EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2010-8404 - MR FINAL

FINAL REPORT OF A MISSION

CARRIED OUT IN

BULGARIA

FROM 09 TO 19 NOVEMBER 2010

IN ORDER TO EVALUATE THE ANIMAL HEALTH CONTROLS IN PLACE IN RELATION TO THE ERADICATION PROGRAMME FOR RABIES

Executive Summary

The mission was carried out as part of the FVO's mission programme for 2010. It evaluated the implementation of the Community-funded rabies eradication programmes started in 2009, which include biannual oral vaccination campaigns in wildlife reservoirs, and controls to monitor the efficacy of these campaigns.

Historically, the incidence of rabies has fluctuated significantly over time. While a peak was noted between 2007 to 2009, the incidence of the disease in domestic and wild animals appears to be declining once again. Initially, the vaccination area covered the entire Bulgarian territory north of the Balkan range. Following a number of outbreaks south of the Balkan range in 2007, the CA extended the programme to cover the relevant regions.

The subcontractor responsible for the purchase, storage, distribution and dispersal of vaccine baits is generally well-organized and subject to daily official supervision during the campaign. Thus, the systems in place can enable the CA to bring the disease under control and the CA has demonstrated their ability to respond promptly to the notification of suspect disease and individual confirmed cases.

However, the results of national surveys performed to evaluate the efficacy of vaccination are generally disappointing (low levels of sero-conversion & bait uptake). Furthermore, a significant shortfall in the number of samples analysed reduce the reliability of conclusions drawn from these results. These weaknesses in sampling make it difficult for the CA to monitor progress of the vaccination programme accurately and refine their approach (e.g. changes to bait density, regions targeted, use of manual placement etc) as and when required.

The report includes recommendations to the CA addressing areas in which further improvements are required.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
CA	Competent Authority
CCA	Central Competent Authority
CDB	Central Database
DG(SANCO)	Health and Consumers Directorate-General
ELISA	Enzyme Linked ImmunoSorbent Assay
EU-RL	European Union Reference Laboratory
FVO	Food and Veterinary Office
IFT	Immuno-fluorescence test
LV	Licenced Veterinarian
MEC	Municipal Epizootic Committee
MoAF	Ministry of Agriculture and Forestry
MoEW	Ministry of Environment and Water
MoH	Ministry of Health
MS	Member State
NVS	National Veterinary Service
NRL	National Reference Laboratory
NVI	National Veterinary Institute
OV	Official Veterinarian
SCAHAW	Scientific Committee on Animal Health and Animal Welfare

1 Introduction

The mission took place in Bulgaria from 9 to 19 November 2010. The mission was undertaken as part of the FVO´s (Food and Veterinary Office) planned mission programme and was carried out as a combined mission with the FVO mission DG(SANCO)/2010-8398 on the classical swine fever eradication programme. The mission team comprised two inspectors from the FVO and a National Expert. The mission team was accompanied during the whole mission by representatives of the National Veterinary Service (NVS) of Bulgaria, which is the Central Competent Authority (CCA) within the scope of this mission.

2 Objectives Of The Mission

The objective of the mission was to evaluate the implementation measures of the programme for the eradication of rabies, approved by Commission Decision 2008/897/EC, as amended by Commission Decision 2009/858/EC and by Commission Decision 2009/883/EC.

In pursuit of these objectives, the following sites were visited:

MEETINGS/VISITS		n	COMMENTS
COMPETENT AUTHORITIES	**Central**	**2**	Initial and closing meetings
	Regional	**4**	
LABORATORIES		**1**	NRL Centre for Animal Health, Sofia
VACCINE DISTRIBUTOR		**1**	Subcontractor responsible for the aerial vaccination programme

3 Legal Basis for the Mission

The mission was carried out under the general provisions of Union 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.

Full legal references are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the last amended version.

4 Background

The Community-funded rabies eradication programmes have been approved since 2007 and include biannual oral vaccination campaigns in wildlife reservoirs, and controls to monitor the efficacy of these campaigns. However, for financial reasons, implementation of these multi-annual plans only began in January 2009. At the time of the mission, the independent subcontractor (responsible for the aerial distribution of vaccine bait) was awaiting the transfer of funds to begin the autumn campaign. The annual plans for 2009 and 2010 were approved by Commission Decisions 2008/897/EC and 2009/883/EC respectively.

Data

The CCA provided details of confirmed cases of rabies and the total number of investigations (in brackets), which are summarised as follows:

Year	Domestic carnivores	Other domestic animals	Wild animals	Total
2009	4	6	49	59 (417)
2010	4	0	2	6 (141)

Initially, the vaccination area covered the entire Bulgarian territory north of the Balkan range, as these mountains have provided a natural barrier to the spread of rabies from north to south. Following a number of outbreaks south of the Balkan range in 2007 (South West Bulgaria) and 2008 (Burgas), the NVS extended the programme to cover the relevant regions/municipalities.

Historically, the incidence of rabies has fluctuated significantly over time. While a recent peak was noted between 2007 to 2009, the incidence of the disease in domestic and wild animals appears to be declining once again. There have been no cases of human rabies since 2001.

The objective of the programme in 2011 is to ensure eradication of rabies on the territory of Republic of Bulgaria. This vaccination is to be performed for a further period of at least 5 years (i.e. 2011 - 2016), twice per year in spring and autumn (April-May and September-October).

5 Findings And Conclusions

5 Rabies eradication programme

5.1 Legal requirements

Prior to 24 May 2009, Article 24 of Council Decision 90/424/EEC empowered the Commission to reimburse from Community funds the expenditure incurred by MSs in the course of implementing national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses, including rabies. From that date, Articles 25, 26 and 27 of Council Decision 2009/470/EC provide equivalent powers.

Annex III to Council Decision 90/638/EEC establishes the criteria that programmes for the control of rabies must satisfy in order to qualify for Union funding. These include:

- description of the epidemiological situation of the disease;
- detailed information regarding the vaccination programme, including the regions to be included and the vaccines to be used;

- information concerning the costs, benefits and duration of the programme;
- designation of CAs responsible for supervising and co-ordinating the programme;
- details of the system in place to ensure the notification of all suspected or confirmed outbreaks of the disease;
- details of the control procedures and inspections carried out within the areas concerned.

Article 19 of Commission Decisions 2008/897/EC and 2009/883/EC establish certain conditions that MSs conducting programme for the eradication of animal diseases during 2009 and 2010, including rabies, must satisfy in order to be eligible to receive payment. These include:

- implementation in accordance with the provisions of Community law, including rules on competition and on the award of public contracts;
- introduction of regulations and administrative provisions necessary for the implementation of the programme;
- submission of intermediate and final technical and financial reports covering each year of the programme;
- ensuring that the programme is implemented efficiently.

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. 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 Bulgarian 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 fox to increase, diluting the overall level of population immunity. The report specifically recommends that foxes found dead and road kills 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;
- 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.

5.2 Findings

Legislation

The mission team received copies of, or information, on the main relevant Bulgarian legislation, which includes, the Law on Veterinary Activities; Ordinance No. 23 on prophylaxis and control of rabies in animals; and the Animal Protection Act.

In relation to the approved rabies programmes, Ministerial Orders approved the national programmes for control and eradication of rabies on the territory of the Republic of Bulgaria in 2009/2010 and Order No. RD 11-389 of the Director of the National Veterinary Service (NVS) established a central operation centre and regional operational centres to organise and control the implementation of the programme for the oral vaccination of foxes against rabies.

This legislation, in combination with the approved budgets for 2009 and 2010 of the Minister of Agriculture and Forestry (MoAF), and the contract signed with the contractors (these changed from 2009 to 2010) have allowed implementation of the programme (to-date, up to the spring campaign in 2010) and the control measures in domestic animals.

Organisation

While changes to the structure of the CA are foreseen in 2011, there have been no recent changes and the general organisation is as described in the most recent country profile http://ec.europa.eu/food/fvo/last5_en.cfm?co_id=BG. The implementation of the vaccination programme at a national level is steered by the NVS (MoAF) and in particular, by the Animal Health Directorate. The NVS co-operates on a regular basis with the National Forestry Administration (MoAF), the Union of Hunters and Anglers, and their district and local units. There is also co-operation with the Ministry of Health (MoH), the Ministry of the Environment and Water (MoEW) and other relevant bodies/persons. The mission team noted that:

- With regard to the vaccination programme, the NVS ensured daily control by an OV on the storage and distribution of vaccine baits by the authorised contractor.
- In response to a case of rabies the NVS co-operate with the local (municipal) authorities. In particular, the Law on Veterinary Activity permits the NVS to establish a Municipal Epizootic Committee (MEC). According to this Law, the local government bodies that make up the MEC are obliged to co-operate with and act on, the advice of the NVS.
- An Epizootic Committee can also be established at the national level by the relevant Minister (as was the case with the avian influenza threat) or at the regional level by order of the regional Governor.
- The NVS prepared awareness brochures, posters (copy provided) and other information,

which was distributed/posted in public places and alongside roads.

Vaccine used for oral immunisation

The NVS has selected an attenuated SAD Berne vaccine. In the opinion of the NRL for Rabies in Sofia, vaccination strains SAD B19 and SAD P5/88 are the most appropriate for use in Bulgaria. The contract obliges the contractor to carry out vaccination by air in accordance with SCAHAW recommendations. The mission team noted that:

- Following tests on the vaccine in 2009, the Veterinary Activity Act was amended and the product awarded a marketing authorisation. Viral titration tests are not required or performed on each batch of vaccine delivered.
- Vaccine potency (following distribution) and bait integrity is not monitored following distribution by air. The CA indicated that they would seek to determine vaccine potency during the period of uptake in the forthcoming autumn campaign.
- The CA acknowledged that much of the vaccine would be consumed by golden jackals, which have displaced foxes from some habitats. At present, vaccine uptake and seroconversion is not monitored in these animals.

Storage and distribution of oral vaccine

The contract stipulates the storage conditions and means by which the vaccine is distributed. Specifically, the cold chain (-20^0C or less) must be maintained up to the point of loading in the aircraft. Furthermore, the distribution equipment must accurately deliver the vaccine and make a permanent record of the drop sites. The mission team noted that:

- Daily logs maintained by the OV demonstrated that the vaccine storage temperature was maintained below -20^0C.
- Aircraft/helicopters flew at low level (<150 m) with a flightline distance of 500m.
- Vaccine was automatically distributed (taking account of airspeed) at a rate of 20 vaccine baits/km^2 with a gap of 100m between bait sites.
- A Global Positioning System (GPS) recorded each vaccine drop and the data was down-loaded to a computer, so that the NVS could confirm vaccine coverage.
- The contractor has reduced the total distribution time to 15 days or less (weather permitting).
- There is no distribution by hand in urban and suburban areas.

Monitoring of vaccination

The NVS carries out national surveys intended to determine both the rate of vaccine uptake and the level of immunity among wild foxes. It is estimated that a vaccination coverage of approximately 60-70 % of the fox population is sufficient to break the rabies cycle of transmission. In the CA view,

the low number of foxes in Bulgaria (approximately 40,000) already brings fox densities close to the number that will only just maintain an epizootic (0.5 fox/km^2). However, golden jackals and stray dogs (mainly in urban areas) are present in similar numbers. The mission team noted that:

- In one region, census data from 2008 – indicates a fox density of 0.23/km^2, although the CA acknowledges this in reality may be nearer to 0.5/km^2.

- The target is to take samples from 8 foxes per 100km^2 (a clear sampling protocol has been distributed to OVs, who facilitate carcass collection from hunters). The approved rabies programme for 2010 estimates 4480 foxes to be sampled for rabies virus (IFT test), sero-conversion following oral vaccination (ELISA test) and confirmation of vaccine uptake (using a tetracycline bio-marker).

The following information, which was supplied by the CCA, indicates the number and outcome of the analyses performed:

	Vaccine uptake (biomarker assay)			Immunity (presence of antibodies)		
	Tested	Positive	% positive	Tested	Positive	% positive
2009	300	39	13%	235	40	17%
2010 *(up to October)*	29	3	10%	12	4	33%

- The number of samples collected during these surveys was far less than stipulated in the approved programme (less than 10% of the target has been achieved so far).

- At present, no budget is foreseen to provide hunters with any incentive to shoot fox for sampling purposes. As a result, the number of samples analysed has fallen well below target (see table above). A bounty is paid by the National Forestry Administration for each jackal shot (approximately 12 euro), due to their impact on other wildlife. However, they are not tested, unless rabies is suspected.

Laboratory analysis

The NRL for rabies (centre for animal health) passed the accreditation procedures in March 2010 and now awaits certification by the Bulgarian Accreditation Service. The NRL carries out the following tests: IFT-test - direct immune-fluorescent test for detecting the presence of the rabies virus and an indirect ELISA - immune-enzyme test for proving the presence of antibodies after vaccination (both tests are within the scope of accreditation). They also carry out direct microscopic detection under ultraviolet light for tetracycline in tooth/bone sections (indicating bait uptake). The mission team noted that:

- The NRL does not routinely examine virus isolates from confirmed field isolates (e.g. using monoclonal antibodies) in vaccinated areas to distinguish vaccine and field virus strains.

The CA stated that a request has been made to the EU-RL for instructions on this method.

- The NRL has not participated in proficiency tests foreseen under Commission Decision 2010/436/EU for the serological tests (ELISA) used to monitor the effectiveness of the rabies vaccine, as they have only been in operation 2 years.

Investigation of suspect cases and measures in case of a positive result

The NVS regularly investigates reports of suspected cases of rabies received from the general public and from hunters. Public awareness is ensured through local media, meetings with the public and poster campaigns (particularly during aerial vaccination). Suspect cases in domestic animals are subject to official investigation and supervision during "in house" quarantine. The mission team noted that:

- A review of a number of dossiers showed a clear description of the measures taken in a suspect case, with rapid laboratory testing (less than 24 hours where checked), imposition of restrictive measures, including a movement ban (outside the affected settlement), public announcement and an epidemiological enquiry. Contact animals were either euthanaised, or subject to supervision in quarantine.

- On disease confirmation, the Director of the RVS ordered the measures to be applied and the formation of the MEC. The MEC implemented measures such as the vaccination of all domestic and farm animals in the settlement/part of the settlement affected (i.e. an administrative boundary), prohibition of slaughter, cleaning and disinfection, registration of pets and their confinement, and if necessary, shooting of stray dogs and wild carnivorous animals. There is a daily clinical examination of all animals by the OV/LVs and measures are lifted 30 days after the last rabies case.

Control in domestic animals

The identification, registration and vaccination of dogs against rabies are compulsory in Bulgaria under the Animal Protection Act. The details are to be entered into a central register which is accessible to the RVS. The mission team noted that:

- The central database put in place by the CA has only just begun operation. With the limited access to vaccination data and the absence of an accurate up-to-date pet census – it is not possible, at present, to determine the level of vaccine coverage.

- There are large numbers of stray dogs and the CA operates a programme (mainly in urban areas) where dogs are captured, ear-tagged, treated/neutered, vaccinated and then, in most cases released back in the area they were found – under the supervision of a "surveillance officer".

- Most stray dogs seen during the mission did have an ear-tag. While the CA had hoped to eliminate stray dogs by 1/1/12 (principally through re-homing and neutering), they acknowledge that the current situation may continue for some time.

- There have been 4 cases in domestic carnivores so far in 2010.

5.3 Conclusions

- Campaigns for the vaccination of wild foxes are generally well-organised and supervised, although it does not include manual bait distribution, and the approved programme does not take account of the significant golden jackal population.

- The subcontractors responsible for the purchase, storage, distribution and dispersal of vaccine baits carried out their tasks in accordance with the contract as demonstrated through the documented daily official supervision.
- The results of national surveys performed to evaluate the efficacy of vaccination are generally disappointing (low levels of sero-conversion & bait uptake). Furthermore, a significant shortfall in the number of samples analysed reduce the reliability of conclusions drawn from these results. The primary reason for the low number of samples is that the CA does not pay a bounty to hunters to shoot foxes and submit samples.

- The NRL has made good progress towards accreditation and can reliably detect the rabies virus circulating in Bulgaria. However, the NRL has yet to take part in proficiency tests for their indirect ELISA (used to determine sero-conversion following vaccination) and they do not routinely examine virus isolates from confirmed field isolates in vaccinated areas to distinguish vaccine and field virus strains.

- Systems are in place to ensure that suspect cases of disease in domestic and wild animals are notified and investigated. Furthermore, the CA takes prompt measures following a confirmed case, to stop the spread of disease, albeit that these measures were confined to the settlement affected.

- The numbers of stray dogs is unlikely to reduce significantly in the near future.

6 Overall Conclusions

The systems in place can enable the CA to bring the disease under control and the CA has demonstrated their ability to respond promptly to the notification of suspect disease and individual confirmed outbreaks. However, the weaknesses in sampling make it difficult for the CA to monitor progress of the vaccination programme accurately and refine their approach (e.g. changes to bait density, regions targeted, use of manual placement etc) as and when required.

7 Closing Meeting

During the closing meeting held in Sofia on 19 November 2010, the FVO audit team presented the findings and preliminary conclusions of the mission to the CAs.

8 RECOMMENDATIONS

The CCA is requested to provide the Commission services with an action plan, including a timetable for its completion, within one month of receipt of the report in order to address the deficiencies identified in the report and in particular, the following:

N°.	Recommendation
1.	Ensure that relevant data are collected (i.e. from sampling in foxes) and analysed after each oral rabies vaccination campaign, in order to monitor and ensure its efficacy, as per the 1st recommendation of the SCAHAW report on oral vaccination of foxes against rabies and to improve the reliability of the information on the epidemiological situation submitted in accordance with Article 1 of Council Decision 90/638/EEC.
2.	Consider distribution of vaccine bait by hand in urban and suburban areas as per recommendation 12 of the SCAHAW report on oral vaccination of foxes against rabies.
3.	The NRL should participate in a proficiency test each year on the serological tests to monitor the effectiveness of rabies vaccine as foreseen in Article 1(1) of Commission Decision 2010/436/EU.
4.	The NRL should consider typing all rabies isolates in the vaccinated areas, in order to distinguish between vaccine and field virus strains as per recommendation 4 of the SCAHAW report on oral vaccination of foxes against rabies.
5.	Where a positive rabies case has been identified, the CA should consider extending the vaccination buffer zone (in domestic animals) beyond the settlement to take account of the distance travelled by foxes (see recommendation 16 of the SCAHAW report on oral vaccination of foxes against rabies).

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

http://ec.europa.eu/food/fvo/ap/ap_bg_2010-8404.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dec. 90/638/EEC	OJ L 347, 12.12.1990, p. 27-29	90/638/EEC: Council Decision of 27 November 1990 laying down Community criteria for the eradication and monitoring of certain animal diseases
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
Dec. 90/424/EEC	OJ L 224, 18.8.1990,	90/424/EEC: Council Decision of 26 June 1990 on

Legal Reference	Official Journal	Title
	p. 19-28	expenditure in the veterinary field
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