countries, and the Bulgarian chief veterinary officer is the team leader of the Serbian rabies vaccination project, which started in 2010. There has been no coordination of rabies vaccination campaigns and the aerial spread of baits in neighbouring countries has taken place during different periods.

Since the approval of the 2014 rabies eradication plan, which included manual bait distribution, the BFSA had decided not to carry out any manual spread of baits this year due to the misunderstanding of a communication from the Commission services in connection with the on-the-spot visit in October 2013. Following clarification by the FVO team, the BFSA stated that manual

spread of vaccine baits will take place in the no-fly zones around a major power plant and in the green areas surrounding Sofia, in line with the recommendations by the 2011 Task Force.

The FVO team noted that:

- the planned distribution of 20 vaccine baits per square kilometre extending up to a ground altitude of 2000 metres is in accordance with the recommendations in the 2002 Scientific Report and the report of the 2011 Task Force, respectively;

- the planes, the freezer lorry for vaccine storage and the technical equipment and the equipment for comprehensive documentation of the planned flight routes for 2014 were in place at the airfield visited;

- the aerial vaccination campaign for the spring 2014, which was planned to start during this audit, had been delayed pending the receipt of test results from the EU-RL so the FVO team could only see a demonstration of procedures at the airfield. During a demonstration of vaccine distribution along the runway, the FVO team were able to see the flight route data being provided to the pilot on a GPS device before the flight. They could also observe GPS data for actual flights and bait drops being logged in real time, downloaded by the flight operator and forwarded to the BFSA where receipt and opening of these data files was demonstrated later the same day.

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

The BFSA is responsible for supervising the flight lines and the vaccine bait distribution whilst the RFSAs, through its official veterinarians, are responsible for the day-to-day supervision and official controls of the storage, transport and distribution of vaccine baits in cold stores and at the airfields.

During the visit to the cold store the FVO team noted that:

- the storage room for the vaccine was kept locked and the vaccine consortium and the official veterinarian held keys for this room;

- one of the two vaccine batch numbers hand-written on the hand-over document did not match the batch number indicated on the certificate, packing list and on the boxes in storage. This had not been noted by the official veterinarian accepting the two batches;

- official controls in the Sofia cold store had been documented during checks carried out every 1-2 days by the official veterinarian, detailing time, date, vaccine type, batch numbers and the registered temperature of the storage chamber. When these recordings were compared to two-hourly and continuous temperature charts from the fixed temperature probe in the cold store, there were a number of differences of several degrees between the three recordings. Some of the data indicated that the temperature on several occasions had been warmer than the -20 degrees recommended by the manufacturer. The official veterinarian had not checked these continuous data of the temperature in the storage room but relied only on his own records taken 24-48 hours apart, which indicated a stable temperature of -20.0 Centigrade. It was not possible during the visit to check the thermometer used by the official veterinarian since he did not have it with him;

- after the closing meeting, the BFSA provided the FVO with a document in which the

manager of the vaccine consortium explained that an electronic temperature monitoring device, recording the temperature every 15 minutes, and a control-thermometer had been installed in the storage room. The BFSA had also been supplied with a calibration certificate for a temperature recording device.

During the visit to one of the airfields the FVO team noted that:

- documents of the temporary release of vaccine from the warehouse and receipt of same at the airfield by the official veterinarian were available when a small quantity of vaccine was transported to the airfield, for a demonstration of bait distribution to the FVO team;

- from the previous vaccination campaign in 2013, records by the official veterinarians at the airfield covered flight times, distance flown, quantity of vaccine loaded and any vaccine returned from the plane and confirmed the presence of an official veterinarian during vaccine distribution. However, checks that the baits returned from the last planes had still been frozen when returned to the freezer over night were not documented;

- as in 2013, the BFSA has access, in real time, to the actual flight routes recorded by the GPS device in each plane;

- as recommended by the Commission services following on-the-spot visit in October 2013, from 2014 the BFSA will also receive daily logs of the actual locations for bait drops. From the airfield visited (out of three) there will be approximately ten flights per day;

- no BFSA official had been nominated for the task of checking the daily bait distribution data;

- no instructions or guidelines had been drawn up to define unsatisfactory/satisfactory bait distribution or which action to take if the data indicated an unsatisfactory distribution of vaccine baits.

5.2.5 Conclusion on oral vaccination of foxes

There are procedures in place and documented official controls on the storage, transport and distribution of vaccine baits. However, the documentation of the handover logs and temperature checks on the 2014 vaccine batches and vaccine baits returned to the freezers in the airfield showed evidence of certain weaknesses in the control practices.

The aerial distribution of vaccine baits had been prepared and the vaccine consortium was ready to start as soon as the BFSA would initiate the campaign. There is official supervision on site at the airfield and comprehensive and reliable documentation will be provided to the BFSA on a daily basis, which together provide the basis for effective supervision of the bait distribution. However, the lack of preparation by the BFSA for how to evaluate the large volumes of flight and bait data, and when to take corrective action, may delay the evaluation and reduce the effectiveness of the supervision carried out by the BFSA.

5.3 MONITORING, SURVEILLANCE AND AWARENESS

5.3.1 Legal requirements

Commission Decision 2008/341/EC; Commission Decision 2008/425/EC; Article 16 of Commission Implementing Decision 2012/761/EC (2013 programme); Article 15 of Commission Implementing Decision 2013/722/EC (2014 programme).

5.3.2 The basic principles for monitoring 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 virus is detected in brain tissue of infected animals. 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 demonstrate vaccination.

5.3.3 Monitoring of bait uptake and population immunity

Monitoring is carried out on apparently healthy foxes which have been shot by hunters. These animals are also used for active surveillance for rabies cases (see point 5.3.4).

The following table summarises laboratory data for foxes sampled under the vaccination monitoring programme in 2012, 2013 and the first quarter 2014.

	Fox samples in plan#	**Rabies cases**	**Number of foxes tested for**			% tested foxes in contact with bait	% tested foxes vaccinated
Year			Rabies virus	Tetracycline (marker for bait contact)	Antibodies to rabies virus (vaccinated)		
2010		2 dogs 2 foxes	158	167	69	9	20
2011		1 fox*	776	775	333	41	9
2012	2520	1 fox**	456	455	219	39	10
2013	2662	none	253	253	133	76	41
2013 only Kyustendil			*107*	*107*	*94*	*80*	*44*
2013 the other 19 regions			*146*	*146*	*39*	*72*	*33*
2014	3082	1 fox*	184	183	69	86	59

Jan-March							

based on the area covered by vaccination; *detected under the monitoring programme/active surveillance (apparently health fox); **detected in the passive surveillance (suspect case).

The FVO team noted that:

- the sample numbers for monitoring of the vaccination campaign 2013 and 2014 were set at four foxes per 100 square kilometres, which is in accordance with the recommended target in the 2010 Scientific Report. However, the current BFSA instruction for the monitoring programme, for RFSAs and official veterinarians, was issued in 2009 and has not been amended since. This instruction specifies that eight foxes per 100 square kilometres should be sampled;

- national wildlife and hunting data showed that the estimated fox population has increased by 6% since the start of the vaccinations in 2009. During the same period the population of golden jackals has increased by 23%. Hunters were allowed to shoot up to 36,400 foxes in 2013 and actually shot 21,811. A rough estimate, based on the geographical area, indicates that at least 10,000 foxes would be shot each year in the vaccination areas;

- sample numbers decreased by more than 40% per year between 2011 and 2013 and in 2013 less than 10 % of the number of foxes in the approved rabies eradication plan were submitted for testing by the hunters. In 2013, compared to the planned number of samples from foxes for each of the 20 regions: one region met its target; three regions submitted no samples; twelve regions submitted 0.6-4.8%; one region submitted 8% and three regions submitted 18-28 % of the planned samples;

- many hunters bring only the fox head, which has always been the appropriate sample for detection of rabies infection, to the official veterinarian. In 2013, only 5% of the planned number of tests for rabies antibodies in foxes were carried out, because for more that half the sampled foxes no serum/body fluids had been submitted to the laboratory;

- although the lack of serum/body fluid samples has been a constant feature since the start of the vaccination campaigns, no information or instructions have been provided by the BFSA for official veterinarians and for hunters, explaining why a fox's head is not sufficient for the monitoring of the vaccination campaign and why extraction of serum/body fluids from the whole carcass should be done by the official veterinarian;

- a payment of 5 EUR was introduced in 2013 to hunters for providing samples for the monitoring programme. This sum was paid out also for incomplete samples, i.e. only fox heads, which did not allow for antibody testing;

- during 2012 and 2013:

  - eight of the 20 regions in the vaccination zone did not have any results from foxes showing evidence of vaccination (antibodies to rabies virus detected). In five of these regions no samples had been submitted for antibody testing in 2013;

  - six regions had results from one fox in two years showing evidence of vaccination;

- five regions had results from two to nine foxes each showing evidence of vaccination;
- one region, Kyustendil, had results from 45 foxes (4 in 2012 and 41 in 2013) showing evidence of vaccination;

- the results from Kyustendil region, which met the sample target for 2013, indicated that the proportion of vaccinated foxes had increased in 2013 compared to previous years;

- the results from Kyustendil have a disproportional effect on the national results. When Kyustendil is excluded from the 2013 data, only 6% of the planned number of foxes were sampled and 1.5% of the planned antibody tests were carried out from the other 19 regions in 2013. The dominance of Kyustendil is evident also for the first quarter of 2014 when this region was responsible for 32% of all fox samples;

- the monthly sample distributions for 2012 and 2013 showed that approximately 40% of all fox samples had been submitted during the first quarter and 40-50% of the samples in the last quarter, i.e. 80-90% of all samples are taken during the hunting season. Based on these data the sampling results for the first quarter of 2014 indicate that:
  - less than 500 of the planned 3082 foxes may be sampled this year;
  - only Kyustendil is likely to meet the sampling target;
  - if the proportion of incomplete samples (only head, without serum/body fluids) is similar to previous years (five year average 55%), less than 10% of the planned antibody tests will be carried out in 2014.

5.3.4 Active/ targeted surveillance

All foxes submitted to the laboratory under the vaccination monitoring programme, are tested for rabies virus before any other tests are conducted. These are apparently healthy foxes which have been shot during the hunting season in the areas covered by the vaccination programme and are less likely to have rabies than foxes which are showing clinical symptoms or are found dead, as explained in the 2010 Scientific Report. The under-implementation and uneven geographical distribution of the monitoring programme affects the value of the active surveillance.

The FVO team noted that:

- no active surveillance for rabies has been carried out outside the vaccination areas;

- between 1/1 2011 and 31/3 2014, 1,669 foxes have been examined for rabies virus under the active surveillance programme. Out of these, two foxes were found to be infected with rabies, one in 2011 and one in 2014.

5.3.5 Passive surveillance and awareness

The 2010 Scientific Report states that the best chance of finding rabies cases, and to declaring freedom from rabies, is 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. The Commission services have

recommended Bulgaria to include also ruminants found dead on pasture in the passive surveillance for rabies. An important part of any passive surveillance is that veterinarians, hunters, the general public, animal keepers and other stakeholders are aware of the manifestations of rabies and aware of which animals should be reported to the authorities for sampling under the passive surveillance. Passive surveillance should cover the whole country.

Under national legislation, suspicions of rabies must be notified immediately to the local official veterinarian, who will carry out a clinical examination and decide if the animal needs to be killed and tested for rabies or if a 14 day observation period can be imposed. If other animals have been bitten these animals will be kept confined and under observation for 30 days.

The FVO team noted that:

- for years, passive rabies surveillance in Bulgaria has focused on swift sampling and investigation of suspect cases. Measures in villages involved in outbreaks are laid down in legislation and were well known by the officials interviewed;

- very few, if any, animals found dead (except dogs in urban areas) and no road-kills have been tested for rabies under the passive surveillance. The representatives for BFSA and RFSAs stated that if foxes had ever been found dead by the road or elsewhere, none had been notified to them;

- in 2012, 21 suspect samples were tested for rabies (10 dogs, 5 foxes, 2 cats, 4 others) with negative results. In addition, one rabies infected fox, which had bitten a dog, was diagnosed. The official veterinarian was notified and organised the killing and testing of the fox and the bitten dog was placed under surveillance until laboratory result were received one day later;

- during 2013, 120 suspect samples (50% from Sofia city), mostly from stray dogs and foxes but also from dogs, cats, large and small ruminants and badgers, were tested for rabies. Seven samples from ruminants suspected of transmissible spongiform encephalopathy were referred for rabies testing within the laboratory. No cases of rabies were detected among these samples;

- information about rabies is available on the BFSA website and targeted information campaigns are implemented when rabies cases have been detected. Information about ongoing vaccination campaigns, including what to do if humans or animals come in contact with baits, is provided on posters in the vaccination area;

- a new awareness leaflet, printed in 100,000 copies, had been perovided to the 28 RFSAs and the Directors of the RFSAs had been informed at the General Meeting of Directors at the beginning of April. These leaflets will be distributed further once the BFSA has issued instructions to the RFSA. The leaflet explains how to recognise a suspect case of rabies and explains how the suspicion should be reported. It also provides a telephone number to a "national hotline";

- target numbers for passive surveillance in all 28 regions have been included (for the first time) in the 2014 sampling plan. These targets were set with the aim of obtaining twice as many samples for passive surveillance in 2014 as in 2013. During the first quarter of 2014, 39 suspect samples had been analysed in the laboratory predominantly from dogs (21) and foxes (15). No cases of rabies were detected. It was not possible from the available data to

see how many animals tested under the passive surveillance programme in 2013 and 2014 had been found dead, as opposed to being killed and sampled due to rabies-like symptoms;

- the 2014 sampling plan provides no assistance to official veterinarians and RFSAs by defining suitable targets (other than suspect cases) for passive surveillance for rabies, such as road kills or animals found dead.

5.3.6 Vaccination of dogs and cats against rabies

Registration of dogs in each municipality (for dog tax) and annual vaccination of dogs and cats against rabies is mandatory in the whole country and each owner is obliged to keep a vaccination passport for each animal where the vaccinating veterinarian records the vaccinations. Rabies is usually included in the multivalent, routinely used dog vaccines. In the regions visited the officials explained that many persons choose not to register their dogs and during epizootic investigations in villages involved in rabies outbreaks, the investigation teams had noted that a number of dogs had not been rabies vaccinated annually.

Municipalities are responsible for vaccinating all stray dogs entering shelters against rabies, using a monovalent vaccine. Some of these dogs remain in the shelter while others are released or homed. There is a national register for dogs which have been electronically identified, issued with a pet passport and vaccinated against rabies, but the BFSA stated that registration is voluntary. In response to the pre-audit questionnaire, the BFSA presented an overview per region, which listed 44,341 dogs as registered and 109,166 as vaccinated against rabies, but stated that the actual numbers of dogs and stray dogs are not known.

5.3.7 Investigation of suspect cases and measures taken when rabies has been confirmed

Measures on suspicion and confirmation of rabies are laid down in national Ordinance No. 23 of 17.05.2002 on the prophylaxis and control of rabies in animals. If rabies is suspected in a fox, care is taken to investigate if humans or domestic animals may have been exposed. In case of human exposure the local health authorities are informed. If domestic animals have been exposed, temporary movement restrictions are imposed until the laboratory tests have been carried out.

If rabies is confirmed in a fox, the RFSA imposes restrictions on all villages within 10 kilometres of the case and these are visited by an epizootic committee. All dogs, cats and domestic animals on pasture are vaccinated (by the private veterinarian); all cats and dogs must be registered and kept confined by the owners. No movements or slaughter of animals are allowed for 30 days, during which the private veterinarian is obliged to carry out daily clinical inspections. The official veterinarian must be notified of all dead animals during this period. If no suspect cases have been observed, restrictions can be lifted after 30 days.

The FVO noted that:

- in case of an outbreak, all dogs and cats in the affected area will be vaccinated with mono-valent rabies vaccine, irrespective of their previous vaccination status;

- when rabies has been confirmed in a fox, the measures target domestic animals but do not include any active surveillance to determine if more foxes in the area are infected. For the cases detected in 2011 and 2012, only a few foxes from the same region were tested during the months after the case was detected;

- the clinical inspections in the village involved in the 2012 rabies case, clinical inspections by the private veterinarians were not carried out daily but every 2-3 days following an agreement with the RFSA;

- following the detection of the 2012 case, manual spread of vaccine baits took place around the settlement nearest to where the rabies-infected fox had been shot.

5.3.8 Supervision of the monitoring and surveillance programmes

The BFSA is responsible for the overall supervision of the implementation of the eradication programme, whilst the RFSAs are responsible for supervising the implementation of monitoring and surveillance at local level and, where relevant, for official controls on the storage, transport and handling of vaccines.

The FVO team noted that:

- hunters are informed via the RFSAs about the need for samples at the beginning of the year and the total numbers of samples received and tested are compiled in a final report at the beginning of the following year;

- although copies of all test results are provided by the laboratory to the BFSA there are no procedures or routines in place at central level to supervise the number and quality of samples taken (in each region) during the year;

- no corrective action has been taken or initiated by the BFSA, during a sampling year, to address the consistent under-implementation of the monitoring programme or the high proportion of incomplete samples submitted (without serum/body fluids).

5.3.9 Analysis of the effectiveness of the rabies eradication programme

The FVO team noted that:

- the results obtained from the monitoring of bait uptake and fox population immunity have not been analysed by the BFSA to evaluate the efficiency and effectiveness of the measures (vaccination) since the beginning of the vaccination campaigns in 2009. This is not in compliance with the requirements under point 6(c) in the Annex to Commission Decision 2008/341/EC;

- data which were suitable for such analyses were available in the laboratory but had not been requested by, or shared with, the BFSA;

- in 2012 the Risk Assessment Centre produced the report "Epizootic and epidemiological analysis of rabies in Europe in 2012 and forecast for Bulgaria". This report had subsequently been updated in preparation for the FVO audit. The report deals mostly with the rabies situation in other countries but states that the Bulgarian oral vaccination programme has been successful as there had been no rabies cases detected in 2012 (which is not correct) or 2013 and one case detected in March 2014. The report concludes that the main risk for Bulgaria is incursion of sporadic rabies infected foxes from Romania and, less likely, from Greece or the former Yugoslav Republic of Macedonia. The report does not include any analysis of the vaccination campaigns based on data from tests of bait uptake or fox

immunity.

5.3.10 Conclusions on monitoring, surveillance and awareness

Orders of the Executive Director of the BFSA for monitoring samples are issued at the beginning of each year, but the absence of any supervision and corrective action by the BFSA during the sampling year has allowed a patchy, and consistently severe, under-implementation of the sampling to continue year after year. This makes it impossible for the BFSA to verify the effectiveness of the last five years' co-financed rabies vaccination campaigns. The lack of updated and targeted information and instructions for official veterinarians and for hunters, and the payments made to hunters for incomplete samples, are likely to have contributed to the very low numbers of samples for monitoring of fox immunity. Without a major effort by the BFSA to achieve the full cooperation of hunters it is unlikely that the monitoring in 2014 will improve the situation.

Although data are available, and collated in the laboratory, the BFSA has not carried out any analyses of the effectiveness and progress of the rabies eradication.

The general public has been made aware of characteristic rabies symptoms, risks to humans and animals and how to report suspect cases. Actions taken when rabies is suspected or confirmed are adequate to handle the risks to humans and domestic animals. Few rabies cases have been detected in recent years. Although this may indicate that the rabies incidence has gone down, it cannot be taken as evidence of an effective rabies eradication since the active surveillance is patchy and limited to vaccination areas and passive surveillance is still focused mainly on suspect cases. The results of this surveillance are not sufficient to reliably assess the rabies incidence nationwide. In addition, the lack of targeted follow-up, through additional sampling of foxes in areas where rabies-infected foxes have been detected, may lead the BFSA to under-estimate the extent of an outbreak.

5.4 Laboratory

5.4.1 Legal requirements

Article 4(2)(c), Article 12 Article 33 of Regulation (EC) No 882/2004. Point 5(f) of the Annex to Commission Decision 2008/341/EC.

5.4.2 Diagnostic capability

All samples for rabies virus detection and monitoring of bait uptake and rabies antibodies within the framework of the approved rabies eradication programme are analysed by the National Reference Laboratory (NRL) for Rabies and Monitoring the Effectiveness of Vaccination, in the National Diagnostic and Research Veterinary Institute. The NRL is located in the same building as the BFSA and is accredited to ISO 17025. The test methods for detection of rabies virus (fluorescent antibody test, FAT) and antibodies to rabies virus (enzyme-linked immuno-sorbent assay, ELISA) are included in the scope of accreditation, while the method for detection of the bait uptake marker is not.

The NRL does not carry out testing for virus titres in vaccine baits, virus isolation or typing or sequencing of the rabies virus. Such tests, where needed, are carried out for Bulgaria by the EU-RL.

The FVO team noted that:

- the methods used to detect rabies virus and to monitor bait uptake and the presence of

antibodies are those listed in international standards;

- the NRL does not have an electronic laboratory information management system so submission forms and results are kept in hard copies. However, mainly for scientific purposes staff of the NRL manually enters data in Excel files for all samples and test results under the rabies monitoring and surveillance programmes. These data are collated in several files and the information is currently not protected;

- since the report from the 2011 Task Force, the national reference laboratory for rabies has received training on site in Bulgaria from the EU-RL, on tetracycline detection and age determination on fox teeth (March 2012) and diagnostics of rabies by FAT (2013);

- determining the age of the fox may contribute to the understanding of bait uptake in different age groups and the vaccination patterns in the fox population. The age of a fox can be determined *inter alia* by counting age lines in cross-sections of teeth. Since receiving training in March 2012 the NRL has classified all tested foxes as juveniles (<1year) or adults (> 1 year);

- the laboratory has participated with satisfactory results in two comparative tests (organised by the EU-RL): for tetracycline determination in fox teeth (October 2012) and for rabies diagnosis by FAT (2013);

- the ELISA method routinely used for detection of antibodies has not been subject to any comparative tests. This is a commercially available ELISA test kit for the detection of rabies antibodies in dogs, cats and foxes. Positive and negative control samples, provided by the manufacturer, are included in each run. Information on the sensitivity and specificity for this test could not be provided during the visit to the laboratory but the NRL provided the FVO team with such data at the closing meeting (diagnostic sensitivity 88.8% and diagnostic specificity 98.6%);

- the rabies isolate from 2011 has been determined by the EU-RL to be identical to recent isolates from former Yugoslav Republic of Macedonia. However, no results were available for the possible origin of the 2012 case which had been sent to the EU-RL at the end of 2013 following a request from the EU-RL and the 2014 material had not yet been sent to the EU-RL;

- the submission forms to the laboratory do not require the official veterinarian submitting the sample to clearly identify if the sample has been obtained from the monitoring programme or found dead during passive surveillance. However, if human exposure was mentioned the laboratory prioritised the analysis;

- suspect samples are sometimes submitted to the laboratory without information about the clinical symptoms, although there is a field on the submission form for such descriptions and for the suspected disease (in free text). Where included on the submission form, these clinical observations were only stored in hard copy and not included in the data files maintained by the NRL. The sample submission forms did not contain fields for information about the sampler, the date of sampling or whether the sample had been collected under the active or the passive surveillance programmes.

5.4.3 Role of the NRL in the rabies eradication programme

The NRL is responsible for testing samples as described above. In addition, staff of the NRL maintain, for their own use, several electronic data sheets listing the variables and results for the samples analysed under the rabies eradication programme.

The FVO team noted that:

- the NRL had no active role in the planning of the eradication programme or in the evaluation of the effectiveness of the programme;
- no agreement had been made between the BFSA and the NRL on how to record and collate the information about the samples submitted under the surveillance programme and the vaccination monitoring programme, respectively;
- the electronic files maintained in the laboratory would be suitable for day-to-day monitoring of the progress of sampling as well as for basic evaluations of the effectiveness of the vaccination campaign;
- the electronic data maintained by the NRL for the passive surveillance does not identify if the sampled animals were found dead or which symptoms they may have displayed. Thus, in their current form the data files are less suitable for analysis of the passive surveillance programme.

5.4.4 Conclusions on the laboratory

The laboratory has the appropriate methods for detection of rabies, age determination of foxes and for monitoring of the vaccination programme, although the validation of these methods through international comparative tests has been limited. Although included in the scope of accreditation, the method used for detection of antibodies to rabies virus, i.e. for assessing the effectiveness of the vaccination programme, has never been included in a comparative test and the validation data for this test were not familiar to the head of the laboratory. This makes it difficult for the competent authority to assess the reliability of the results and to evaluate the effectiveness of the vaccination programme. The sample data and test results collated by the NRL are suitable for day-to-day monitoring and analysis of the effectiveness of the vaccination programme but have never been used for that purpose by the BFSA. Neither has the BFSA ensured that data are registered by the NRL in the most suitable way for future analysis, in particular of the passive surveillance. The lack of results from detailed analysis of the rabies virus from the 2012 and 2014 cases undermines the epidemiological investigation of the possible origin of the infection.

5.5 Actions taken in response to recommendations made in the 2010 FVO report, by the 2011 Task Force and in recent letters from the Commission Services

As described in this report, the competent authorities have satisfactorily addressed recommendations 1, 7, 8, 9, and 10 made by the 2011 Task Force but have failed to act on recommendations 2, 3, 4, 5, and 6 (see point 4 above).

The satisfactory implementation of actions described in the Action Plan from the competent authorities in response to recommendations 2-5 in the 2010 FVO report were confirmed during the current audit. However, recommendation 2010-8404-01 in the follow-up module of the Country

Profile (DG(SANCO)/2012/6413 Final) has not been satisfactorily addressed since data collected through monitoring are still insufficient for an assessment of the efficacy of the vaccination campaigns.

This latter deficiency also relates to recommendations made by the Commission services in letters to the Bulgarian competent authority on 2013-12-04 and 2013-10-31 but the current audit verified that the following recommendations from these letters had been addressed: all vaccine batches had been sent for titre controls before the start of the campaign; bait drop data files will be provided to the BFSA on a daily basis; manual distribution of vaccine will be limited to specific large areas.

6 Overall Conclusions

Quality controls on rabies vaccine baits are adequate and the distribution of baits (aerial and manual) is suitable for achieving the objectives of the eradication programme. However, the competent authority is not prepared for the task of verifying that bait distribution is carried out correctly through daily checks of bait drop data, which will be provided from this year by the company responsible for aerial distribution as required by the Commission services.

The monitoring of vaccine uptake and fox population immunity is inadequate for an evaluation of the effectiveness of the programme. Sampling has been seriously under-implemented since the start of the vaccination campaigns in 2009 and the geographical coverage is patchy. The supervision of the sampling during the year is ineffective and is hampered by the reliance on the voluntary cooperation of private hunters, who frequently deliver incomplete samples, i.e. only fox heads which do not allow for antibody testing. The competent authority has failed to convince the hunters of the importance of this sampling and, although hunters have started to receive payments for samples, payments have been made for incomplete samples and no up-to-date information or instructions have been issued to hunters or to official veterinarians to ensure that complete samples are obtained.

Passive and active surveillance programmes for rabies are in place and the public have been made aware of the risks and typical symptoms of rabies. Adequate actions have been taken to control the risk for spread to humans and domestic animals in the vicinity of rabies cases in foxes. However, there are no procedures in place to investigate, by targeted active surveillance, if more foxes in the same area are infected. This is likely to lead to an under-estimation of the extent of an outbreak. Furthermore, the lack of results from detailed analysis of the rabies virus from the 2012 and 2014 cases undermines the epidemiological investigation of the possible origin of the infection. In addition, the passive surveillance focuses on clinically suspect cases, and the active surveillance is only carried out in areas covered by the vaccination campaign, so the results of this surveillance are not sufficient to reliably assess the rabies incidence nationwide.

The laboratory provides rapid reliable results for suspect cases, using a method to detect rabies which is in the scope of accreditation and validated in a comparative test organised by the EU-RL. Although included in the scope of accreditation, the method used for detection of antibodies to rabies virus, i.e. for assessing the effectiveness of the vaccination programme, has never been included in a comparative test, and the validation data for this test was not known by the laboratory, which makes it difficult for the competent authority to assess the reliability of the results.

The competent authority has not analysed the effectiveness or the progress of the rabies eradication

in spite of the fact that sample data and test results collated by the laboratory are suitable both for day-to-day monitoring and for analysis of the overall effectiveness of the vaccination programme.

7 Closing Meeting

A closing meeting was held on 11 April 2014 with representatives of the BFSA and the NRL. At this meeting, the main findings and preliminary conclusions of the audit were presented by the audit team. The representatives of the competent authority did not indicate any major disagreement with these findings and preliminary conclusions.

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.

N°.	Recommendation
1.	Ensure that staff responsible for the daily official controls on data from vaccine bait drops and flight lines have received appropriate training and that documented procedures are in place for these controls to verify that baits are being distributed correctly. The procedures should also include the relevant corrective actions which may be needed if these controls reveal non-compliances. Article 6 and Article 8(1) of Regulation (EC) No 882/2004.
2.	Ensure, through effective management of the programme, that the target sample numbers, as defined in the approved 2014 rabies eradication programme and in the national order for the 2014 sampling, 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.
3.	Ensure that EU co-financed payments for fox samples are made only for complete samples (whole fox carcass or head and serum/body fluids) in order to provide material for all necessary monitoring tests. Points 6(a) and 7(b) of the Annex to Commission Decision 2008/341/EC.
4.	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. Points 6(c) and 7(a)(b) of the Annex to Commission Decision 2008/341/EC.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2014-7057

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
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. 2008/341/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