EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2012-6392 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ROMANIA

FROM 21 TO 25 MAY 2012

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 an audit carried out by Food and veterinary Office (FVO) in Romania from 21 to 25 May 2012.

The objective of the audit was to evaluate the implementation of measures contained in the programme for the eradication of rabies, approved by Commission Decisions 2010/712/EU and 2011/807/EU. The audit was conducted through data and document review, interviews with officials and verifications on-the-spot.

The Romanian authorities have made a satisfactory start in respect of the implementation of their first aerial fox vaccination campaigns 2011. Deficiencies identified by the FVO audit team are of a nature that can be addressed in future campaigns with minor alterations to procedures. It is, however, of major concern that at the time of the audit fox vaccination campaigns had not yet been resumed for the 2012 eradication programme due to legal and administrative difficulties. If vaccination is not resumed soon, the resource that has been already been committed to vaccination of foxes will have been wasted.

The report makes recommendations to the Competent Authorities aimed at addressing areas in which improvements are required.

Table of Contents

Abbreviations and definitions used in this report

Abbreviation	Explanation
2002 SCAHAW report	Scientific Committee on Animal Health and Animal Welfare report on the oral vaccination of foxes against rabies(http://ec.europa.eu/food/fs/sc/scah/out80_en.pdf)
2011 rabies plan	The Romanian rabies eradication plan for 2011
2012 rabies plan	The Romanian rabies eradication plan for 2012
CA	Competent Authority
CCA	Central Competent Authority
CSVFSD	County Sanitary Veterinary and Food Safety Directorates
DG(SANCO)	Health and Consumers Directorate General
ELISA	Enzyme Linked ImmunoSorbent Assay
EURL	European Union Reference Laboratory
FAT	Fluorescent Antibody Test
FVO	Food and Veterinary Office
ICVBPM	Institute for the Control of Veterinary Biological Products and Medicines
IDAH	Institute for Diagnosis and Animal Health
IFT	Immuno-Fluorescence Test
MIT	Mouse inoculation test
MS	Member State
NAF	National Administration of Forests
NRL	National Reference Laboratory for Rabies (IDAH)
NSVFSA	National Sanitary Veterinary and Food Safety Authority (the CCA)
OV	Official Veterinarian
SCAHAW	Scientific Committee on Animal Health and Animal Welfare

1 Introduction

This audit took place in Romania from 21 to 25 May 2012 and was undertaken as part of the FVO (Food and Veterinary Office) planned audit programme. The audit team comprised two auditors from the FVO. The team was accompanied throughout the audit by representatives of the National Sanitary Veterinary and Food Safety Authority (NSVFSA) of Romania which is the Central Competent Authority (CCA) within the scope of this audit.

2 Objectives

The objective of the audit was to evaluate the implementation of measures contained in the programme for the eradication of rabies, approved by Commission Decision 2010/712/EU (as amended by Commission Decision 2011/862/EU and 2001/807/EU). The audit was conducted through data and document review, interviews with officials and verifications on-the-spot.

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

MEETINGS / VISITS		no.	COMMENTS
Competent Authorities	Central	2	Opening and closing meetings
	Regional	2	CSVSFDs in two counties
Laboratories		4	Two CSVSFD laboratories, one NRL for rabies (IDAH) and one laboratory for the assessment of veterinary medicinal products (ICVBPM)
Vaccine distributor		1	Demonstration of manual distribution of vaccine at a fox den

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

Prior to the accession to the EU vaccination of foxes in Romania was organised on a county basis

with distribution of vaccine bait being carried out manually by hunters. Following the accession of Romania to the EU in 2007 a decision was taken that vaccination would be organised centrally by the NSVFSA and the previous county vaccination campaigns were stopped in order that a Union-funded rabies eradication programme could be implemented. This is the first FVO audit of the rabies eradication programme in Romania.

5 Findings And Conclusions

5.1 Competent Authorities

EU requirements:

Regulation No 882/2004 sets out requirements applicable to competent authorities, including co-operation and co-ordination within and between competent authorities, training of staff, the provision of written procedures and the verification of effectiveness of official controls.

Commission Decision 2008/341/EC establishes the criteria that national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses must satisfy in order to qualify for Union funding. These include among the others:

- the designation of competent authorities responsible for supervising and coordinating the programme;
- details of the control procedures and inspections carried out within the areas concerned.

Details of the competent authorities involved in the control of rabies in Romania can be found in the 2012 rabies plan and also in the FVO Country Profile for Romania which is available on the FVO website:

http://ec.europa.eu/food/fvo

In summary the **NSVFSA** takes central responsibility for ensuring the funds for implementing the programme and coordinates the activities of other bodies involved; **County Sanitary Veterinary and Food Safety Directorates (CSVFSD)** oversee implementation the programme at local level including monitoring of vaccine transport and storage and training of personnel carrying out vaccination; **the Institute for Diagnosis and Animal Health (IDAH)** is the national reference laboratory for rabies (NRL) and coordinates diagnostic activities in **county laboratories**, prepares epidemiological reports and liaises with the community reference laboratory (EURL) for identification of rabies virus isolates; **the Institute for the Control of Veterinary Biological Products and Medicines (ICVBPM)** authorises rabies vaccine for use in Romania and carries out quality control on batches of rabies vaccine; t**he National Administration of Forests (NAF)** is a Department in the Ministry of the Environment and determines the size of fox populations and oversees control of foxes by regulating hunting. NAF, through the provision of funding to hunting territories, also carries out sampling of foxes for detection of rabies and determination of the effectiveness of the rabies vaccination programme; the **Associations of Rangers, Hunters and Fishermen of Romania** carry out the hunting of foxes to provide samples to determine the effectiveness of the fox vaccination programme.

Findings

A technical audit and control directorate reporting directly to the President of the NSVFSA has been

established in 2010. This directorate has developed a checklist for the carrying out of audits on the implementation of the rabies eradication plan and has carried out audits on the CSVFSDs in respect of the implementation of the rabies eradication plan between December 2011 to January 2012.

The audit team noted that:

- In respect of vaccination of foxes written procedures are in place to cover: transport and storage of rabies vaccine, the distribution of vaccine both by aerial and manual means, the designation of responsibilities responsible for supervising the campaign at county level, the procedure for shooting foxes and sampling to assess efficacy of the vaccination campaign.

- Documentation is in place in respect of the compulsory vaccination of dogs and cats.

- The NRL has a rabies diagnostic manual in place which covers the performance of the fluorescent antibody test for rabies antigen, confirmatory Mouse Inoculation Test (MIT), ELISA for the detection of post-vaccinal antibodies and the determination of tetracycline in bone to determine the uptake of rabies vaccine bait by foxes.

- The CSVFSDs in which airfields used by planes taking part in the vaccination campaigns are located are responsible for supervising the work of the contractor that distributes the vaccine baits including the cases where these baits are dropped on the territory of neighbouring CSFVSDs.

- The management of hunting territories was under the responsibility of the Ministry of Agriculture until 2011 when they were privatised. This has led to an increased number of hunting territory managers involved in the shooting of foxes to assess efficacy of the vaccination campaign. In one of the CSVFSDs visited the number of hunting territory managers to be dealt with increase from three to eight between the spring and autumn vaccination campaigns in 2011.

- In one of the CSFVFSDs visited the FVO audit team confirmed that an audit of the implementation of the rabies eradication plan that had been carried out by the local CSFSD audit department under the direction of the NSVFSA Technical Audit and Control Directorate. The recommendations of the audit related to documentation of the manual rabies vaccination carried out by hunters, ensuring technical training for hunters participating in manual vaccination of foxes and on the documentation and quality certification required for the purchase of inactivated rabies vaccine used for the vaccination of domestic animals. The competent authority (CA) indicated that the recommendations were of a generic nature and not based on the non-compliances detected during the audit.

Conclusions

In terms of implementation of a rabies eradication programme there is co-operation and co-ordination within and between competent authorities involved and written procedures are in place.

Audits of the implementation of the rabies eradication plan have taken place as required by Regulation (EC) No 882/2004 However, recommendations made following these audits are of a generic nature and do not necessarily reflect non-compliances detected during the audits.

5.2 Health situation regarding rabies

In recent years rabies has been endemic in wildlife (in particular foxes) in Romania. Details of the incidence of the disease in wildlife and domestic animals can be found in the 2011 Eradication programme for rabies in Romania (hereafter referred to as: 2011 rabies plan) available at:

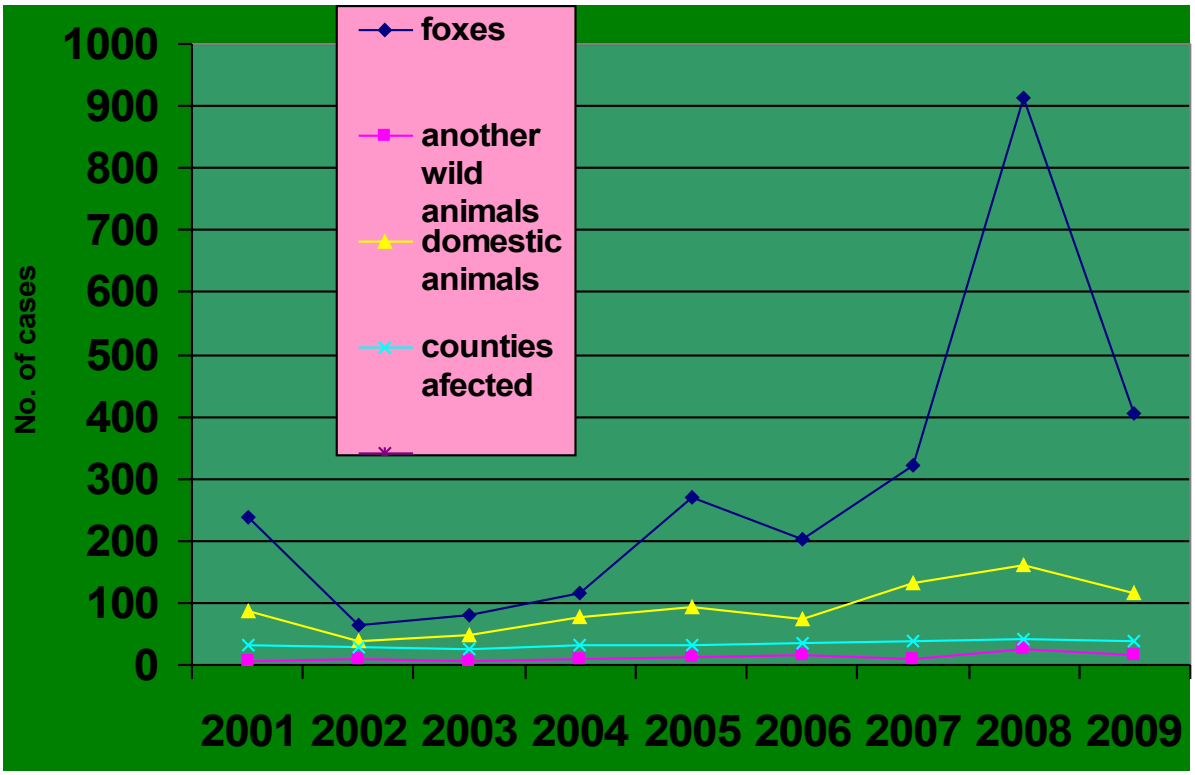
http://ec.europa.eu/food/animal/diseases/eradication/programme2011/rabies_romania.pdf

(The rabies approved rabies eradication plan for 2012 (hereafter referred to as:**2012 rabies plan**) can be found at:

http://ec.europa.eu/food/animal/diseases/eradication/programme2012/rabies_ro.pdf)

The following figure shows an overview of the incidence of rabies in Romania from 2001 to 2009.

Figure 2 Number of rabies cases in wildlife and domestic animals in Romania 1999 to 2009



There is an estimated population of 55,000 foxes in Romania so the peak of 900 cases in 2008 represents a rabies incidence of approximately 2% in the fox population.

With respect to human rabies cases the WHO database (http://www.who-rabies-bulletin.org/Queries/Surveillance.aspx) reports 1 human case in 2007.

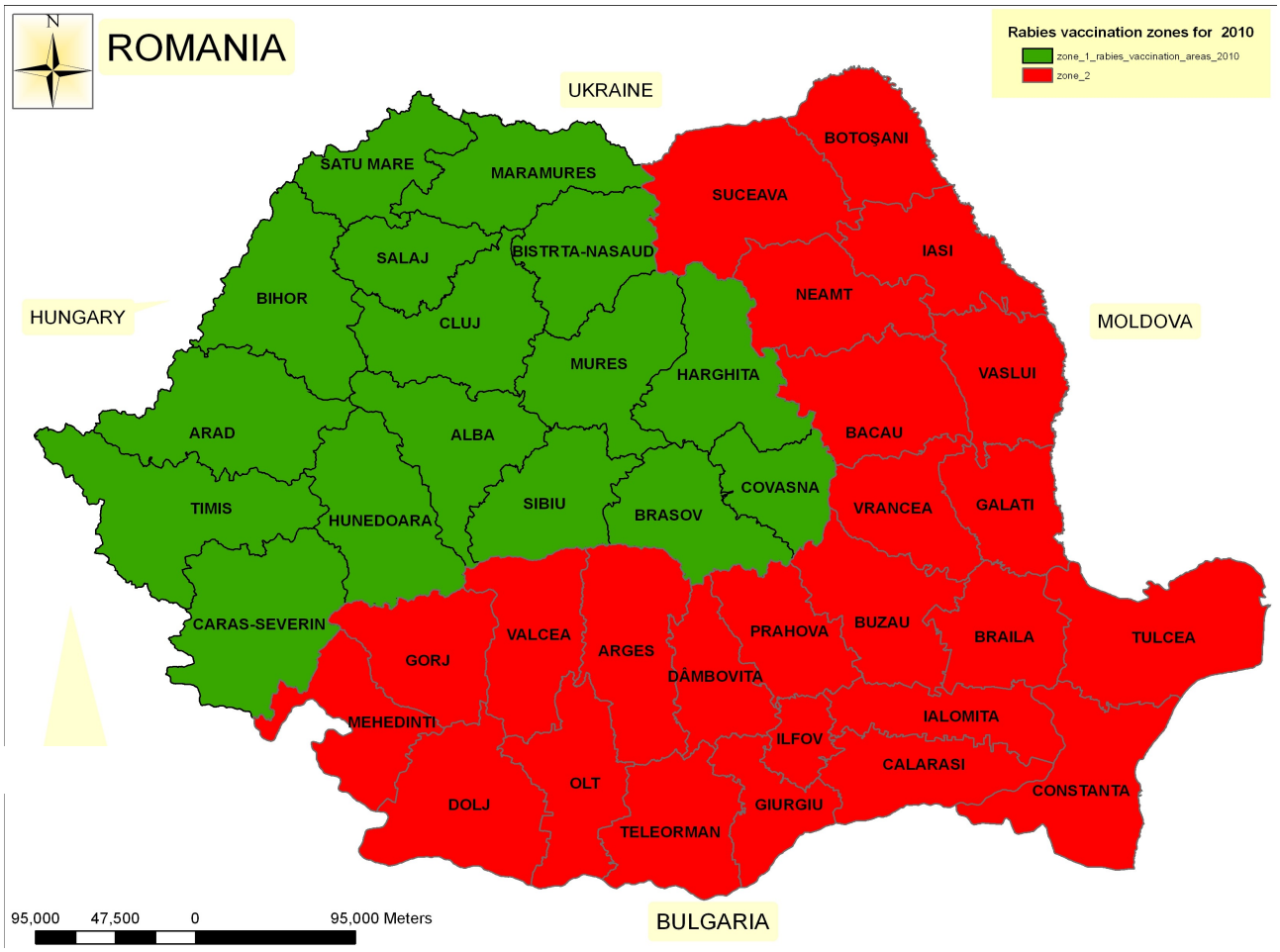
5.3 Rabies eradication programme

5.3.1 Overview of the rabies eradication programme

Rabies eradication programmes in Romania have been approved since 2007 by the European

Commission and include biannual oral vaccination campaigns in wildlife reservoirs throughout the whole territory, and controls to monitor the efficacy of these campaigns. However, implementation of the rabies eradication plan in foxes only commenced in 2011 in the North-West region of the country an amendment to the programme validated by Commission Implementing Decision 2011/862. This region consists of 16 Romanian counties and is bounded by the Carpathian mountains to the South and East and by Ukraine, Hungary and Serbia and Montenegro in the North and West (see Figure 1).

Figure 1 Rabies vaccination zones for foxes



5.3.2 Implementation of the eradication programme

EU requirements:

Article 27 of Council Decision 2009/470/EC provides that the Commission may reimburse from Union funds the expenditure incurred by Member States (MS) in the course of implementing national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses, including rabies. MS must submit disease control programmes to the Commission which must include:

- description of the epidemiological situation of the disease;
- a description of the areas in which the programme is to be applied:
- the duration of the programme and the objective to be obtained;
- an analysis of the costs and benefits of the programme;

Article 10 of Commission Implementing Decision 2010/712/EU and Article 10 of Commission Implementing Decision 2011/807/EU approve the plans submitted by Romania for 2011 and 2012.

Prior to the establishment of the European Food Safety Authority in 2003, the Commission received scientific guidance from committees composed of independent scientists, including the Scientific Committee on Animal Health and Animal Welfare (SCAHAW). At the request of the Commission, SCAHAW issued a report in 2002 assessing the reasons for failures noted in the implementation of certain rabies control protocols within the EU and recommending actions that should be taken to bring about the eradication of rabies in the Community as soon as possible (hereafter: the 2002 SCAHAW report). A copy of this report may be downloaded from: http://ec.europa.eu/food/fs/sc/scah/out80_en.pdf. It makes reference to a number of issues, which are particularly relevant in the context of the Romanian eradication programme:

- Monitoring rabies incidence, bait uptake and immunity in the fox population - this is particularly important because a drop in the disease incidence allows the number of foxes to increase, diluting the overall level of population immunity. The report specifically recommends that foxes found dead should be investigated for evidence of rabies infection;
- All rabies virus isolates should be typed in areas where attenuated rabies virus vaccines are used, in order to distinguish between vaccine and field virus strains;
- Serological methods to be used for quantification of the antibody response in foxes following vaccination should be standardised;
- Vaccine titre in baits at batch release should be at least ten times the experimental 100% protective dose and the vaccine titre should not fall below the indicative 100% protective dose following exposure to 25°C for seven days.
- Each vaccine batch should be tested and approved for titre and stability and laboratories involved in the monitoring and evaluation of rabies programmes should monitor these titres before and during release into the field;
- The use of fixed-wing aircraft is only recommended for the treatment of uniform and large areas of low density inhabitation (e.g. large forests, mono-agricultural areas). Distribution by hand is the preferred system in urban and suburban areas, in combination with the use of an aerial distribution whenever possible;
- A biomarker (tetracycline) should be incorporated in vaccine so that vaccine bait-intake in target species can be evaluated;
- Each vaccination area should be at least 5 000 m2 and should overlap previously vaccinated areas. Buffer zones of 50 km should be created and vaccination areas should be

synchronised across borders;

- When using the aerial method of bait distribution, flight line distance should not exceed 500 metres, dropping to 300m in areas of high fox population density. Vaccine distribution should ensure 18 to 30 baits/km2, according to fox population density and/or at least 10 baits per den.

- Strict adherence to transportation and cold-chain requirements should be ensured;

- Vaccination should be carried out on a biannual basis. Vaccination at fox dens should be used to complement Spring vaccination or at other times when foxes are re-emerging.

Findings

National legislation

Government Decision 55/2008 approves and provides funding for the strategic programme for the supervision, control and eradication of rabies in foxes.

The audit team noted that:

- The current version of Government Decision 55/2008 only provides legal power for the vaccination of 16 Counties in the North-West of Romania.

- A contract for the distribution of baits on the whole territory had already been awarded to a distribution company for the coverage of the whole territory. Inflexibilities in the contract have prevented a reconsideration of the price for a distribution on the current 16 counties: this has led to a cessation of the vaccination programme - at the time of the FVO audit the 2012 spring vaccination programme had not started.

- Article 7 of the current version of Government Decision 55/2008 legally restricts vaccination of foxes to the months of May/June and October/November. Even if weather conditions are favourable to vaccinate outside these periods vaccination cannot take place. This was a problem in 2011 when the Autumn campaign had to stop before two of the 16 counties to be covered were vaccinated. This article has been proposed for revision in an amended version of the Decision.

- The NFVFSA has prepared an amendment to Government Decision 55/2008 to cover the entire territory of Romania and to give flexibility in the dates of the vaccination campaign. However, at the time of the FVO audit the amended Decision had not been agreed by the Ministry of Justice and the approval of the amendment has stalled.

Public awareness

Public awareness campaigns are not included as part of the Romanian rabies eradication programme.

The audit team noted that:

- Information on the rabies campaign is available on the NSVFSA website.

- In areas taking part in the vaccination campaign posters were displayed in public areas.

- Local television programmes carried news items about the rabies vaccination of foxes during the time of the vaccination campaigns.

- The hunters met during the on-the-spot visit were fully aware of the rabies vaccination campaigns and demonstrated the manual distribution of vaccine around a fox den.

Vaccine used for oral immunisation of foxes

The vaccine is from an EU based company and and uses the SAD Bern strain (one of the strains recommended in the WHO, OIE and EU guidelines). This vaccine strain has been widely used in the last 30 years in several EU countries. The tender for the supply of vaccines is organised centrally by the NSVFSA. According to the Romanian rabies eradication plan the vaccine titre should be at least 10 times the 100% protective dose at distribution of the vaccine and after exposure at 25ºC for 7 days the vaccine titre should be at least 100% of the protective dose. The melting point of the vaccine bait cover should be at least 40ºC. Romania recognises the results of tests of official laboratories in other member states in order to issue a marketing authorisation for the rabies vaccine baits. The vaccine bait must also include tetracycline as a biomarker in order that the uptake of the vaccine baits by foxes can be assessed.

All batches of vaccines to be used in vaccination campaigns are tested by an official laboratory in the member state of vaccine production before being supplied to the Romanian authorities.

The audit team noted:

- Approximately 3.2 million rabies vaccine bait were used during the spring and autumn vaccination campaign in 2011. These vaccine baits were from 10 different batches of vaccine. The vaccine bait specification was for a minimum of 1.8 ml containing 1.8×10^7 to 1.8×10^8 $TCID_{50}$ per dose.
- All batches of vaccine were accompanied with batch release certificates issued by an official laboratory of the member state of production. No further testing was carried out on the vaccines in Romania.
- The laboratory of the ICVPM was not accredited for carrying out potency tests on rabies vaccine in 2011. It received accreditation from the Romanian Accreditation Body for carrying out these tests in March 2012. The FVO audit team were informed that stability testing would be carried out by the ICVPM laboratory on batches of rabies vaccine used in future rabies vaccination campaigns.
- In the case of three of the 10 batches, certification of testing for the stability of the vaccine was provided. This testing was carried out (at the request of the vaccine manufacturer) in an official laboratory in a third member state. The vaccine baits were exposed for seven days to four different temperatures (-20ºC, 4ºC, 25ºC and 40ºC). Protective vaccine titres were demonstrated in all tests apart from the bait stored at 40ºC were no virus activity was detected. At 40ºC the consistency of the bait casing became sticky and soft but still remained intact.

Storage and distribution of vaccine

As there was no vaccination campaign under way at the time of the FVO audit it was not possible to make a direct on the spot assessment. Instead, the audit team were provided with documentation as to how the campaign was organised and were shown videos of receipt and storage of vaccine baits and aerial distribution of vaccine during the 2011 vaccination campaigns. The FVO audit team were also shown a demonstration of manual distribution of vaccine baits at a fox den. Reports of vaccination flights were supplied to NSVFSA on a daily basis. The vaccine baits were delivered to Romania in refrigerated lorry containers by the supplying company. On receipt the batches were transferred into further refrigerated lorry containers which acted as mobile storage facilities at the airfields from which distribution flights took off. Electrical power was provided at these airfields to maintain the refrigeration. In addition, the containers had back-up generators to maintain refrigeration in the event of a power cut.

Aerial vaccine distribution in rural areas was provided by a private company contracted to do the work using a fixed wing plane. Flight lines were drawn up using a geographical information system at NSVFSA HQ. The actual flight lines and the location of every vaccine bait dropped were recorded by a satellite navigation device. A distance of 1km was set between flight lines and the density of baits was set to 20 baits per km^2. The air speed was set at 250 km/hr and the altitude 250 m with 50 m between bait drops. Neighbouring countries were informed of the vaccination campaign by letter but there was no synchronisation of campaigns across borders.

In areas unsuitable for aerial vaccination distribution (close to rivers, towns and other settlements) distribution of vaccine was carried out manually by hunters accompanied by veterinarians from the CSVFSDs. The location of fox dens was determined by hunters from the hunting territories. Approximately 25 vaccine baits were placed at and in the immediate area surrounding fox dens.

The instructions on the vaccination campaign include a procedure for collection of baits on the ground after aerial distribution in order to assess their integrity.

The audit team noted:

- Following one of the first aerial distributions an attempt was made to locate distributed baits to assess their condition. The CA reported that it took three people with one dog six hours to locate just one vaccine bait. This bait was intact. Due to the resource intensive nature and limited success of this effort no further attempts were made to locate vaccine bait following its distribution.

- Reports of temperature checks on the vaccine storage facilities indicated that the storage temperatures were occasionally higher than -20ºC. No procedures were in place indicating critical temperature limits for storage and actions to be taken when this limit is reached.

- The distance between flight lines at 1km is double that recommended in the annex to the 2002 SCAHAW report. This distance is not set in the contract with the distribution company.

- The CA reported that the actual distribution density achieved in 2011was just over 19 baits per km^2.

- In locations not suitable for aerial distribution vaccination was carried out be hand. Local

hunters were used to identify the dens and distributed bait working along side official vets from the CSVFSDs who were responsible for supervising the procedure. In one of the counties visited approximately 4 baits were distributed at each den but the FVO audit team were informed that the actual number of baits could be higher if there was evidence of a lot of activity at the den. The density of manual distribution of baits was reported to be same in both the case where the manual distribution was a complement to aerial distribution or in the case where it was a replacement to aerial distribution. The The GPS coordinates of the dens where the baits were distributed were recorded and submitted to NSVFSA HQ by email.

- In the spring campaign of 2011 (the first ever aerial vaccination campaign in Romania) the GPS records locations of dropped vaccine baits were incompatible with the reporting software. Many baits were recorded as having been dropped outside of Romanian territory. This problem was corrected for the autumn campaign and accurate maps showing the location of each bait dropped were available. The total number of baits dropped in the spring 2011 campaign was 1,844,757 compared to 1,386,071 in the autumn campaign (due to insufficient time, two Counties that should have been covered were not vaccinated in the autumn campaign)

Monitoring of vaccination in foxes

In the 2011 rabies plan, the effectiveness of the vaccination campaign in foxes was to be assessed by the testing of shot foxes for vaccinal antibody and the presence of tetracycline in the mandibular bone. A target of four to eight foxes per 100km^2 was set. The shooting of foxes was scheduled to commence 45 days after the end of the vaccination campaign. The shooting was organised by the CSVFSD through the managers of the hunting territories. A payment of 50 Lei (approximately €10) was made for each fox submitted. Targets for the number of foxes to be tested are set out in the 2011 rabies evaluation plan. Shot foxes were submitted to the CSVFSD laboratories and were initially tested for the presence of rabies virus in brain tissue using the Fluorescent Antibody Test (FAT). In the case of the FAT test being negative, samples of mandibular bone and chest fluid were sent to the NRL for rabies where testing for rabies antibody was carried out using ELISA. In addition the presence of tetracycline was checked for in the mandibular bone. In any cases where the initial FAT was positive the samples from the case were sent to the NRL for genotyping in order to determine whether a field strain of virus or a vaccine strain was present.

The audit team noted:

- Data supplied by the NRL showed that following the spring vaccination campaign the mandibles of 1 372 foxes were tested for the presence of tetracycline. There were 404 tetracycline positive results (29.45%). Chest cavity fluid was available for 1064 foxes and 128 were positive for rabies antibodies (12.03%). At the time of the FVO audit testing of foxes following the autumn 2011 vaccination campaign was still ongoing. The intention had been to stop testing to assess the effectiveness of the autumn 2011 campaign once the spring 2012 vaccination campaign had started. As the spring 2012 campaign had not started, no instruction to stop testing for the effectiveness of the autumn 2011 campaign had been issued. The most recent data presented to the FVO audit team showed that out of 1169 mandibles tested for tetracycline, 455 were positive (38.92%). Out of the 962 samples of chest cavity fluid tested 236 were positive for rabies antibodies (24.53%).

- The end date for shooting of foxes following the spring 2011 vaccination campaign was later than the end date of the autumn 2011 vaccination campaign. For example, in one of the

CSVFSDs visited the spring vaccination campaign ran from the 15 to 26 May 2011; shooting to determine the effectiveness of the campaign started on 11 July 2011 and only ended on 16 January 2012 (the autumn vaccination campaign having taken place from 17 to 30 November 2011). The CA explained that this was considered to be acceptable as following the autumn campaign there would be a delay in the development of vaccine titres in the recently vaccinated foxes so any vaccine titre would have been due to the spring vaccination.

- In the two counties visited shooting of foxes to assess the 2011 autumn campaign was still ongoing and a total of 390 (target 450) foxes had been sampled in the first county and 103 (target 500) foxes in the second county. In discussions with CA staff and hunters met on-the-spot the reasons given for this shortfall were that the Ministry of the Environment sets a quota on foxes that limits the number that are allowed to be shot. In addition hunters do not like to shoot foxes at certain times in the summer as it can disturb more attractive game species and drive them away making them unavailable for hunting later in the year.

Conclusions on the rabies eradication programme

The vaccine titre in baits purchased for the 2011 vaccination campaigns and the vaccine batches tested for stability were in line with the recommendations of the 2002 SCAHAW report. However, the Romanian authorities did not test each vaccine batch for titre and stability by directly monitoring vaccine titres before, during and after release into the field as recommended in the 2002 SCAHAW report.

The CA do not have procedures in place to ensure that corrective actions are taken when the specified temperature parameters are not met for storage of vaccine.

The current legislation providing for implementation of the 2012 rabies plan does not provide sufficient powers for the implementation of the campaigns for the vaccination of rabies on the entire territory of Romania. This, coupled with inflexibilities in the contract with the company distributing the vaccine baits by air, has led to a failure to commence the spring 2012 rabies vaccination campaign. In addition the absolute requirement in the current legislation to vaccinate during specific time periods does not allow flexibility to vaccinate outside these periods even if weather conditions are suitable.

The implementation of the two vaccination campaigns in 2011 shows that the CA can successfully organise such campaigns. There were minor deficiencies in respect of flight lines being further apart than recommended and a borderline bait density compared with the recommendations in the the 2002 SCAHAW report.

There has been difficulty in obtaining sufficient foxes to determine the effectiveness of the vaccination campaign. Of the foxes that were shot and sampled there is a reasonable uptake of bait (indicated by the presence of tetracycline in the mandible) at nearly 40% taking both of the 2011 campaigns together. The levels of protective immunity are less at approximately 25%.

5.4 Controls on rabies

NSVFSA Presidential Order 79/2008 includes rabies as a notifiable disease while NSVFSA Presidential Order 29/2008 legislates for the general measures for control of rabies in domestic and wild animals. Order 29/2008 covers the actions to be taken if there is a suspect or confirmed case

of rabies and lays down rules for the compulsory vaccination of domestic carnivores. It also makes it compulsory to vaccinate any domestic animal in contact with an animal suspected or infected with rabies.

Findings

Investigation of suspect cases

Animals suspected of rabies, displaying abnormal behaviour or carnivores found dead must be immediately reported to a veterinarian or the police who must in turn inform an official veterinarian of the CSVFSD. In the case of carnivores found dead they must be examined for rabies at the CSVFSD laboratory.

Any suspect wild animal should be immediately killed and its carcase submitted to the CSVFSD laboratory for testing for rabies. Suspect domestic animals must be isolated and kept under veterinary observation for a period of 14 days. A census of susceptible animals must be carried out and the relevant family doctor must be informed. An epidemiological enquiry must be carried out and restrictions imposed on at risk animals.

Dogs and cats that have bitten or scratched people must be isolated in cages and placed under veterinary surveillance. This can be done either at a veterinary clinic or at the owners premises. They must be clinically examined at least at the 5th 10th and 14th days after the bite or scratch after which a certificate indicating that the animal has shown or has not shown signs of rabies is issued. If signs of rabies are seen during the isolation period the animal must be killed and samples sent to the CSVFSD laboratory for testing. Other animals with suspect signs of rabies such as horses, ruminants and pigs must also be placed into isolation for a period of 14 days and similar procedures followed as for dogs and cats.

Measures taken in response to positive cases

In the case of confirmed cases, the CSVFSD, the NRL and NSVFSD are notified. An official declaration of rabies is made by the town hall of the municipality. The CSVFSD must conduct an epidemiological enquiry and establish protection and surveillance zones around the outbreak and action plan for dealing with the disease must be developed. Dogs and cats that were bitten or scratched by the infected animal must be euthanised unless they they have had a vaccination for rabies at least 21 day previously. Vaccinated animals must be placed into isolation and observed for 14 days. At the end of this surveillance period the animals must not be disposed of by the owner for a period of 3 months. In the surveillance zone a census of dogs and cats must be carried out. These dogs and cats must be vaccinated with inactivated vaccine.

The audit team noted:

- Three confirmed cases were discussed in the two CSVFSDs visited. One case was a dog in an isolated premises and the remaining dogs on the premises were killed. In another case an 11 month old bull died and was confirmed as rabies. In the protection zone there were three farms and all the at risk cattle, sheep and pigs were vaccinated as a protective measure. The third case discussed related to a cat in a premises with 21 cats and five dogs. Although the remaining cats were not previously vaccinated they were not euthanised but were vaccinated

with inactivated vaccine. Emergency rabies vaccination of all other animals in the locality was also carried out. The was no documentation on file as to why the 20 remaining cats on the outbreak premises were vaccinated rather than being euthanised or about the checks on previous vaccination of animals. In addition, documentation was not available at the CSVFSD concerning emergency vaccination, surveillance, and movement controls performed in the surveillance zone.

Conclusions on controls on rabies:

Rabies cases are generally dealt with in line with the relevant Romanian legislation. The 14 day period of isolation and observation of contact animals would, however, be insufficient to ascertain that such animals are not incubating rabies.

5.5 LABORATORIES

EU requirements

Requirements for the designation of laboratories are laid down in Article 12(1) and requirements for accreditation of laboratories are laid down in Article 12(2) and (3) of Regulation (EC) No 882/2004. Requirements pertaining to the capacity and capability of laboratories are described in Article 4(2) (c) of Regulation (EC) No 882/2004.

Article 32 of Regulation (EC) No 882/2004 defines the tasks of EU reference laboratories and Annex VII of this Regulation names *inter alia* the EURL for rabies. Article 33 of Regulation (EC) No 882/2004 requires each Member State to designate a NRL for each EURL and defines the tasks of a NRL. Specific requirements for those laboratories testing samples for those national eradication programmes which are financed by the EU are laid down in point 5(f) of the Annex to Commission Decision 2008/341/EC.

Findings

IDAH is the NRL for rabies. It coordinates the activities of the 32 out of 42 CSVFSD laboratories that are accredited for carrying out the FAT and MIT for rabies diagnosis. With respect to rabies IDAH is accredited to carry out: FAT, RT-PCR, ELISA for antibodies, genotyping of rabies viruses, fluorescent antibody virus neutralisation test and detection of tetracycline in bone used as a rabies bait marker. The NRL has successfully participated in proficiency tests organised by the EURL for rabies. The NRL also provides technical advice to the NSVFSA and is consulted in the drafting of legislation and surveillance programmes for rabies.

The 32 CSVFSD laboratories that are involved in the diagnosis of rabies use the FAT and the MIT for the diagnosis of rabies. In the counties taking part in the wildlife vaccination campaign the CSVFSD laboratories are also in charge of the reception, sampling and initial testing of foxes tested to assess the efficacy of the campaign.

The audit team noted:

- The NRL organises annual proficiency tests for CSVFSD laboratories. In cases where a CSVFSD laboratory fails to meet required standards staff from NRL will visit the laboratory

and carry out any training necessary to address the problem. The CSVFSD laboratories visited had recently successfully completed the annual proficiency test organised by the NRL.

- A comprehensive diagnostic manual is in place for rabies diagnosis. It includes the procedure for detection of post vaccinal antibodies using an indirect ELISA test based on the OIE Terrestrial Manual. The cut-off level for protective immunity is set at 0.5IU /ml in line with the WHO standard.

- Instructions are in place for determination of the age of foxes based on the pattern of dentition and counting layers of dentine in canines. However this was not always done in the CSVFSD laboratories.

- Data on the location of shooting of foxes was not always recorded represents a lost opportunity to capture epidemiological information on the effectiveness of the vaccination campaign.

- There were no plans in place to critically analyse data on the intake of vaccine bait or the effectiveness of the vaccination campaign.

- Data for 2011 provided by the NRL showed that out of 99 rabies positive cases in the rabies vaccinated counties, 27 had been genotyped to determine if they were wild rabies virus or the vaccine strain.

Conclusions on Laboratories:

A NRL for rabies diagnosis is in place as required by Article 33 of Regulation (EC) No 882/2004 and has been accredited for the tests used in respect of diagnosis of rabies and in implementation of the rabies eradication plan. There is sufficient laboratory capability and capacity for carrying out rabies related work as required by Article 4(2)(c) of Regulation (EC) No 882/2004.

The monitoring of the efficiency of oral vaccination campaigns is not fully ensured by an effective collection, transmission and analysis of sufficient data for the assessment and possible adjustment of vaccination campaigns.

Only some virus isolates from rabies positive cases are typed in order to distinguish between vaccine and field virus strains. This is not in accordance with recommendation (4) of the 2002 SCAHAW report which requires all rabies virus isolates to be so typed.

5.6 Controls in domestic animals

Findings

The registration of dogs and cats is compulsory in Romania. From the age of 3 months dogs in rural areas are vaccinated as part of an annual vaccination campaign run between October to December each year. Vaccination must be renewed each year. The vaccine is provided free of charge in the case of dogs but in the case of cats a small administration charge is made. In the case of towns and cities it is the responsibility of owners to bring their pets to private veterinarians for vaccination each year. Dogs and cats should have a document identifying them and maintaining an up-to-date record of their vaccination history.

A record of the animals vaccinated is maintained by the local official vet in the case of rural areas where official vaccination campaigns are carried out. In urban areas it is the responsibility of the private veterinarians to maintain records of vaccinated pets. The CA informed the audit team that these records are reported to the CVSFSDs. In the counties visited animal shelters were provided for stray dogs. A programme was in place whereby stray dogs where either euthanised or were vaccinated for rabies before leaving the shelter.

The audit team noted:

- In 2011out of an estimated population of 3.72 million dogs there were 3.42 million recorded as being vaccinated.

- Records of vaccinations of stray dogs carried out in animal shelters were seen in one of the CSVFSDs visited but these vaccinations had not been directly supervised by the official services.

- The audit team did not see any records of vaccination of cats but data provided to the audit team showed that approximately 74 % of the cat population of approximately one million were vaccinated for rabies in 2011.

Conclusions on Controls in domestic animals:

The vaccination of dogs is largely in line with the requirements in the Romanian rabies eradication plan. The vaccination of cats is less well controlled.

6 Overall Conclusions

The Romanian authorities have made a satisfactory start in respect of the implementation of their first aerial fox vaccination campaigns 2011. Deficiencies identified by the FVO audit team are of a nature that can be addressed in future campaigns with minor alterations to procedures. It is, however, of major concern that at the time of the audit fox vaccination campaigns had not yet been resumed for the 2012 eradication programme due to legal and administrative difficulties. If vaccination is not resumed soon, the resource that has been already been committed to vaccination of foxes will have been wasted.

7 Closing Meeting

A closing meeting was held on 25 May 2012 with the representatives of the CCA. At this meeting, the main findings and preliminary conclusions of the audit were presented by the audit team.

The CCA agreed with the main findings and preliminary conclusions presented and informed the audit team that they anticipated the current legal difficulty, that was preventing the resumption of the rabies vaccination campaign in 2012, would soon be resolved.

8 RECOMMENDATIONS

N°.	Recommendation
1.	The CCA should ensure that they have sufficient legal power to implement the eradication programme approved by Commission Implementing Decision 2011/807/EU, for the duration required to eradicate rabies. Legal powers should be sufficiently flexible in order not compromise objective of eradication of rabies.
2.	The CCA should ensure that audits of the implementation of rabies eradication programme in CSVFSDs include recommendations which are specific to the non-compliances detected by those audits, in order to ensure that appropriate measures are taken in the light of their results, as required by Article 4(6) of Regulation (EC) No 882/2004
3.	The CCA should ensure that the virus titre of each batch of oral rabies vaccine used in fox vaccination campaigns is monitored before and during realise into the field, as per recommendation (6) of the 2002 SCAHAW report.
4.	The CCA should ensure that the flight line distance should not exceed 500 m when using the aerial method of bait 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.
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 reduced 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.
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.
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

N°.	Recommendation
	needed, as required by Article 8 (3)(b) of Regulation (EC) No 882/2004.
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.

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=2012-6392

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. 2008/897/EC	OJ L 322, 2.12.2008, p. 39-49	2008/897/EC: Commission Decision of 28 November 2008 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2009 and following years
Dec. 2009/883/EC	OJ L 317, 3.12.2009, p. 36–45	2009/883/EC: Commission Decision of 26 November 2009 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2010 and following years
Dec. 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. 2008/940/EC	OJ L 335, 13.12.2008, p. 61-90	2008/940/EC: Commission Decision of 21 October 2008 laying down standard reporting requirements for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses co-financed by the Community
Dec. 2009/858/EC	OJ L 314, 1.12.2009, p. 75-78	2009/858/EC: Commission Decision of 27 November 2009 approving certain amended programmes for the eradication and monitoring of animal diseases and zoonoses for the year 2009 and amending Decision 2008/897/EC as regards the reallocation of the Community's financial contribution to certain Member States for programmes approved by that Decision and by Decision 2009/560/EC

Legal Reference	Official Journal	Title
Dec. 2011/416/EU	OJ L 185, 15.7.2011, p. 77-78	2011/416/EU: Commission Implementing Decision of 14 July 2011 approving certain amended programmes for the eradication and monitoring of animal diseases and zoonoses for the year 2011 and amending Decision 2010/712/EU as regards the financial contribution from the Union for certain programmes approved by that Decision
Dec. 2010/712/EU	OJ L 309, 25.11.2010, p. 18-30	2010/712/EU: Commission Decision of 23 November 2010 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2011 and following years
Dec. 2010/732/EU	OJ L 315, 1.12.2010, p. 43-47	2010/732/EU: Commission Decision of 30 November 2010 approving certain amended programmes for the eradication and monitoring of animal diseases and zoonoses for the year 2010 and amending Decision 2009/883/EC as regards the financial contribution by the Union for programmes approved by that Decision
Dec. 2009/560/EC	OJ L 194, 25.7.2009, p. 56-59	2009/560/EC: Commission Decision of 22 July 2009 approving certain amended programmes for the eradication and monitoring of animal diseases and zoonoses for the year 2009 and amending Decision 2008/897/EC as regards the Community's financial contribution to certain Member States for programmes approved by that Decision
Dec. 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