EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2012-6391 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

POLAND

FROM 16 TO 20 APRIL 2012

IN ORDER TO EVALUATE THE IMPLEMENTATION OF THE RABIES ERADICATION PROGRAMME

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

Executive Summary

The reports describes the outcome of an audits carried out by the Food and Veterinary Office in Poland from16 to 20 of April 2012

The objective of the audit was to evaluate the implementation of measures contained in the Rabies eradication programme (REP), approved by Commission Decision 2010/712/EU. The audit was be conducted through data and document review, interviews with officials and, where appropriate, other parties concerned, and system verifications on-the-spot.

The Polish competent authorities (CA) have a system in place that can generally guarantee the correct implementation of the REP. The system has been recently improved in particular by straightening the collaboration between the official bodies involved in the management of the REP. The controls operated by the regional veterinary offices can guarantee the correct application of the EU and Polish rules on vaccination of foxes from acquiring and spreading of the vaccines to the monitoring of the vaccination. At the same time the flexibility in the strategy of vaccination can guarantee that an effective answer can be given to mutating epidemiological conditions in rabies.

Evidence demonstrates a high level of awareness among the population to rabies in wild and domestic animals. The high level of awareness is also reflected by the general good level of collaboration between authorities and hunters associations. However this collaboration suffers from some discrepancies in the information given to hunters across the country. In turn these discrepancies could cause some uncertainty in the interpretation and evaluation of the work carried out in the field especially concerning the monitoring of vaccination, and the evaluation of the effects of vaccination.

The striking difference between the district veterinary offices visited in the handling of outbreaks in domestic animals suggest that although the procedures established can be effectively applied, these can also be overlooked. These inconsistencies can affect negatively the implementation of the otherwise good system of rabies control in the domestic environment. In this regard the situation is further complicated by the fact that the access and information the official veterinary services have regarding the domestic population of cats and dogs can be considered at most as limited.

Concerning the diagnostic network, this operates, in general, to a very good, good or satisfactory standard. However the quality of the system is weakened in certain aspects that regard the use of non accredited methods and the organisation and participation levels of the laboratories in comparative or ring trials.

Eventually the success of the REP in Poland will depend also on the epidemiological situation in neighboring countries. In this regard the constant efforts made by the Polish authorities are not always supported due to the slow decision making procedures of some of the neighboring authorities.

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

Table of Contents

Abbreviations and definitions used in this report

Abbreviation	Explanation
CA	Competent Authority
CCA	Central Competent Authority
CVO	Central Veterinary Officer
DG(SANCO)	Health and Consumers Directorate General
DVO	District Veterinary
ELISA	Enzyme Linked Immuno-Sorbent Assay
EU-RL	European Union Referance Laboratory
FAT	Fluorescent antibody test
FVO	Food and Veterinary Office
IFT	Immuno-Fluorescence Test
MIT	Mouse inoculation test
MS	Member State
OV	Official Veterinarian
RFFIT	Rapid fluorescent focus inhibition test
RTCIT	Rabies tissue culture infection test
RVO	Regional Veterinary Office
REP	Rabies Eradication Programme
SCAHAW	Scientific Committee on Animal Health and Animal Welfare

1 Introduction

This audit took place in Poland from 16 to 20 April 2012 and was undertaken as part of the Food and Veterinary Office FVO planned audit programme. The audit team comprised two auditors from the FVO. The team was accompanied throughout the audit by representatives of the Polish Central Competent Authority (CCA) within the scope of this audit.

2 Objectives

The objective of the audit was to evaluate the implementation of measures contained in the programme for the eradication of Rabies, approved by Commission Decision 2010/712/EU. The audit was be conducted through data and document review, interviews with officials and, where appropriate, other parties concerned, and system verifications on-the-spot.

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

MEETINGS / VISITS		no.	COMMENTS
Competent Authorities	Central	1	
	Regional	2	Malopolskie and Podkarpaczkie
	District	2	Gorlitze and Krosno
Laboratories		2	The National Reference Laboratory (NRL) and the regional laboratory in Krosno
Vaccine distributor		1	Krosno airfield

3 Legal Basis

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

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

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

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

4 Background

Mass vaccination campaigns of foxes in Poland started 20 years ago. From 2002 on-wards the

vaccination of foxes has been carried out in all country. Since 2006 annual co-financed rabies eradication programmes (REP) are implemented in the country aimed at eradicating the diseases. The programmes are based on two vaccinations campaigns, in spring and in autumn and on the monitoring of those campaigns. Audits to to verify the implementation of the REPs were carried out by the FVO in 2004 and 2007. The audits focused, among the others, on the organisation of the vaccination campaigns and and the monitoring on those campaigns. Since the last FVO audit (DG(SANCO)2007-7361) 5 programmes were approved, being the last the programme approved in November 2011 for the current year. A part from the FVO audits the Commission has also carried out in Poland two financial audits on the REPs.

Concerning the epidemiology of rabies :

- more than 2000 cases of rabies per year were reported in Poland until the middle of 90s. Most of the cases were in wild animals, mainly foxes. In 1993 vaccination was introduced, and as a result it appears that two broad regions of different frequency were created: the western with a low frequency or no disease and the east with high frequency. In the year 2001 almost 3000 cases were recorded while the difference in the frequency of the disease between the western regions and the eastern regions had by then become more and more clear. After that the situation improved until 2010 and the frequency of the disease decreased both in wild and domestic animals;
- a highly significant reduction in the number of cases of rabies was recorded in 2003, the first year after the vaccination of foxes was extend to all country. In 2009 only 6 cases of rabies were reported in terrestrial animals and all in foxes, as well as two cases in bats. However in 2010 and 2011 an epidemic or rabies happened in the Malopolskie and Podcarpackie regions. The increase in incidence regarded mostly foxes but other wild life were also involved as well as domestic animals. The situation in the rest of the country remained largely favourable;
- more specifically in 2011, rabies was diagnosed in wild terrestrial animals (122 cases) in 6 regions. Wild species involved were, a part from foxes (> 80%), martens, badgers, raccoons and some deer. Rabies was also found in bats in three regions. Cases among domestic animals amount to 34 in 4 regions; 14 cases were found in cattle, 10 in cats and 9 in dogs, including 1 in a stray dog;
- broadly speaking, the areas interested by the disease remain the eastern and south eastern regions. A complete history of the evolution of the epidemiology of the disease and of the measure to control it, including vaccination, in the last 20 years can be found in the REP for 2012, submitted by the polish authorities to the EC.

5 Findings And Conclusions

5.1 Competent Authorities

EU requirements:

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

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

• The designation of CAs responsible for supervising and coordinating the programme;

• Details of the control procedures and inspections carried out within the areas concerned.

Findings:

The structure of the Polish competent authorities has been described in the Country Profile (*DG SANCO 2009/8112-Final, January 2010).* Tasks of competent authorities within the REP are still as described in the 2007 FVO report , and before that in other documents such as the report on a task force meeting of 2006 (SANCO/10506/2006). The CA management structure of the annual REP has remained fundamentally unchanged since the previous mission on the sector. Most of the management and control activities of the vaccination campaigns, monitoring and related activities are carried out by the regional veterinary offices (RVO). However the collaboration has been strengthened between all partners: CCAs, regional veterinary offices and NRL. The RVO are the key players in the organisation and implementation of the vaccination campaigns. The CCAs maintain, however a coordination role and now a closer working relationship on the management of the programme exists.

As an example of this it was explained that the CCA invites the RVOs officially by letter at the end of the year to make a proposal on the strategy for the annual programme. The regional authorities liaise with the NRL and other regions to comment on the draft. The CCA then finalise the draft taking in consideration the proposals from the regions and liaise again with the NRL to produce a final draft. Coordination activities among the regional and central authorities and NRL could also be verified on documents and reports concerning the change of strategy adopted during the epidemics in Malopolskie and Podkarpaczkie. It has also to be said that the structure has also been reinforced at central level with a staff member dedicated to the coordination of the REP, since 2009.

The management of positive cases is still carried out by the district veterinary offices (DVO), at municipal level. Is the responsibility of the district veterinary officers to impose the restrictions in an area affected, to carry out the epidemiological investigations and all the other necessary tasks such controlling the vaccination status of domestic animals in the area and organising the sampling of foxes. The activities of the DVOs will be described more in depth in the chapter dedicated to the control of the disease in domestic animals.

Concerning more in general the controls by the CCA on the general implementation of the REP the CCA stated that a programme has been prepared for 2012 to audit a certain number of regions. The audit in those region will include the implementation of the REP.

Conclusions on Competent Authorities:

The Polish CA have in the course of the years improved the system in place to manage and control the eradication of rabies. The increased collaboration between the bodies responsible of the REP allows to conclude that CA will be able to carry out effectively their duties even in emergency situation.

5.2 Controls on Rabies

EU requirements:

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

Commission Decision 2008/341/EC establishes the criteria that national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses must satisfy in order to qualify for Union funding. These include the details of the system in place to ensure the notification of all suspected or confirmed outbreaks of the disease.

Article 19 of Commission Decision 2008/897/EC, Article 19 of Commission Decision 2009/883/EC and Article 15 of Commission Decision 2010/712/EU establish certain conditions that MSs conducting programmes for the eradication of animal diseases, including rabies, during 2009, 2010 and 2011, must satisfy in order to be eligible to receive payment. These include:

- implementation in accordance with the provisions of Union law;
- introduction of regulations and administrative provisions necessary for the implementation 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 Polish eradication programme:

- Monitoring rabies incidence, bait uptake and immunity in the fox population - this is particularly important because a drop in the disease incidence allows the number of foxes to increase, diluting the overall level of population immunity. The report specifically recommends that foxes found dead should be investigated for evidence of rabies infection;
- All rabies virus isolates should be typed in areas where attenuated rabies virus vaccines are used, in order to distinguish between vaccine and field virus strains;
- Serological methods to be used for quantification of the antibody response in foxes following vaccination should be standardised, as recommended by OIE and WHO ;
- Vaccine titre in baits at batch release should be at least ten times the experimental 100% protective dose and the vaccine titre should not fall below the indicative 100% protective dose following exposure to 25°C for seven days.

- Each vaccine batch should be tested and approved for titre and stability and laboratories involved in the monitoring and evaluation of rabies programmes should monitor these titres before and during release into the field;
- The use of fixed-wing aircraft is only recommended for the treatment of uniform and large areas of low density inhabitation (e.g. large forests, mono-agricultural areas). Distribution by hand is the preferred system in urban and suburban areas, in combination with the use of an aerial distribution whenever possible;
- A biomarker (tretracycline) should be incorporated in vaccine so that bait-intake in target species can be evaluated;
- Each vaccination area should be at least 5 000 m^2, should overlap previously vaccinated areas. Buffer zones of 50 km should be created and vaccination areas should be synchronised across borders
- When using the aerial method of bait distribution, flight line distance should not exceed 500 metres, dropping to 300m in areas of high fox population density. Vaccine distribution should ensure 18 to 30 baits/km^2, according to fox population density and/or at least 10 baits per den.
- Strict adherence to transportation and cold-chain requirements should be ensured;

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

Findings:

5.2.1 Rabies eradication programme

5.2.1.1 National Legislation

Few changes were made by Polish authorities to the legal framework supporting the eradication of rabies since last FVO mission in 2007. In fact the legal instruments quoted under point 6.1 in the DG(SANCO)/2007-7361 FVO report have not been repealed or replaced. Two amendments were however made to the Act of 2004 concerning the protection of animal health and control of animal infectious diseases. One of the amendments regards the procedures for inter-ministerial consultation at the stage of preparation of the annual eradication programme. The draft programme shall be now agreed with:

1) the Minister of Finance - in financial terms,
2) the Minister of Agriculture and Rural Development - in terms of content.

Only after the above consultation has taken place the agreed draft is sent by the Chief Veterinary Officer to the EC, for approval.

The second amendment addresses a finding of the 2007 report *i.e.* the penalty for evading the protective vaccination of dogs against rabies. The legislation now allows for any person evading the vaccination of dogs to be fined. CA stated also that a change in legislation has been requested concerning the categorisation of the regions regarding the presence of rabies. At present any case of rabies in any animal species including bats means that the region is infected with rabies. Freedom from rabies includes also freedom from the infection in bats. In turn the status of freedom in a region and the length of freedom have an influence on the decision of phasing out vaccination in that region. CA are seeking, for that reason, to have rabies in bats considered in a different category

so that the status of freedom and or infection will be determined according the presence of the infection in all the others species affected.

Concerning the procedures for the implementation of the eradication programme almost all of these were also already established in 2007. A procedure has been added in 2011 (Guidance of Chief Veterinary Officer of 26 August 2011) on the method and conditions of laying doses of vaccine in the field for the tests on stability of antigen titre.

5.2.1.2 Public awareness

The awareness activities are one of the core tasks carried out by DVOs in the framework of the eradication programme. The CA at central and regional level are not involved in the programming and developing of the awareness campaigns in the distrcits. However the CCA developed guidelines on the recognition of rabies symptoms. Continued awareness on the carrying out of the vaccination campaign is an obligation. DVO must coordinate with the general public and in particular with hunters organisation on any activity concerning vaccination. The FVO team understood that various means of awareness are used including the diffusion of leaflets, the use of radio and TV broadcasting and meetings with the general public, schools and hunters. Examples of leaflets used were provided to the FVO team in one of the districts and documents related to various meetings were made available.

Proof of the knowledge on rabies by the population is the immediate reporting of suspect behaviour by domestic animals for instance. Effects of the awareness campaigns can be also considered the involvement of hunters in the monitoring of the vaccination. This is demonstrated for instance by the good results obtained in the sampling of foxes for monitoring purposes. In fact the numbers of foxes shot and handed to the DVOs, under the CA instruction is very close to the theoretical number required across all the country, with some non significant differences. Furthermore the hunters association update regularly the veterinary services on statistics of fox population. On the basis of this collaboration the CA can then plan the monitoring of the vaccination against rabies.

On the other hand it was found that the information provided by the hunters on the shot foxes is not consistent across the country. It is evident from statistics shown to the FVO team that in a significant number of regions hunters do not record or do not communicate the age of the foxes shot. Furthermore it was found that different instructions had been given to hunters association in the visited regions. Further details on this point will be given in the chapter dedicated to the monitoring of the vaccination.

5.2.1.3 Vaccine used for oral immunisation

The vaccines used are from two different EU based companies and are the same vaccines already used in 2007 (chapter 6.3.4. of that report). The strains used for the production of the two vaccines are SAD 19 and SAD Bern. The SAD strain is among the ones recommended in the WHO', OIE and EU guidelines. Both vaccines have been widely used in the last 30 years in several EU countries.

Each region is supposed to organise a tender for the supply of vaccines, at the beginning of each year. The FVO team understood that any citizen can file a complaint against the results of the tender. All complaints related to tender need to be taken in consideration and this can have an effect on vaccination delaying the start of the campaign. The start of the vaccination campaigns can also be influenced by the signing of the budged. Monetary commitments can not be taken until the Department of finances will not have assigned the money, for instance for the vaccine. Documents related to the tenders for the present campaign were made available for the FVO team to evaluate

them.

All batches of vaccines to be used in a campaign need to be tested by the NRL before being used. The FVO understood and verified that companies providing the vaccine also provide results of test carried out on batches before the delivery. However also in this case the NRL will perform an independent test on the same batches. Results of the checks carried out by both the NRL and the companies were available in the regional offices visited.

5.2.2 Implementation of the eradication programme

5.2.2.1 Storage and distribution of vaccine

The strategy to achieve the general objective to eradicate the disease hasn't changed since the previous report of 2007. The CA give a full description of the eradication strategy in their annual REPs. Since 2002 the vaccination in foxes is carried out in all regions twice a year, in May and in September.In Dolnośląskie (Lower Silesia) region only, oral vaccines against rabies are administered to wild foxes once a year, in autumn. A single vaccination campaign has been the practice in this region since 2010. This is in line with the Polish procedures regarding the length of time a region is supposed not to report case of rabies before been declared free and vaccination be discontinued. CA stated that facing out of vaccination although taken in consideration is still considered a risky option. CA added that experience in other EU countries suggests that where vaccination is performed early facing out of the programme could expose countries to rabies come back. The increase in frequency in the two southern regions seems to support the above concerns.

Concerning the implementation of the vaccination programme the vaccine is mostly distributed by air, as it was in 2007. Still a very small proportion of doses is placed by hand in areas not suitable for air vaccination such as urban agglomerations, cemeteries, dumping grounds etc. As in in 2006 (see report on task force meeting) and 2007 and the following years till 2012 the distance between the flying lines has been established at 1000m. and not at 500 as recommended by the Scientific Committee on Animal Health and Animal Welfare in 2002. However the possibility exists of changing the distance to increase the concentration depending on the epidemiological situation. The CAs effectively used this possibility in several regions (see below).

The distribution of vaccines is contracted by the regions to aviation companies. Before the start of the campaign the CA decide the fly routes that the companies will need to follow when spreading the vaccine. In order to make a contract with a company the regional CA must before organise a tender and publish it in the official journal. Citizens have the right to appeal the results of the tender, in the same way as for the vaccine supply. It was understood that in one of the regions visited the start of the vaccination had to be delayed for the spring campaign due to a complaint. Only after the complaint was evaluated and resolved the tender could be repeated and go ahead. The FVO team had access to the documents related to the tender procedure followed for the 2012 campaign and to the subsequent contracts signed, in the regions visited; the evaluation of those documents was satisfactory.

Once the campaign starts the regional the CA control daily the implementation of it. Vaccines are handed over to the air companies in the presence of the regional officials. The officials check the correct storage of vaccines including the temperature records. The vaccine provider is responsible for the correct maintenance of the cold chain. The FVO team had access to all records on the above controls activities and to some example of temperature records; it could also verify that the procedure of controls was properly followed.

The officials control also the return of the flights. This allows then to check and record the

information concerning the number of doses used in a flight and in a day and the precise area covered. The CA explained on the spot the method used to drop the vaccines and the methods to record the number of baits and the locations. From the explanation given and print-outs shown it appears that it is now possible to know at which exact point in space and time a vaccine dose is delivered, and how the delivering of baits is adjusted by computer to the speed of the aircraft and of the wind. All those activities are managed through informatics technology applied to the air-craft. The need for the air-craft to be fitted with such technologies are specifies in the tender documents and in the contracts. Records on the checks on vaccine doses used and flight routes followed were also made available for the FVO team.

It has to be noted that Polish law does not allow the use of helicopters to distribute the oral vaccine against rabies to wild foxes.

The density of vaccine doses has been established at 20 doses per square Km (see also the 2007 report and and approved REPs for Poland). The vaccination strategy can be changed at any moment, however, for the density to be adjusted to the epidemiological situation in a specific area, as happened for instance in several regions in 2010. The possibility of adjusting the vaccination strategy allowed also the CA to quickly respond to the sudden increase of cases of rabies in Malopolskie in 2010, and subsequently in Podkarpaczkie. In areas of those regions the density of vaccine was increased from the planned 20 baits to a maximum 30 baits per square Km. The increase was obtained both by reducing the distance between the flight lines (from 1000 m to 500 m.) and/or by increasing the hand distribution in chosen districts.

In 2011 the concentration of vaccine was also increased in certain regions at the border with Ukraine, in a strip 15 km deep from the border. The FVO team was able to evaluate through records all the decision process that lead to the change of strategy in the two regions visited, including minutes of meetings and contacts with the NRL. The concentration of baits was also increased in other regions, for instance the region bordering with the Russian Federation (Kaliningrad), in 2010.

It should also be pointed out that the possibility of revising the strategy, although correctly and effectively applied in the last two years, is not reflected in the REPs for 2011 and 2012. In this regard the CA stated that in order to maintain flexibility of adapting the vaccination strategy to any epidemiological change that may happen after the programmes are approved by the Commission (normally only at the end of the year) the REPs reflect the implementation of a programme in a normal situation (at least 20 baits per square km.) without specifying the increase of density in specified areas.

Concerning more in general the vaccination strategy the CCA commented extensively during the audit on the possibility to implement with the Ukrainian authorities a common agreed vaccination programme at the border between the two countries. This possibility has been under discussion at least since 2007; furthermore this had been taken in consideration in the REP submitted to the Commission for 2012. In spite of formal contacts and meetings between the two authorities even at the beginning of 2012, the combined planned actions had not yet started at the time of this audit. It was announced at the final meeting that Ukrainian authorities had in those days contacted by letter the Polish CCA regarding the programme.

Due to the nature of the disease and the main hosts, especially wild animals for which is impossible to control the movements, it is very important to stress that the epidemiological situations in border regions depends on activities carried out in all the countries sharing the borders. So that a high prevalence in one area can easily result in high prevalence in an adjoining area in an other country.

5.2.2.2 Monitoring of vaccination

The monitoring of fox vaccination is one of the fundamental parts of any annual REP and all the technical aspects (number of foxes to be shot etc.) are discussed in those documents. Monitoring concerns the level of sero-conversion and the level of vaccine uptake in the fox population. A summary table on the monitoring activities was given to the FVO team before the start of the audit. The table allows records all the sampling and laboratory analyses carried out in 2011. However the table shows also that the accuracy of data collection can vary significantly from one region to the other.

For instance data on the age of foxes shot for monitoring purposes are not available for 6 regions, with no reason evident from the table. In fact in one region it was understood that hunters associations were advised not to shoot young animals. This was not the case in the second region visited. It is important to stress at this point that not knowing the age of shot fox can have an impact on the understanding of the effect of the vaccination on the foxes population as a whole. This is especially true knowing that young animals might have limited access to vaccine. In fact during the spring campaign young foxes could be too young or newly born and so not come in contact with vaccine at all and as a result, remain unprotected. The missing data on the age of foxes do not allow to know if young foxes were included in the sample which eventually leads to not knowing the real level of protection in all the fox population.

Apart from the discrepancies described above it appears also, from the table mentioned above, that although the number of foxes shot for monitoring is generally satisfactory, in some regions, in particular in two of them, the number of serological analyses is much smaller than the number of foxes shot or than the number of analyses carried out to calculate the vaccine uptake (biomarker). The CA explained and gave written evidence that these differences were due to the non suitability of the carcases for the sero-sampling. It was in fact explained that, contrary to requirements, the shot foxes had been frozen by the hunters before being handed to the veterinary services. The freezing of the carcases apparently compromised the possibility of extracting good samples.

In spite of the shortcomings described above the results shown to the FVO team are in line with the results expected by the CA. Sero-conversion is in general above or equal to the level of 75 %, across all the regions. The same applies to the level of vaccine intake, where the bio-marker presence shows that vaccine intake is well above 80%. However considering the shortcoming discussed above on the age of foxes, it could be difficult in certain regions to know if those percentages relate to the fox population as a whole or only to a certain category. Broadly speaking it seems that there's a positive correlation between the two sets of results on serology and bio-markers. However in certain regions results on vaccine intake do not match the results on sero-conversion. It might not be a coincidence that among these are also the two regions where a low number of foxes were suitable for sero-sampling.

The controls on vaccines potency are ensured by tests carried out on doses laid out specifically during the vaccine distribution. For this purpose a certain number of vaccine doses are laid on the field protected by a metal grid. Guidelines on how to protect and lay those doses were produced by the CCA. The NRL has the task of analysing the vaccine after 10 days of being laid in the field. From the analyses carried out no significant change in vaccine potency was registered after the laying of vaccine in the field.

5.2.2.3 Investigation of suspect cases

Rabies is a notifiable disease in Poland. According to the Polish Act of March 2004 on animal health it is compulsory to notify any suspect of rabies in animals. All suspects in this regard should be reported to the nearest DVO. In practical terms, members of the public can inform a private veterinarian on any suspect of rabies. Private veterinarians can evaluate the case and then according to their diagnosis or suspect, must report to the relevant DVO.

The continuous monitoring of rabies in the wild is also ensured by the DVOs. To this end a system of passive surveillance is established all over the country where all dead foxes have to be reported to the DVOs. Foxes dead as a result of traffic accidents, killed near farms or shot while presenting clinical symptoms, are all part of the passive surveillance system. As a result in 2011, 1290 foxes carcases were presented for rabies testing to the veterinary services.

The Polish regulation on the eradication of rabies (Dz.U. of 21 January 2005) describes the procedures and actions that CA must implement in a case of rabies suspected and/or confirmed. The implementation of those rules was evaluated in two examples of rabies in domestic animals, one from each region visited. In both cases the suspicion of unusual behaviour in domestic carnivores was reported by the owners to private veterinarians and the private veterinarians informed then the DVO. However, the FVO team found some significant differences in the way the two cases were subsequently handled.

In particular in one case, after the official vet visited the suspect animal only limited actions were taken for one week, these were the culling (euthanasia) of the suspect animal: (a cat), information sent to the human health inspection and the disinfection of the site. Other than that samples were sent to the laboratory with a significant delay, and any investigation in the surrounding area initiated after a week on the receipt of the positive result from the laboratory. The CA explained and gave evidence that the case was registered at the beginning of the weekend of Christmas in 2011, and this caused the postponement of the control actions, including: the information to the regional CA and neighbouring districts and the epidemiological investigation. No controls were imposed, on suspicion, on the movements of animals that had be in contact with the rabid cat. Those animals were eventually euthanatized and disposed of with no further analyses after one week. The checks on the vaccination status of the animals in the surroundings was also delayed for one week.

The documentation of the case was found to be insufficient regarding in particular the epidemiological aspects. On the other hand complete documentation was available in the second case evaluated by the FVO team. In this case it was possible to verify that the district CA had taken and recorded all the actions prescribed in the mentioned regulation. The difference on the measures taken in a suspect and /or confirmed case, the timing and extent of those measures are further discussed in the chapter below.

5.2.2.4 Measures taken in response to positive cases

As in a case of suspicion, in case of confirmation of rabies the responsibility to take action remains with the district CA. The procedure to follow and actions to implement are also described in the Polish regulation mentioned in the chapter above. It should be mentioned that the DVOs have in particular the duty to inform about the case all stakeholders: general public, public administrations, local crisis centres and human health services. The communication to the latter is essential because the human health service will be in charge on any decision on the vaccination to be given to people

exposed to a rabid animal

In the second case evaluated by the FVO team it was possible to verify all actions taken following the confirmation of rabies. Data and materials were available to verify the awareness activities carried out by the DVOs, including the distribution of leaflets, posters and press articles. Documents were also available describing the flow of information between the DVO, the human health services, municipal authorities and prefect, neighbouring districts and all parties concerned. Administrative decisions were also available that had been taken to impose restrictions in and around the outbreak. These latter concerned in particular instructions that had been provided to dog owners on the obligation to keep the animals isolated.

From the documents it was also possible to verify that a complete epidemiological investigation had been carried out and properly recorded. Records on the fine imposed for failing to vaccinate dogs were also available. From all the above documentation it was understood that all the activities had been carried out in 5 days, and that the laboratory results were available in less than two days.

Concerning surveillance in the area surrounding the outbreaks the results were available of the activities carried out including the check on the vaccination status of the dog population and the census of susceptible animals. In this regard the CAs have clear instruction on which restriction measures should be imposed and on the length of those measures according to the distance from the focal point. Restrictions are released after the established time has elapsed and the sanitary shooting of at least two foxes with negative results has been achieved. The CA gave also details of the surveillance activities that would be carried out in case the rabid animal would be a ruminant, and on the monitoring that would be carried out following the detection of the case

Conclusions on Rabies Eradication Programme:

The evolution of rabies cases numbers in domestic and wild animals suggests that the continuous vaccination of foxes have had a positive effect on the epidemiology of the disease in Poland. Still the re-occurrence of outbreaks in previously free area suggest that caution should be maintained on radically changing the strategy or phasing out the vaccination.

The CA have maintained and improved since the last mission their generally effective legal framework concerning the REP. The level of awareness and communication with all stakeholders can also be considered satisfactory, however the level of communication with some hunters' associations is insufficient and distorts the data collected on the vaccination campaigns. Concerning the vaccines used all documentary evidence demonstrates that the CA maintain a close control over this item.

Furthermore the Polish CA have a set of rules and procedures that can guarantee a correct implementation of the REPs. Procedures for controls can also ensure that the vaccination programme is carried out in accordance with the strategy agreed between the CCA, the RVOs and the NRL. Flexibility in the application of some technical parameters also ensures that the vaccination programme can be adjusted to the real epidemiological situation in the field. CAs continue also to carry out an effective monitoring campaign. These results allow to conclude positively on the effect of the vaccination. However, misunderstandings between CAs and hunters associations, especially in certain regions, are having an influence or even introducing a bias in the effect of vaccination over the total fox population. Eventually, in spite of the efforts of the Polish CAs to involve neighbouring countries in the eradication campaign, no satisfactory action could be implemented with Ukraine. This can result in a certain degree of uncertainty on the evolution of the REP in the areas bordering with that country.

The rules in place, if implemented correctly, can guarantee the detection and control of rabies outbreaks. In particular it can be concluded that these rules and procedures applied in case of suspicion and or confirmation of rabies have a protective effect on the human population. However the efficacy of those rules can be undermined by a non consistent implementation, exposing animals and people to the risk of being infected.

5.3 LABORATORIES

EU requirements:

Requirements for designation of official laboratories are laid down in Article 12 of Regulation (EC) No 882/2004.

Article 4(2)(c) of Regulation (EC) No 882/2004 requires CAs to ensure that they have access to an adequate laboratory capacity for testing.

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

Findings:

The Laboratory of Virology at the National Veterinary Research Institute in Pulawy was officially designated as the NRL for rabies in 2003. This designation was updated under Regulation of the Minister of Agriculture and Rural Development of 23 December 2010 on national reference laboratories. As required under Article 33(4) this information has been made publicly available on the website of the Commission.

The NRL has all the methods used for the rabies eradication programme, i.e. detection of virus antigen in brain imprints by fluorescent antibody test (FAT), virus isolation by rabies tissue culture infection test (RTCIT) and by mouse inoculation test (MIT), detection of rabies virus genome by reverse-transcription polymerase chain reaction (RT-PCR), detection of rabies antibodies by rapid fluorescent focus inhibition test (RFFIT) and fluorescent antibody virus neutralisation, and detection of the vaccine marker tetracycline in bone tissue (TC-test).

The NRL is responsible for quality controls on the oral vaccine for foxes and carries out tests on each batch before market authorisation is granted, before spread of vaccine and after 10 days under field conditions. The NRL also carries out confirmatory analyses of all samples with inconclusive results for rabies virus in regional laboratories, carries out genotyping of all rabies virus isolates from domestic and wild animals as well as sequencing of virus genomes for epidemiological studies.

The audit team visited the NRL and noted that:

- as required under Article 12 points (2) and (3) of Regulation (EC) No 882/2004 the laboratory is accredited to EN ISO/IEC 17025 by the Polish Centre for Accreditation (*Polskie Centrum Akredytacji*). The accreditation scope is fixed, i.e. specific approval is required for accreditation of each new method. Out of the seven methods available in the NRL for the rabies eradication programme four (MIT, RT-PCR, RFFIT and TC-test) were not included in the scope of accreditation, which is not in line with the requirements of Article 12 points (2) of Regulation (EC) No 882/2004;

- the laboratory regularly carried out its NRL task as required under Article 33 of Regulation (EC) No 882/2004. Activities have included technical and scientific support to the competent authorities at all levels, collaboration with the EURL, dissemination of information to regional laboratories, coordination of certain activities in regional laboratories, regular training of laboratory staff and organisation of proficiency tests;
- copies were available of approval certificates (for specified test methods) for staff of regional laboratories who had been trained in the NRL during 2012;
- there were two general standard operating procedures (SOP) for validation of serological and microbiological/molecular methods, respectively, for the National Veterinary Research Institute. The appropriate validation SOP was used when methods were validated. The validation report for RTCIT was checked and contained data on sensitivity, specificity and comparisons with another method (FAT). Successful participation in proficiency tests was considered sufficient to meet the other relevant validation criteria;
- during the past three years (2009-2011) the NRL had organised proficiency tests for FAT (three times) and MIT/RTCIT (twice) for the regional laboratories. The NRL's own diagnostic laboratory had not participated in these proficiency tests;
- during the past three years (2009-2011) the NRL had participated in annual proficiency tests organised by the EURL for FAT, RTCIT and RT-PCR with satisfactory results as required under Point (5)(f) of the Annex to Commission Decision 2008/341/EC;
- although the NRL responsibilities included supervision of regional laboratories carrying out TC-tests and RFFIT for monitoring of the vaccination programme the NRL had not organised any proficiency tests or comparative tests for these two methods. Nor had the NRL participated in any such tests for these methods. The head of the virology laboratory stated that comparative tests for the TC-tests were provisionally planned for 2013.
- when assessing the progress of the oral vaccination programme the NRL relied on the results of certain laboratories using analytical methods which had neither been accredited nor assessed in comparative tests/ring tests during the past three years. These methods were RFFIT in one regional laboratory responsible for the analysis of samples from six regions (approximately 50% of all foxes in the monitoring) and TC-test in another regional laboratory responsible for the analysis of samples from one region.

There are 16 regional laboratories and 3 local units/laboratories which each carry out certain analyses linked to the rabies eradication programme. All are accredited to ISO 17025 as required under Article 12 points (2) and (3) of Regulation (EC) No 882/2004. For 2012 all the regional laboratories carry out FAT, eight of them carry out MIT, six carry out TC-tests, six carry out RTCIT and three carry out RFFIT. According to a summary provided by the competent authority four of the regional laboratories are using methods for official controls under the rabies eradication programme which are not included in their respective accreditation scopes.

Designated laboratory status for testing samples under the rabies eradication programme is granted by the central veterinary officer (CVO) and lists of approved regional laboratories are published in Decisions. Before a method can be listed the laboratory must submit proof of validation, results of proficiency tests and an opinion from the NRL verifying that the laboratory has appropriately trained staff. The designated regional laboratories are obliged to participate in proficiency tests and comparative tests organised by the NRL but participation in such tests organised by other laboratories is not compulsory.

In addition to the proficiency tests provided by the NRL for FAT, MIT and RTCIT, the regional laboratory in Ostroleka has organised comparative tests/ring tests for TC-test and RFFIT in regional

laboratories.

Data provided by the CA showed that in 2009, 2010 or 2011 the regional laboratory in Bydgozcz did not participate in the comparative tests for RFFIT and the regional laboratory in Lodz did not participate in the comparative tests for the TC-test. Both these laboratories are listed by the CVO for use of these methods, which are not included in their respective scopes of accreditation, for analysis of official samples for the 2012 rabies eradication programme.

The audit team visited the regional laboratory in Krozno, which carries out FAT, RTCIT and TC-tests for the rabies eradication programme in Podcarpackie region, and noted that:

- one (RTCIT) of the three methods used for the rabies eradication programme was not included in the scope of accreditation. However, staff had been trained by the NRL, the validated method had been successfully used in a recent proficiency test and an application for accreditation had been submitted to the Polish Centre for Accreditation in preparation for the next accreditation audit in May 2012. From 21 March 2012 the Krosno laboratory had been added by the CVO to the list of laboratories authorised to use RTCIT under the rabies eradication programme;
- there was a general SOP for validation for the laboratory. In addition a detailed, method-specific technical instruction was prepared within the framework of the quality system before validation of a method took place. The validation report for the recently validated RTCIT included all aspects defined in the technical instruction for this validation, including *inter alia* sensitivity, intra-laboratory variation, accuracy, consistency repeatability and reproducibility, inter-laboratory comparison, robustness and sources of uncertainty;
- the laboratory had participated in all relevant proficiency tests and comparative tests during the past three years. The results had been mostly satisfactory;
- in addition to the regular participation in proficiency and comparative tests, a program for method specific quality controls was available. For FAT and TC-test series of eight positive/negative control samples were added to the incoming samples once per year. Records of such quality control series were available for the three years checked (2009, 2010, 2011). Every sample was tested in duplicate. For FAT, positive and negative control samples were also added every ten samples and at the beginning of each series of samples tested;
- training records were available for staff and method-specific individual authorisations had been issued by the head of the laboratory and were kept updated;
- samples were given unique laboratory numbers on arrival and were registered in a laboratory information system;
- for the vast majority of rabies positive samples in 2012 results had been issued to the relevant competent authorities on the day the sample arrived in the laboratory or on the following day;
- this laboratory had managed to extract serum for antibody-testing from the vast majority of foxes submitted by hunters under the monitoring programme. These serum samples were sent to another regional laboratory for analysis by RFFIT once it had been established that the sampled fox was virus-negative.

Conclusions on Laboratories:

Whilst all laboratories in the network are accredited to ISO 17025 and all regional laboratory staff has been trained by the NRL a number of the analytical methods used for the rabies programme in the NRL and in four of the nineteen regional laboratories are not included in the scopes of accreditation in those laboratories, which fails to meet the requirements of Article 12 points (2) of

Regulation (EC) No 882/2004. The NRL meets most of its tasks but does not provide the laboratory network with proficiency tests for all relevant methods. In addition, the evaluation of the overall effectiveness of the fox vaccination programme by the competent authorities is undermined by the fact that a large proportion of the antibody results, upon which this evaluation is based, are generated by one regional laboratory where the analytical method has neither been accredited nor assessed in comparative tests/ring tests in recent years.

5.4 Controls in domestic animals

Findings:

There is no obligation for the veterinary services to register dogs and maintain statistics on the dog population. The municipal councils may impose a charge for dog ownership, but it is not a requirement to do so. Under the provisions in force, the registration of dogs is not compulsory. Some municipal authorities have programmes for the electronic identification and registration of dogs. The stray/feral dog population is estimated at around 40.000 dogs, while about 100.000 dogs are estimated not to be kept under proper control. No particular actions are in place to control the feral dog population. However, the CA stated that if an uncontrolled dog is captured, it is identified and vaccinated.

Furthermore starting from 2012 it is required from the regions the establishment of programmes to reduce the phenomenon of free-roaming dogs. This is in accordance with new Polish rules on animal welfare. In accordance with the provisions in force, dogs may not be released from the control of their owners. Restrictions have also been introduced on the sale of dogs outside breeding sites or kennels and the commercial breeding of dogs from places other than registered kennels. In the meanwhile it is no longer allowed for hunters to shoot stray dogs. In this regard it should also be highlighted that, at least in one region, a stray dog was found to be rabies positive.

According to Polish legislation from 2004 on animal health, any dog above 3 months of age should be vaccinated against rabies; vaccination should be repeated every year. However only about 2,500,000 dogs were vaccinated in 2010. This represents about 50% of the domestic dog population according to the CA and according to statistics calculated during investigation of positive cases. One of the changes on legislation concerning rabies concerns the fine to be imposed on dog owners failing to apply the vaccination rule. The vaccination of cats was included among the measures suggested to contain an outbreak of rabies in domestic animals, however this is not a requirement in Polish legislation. A document was also made available where the CCA instructed the regions to promote the vaccination against rabies in cats and dogs and to collaborate with local enforcing bodies to enforce this requirement.

Vaccination of dogs is done by private vets, who need to report monthly to the CA the number of vaccinated animals. The FVO team understood that the veterinary service at district level have a certain degree of responsibility but limited man-power and few occasions to check on the correct application of the vaccination rules. One such occasion is represented by the surveillance activities carried out around the outbreaks (3 km area) of rabies. In the framework of such activities the vaccination status of domestic animal is verified. In those circumstances official veterinarians can also calculate the number of domestic animals including cats and dogs. The FVO team was provided with evidence of those checks. Evidence was also available of fines imposed in the case that owners had not vaccinated their dogs.

Conclusions on Controls in Domestic Animals

The CAs have limited responsibilities on the control of dog population both domestic and wild, and limited power to check on the vaccination status of dogs, or other domestic animals. In spite of that they make good use of the opportunities given to them by the REPs and their general power on the control of animal diseases to enforce the rules on vaccination and to update their knowledge on the dogs population.

6 Overall Conclusions

The Polish CAs have a system in place that can generally guarantee the correct implementation of the REP. The system has been recently improved in particular by straightening the collaboration between the official bodies involved in the management of the REP. The controls operated by the RVO can guarantee the correct application of the EU and Polish rules on vaccination of foxes from acquiring and spreading of the vaccines to the monitoring of the vaccination. At the same time the flexibility in the strategy of vaccination can guarantee that an effective answer can be given to mutating epidemiological conditions in rabies.

Evidence demonstrates a high level of awareness among the population to rabies in wild and domestic animals. The high level of awareness is also reflected by the good level of collaboration between authorities and hunters associations. However this collaboration suffers from some discrepancies in the information given to hunters across the country. In turn these discrepancies could cause some uncertainty in the interpretation and evaluation of the work carried out in the field especially concerning the monitoring of vaccination, and the evaluation of the effects of vaccination.

The striking difference between the DVOs visited in the handling of outbreaks in domestic animals suggest that although the procedures established can be effectively applied, these can also be overlooked. These inconsistencies can affect negatively the implementation of the otherwise good system of rabies control in the domestic environment. In this regard the situation is further complicated by the fact that the access to and information of the official veterinary services have regarding the domestic population of cats and dogs can be considered at most as limited.

Concerning the diagnostic network, it can be concluded that this operates, in general, to a very good, good or satisfactory standard. However the quality of the system is weakeaned in certain aspects that regard the use of non accredited methods and the organisation and participation levels of the laboratories in comparative or ring trials.

Eventually the success of the REP in Poland will depend also on the epidemiological situation in neighboring countries. In this regard the constant efforts made by the Polish authorities are not always supported due to the slow decision making procedures of some of the neighboring authorities.

7 Closing Meeting

A closing meeting was held on 20 April with the representatives of the CCA, the NRL and RVOs. At this meeting, the main findings and preliminary conclusions of the audit were presented by the audit team.

The CA provided the FVO team with a series of documents in relation to issues discussed during the audit. The CA stated also that the programme of audits on RVOs for 2012 would be modified to take in consideration some of the findings[1]. Other comments were made on the duties and power of

1 In their response to the draft report, the CA noted that, due to the broad scope of the audits, shortage of staff and the significance of the shortcomings found by the FVO team, the audit from the central CA did not take place, as stated at the final meeting. It also stated that the audits would, however be carried out at regional and central level, not at district level.

veterinary services toward the controls on the dog population and on the laboratory performances.

8 RECOMMENDATIONS

N°.	Recommendation
1.	The CCA should coordinate the activities of RVOs to ensure that consistent instructions are diffused across the country to hunters' associations concerning the sampling of foxes in the monitoring activities to satisfy the requirement of Article 15 (f) of Commission Decision 2010/712/EC.
2.	The CCA should ensure a consistent implementation across the country of the rules on rabies eradication including Polish regulation on the eradication of rabies (Dz.U. of 21 January 2005) and in line with Commission Decision 2010/712/EC Article 15 (a) and (f).
3.	Ensure that the NRL organises comparative tests for those analyses which are relevant to the rabies eradication programme as required by Article 33.2.(c) of Regulation (EC) No 882/2004.
4.	Ensure that all laboratories testing official samples for the rabies eradication programme use analytical methods which are i) included in the scope of accreditation in order to meet the requirements of Article 12 points (2) of Regulation (EC) No 882/2004 and ii) assessed in national comparative tests/ring tests as required by Point (5)(f) of the Annex to Commission Decision 2008/341/EC.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6391

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Dec. 2008/897/EC	OJ L 322, 2.12.2008, p. 39-49	2008/897/EC: Commission Decision of 28 November 2008 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2009 and following years
Dec. 2009/883/EC	OJ L 317, 3.12.2009, p. 36–45	2009/883/EC: Commission Decision of 26 November 2009 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2010 and following years
Dec. 2009/470/EC	OJ L 155, 18.6.2009, p. 30-45	2009/470/EC: Council Decision of 25 May 2009 on expenditure in the veterinary field (Codified version)
Dec. 2008/940/EC	OJ L 335, 13.12.2008, p. 61-90	2008/940/EC: Commission Decision of 21 October 2008 laying down standard reporting requirements for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses co-financed by the Community
Dec. 2009/858/EC	OJ L 314, 1.12.2009, p. 75-78	2009/858/EC: Commission Decision of 27 November 2009 approving certain amended programmes for the eradication and monitoring of animal diseases and zoonoses for the year 2009 and amending Decision 2008/897/EC as regards the reallocation of the Community's financial contribution to certain Member States for programmes approved by that Decision and by Decision 2009/560/EC

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