EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Food and Veterinary Office

DG(SANTE) 2015-7624 - MR

FINAL REPORT OF AN AUDIT
CARRIED OUT IN
HUNGARY
FROM 02 FEBRUARY 2015 TO 06 FEBRUARY 2015
IN ORDER TO
EVALUATE THE IMPLEMENTATION AND PROGRESS 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 Hungary carried out 2- 6 February as part of the FVO audit programme for 2015. The objective of the audit was to evaluate whether, the programmes for eradication of rabies in Hungary for the years 2013 and 2014 approved by Commission Implementing Decisions 2012/761/EU and 2013/722/EU, have been implemented effectively and if the competent authority has sufficient data to demonstrate that the rabies eradication is progressing according to the objectives of the programmes.

It is concluded that overall, the quality controls on baits and bait storage are hampered by a lack of accreditation of the laboratory carrying out the bait titre tests, absence of inter-laboratory comparison results for the test method and by the lack of un-announced official controls on the storage conditions (cold chain) of the baits. However, there are no indications from the monitoring results that the vaccine used in 2014 had reduced potency or quality.

Monitoring of effectiveness of vaccination campaigns is carried out as outlined in the approved eradication plan. Following sampling problems in certain counties in 2013 adequate sample quality, sample numbers and test results are now available from all relevant regions for the monitoring of the 2014 vaccination campaign.

Monitoring data show that the distribution of baits has been suitable for achieving acceptable bait uptake and data of fox population immunity in 2014 show that also young foxes have been vaccinated although population sero-prevalence is less than the target of 60-70% proposed in scientific publications. However, the organisation of official supervision and control of bait distribution is such that non-compliances would only be detected after the campaign and not in time for corrections of an ongoing campaign.

Passive surveillance is effectively implemented and reliable data are available from all parts of the territory. In addition, active surveillance is implemented in vaccination areas. The results indicate that the measures taken to eradicate the 2013-2014 rabies outbreaks were effective.

The laboratories involved in the monitoring and surveillance programmes are accredited, have regular contacts with the EU reference laboratory and deliver timely and reliable results, as verified by participation in international inter-laboratory comparisons for most methods. However, not all relevant methods are included in the scope of accreditation.

The competent authority has a system in place for gathering, stratifying and analysing data which enables them to assess the effectiveness and progress of the rabies eradication. Until now the numbers of rabies cases have been the main criteria for these assessments.

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
DG(SANCO)	Health and Consumers Directorate General
DG(SANTE)	Directorate General for Health and Food Safety
EC	European Community
EDQM	European Directorate for the Quality of Medicines & Health Care
ELISA	Enzyme Linked Immuno-Sorbent Assay
EU	European Union
EURL	European Union Reference Laboratory
FVO	Food and Veterinary Office
FAT	Fluorescent antibody test (for rabies)
ISO	International Organisation for Standardisation
MA	Ministry of Agriculture
MARD	(former) Ministry of Agriculture and Rural Development
MS	Member State
NFCSO	National Food Chain Safety Office
NFCSO-VDD	NFCSO Veterinary Diagnostic Directorate
NFCSO-VMPD	NFCSO Veterinary Medicinal Products Directorate
NRL	National Reference Laboratory (for rabies)
OMCL	Official Medicines Control Laboratory

1 INTRODUCTION

This audit took place in Hungary from 2 to 6 February 2015 and was undertaken as part of the planned audit programme of the Food and Veterinary Office (FVO). The audit team comprised two auditors from the FVO. The team was accompanied throughout the audit by representatives of the National Food Chain Safety Office (NFCSO) which is the central competent authority for the scope of this audit.

2 OBJECTIVES

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

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

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

MEETINGS / VISITS		no.	COMMENTS
Competent Authorities	Central	3	Opening and closing meetings with representatives of the Ministry of Agriculture, NFCSO, and regional competent authorities One meeting with NFCSO: Directorate of Animal Health and Animal Welfare; Directorate of Veterinary Medicinal Products; Directorate of Veterinary Diagnostics; Public Procurement Office
	Regional/ local	3	County and District Offices of Bács-Kiskun County (Kecskemét Office); Jász-Nagykun-Szolnok County (Szolnok Office); Pest County (Cegléd Office)
Laboratory		1	NFCSO Veterinary Diagnostic Directorate in Budapest (National reference laboratory for rabies)
Other		3	Two meetings with representatives for local hunting associations in Bács-Kiskun and Pest counties One meeting with the contractor for vaccine distribution

3 LEGAL BASIS

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

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, and

- Article 37 of Regulation (EC) No 652/2014 of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC.

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

4 BACKGROUND

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

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

- 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 population. This report has been published here: http://www.efsa.europa.eu/en/supporting/pub/67e.htm.

- Points 5 and 6 of the Annex to Commission Implementing Decision of 16.10.2014 on the adoption of the financing decision for the year 2015 for the implementation of Union co-funded programmes for the eradication, control and surveillance of animal diseases and zoonoses sets out the objectives and expected outcomes of national veterinary programmes from 2015 (C(2014)7437 final). These objectives and expected outcomes are further explained in Commission Guidelines for the Union co-funded programmes of eradication, control and surveillance of animal diseases and zoonoses for the years 2015-2017 (Working Document SANCO/10181 Rev2). Indicators for such programmes are outlined in the Commission's Draft Working Document Animal disease eradication, control and surveillance programmes – Indicators (SANCO/12915/2012 Rev.2.) These documents are available here: http://ec.europa.eu/food/animal/diseases/index_en.htm.

Rabies has been a notifiable disease in Hungary since 1928. From the 1970's the whole country was considered infected with sylvatic rabies. In the years 1978 to 1992, between 880 and 1465 rabies cases per year were reported, 80% of which were detected in wild foxes. Vaccination of foxes started as a national programme in 1992 in parts of the country. During 2004-2007 the oral vaccination campaign covered the whole territory and a sharp decline in the number of rabies cases was seen already in 2005. The vaccination programme has been co-financed by the EU since 2007. From 2008, the vaccination area was reduced to a 50 km zone along the borders with Slovenia, Croatia, Serbia, Romania and Ukraine, however, slightly larger vaccination areas were covered 2008 and 2009 due to the epidemiological situation, and an emergency ring vaccination was performed around outbreaks in 2010. Very few cases of rabies were detected between 2005 and 2012.

However, in September 2013 rabies cases were detected in non-vaccinated areas in the middle of Hungary (in the border area of counties: Bács-Kiskun, Jász-Nagykun Szolnok, and Pest). During the last four months of 2013, rabies was detected in 22 foxes and 2 bovines. In 2014 rabies was detected in 20 foxes, 1 dog, 1 goat and 1 roe deer. All cases 2013-2014 were found in an area which had not been subject to oral vaccination since 2007. No cases were detected in the 50 km buffer zone along the southern and south-eastern borders, which has been subject to vaccinations every year since 2004.

Table 1: Rabies cases (excluding cases in bats) detected during 2008-2015 to date as well as the number of vaccination campaigns each year:

Animal species	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015 January**
Wild animals	6 foxes	2 foxes	9 foxes	0	0	22 foxes	20 foxes 1 roe deer	0
Domestic animals	1 dog	0	1 dog	0	0	2 bovines	1 dog 1 goat	0
Vaccination campaigns	spring autumn	spring autumn	spring autumn	spring autumn	spring autumn	spring autumn + emergency ring vaccination	spring autumn (extended area)	Planned spring and autumn (extended area)

The previous FVO audit report (DG(SANCO)2007-7363) on rabies eradication in Hungary is available on the Commission website: http://ec.europa.eu/food/fvo/index_en.cfm. No recommendations from that report remain open in the follow-up module of the Country Profile for Hungary (DG(SANCO)2013-6840), which has been published here: http://ec.europa.eu/food/fvo/follow_up_en.cfm?co_id=HU

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

Legal requirements

Articles 3 to 8 of Regulation No 882/2004.

Findings

1. National legislation provides the competent authorities with the necessary rules and legal powers to implement an effective rabies eradication programme, as required under Article 4(2)(e) of Regulation (EC) No 882/2004.

    - Under Act XLVI of 2008, on the food chain and official control, animal keepers are obliged to notify the private veterinarian and the competent authority of suspicious disease signs or deaths among their animals. Rabies is a notifiable disease under Decree No 113/2008 of the Ministry of Agriculture and Rural Development (MARD) on the rules of notification of animal diseases, which includes the rules for notification of rabies cases to Hungarian authorities and to the EU. Under MARD Decree No 81/2004 on animal health measures for protection against specific zoonoses, NFCSO is obliged to notify the national human health authorities of confirmed rabies cases and District Offices must report human exposure to local human health authorities.

- The main legislation for control and eradication of rabies is MARD Decree No 164/2008 on detailed rules for the protection against rabies. This Decree comprises the obligation for dog owners to keep their dogs vaccinated, rules for vaccination of other animals, definitions and measures when rabies is suspected or confirmed, and rules for passive surveillance in wild animals.
- MARD Decree No 128/2009 on veterinary medicinal products comprises *inter alia* rules for quality controls on veterinary vaccines.
- Implementing rules for each vaccination campaign are issued as a circular letter from NFCSO to all concerned County Government Offices, which subsequently issue instructions to hunting associations and District Offices.

2. In line with the requirements in Articles 4(1) and 4(2)(c) of Regulation (EC) No 882/2004 competent authorities and laboratories have been designated for all the tasks related to the rabies eradication programme. The division of tasks and chain of command is conducive to effective coordination and cooperation between the units at central level as well as between all competent authorities involved required under Articles 4(3) and 4(5) of the Regulation.

   - Department of Food Chain Control in the Ministry of Agriculture (MA) is responsible for policy and legislation *inter alia* on animal health and Department of Forestry and Game Management is responsible for policy and legislation *inter alia* on hunting. Until recently MA was called Ministry of Rural Development.
   - The NFCSO, which reports to MA, is the central competent authority for the rabies eradication programme. The national coordinator for the rabies eradication programme is placed in the Epidemiology Department of the NFCSO Animal Health and Animal Welfare Directorate. This department is responsible for determining the dates and areas for the vaccination campaigns, contacts with other national authorities and with the EU, and for supervising the implementation of the monitoring and surveillance programmes. Each vaccination and monitoring campaign is initiated by a Circular letter from NFCSO to the relevant regional competent authorities (County Government Offices).
   - The NFCSO Veterinary Medicinal Products Directorate (NFCSO-VMPD) is responsible for registration and testing of the vaccines related to the eradication programme, approval of batches delivered from the manufacturer, supervision of vaccine distribution and storage, and supervision of the vaccination campaigns (e.g. batch traceability, flight lines and bait drop data).
   - The NFCSO Public Procurement Office handles the tender procedure but professional terms and requirements of the public procurement and the contract are defined by the VMPD and by the Animal Health and Animal Welfare Directorate of the NFCSO. Once the contracts have been signed NFCSO-VMPD is in charge of contacts with the contractors for vaccine supply and vaccine distribution (aerial and manual).
   - The Veterinary Diagnostics Directorate (NFCSO-VDD) of the NFCSO Animal Health and Animal Welfare Directorate operates the three laboratories which carry out all testing for the rabies eradication programme. NFCSO-VDD has close cooperation with the NFCSO Epidemiology Department on the monitoring and surveillance programmes. The central laboratory in Budapest is the national reference laboratory (NRL) for rabies and the regional laboratories in Debrecen and Kaposvár function as control laboratories. Most samples for rabies surveillance and all samples for vaccination monitoring are submitted via local (District) competent authorities.
   - In each of the 19 County Government Offices there is a Food Chain Safety and Animal Health Directorate (hereafter referred to as County Office) which determines (for each hunting association) the number of foxes to be shot for sampling each year, issues the sampling orders to the hunting associations, organises pre-campaign meetings and supervises the implementation of the rabies eradication programme by official staff of Food District Government Offices (hereafter referred to as District Offices). All personnel

in County Offices are employed by County Governments but each Food Chain Safety and Animal Health Directorate receives its professional instructions from the NFCSO.

- Each County Government Office also has a Hunting Authority, which receives its professional guidance from the Hunting and Fishing Division of the NFCSO Agricultural Department. Prior to each vaccination and monitoring campaign the County Offices involved in the campaign issue instructions to District Offices and hunting associations. Hunting associations are legally obliged to carry out tasks included in such instructions and County Government Offices can impose penalties if hunters associations fail to meet sampling targets.
- The District Offices are implementing the tasks related to the rabies vaccination campaigns defined in the circular letters from the County Office prior to each campaign. District Offices are also involved in rabies surveillance. Their tasks include controls on the storage conditions for vaccine baits, collection of fox samples from hunters, submission of foxes to the laboratories, measures and investigations when rabies is suspected or confirmed in wildlife or domestic animals, contacts with local health authorities when humans may have been exposed to rabies and imposition of penalties *inter alia* when movement restrictions are not respected or if owners fail to vaccinate their dogs.

3. Staff performing official controls have received appropriate training enabling them to undertake their duties related to the rabies eradication competently and regularly meetings organised by the competent authorities ensure that official staff is kept up-to-date as required under Article 6 of Regulation (EC) No 882/2004.

    - There have been numerous meetings and training sessions organised by the County Offices where information on rabies surveillance, measures when rabies is suspected/confirmed, oral vaccination, monitoring of the effectiveness of vaccination has been provided to hunters, official and approved veterinarians, veterinary practitioners and occasionally the general public.
    - Before each vaccination campaign the NFCSO initiates information meetings for all relevant parties in each county. Dates and locations for these meetings are included in the NFCSO Circular letter for each campaign and participation is compulsory for the representatives of hunting associations involved in the monitoring.
    - The NCFSO-VDD holds regular meetings with representatives from County Offices on issues related to sampling and surveillance.

4. There are no documented procedures containing information and instructions for officials carrying out *inter alia* controls on storage conditions, transport and handling of vaccine baits[1]. Such procedures are required under Article 8(1) of Regulation (EC) No 882/2004 and are aimed at ensuring the quality and consistency of official controls that is required under Article 4(4) of the Regulation.

Conclusions on competent authorities

5. National legislation provides sound legal basis for all relevant aspects of the rabies eradication programme. The competent authorities have a clear division of responsibilities and a chain of command which is suitable for planning, implementation, supervision and enforcement of monitoring of the effectiveness of rabies vaccinations and rabies surveillance and prevention. Staff and stakeholders receive training and information regularly. The system is strengthened by the legal obligation for hunters to assist the authorities when directed to do so.

[1] In their comments to the draft report the competent authority stated that a checklist for district officials was issued before the 2015 spring campaign in order to harmonize the field controls on bait storage and distribution.

6. Although training on rabies eradication and surveillance takes place at all relevant levels, the lack of documented procedures for official controls by official veterinarians on the storage of oral rabies vaccine may lead to inconsistencies in the implementation of these controls.

5.2 ORAL VACCINATION OF FOXES

Legal requirements

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

Findings

5.2.1 Vaccine, vaccine storage and quality criteria

7. The winner of the public procurement contract for supply of vaccine is responsible for the supply and delivery of the vaccine baits to one cold store facility in Pest County. The oral vaccine used in recent years contains a modified attenuated SAD (Street Alabama Dufferin) Bern rabies virus strain, i.e. one of the rabies strains recommended in international guidelines.

8. The winner of the public procurement contract for vaccine distribution is responsible for storage conditions, batch traceability and vaccine distribution. The current contract covers the autumn campaign 2014 and two campaigns in 2015. The contract for the spring campaign 2014 was negotiated separately due to certain problems in the originally proposed contract.

9. The quality of each vaccine batch is checked through document checks on arrival to the cold store in Hungary and official sampling for titre control of each batch takes place before each vaccination campaign.
   - Quality criteria are specified in the tender and verified based on the documentation provided from the vaccine manufacturer, including the batch release certificate from the competent authority in the MS of origin.
   - There are no routines in place for checking the vaccine titre again if storage conditions are not met or after exposure to the elements during the period of vaccine distribution and such testing has not been carried out in recent years[2].

5.2.2 Distribution of vaccine baits

10. The 2014 oral vaccination campaigns covered 56,904 km^2 and included an area in the centre of the country where intensified vaccination took place. For 2015-2016, in addition to a 50 km zone along the southern borders, the whole territory east of the Danube River will be included in the vaccination campaigns, thus creating a total vaccination area of 66,904 km^2 (72% of the national territory).

11. Vaccination campaigns in 2013 and 2014 took place at the times indicated in the approved plans.

[2] In their comments to the draft report the competent authority stated that as of the 2015 spring campaign baits left over (in cold store, airfield storage, and following manual distribution) after distribution will be sampled and tested.

- The timing and extent of each vaccination campaign is laid down in a Circular letter from the NFCSO.
- The contractor for vaccine distribution draws up a plan for each vaccination campaign where *inter alia* areas for aerial and manual distribution are shown and numbered flight routes out of each airfield are indicated. The plan also outlines the dates for transport of vaccine baits to the airfields and proposed flight days out of each airfield and is based on dates specified in the contract. In each campaign flight lines are rotated 90 degrees compared to the lines of the previous campaign. The plan is presented to NFCSO-VMPD for approval before the start of each campaign.
- NFCSO-VMPD and the contractor hold pre-campaign meetings with the pilots so that compliance with the approved programme can be ensured.
- The same contractor and flight companies have been responsible for the aerial distribution of oral rabies vaccine during the past 10 years. The two subcontractors (flight companies) responsible for aerial distribution use seven fixed-wing airplanes operating out of six airfields. The subcontractors are responsible for the day-to-day planning and implementation of the vaccination campaign. In 2013 and 2014 the two flight companies operated on either side of river Tisza.
- There was no bait distribution at the time of this audit but the NFCSO-VMPD explained that flight routes are provided to the pilots from the subcontractors for each flight and the actual flight lines are recorded electronically. Baits are dropped from the plane by GPS-controlled equipment and each bait drop location is recorded electronically.
- Prior to each vaccination campaign the NFCSO-VMPD holds a meeting with the contractor and subcontractors (pilots) to discuss the campaign and provide updated information from the competent authorities.
- Manual distribution of approximately 2% of the baits has been subcontracted to a group of wildlife biologists linked to a university. Manual distribution takes place in a few well-defined areas around Lake Balaton and certain industrial plants and baits are distributed near fox dens and routes used by foxes. This subcontractor reports the exact routes driven or walked for bait distribution to the contractor.

12. Bait densities in 2014 were slightly higher than the average density described in the approved eradication plan.

    - According to the approved plan flight lines should be 1000 m apart and bait density 20 vaccine baits/km^2. The new areas added to the 2014 campaigns were subject to intensive vaccination, with flight line distances of 500 m, distributing 40 vaccine baits/km^2.
    - Random checks of the 2014 data carried out by the FVO team showed that the bait density had often exceeded 20 baits/km^2. None of the random checks indicated that bait densities had been lower than in the approved plan. The NFCSO-VMPD confirmed this and stated that the total number of vaccine doses had been calculated based on the total territory. When waters and settlements were excluded a higher density (average 26 baits /km) was required in order not to waste baits but operators had been instructed not to exceed 33 bait drops per km flown. Thus the bait densities vary between 20 and 33 baits /km^2 where flight lines are 1000 m apart and between 40 and 66 baits/km^2 in the new area added in 2014.

13. The contractor has delegated the responsibility for keeping records of storage temperatures, the quantities of vaccine baits loaded and unloaded from each plane, the time of loading and the number of each flight route (referring to the numbers in the plan) to the two subcontractors for aerial distribution. Such records had been kept in a standardised format and were available from all airfields in the documentation from the 2014 campaign studied by the FVO team.

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

14. Official controls on the documentation and transport conditions of vaccine batches are carried out by the competent authority on arrival of the consignment and before the vaccine can be moved into the cold store, whereby custody of the consignment is transferred from the supplier to the contractor for distribution.

    - On arrival to the Hungarian cold store the documentation and transport conditions of the vaccine consignment are examined by representatives from the NFCSO-VMPD in the presence of the relevant District Office, the contractor for supplying the vaccine, the contractor for bait distribution, and staff of the cold store facility. Compliant results of these controls (2014) were confirmed by a signature by the NFCSO-VMPD official on the delivery note.
    - Once the delivery note has been signed by NFCSO-VMPD the consignment is allowed to enter the cold store and the custody of the consignment is transferred from the contractor for vaccine supply/trading partner to the contractor for vaccine distribution.
    - Twenty baits are sampled from each vaccine batch and submitted to the NFCSO-VMPD laboratory for verification that the vaccine titre is in accordance with the manufacturer's documentation. From each 20-bait sample three baits are selected, pooled and tested in the laboratory, resulting in one titre result for each batch.
    - These samples for titre testing are taken immediately before the start of the aerial distribution campaign and test results for the vaccine batches used in 2013 and 2014 were received by the NFCSO-VMPD after the end of the relevant vaccination campaign. All vaccine batches had compliant results in 2013 and 2014.
    - No vaccine may leave the initial cold store before official sampling for titre control of each batch has been carried out by an official veterinarian in the presence of the contractor. NFCSO-VMPD confirms to the contractor that the batch samples have arrived in the laboratory.
    - The permit to move the vaccine from the cold store is not documented per se but records checked, from the two recent campaigns, showed that all vaccine batches had remained in the cold store until official samples had been taken.

15. Should a titre test result be non-compliant the contract with the vaccine supplier stipulates that a penalty will be imposed and new vaccine baits must be supplied. However, the costs for spreading a replacement batch would have to be negotiated with the distributor and paid by the competent authorities. In addition, the renewed vaccination campaign would take place at suboptimal seasons (summer or winter) and the competent authority would have to rely on documentation kept by the subcontractors on batches and flight routes to determine where the non-compliant batch of vaccine had been distributed.

16. Article 3(2) Regulation (EC) No 882/2004 states that official controls shall be carried out without prior warning. However, all controls on storage conditions, transport and distribution of the oral rabies vaccine carried out by the competent authorities are pre-announced to the operators.

    - Before the start of each campaign Circular letters are sent from NFCSO to the Food Chain Safety and Animal Health Directorates of County Government Office, comprising *inter alia* the schedule and area of the campaign, information on vaccine storage/ distribution and instructions to carry out an official control at each airfield during the vaccine distribution. For the autumn campaign 2014 this circular letter was issued three weeks before the start of the campaign and indicated suitable days for visits by official veterinarians to each airfield and contact details for agreeing the date and time for the visit with the subcontractors.

- Visits to each airfield by NFCSO-VMPD were pre-announced to the subcontractor and dates for these visits were indicated in the contractor's plan for the 2014 autumn campaign.

17. Once the 2014 vaccine batches had been accepted into the cold store the responsibility for maintaining the cold chain was delegated to the contractor/subcontractors and not closely verified by the competent authorities.

    - The contractor for aerial bait distribution had delegated the responsibility for ensuring that the cold chain was maintained from acceptance of the vaccine batches at the cold store until the end of the vaccination campaign 3-4 weeks to several subcontractors.
        - In one airfield the subcontractor (flight operator) had the day-to-day responsibilities for correct storage of the vaccine consignment, transport of vaccine baits to the airfield, storage there, batch traceability, aerial distribution of baits and manual distribution to subcontractors.
        - Two other subcontractors were responsible for transporting the vaccine from the cold store and storage at all the other airfields in the refrigerated trucks used for the transport.
        - One subcontractor was responsible for manual distribution of vaccine baits.
    - NFCSO-VMPD had planned to carry out one announced visit to each airfield during each distribution period. Records from the 2014 autumn campaign showed that such visits (by staff from central level) had been made to five of the six airfields.
    - The NFCSO-VMPD visits were recorded on standardised check lists and had been made in the presence of the operator and sometimes the official veterinarian. The check list includes checks on records of vaccine stock, manually kept temperature records, storage temperature at the time of the visit, the functionality of planes and bait drop equipment, and the texture of vaccine baits.
    - The NFCSO-VMPD visits did not include checks on flight route data or bait drop data at the airfield and neither the NFCSO nor the contractor could cross-check the manual temperature records against the built-in temperature recording devices in the transport/storage vehicles as they had no access to the readings of these during the campaign.
    - In the Circular letter for the 2014 autumn campaign District Offices were instructed to carry out one announced inspection on each airfield during the distribution period. Records from the 2014 autumn campaign showed that four of the six airfields had not been inspected from District Offices.

18. The procedures agreed between the competent authority and the contractor for immediate reporting of non-compliant storage temperatures were not adhered to in 2014.

    - The contractor for vaccine distribution does not carry out any checks on the activities of the subcontractors during the vaccine storage period or during vaccine distribution. However, the subcontractors are instructed to contact the contractor in case of problems. NFCSO-VMPD stated that it had been agreed with the contractor that such contacts should be made if the storage temperatures exceeded -15^{o}C and records of such interventions should be provided in the final report from the campaign.
    - Records in the final report from the 2014 autumn campaign showed no evidence of contacts between the subcontractor and the contractor when storage temperatures had exceeded -15^{o}C for 4 days in two of the airfields. In the second of these airfields storage temperatures up to -5^{o}C were recorded. Further checks showed that these problems had concerned one transport vehicle which, although a malfunctioning cooling unit had been identified by the flight subcontractor at one airfield, had subsequently been used by the transport subcontractor for storing vaccine at a second airfield. The contractor stated that

the subcontractor for vaccine transport and airfield storage would be requested not to use this vehicle in the next vaccination campaign.

- No deviating results in population immunity for 2014 were seen in in the areas serviced by the two airfields where non-compliant storage temperatures had been recorded however the monitoring results cover the whole year.

19. The Competent authority supervision of flight routes and bait drop data takes place after each campaign and there is no supervision which allows for corrections of vaccine distribution during a vaccination campaign.
    - NFCSO-VMPD receives verbal information daily on which of the numbered flight routes indicated in the plan have been executed that day.
    - Electronic records of flight lines and bait drop locations are kept by the subcontractors for aerial distribution until the campaign is finished. These records are then sent to an IT consultant who prepares a merged data set on a map which is provided to the contractor 2-4 week after the end of each vaccination campaign.
    - The contractor merges all information from the subcontractors and official control records into a draft final report of each vaccination campaign. Three hard copies of this report is provided to NFCSO-VMPD together with the merged data set: one for NFCSO-VMPD; one for NFCSO Animal Health and Animal Welfare Directorate; one accompanying the invoice.
    - The draft final report comprises all records from the airfields, printed maps of flight routes, temperature charts from the transport/storage vehicles, protocols from official controls and maps of routes along which manual distribution of baits have taken place. NFCSO-VMPD stated that the authority has neither the capacity nor the technical equipment required for receiving and checking electronic flight and bait drop data on a daily basis[3].
    - The merged dataset provided with the final report does not link back to the numbered flight routes and it is not possible to cross-check with individual flight times since neither the NFCSO-VMPD nor the contractor has access to the flight logs from each plane.

20. After each campaign a wrap-up meeting is organised with the subcontractors, where NFCSO-VMPD and the contractor for vaccine distribution discuss their observations from the draft report with the pilots. The report is finalised after this meeting. The report from the 2014 autumn campaign showed that vaccine appeared to have been distributed over water and that there were gaps in the bait distribution over land. The NFCSO-VMPD stated that in most of these cases the pilots' explanations were that gaps had been caused when bait distribution was stopped over fields with vehicles and workers and that the mapping software used was inaccurate and did not show open water in the correct locations. These explanations were accepted by NFCSO-VMPD.

Conclusions on oral vaccination of foxes

21. Once the vaccine has been accepted upon delivery to the cold store the responsibility for the implementation of an oral vaccination campaign rests with private operators (subcontractors) who are neither supervised by the main contractor nor subject to unannounced official controls by competent authorities during the campaign. This system is not effective as illustrated by the fact that deficiencies in the cold chain during 2014 had neither been corrected by the contractor nor reported at the time to the competent authorities.

22. Although documentation provided after the campaigns indicate that the vaccine distribution had been correctly implemented the mapping software used is considered to be inaccurate and

[3] In their comments to the draft report the competent authorities stated that as of the 2015 spring campaign GPS data are submitted daily to the competent authority.

the official control system does not include official controls on vaccine distribution at the airfields. The consequence is that the competent authority is unable to detect non-compliances or request corrections of flight routes and bait drops during a vaccination campaign.

5.3 MONITORING, AWARENESS AND SURVEILLANCE

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

- Rabies cases are detected by demonstration of rabies virus in brain tissue of infected animals. The 2010 Scientific Report states that the best chances of finding rabies cases and to declare freedom from rabies are by sampling and testing indicator animals under a passive surveillance programme i.e. testing animals that display abnormal behaviour particularly if humans have been exposed (suspect cases), road-kills, and animals found dead.
- Detection of tetracycline in teeth or bone indicates that the fox has licked or chewed the vaccine bait. In order to demonstrate that the fox has actually been vaccinated against rabies (by ingesting the vaccine inside the bait) antibodies to rabies virus must be detected in serum or body fluids. Whilst testing for tetracycline provides data on the distribution of vaccine baits, only antibody testing can demonstrate what proportion of the fox population has become protected against rabies. No animals infected with rabies are expected to survive long enough to produce antibodies, so antibodies indicate that the animal has been vaccinated. Publications of epidemiological modelling and case studies suggest that a population seroprevalence of 60-70% is needed to eliminate rabies from a fox population within a few years. A lower seroprevalence usually requires more vaccination campaigns.

Legal requirements

Article 1 of Commission Decision 2008/425/EC; Article 16 of Commission Implementing Decisions 2012/761/EC; Article 6 of the Annex to Commission Decision 2008/341/EC; Article 15 of Commission Implementing Decision 2013/722/EC; and from 2015 Articles 3(2) and 4(a)(iv) of Commission Implementing Decision 2014/288/EU.

Findings

5.3.1 Monitoring of bait uptake and population immunity

23. There is an effective system in place to ensure that sufficient monitoring samples are collected in all areas covered by oral vaccination.

    - Sampling of foxes starts 30 days after the end of each vaccination campaign and continues for approximately 100 days.
    - The Circular letter issued before each vaccination campaign stipulates the number of healthy foxes to be shot for the monitoring campaign in each country and the time period for this sampling. The Circular letter also lists the dates and locations for pre-campaign meetings with hunting association representatives and local authorities in each county.
    - The contractor responsible for bait distribution is responsible for providing kits with sampling equipment and instructions to hunters and for processing payments to hunting associations for the submission of foxes under the monitoring programme. Sampling kits are provided by the County Office to each hunting association during the pre-campaign meeting.
    - Hunters are legally obliged to provide foxes for monitoring or surveillance when instructed by the competent authorities. County Government Offices can issue penalties for failure to meet targets.

- The target number for each campaign is two foxes/100 km^2 in the areas covered by oral vaccination (4 foxes/100 km^2/year). The County Offices provide a breakdown for each hunting association in the areas covered by the vaccination campaign, based on the hunting area. The minimum number of foxes per hunting association has been set at one (for hunting areas smaller than 50 km^2). The examples seen in the counties visited showed that these procedures were timely and followed a standardised format.
- Hunters submit the whole carcases of shot foxes to an official veterinarian in a District Office. From there the foxes are transported to one of the three laboratories either by District staff or with the weekly sample collection vehicle from the laboratories.
- The contractor is responsible for processing payments to hunting associations for the sampled foxes. Hunters receive 7000 HUF per sampled fox and the hunters interviewed were satisfied with the swift processing of their invoices.

24. The monitoring of healthy foxes provides reliable data for an assessment of the effectiveness of oral vaccination. These data show that the population seroprevalence is below 50% in most counties after the 2013 and 2014 campaigns.

    - The age of the sampled foxes is determined by laboratory methods which provide reliable assessments of the age of each fox (see part 5.4).
    - The sample numbers in 2013 exceeded the national target by 10% partly as an effect of extra monitoring in the outbreak areas. Three counties achieved less than 100% (91%, 95% and 99%, respectively).
    - When three weeks remained of the 2014 sampling period 92% of the planned foxes had been submitted and only three counties had delivered less than 85% of the target numbers (84%, 69% and 70%, respectively). All these animals were tested for rabies virus and the vast majority were also tested for the bait marker (tetracycline).
    - In 2013 only 45% of the monitoring foxes tested for rabies virus were also tested for antibodies. The NFCSO-VDD explained that no serum or body fluids could be obtained from the remaining foxes. Following a review of the sample qualities and sample handling procedures in each county, instructions were issued to avoid freezing fox carcases before sending them to the laboratory. The effect of these measures can be seen in the still ongoing 2014 sampling where antibody testing has been carried out on 73% of the monitoring foxes tested for rabies virus.
    - Results from the monitoring of the 2013 vaccination campaigns show that 68% of all tested foxes had been in contact with vaccine baits. In this group, 89% of foxes 2 years or older were positive while in foxes less than one year old only 27% were positive.
    - For the ongoing monitoring of the 2014 campaigns the bait contact in foxes below one year had increased to 46% whilst the other figures were similar to those in 2013.
    - Antibody test results from the monitoring of the 2013 vaccination campaigns showed that 22% of all tested foxes had detectable antibodies against rabies virus but none of the foxes younger than one year were seropositive.
    - In the ongoing monitoring of the 2014 campaigns the sero-prevalence had risen, in that 36% of all tested foxes had detectable antibodies and for foxes below one year the figure was 25%.

25. When the antibody test results for 2013 are broken down to county level large differences between counties are evident. Of special concern is the fact that the proportions of seropositive foxes in the four counties along the Romanian and Ukrainian borders, i.e. east of river Tisza, were 3-11% whilst in counties west of river Tisza the proportion of seropositive foxes were 20-57%. River Tisza is the border between two different subcontractors (flight companies). No investigation had been carried out by NFCSO to study if inadequate handling of vaccine baits by one of the flight operators could have contributed to this difference.

26. The NFCSO-VDD stated that the poor antibody results from the counties east of river Tisza had most likely been caused by poor sample quality, presumed to have given false negative test results. This theory is supported by the results from the monitoring of the 2014 vaccination campaigns (carried out by the same flight operators) which show that once new sampling instructions had been issued the proportion of seropositive animals on both sides of river Tisza were more similar: east of Tisza 29-45%, west of Tisza 17-48%.

5.3.2 Active/targeted surveillance

27. In addition to the nationwide passive surveillance for rabies which is described under point 5.3.3., all foxes killed for monitoring of the effectiveness of the oral vaccination programme (up to four foxes per 100 km^2) are also tested for rabies virus, although such animals are not the prime targets for rabies surveillance.

- To investigate the extent of the 2013 rabies outbreak and the effectiveness of emergency vaccination NFCSO ordered that 140 foxes should be sampled in the new areas added to the vaccination zone (emergency vaccination). When these animals were included the target number of samples in the monitoring of the 2013 vaccination programme was 1818. In fact, due to over-sampling mainly in two "outbreak counties" 2005 foxes were submitted for testing to monitor the 2013 vaccination campaigns.
- Four rabid foxes were detected among the apparently healthy foxes tested to monitor the 2013 vaccination campaigns. These cases were all identified in areas that had not been vaccinated since 2007 but had been included in the emergency vaccination 2013.
- No rabies cases have been found among the 2100 foxes tested to date in the ongoing monitoring of the 2014 vaccination campaign.

5.3.3 Passive surveillance and awareness

28. Rabies is notifiable at suspicion and there is a comprehensive system of passive surveillance for rabies in wildlife and domestic animals in the whole territory of Hungary. Passive surveillance, which is the method of choice for detecting (both absence and presence of) rabies cases, is clearly distinguishable from active surveillance/monitoring throughout sampling, submission to the laboratories, analysis and reporting although certain information of relevance for the assessment of the effectiveness of the rabies eradication is not transferred from sampling forms to the electronic records.

- The passive surveillance comprises wild animals found dead and animals which have been killed because they have shown rabies-like symptoms (rabies suspect animals).
- The submission form used for the passive surveillance of wildlife includes all relevant information, e.g. potential human exposure, location, hunter, and information of whether the animal was found dead or was symptomatic. The information on whether the animal was found dead or had clinical symptoms is currently not entered by the laboratory into the electronic records used by the NFCSO to supervise and assess the surveillance.
- Thirty-eight of the 42 rabies cases in foxes 2013-2014 were found through passive surveillance. All rabid foxes were found within 70 km of the first case, in areas not vaccinated since 2007.
- The 2013-2014 rabies cases in other species than foxes were all detected via passive surveillance. These rabies-infected animals were all found in the same area as the fox rabies outbreak and the epidemiological investigations in domestic animals identified direct contact with wild foxes as the likely source of infection.
- Due to increased awareness among the population and regular meetings between NFCSO and country directors the passive surveillance almost doubled between 2013 and 2014. The increase was most prominent in the six counties in north-eastern Hungary, where the surveillance had been poor in 2013.

- During 2014, 2291 domestic and wild animals were tested for rabies under the passive surveillance programme according to a printout from the national reference laboratory (NRL). Approximately 61% of these animals were foxes and 66% of these foxes came from the three counties involved in the 2013-2014 rabies outbreaks.
- Of the foxes tested under the passive rabies surveillance in 2014 approximately 11% were from areas totally outside the 2014 vaccination area (Budapest city + five counties), 39% were from the seven counties partially covered by aerial vaccination and 50% from seven counties inside the vaccination area (one of the three counties involved in the outbreak was inside the 2014 vaccination area and two were partially covered by the 2014 vaccination).

29. The level of awareness in the population about rabies is good. Targeted information activities precede each vaccination and monitoring campaign and information material about rabies and outbreaks is provided to local authorities.

    - The contractor for vaccine distribution is responsible for printing information material for the general public prior to each campaign. Such information material is approved by NFCSO and is handed out by the County Office to local hunting associations at the meetings held in each county prior to each vaccination campaign. The material includes posters with comprehensive information for settlements and red signs to be placed outside the settlement in locations where the public would enter vaccination areas. The information on the red signs is written in Hungarian and in English. On the red signs the public is informed about the vaccination period, told not to touch vaccine baits, what to do if in contact with baits, to keep dogs on a leash and not to leave children unattended in the vaccination area.
    - NFCSO had provided municipal authorities with fact sheets and other information about the rabies outbreak and the measures taken to eradicate rabies. These authorities have the main responsibility for informing the public via announcements from mobile units and through local media. They are also the main interlocutors with media, although NFCSO also provided information via media and on their website in connection to the recent outbreak.
    - In accordance with national legislation and the circular letters sent before each vaccination campaign, the District Offices order the confinement of all dogs and the prohibition of grazing (by unvaccinated animals) in all settlements covered by the vaccination campaign for 14 days counted from the beginning of the vaccination. These grazing restrictions may be monitored by official veterinarians but NFCSO stated that the oral vaccination normally takes place during periods with no or very limited grazing.

30. Livestock in open-grazing herds may be rabies vaccinated at owner's request and expense.

31. Vaccination of dogs against rabies is compulsory and all dogs must be vaccinated within 30 days of reaching three months of age, six months later and annually thereafter. The NFCSO stated that it is not possible to assess what proportion of the dog keepers adhere to this rule and checks have been restricted to investigations around rabies outbreaks.
    - Both dog keepers and veterinarians are obliged to keep records of rabies vaccinations and veterinarians report the number of vaccinated dogs to the County Offices once per year.
    - From 2014 only dogs with microchip identification can be given rabies vaccine. It had not been assessed by the authorities if this new requirement had had a negative impact on the number of dogs being vaccinated since vaccination data from veterinary practitioners for 2014 were not yet available.
    - The County Offices decide how and when rabies vaccination of dogs should be controlled. In the three counties involved in the 2013-2014 rabies outbreak controls had been carried out only in dwellings close to suspect or confirmed rabies cases.

- Documented examples were seen where door-to-door checks had been carried out in an area where one dog had been diagnosed with rabies. Such investigations had all revealed non-vaccinated dogs.
- District Offices can issue fines of minimum 15000 HUF to owners who fail to keep their dogs vaccinated and examples were seen when such fines had been issued in areas subject to restrictions due to rabies outbreaks.
- National legislation from 2013 requires all municipal authorities to carry out a dog census every three years. No other data are available to assess the level of compliance with the dog vaccination requirements.

5.3.4 Suspect cases and measures taken when rabies has been confirmed

32. Emergency vaccination was implemented in October 2013 in a 50 km zone (6999 km^2) around the first rabies case, which was detected in the middle of September that year, in line with the recommendations in the 2002 scientific report. In 2014 vaccination areas were extended to the middle part of the country, where all rabies cases had been detected.

33. Case files studied at district levels showed that appropriate measures had been implemented swiftly and that comprehensive records of measures, tests and investigations were maintained.

- Anyone suspecting rabies in an animal (wild or under their care) is obliged to notify the private veterinarian or the local authorities directly. Evidence seen in District Offices showed that once notified the authorities took immediate action to investigate the case and ensure that appropriate samples were submitted to the laboratory. In cases where humans could have been exposed to an animal suspected of having rabies the local human health authorities were immediately notified by the District Office.
- National legislation is prescriptive with regard to measures when rabies is suspected or confirmed. Clear definitions are included for different levels of potential exposure of domestic animals, which regulate the extent of measures taken. Briefly, suspect (potentially rabid) animals are killed and examined for rabies virus; domestic animals which may have had contact with a suspect or confirmed rabies case are placed under official observation for 90 days or until the suspect animals have been declared rabies-free; a non-symptomatic, non-vaccinated animal that has bitten a human is placed under official observation for 14 days to determine if it was incubating rabies at the time of the bite.
- Case files for three rabies cases in domestic animals and five in foxes were studied in three counties. In all cases the District Office had responded swiftly to the reported suspicion and official veterinarians had visited the location the same day, carried out a preliminary investigation, organised sampling, and placed movement restrictions on domestic potential contact animals. Where domestic animals had been placed under 90 days' official monitoring the official veterinarian (or in the case of a remote village by a private veterinarian appointed by the District Office) had visited the premises every three weeks.
- Once rabies had been confirmed movement restrictions were extended to the whole settlement. Such restrictions were issued by the District Office to the notary of the settlement, public health authorities, hunting associations, municipalities, dog wardens, and the County Office. Examples were seen where fines had been issued by the District Office when movement restrictions had been violated.
- NFCSO ordered compulsory vaccination against rabies of all livestock at risk once the first rabies case in cattle was detected. Such vaccination can only be paid by the state budget if rabies has been detected in domestic animals. The County Office carried out a census of livestock and 10,887 food producing animals (sheep, cattle, horses, swine, goats and donkeys) were vaccinated on the state budget.

- District Offices often issued recommendations to vaccinate cats in areas where rabies has been detected. They can also order compulsory vaccination of cats at the owners' expense.

5.3.5 Supervision of the monitoring and surveillance programmes

34. In general, the monitoring and surveillance programmes were running to plan in 2014. Overall supervision of the sampling for the monitoring programme took place at NFCSO and corrective action was taken where necessary.

- After the spring campaign 2014 a letter were sent to the County Offices detailing the sampling results for each county. If a county had submitted fewer samples than planned for monitoring of the spring campaign they were told to add extra samples to the autumn/winter sampling.
- County Offices also maintained logs of planned samples and results from the laboratories and could issue fines to hunting associations failing to submit the correct number of foxes for monitoring. In the counties visited sample targets were met and no fines had been issued.
- The competent authority and the national reference laboratory had analysed the monitoring data from 2013 and noted that certain very young foxes had been submitted and that freezing and thawing of carcasses may have had a negative effect on sample quality for antibody testing. Amended sampling instructions were given during the pre-campaign meetings in 2014.

5.3.6 Analysis of the effectiveness of the rabies eradication programme

35. NFCSO has resources and reliable data for analysing the effectiveness of the rabies eradication programme and can rapidly produce breakdowns of monitoring and surveillance data e.g. by geographical areas, age groups and species. The overall effectiveness of the eradication programme is measured by the number of rabies cases detected through passive and active surveillance.

- All rabies-positive samples are subject to sequencing, which provides data on possible links between outbreaks in Hungary or between Hungary and other countries. The NFCSO-VDD stated that none of the cases 2013-2014 had been caused by the rabies strain used in the vaccine.
- There are data available on assessment of wildlife populations (estimates) and the exact number of wildlife hunted (hunting bag) from all hunting areas, which allows for monitoring of changes in the wildlife populations. Information provided to the FVO team indicated that fox populations followed a cyclic fluctuation while the gold jackal population was increasing in certain areas.
- NFCSO has evaluated the effectiveness of the measures taken to eradicate the 2013-2014 rabies outbreak and concluded that the outbreak was detected in time, before it spread over large areas, and that measures were successful in containing and eradicating the outbreak.
- Following the improved sampling procedures in 2014 the NFCSO has sufficient and reliable data on seroprevalence from the whole vaccination area to use for the assessment of the effectiveness of rabies vaccination. This evaluation of sample quality and a critical evaluation of the proportion of samples suitable for antibody testing only took place after the 2013 rabies outbreak, although the EU co-funded eradication programme has been in place since 2007.
- With regard to the effectiveness of the vaccination programme (sero-conversion of foxes) data have not yet been formally evaluated and no target level for fox population immunity has been set by the NFCSO.

Conclusions on monitoring, awareness and surveillance

36. The sampling for monitoring of vaccine uptake and population immunity is effectively implemented and supervised in all relevant counties. Intervention by the competent authority led to improved sample quality from the eastern part of the country in 2014 compared to 2013, which increased the reliability of the data on population immunity that are used for assessing the effectiveness of the 2014 vaccination campaigns.

37. Monitoring results of bait uptake and rabies antibodies show improved effectiveness of the vaccination campaigns in 2014 compared to 2013, particularly in foxes younger than one year. However, fox population seroprevalence is below the target levels of 60-70% proposed in scientific publication for successful rabies eradication.

38. Rabies surveillance is effectively implemented and provides reliable data to assess the effectiveness of the rabies eradication.

39. Suspicion of rabies is notifiable and suspect and confirmed rabies cases were dealt with in line with comprehensive national legislation and available scientific knowledge including swift implementation of emergency oral vaccination of foxes. None of the cases detected in 2013-2014 had been caused by the rabies strain used in the vaccine.

40. The competent authority monitors the effectiveness of the eradication programme mainly by analysing rabies surveillance data. An analysis of 2014 data indicates that the rabies outbreak in 2013-2014, which was confined to an area which had not been vaccinated since 2007, was effectively eradicated by emergency vaccination.

5.4 LABORATORY NETWORK

Legal requirements

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

Findings

41. The laboratory carrying out titre controls on vaccine batches is not accredited to ISO/IEC 17025 and the test method used has not been evaluated in inter-laboratory tests although such an inter-laboratory test for titre testing of oral rabies vaccine was organised by the EU reference laboratory for rabies (EURL) in 2011. Under Article 12 of Regulation (EC) No 882/2004, laboratories may only be designated for carrying out analysis of samples taken during official controls if they are assessed and accredited in accordance with specified European standards.

    - The laboratory in the Immunological Department of NFCSO-VMPD, which is responsible *inter alia* for titre tests on vaccine batches, is not accredited by the national accreditation body. However, the NFCSO-VMPD laboratory is an Official Medicines Control Laboratory (OMCL) and has been audited within the OMCL Network Mutual Joint Audit Scheme of the Council of Europe European Directorate for the Quality of Medicines & Health Care (EDQM). EDQM has the status of "recognised stakeholder" of the European Co-operation for Accreditation and has issued quality guidelines aiming to support laboratories in implementing ISO/IEC 17025 requirements, while taking into account the specific OMCL environment.

- The current EDQM attestation is valid from 14 January 2014 until July 2016 and declares that this laboratory has satisfactorily implemented a Quality Management System in accordance with ISO/IEC 17025. The attestation certificate does not list any methods.
- The laboratory had participated in an inter-laboratory comparison for quality controls on killed rabies vaccines for injection but the method for assessing the titre of live virus, used for testing of vaccine for the oral vaccination campaigns has not been evaluated in any inter-laboratory comparison.
- The test results for the batches used in the two 2014 campaigns were issued 22 and 16 days, respectively, after the sampling day and well after the end of each campaign.
- The certificate of analysis from 24 April 2014 provided to the FVO team includes the trade name of the vaccine, the batch numbers and expiry dates for these, and one result of titration for each batch.
- The certificate of analysis does not specify when the samples were taken and delivered to the laboratory, when the tests were performed, which method was used or how many vaccine baits were tested from each batch. Such information is normally required under ISO/IEC 17025 accreditation.

42. The NFCSO-VDD in Budapest is the NRL for rabies and is accredited to ISO/IEC 17025 together with the two other laboratories in the NFCSO-VDD network as required under Article 12 of Regulation (EC) No 882/2004. The methods and diagnostic pathways follow international standards as required under Article 5(f) of the Annex to Commission Decision 2008/341/EC. Although a majority of the relevant methods have been assessed as satisfactory in inter-laboratory comparisons organised by the EURL, only one of the test methods (FAT) used for the rabies eradication programme is included in the scope of accreditation.

- The current accreditation certificate was issued in 2014 following a period of reorganisation of the laboratory services, creating the NFCSO-VDD laboratory network with three laboratories in three locations, i.e. the NRL and two regional control laboratories, in the same quality management system and accreditation. The FAT method is included in the scope of accreditation in all three laboratories.
- The diagnostic methods and pathways are based on international standards. All three NFCSO-VDD laboratories carry out tests for rabies surveillance by FAT (all species), detection of the vaccine biomarker tetracycline in lower mandible and age determination by counting *cementum* lines and observing dentine width in un-decalcified teeth. The NRL is responsible for confirmation of rabies positive FAT results by molecular methods and cell culture test, sequencing of rabies virus, and for all detection of rabies antibodies in foxes using a commercial enzyme-linked immunosorbent assay (ELISA).
- The NRL has regular contacts with the EU reference laboratory (EURL) for rabies and participates in their annual inter-laboratory comparisons for FAT, molecular virus detection and sequencing, and fluorescent antibody virus neutralisation tests (not used for the fox programme). The test results from the last three years were all satisfactory. In 2014 the EURL organised an inter-laboratory comparison on biomarker testing and age determination and the report showed that the NRL obtained the same results as the EURL.
- No inter-laboratory comparison tests have been available for ELISA on fox samples and the ELISA method is not included in the scope of accreditation.
- All 47 FAT positive results 2013-2014 were confirmed and sequenced by molecular methods. None of the results indicated that the infection had been caused by vaccine virus.
- Testing samples for rabies is fast (6-8 hours) and the competent authorities routinely have the FAT results the same day or the day after, depending on when the sample arrived in the laboratory. If there has been human exposure these turnaround times apply also on weekends.

- Monitoring samples for serology are batched in groups of 46 in order to make full use of ELISA plates. Samples for testing of bait biomarker are also batched, stored in formaldehyde, before testing. This leads to a delay between sample submission and results.
- The NFCSO has information of incoming samples as well as results and thereby has an up-to-date overview over monitoring and surveillance. Supervision by County Offices is based on test results from the laboratories but County Offices are not informed of when samples are submitted to the laboratories from District Offices.

43. The NFCSO-VDD Budapest meets the requirements for an NRL as laid down in Article 33 of Regulation (EC) No 882/2004.

- The NRL has an active role in monitoring the progress of the sampling and participates in meetings organised by the NFCSO with County Offices after each vaccination campaign. The NFCSO-VDD also holds separate monthly meetings with the directors of County Offices where all issues related to sampling and laboratory results would be discussed.
- Laboratory information is paper-based and each sample receives a unique case number in a common NFCSO registration system. Test results are subsequently registered in the system by the laboratory and are accessible to the NFCSO e.g. for monitoring the progress of sampling.
- Following an evaluation in the NRL which showed variable sample qualities between counties the NRL and NFCSO issued amended sampling instructions in 2014 which increased the proportion of monitoring samples suitable for serology.
- In 2014 the NRL organised an inter-laboratory test of FAT for the two regional laboratories, using the material provided in the tests issued by the EURL. Both laboratories had satisfactory results.

Conclusions on laboratory network

44. The NFCSO-VDD laboratory network is accredited and has the appropriate methods for detection of rabies and for monitoring of the vaccination programme. A number of relevant methods are outside the scope of accreditation, which is mitigated to some extent by regular, successful participation in available international inter-laboratory comparisons. Such results indicate to the competent authority that those test methods are reliable and fit for purpose. However, as there have been no international inter-laboratory tests available for the method used for antibody detection in foxes the lack of accreditation of this method makes it more difficult for the competent authority to assess its reliability. The short turnaround times for samples tested for rabies virus helps the competent authorities to detect rabies cases and take timely measures.

45. The lack of accreditation of the laboratory carrying out the titre tests on vaccine batches, and the lack of results for this method from inter-laboratory comparisons makes it difficult for the competent authority to evaluate the reliability of the test results.

6 OVERALL CONCLUSIONS

The quality controls on baits and bait storage are hampered by a lack of accreditation of the laboratory carrying out the bait titre tests, absence of inter-laboratory comparison results for the test method and by the lack of un-announced official controls on the storage conditions (cold chain) of the baits. However, there are no indications from the monitoring results that the vaccine used in 2014 had reduced potency or quality.

Monitoring of effectiveness of vaccination campaigns is carried out as outlined in the approved eradication plan. Following sampling problems in certain counties in 2013 adequate sample quality, sample numbers and test results are now available from all relevant regions for the monitoring of the 2014 vaccination campaign.

Monitoring data show that the distribution of baits has been suitable for achieving acceptable bait uptake and data of fox population immunity in 2014 show that also young foxes have been vaccinated although population sero-prevalence is less than the target of 60-70% proposed in scientific publications. However, the organisation of official supervision and control of bait distribution is such that non-compliances would only be detected after the campaign and not in time for corrections of an ongoing campaign.

Passive surveillance is effectively implemented and reliable data are available from all parts of the territory. In addition, active surveillance is implemented in vaccination areas. The results indicate that the measures taken to eradicate the 2013-2014 rabies outbreaks were effective.

The laboratories involved in the monitoring and surveillance programmes are accredited, have regular contacts with the EU reference laboratory and deliver timely and reliable results, as verified by participation in international inter-laboratory comparisons for most methods. However, not all relevant methods are included in the scope of accreditation.

The competent authority has a system in place for gathering, stratifying and analysing data which enables them to assess the effectiveness and progress of the rabies eradication. Until now the numbers of rabies cases have been the main criteria for these assessments.

7 CLOSING MEETING

A closing meeting was held on 6 February 2015 with representatives of the competent authorities. At this meeting, the main findings and preliminary conclusions of the audit were presented by the audit team.

8 RECOMMENDATIONS

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

No.	Recommendation
1.	Ensure that adequate un-announced official controls are carried out, based on documented procedures, on vaccine bait storage before and during vaccine distribution to verify the maintenance of the cold chain and that the vaccine quality is maintained until distribution. Articles 3(2) and 8(1) of Regulation (EC) No 882/2004. Recommendation based on conclusions 6 and 21 Associated findings 4, 16, 17 and 18
2.	Ensure that the mapping software used for monitoring of flight routes and bait drop locations is reliable and fit for purpose and that the frequency of official controls and verifications on the vaccine distribution are sufficient to verify if vaccine distribution is carried out as described in the approved rabies eradication plan and to take timely corrective action where necessary. Articles 3(1) and 4(2)(d) of Regulation (EC) No 882/2004; Article 6(a) and (c)(i) of the Annex to Commission Decision 2008/341/EC. Recommendation based on conclusion 22 Associated findings 15,19 and 20
3.	Ensure that also the laboratory testing official samples of vaccine baits is assessed and accredited in accordance with ISO/IEC 17025 and that all test methods used for official samples tested under the approved rabies eradication programme are within the scope of accreditation in each of the relevant laboratories. Article 12 of Regulation (EC) No 882/2004. Recommendation based on conclusions 44 and 45 Associated findings 41 and 42

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dec. 2009/470/EC	OJ L 155, 18.6.2009, p. 30-45	2009/470/EC: Council Decision of 25 May 2009 on expenditure in the veterinary field (Codified version)
Dec. 2013/722/EU	OJ L 328, 7.12.2013, p. 101-117	2013/722/EU: Commission Implementing Decision of 29 November 2013 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2014 and the following years
Dec. 2012/761/EU	OJ L336, 8.12.2012, p.83-93	2012/761/EU: Commission Implementing Decision of 30 November 2012 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2013
Dec. 2008/940/EC	OJ L 335, 13.12.2008, p. 61-90	2008/940/EC: Commission Decision of 21 October 2008 laying down standard reporting requirements for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses co-financed by the Community
Dec. 2014/288/EU	OJ L 147, 17.5.2014, p. 88-113	2014/288/EU: Commission Implementing Decision of 12 May 2014 as regards the standard reporting requirements for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses co-financed by the Union and repealing Decision 2008/940/EC
Dec. 2008/425/EC	OJ L 159, 18.6.2008, p. 1-45	2008/425/EC: Commission Decision of 25 April 2008 laying down standard requirements for the submission by Member States of national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses for Community financing

Dec. 2008/341/EC	OJ L 115, 29.4.2008, p. 44-46	2008/341/EC: Commission Decision of 25 April 2008 laying down Community criteria for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses
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