



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

Ares(2013)695561

DG(SANCO) 2012-6602 - MR FINAL

FINAL REPORT OF AN AUDIT  
CARRIED OUT IN  
BULGARIA  
FROM 19 TO 26 NOVEMBER 2012  
IN ORDER TO EVALUATE THE ANIMAL HEALTH CONTROLS ON CLASSICAL SWINE  
FEVER

## ***Executive Summary***

*This report describes the outcome of a Food and Veterinary Office (FVO) audit in Bulgaria, carried out 19 to 26 November 2012, as part of the published programme of FVO audits in European Union (EU) Member States and in third countries.*

*The objective of the audit was to evaluate the implementation of Council Directive 2001/89/EC and in particular the measures contained in the Bulgarian programme for control and monitoring of classical swine fever (CSF), as approved by Commission Implementing Decision 2011/807/EU. Attention was also paid to the actions taken by the competent authorities in response to the recommendations in FVO report DG(SANCO)2010-8398.*

*An effective central database is in place and kept updated for the majority of pig movements. However, as in 2010 a lack of registration of all small farms and significant gaps in recording of movements of pigs, particularly on to these farms compromise the effectiveness of the pig identification and traceability system. Although most of the domestic pigs are kept on holdings meeting the minimum biosecurity requirements in EU legislation the other 18% of the pigs remain the population most at risk for classical swine fever.*

*Whilst the inspection programme for domestic pigs was mostly implemented in accordance with the CSF plan the under-implementation in pig herds with low levels of biosecurity and the sometimes unreliable results of the verification of official controls undermine the effectiveness of the programme. Substantial amendments were made to the wild boar vaccination programmes for 2011 and 2012 without the approval by the Commission and the report to the Commission for the first half of 2012 was inaccurate. There are indications of poor effectiveness of the vaccination campaigns which undermines the overall effectiveness of the vaccination programme.*

*The competent authority can generally have confidence in the laboratory test results. However, test methods have periodically been unavailable in the national reference laboratory due to a lack of consumables following insufficient procurements of important reagents and kits.*

*With regard to pig meat potentially dispatched to other Member State the overall farm inspection, sampling and certification systems in place meet the requirements in EU legislation. However, the system in place for pre-slaughter certification does not ensure that the requirements of Article 6(1) (b) are met for all batches of pigs sent to slaughter.*

*In general, extensive control measures are in place to monitor and control classical swine fever in domestic and wild pig populations. However, the implementation of the relevant EU legislation does not cover all pig holdings and recommendations 1, 2, 3 and 6 in the 2010 FVO report have not been satisfactorily addressed. The failure to register all pig holdings and pig movements, the under-implementation of certain parts of the inspection and testing programme, the lack of epidemiological analysis of the results and the lack of targeting of wild boar sampling undermine the ability of the competent authority to verify the effectiveness of the vaccination programme and to demonstrate freedom from CSF.*

*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.*

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## ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

<b>Abbreviation</b>	<b>Explanation</b>
BFSA	Bulgarian Food Safety Authority
CDB	Central Database
CSF	Classical Swine Fever
CSF-CMP	Programme for the control and monitoring of Classical Swine Fever
DG(SANCO)	Health and Consumers Directorate-General
EC	European Community
ELISA	Enzyme-Linked Immuno-Sorbent Assay
EU	European Union
EU-RL	European Union Reference Laboratory ( <i>here: for classical swine fever</i> )
FVO	Food and Veterinary Office
ISO	International Organisation for Standardisation
NDRVI	National Diagnostic and Research Veterinary Institute
NRL	National Reference Laboratory
PCR	Polymerase Chain Reaction
RFSD	Regional Food Safety Directorates
VN	Virus Neutralisation test

## 1 INTRODUCTION

The audit took place in Bulgaria from 19 to 26 November 2012. The audit team comprised two auditors from the Food and Veterinary Office (FVO) and one expert from a European Union (EU) Member State. The audit was undertaken as part of the FVO's planned audit programme.

An opening meeting was held on 19 June 2012 with the central competent authority, the Bulgarian Food Safety Authority (BFSA). At this meeting, the objectives of, and itinerary for, the audit were confirmed by the audit team and the control systems were described by the authorities. Representatives from the BFSA accompanied the audit team during the whole audit.

## 2 OBJECTIVES

The objective of the audit was to evaluate the implementation of Council Directive 2001/89/EC and in particular the measures contained in the Bulgarian programme for control and monitoring of classical swine fever (CSF), as approved by Commission Implementing Decision 2011/807/EU (hereafter referred to as the 2012 CSF-CMP). Attention was also paid to the actions taken by the competent authorities in response to the recommendations in FVO report DG(SANCO)2010-8398.

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

Meetings/Visits		No.	Comments
Competent authorities	Central	2	Opening and closing meetings with the Bulgarian Food Safety Authority
	Regional	4	Visits to four Regional Food Safety Directorates outside (Gabrovo and Shumen) and inside (Veliko Tarnovo, and Ruse) the zone of classical swine fever vaccination of wild boar.
Laboratories		1	The National Reference Laboratory for CSF: Testing Laboratory for Exotic and Extremely Dangerous Infections in the National Diagnostic and Research Veterinary Institute
Animal holdings		4	Pig holdings of the following categories: 2 family farms type A, one family farm type B and one farm for East Balkan Pigs
Establishments		1	One slaughterhouse for pigs (including East Balkan pigs), sheep and cattle.
Others		2	One private veterinary practice; one site for pre-slaughter confinement of East Balkan pigs

## 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 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.

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

## **4 BACKGROUND**

### **4.1 SUMMARY OF PREVIOUS FVO AUDIT RESULTS**

The two most recent FVO audits on classical swine fever were carried out from 17 to 26 June 2008 (DG (SANCO)2008-7800) and from 9 to 19 November 2010 (DG (SANCO) 2010-8393, hereafter referred to as the 2010 FVO report).

The reports of both audits have been published on the website of the Directorate-General for Health and Consumers ([http://ec.europa.eu/food/fvo/ir\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm)).

The 2010 FVO report concluded that there was a system in place for identification and farm registration for domestic pigs, but the information in the database was not always up-to-date and the usefulness of was hampered by limitations in the software for filtering of data. The 2009 outbreak of CSF in wild boar had been successfully contained. Vaccination (wild boar only) and surveillance and programmes were in place. The work of the laboratories was largely in line with EU requirements. However, the ability of the competent authority to demonstrate freedom from CSF was undermined by an incomplete surveillance of pig farms with limited/poor biosecurity and a lack of targeted sampling in feral pig populations.

### **4.2 CLASSICAL SWINE FEVER SITUATION IN BULGARIA**

No cases of CSF were detected in 2010, 2011 or 2012 to date. The CSF situation before November 2010 was described in the 2008 and 2010 FVO reports. Vaccination of domestic pigs ceased in 2006. The most recent outbreak of CSF was detected in one family farm on the western border in 2008. In September-November 2009 eight cases of CSF in young wild boar were detected in one 25 km<sup>2</sup> area in the north-east. Oral vaccination campaigns of wild boar are carried out in a 40 km zone along Bulgaria's western and northern borders 2-3 times per year. Active and passive surveillance programmes in domestic and feral pigs are in place as well as monitoring of vaccine bait uptake.

The whole territory of Bulgaria is currently listed in Part II of the Annex to Commission Decision 2008/855/EC. This Decision imposes restrictions on the movement and transit of live pigs, dispatch of consignments of porcine semen and ova and embryos of swine, as well as on the dispatch of fresh pig meat and of certain meat preparations and meat products containing pig meat.

The Bulgarian programme for the control and monitoring of CSF during 2012 was approved by Commission Implementing Decision 2011/807/EU. The proposed control and monitoring programme for 2013 was approved by Commission Implementing Decision 2012/761/EC.

The Commission and the EU Member States have been kept informed of the CSF situation in Bulgaria *inter alia* through several presentations made to the Standing Committee on the Food Chain and Animal Health, Section Animal Health & Animal Welfare. These presentations have been made available on the internet:

[http://ec.europa.eu/food/committees/regulatory/scfcah/animal\\_health/index\\_en.htm](http://ec.europa.eu/food/committees/regulatory/scfcah/animal_health/index_en.htm).

## **5 FINDINGS AND CONCLUSIONS**

### **5.1 LEGISLATION**

#### **Legal requirements**

Article 4 of Regulation 882/2004 requires the competent authority to have the legal powers to carry out official controls.

#### **Findings**

The Law on Veterinary Activities No. 87 of 1 November 2005 provides the legal basis empowering the central competent authority 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. Ordinance No 4 of 15.02.2007 deals specifically with the prevention, limitation and eradication of classical swine fever and transposes Council Directive 2001/89/EC. Concerning the legal powers of the competent authority to carry out controls at establishments, Regulations (EC) No 853/2004 and No 854/2004 are directly applicable. The FVO team noted that:

- Ministerial Orders to all RFSDs concerned had been issued for each vaccination campaign.

#### **Conclusion on legislation**

The competent authority has the legal powers to carry out official controls and additional legal documents can be issued when needed.

### **5.2 COMPETENT AUTHORITIES**

#### **Legal requirements**

Regulation (EC) No 882/2004 lays down general rules for the performance of official controls to verify compliance with rules aimed at preventing, eliminating or reducing to acceptable levels, risks to humans and animals. In particular, this includes Article 3 in respect of the general obligations with regard to the organisation of official controls, Article 4 in respect of designation of competent authorities, operational criteria and audits, Article 6 in respect of staff performing official controls, Article 8 in respect of control and verification procedures, Article 9 in respect of reports, Article 54 in respect of action in case of non-compliance and Article 55 in respect of sanctions.

Article 20 of Council Directive 2001/89/EC requires the competent authority to ensure consistency between the vaccination plan in an area close to a border with another EU Member State and measures taken to eradicate CSF from feral pigs in that Member State, where applicable.

Section I of Annex I to Regulation (EC) No 854/2004 requires that, in slaughterhouses, inspection tasks have to be carried out by official veterinarians (Chapter II) and health marking has to be supervised by official veterinarians (Chapter III).

## **Findings**

The competent authorities and their tasks were described in detail in FVO report dealing with the animal health controls for foot-and-mouth disease in June 2012 (DG SANCO 2012-6390).

In summary, the central competent authority for animal health is the BFSA under the Ministry of Agriculture and Food. The departments in the BFSA of interest for this FVO audit are the Animal Health and Welfare Directorate, the Training and Qualification Directorate, the Internal Audit Directorate, the 28 Regional Food Safety Directorates (RFSD) and the Laboratory Activities Directorates which includes the National Diagnostic and Research Veterinary Institute (NDRVI) and its national reference laboratory (NRL) for CSF.

Each RFSD is responsible for planning, coordination, supervision and verification of the effectiveness of official controls in the region. There are official veterinarians in each of the 275 municipalities, who are responsible for the implementation of official controls in their municipality. In addition, the RFSDs sign annual contracts with private veterinarians (organised in approximately 1000 districts) for tasks related to *inter alia* identity controls on animals and farms, movement certificates and sampling and clinical checks of domestic pigs for the CSF programme.

The Executive Forest Agency is the central competent authority for *inter alia* hunting of wild game and sorts under the same ministry as the BFSA. The Regional Directorates of Forestry are involved in the spreading of vaccine baits and the monitoring of CSF in wild boar, with the help of members of the National Union of Hunters and Anglers.

Between January 2011 and April 2012 audits in the field of animal health had been carried out by the BFSA Internal Audit Directorate in 11 RFSDs, one of which (Veliko Tarnovo) was visited by this FVO team. In addition, an audit had been carried out in the Testing Laboratory for Exotic and Extremely Dangerous Infections in the NDRVI in June 2012. This testing laboratory is the NRL *inter alia* for CSF and foot-and-mouth disease.

The effectiveness of official controls in municipalities is checked by RFSD using standardised check lists. The FVO team noted that:

- a list of enforcement measures, during 2011 and 2012 to date, relevant within the framework of the CSF-CMP showed that 185 non-compliances had been identified, 92 of which had led to prescriptions about corrective actions and 83 cases resulted in penalties of between 50 and 1600 BGN. Non-compliances had been found in eight of the regions involved in the vaccination programme for wild boar;
- one of the RFSDs visited, in the vaccination zone, had reported to the BFSA a satisfactory implementation of its implementation of the CSF programme in 2011. However, in this RFSD the figures provided to the FVO audit team during the visit showed that the CSF sampling of domestic pig herds had been seriously under-implemented in 2011 and the first half of 2012.

## **Conclusion on competent authorities**

The division of responsibilities between competent authorities at all levels is well defined. There is a system in place for audits and verification. However, one regional office had failed in its verification report to inform the central authority of serious deficiencies in the implementation of the CSF programme, which shows that the BFSA cannot always rely on those verifications of official controls at regional and local levels which are carried out by the RFSDs.

### **5.3 HOLDING REGISTRATION, ANIMAL IDENTIFICATION AND MOVEMENT CONTROL**

#### **Legal requirements**

Article 18 of Council Directive 64/432/EEC obliges all Member States to establish a computer database (CDB) comprising inter alia holding details (holding number, name and address), holding numbers of origin for all groups of pigs on each holding and details of 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 and the maintenance of holding registers on each holding. Commission Decision 2000/678/EC refines further the requirements for the information to be held in the CDB concerning each holding, requiring geographic coordinates of each holding or other geographical indicator of its location and a field in which data on the health status of the holding may be entered.

#### **Findings**

##### *5.3.1 Central database (CDB)*

The CDB records data relating to pig holdings, animals and animal movements. It is the main tool used in the issue of movement documents. Contracted private veterinarians responsible for the issuing of movement documents and for clinical surveillance on farms now have access to the CDB as it is a web based system. The FVO team noted that:

- in the RFSD offices visited access to the CDB was available. It appeared to be a robust, responsive and easy to use system and data on holdings in all regions of Bulgaria was accessible from any region visited. Full information on each registered holding including the geographic location and a field for entering any health restrictions were available;
- with respect to individual animals the CDB was able to provide information on where they had been or where they had moved to. Checklists of clinical examinations and blood sampling carried out had also been scanned and were available as attached files in the CDB.
- contracted private veterinarians had access to the database by the mobile telephone system but the FVO team were unable to verify this on-the-spot.

##### *5.3.2 Registration of holdings*

The Bulgarian Law on Veterinary Activities requires that all livestock holdings are registered. This requirement includes those holdings producing pigs solely for the production of meat for the personal consumption of the owner – so called “personal farms”. The definition of personal farms is set out in a 2010 amendment to the additional provisions of the Bulgarian Stock Breeding Act of 9 September 2000. Briefly, they may house up to five pigs for fattening but are not allowed to keep a sow or to trade in pigs. Personal farms are an important aspect in respect of disease control in pigs as there is a strong tradition of pigs being kept on an intermittent basis in “back-yard” locations

especially in the period up to Christmas.

Other holdings are categorised into one of four categories: Industrial farms and family farms type A with approved biosecurity measures in place and family farms type B and farms with free ranging East Balkan pig herds which are not required to have any biosecurity measures in place (see section 5.4 below). The FVO team noted that:

- in the regions of Gabrovo, Veliko Tarnovo, Shumen and Ruse there were respectively 47, 28, 20 and 35 holdings in the combined category of Industrial, Type A and Type B farms registered. There were also significant numbers of personal farms identified with 424, 1207, 1441 and 48 back yard locations respectively listed in the four regional offices. Sample checks on the CDB confirmed that these farms were active and available for recording of movements of pigs;
- on one family farm type A visited the FVO team identified a gap in the competent authority knowledge of the whereabouts of personal farms at back-yard locations. According to information on pig movements extracted from the CDB 16 movement documents had been issued for a total of 23 pigs leaving the farm in 2012. Examination of the herd register showed that approximately 90 pig movements had taken place from this farm in 2012. Immediately following this visit the competent authority carried out an investigation which showed that 47 pigs had been moved to back-yard locations which were not registered in the CDB. This meant that in these cases movement documentation could not be issued and consequently the movements were not recorded on the CDB. Other animals missing from the farm were accounted for by deaths on the farm and pigs which were slaughtered on the farm and sold as carcasses. The RFSD concerned stated that the newly identified back-yard personal farm locations would be registered on the CDB;
- on the family farm type B visited there were 22 pigs on the farm including eight pigs that had moved onto the farm with a movement document. However, there were no movement documents to show where pigs leaving the farm had moved to. The private veterinarian responsible for the farm explained that when carrying out checks on the farm he would ask what had happened to pigs missing since the previous visit and enter the information given by the owner in the holding register. Thus he had registered 14 pigs as slaughtered on farm on the day of his last visit. However, he was usually not in a position to vouch for the accuracy of this information;
- the private veterinarian, who was responsible for providing veterinary services and contracted to carry out certain official tasks in villages with several family farms type B and personal farms reported that many pigs may have been moved to unregistered locations without movement documentation as he frequently encountered pigs without such documentation on registered and unregistered personal farms;
- the classification as family farm type B or personal farm was established according to the number of animals, type of animals and type of trade at the time of an inspection visit. If the farm kept a breeding sow, more than five fattening pigs or sold animals it was defined as family farm type B, otherwise it was a personal farm. Transitions between these two categories could take place at any time and were up to the owner. The classification could be changed in the database by an official veterinarian at municipal or regional level.

### 5.3.3 *Holding registers*

The FVO team noted that:

- holding registers were available on all the farms visited. They were usually adequately completed by the owner/keeper and could provide information on movements that had not been officially recorded as in the second bullet point of section 5.3.1 above;
- the private veterinarian of the family farm type B visited explained that he usually assisted farmers in entering the information in the herd registers of type B and personal farms based on the information that animal keepers would give to him when he enquired about the whereabouts of animals that were no longer present on the farm.

### 5.3.4 *Animal identification*

The Bulgarian Law on Veterinary Activities and National Ordinance 61 of 9 May 2006 on the measures for the identification of animals establish the rules for the identification of animals. All pigs must be individually identified with an ear tag bearing the number of the holding and an individual animal number at the latest before they leave the holding. In practice, pigs are usually identified at weaning or when blood sampled as part of the CSF surveillance programme. Identification is carried out by the private veterinarian of the farm who is also responsible for entering data on animal identification onto the CDB. In the case of industrial and family farms type A sending fattening pigs directly to slaughter there is the possibility to use ear tags bearing only a holding number. This exception is only available to farms with more than 50 sows and must be approved by the competent authority for the holding in question. This is the only exception to the requirement for all pigs to be identified with an individual number. The FVO team noted that:

- pigs seen during farm visits were identified with ear tags in accordance with Bulgarian requirements. This included the free ranging East Balkan pigs seen on one of the farms visited.

### 5.3.5 *Movement controls*

When live pigs are moved from one holding to another holding or to a slaughter house they must be accompanied by a movement document issued by the private veterinarian of the holding following an inspection of the animals to confirm they are healthy. The movement document is produced in the CDB and can only be issued once all the required information including a valid number of the holding of destination is entered into the CDB. In the case of pigs going to slaughter the movement document must be supplemented by a checklist verifying that the required clinical examinations including checks on the body temperature on sufficient pigs have been carried out. A pig movement is only recorded as being completed on the CDB once the holding or establishment of destination has recorded the presence of the animals at the new location. The FVO team noted that:

- copies of movement certificates could easily be extracted from the CDB in the RFSO offices visited. Where movement certificates had been issued for moved pigs they were available for inspection at the holdings visited. However, movement certificates had not been issued for all pig movements on the farms visited (see section 5.3.1 above);
- copies of movement documents and the health checklists were also available for consignments of slaughter pigs that arrived at the slaughterhouse visited.

## **Conclusions on animal identification, movement control and holding registration**

An effective CDB is in place which meets both the requirements of Article 18 of Council Directive 64/432/EEC and the additional requirements set out in Commission Decision 2000/678/EC.

National legislation is in place to implement the requirements of Council Directive 2008/71/EC relating to the establishment of a national register of pig holdings and movement documents to accompany pigs when they move between holdings or other establishments. A good system of movement control is in place for the majority of pig movements. However, the lack of registration of all personal farms at back-yard locations and the significant gaps in recording of movements of pigs, particularly on to these personal farms from farms of all types, compromise the effectiveness of the pig identification and traceability system and show that the competent authority has not satisfactorily addressed recommendations 1 and 2 in the 2010 FVO report.

### **5.4 BIOSECURITY ON HOLDINGS WITH PIGS**

#### **Legal requirements**

Article 11(a) of Commission Decision 2008/855/EC establishes biosecurity requirements concerning pig holdings, which applies the whole territory of Bulgaria (part II of the Annex to this Decision). These provisions are laid down in the second and the fourth to seventh indents of Article 15(2)(b) of Council Directive 2001/89/EC.

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. In addition, Article 11(b) of Commission Decision 2008/855/EC establishes that vehicles used to transport pigs from holdings anywhere in Bulgaria must be cleaned and disinfected immediately following such operations.

#### **Findings**

Ministerial Order No 44/20.04.2006 defines the minimum levels of biosecurity for livestock holdings. For pig farms it includes general and specific levels of biosecurity needed for classification into the various farm biosecurity types.

Family farms type A are required to have a perimeter fence, facilities for hand and shoe disinfection at the entrance to the premises and an area for disinfection of vehicles transporting feed and pigs to or from the farm. They must also have a designated place where staff can get changed and disinfection mats at the entrance of the premises as well as a container for dead pigs.

Industrial farms are also required to have *inter alia* clean and dirty zones with changing rooms, toilets and disinfection areas for staff, a loading ramp for pigs, quarantine facilities, a feed delivery ramp, post mortem room and a refrigerated room for storage of carcasses between the two zones. The industrial farms must also have areas for cleaning and disinfection of vehicles and equipment as well as facilities for treatment and safe storage of manure. If an industrial farm keeps more than 100 sows and/or more than 700 fattening pigs and all-in-all-out system is required in the fattening stables.

Personal farms may have up to five fattening pigs (but no breeding animals) and are exempted from most of the biosecurity requirements set out in Ministerial Order No 44/20.04.2006 apart from the

obligation to have a fence around the yard where the building housing the pigs is, a disinfecting mat for shoe disinfection at the entrance to the yard and the need to keep working clothes separated from the keepers everyday clothes.

Family farm type B is an administrative category which is judged to not meet the requirements of Ministerial Order No 44/20.04.2006 and therefore not eligible to send pigs to slaughter as the meat from such pigs would not meet the requirements for trade to other member states (see section 5.9 below).

In addition, Ordinance No 6 of 20.03.2007 on the keeping of East Balkan pigs stipulates that newly purchased pigs should be kept in quarantine for 30 days on the farm, checked, tested and declared healthy by the official veterinarian, who is responsible for establishing and lifting the quarantine.

The requirement in national legislation, as described in the 2010 FVO report, for all family farms type B to upgrade their biosecurity measures to meet the requirements for family farms type A by 1 January 2009 was never enforced. The FVO team noted that:

- for industrial pig farms and for family farms type A the biosecurity measures required under national legislation meet the minimum requirement of Article 11(a) of Commission Decision 2008/855/EC and the second and fourth indents of Article 15(2)(b) of Council Directive 2001/89/EC;
- there are no restrictions in national legislation regarding the introduction of pigs from farms with any other (lower) biosecurity classification, i.e. industrial farms and family farms type A may introduce pigs from family farms type B, which are not required to have any biosecurity measures in place and do not meet the requirements in EU legislation (see below);
- only industrial farms have restrictions with regard to the handling of manure;
- the two family farms type A visited by the FVO team had very different degrees of biosecurity measures. One barely met the absolute minimum requirements in national legislation while the other had implemented several additional biosecurity measures;
- the farming practices for East Balkan pigs do not meet the requirements under Article 11(a) of Commission Decision 2008/855/EC and the second and fourth indents of Article 15(2)(b) of Council Directive 2001/89/EC since these animals are traditionally allowed to roam in forest areas during daytime. This has been recognised in national legislation, which has no biosecurity requirements for East Balkan pig farms except for quarantines for new animals introduced into the herd. These pig herds would normally have very limited contacts with other domestic pigs (see also point 5.9);
- for family farms type B the biosecurity measures required for pig holdings in Bulgaria under Article 11(a) of Commission Decision 2008/855/EC and the fourth indent of Article 15(2)(b) of Council Directive 2001/89/EC are not met as these farms do not necessarily meet the national or EU requirements for perimeter fencing or appropriate means of disinfection at the entrance and exits of buildings housing pigs and of the holding itself;
- although national legislation comprises basic biosecurity measures for personal farms (backyard herds) some of these farms remain unidentified, there are few official controls on

these farms, and few opportunities to check and enforce the legally required biosecurity measures;

- on 1 November 2012 according to the official database approximately 82% of the pig population was kept in 170 farms with some level of biosecurity (53 industrial farms and 117 family farms type A) while the remaining 18% of the pigs were kept in approximately 40 000 farms with no or poor biosecurity (family farms type B, personal farms or East Balkan pig farms). In the 2010 FVO report the corresponding figures were 75% of the pigs in 162 farms with biosecurity and 25% of the pigs in approximately 52 700 farms with no or poor biosecurity.

## **Conclusions on biosecurity on holdings with pigs**

The traditional farming practices, legal requirements and pre-slaughter isolation of East Balkan pigs do not meet the requirements for biosecurity and separation between domestic and wild pigs in Article 11 of Commission Decision 2008/855/EC. These herds actually function as sentinels for classical swine fever in wild boar in those areas where East Balkan pigs are kept. This has been recognised in national legislation, which comprises no biosecurity requirements for East Balkan pig farms except for quarantines for new animals introduced into the herd. In addition, there are poor controls on the limited biosecurity requirements which apply to personal farms and the biosecurity requirements on family farms type B are not clearly defined in national legislation. This leads to an increased risk of transmission of pig diseases, such as CSF, to and from personal farms, family farms type B and East Balkan pig herds.

The biosecurity requirements for farms which are allowed under national legislation to provide pigs for slaughter for other Member States (industrial farms and family farms type A) are generally in line with EU requirements, although there is a large variation in biosecurity standards in different family farms type A. However, the health status of these farms may be compromised if they avail of the possibility under national legislation to introduce pigs from farms with poor or no biosecurity.

## **5.5 SURVEILLANCE IN DOMESTIC PIGS**

### **Legal Requirements**

In accordance with Point 2 of Article 16 of Council Directive 2001/89/EC the measures set out in an approved CSF eradication plan replace the initial measures laid down in Article 15 of the Directive. In accordance with the provisions under Article 27(5) of Council Decision 2009/470/EC the Bulgarian CSF eradication plan for 2012 was approved by Commission Implementing Decision 2011/807/EU.

Article 12 of Commission Decision 2008/855/EC requires the Member States concerned to inform the Commission and Member States of the results of CSF surveillance, as provided for in the approved control and monitoring programmes. 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 15(2)(b) of Council Directive 2001/89/EC sixth indent: all dead or diseased pigs with CSF symptoms on a holding be tested for the presence of CSF.

### **Findings**

The number of clinical inspections and sampling visits per quarter, six month period or year for each type of holding are laid down in the CSF-CMP. Each inspection results in a check list which is entered into the CDB. Check lists are also drawn up at pre-movement and pre-slaughter inspections and at sampling.

In summary, official veterinarians of the municipalities are obliged to carry out clinical inspections of industrial, family farms type A and East Balkan pig farms once per six month period. They are also obliged to inspect 50% of the family farms type B and 10% of the personal farms each quarter.

Contracted private veterinarians are required to carry out clinical inspections of all pigs in industrial farms and family farms type A intended for slaughter every month and carry out pre-slaughter health checks. These inspections are often combined. The contracted private veterinarians are also obliged to carry out clinical inspections in family farms type B every two months and in private (back yard) farms every three months.

All CSF sampling in pig farms are carried out on farm by the contracted private veterinarians. In industrial farms, family farms type A and type B and East Balkan pig herds samples are taken once during each six month period. Sampling is carried out with the aim of detecting at least a 10% prevalence of CSF antibodies with 95% confidence. In 2011 most of the sampling from industrial farms and family farms type A took place in the slaughterhouses.

Verifications of official controls carried out by RFSDs during 2011-2012 and reported to the BFSA covered the implementation of the CSF-CMP in domestic pigs by the municipal official veterinarians and contracted private veterinarians. A summary of the results of these verifications provided by the BFSA shows that the CSF-CMP had been reported as satisfactorily implemented in 12 out of the 28 regions. Of the 13 regions in the vaccination zone five had satisfactorily implemented the CSF-CMP while for most of the other regions controls had not met the target frequencies in family farms type B and or personal farms. The FVO team noted that:

- in a summary by the BFSA for the year 2011 the total numbers of clinical inspections carried out by official veterinarians exceeded the minimum numbers indicated in the CSF-CMP for industrial farms, for family farms type A and for East Balkan pig herds. However, the number of inspections in family farms type B was slightly below target and 26% of the planned inspections had been carried out in personal farms;
- there were no target sample numbers for the different farm categories in the presentations used by the competent authorities to demonstrate the implementation of the CSF-CMP. Without target numbers or information on the number of pigs in each holding at the time of sampling it was not possible to verify if the total numbers of samples taken from a particular farm category in a region or in the country were in line with the requirements;
- pigs on personal farms are only sampled if there is a suspicion of CSF. During 2012 samples from two such pigs from two personal farms had been analysed and found negative for CSF. In addition six samples from personal farms in one village, taken in the context of foot and mouth disease surveillance, had also been tested and found negative for CSF;
- in one of the RFSDs visited, Ruse which had reported to the BFSA that the implementation of the CSF-CMP had been satisfactory, the number of samples taken from family farms type A and type B had not met the CSF-CMP targets in the 2011 and 2012 CSF-CMPs as:

- in 2011 no samples at all had been collected from the six family farms type A and 12 samples in total had been collected from the 22 family farms type B;
- in 2012 until 1 November, 10 and 21 samples had been collected from family farms type A and type B, respectively. However, during the two weeks prior to the FVO visit a further 98 samples had been taken from family farms type A and 81 samples from family farms type B;
- in three cases where surveillance samples from domestic pigs had tested positive in a regional laboratory measures were taken to place movement restrictions on the herd during the confirmatory testing and the follow-up investigations. In all three cases the comprehensive investigations and additional sampling demonstrated that the pigs did not have antibodies to CSF.

### **Conclusions on surveillance in domestic pigs**

There is a comprehensive system in place for active surveillance of CSF in approximately 3.3% of the holdings, which keep 87% of the total pig population. Timely and comprehensive investigations are carried out and adequate protective measures are taken when suspect cases are detected. All samples have been negative for CSF which supports the assumption that CSF is not present in the domestic pig population. However, without specific targets for sample numbers, based on the number of pigs in each farm, it is not possible for the BFSA or for the Commission to assess if the samples are sufficient for safely detecting a 10% prevalence of CSF antibodies with 95% confidence, which is the target set in the monitoring and control plan.

However, in some regions, also in “high risk” areas in the vaccination zone, the surveillance had not been implemented as planned, particularly with regard to testing and checks in the farms with the lowest level of biosecurity. This shows that the competent authority has not satisfactorily addressed recommendation 3 in the 2010 FVO report. Since some of these farms are allowed to sell live pigs to all other farm categories and to dispatch slaughtered pigs directly to clients they pose a risk of spreading undetected CSF at least locally, should their pigs be infected. The lack of samples from the passive surveillance in personal farms indicates that this part of the control programme is difficult to implement in order to meet the requirements of the sixth indent of Article 15(2)(b) of Council Directive 2001/89/EC.

## **5.6 VACCINATION OF FERAL PIGS**

### **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. In accordance with the provisions under Article 27(5) of Council Decision 2009/470/EC the Bulgarian CSF eradication plan for 2012 was approved by Commission Implementing Decision 2011/807/EU.

### **Findings**

The CSF eradication plans for 2010, 2011 and 2012 all comprised three oral (bait) vaccination campaigns of wild boar in a 40 km zone along the borders with the former Yugoslav Republic of Macedonia, Serbia and Romania. The procedures for the vaccinations under the 2012 CSF-CMP are laid down in the 2012 State Prophylactic Programme, published as an Appendix to Order No 09-

776/17.09.2011, which stipulates that three vaccination campaigns, each comprising two distributions of baits with 10-14 days interval, should take place during 2012.

In 2010 these campaigns were carried out in April/May, August and November/December. In 2011 only two vaccination campaigns were carried out (end of July and November/December). In their final report to the Commission the BFSA stated that the campaign planned for February 2011 could not take place due to delays in the procurement of vaccine baits. In 2012, two vaccination campaigns were carried out in the end of March and the second half of July and the third campaign was to be carried out during the last days of this audit.

The 2012 CSF-CMP specifies that the numbers of baits are calculated from the estimated target wild boar population in each municipality in the 40 km zone. There is a national census of certain wild species each spring, carried out by the hunters. Each campaign should distribute two baits (1-1) per wild boar in the estimated target population, i.e. six baits per wild boar per year.

Once the annual contract has been signed all vaccine baits for the year are delivered to each one of the relevant RFSDs by the licence holder for the vaccine in Bulgaria. Due to the lengthy procurement procedures vaccine contracts in 2011 and 2012 were not signed until early summer. Therefore, the BFSA decided that the vaccine baits left over from 2011 should be used for the first campaign in 2012 and the baits distributed to the RFSDs in July 2012 should be used for the summer and autumn campaign in 2012 and for the first campaign 2013. The same pattern would be followed in 2013. The FVO team noted that:

- it is not clear from the 2012 CSF-CMP that the vaccine doses included in the plan are intended for two vaccination campaigns in 2012 and one in 2013, neither is it clear in the 2013 programme if the baits are intended for two campaigns in 2013 and one in 2014;
- neither when the decision was taken to amend the vaccination programme from three to two vaccinations in 2011 nor when it was decided to use vaccine doses from 2011 for the first campaign in 2012 and vaccine doses from 2012 for the first campaign in 2013 did the BSFA submit these amendments for approval as required under Article 27(6) of Council Decision 2009/470/EC;
- for each vaccination campaign the BFSA has issued an Order to all RFSDs involved in the vaccination programme, where the exact dates for the spreading of baits were defined;
- after the annual batch had been delivered to the RFSDs, vaccine was stored frozen in the RFSD office until collected by the municipal veterinary officers shortly before each campaign. The municipal veterinary officers hand over the vaccine doses, instructions and standardised reporting forms to the responsible contact person in each hunting team, whose members distribute the vaccine on the stipulated days;
- there were no quality checks of the potency of the vaccine baits after storage in the RFSD (up to eight months);
- the vaccine baits were spread where wild boar come to forage or to wallow and the baits were dug into the ground or hidden in such a way that consumption by other species was avoided. The wild boar were lured to the site with feed and scents;
- the instructions for spreading vaccine baits included measures to ensure that young wild

boar would have access to the baits as envisaged by Article 20(2)(d) of Council Directive 2001/89/EC;

- data provided by the BFSA from the 94 participating municipalities for the first two vaccination campaigns in 2012 showed that:
  - in the first vaccination campaign in 2012, 22190 baits were distributed which was approximately 70% of the doses indicated in the 2012 CSF-CMP (31410 doses per campaign) and corresponded to 1.37 baits per animal in the estimated target population. No vaccinations took place in 12% of the municipalities and 14% of the participating municipalities distributed less than one bait per wild boar;
  - the baits distributed were only those “left over” from the 2011 programme, and instructions to use them for the first 2012 campaign had been issued from the BFSA before the 2011 autumn campaign;
  - in the second campaign 2012, 31500 baits were distributed (1.95 baits per animal). However, no vaccinations took place in three municipalities. One of these municipalities did not participate in any of the first two campaigns in 2012. Seven per cent of the participating municipalities distributed less than one bait per wild boar;
- in July 2012 between 3.1 and 45.5 vaccine doses per wild boar in the estimated population were allocated to the 13 RFSDs in the vaccination zone. Two of the regions received less than four doses per wild boar and six regions less than five. The region (Silistra) with a land border with Romania and the region (Ruse) with the most industrial pig farms and islands close to Romania received 45.5 and 9.3 doses per wild boar, respectively. The BFSA explained that these differences were founded on a risk evaluation;
- the first vaccination campaign in 2012 in one of the high risk regions (Ruse) was carried out using 1200 doses of vaccine instead of the planned 3200 doses because more doses than originally planned had been used in the two 2011 campaigns. Risk-based considerations by the RFSD led to vaccination only in the three state forests and in two of the eight municipalities. The RFSD had not informed the BFSA in advance about the lack of vaccine, nor had they discussed the most strategic use of the limited doses of vaccine;
- parameters which could be considered to verify the effectiveness of the vaccination programme have not been presented by the competent authority as envisaged by Article 20(2)(i) of Council Directive 2001/89/EC;
- the intermediate technical and financial report submitted to the Commission for the first six months of the 2012 CSF-CMP states that 31,670 vaccine doses had been administered to wild boar during this period, which is 49% more than actually distributed (21,190) according to the information received by the FVO team;
- when comparing the 2012 CSF-CMP with the 2013 CSF-CMP the FVO team noted that:
  - in the approved 2013 CSF-CMP only the 44 municipalities directly on the borders are included in the vaccination area compared to 94 municipalities in a 40 km zone in 2012. This reduction of participating municipalities is proposed also in regions where there were very few samples of wild boar in 2011-2012 and a low sero-prevalence of CSF

antibodies in those samples which were analysed;

- the number of vaccine baits per wild boar will be increased from six to 12 baits /wild boar per year;
- in Ruse, which was identified as a high risk area in 2012 with 9.3 vaccine baits/wild boar, seven of the 12 vaccination areas will no longer participate – including four of the areas which were prioritised when the availability of vaccine was limited in the beginning of 2012. The number of baits for 2013 is proposed to be 12/wild boar;
- for Silistra, the region with 45.5 vaccine per estimated wild boar in 2012 in seven municipalities, the proposed allocation for 2013 is 12 baits/wild boar in five municipalities;
- the estimated wild boar populations listed for the participating municipality in the 2013 CSF-CMP are sometimes very different from the numbers estimated for the same municipality in 2012. Examples are for 2012 vs. 2013: 270 vs. 44; 228 vs. 33; 135 vs. 30; 338 vs. 94 and 37 vs. 128;
- there was no documented evidence that epidemiological reviews of the vaccination strategies and the results of the serological and virological monitoring in wild boar during 2011 and 2012 had been carried out as a basis for the changes to the vaccination strategy planned for 2013.

### **Conclusion on vaccination of feral pigs**

There is a well-functioning system in place for coordination of the timing of the vaccination campaigns in all municipalities in the defined vaccination zone. In contrast with the description in the 2012 CSF control and monitoring programme (6 baits/wild boar/year in all areas) baits have been allocated to the regions, and distributed within regions, not only based on the estimated pig population but also based on the perceived risk of CSF. However, the proposed distribution of baits for 2013 does not follow the same risk pattern as in 2012. In addition, the estimations of the wild boar populations in the vaccinating municipalities vary substantially between the 2012 and 2013 control and monitoring programmes. This puts in questions the basis for the allocation of vaccine baits between and within regions.

Due to delays in vaccine procurement in 2011 the vaccination campaigns in 2011 and the first half of 2012 failed to meet the targets in the approved CSF control and monitoring programmes and the risk-based strategy failed to prevent a serious under-implementation of vaccination in one 2012 campaign in a region defined as “high risk”. These deficiencies undermine the overall effectiveness of the vaccination campaigns and against this background it is not clear why a reduction of the area covered by the vaccination campaigns is proposed in the 2013 CSF control and monitoring plan. In addition, when amendments were made to the vaccination campaigns in 2011 and 2012 no prior approval was sought from the Commission.

### **5.7 MONITORING IN FERAL PIGS**

#### **Legal Requirements**

Point H (1) of Chapter IV 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 IV 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 (1) of Article 16 of Council Directive 2001/89/EC requires that the CSF-CMP shall contain information on the epidemiological enquiry which is carried out on each wild boar, whether shot or found dead.

## Findings

The CSF-CMPs for 2011 and 2012 state that the programmes target testing of all wild boar shot on the whole territory of Bulgaria (active surveillance). The 2012 CSF-CMP states that by applying a strategy to combine CSF sampling with *trichinella* testing the target is to test 30% of the total wild boar population for CSF virus and the presence of antibodies to CSF. The BFSA stated that the sampling of wild boar was carried out with the aim of detecting a 5% prevalence of CSF with 95% confidence.

Hunters are instructed to collect blood and tissue samples from each animal and to submit these samples to the official veterinarian in the municipality together with a standardised form indicating the geographical coordinates for the sampling site, the gender and the estimated age of the wild boar. In 2012 a specific instruction was issued by the BFSA for assessing the age of wild boar based on teeth inspections. The CSF-CMPs also foresee sampling of all wild boar found dead or killed in road traffic accidents (passive surveillance). The municipal veterinarian submits the samples to the CSF NRL in Sofia for analysis. There are no restrictions on use of the carcass pending the result of the analysis. All samples have been negative for CSF virus in 2010, 2011 and 2012 to date. The FVO team noted that:

- the results of the monitoring in wild boar have been entered into the European database (<http://public.csf-wildboar.eu/>) which provides an overview over the sampling and the results in recent years and facilitates the statistical and spatial analysis of the monitoring as well as addresses recommendation 5 in the 2010 FVO report;
- no samples had been analysed from wild boar found dead or killed in road traffic accidents in 2012 (passive surveillance). The RFSD staff interviewed stated that dead wild boar had never been found in their regions;
- the sampling of wild boar for CSF has not yet been combined with the *trichinella* testing as indicated in the 2012-CMP;
- the vast majority of samples from wild boar were collected during the hunting season from the beginning of October to the first week(s) of January. Tissue samples for testing for virus had been collected from all sampled wild boar while serum samples had not always been collected or had not been suitable for analysis. In 2011 tissue samples from 5759 wild boar had been tested for CSF virus while serum samples had been tested for CSF antibodies from 81% of these animals;
- a comparison of population census and hunting data carried out by the FVO team in one of the regions visited confirmed that the number of shot wild boar in 2011 represented approximately 26% of the total population. In this region (outside the vaccination zone) 26%

of the shot wild boar had been sampled, which corresponded to 7% of the estimated wild boar population;

- for 2011 the total number of wild boar in Bulgaria was estimated to be 62000 animals and 5759 wild boar in total were sampled, which equals approximately 9% of the population;
- according to data provided by the BFSFA the estimated total population of wild boar in 2012 in the whole vaccination zone was 25197. In 2011, 1204 blood samples were tested for CSF antibodies from wild boar in the vaccination zone, which equals approximately 5% of the population;
- it is not clear how the BFSFA had defined the different populations of wild boar to be sampled in order to determine the numbers and types of samples necessary for each population in order to ensure the detection of a 5% CSF prevalence with 95% confidence. There were no targeting criteria regarding sample numbers per hunting area or the ages or genders of the sampled pigs presented by any of the four RFSDs visited;
- as the recommendation to hunters is to sample all shot wild boar, there are no specific instructions to target certain age groups or numbers of animals per hunting area for sampling in order to meet the recommendations in Chapter IV, point H(3) of the Annex to Commission Decision 2002/106/EC;
- the hunters themselves selected which wild boar to sample out of all the wild boar shot by the hunting team. In practice, 25-30% of the shot boar had been sampled but the proportion of sampled animals varied between municipalities. In 2011 31% of the sampled animals were less than 12 months old, which is less than the 50% recommended in Chapter IV, point H(3) of the Annex to Commission Decision 2002/106/EC;
- as can be seen from the maps presented by the BFSFA to the Standing Committee on the Food Chain and Animal Health (Animal Health and Welfare) on 2 October 2012 the sampling of wild boar in the vaccination zone varied widely between regions in 2011. In some regions a large proportion of samples were positive for antibodies to CSF, as should be expected in a vaccinated population. However, in three of the regions on the border with Romania and one on the border to Serbia there were very low proportions of seropositive samples, if any, and sometimes very few samples taken. The BFSFA stated that they had no explanation for the low sero-prevalence in these regions. Three of these regions had been allocated less than five baits per wild boar for the 2012 campaigns;
- the 2012 sampling of wild boar had been discussed in a meeting between the BFSFA and the RFSDs prior to this FVO audit and the lack of sampling in certain regions had been pointed out;
- although the implementation and results of the measures under the CSF-CMP have been presented and discussed regularly at meetings between the BFSFA and representatives from the RFSDs there had been no reviews of the results of the vaccination campaigns by an expert group comprising veterinarians, epidemiologists, wildlife biologists and hunters as foreseen by Articles 15(2)(a) and 20(2)(k) of Council Directive 2001/89/EC. The BFSFA stated that no such group had been appointed but there were two groups of CSF experts from the BFSFA, the NRL and the BFSFA risk assessment centre identified in the CSF contingency plan.

## **Conclusion on monitoring in feral pigs**

All samples of wild boar are linked to sampling reports which comprise the information necessary for an epidemiological evaluation of the programme and the entry of results into the European database has satisfactorily addressed recommendation 5 in the 2010 FVO report. The 2011 and 2012 CSF monitoring and control plans mention that all shot wild boar will be sampled for CSF testing, in practice approximately 25-30 % of these animals have been sampled. All samples have been negative for CSF virus in 2010, 2011 and 2012 which supports the assumption that there is no CSF virus circulating in the wild boar population. However, there is no targeting criteria for how many animals should be sampled in pre-defined areas or the age distribution of sampled animals, which shows that the competent authority has not satisfactorily addressed recommendation 3 in the 2010 FVO report. Without an epidemiological assessment of the sampling and the results in predefined sub-populations of wild boar it is not possible for the BFSa or for the Commission to assess if the samples were sufficient for safely detecting a 5% prevalence of CSF with 95% confidence, which is the target set in the plan. The low sample numbers in certain areas in the vaccination zone also reduce the chance of early detection of CSF virus, should it be introduced.

The great variation in sample numbers and proportions of seropositive wild boar between regions in the vaccination zone in 2011 indicate a highly variable effect of the vaccination programme between regions. It is not evident that this variation had been addressed in the planning or implementation of the 2012 programme or in the drafting of the 2013 programme. The lack of the expert group required under EU legislation, which could have assisted the competent authority in reviewing the effectiveness of the vaccination programme, may have hampered this planning process.

## **5.8 LABORATORIES**

### **Legal 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 the competent authorities 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 a national reference laboratory (NRL) for each EU reference laboratory (EU-RL) and defines the tasks of an NRL.

Article 17 of Council Directive 2001/89/EC requires Member States to perform diagnostic tests for CSF in accordance with the diagnostic manual, which is established by Commission Decision 2002/106/EC. 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.

### **Findings**

The NDRVI is designated as the NRL for inter alia FMD and swine vesicular disease. As required under Article 33(4) of Regulation (EC) No 882/2004 this information has been made publicly available on the website of the Commission.

Two regional laboratories, in Stara Zagora and in Veliko Tarnovo, have been designated by the

BFSA for serological surveillance of CSF in domestic pigs by antibody ELISA. Both laboratories are accredited to the standards of International Organisation for Standardisation (ISO) 17025:2005 by the Bulgarian Accreditation Service and the CSF antibody ELISA is included in the scopes of accreditation for both laboratories. The FVO team did not visit any of these laboratories.

The FVO team visited the Testing Laboratory for Exotic and Extremely Dangerous Infections, within the NDRVI, which is the NRL for CSF. The NDRVI is accredited to the standards of ISO 17025:2005 by the Bulgarian Accreditation Service and the current method-specific accreditation certificate is valid until 30 June 2013.

The NRL analyses all samples from suspect CSF cases and carries out confirmatory tests on seropositive samples analysed in the two regional laboratories. In addition, all samples from wild boar for CSF antigen and antibody detection under the CSF-CMP are analysed in the NRL. Wild boar samples are submitted to the NRL from the local sampling staff, via the regional offices, together with a standardised sample submission form. Staff dealing with CSF samples comprises one veterinarian and four other laboratory employees. One veterinary post in the CSF NRL is currently vacant but the head of the laboratory stated that it will be filled again through a competition procedure.

The NRL has well-established cooperation with the EU reference laboratory (EU-RL) for CSF and scientists from the EU-RL have paid extended visits to the laboratory.

In the NRL the FVO team noted:

- that the NRL had provided regular training for staff of the two RFSD laboratories and organised inter-laboratory comparative tests for the antigen-ELISA, using *inter alia* the samples provided in the proficiency tests organised by the EU-RL. Recent results from the RFSD laboratories had been satisfactory;
- with regard to the methods and accreditation status that:
  - test kits and reagents were purchased through a regulated procurement procedure and were normally delivered to the laboratory once per year in the beginning of November (7/11/2011 and 1/11/2012, respectively);
  - the polymerase chain-reaction (PCR) amplification kits in the CSF laboratory had expired in March 2012. The CSF PCR was not available between April and July 2012. However, in August amplification kits remaining after the end of the period for foot-and-mouth disease testing were transferred to the CSF laboratory and PCR testing for CSF resumed. On at least two occasions the lack of appropriate kits had hampered the pre-slaughter testing of East Balkan pigs by PCR, which is the test method required under national legislation:
    - in December 2011 pre-slaughter samples from East Balkan pigs had been analysed by antigen enzyme-linked immuno-sorbent assays (ELISA) instead of PCR, reportedly due to a temporary unavailability of the PCR method;
    - during April 2012 samples from 64 East Balkan pigs from three herds submitted for PCR-testing had instead been analysed by the laboratory using an antibody-ELISA. At the time, neither the PCR method nor the antigen-ELISA was available in the

laboratory;

- the antigen-ELISA had not been available in the laboratory since the kits in the laboratory expired during December 2011. This method was not included in the 2012 tender so it will not be available for use again until after the 2013 tender (i.e. November 2013), at the earliest. However, this method is included in the 2013 CSF-CMP which has been submitted to the Commission for approval;
  - the methods for detection of CSF antigen, isolation of virus and detection of virus genome are those listed in Chapter IV of Commission Decision 2002/106/EC and for detection of CSF antibodies the laboratory applies those serological tests recommended in Chapter VII of the Decision;
  - for CSF, the fluorescent antibody test for tissue sections, and the methods for antigen and antibody detection by ELISA are included in the scope of accreditation. However, the antigen-ELISA is no longer available (see above);
  - although mentioned in the 2010 FVO report as in the process of accreditation the frequently used CSF virus neutralisation test (VN), the virus isolation method and the PCR have not yet been included in the accreditation scope. Neither have the VN tests for bovine virus diarrhoea virus and border disease virus, which are used in the differential diagnosis of CSF seropositive samples;
  - the PCR method for CSF had recently been submitted for the second time to the accreditation body for assessment. If accepted, it would be included in the scope of accredited methods when the new certificate would be issued in the summer of 2013;
  - while the laboratory plans to submit the CSF VN and virus isolation for accreditation next year there are currently no plans to include any methods used for African swine fever in the scope of accreditation. The reason was that these methods were only rarely used;
  - samples from domestic pigs which have been seropositive in a regional laboratory are re-tested by antibody-ELISA in the NRL. If the result is positive the sample is tested with VN for CSF on PK15 cells and if this result is negative VN tests are carried out for BVDV and BDV. These procedures had been followed and timely results had been provided in the three such case files studied;
  - suspect samples were tested for CSF using PCR, FAT on cryostat tissue sections and virus isolation in cell culture in parallel. Any positive result in any of the tests deems the sample as CSF positive and triggers the sending of the sample to the EU-RL for verification. The official veterinarian submitting the suspect samples would decide if the sample should be tested also for differential diagnoses such as African swine fever;
  - for samples from wild boar the laboratory tests tissue and blood samples in parallel by PCR and antibody ELISA, respectively. There is a system of pooling samples to reduce the use of consumables. The unavailability of the PCR in 2012 did not affect this testing as it was outside the hunting/sampling period;
- with regard to quality controls and verification procedures that:

- the laboratory regularly participated in proficiency tests organised by the EU-RL for CSF. The PCR, antigen-ELISA, antibody-ELISA, virus isolation and VN test methods had regularly been assessed in these tests. Results from such tests carried out in 2009 and 2010 included certain unsatisfactory results while in 2011 the test results had been fully in line with the expectations of the EU-RL;
- in 2012 the NRL participated in a proficiency test organised by the EU-RL for African swine fever. The outcome of testing of serum and tissue samples for the detection of virus and antibodies had been in line with the expectations of the EU-RL, which had deemed the methods used in the NRL fit for purpose;
- verification procedures in the CSF NRL included one week of testing to verify the performance of new diagnostic kits and new cell cultures on arrival. The EU-RL for CSF had provided panels of reference samples for these procedures, including high and low titre sera and virus for CSF, BVDV and BDV;
- sample reports from the NRL studied in RFSD offices showed that:
  - for the compulsory samples taken from East Balkan pigs for PCR analysis prior to slaughter the laboratory routinely failed to issue test results in writing (letter, e-mail or fax) within the time frame necessary to meet the requirements in national legislation, i.e. sampling no more than 7 days before slaughter. Instead a practice had developed whereby the veterinarian issuing the movement certificate for such pigs had to request the test results over the phone, which on occasion had led to misunderstandings;
  - samples from several wild boar submitted on the same sampling form had not always been separately identified in the test results issued by the NRL.

## **Conclusions on laboratories**

The reliability of results for the serological monitoring for antibodies against CSF is underpinned by the use of accredited test methods and the successful participation in international and national comparative tests. Although not included in the scope of accreditation the results obtained in proficiency tests organised by the EU reference laboratory indicate that the methods used for antibody detection, virus isolation, virus genome detection and differential diagnoses are fit for purpose. However, the current reporting routines in the laboratory complicate some of the CSF control measures, particularly in East Balkan pigs due to delays in issuing test results.

The annual procurement of laboratory reagents and diagnostics kits in the NRL does not provide the quantities necessary to carry out all tests included in the State monitoring programme for CSF. This recurrent lack of sufficient consumables has led to the unavailability of the PCR method during several months of 2012 and the unavailability of an accredited antigen-ELISA since January 2012. Such deficiencies hamper investigations of suspect cases and undermine the pre-slaughter testing of East Balkan pigs for CSF virus which is compulsory under national legislation.

## **5.9 ANIMAL HEALTH CONTROLS ON MEAT PRODUCTION**

### **Legal requirements**

Articles 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 (the whole territory of Bulgaria) of the Annex of the Decision and the measures relating to fresh meat, meat preparations and meat products consisting of or containing meat from feral pigs. 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.

## Findings

Registered industrial farms and family farms type A are issued with an official certificate, which is a prerequisite for issuing a movement certificate for transport of pigs to a slaughterhouse. Although registered with the competent authorities, family farms type B, personal farms and East Balkan pig farms cannot be issued with an official certificate.

From July 2008, under Ministerial Order 11-572/31.7.2008, family farms type B could no longer deliver pigs for slaughter in slaughterhouses approved for dispatch to other Member States (hereafter referred to as an EU-approved slaughterhouse). The pigs could only be slaughtered in slaughterhouses catering for the domestic market and the meat had to be marked with a diamond stamp.

Once all Bulgarian slaughterhouses were EU-approved Order 9-27/15.01.2010 prohibited the slaughter of pigs from farms without adequate biosecurity in an EU-approved slaughterhouse. The implementation of this requirement allowed such slaughterhouses to slaughter only pigs from family farms type A or from industrial farms.

All pigs intended for dispatch to a slaughterhouse must be subject to a clinical inspection, including temperature checks, within 24 hours prior to the issuing of the movement certificate by the contracted private veterinarian (or by an official veterinarian). The movement certificate is valid for three days and must accompany the pigs to the slaughterhouse, as must the clinical inspection check list, an owner-declaration regarding treatments with veterinary medicinal products and the food-chain information.

Order 9-27/15.01.2010 introduced a derogation for slaughter of East Balkan pigs in an EU approved slaughterhouse provided that the group of pigs have been isolated from other pigs and wild boar for at least 30 days before dispatch to the slaughterhouse. Within 7 days of dispatch the pigs must be subject to PCR tests for CSF with negative results. The sample numbers should be sufficient to detect a 5% prevalence of CSF with 95% confidence. The meat from East Balkan pig must be marked with a diamond stamp and the meat and meat products can only be used on the domestic market.

Those slaughterhouses authorised to accept East Balkan pigs which meet the animal health requirements laid down in Order 9-27/15.01.2010 are listed in Order 11-45/26.01.2010. The FVO team visited one EU approved slaughterhouse which is authorised for slaughter of bovine, ovine and porcine animals, including East Balkan pigs. There were no East Balkan pigs or products thereof in the slaughterhouse at the time of the visit. The FVO team noted that:

- this slaughterhouse slaughtered approximately 2000 pigs per year, of which approximately 100 were East Balkan pigs. The East Balkan pigs had arrived in three batches during 2011;
- the daily slaughter log book showed that East Balkan pigs and other domestic pigs had not been slaughtered on the same days during 2012. The most recent lot had been slaughtered in

April 2012;

- the movement certificates and check lists for the East Balkan pigs were in line with national legislation. However, in April 2012, 79 East Balkan pigs had been accepted for slaughter based on a verbal declaration of negative PCR-test results from the laboratory to the veterinarian signing the pre-slaughter check list, when in fact the subsequent laboratory test report showed that the samples had been tested with an antibody-ELISA, thus not meeting the requirements in national legislation;
- from January 2011 the slaughterhouse had implemented a written procedure for ensuring separation of East Balkan pigs and products thereof from other pigs and pig products;
- each lot of East Balkan pig meat and edible offal had been dispatched with a trade document clearly stating that the product was allowed for trade within Bulgaria only;
- the three consignments of meat dispatched to another Member State during 2012 were traceable to domestic pigs.

The FVO team visited one family farm type A which regularly dispatched pigs to a slaughterhouse and noted that:

- under Article 6(1)(b) of Commission Decision 2008/855/EC pigs in the consignment intended for slaughter must have been resident on the farm at least 90 days before slaughter and no live pigs must have been introduced into the holding during the 30-day period immediately prior to the date of dispatch to the slaughterhouse. The contracted private veterinarian on this farm was not aware of any such requirements and, in addition, there is no check point on the check list used for pre-slaughter checks where the signing veterinarian must verify that the time frames in Article 6(1)(b) of Commission Decision 2008/855/EC have been respected;
- movement records on the farm visited showed that during the month before the FVO visit a batch of pigs had been sent to the slaughterhouse accompanied by the required official documents in spite of the fact that live pigs had been introduced into the holding (from another Member State) 21 days earlier;
- the official veterinarian at the slaughterhouse was not in a position to verify on the documents arriving with the pigs that this aspect of the legislation had been checked by the veterinarian issuing the movement certificate.

The FVO team visited one farm with East Balkan pigs which occasionally supplied pigs to the slaughterhouse visited and noted that:

- in line with national legislation the East Balkan pigs were kept locked up at night and routinely allowed to roam free in the area and in the nearby forest during the day. The farm area had no perimeter fence or other biosecurity measures;
- all pigs seen on the farm had ear tags and the herd book on the farm contained all relevant information about the herd and any pigs leaving the premises, including those killed on the farm and sold as carcasses;

- the building and outdoor enclosure where pigs were kept for the 30 days pre-slaughter isolation was adjacent to the area where the remaining East Balkan pig herd passed daily on its way to the nearby forest and where these pigs congregated and were fed before being locked up for the night. There were ample opportunities for the isolated pigs, when kept in the outdoor enclosure, to have direct contact with the rest of the herd through the wooden gate or over the stone wall upon which smaller pigs from the herd were walking at the time of the visit. These facilities had been approved by the official veterinarian for pre-slaughter isolation.

## **Conclusions on animal health controls on meat production**

Measures are in place in national legislation to ensure that only meat from farms meeting the EU requirements for biosecurity is dispatched to other Member States. However certain requirements in EU legislation regarding the population of pigs on the farm supplying pigs for slaughter are not always met and checks on this are not covered in the pre-slaughter check list. As a consequence pig meat dispatched to other Member States may not always meet all the requirements of Article 6(1)(b) of Commission Decision 2008/855/EC.

The approved facilities for 30 day isolation before slaughter of East Balkan pigs (intended for dispatch on the domestic market) in a slaughterhouse do not always provide a satisfactory isolation of these pigs from the rest of the herd or from direct/indirect contact with feral pigs and shows that the competent authority has not satisfactorily addressed recommendation 6 in the 2010 FVO report.

## **6 OVERALL CONCLUSIONS**

An effective CDB is in place and kept updated for the majority of pig movements. However, as in 2010 a lack of registration of all small farms and significant gaps in recording of movements of pigs, particularly on to these farms compromise the effectiveness of the pig identification and traceability system. Although most of the domestic pigs are kept on holdings meeting the minimum biosecurity requirements in EU legislation the other 18% of the pigs remain the population most at risk for classical swine fever.

Whilst the inspection programme for domestic pigs was mostly implemented in accordance with the CSF plan the under-implementation in pig herds with low levels of biosecurity and the sometimes unreliable results of the verification of official controls undermine the effectiveness of the programme. Substantial amendments were made to the wild boar vaccination programmes for 2011 and 2012 without the approval by the Commission and the report to the Commission for the first half of 2012 was inaccurate. There are indications of poor effectiveness of the vaccination campaigns which undermines the overall effectiveness of the vaccination programme.

The competent authority can generally have confidence in the laboratory test results. However, test methods have periodically been unavailable in the national reference laboratory due to a lack of consumables following insufficient procurements of important reagents and kits.

With regard to pig meat potentially dispatched to other Member State the overall farm inspection, sampling and certification systems in place meet the requirements in EU legislation. However, the system in place for pre-slaughter certification does not ensure that the requirements of Article 6(1)(b) are met for all batches of pigs sent to slaughter.

In general, extensive control measures are in place to monitor and control classical swine fever in domestic and wild pig populations. However, the implementation of the relevant EU legislation does not cover all pig holdings and recommendations 1, 2, 3 and 6 in the 2010 FVO report have not been satisfactorily addressed. The failure to register all pig holdings and pig movements, the under-implementation of certain parts of the inspection and testing programme, the lack of epidemiological analysis of the results and the lack of targeting of wild boar sampling undermine the ability of the competent authority to verify the effectiveness of the vaccination programme and to demonstrate freedom from CSF.

## 7 CLOSING MEETING

A closing meeting was held on 26 November 2012 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement and stated that they would take whatever actions were necessary in order to rectify the identified deficiencies.

## 8 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 audit report.

N <sup>o</sup> .	Recommendation
1.	Ensure that all pig holdings including personal farms at back-yard locations are listed and that the list is kept up-to-date as required by Article 3 of Council Directive 2008/71/EC.
2.	Ensure that all pig movements, including those relating to personal farms at back-yard locations, are recorded as required by Article 4 of Council Directive 2008/71/EC.
3.	Ensure that the requirements in Article 11(a) of Commission Decision 2008/855/EC are enforced on all holdings for domestic pigs.
4.	Ensure that procedures are in place to verify that the monitoring and control measures in domestic pigs meet the targets laid down, also at herd level, in the 2013 CSF monitoring and control plan approved by Commission Implementing Decision 2012/761/EC.
5.	Ensure that the sampling of feral pig populations takes into account the guidelines in Point H, Chapter IV of the Annex to Commission Decision 2002/106/EC.
6.	Ensure that an expert group is appointed in line with the requirements of Article 15(2) (a) of Council Directive 2001/89/EC and that a system is established in order that this group can review on a regular basis the results of the vaccination campaign in wild

N°.	Recommendation
	boar as required by Article 20(2)(k) of this Directive.
7.	Ensure that any amendments to the 2013 CSF monitoring and control plan approved by Commission Implementing Decision 2012/761/EC, are submitted to the Commission for approval as required under Article 27(6) of Council Decision 2009/470/EC.
8.	Ensure that all analytical methods used for official samples are included in the scope of accreditation in order to meet the requirements of Article 12(2) of Regulation (EC) No 882/2004.
9.	Ensure that all laboratories analysing samples for the CSF control and monitoring plan have adequate resources for reliable testing of official samples for CSF virus and antigen as indicated in the plan and in order to meet the requirements of Article 4(2)(c) of Regulation (EC) No 882/2204.

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=2012-6602](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6602)

## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
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
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
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
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)
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
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

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
Dec. 2011/807/EU	OJ L 322, 6.12.2011, p. 11-22	2011/807/EU: Commission Implementing Decision of 30 November 2011 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 2012 and following years
Dir. 2008/71/EC	OJ L 213, 8.8.2008, p. 31-36	Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (Codified 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. 2012/761/EU	OJ L336, 8.12.2012, p.83-93	2012/761/EU: Commission Implementing Decision of 30 November 2012 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2013