EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2010-8398 - MR FINAL

FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

BULGARIA

FROM 09 TO 19 NOVEMBER 2010

IN ORDER TO EVALUATE THE ANIMAL HEALTH CONTROLS IN PLACE FOR CLASSICAL SWINE FEVER

IN THE CONTEXT OF A GENERAL AUDIT

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) specific audit in Bulgaria, which took place between 9 to 19 November 2010, as part of the general audit of Bulgaria carried out under the provisions of Regulation (EC) No 882/2004 on official food and feed controls.

The specific audit evaluated the implementation of national measures, aimed at the control of CSF in domestic and feral pig populations in Bulgaria.
It is concluded that the CA has introduced a somewhat complex identification and farm registration system for the domestic pig population. A comprehensive surveillance programme has been established based on clinical examinations and sampling and the vaccination of wild boars has been restricted to a 40 km zone along the border since 2008. The outbreak in a wild pig population was successfully contained in 2009 by combining measures foreseen for disease outbreaks in both domestic and feral pigs.

However, information in the central data base is not fully up to date and the lack of facilities for extraction and filtering of animal movement data limit its usefulness for epidemiological enquires. Furthermore, there are weaknesses in the implementation of the control and eradication programme of CSF, particularly the incomplete surveillance of type B and backyard farms with poor biosecurity and the lack of targeted sampling in vaccinated and non-vaccinated feral pig populations, which undermine the ability of the CA to demonstrate their freedom from CSF.

In spite of the intensive monitoring programme, East Balkan pigs remain the population at most risk of being infected as contacts with wild boars cannot be excluded. Furthermore, the spread of infection would be difficult to control among different herds as they share extensive grazing areas. The FVO team was not in the position to verify whether animals to be slaughtered for intra Union trade are kept isolated for 30 days and under strict veterinary control to assure freedom from CSF and traceability of meat at all stages of production, processing and distribution.

The report makes a number of recommendations to the Bulgarian competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.

Table of Contents

Abbreviations and definitions used in this report

Abbreviation	Explanation
Ab-ELISA	Enzyme-linked-immunosorbent assay for detection of antibodies
Ag-ELISA	Enzyme-linked-immunosorbent assay for detection of antigens
APV	Authorized Private Veterinarian
CA	Competent Authority
CDB	Central Database
CSF	Classical swine fever
CSF-EP	Classical swine fever Eradication Plan
CP	Contingency plan
DAHW	Directorate for Animal Health and Welfare
DG(SANCO)	Health and Consumers Directorate-General
EB pig	East Balkan Pig
EC	European Community
EU	European Union
EU-RL	European Union Reference Laboratory
FAT	Fluorescent antibody test
FBO	Food Business Operator
FVO	Food and Veterinary Office
LVA	Law of Veterinary Activities
MAF	Ministry of Agriculture and Food
MANCP	Single Integrated Multi-Annual National Control Plan
MS	Member State
MVS	Municipal Veterinary Services
NDRVI	National Diagnostic and Research Veterinary Institute
NRL	National Reference Laboratory
NVS	National Veterinary Service
OMV	Official Municipal Veterinarian
PCR	Polymerase chain reaction
RDVI	Regional Diagnostic Veterinary Institutes
RVS	Regional Veterinary Service
SA	Specific Audit
VN	Virus neutralisation test
VI	Virus isolation

1 Introduction

The Specific Audit formed part of the Food and Veterinary Office´s (FVO's) planned audit programme and was carried out as a combined audit with the FVO audit DG(SANCO)/2010-8404 on the rabies eradication programme conducted in parallel. They took place in Bulgaria from 9 to 19 November 2010. The FVO audit team comprised two auditors from the FVO and two experts from a European Union (EU) Member State. An opening meeting was held on 9 November with the central competent authority (CCA). At this meeting, the objectives of, and itinerary for, the audit were confirmed by the FVO audit team and the control systems were described by the authorities. Representatives from the CCA accompanied the audit team for the duration of the audit.

2 Objectives Of The Mission

The **objectives** of the audit were to:

- verify that official controls are organised and carried out in accordance with relevant provisions of Regulation (EC) No 882/2004, and the multi-annual national control plan (MANCP) prepared by Bulgaria;
- to evaluate animal health controls in place concerning classical swine fever, with particular attention being paid to:
    - Actions taken by the CA to control CSF outbreaks in feral pigs;
    - Measures taken to prevent its spread outside the infected area;
    - Control and eradication programme and contingency planning for CSF.

The **scope** of the audit was:

- The implementation of Regulation (EC) No 882/2004
- To review the actions taken by the CA to address the recommendations made in FVO inspection report DG(SANCO)/2008-7800
- The assessment of the system in place introduced by Bulgaria in order to authorize intra-Union trade of live pigs or fresh meat derived from East Balkan (EB) pigs from certain regions of the country

The table below lists sites visited and meetings held in order to achieve that objective:

MEETINGS/VISITS		n	COMMENTS
COMPETENT AUTHORITIES	**Central**	**2**	Initial and final meetings Visit to four regional CA offices and one municipality office
	Regional	**5**	
LABORATORIES		**2**	National reference laboratory and one regional laboratory
FARMS		**6**	One type A, two type B and one backyard farm, two EB pig herds in their grazing areas
ESTABLISHMENTS		**1**	Slaughterhouse for cutting EB pigs
OTHER SITES		**2**	Game collection and cutting centres

3 Legal Basis for the Mission

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

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

A full list of the legal instruments referred to in this report is provided in the Annex and refers, where applicable, to the last amended version.

4 Background

4.1 Contribution to the General Audit

Article 45 of Regulation (EC) No 882/2004 requires the Commission to carry out general and specific audits in Member States. The main purpose of such audits is to verify that, overall, official controls take place in Member States in accordance with the multi-national control plans referred to in Article 41 and in compliance with Community law.

This specific audit was carried out as a component of a General Audit of Bulgaria. Section 5 below contains findings and conclusions relating to the implementation of Regulation (EC) No 882/2004; Section 6 below contains findings and conclusions relating to sector specific issues.

4.2 Overview of the disease situation in Bulgaria regarding CSF

4.2.1 Historical data on the epidemiological evolution of CSF in Bulgaria

Despite prophylactic overall vaccinations which have been performed in the whole country for many years, sporadic outbreaks of CSF have occurred in Bulgaria every year. Because of serious deficiencies in performing prophylactic vaccination and illegal trade in live pigs, 32 outbreaks of CSF were registered in 14 of the 28 administrative districts of Bulgaria in 2002. In 2003 16 CSF outbreaks in 4 districts were observed, while in 2004 the number of CSF cases was only 2 in the domestic pig population. However, and for the first time since 1996, there were 48 cases of CSF identified in the wild boar population of 2 districts in that year.

In 2005, serious measures for confinement and containment of CSF were taken. The regular prophylactic vaccination of all domestic pigs in the country ceased in July but a ban of animal markets was introduced. There were no outbreaks in domestic pigs, but in spite of the continuing vaccination campaign in the wild boar population, 88 CSF cases in wild boar were found in 7 administrative districts of the country.

In 2006 seven outbreaks of CSF were found in domestic pigs but none in the wild boar population. The oral vaccination was continued in 2006 by performing two vaccination campaigns in the wild boar population.

During the first 3 months of 2007, there were 3 outbreaks of CSF, two of them confirmed in East-Balkan pig herds and one in domestic pigs (farm with inadequate bio-security measures applied).

In 2008 CSF was detected in one farm located 6 km from the Serbian border. The disease was

identified during a routine clinical investigation, part of the implementation of the control and eradication programme for CSF.

During the autumn of 2009 8 cases of CSF in wild boars were detected in a 25 km^2 forest area close to the Danube River and the Romanian border.

4.2.2 Current animal health controls in Bulgaria as regards CSF

Taking account of the history of the disease and the progress made to control it, Commission Decision 2008/855/EC established certain animal health control measures for Bulgaria and placed the whole territory of Bulgaria into Part II of the Annex of the Decision.

Dispatch of fresh pig meat, meat preparations and meat products are only allowed from Bulgaria if no evidence of CSF has been recorded in the previous 12 months in the holding of origin, the pigs have been resident for at least 90 days on the holding and no new pigs were introduced into the holding during a 30 days period immediately prior to the date of dispatch to the slaughterhouse, the holding has been subject twice a year to inspections by the competent veterinary authority following the requirements laid down in point (c) of Article 6 of Commission Decision 2008/855/EC and the pigs to be slaughtered are subject to clinical examination for CSF before authorization is given for dispatch.

The national control and eradication programme for CSF (CSF-EP) is applied on the whole territory of Bulgaria, taking into consideration several key issues in the epidemiology of the disease. The basic elements are:

- the active clinical monitoring of pigs for CSF including a targeted sampling and testing scheme;
- continued enforcement of the ban on prophylactic vaccination against CSF of the domestic pig population, including East-Balkan pigs;
- vaccination of wild boar population in the high risk areas;
- quick and effective application of the required measures for control and eradication of any outbreaks of the disease.

4.2.3 Request for regionalization

The Bulgarian CA sent an official request to DG SANCO on 10 February 2010 requesting an amendment of the Annex of Decision 2008/855/EC in order to move the Shumen region of Bulgaria from Part II to Part I of the Annex. The favourable CSF situation of the Region was described and additional guarantees were provided by the representatives of the CA in a meeting with other Member States and the Commission in March 2010.

4.3 SUMMARY OF PREVIOUS FVO MISSION RESULTS

Three FVO missions relevant to the scope of this audit were carried out in 2007, 2008 and 2009:

FVO mission DG(SANCO)/2007-7483, which was carried out in June 2007 in order to evaluate the protection measures in place relating to CSF. The conclusions of the audit were that while the CA has an adequate structure and there was adequate cooperation between different Cas, but the cooperation between the public health and animal health units was not ssufficient to ensure

implementation of the required measures in the slaughterhouses. The laboratory carrying out the analyses of samples was insufficiently staffed and equipped and even the national reference laboratory (NRL) failed to provide the necessary level of confidence that all samples received had been adequately analyzed. Improvements were noted in the design of the centralized database (CDB), but due to structural deficiencies it was still not fully operational. Evaluation of the measures taken in the case of suspicion or confirmation of the disease revealed that definition of the protection and surveillance zones, the surveillance of holdings and enforcement of movement controls were particularly weak. Proper actions were taken to apply the ambitious plan for eradication of the disease with vaccination in feral pigs but there were significant delays in analysis and the dead or shot feral pigs were not properly handled to avoid the spread of virus. The extensive sampling plan for surveillance in domestic pigs was effectively implemented but its specific supervision was not ensured. There was no proper solution for the control and enforcement of the ban on catering waste on national level, especially in the traditional husbandry systems. Safety of pig meat regarding CSF was not guaranteed due to the lack of application of biosecurity measures at the slaughterhouse, sampling of pigs coming from restricted areas and tracing back meat which might have been contained virus. The report contained 11 recommendations to the CAs.

FVO mission DG(SANCO)/2008-7800 was carried out in June 2008 in order to evaluate the surveillance, control and eradication of CSF in domestic and feral pigs. The overall conclusion of the audit was that progress had been made in practically all aspects of the CSF control system since the previous audit. Particular improvements were noted in the areas of pig holding registration, the clinical surveillance of domestic pigs and the laboratory network. Concerns regarding the health status of type B family farms and backyard holdings as well as the efficacy of the wild boar vaccination remained.

The audit report contained six recommendations concerning

- use of newly developed reporting tools
- further improvement of the CDB,
- regular supervision of holdings,
- targeted surveillance and vaccination of wild boar populations,
- review of the contingency plan (CP) and the
- accreditation of the laboratories.

FVO mission DG(SANCO)/2009-8210 was carried out in September 2009 in order to evaluate the disease CPs for epizootic diseases. The overall conclusion of the audit was that a number of actions undertaken by the Bulgarian CA should enable them to intervene rapidly in the case of most epizootics. Some of these actions addressed recommendations from previous missions but some problems remained to be solved for example the state of preparedness of the NRL in the event of outbreaks of African swine fever.

Some of the recommendations have relevance for the present audit such as

- the access to an emergency funding system for disease outbreaks and
- the importance of continuous training for official staff particularly by organizing the required real-time exercises.

A number of the above mentioned recommendations have not been addressed yet in a satisfactory way.

Copies of the above mentioned FVO audit reports are available for download at

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

5 Findings And Conclusions related to implementation of Regulation (EC) no 882/2004

5.1 Competent Authorities

5.1.1 Designation of Competent Authorities

Legal Requirements

Article 4(1) of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for official controls.

Findings

► The *National Veterinary Service* (NVS) at the Ministry of Agriculture and Food (MAF) has overall responsibility for food safety (including animal health, animal welfare and plant health) in Bulgaria. The CAs within the MAF are the following:

► The *Directorate for Animal Health and Welfare (DAHW)* with the role of coordination of the control authorities within the ministry and the audit function. The Directorate is responsible for defining the food safety strategy, harmonization of legislation and co-ordination of the control authorities within the Ministry. The Directorate also performs audits within the meaning of Regulation (EC) No 882/2004. The Directorate represents the Ministry at international forums including WHO, FAO and Codex Alimentarius.

► The NSV is a specialized body of the Ministry and it is responsible for official controls in the area of animal health, TSE and animal by-products, animal nutrition, medicated feeding stuffs, veterinary medicinal products and residues thereof and animal welfare and animal feeding stuffs. It is also responsible for official control of establishments producing and handling food of animal origin, warehouses for food of animal origin and retail establishments trading solely products of animal origin.

The NVS has its central headquarters in Sofia and an operational structure in 28 regions of the country. Each region has a Regional Veterinary Service (RVS) and is responsible for a number of municipalities.

5.1.2 Co-operation between Competent Authorities

Legal Requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination and co-operation between competent authorities.

Findings

► National Forestry Agency under the Council of Ministers

Cooperate with the DAHW at the NVS headquarters on the planning for the oral

vaccination of the wild boar population and its surveillance for 2010,

Implements its parts of the 2010 programme as regards the surveillance of wild boar.

► Regional Forestry Directorates at National Forestry Agency

Coordinates the distribution of the baits and the surveillance measures concerning wild boar at regional level in the areas near to the borders of the country together with the Animal Health Departments at the RVS, and carry out the baiting on the spot in areas of their direct competence,

In the other regions of the country provide carcasses or material from wild boar (shot at hunting, fallen stock or killed in car accidents) for inspection and sampling to the Animal Health officers at the Municipal Veterinary Services (MVS).

► National Union of Hunters and Anglers

Carries out the baiting on the spot and performs surveillance of the oral vaccination campaign in this context,

Reports to the Animal Health officers at the MVS and the Regional Forestry Directorates at National Forestry Agency

Provides carcasses or material of wild boar (shot at hunting, fallen stock or killed in car accidents) for inspection and sampling to the Animal Health officers at the MVS.

However, the FVO team did not audit these authorities.

5.1.3 Co-operation within Competent Authorities

Legal Requirements

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units.

Findings

► Since the previous FVO audit in 2008, there have not been any changes in the structure and CA responsible for the area.

► During the farm visits the official veterinarian (OV) and the authorized private veterinarian (APV) use the same checklist for the control of the farms.

5.1.4 Delegation of specific tasks related to official controls

Legal Requirements

Article 5 of Regulation (EC) No 882/2004 sets out the scope of possible delegation to control bodies, the criteria for delegation, and the minimum criteria which must be met by control bodies. Where such delegation takes place, the delegating competent authority must organise audits or inspections of the control bodies as necessary. The Commission must be notified about any intended delegation.

Findings

► No official controls within the scope of this audit have been delegated to control bodies.

5.1.5 Contingency planning

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 also requires that competent authorities have contingency plans in place, and are prepared to operate such plans in the event of an emergency. Article 13 of Regulation (EC) No 882/2004 requires Member States to draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to present a serious risk.

Findings

► The CSF contingency plan[1] follows the EU guidelines and is updated to meet new EU requirements or changes in the epizootic situation. It is part of a general contingency plan available on the NVS website. The first part contains information about the strategy and resources, the second part contains specific information about the different animal diseases and the third part contains the instructions.

► An operational manual was prepared in accordance with the Ordinance No 4 of 15 February 2007 for the prevention, limitation and eradication of CSF, transposing Council Directive 2001/89/EC introducing Community measures for the control of CSF. The purpose of the manual is to give a detailed instruction and information about how to carry out the practical matters in connection with an outbreak of CSF. The operational manual for CSF and the strategy and resource plan for emergency diseases form the Bulgarian contingency plan.

► The contingency plan has been recently updated in October 2010 and special instructions for CSF were added which were based on the experiments of the control and eradication of the disease in wild boars in the Tutrakan district in 2009.

► Real time alert exercises for CSF were not organized during recent years.

Conclusions on Competent Authorities

Generally the requirements of Regulation (EC) No 882/2004 regarding CA were respected.

1 http://www.nvms.government.bg/content.php?cntid=63
http://www.nvms.government.bg/content.php?cntid=82

5.2 Resources for performance of controls

5.2.1 Legal basis for controls

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires that the necessary legal powers to carry out controls are in place and that there is an obligation on food business operators to undergo inspection by the competent authorities. Article 8 of the above Regulation requires that competent authorities have the necessary powers of access to food business premises and documentation.

Findings

► The Law on Veterinary Activities No. 87 of 1 November 2005 (LVA) provides the legal basis empowering the CCA to establish national requirements in the fields of holding registration, animal identification and disease notification and to apply control measure in cases of disease outbreaks.

► The Ordinance 04/ 15.02.2007 on prevention, limitation and eradication of classical swine fever is the other relevant national legislation concerning the topic of this audit.

► Concerning the legal powers of the CA to carry out controls at establishments, Regulations (EC) No 853/2004 and No 854/2004 are directly applicable and in force.

5.2.2 Staffing provision and facilities

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the competent authority to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Findings

► Clinical examinations and the sampling relevant for the control and eradication of CSF in Bulgaria are carried out by 64 OVs and 1095 APVs. Due to budgetary constraints, the CA could not comply with the contract signed with the APVs and this had a negative effect on the implementation of the surveillance programme.

5.2.3 Staff qualifications and training

Legal Requirements

Article 6 of Regulation (EC) No 882/2004 requires competent authorities to ensure that staff receive appropriate training, and are kept up-to-date in their competencies.

Findings

► In the frame of a Twining Project a special 3 days training was organized on the CSF control measures in Shumen in 2010. The seminar was obligatory for the 265 OVs.

► Epizootic issues were regularly discussed in the monthly meetings with the Heads of the RVSs during the 2009 outbreak.

► A general training was held on CSF diagnostic techniques by international experts in 2008 and laboratory staff at the regional laboratories receive annual training organised by the NRL as part of the accreditation procedure.

► The head of the NRL received a one month training in The Netherlands in 2010 and visited the Valdemos Institute in Spain and received training in the diagnosis of African swine fever in 2009.

► Hunters involved in the sampling of wild boars shot are trained by the OVs who also supervise this activity during the hunting season. Hunters are also distributing the oral vaccine under the supervision of the OVs.

Conclusions on Resources for Performance of Controls

There were no major issues in the field of resources for the performance of official controls apart from the the problem with the contract with the APVs.

5.3 Organisation and implementation of official controls

5.3.1 Registration / approval of food business operators

Legal Requirements

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration/approval of food and feed business operators, for reviewing compliance with conditions of registration and for the withdrawal of approvals.

Findings

► The approved slaughterhouse visited by the FVO team worked under a specific Ministerial Order Nr 11-45 26.1.2010 issued in January 2010 which also describes the specific animal health requirements for slaughter.

5.3.2 Control activities, methods and techniques

Legal Requirements

Article 10 of Regulation (EC) No 882/2004 specifies the control activities, methods and techniques that should be deployed.

Findings

► A specific check-list has been designed for the surveillance and control of CSF on pig farms. The FVO team have seen that this check-list is used in all regions visited.

► During the farms visits samples are taken according to a predefined sampling plan.

5.3.3 Sampling and Laboratory analysis

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires competent authorities to have, or to have access to, adequate laboratory capacity. Article 11 of the Regulation establishes requirements for sampling and analysis and Article 12 requires the competent authority to designate laboratories that may carry out analysis of samples taken during official controls. It also lays down accreditation criteria for laboratories so designated.

Findings

The *National Diagnostic and Research Veterinary Institute* (NDRVI) in Sofia provides laboratory support to the NVS. It acts as the National Reference Laboratory (NRL) for a number of the most important animal diseases. A second part of the NDRVI is situated in the National Reference Centre of Food Safety, containing five NRLs for the most important food-borne pathogens and control on feed materials of animal origin. The other specialized structures within the NVS are the *Regional Diagnostic Veterinary Institute*s (RDVIs) in Veliko Tarnovo and in Stara Zagora.

► The NRL for CSF Sofia:
Processes samples collected from both domestic pigs and wild boar for CSF virus isolation and serology testing, records test results in the traceability database system and reports to the NVS (tests and methods are discussed in the Sector specific findings and conclusions under 6.7),

Undertakes confirmation tests on samples with doubtful test results sent by the RDVIs,

Monitors the procedures at the RDVIs and organizes ring-tests with them

Forwards virus isolates to the CRL for CSF, Hanover and takes part in ring-tests.

► The regional CSF Laboratories in Stara Zagora and Veliko Tarnovo
Perform CSF serology testing on samples from domestic pigs collected according to the sampling plans, record test results in the traceability database system and report to the NVS (tests and methods are discussed in the Sector specific findings and conclusions under 6.7),

Forward all samples with doubtful and positive test results for confirmation or rejection of the diagnosis to the NRL Sofia;

Convey the results to the NVS and the RVS which sends the samples for testing.

► The NRL and the regional CSF laboratory visited have their laboratory management system and some of the methods used for the diagnosis of in the CSF accredited.

5.3.4

Conclusions on Organisation and Implementation of Official Controls

As far as the different aspects of the organisation and implementation of official controls were checked, the relevant requirements of Regulation (EC) No 882/2004 were complied with.

5.4 Enforcement Measures

5.4.1 Sanctions

Legal Requirements

Article 55 of Regulation (EC) No 882/2004 states that Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and other Community provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

Findings

► In one region visited, the FVO team saw documentary evidence of four cases where penalties were issued by the CA for unauthorized movement of animals.

► A veterinarian had to pay three months salary as a penalty because he took all samples for an epidemiological survey from the same animal.

Conclusions on Enforcement Measures

The CA applied in a number of cases sanctions which can be considered as proportionate and dissuasive.

5.5 Verification and review of official controls and procedures

5.5.1 Verification procedures

Legal Requirements

Article 4 of Regulation (EC) No 882/2004 requires the competent authorities to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls. Article 8 states that they must have procedures in place to verify the effectiveness of official controls, to ensure effectiveness of corrective action and to update documentation where needed.

Findings

► The NRL supervises the activities of the regional laboratories.

5.5.2 Audit

Legal Requirements

Under Article 4 of Regulation (EC) No 882/2004 competent authorities are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Findings

► Regional laboratories are subject to internal audits both from the RVS and from the NRL. The last internal audit in the regional laboratory visited was performed in 2009.

Conclusions on Verification Procedures

As far as this point was checked verification reviews of official controls are in place.

5.6 Multi Annual National Control Plan

Legal Requirements

Article 41 of Regulation (EC) No 882/2004 requires that each Member State prepares a single integrated multi-annual national control plan (MANCP). According to Article 42 it should be implemented for the first time no later than 1 January 2007 and be regularly updated in light of developments. Details on the type of general information on the structure and organisation of the systems of feed and food control and of animal health and welfare control in the Member State concerned are provided.

Findings

► The first MANCP (2008-2010) was approved by the National Council for Co-ordination of Controls in October 2008. The plan is structured vertically according to the competent authorities involved in official controls and was prepared in accordance with Commission Decision 2007/363/EC and published on the Ministry of Agriculture and Food website.

► It covers animal health controls in general but it does not contain specific measures regarding CSF control.

Conclusions on Multi-Annual National Control Plan

It is not possible to draw any conclusions regarding the CSF controls in the MANCP as they are not specifically covered.

6 Sector Specific findings and conclusions

6.1 Animal identification and movement control, holding registration

6.1.1 Legal Requirements

Article 18 of Council Directive 64/432/EEC obliges all MSs to establish a computer database (CDB) complying with the provisions laid down in Article 14 in that Directive.
These include:

- holding details (holding number, name and address);
- holding numbers of origin for all groups of pigs on each holding.

Article 18 of the Directive also an entry in the CDB to be made for each separate movement of porcine animals.

Council Directive 2008/71/EC establishes requirements for:

- the establishment of a national register of pig holdings in each MS (Article 3);
- the maintenance of holding registers on each holding (Article 4). The register shall include
- an up-to-date record of movements, stating the origin or destination and the date of such movements;
- the identification of pigs, by means of ear tags or tattoos, before they leave the holding of birth (Article 5).

Commission Decision 2000/678/EC refines further the requirements for the information to be held in the CDB concerning each holding, with the inclusion of:

- geographic coordinates of each holding or other geographical indicator of its location;
- a field in which data on the health status of the holding may be entered.

6.1.2 Findings

CDB

The last version of the CDB was introduced on 26 May 2010 but it is still under development. Electronic veterinary certificates will be gradually introduced and issued for local trade and movement and will replace the paper certificates completely from 15 November 2010.

The aim of the NVS is to include all farmed animal species and to cover all major diseases, but when the FVO team selected a region at random it was found that not all type B farms have been introduced into the CDB. During the on line demonstration the CA acknowledged that only those type B farms were available which have been visited since the introduction of the system.

In its present form the CDB includes the type of the pig farm, all individually identified animals present on the farm with the dates of arrival and departure, but there are no data available about the previous and the next place of stay.

The possibility to extract or filter information is very limited. For example it was not possible to create a list of farms of a region belonging to a similar biosecurity category.

In one regional office the FVO team found a discrepancy between the number of pigs recorded for a holding on the CDB and the actual number of animals identified by ear tags.

The CDB system is based largely on the issue of ear tags and in principle, permits the traceability of tindividual animals. The introduction of new animals is the task of the APVs but there is no possibility to indicate the origin of the animals or the destination if they are moved from the farm. Animals sold, culled or dead are not visible after their removal from the electronic farm register.

In its present form the CDB system does not allow a search for movements on/off a certain farm during a specified time period. The origin or destination of any animal moved from or to the farm is registered on the farm register but not in the electronic system.

The CA has plans to introduce a database system for the identification of wild boars and 50.000 € has been allocated to purchase the database system used for this purpose in Germany.

The holding number is a sequential number and does not provide any information about the farm category.

On the spot checks

The farm registration forms were available on 5 out of 6 farms visited by the FVO team, except one type B farm. Data about origin of animals, animal movements or identification of young animals were in general kept in good order.

Two out of 9 sows had no ear tags on one B type farm, on another B type farm the farm register was not available.

The farm register at the type A family farm was kept in good order and there was a visitor book in which animal movements and and feed deliveries were noted.

The farm was visited by the OV and the APV with the frequency required in the control programme.

The sows were purchased from an industrial farm and arrived with a green ear-tag. A yellow ear-tag is applied on the day of arrival.

The yellow ear-tags have an individual number consisting of the abbreviation of the name of the country, the number of the region and an individual number (e.g. BG- 15 D 0338025).

Animal movements

All animal movements must be accompanied with a veterinary health certificate (based on a clinical examination) and a health statement about the place of origin.

In one region the FVO team was informed that unannounced movements may occur specially when animals are sold from one backyard farm to an other. Among the 23 sanction orders and fines issued in 2010 in one region, missing identification, unauthorised animal movements were the main reasons. In 10 out of the 23 cases, EB pigs were concerned.

Pigs may remain unregistered if they are slaughtered for own consumption or sold directly to less controlled backyard farms.

6.1.3 Conclusions

There is a complex identification and farm registration system in place consisting of a Central Data Base (CDB) and the use of individual ear tags and farm registers. Due to the constraints in data retrieval and filtering capacity, the use of the CDB for epidemiological investigations is limited.
The data held on the CDB may be incomplete, requiring on farm visits to establish the actual situation with certainty.

6.2 BIOSECURITY ON HOLDINGS

6.2.1 Legal Requirements

Article 11 of Commission Decision 2008/855/EC establishes requirements concerning holdings in territories of MSs subject to additional control measures for CSF, including:

– all pigs on the holding be kept in their living quarters or some other place where they can be isolated from feral pigs. The feral pigs must not have access to any material which may subsequently come in contact with the pigs on the holding;

– appropriate means of disinfection be used at the entrance and exits of buildings housing pigs and of the holding itself;

– appropriate hygienic measures be applied by all persons coming in contact with feral pigs, to reduce the risk of spread of CSF virus. Measures may include a temporary ban on persons having been in contact with feral pigs from entering a pig holding;
– all dead or diseased pigs with CSF symptoms on a holding be tested for the presence of CSF;
– no part of any feral pig, whether shot or found dead, as well as any material or equipment which could be contaminated with CSF virus shall be brought into a pig holding;
- vehicles used to transport pigs from holdings within Bulgaria must be cleaned and disinfected immediately following such operations.

Point 2 (b) second indent of Article 15 of Council Directive 2001/89/EC requires that all pigs on the holdings be kept in their living quarters or some other place where they can be isolated from feral pigs and its fourth indent requires appropriate means of disinfection be used at the entrance and exits of buildings housing pigs and of the holding itself. However, Point 2 of Article 16 of Council Directive 2001/89/EC foresees that after approval of the CSF-EP the initial measures laid down in Article 15 are replaced by the measures set out in the CSF-EP.

Article 8 of Commission Decision 2008/885/EC requires all vehicles used for the transportation of pigs to be cleaned and disinfected immediately following each operation and the transporter is required to provide proof of such disinfection.

Point 6 of Chapter 2, in Section I to Annex III of Regulation (EC) No. 853/2004 requires all equipment used for collecting and delivering live animals to slaughterhouses to be cleaned and disinfected immediately after emptying.

6.2.2 Findings

National Ordinance No. 44 of 20 April 2006 establishes the minimum animal health requirements for livestock holdings. On this basis, pig holdings are assigned to one of the five categories, based on the biosecurity measures they have in place to prevent the introduction of CSF. The categories were described in detail in the *DG(SANCO)/2008-7800* report and have not changed.

Industrial holdings, where approximately 50% of the country's domestic pig population is kept, comply with strict biosecurity requirements, in order to prevent contact with other domestic pigs and wild boars. Each industrial holding must employ an APV who may not work on any other pig holdings. These holdings receive only animals from approved industrial farms but may send pigs to holdings in any of the other categories. However, in practice they are mostly sent to other industrial farms or to slaughterhouses.

Type A family farm holdings are subject to similar biosecurity requirements as industrial holdings. However, structural requirements are not as strict. They supply pigs to slaughterhouses and to holdings other than those in the industrial category;

On the ***type B family farm holdings*** biosecurity measures were not mandatory at the time of the previous FVO audit, but the FVO team was told that they must upgrade to the type A family farm category by 1 January 2009. Typically, the pigs from these holdings are sent to slaughterhouses, although they may also supply other type B family farms and backyard holdings;

Traditional ***EB pig herds*** are authorised to operate in three of the eastern regions of Bulgaria where there are approximately 7.700 pigs grazing extensively in forested areas. They are likely to come into close direct or indirect contact with wild boars. Due to the extensive nature of these holdings, keepers are not obliged to implement the biosecurity arrangements required for family farms. The pigs from these holdings may only be sent to slaughterhouses;

***Backyard holdings*:** These holdings are not subject to any biosecurity requirements. However, they are included in the ban prescribed by the LVA on the feeding of catering waste to farmed animals. No more than five fattening pigs for personal consumption may be kept in each holding. Pigs raised on these holdings cannot be sent to slaughterhouses or other farms.

More than 75% of all pigs, 468.981 animals are kept on 150 industrial and type A farms with the remaining 148.225 on more than 60.000 type B farms or in backyards. There were 98 EB pig herds registered with 10.104 animals in 2009.

The FVO team found that

> The type A farm visited has been upgraded from a type B farm in April 2009. The farm met the biosecurity measures required; there was a fence around the premises, disinfection for vehicles and changing room for the workers are provided, dead animals are collected and transported to a rendering plant.
>
> The type B farms visited had a lower standard. The number of farms falling into this category at the time of the audit was 1989 in Bulgaria. The CA explained that instead of upgrading them, owners of these type of farms tend to discontinue the operation due to financial (swill feeding is not allowed and the feed is expensive) and social (ageing) reasons.
>
> The FVO team visited two EB pig herds in two regions on their grazing areas. Herds may only use territories defined in their official licence. However, in practice, different herds are in close contact and are often roaming on the same parts of the forest or pasture.
>
> These semi-wild animals are kept in fenced areas at night. However, the primitive stables surrounded by wire fence do not provide secure means of isolation and occasional contacts with wild boars cannot be excluded.
>
> During the visit the CA stated that animals selected for slaughter are kept isolated for 30 days under strict veterinary control, but it only became evident at the final meeting that pigs are kept and fed on other premises than those shown to the FVO team during the audit.

6.2.3 Conclusions

About 25% of the domestic pig population is kept on farms with a poor biosecurity and these type B and backyard farms mostly operate in villages and sparsely inhabited areas where disease control measures in general are also difficult to maintain.

EB pigs are the most exposed to contacts with wild boars. Due to the extensive farming method, the epidemiological unit cannot be defined. The FVO team was not in a position to verify whether animals were kept isolated 30 days and under strict veterinary control before slaughter.

6.3 Surveillance in domestic pigs

6.3.1 Legal Requirements

Point 2 (b) of Article 15 of council Directive 2001/89/EC requires that pig holdings in the infected area shall be placed under official surveillance. However, Point 2 of Article 16 of Council Directive 2001/89/EC foresees that after approval of the CSF-EP the initial measures laid down in Article 15 are replaced by the measures set out in the CSF-EP.

Point 1 of Article 16 of Council Directive 2001/89/EC requires the Member States (MS) to draw up an eradication plan for CSF following confirmation of a CSF outbreak in wild boars and to send this plan to the Commission for approval.

Point 3 (b) of Article 16 of Council Directive 2001/89/EC requires that the CSF-EP contains information on the infected area which has to be defined. Point 3 (i) of the same Article requires the CSF-EP to provide information about measures adopted to reduce the susceptible feral pig population and in particular young piglets. Point 3 (m) of the same Article requires that the CSF-EP shall contain information on surveillance programmes and prevention measures applicable to the holdings in the infected area.

Point 1 of Article 22 of Council Directive 2001/89/EC requires each MS to draw up a contingency plan specifying the national measures to be implemented in the event of an outbreak of CSF.

Point (g) (ii) of Annex VII to Council Directive 2001/89/EC requires staff to regularly take part in alarm drills organized at least twice a year.

Article 16 of Council Directive 2001/89/EC establishes requirements for CSF control and monitoring plans in feral pig populations. Information should be provided on the current animal health situation and on the surveillance programmes and preventative measures applicable to pig holdings in the infected area.

Chapter IV(H) of the Annex to Commission Decision 2002/106/EC establishes serological surveillance procedures for areas in which CSF is suspected to occur in feral pigs.

Article 12 of Commission Decision 2008/855/EC requires relevant MSs to inform the Commission and MSs of the results of CSF surveillance, as provided for in approved control and monitoring programmes.

Commission Decision 2009/883/EC approved the Bulgarian CSF eradication programme for 2010.

6.3.2 Findings

According to the Commission Decision 2009/883/EC 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, Bulgaria received 240.000 € for 2010 for the eradication and control programme for the CSF.

6.3.2.1 Active surveillance

The approved programme for the control and eradication of CSF in BG requires clinical examinations and serological and virus analyses to be completed annually according to a predefined scheme. As a principle, farms belonging to those categories where the biosecurity is poor should be subject to more frequent clinical examinations and sampling. The frequency of surveillance inspection to be performed by the OVs and the APVs according to the programme and the sampling regime are summarized in Table 1:

Table 1

Holding	Clinical surveillance/check-list		Sampling	
	Official vet.	Authorized private vet.	Official vet.	Authorized private vet.
Industrial farms	Once in every	Once in every month		At least 29 samples

	three months			every six months
Type A	Every month	Once in every two weeks		At least 29 samples every six months
Type B	Once in every two months	Once in every month		At least 10 samples every six months
EB	Once in every two months	Once in every month		At least 10 samples every six months
Backyard	10% of the farms per year	Once in every three months		Only in case of disease suspicion

The FVO team found that the targets have not been met during the last three years (for 2008 see the FVO report *DG(SANCO)/2008-7800*).
The actual number of tests and clinical examinations planned and performed in 2009 and in 2010 until 30 September are summarized in Table 2.

Table 2

	Number of		Serological tests (Ab-ELISA)		Clinical examinations /checklists	
2009	farms	pigs	planned	performed	planned	performed
Industrial	61	444341	3538	11959	976	5775
Family type A	89	24640	5162	***3222***	3204	***2145***
Family type B	1728	41297	34560	***17596***	31104	***13118***
Backyard	58673	106928	0	649	258161	***74244***
EB pigs	98	10104	1960	4570	1764	***878***

	Number of		Serological tests (Ab-ELISA)		Clinical examinations /checklists	
2010 until 30/9	farms	pigs	planned	performed	planned	performed
Industrial	59	438798	2566	4390	708	3982
Family type A	103	30715	4480	***2105***	2781	***1521***
Family type B	1989	33653	29835	***6404***	26851	***6978***
Backyard	50685	85783	0	13	217946	***38822***
EB pigs	86	7226	1290	2496	1161	***492***

In ***industrial farms,*** the actual number of samples collected exceeded the plan in 2009 and in 2010 due to the fact that samples are collected at farms or in the slaughterhouse and there is no system in place to check if the requested number of tests was achieved.

In 2009, the number of samples collected and clinical investigations performed on ***type A***

and type B farms was 40 to 60% fewer than planned (see Table 2) and the figures available at the end of September suggest that the targets for 2010 will be difficult to meet.

There were shortcomings in all regions visited by the FVO team including the region selected for regionalisation (Shumen). The table below summarizes the number of planned clinical examinations/samples and the number of controls actually performed.

Table 3

Type A farms	Clinical examinations /checklists		Serological tests (Ab-ELISA)	
	planned	performed	planned	performed
Varna	72	***0***	116	91
Gabrovo	160	***106***	290	***164***
Dobrich	108	103	174	***97***
Silistra	144	***108***	232	***50***
Shumen	144	162	232	***109***

Table 4

Type B farms	Clinical examinations /checklists		Serological tests (Ab-ELISA)	
	planned	performed	planned	performed
Varna	324	***145***	360	348
Gabrovo	846	***524***	940	***724***
Dobrich	2250	***1236***	2500	***2028***
Silistra	252	273	280	***155***
Shumen	216	246	240	493

According to the CA, discrepancies can be partially explained by the fluctuations in numbers of animals on the farms and that some farms do not operate through the year.

Clinical examinations are the only means of control in ***backyard farms***. However, approximatively 70 % of the required visits were not performed in 2009 and the targets were not met in four out of five regions inspected.

Table 5

Backyard farms	Clinical examinations /checklists	
	planned	performed
Varna	5871	***1509***
Gabrovo	2324	***1035***
Dobrich	5680	***2396***
Silistra	3677	3879
Shumen	3501	***2016***

Controls applied on the two ***EB pig herds*** visited by the FVO team consisted of regular clinical examinations and identity checks (unique ear tags), sampling according to the sampling scheme similar to that applicable on type B farms and random blood sampling 7 days before slaughter for virological analyses.

Domestic pigs in the Shumen region are not subject to intensive virological testing as foreseen for the EB pigs.

Controls were well documented in the register forms of both herds visited and adequate number of samples were taken as required.

On the regional level only 44% (Varna) and 78% (Shumen) of the required clinical examinations were conducted but the total number of samples collected was adequate in 2009.

The biosecurity of the sheds used for the isolation of the pigs before slaughter and the special checks performed by the APV or OV during the 30 days isolation remain to be assessed.

6.3.2.2 Animals excluded form the active surveillance

Vaccination of domestic pigs was compulsory throughout the country until 2005. The CA excluded older vaccinated sows from the active surveillance as they may still be sero-positive.

In spite of this attempt, older pigs with sero-positive results had been occasionally identified, although in decreasing numbers during recent years. The FVO team found laboratory results of four such cases which occurred on two type A and two type B farms in 2009. The FVO team was told that these animals had seroconverted due to vaccination. According to the data available in the archives of the NVS, these cases were immediately investigated and the epidemiological surveys could not find any evidence of infection. However, the link between previous vaccination and the positive result was not possible to establish in all cases due to the lack of ear-tags, to uncertainties about the age of the sero-positive pigs and because in two cases all survey samples were taken from one animal.

6.3.2.3 Passive surveillance

Owners are obliged to report any unusual events or symptoms of disease and material (blood, whole carcasses or organs) from dead domestic pigs must be investigated. The accompanying form (Form 34) used for submissions contains a request for exclusion of CSF irrespective of the symptoms or post mortem findings.

As part of the passive surveillance, pathological material or blood from 415 dead domestic pigs was submitted to the NRL in 2009 and investigated with PCR and FAT for the presence of CSF virus with negative results. Samples were collected from each region of the country and not based on risk assessment. According to the laboratory these samples were sent routinely from dead animals without real suspicion and analysed for training purposes. It is interesting to note that the number of virological examinations using blood form EB pigs have been increased due to the intensified control programme in 2010.

	Virological tests	
	2009	**2010** until 30/9
Industrial farms	167	33
Family type A	37	0
Family type B	202	50
Backyard	5	0
EB pigs	4	458
Total	415	

The FVO team studied documents of three cases in three regions where material from dead animals was send for laboratory investigation.
In one region three pigs died in a backyard farm. Serum samples were sent to the regional laboratory and a decision on restrictions was made on the day of the submission. An epidemiological survey was conducted and restrictions were lifted when the negative serological result was received 5 days later. A similar procedure was followed in the second region when one pig died on an backyard farm. Virological investigation was not carried out in either of these cases.
The third case occurred in the area restricted due to the CSF outbreak in wild boars. One of the two fattening pigs on a backyard farm stopped eating, was treated with high fever and died five days later. Lung oedema was found by the post mortem examination and organs were sent to the NRL requesting analysis for CSF three days after the death. The negative PCR was received after one week. The other pig on the farm was examined four times clinically by the OV while waiting for the laboratory result but further measures were not considered.

6.3.3 Conclusions

The approved programme for the control and eradication of CSF takes into consideration the biosecurity of the different holdings and the level of risk of introduction of infection. Targets of this programme were not fully met in 2009 and holdings, especially type B farms and backyard farms, with a higher risk of infection were not entirely under control throughout the year and in every region.

In spite of the intensive sampling programme, EB pigs remain the most exposed population and due to the extensive conditions. Spread of infection would be difficult to control as close contacts between the herds or between these pigs and wild boars cannot be excluded.

The low number of real suspected cases in domestic pigs investigated with laboratory support in 2009 and 2010 and the inconsistency in measures imposed on the farms of origin questions the efficacy of the passive surveillance.

6.4 Monitoring in feral pigs

6.4.1 Legal Requirements

Article 15 of Council Directive 2001/89/EC describes the measures to be applied in case of suspicion and confirmation of the presence of CSF in feral pigs.

Point H (1) of Chapter V of the Annex to Commission Decision 2002/106/EC requires that in the case of serological monitoring in wild boars the size and the geographical area of the target population to be sampled should be previously defined in order to establish the number of samples to be taken. Sample size must be established as a function of the estimated number of living animals and not as a function of shot animals.

Point H (3) of Chapter V of the Annex to Commission Decision 2002/106/EC requires that at least 59 animals must be sampled in each area which has been identified.

Point 3 (l) of Article 16 of Council Directive 2001/89/EC requires that the CSF-EP shall contain information on the epidemiological enquiry which is carried out on each wild boar, whether shot or found dead.

6.4.2 Findings

Surveillance of CSF in feral pigs is largely based on the serological and virological investigations of shot animals or animals found dead.

There are about 700 hunting grounds in Bulgaria and the estimated population of the wild boars in Bulgaria was 64.832 in 2009. The number of animals is an estimate based on the annual census which takes place in every March at the same time in the whole country. It is based on visual observations (head counts) in daylight. All animals, including piglets are counted. The hunting season lasts from 1/10 until 31/12.

The CA is considering the introduction of a global positioning system (GPS) which would allow for more accurate recording of the place and the time when the wild boar was shot and which could be connected to the CDB.

Wild boars shot at hunting grounds close to one of the cutting establishments or to the game collection centre are transported to these places and sampled. Wild boars shot on other hunting grounds are butchered on the spot and not all of them are subject to CSF examination.

From the 22.364 wild boars shot, 7557 were tested with PCR for the presence of CSF virus and 5864 serum samples were tested from the same animals for antibodies.

In each hunting group at least one, but usually a few, hunters receive training about the proper sampling. Hunters are not allowed to keep domestic pigs at home.

Hunting mainly occurs during the weekends in the hunting season and consequently a high number of wild boar samples must be processed in a relatively short time. In order to deliver a quick result, positive laboratory results are communicated by phone to the Director of the Animal Health Department of the NVS who forwards an ad hoc ordinance about rendering of the positive animal to the hunter associations. All samples without such feed back are considered as CSF negatives and the meat is distributed among the hunters or sold locally.

Animals younger than 6 months are important indicators of virus circulation in vaccinated areas, but hunters shot only few young wild boars in the regions visited by the FVO team.

Results of sub-adults, 12-24 months old animals born after 2008, would provide valuable information about natural infection in the non vaccinating regions but this age class was also under-represented in the summarized data.

Difficulties with the determination of age was mentioned as a possible explanation. The CA acknowledged that no such training was provided but at the final meeting the team was informed that the CA is considering the organization of courses for the hunters and making

the information available in the hunters magazine and in special leaflets.

The low number of samples from road-killed animals or wild boars found dead is insufficient for statistic purposes.

6.4.3 Conclusions

The CSF monitoring system in place for the wild boar populations is in general satisfactory. The total number of serum samples analysed is sufficient but the actual numbers cannot be considered as representative for all geographical areas.

The special recommendations of the Diagnostic Manual (Chapter V, (H) of the Annex) concerning virological monitoring and sampling procedures and the recommended proportion of the targeted age classes of feral pigs were not followed.

6.5 Vaccination in feral pigs

6.5.1 Legal Requirements

Articles 18-20 of Council Directive 2001/89/EC establish requirements for the use of CSF vaccines and the organization of emergency vaccination programmes in domestic and feral pigs.

6.5.2 Findings

Annual prophylactic vaccination in the wild boar population has been carried out on the territory of the country from 2005 to 2008 including two vaccination campaigns with two distributions of baits within 14 days.

In August 2008 the second annual vaccination was limited to a 40 km zone at the Northern and Western borders of Bulgaria. The CA undertook two distributions of baits (20 km high risk zone and 20 km buffer zone on the territory of the municipalities adjacent to the borders with FYROM, Serbia and Romania).

This approach was followed in 2009 and 2010 with three vaccination campaigns per year (February – March, June, November) with two distributions of baits in the zone. In 2009, 104 533 doses of vaccine were distributed in the country.

The number of baits distributed in each vaccination campaign is based on the estimated wild boar population. The population estimate takes place during the annual census and is based on visual observations performed in March throughout the country. All animals, including piglets are counted.

The baits are placed by hunters, supervised by the local veterinarians who often are members of the hunting groups. In one region, hunters have obligatory meetings and receive information from OVs about the vaccination two weeks before the placing of the baits. However, attendance lists for the meetings were not available.

Control of uptake is also checked by the hunters who report to the OV. The FVO team found that in two of the regions visited this collaboration was very close and efficient while in the third region the personal contacts have not been fully established yet.

The vaccine (a German product produced from the C1 strain) is transported with the producers vehicle directly to the RVSs and is kept in -20C° freezers until use. The storage time was minimal (2 days in April and 14 days in August) in one region as the consignments arrived just before the vaccinations, however in another region the annual request was delivered in one consignment in April.

The FVO team was told that vaccination campaigns are not coordinated with the neighboring countries.

6.5.3 Conclusions

The intensified vaccination campaign in the 40 km zones established on the borders to three neighbouring countries proved to be an effective measure against the introduction of classical swine fever (CSF) by infected wild boars and no outbreaks have occurred since November 2009.

However, low seroconversion rates in certain regions involved in the vaccination campaign and the low number of samples submitted for laboratory investigations in some of the regions suggest that collaboration between the hunters and the NVS is poor.

6.6 OUTBREAK OF CLASSICAL SWINE FEVER IN FERAL PIGS IN 2009

6.6.1 Legal Requirements

Article 15 of Council Directive 2001/89/EC establishes measures in case of suspicion and confirmation of the presence of CSF in feral pigs.

Article 16 of Council Directive 2001/89/EC establish requirements concerning plans for the eradication of CSF from a feral pig population.

6.6.2 Findings

The last CSF outbreak in Bulgaria affecting feral pigs took place in a forest area close to the Danube River, in the municipality of Tutrakan, (Silistra region) between August and November 2009. The area belongs to the vaccination belt of 40 km established along the border where oral vaccination has been conducted since 2005. The wild boar population within the affected area had been estimated to be 156 animals with an high overall seroprevalence of 86 %.

CSF virus was detected in September 2009 in a four month old piglet which was found dead and three five months old piglets without clinical signs of the disease.

For control and eradication of the disease, the veterinary service developed a strategy considering both the domestic and the feral pig population in the region.

The increased surveillance in domestic pigs included the establishment of protection and eradication zones as instructed by the Director of NVS, and kept under restrictions from 8 September to 31 December 2009. The farm registers were updated, clinical examination of all pig holdings using the check list was performed and the owners were reminded to the obligation to report any symptoms of disease. The OVs sent weekly reports about the controls to the RVS.

An expert group was established when the outbreak was confirmed and functioned as an

advisory body while the operations were largely initiated and decisions taken by the RVS or in the NVS.

Although the zones should have been extended to a part of the neighboring country, there was no evidence of collaboration provided to the FVO team.

Serological investigations in domestic pigs were targeted at the type B farms and backyard holdings. During a period of three weeks in September 39 type B farms, 339 backyard farms were visited twice by APVs and OVs of the municipality and in total 686 serum samples and 162 samples for virological investigations were collected from the 927 domestic pigs.

Log books and the weekly reports sent by the OVs about the measures taken were available at the RVS.

The number of positive cases in the official report sent to the Commission and in the log book was the same but the dates indicated for the investigation of these animals did not match. Positive PCR results were confirmed by VI but the latter was not mentioned in the laboratory reports.

The FVO team was told that the whole municipality was considered as a surveillance area.

During the three months period, one domestic pig died and was examined as described in the last paragraph of 6.3.2.

Concerning wild boars in the area, every shot, trapped or wild boar found dead was sampled and the carcasses were kept in the game collection center until laboratory results became available. Under-developed pigs were sent to the rendering plant directly after sampling.

The defined infected area was restricted to the 25 km^2 forest and did not take full account of the geographical aspects and the migratory pathways of the wild boar population considered by the control measures.

An additional (third) vaccination campaign was carried out around the "hot spot" in order to increase the immunity. Vaccination was also extended to seven islands in the Danube.

In total 124 wild boars were removed (119 of them trapped and shot) from the infected area within three months. Eight virus positive animals have been detected, all of them younger than six month of age. The last positive case was found end of November 2009.

Disposal of catering waste was considered as the source of virus introduction.

6.6.3 Conclusions

The CA took prompt and successful action to control the outbreak in wild boars in 2009.
In general, the measures required in case of suspicion and confirmation of the presence of CSF in feral pigs were applied, but instead of defining the infected area and eradicate the disease by taking into account the special conditions, protection and eradication zones were established as required in case of suspicion and confirmation of the presence of CSF in domestic pigs.

6.7 LABORATORIES

6.7.1 Legal Requirements

Article 17 of Council Directive 2001/89/EC requires MSs to perform diagnostic tests for CSF in

accordance with the diagnostic manual, which is established by Commission Decision 2002/106/EC. Article 17 also obliges MSs to establish a national laboratory responsible for the diagnosis of the disease, which should liaise with the European Union Reference Laboratory (EU-RL) for CSF.
Annex III of the Directive establishes the role for the NRL in controlling the quality of the reagents used in national laboratories, in organising proficiency tests for the participants in the network and for holding isolates of viruses recovered from confirmed cases of the disease.
Chapter IX of Commission Decision 2002/106/EC establishes minimum safety requirements for CSF laboratories.
Article 17 of Council Directive 2001/89/EC lays down requirements for diagnostic procedures and bio-safety.

Point 2 of Annex III to Council Directive 2001/89/EC requires that the national CSF laboratories are responsible for ensuring that in each MS the laboratory testing to detect the presence of CSF and the identification of the genetic type of the virus isolates are carried out in accordance with the diagnostic manual.

Paragraph B 6 of Chapter VII of Commission Decision 2002/106/EC requires that quality control on sensitivity and specificity of each batch of an ELISA must be regularly performed by the national laboratories.

Table 1 of Chapter IX of Commission Decision 2002/106/EC lays down principles of biological containment appropriate for diagnostic laboratories.

6.7.2 Findings

6.7.2.1 Accreditation, quality management, proficiency tests

National reference laboratory

The National reference laboratory (NRL) for the CSF at the Department of Exotic diseases is one of the laboratories of the National Diagnostic and Research Veterinary Institute.

The laboratory primarily investigates suspected cases of CSF, processes all samples from wild boars and receives serum samples for confirmation from the two regional laboratories involved in the diagnosis of the CSF.

The staff comprises two veterinarians and two assistants.

The laboratory management system of the NRL has been accredited in 2008 according to ISO 17025 including common procedures such as sample reception and result reporting.

Samples collected by the APVs are sent from the municipality veterinary office to the regional office which forwards them to the NRL. Samples must arrive accompanied by the Form 34 in which CSF testing is clearly required for all samples submitted.

The laboratory participates regularly in international proficiency test organized by the EU-RL. The samples of the ring test panel include samples in different matrices (blood and organ) and are analysed with PCR. The results of the 2009 and 2010 ring tests were satisfactory.

The fluorescent antibody test (FAT) and the antigen ELISA are also accredited for the detection of virus antigen.

An antibody ELISA is accredited for the detection of specific antibodies. Validation of this antibody ELISA kit is the responsibility of the Institute for Veterinary Substrates.

The accreditation of PCR, VI and VN, the methods which are also routinely used is in progress.

There is no official requirement for the differential diagnosis with Border disease or for BVDV. However, the laboratory performs these tests in case of CSF sero-positives to exclude cross reactions.

The NRL has organised ring tests for the two other regional laboratories involved in the CSF serological CSF surveillance since 2007 and sent 6 samples in 2008 and 22 samples in 2010 for analyses.

Regional laboratory in Veliko Tarnovo

The laboratory was founded in 2007 in Veliko Tarnovo as part of a food hygiene laboratory and was accredited as a CSF serology laboratory performing the antibody ELISA in 2009. serum samples collected according to the control programme are sent to this laboratory from 11 regions.

Testing is performed by one veterinarian and two technicians and the laboratory has adequate equipment.

Serum samples are tested within 2-3 days after arrival and the capacity of the laboratory is about 300 to 400 samples per day.

6.7.2.2 Relevant diagnostic methods

Virus isolation/detection in the NRL

Suspicious materials are tested with PCR and FAT without delay (within 24 hours, overnight). VI is also performed as the golden standard method. Antigen ELISA is also in use for the detection of viral antigen.

The laboratory tested 7557 samples with PCR in 2009. A total of 7134 samples were collected from wild boars and 8 were found positives (see the 2009 outbreak in Tutrakan under chapter 6.6 of this report). In 2010 1380 samples were analysed with PCR and 1419 with FAT, all with negative results.

Positive results are routinely sent to the EU-RL for confirmation.

VN and VI are also routinely performed and used for confirmation, but laboratory reports by the NRL do not mention results of the VN or VI tests. Out of the four positive cases followed in a traceability exercise there was only one laboratory investigation where the VI test protocol confirming the PCR result was available in the laboratory.

The PCR is routinely used for the detection of CSF virus in blood. The method is not validated for this matrix but it is internationally acknowledged (blood samples are also involved in the international ring test panel). The extraction and amplification kits are in principle fit for this purpose but due to the tender procedures the laboratory is supplied with different kits each year making the validation and standardization of these procedures difficult.

The NRL uses PCR primers recommended by the EU-RL.

Serological methods

The NRL tests all serum samples collected from wild boars and the positive ELISA results are confirmed by virus neutralization test. The same ELISA test is used in the regional laboratories for conformity because the serological analysis of the surveillance samples is largely delegated to two regional laboratories.

Serum samples from wild boars positive to ELISA are retested by VN for confirmation. Out of the 398 ELISA positives, 210 samples were also positive to VN in 2009. In the same year, 1382 sera from domestic pigs were found positive to ELISA but gave only weak positive or ambiguous results in the VN. Epidemiological investigations revealed that these sera were collected form older vaccinated pigs.

6.7.3 Conclusions

Good progress has been made in strengthening the diagnostic capacities of the NRL. The laboratory has been accredited in 2008 and uses accredited methods for antibody and antigen detection and identification. Serological analysis of the surveillance samples collected from domestic pigs is carried out in two regional laboratories that are supervised by the NRL and use an accredited test for this purpose.

6.8 ANIMAL HEALTH CONTROLS ON MEAT PRODUCTION

6.8.1 Legal Requirements

Article 6 and 8 b of Commission Decision 2008/855/EC describe the conditions applicable for dispatch of fresh meat from areas listed in Part II of the Annex of the Decision and the measures relating to fresh meat, meat preparations and meat products consisting of of or containing meat from feral pigs.

The meat products must be accompanied by the appropriate intra-Community health certificate as laid down in Commission Regulation (EC) No 599/2004.

Point 1 of Article 18 of Regulation (EC) No 178/2002 requires that at all stages of production, processing and distribution as required the traceability of food is established.

Point 3 (m) of Article 16 of Council Directive 2001/89/EC requires that the CSF-EP shall contain information on surveillance programmes and prevention measures applicable to the holdings in the infected area including the transport and movement of animals within, from and to the area.

6.8.2 Findings

Slaughterhouse for the EB pigs

Slaughter of EB pigs in a EU approved SH situated in Shumen is permitted by a specific Ministerial Order Nr 11-45 26.1.2010 issued in January 2010 which also describes the specific AH requirements of slaughter. These requirements are largely identical to those laid down in Article 3 of 855/2008.

The FVO team visited a slaughterhouse approved for the slaughter of small ruminants which is also approved and occasionally processes domestic and EB pigs as well. Domestic and EB pigs are slaughtered on separate days, at a rate of between 18 to 34 animals per day. The live animals arrive from the same region or from a neighbouring region accompanied with veterinary certificates, declarations from the owners about withdrawal periods and a checklist completed by the OV before transport to the slaughterhouse. The identity numbers were provided on an attached separate sheet of paper. The veterinary certificate indicated that the animals were clinically healthy at the time of loading and included the reference to the negative virological result performed within 7 days. Special quarantine measures were not mentioned on the veterinary certificate.

The cut carcasses are stored separately in one of the two cold stores of the slaughterhouse and the meat is marked with a diamond shaped stamp restricting the product to the domestic market. If the result of the trichinella examinations are negative, the meat of the EB pigs is transported to other establishments for further processing. The CA stated that special permission is not needed for the processing of this type of meat.

The edible internal organs are packed in plastic bags, labelled with the diamond health label and sent to local supermarkets but no reference is made that the liver, kidney and lungs originate from EB pigs.

The slaughterhouse had an operational plan and is prepared for suspect or confirmed cases of disease in terms of extra storing capacity, cleaning and disinfection. The meat inspectors are trained to recognize symptoms of the diseases.

Waste is collected in containers and is taken away with a special vehicle owned by the contracted rendering plan.

Game collection centre and game cutting plant

There are two ***game cutting establishments*** and one ***game collection center*** in Bulgaria. One cutting plant is for wild boar and deer; the other visited by the FVO team is used mainly for cutting and storing wild boars, and is owned by a state enterprise. Shot wild boars transported to these establishments are all tested for trichinella and CSF.

The facilities of the cutting establishment were appropriate for the purpose, but the traceability of the meat could not be ensured due to the method used for the identification of the carcasses (i.e. removable plastic label).

Wild boars shot in other regions are eviscerated and processed directly on the spot. Intestines and other non-edible parts are buried on the spot, but there are no special instructions for this procedure. The meat is distributed among the hunters and stored at home until the negative result has arrived for the trichinella investigation. Absence of notification from the NVS is considered as a negative CSF result and the meat is consumed by the hunters or sold.

6.8.3 Conclusions

The EB pigs are slaughtered in designated premises ensuring the traceability of meat. Due to the absence of specific conditions for further processing and oversight by the CA, there is a risk that the meat from these pigs may be mixed with that of domestic pigs destined for intra Union trade.

The labelling of wild boars processed in the establishments was insufficient, but the major concern is that the majority of wild boars shot are not processed in cutting plants or in game collection centres and their meat is not traceable.

7 Overall Conclusion

In order to control the disease situation, the CA has introduced a somewhat complex identification and farm registration system for the domestic pig population. A comprehensive surveillance programme has been established based on clinical examinations and sampling and the vaccination of wild boars has been restricted to a 40 km zone along the border since 2008. The outbreak in a wild pig population was successfully contained in 2009 by combining measures foreseen for disease outbreaks in both domestic and feral pigs.

However, information in the central data base is not fully up to date and the lack of facilities for extraction and filtering of animal movement data limit its usefulness for epidemiological enquires. Furthermore, there are weaknesses in the implementation of the control and eradication programme of CSF, particularly the incomplete surveillance of type B and backyard farms with poor biosecurity and the lack of targeted sampling in vaccinated and non-vaccinated feral pig populations, which undermine the ability of the CA to demonstrate their freedom from CSF.

In spite of the intensive monitoring programme, EB pigs remain the population at most risk of being infected as contacts with wild boars cannot be excluded. Furthermore, the spread of infection would be difficult to control among different herds as they share extensive grazing areas. The FVO team was not in the position to verify whether animals to be slaughtered for intra Union trade are kept isolated for 30 days and under strict veterinary control to assure freedom from CSF and traceability of meat at all stages of production, processing and distribution.

8 Closing Meeting

A closing meeting was held on 19 November 2010 with representatives of the CCA. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities clarified some of the observations made by the team and provided additional information which has been included in the report. They also told the audit team that EB pigs are kept and fed for 30 days in isolation before slaughter on other premises than those shown to the team during the audit.

9 Recommendations

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within twenty five working days of receipt of this specific audit report.

N°.	Recommendation
1.	Ensure that requirements concerning holding registers and identification of animals are fully applied according to Point 1 of Article 4 and Point 2 of Article 5 of Council Directive 2008/71/EC.
2.	Ensure that data are regularly updated and the reporting tools of the CDB are further developed as required by Article 14 (3) of Council Directive 64/432/EEC in order to reliable trace animal movements and facilitate epidemiological inquires.
3.	Ensure that the CSF control and eradication programme is fully implemented in the domestic and feral pig populations as approved by Commission Decision 2009/883/EC and in line with the recommendations of Chapter IV of Annex to Commission Decision 2002/106/EC (i.e. age-stratified epidemiological investigations in feral pig populations).
4.	Ensure that when defining an infected area in case of outbreaks in feral pigs recommendations of point 3 of Article 16 of Council Directive 2001/89/EC about the epidemiological investigation and movements of feral pigs are taken fully into account.
5.	Consider reporting the results of the serological and virological survey in wild boars of the 2010-2011 hunting season to the European Commission as they will give an indication of the CSF status of the non-vaccinated regions.
6.	Provide evidence that the EB pigs are kept isolated and strictly controlled for 30 days before slaughter as required by Article 6 of Commission Decision 2008/855/EC.
7.	Ensure traceability of meat originated from EB pigs and wild boar as required by Article 18 of Regulation (EC) No 178/2002 in able to give assurances provided for in Article 8b paragraph 2 of Commission Decision 2008/855/EC.

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

http://ec.europa.eu/food/fvo/ap/ap_bg_2010-8398.pdf

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
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Dir. 64/432/EEC	OJ 121, 29.7.1964, p. 1977-2012	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine
Dir. 89/662/EEC	OJ L 395, 30.12.1989, p. 13-22	Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market
Dir. 90/425/EEC	OJ L 224, 18.8.1990, p. 29-41	Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra- Community trade in certain live animals and products with a view to the completion of the internal market
Dir. 93/119/EC	OJ L 340, 31.12.1993, p. 21-34	Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Dir. 2001/89/EC	OJ L 316, 1.12.2001, p. 5-35	Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever
Dir. 2008/71/EC	OJ L 213, 8.8.2008, p.	Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (Codified

Legal Reference	Official Journal	Title
	31-36	version)
Dec. 2000/678/EC	OJ L 281, 7.11.2000, p. 16-17	2000/678/EC: Commission Decision of 23 October 2000 laying down detailed rules for registration of holdings in national databases for porcine animals as foreseen by Council Directive 64/432/EEC
Dec. 2002/106/EC	OJ L 39, 9.2.2002, p. 71-88	2002/106/EC: Commission Decision of 1 February 2002 approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever
Dec. 2008/855/EC	OJ L 302, 13.11.2008, p. 19-25	2008/855/EC: Commission Decision of 3 November 2008 concerning animal health control measures relating to classical swine fever in certain Member States
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. 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