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FINAL REPORT OF A MISSION  
CARRIED OUT IN  
BULGARIA  
FROM 17 JUNE TO 26 JUNE 2008  
IN ORDER TO  
EVALUATE THE SURVEILLANCE, CONTROL AND ERADICATION OF  
CLASSICAL SWINE FEVER IN DOMESTIC AND FERAL PIGS.

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

### ***Executive Summary***

*Sporadic outbreaks of Classical Swine Fever (CSF) have been reported in Bulgaria during recent years. The main objective of the mission was to evaluate the measures in place to control the disease.*

*The mission team concluded that the roles, responsibilities and activities of the competent authorities (CAs) and other bodies involved in the control of CSF are well-defined. However, the overall effectiveness of the system is undermined by poor coordination of activities between control units and by the lack of audits. Progress has been made since the previous FVO mission to control domestic pigs. However, the central database is currently of limited use as a tool for the control of CSF. Biosecurity measures in place on large industrial holdings and some family farms help to prevent the accidental introduction of the disease. However, other farm holdings, including many that supply pigs to slaughterhouses, are not currently required to have such measures in place. Holdings are subject to clinical and serological controls, which are generally carried out according to the national CSF programme, except in the case of backyard holdings and some family farms. These controls provide assurance that the CSF virus is not circulating in the domestic pig population. However, investigations are not carried out systematically to determine the likely cause of positive serological test results reported for several holdings. An extensive and ongoing virological and serological survey of wild boar indicates that the CSF virus is not widely distributed in this population. However, the survey's design does not allow conclusions to be reached on the absence of the virus from all hunting areas. The vaccination of wild boars is generally carried out according to the vaccination plan. However, the poor quality of blood samples collected from these animals means that no reliable conclusions can be drawn on the efficacy of vaccination activities. The CAs took prompt action to control an outbreak of CSF in the west of Bulgaria during May 2008 and generally applied the control measures foreseen in the national contingency plan and in Council Directive 2001/89/EC, thereby preventing the dissemination of the disease from the outbreak zones. However, incomplete epidemiological enquiries limited the ability of the authorities to determine the likely source of the outbreak. Structures in place to coordinate the response to outbreaks of CSF have been strengthened since the previous FVO mission. However, the limited roles played by the National Disease Control Centre and the Expert Group could undermine the ability of the CAs to control of future outbreaks. Considerable work has been done to strengthen the National Reference Laboratory since the previous FVO mission. However, operational difficulties currently prevent it from performing tests used to detect the CSF virus in wild boar.*

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

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## ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
CA	Competent Authority
CCA	Central competent authority
CRL	Community Reference Laboratory
CSF	Classical Swine Fever
DG	Director General of the National Veterinary Service and Chief Veterinary Officer
ELISA	Enzyme Linked ImmunoSorbent Assay
FAT	Fluorescent Antibody Test
FVO	Food and Veterinary Office
LV	Licensed veterinarian
LVA	Law on Veterinary Activities No. 87 of 1 November 2005 - ##### ## ##### (####. ##. ##.87 ## 1 ##### 2005#.)
NRL	National Reference Laboratory
NVS	National Veterinary Service (##### #####)
OV	Official veterinarian
PCR	Polymerase Chain Reaction
VNT	Virus Neutralisation Test

## 1 INTRODUCTION

The mission took place in Bulgaria from 17 to 26 June 2008 as part of the planned mission programme of the Food and Veterinary Office (FVO). The mission team, which comprised 2 inspectors from the Food and Veterinary Office, was accompanied throughout the mission by representatives from the central competent authority (CCA), the National Veterinary Service (NVS) of the Bulgarian Ministry of Agriculture and Food.

An opening meeting was held on 17th June 2008 with the CCA in Sofia. At this meeting the mission team confirmed the objectives of, and itinerary for the mission, and additional information required for the satisfactory completion of the mission was requested.

## 2 OBJECTIVES OF THE MISSION

The mission in Bulgaria assessed the implementation of surveillance, control and eradication measures against Classical Swine Fever (CSF) in domestic and feral pigs, as required by Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever (hereafter referred to as 'the CSF Directive'). It also followed up the implementation of actions proposed by the Bulgarian competent authorities in response to the recommendations made in FVO inspection report DG(SANCO)/2007-7483 (hereafter referred to as 'the previous FVO mission report'). This report is available on the Health and Consumers Directorate-General web site at [http://ec.europa.eu/food/fvo/ir\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm).

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

Competent Authorities at central level	Initial and final meetings
Competent Authorities at regional level	Two regional offices were visited and meetings were held with officials responsible for controls at regional and district levels
Laboratories	The National Reference Laboratory (NRL) and one regional diagnostic laboratory
State Forestry Agency	One regional office
Livestock Holdings	One Type A family farm, one Type B family farm and one East Balkan pig holding
Establishment	One Category A pig slaughterhouse (not operational at the time of the visit)

### **3 LEGAL BASIS FOR THE MISSION**

The mission 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.

The EU legislation relevant to this mission is listed in the Annex.

### **4 BACKGROUND**

CSF was regularly detected throughout Bulgaria in the period prior to its accession to the European Union. Consequently, Commission Decision 2006/805/EC defined the whole territory of Bulgaria as an area from which no live pigs may be dispatched to other Member States. In addition, the Decision required products and preparations containing meat of pigs from holdings located in Bulgaria to be clearly identified as such and to be heat-treated before dispatch to any other Member State. Following this mission, Commission Decision 2008/631/EC of 29 July 2008 revoked the prohibition on the dispatch of fresh pork meat, pork meat preparations and pork meat products from Bulgaria to other Member States, in light of the improving disease situation in the country and the additional measures taken to exclude the presence of classical swine fever in pigs on commercial farms which are dispatched for slaughter.

The Bulgarian authorities banned the vaccination of domestic pigs against CSF in 2006. Seven outbreaks of CSF in domestic pigs were reported in the country that year and three further outbreaks during 2007. A single outbreak of the disease was reported on a family farm located in the western part of the country in May 2008. The control of this outbreak is described in section 5.5 of this report.

Commission Decision 2008/77/EC approved plans for the vaccination of wild boar and the eradication of CSF from these animals, which form part of the programme for the control and eradication of CSF in the Republic of Bulgaria 2008 (hereafter referred to as the national CSF programme). Nationwide campaigns for the vaccination of wild boars commenced in 2006 and have been repeated during each subsequent year. No outbreaks of the disease in the wild boar population have been reported since vaccination began. However, the disease continues to occur frequently elsewhere in the Balkan region.

### **5 MAIN FINDINGS**

#### **5.1 COMPETENT AUTHORITY PERFORMANCE**

##### *5.1.1 Management Structure*

The structure of the CCA and the designation of official responsibilities have been

described already in the previous FVO report and have not changed significantly. In summary, the CCA is a vertically integrated organisation with a direct chain of command from the Director General (DG), through 16 regional authorities to official veterinarians (OVs) operating in the municipalities. Some official duties related to animal identification and the control of CSF are delegated to private veterinary practitioners appointed as licensed veterinarians (LVs). The veterinary institutes, including the National Reference Laboratory and the two regional CSF laboratories also report directly to the DG of the NVS.

The CCA is supported in the implementation of the wild boar vaccination programme by the National Forestry Agency (NFA) and the National Union of Hunters and Anglers.

Since July 2007 an advisor seconded from the veterinary services of another Member State has provided advice to the Minister of Agriculture and Food on animal health matters. One of the advisor's first tasks was to analyse the report of the previous FVO mission and to assist with the implementation of corrective actions.

#### *5.1.2 Legal and enforcement powers*

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.

One of the recommendations made in the previous FVO report was to ensure that the CAs had the legal powers and properly enforced provisions for holding registration, animal identification, movement controls and compulsory notification of disease. Since then, an amendment was made to the LVA giving the CAs the powers to seize and destroy animals in certain circumstances, for example, if unidentified animals are moved from holdings or animals have not been presented for official controls.

#### Observations

- The CAs generally had the legal powers necessary to implement CSF control and eradication measures foreseen in Community legislation;
- in the case of one unauthorised East Balkan pig herd, the regional CA considered that the amended law did not empower them to seize the animals immediately. Instead, they imposed an administrative penalty and allowed the keeper to retain the animals on the farm for several weeks until they were ready for slaughter.

#### *5.1.3 Resources and personnel*

The previous FVO report identified a number of areas in which resource limitations undermined the ability of the CCA to control and eradicate CSF. These included a shortage of appropriate staff to apply control measures on backyard and free-range pig holdings and insufficient staff and equipment in the National Reference Laboratory (NRL). The CCA has taken the following measures to address these observations:

- The surveillance of domestic pigs on backyard holdings is now mainly based on clinical observation rather than serological sampling, thereby reducing the workload

for veterinarians in the field and for the laboratory services;

- a framework contract between the CCA and LVs is being negotiated to provide greater incentives and accountability for the prompt completion of official duties, including surveillance visits and the notification of movements;
- two regional laboratories have been authorised to carry out CSF testing (see section 5.6 below), thereby freeing up capacity in the NRL.

Observations:

- The streamlining of CSF controls has reduced the work pressure on officials operating in the field. However, OVs continue to perform a wide range of official duties, including the entry of data received from LVs on the electronic information systems. The CCA is developing the means whereby LVs will be able to report the results of their controls and other activities directly to these systems.

*5.1.4 Cooperation, coordination, verification and audits*

The national CSF programme defines the type and number of control activities to be performed in each region. Documented procedures are in place for most control activities and mechanisms have been established to report the results of these activities to the regional and central levels within the CCA. Regular meetings between the central and regional levels of the CCA are organised throughout the year. In addition, the CCA at central and regional levels hold regular meetings with representatives from the NFA and hunters' associations.

Observations

- A centralised reporting system for domestic pig surveillance visits allowed the CCA to detect differences in the completion of the programme in different regions. However, there was little evidence that this information was being used to initiate corrective actions when problems arose. For example, a shortfall in the reported number of surveillance visits to Category B holdings was evident in data presented by the CCA to the regional authorities at the end of May. The minutes of the meeting did not mention the problem or include any conclusions on its likely cause and the CCA did not initiate any remedial actions subsequently;
- the regional offices visited during the mission had been visited previously by representatives from the CCA responsible for the coordination of CSF control activities. However, the visits were not conducted consistently and, in one case, there were no records of the topics covered during the visit, the results of any checks or any agreed corrective actions. No internal or external audits of the implementation of CSF control and eradication measures were carried out;
- The schedule of clinical surveillance visits (see section 5.3.2 below) requires OVs to visit each holding supervised by an LV. However, during these visits OVs follow the same procedure as the LV, rather than performing checks to verify that the LV had performed the official controls correctly during their visits;

- there was little evidence of coordination between the units responsible for carrying out official control activities. For example, officials in the regions visited did not coordinate the vaccination of wild boar with officials in neighbouring regions even though hunting areas frequently extended across regional boundaries. Similarly, municipal OVAs continued to collect and dispatch blood samples to the NRL even though the overwhelming majority of these samples were unsuitable for testing. Furthermore, although the surveillance zone surrounding the recent disease outbreak in the west of the country extended across a regional boundary, the control activities in each region were managed separately and there was little evidence of information sharing between the control units in order to coordinate their efforts.

## **5.2 ANIMAL IDENTIFICATION REGISTRATION AND MOVEMENT CONTROLS**

### *5.2.1 Registration of holdings*

The LVA requires livestock holdings to be registered. All data must be kept at least three years after the cessation of the activity of the animal holding and after the sale, slaughter or death of the last animal kept on that holding. The LVA is currently being revised in order to distinguish between holdings producing pigs for trade with other food business operators and those keeping pigs for personal consumption. In future, backyard holdings, which are only allowed to slaughter pigs for their own consumption, will be 'listed' and allowed to have no more than 5 fattening pigs, and no breeding animals, present on the farm. Commercial holdings that supply pigs to other food business operators for human consumption will be 'registered' and must comply with biosecurity requirements. The only exception to this will be for the traditional production of pigs in East Balkan herds. All holdings, whether listed or registered, must continue to comply with animal identification, holding register and movement control requirements and data related to them will continue to be entered on the central database (CDB).

#### Observations:

- Discrepancies were noted between the numbers of registered holdings reported at central and at regional levels. The CCA explained that there has been a recent decline in the number of pig holdings, particularly backyard holdings, and in the number of pigs in Bulgaria. It is difficult to estimate the number of pig holdings that are active due to the seasonal nature of production on many farms;
- the routine surveillance visits to farm holdings (see Section 5.3.2) include checks on the registration of the holdings and compliance with identification and movement control requirements. The results of these checks are included in the reports sent to the CCA;
- administrative sanctions were applied over recent months in several cases in which pig keepers failed to comply with holding registration and animal movement requirements.

### *5.2.2 Holding registers*

All pig keepers, including those keeping pigs on East Balkan pig holdings and backyard farms, must maintain an animal movement register. A standard template for these registers was established in 2007 and has been in use since 2008.

Observations:

- Holding registers were available on all three of the holdings visited. The register was well-established and up to date on one of the family farms holding visited. The registers on the other two holdings was established during the early part of 2008. The register for the East Balkan pig herd was up to date but the number of animals on the other family farm could not be reconciled with the information entered in the holding register or with the CDB by the keeper, LV or OV;
- although the presence of the holding register is checked during the routine clinical surveillance visits to pig holdings, the veterinarians performing these controls are not instructed to crosscheck the data in the register against the pigs actually present on the holding.

### 5.2.3 *Animal identification*

The LVA establishes the legal basis for the identification of animals. National Ordinance No 61 of 9 May 2006 establishes rules for the implementation of this requirement. Pigs are identified by official individual eartags which generally bear a unique serial number and must be applied at weaning. However, fattening pigs on industrial holdings may be identified just prior to their departure with green eartags bearing the registration number of the holding. Eartags are applied by LVs and OVs, who are also responsible for notifying data on the identification of animals to the CDB.

Observations:

- Pigs on the holdings visited were identified in accordance with national requirements.

### 5.2.4 *Movement controls*

In order for pigs to be dispatched from a holding to any other destination, including slaughterhouses, the animals must be checked physically by an OV or LV, who issues an official movement document and notifies the central database. Checks are performed at slaughterhouses to ensure that only eligible animals are accepted and that adequate biosecurity precautions are taken, including the requirement set out in Art. 8 (b) of Commission Decision 2006/805/EC that "vehicles are cleaned and disinfected immediately following each operation".

Observations:

- Copies of movement documents were available to account for pigs that had been moved to or from the holdings visited;
- a pig slaughterhouse was visited. Although no pigs had been slaughtered there during the preceding year, it was still approved for the activity and could

resume operation at any time. The cleaning and disinfection of animal transport vehicles was carried out at a facility located several kilometres from the slaughterhouse. Although the operator of these facilities had been approved by another Government body, the facilities were not supervised by the CCA nor were controls carried out to verify that vehicles were cleaned and disinfected immediately. The mission team was informed at the final meeting that the DG would issue a letter to all the regions to make this requirement very clear and ensure that all pig slaughterhouses will in future have on-site facilities for cleaning and disinfection of live animal trucks.

#### 5.2.5 Central database

The central database (CDB), which was established with support from EU funds, records the data concerning registered holdings, pig identification (ear tag) numbers and the movement of pigs. OV's and LV's are responsible for notifying information on the registration of holdings, identification of pigs and movements of these animals to the CDB. The data is generally entered by OV's because most LV's do not have access to the database. However, hardware and design problems continue to dog the CDB. The system crashes frequently and users have limited read access, typically confined to the data for holdings in one municipality. Officials at district and regional level cannot access historical data, such as the movement history of animals. This information can only be obtained on request to the IT administration unit. The CCA is aware of these difficulties and has developed new software modules in an attempt to overcome some of them.

#### Observations

- The database includes *inter alia* the following information for each registered holding: the identification number, holding address, name and address of the person responsible for the animals, a geographic indication of the holding. In addition, a link has been created to information on the health status of animals on each holding, which is stored in a separate data module;
- a large volume of data has been entered onto the CDB, including the individual identification numbers of all the animals present in each of the holdings visited, as well as information concerning their movements. However, the number of pigs on the farm holdings visited never coincided with the number registered in the database. The CCA explained that this was because of delays in the entry of information on pig movements and on-farm deaths on the CDB. Movement documents had, however, been issued before any pigs were allowed to leave the holdings.

### 5.3 SURVEILLANCE OF DOMESTIC PIGS

The CCA introduced a risk-based system for the surveillance of domestic pigs during 2007 in order to make more efficient and effective use of the limited veterinary and laboratory resources available to monitor the entire pig population. The system is based on the categorisation of farm holdings into risk groups and the application of clinical surveillance measures tailored to each group.

### 5.3.1 Farm categorisation

National Ordinance No. 44 of 20 April 2006 establishes the minimum animal health requirements for livestock holdings. On this basis, farm holdings are assigned to one of five categories, based on the biosecurity measures they have in place to prevent the introduction of CSF:

**Industrial holdings:** Approximately 50% of the country's domestic pig population is kept on holdings in this category. They must comply with tight biosecurity requirements, in order to prevent contact with other domestic pigs and wild boars. The measures required include limited access for personnel and vehicles, strict separation between livestock handling facilities and potentially contaminated areas, facilities for the storage and collection of dead animals and a prohibition on staff keeping backyard pigs. Each industrial holding must employ a registered veterinarian who may not work on any other pig holdings. Pigs arriving on these holdings must come from approved industrial farms. The pigs may in theory be sent 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:** These holdings must also satisfy biosecurity conditions but the structural requirements are not as strict and they are not required to employ a registered veterinarian on a full-time basis. These holdings supply pigs to slaughterhouses and to holdings other than those in the industrial category;

**Type B family farm holdings:** Biosecurity measures are not currently mandatory on these holdings. However, 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 East Balkan pig herds:** are authorised to operate in three of the eastern regions of Bulgaria. Altogether, these herds account for approximately 30,000 pigs, which graze extensively in forested areas and 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. However, they must have adequate livestock handling and housing facilities. 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.

#### Observations:

- The holdings visited were correctly categorised according to the national system and the keepers understood their duties and what they were entitled to do. The keeper of the type B family farm holding visited had been instructed on the additional biosecurity measures required in order to qualify as a type A family farm.

### 5.3.2 Clinical surveillance

The CCA has established specific frequencies for clinical surveillance visits by LVs and OV's:

**Industrial holdings:** the contracted veterinarian should visit the farm regularly and perform an official clinical surveillance inspection every month. The OV also performs a clinical inspection once every three months. At least 29 pigs from each holding should be sampled and tested for CSF antibodies every six months. Samples may be collected at slaughterhouses and during clinical surveillance visits;

**Type A family farms:** LVs perform clinical surveillance inspections every two weeks on each holding. OV's also performs a clinical inspection every month. The same sampling regime is applied to type A family farms and industrial holdings;

**Type B family farms and East Balkan pig herds:** LVs perform clinical surveillance inspections every month on each holding. OV's also perform clinical inspections once every two months. At least 10 pigs from each holding should be sampled and tested for CSF antibodies every six months. Samples may be collected on holdings or in slaughterhouses;

**Backyard holdings:** LVs inspect each backyard holding at least once every three months. OV's are expected to visit 10% of the backyard holdings in the municipalities for which they are responsible during the course of three months. Samples are collected from pigs on backyard holdings only in the case of disease suspicion.

The CCA has prepared a standardised checklist for use by OV's and LVs during these visits. In addition to recording the number of animals on each holding and any clinical signs observed, the checklist assesses the bio-security measures in place, the type of animal feed used, the presence of the holding's movement register, animal treatment records and compliance with holding register, animal identification and movement control requirements. The same inspection procedure is followed regardless of the category of holding. The results of the checks on each holding are entered into an electronic database, which is managed centrally. This provides a means for the CCA to monitor implementation of the surveillance programme.

The samples collected from domestic pigs during routine surveillance visits and at slaughterhouses are screened for CSF antibodies using the ELISA test to determine whether undiagnosed viral circulation is occurring. The national CSF programme specifies that, in cases of disease suspicion, pigs are to be sampled and tested in accordance with the requirements of the Annex to Commission Decision 2002/106/EC approving a diagnostic manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of CSF (hereafter referred to as the CSF Diagnostic Manual). If seropositive animals are detected, the holding is placed under movement restriction and the seropositive animals are slaughtered. Samples from these animals are tested for the presence of CSF viral antigen using the Fluorescent Antibody and/or the Polymerase Chain Reaction (PCR) test methods. Blood samples are also collected from other pigs on the affected holding. The restrictions are lifted only if the results of these tests are negative. Otherwise the case is treated as a suspect outbreak.

Observations:

- Training courses were organised for the veterinarians who complete the checklists. The mission team saw records indicating that most veterinarians had been trained;
- although the checklist includes a check that the holding register is present on each holding, the accompanying guidance note does not require the veterinarian to crosscheck the information in the register with the information in the CDB or the pigs that are present on the holding. The database information about the number of animals present in the three farms visited was incorrect and this had never been reported in any of the checklists completed by OV's or LV's;
- surveillance visits have been carried out on nearly all industrial holdings and type A family farms, generally according to the frequency described above. However, shortfalls were noted with regard to the completion of scheduled inspections on farms in the other categories. In the case of type B family farms and East Balkan herds, approximately two thirds of the scheduled visits had been completed and entered on the database at the time of the mission. The proportion of backyard holdings visited was even lower: approximately 17 000 premises from a total of 72 603 had been visited by the start of June. These shortfalls were mainly because the holdings had not been visited, although in some cases the visits had been performed but the report had not yet been entered on the database, due to staff resource limitations. Delays were also noted in the sample collection reports for these holdings. However, the CCA provided updated information following the mission to show that some samples had been collected from 80% of the type B family farms since the beginning of the year;
- during the visit to an East Balkan herd, pigs had been fed for several weeks with a feed composed of rendered oils of unknown origin. This had not been detected during surveillance visits carried out during that period. The CCA took immediate action to seize the feed pending an investigation into its composition and origin;
- the CCA presented details of 40 holdings on which seropositive animals had been detected over the preceding 12 months. More than ten seropositive animals per holding were detected in more than half of the cases. Follow up tests had been performed in each case and in most cases, the suspect animals had been slaughtered and tested, with negative results, for CSF antigens. On this basis, the CCA concluded that CSF infection was not present on 36 of the holdings, with ongoing investigations of the remaining four holdings being carried out;
- comparative endpoint titration of the seropositive samples by means of VNT, which is the test method specified in Chapter VII (C) of the CSF Diagnostic Manual in order to determine whether the reactions were caused by CSF or by a ruminant pestivirus, was not used systematically. Although the illegal use of vaccine was proven on some of the affected holdings, the cause of the seropositive reactions was not determined in most cases;
- Furthermore, the investigation protocol applied by the CCA did not follow the procedure for the investigation of seropositive animals set out in Chapter VII (C) of the CSF Diagnostic Manual, which requires comparative serological testing of the seropositive animals at least two weeks after the original positive result in order to determine whether seroconversion for CSF virus or ruminant pestivirus has

occurred.

#### **5.4 CSF ERADICATION IN WILD BOARS**

The national CSF programme includes surveillance measures to detect the presence of CSF in the wild boars and an oral vaccination programme to prevent the dissemination and circulation of the virus in that population. The CCA implements these measures in conjunction with the NFA and hunters' associations. In practice, the organisation of hunting and vaccination activities for wild boars is quite complicated. The FHA, which is responsible for the annual census of wild boars and for enforcing hunting rules, is organised into 16 regional units, the boundaries of which do not coincide with those of the CCA's regional units. Furthermore, many of the hunting areas also extend across regional boundaries. In addition, each of the hunting areas is subdivided into hunting territories, which are managed separately by groups of hunters, who are responsible for ensuring that hunting rules are respected within their territories.

##### *5.4.1 Surveillance of wild boars*

The eradication programme requires samples to be collected from wild boars shot or found dead for each region in Bulgaria, which typically amounts to approximately 18 000 animals each year. More than 10 000 organ samples were collected from the wild boars shot or found dead during 2007. All of these samples were negative for viral antigen.

##### Observations:

- The national CSF programme sets targets for the number of samples to be collected from wild boars shot or found dead within each region. On average, regions have an approximate area of 5 000 km<sup>2</sup> and a wild boar population of approximately 3 600. No instructions or guidance is provided to the regional authorities on how they should identify target subpopulations of wild boar within each region, taking account of geographical barriers to movement and known migration patterns. As a result, the number of samples collected from some hunting areas falls below the minimum number required to reach a sound conclusion on their health status while in other areas this threshold is grossly exceeded;
- Sampling instructions require hunters to collect internal organs samples, including spleen, kidney and retropharyngeal lymph glands plus a blood sample from each wild boar. However, the laboratory submission forms that accompanied wild boar samples to the laboratory examined by the mission team did not indicate the age of the sampled animals, which would be important information in the event of a positive result. This observation was also made during the previous FVO mission.

##### *5.4.2 Vaccination of Wild Boars*

The national CSF programme includes a vaccination plan which sets the number of vaccine doses distributed to each region based on the estimated wild boar population.

Instructions on the storage and placing of baits have been established at national level and regional veterinary authorities decide how to deploy those baits within each region. The CCA is responsible for controlling the correct implementation of vaccination by the hunters. The vaccination plan is largely unchanged since 2007. However, documented official controls have been introduced to verify that hunters distribute vaccine baits correctly in the field, thereby addressing one of the observations made during the previous FVO mission. The CCA explained that in the light of the absence of CSF outbreaks in wild boars during recent years, vaccination will be limited to hunting areas close to the borders with neighbouring countries from 2009 onwards.

The national CSF programme also includes a survey to assess the efficacy of the vaccination programme. The CCA plans to collect 1 000 samples during 2008.

#### Observations

- The mission team saw evidence that the vaccination campaigns were organised in conjunction with the other authorities and hunting groups;
- the regional veterinary authorities do not receive guidance on how to target hunting territories for vaccination or how the baits should be distributed between them. For example, in one region, the regional authorities decided to vaccinate in 35 of 53 hunting territories within the region, which included approximately 80% of the wild boar population, but did not include the game breeding station operated by the FHA, in which there was a large number of young and unprotected pigs. The intensity of bait distribution was increased in areas that the regional authorities considered to be at high risk (for example, border areas) while in other territories the number of baits laid was less than the number of boars present for the Spring census;
- official controls were performed to verify that the hunters placed the baits and checked that they had been consumed by wild boar;
- the NRL reported that in most cases the blood samples received from wild boars could not be used. This was because, in many cases, field conditions were such that blood could not be collected in clean and dry containers or had frozen prior to the extraction of serum. In fact, usable blood was only tested from 204 of more than 10,000 wild boars sampled during the 2007 hunting season;
- laboratory results for a small number of tested blood samples from wild boar were seen in one region. The wild boar had been shot in different hunting territories over a short period. The laboratory report provided summary information indicating the number of positive and negative samples processed but it did not provide a result for each sample identified on the laboratory submission form, which limited its usefulness when determining the efficacy of vaccination in each territory.

### **5.5 CONTROL OF THE OUTBREAK**

The mission team reviewed the measures taken by the CCA following the detection of suspect animals on a type B family farm in the west of the country on 22 May 2008 during routine surveillance.

#### Observations:

- The CCA responded rapidly to the initial report of disease suspicion and animal health experts visited the location within a very short period;
- the measures required by Article 4 of the CSF Directive were swiftly applied in relation to the outbreak holding, including the imposition of restrictions on the movement of animals and potentially contaminated materials;
- the experts decided, on good veterinary grounds, to consider the adjacent holding to be in contact and ordered the destruction of the single pig that was kept there. This decision was in accordance with the requirements of Article 7 of the CSF Directive. However, no samples were collected from this animal nor was a separate epidemiological enquiry carried out on this holding. These measures are required by the same article of the Directive in order to establish the likely source and possible duration of the outbreak;
- following the confirmation of the disease, the additional measures required by Article 5 of the CSF Directive, including the cleaning and disinfection of the holding and the dispatch of virus samples to the Community Reference Laboratory (CRL) for typing were applied;
- protection and surveillance zones were established as required by Article 9 of the CSF Directive. Meetings with the municipal and regional epizootic commissions were held in order to inform the local authorities of the situation and to ensure that they took the steps necessary to enforce requirements within the zones. Contact was made with the veterinary authorities in a neighbouring Third Country, into which part of the surveillance zone extended. The CAs subsequently visited that country to discuss the control measures applied on both sides of the border;
- the restrictions on livestock movements within the zones and the measures applied to vehicles entering or leaving the zones were enforced by the regional border control police. These measures were still in force at the time of the mission;
- a cleaning and disinfection point was established on the principal route passing through the protection zone and control measures were in place to ensure that vehicles leaving the zone by this route were cleaned, disinfected and inspected prior to departure. Vehicle wheel washes were installed on two other roads leaving the protection zone, which were smaller and less frequently used. However, no measures were put in place to ensure that vehicles used in the transport of pigs leaving the protection zone by these secondary routes were adequately cleaned, disinfected and inspected, as required by Article 10 of the CSF Directive;
- all of the holdings within the protection zone were subject to a census and clinical inspection of pigs within seven days of the confirmation of the outbreak, as required by Article 10 of the CSF Directive. The same measures were extended to cover holdings within the Surveillance zone and this work was completed by the end of May;
- the regional CA ordered clinical inspections to be carried out within the zone each day and a large number of visits were reported. However, no arrangements were made to ensure that the keepers of pig holdings notified the CAs immediately when animals died or were discovered to be diseased. Furthermore, several discrepancies

in the number of pigs on holdings and the number of holdings in the zones were detected in the reports of these visits and in the regular epizootic situation reports sent from the regional CA to the CCA. Although the mission team was able to conclude that these discrepancies did not result in a breakdown of the disease control measures, they had not been detected or investigated by the regional CA or CCA;

- a serological survey of the holdings in the protection and surveillance zone was carried out promptly following the confirmation of the disease. Pigs which gave seropositive results were slaughtered. In the case of one seropositive sow, the regional CAs decided, on good veterinary grounds, to order the destruction of her piglets as well. Samples from all slaughtered animals were taken and found to be negative on virological testing. However, neither the regional CAs nor the expert group considered it necessary to conduct an epidemiological investigation in order to conclude whether these animals, or others on the same holdings, had been involved in the outbreak. This investigation together with other measures is required by Article 4 of the CSF Directive;
- the officials responsible for the control of the outbreak had access to, and in nearly all respects acted in accordance with, the national CSF contingency plan, which was approved by Commission Decision 2007/19/EC.

## **5.6 NATIONAL DISEASE CONTROL CENTRE AND EXPERT GROUP**

One of the recommendations made in the previous FVO report was to establish and operate a National Disease Control Centre (NDCC) and Expert Group in accordance with Article 23 of the CSF Directive.

### Observations:

- Both the NDCC and EG were operational during the recent CSF outbreak and well-appointed facilities were available for their use. Regular meetings of the NDCC were held and were attended by representatives from the CCA, NRL and other CAs. The minutes of these meetings indicated that their main purpose was to disseminate information between the CAs. There was little evidence that the NDCC was involved making decisions on the control measures to be applied or the deployment of staff and other resources. The CCA explained that these executive powers rested solely with the DG, who took personal charge of the management and control of the outbreak;
- meetings of the Expert Group were held to make arrangements for the sampling and testing of animals within the restricted zone and to establish other disease control measures. However, the CA did not seek the assistance of the EG in order to ensure that all appropriate samples were collected and epidemiological investigations carried out so as to determine the likely source and probable duration of the outbreak.

## **5.7 LABORATORIES**

The CCA took measures to address the observations and recommendation made during the previous FVO mission. Two regional laboratories have been authorised to carry out routine ELISA testing of serological samples taken from domestic pigs for the detection of CSF antibodies. The NRL has:

- been assessed by the Bulgarian accreditation agency for some test methods, including the fluorescent antibody test (FAT) and ELISA test, and accreditation in accordance with the ISO 17025 standard is expected to be granted shortly;
- participated in CSF ring tests organised by the CRL and organised relevant ring tests for the regional laboratories;
- developed its capacity to isolate the CSF virus from field samples.
- established a virus culture library and is developing its capacity to carry out the comparative VNT. This will enable the NRL to perform the differential diagnosis of seropositive animals in-house, rather than having to send samples to the CRL for analysis.

Representatives from the CRL assisted the CCA in the completion of this work .

Observations:

- The cell culture and PCR test methods used in the NRL have not yet been assessed by the Bulgarian accreditation agency. An assessment of the test methods carried out in the two regional laboratories is due to take place during 2008;
- well-developed quality manuals had been established in the NRL and in the regional laboratory visited. The FVO team saw evidence that technicians operated according to established procedures;
- both laboratories operated electronic information management systems, which allowed laboratory test forms and reports to be retrieved promptly and reliably;
- the FVO team saw evidence of the positive contribution made by the CRL representatives, including the introduction of a reliable system for the identification of sample materials in the NRL;
- the NRL demonstrated its ability to culture field CSF virus by successfully isolating the causative strain from samples taken from suspect animals during the recent outbreak;
- problems with the reliability of tests carried out in the regional laboratories during the first few months of their operation led to delays in the investigation of seropositive animals. The results of recent ring tests in which the Regional Laboratories participated indicate that these problems have now been resolved;
- operational difficulties currently prevent the NRL from using the PCR test method for the detection of CSF antigens in tissue samples. This is the primary tool used for the detection of virus in wild boar. However, the Director responsible for the NRL expressed his commitment to resolving this problem in advance of the next hunting season.

## **6 CONCLUSIONS**

### **6.1 COMPETENT AUTHORITIES**

Official measures for the control of CSF and the designation of responsibility for implementing them are laid out clearly in the national control and eradication programme. Measures have been taken to ensure that enforcement powers are adequate. However, the regional CAs require further guidance on how these powers should be applied. Steps have also been taken to target staff resources more effectively. However, work pressures on OVs at municipal level continue to interfere with the completion and reporting of official controls. Control activities are generally carried out in line with documented procedures and according to planned schedules. However, the overall effectiveness of the system is undermined by insufficient coordination of official activities between control units and by the lack of audits, as required by Article 4 of Regulation (EC) No. 882/2004 of the European Parliament and of the Council.

### **6.2 ANIMAL IDENTIFICATION, REGISTRATION AND MOVEMENT CONTROLS**

Progress has been made since the previous FVO mission regarding the identification, registration and movement control of pigs. The system in place generally complies with the requirements of Council Directive 92/102/EEC and Commission Decision 2000/678/EC. The inclusion of checks on the registration of holdings in the reporting of routine clinical surveillance visits serves to ensure that all holdings are included in the central register. Although pigs are identified in accordance with national requirements, rules on the maintenance of holding registers are insufficiently enforced. Furthermore, delays in the notification and entry onto the CDB of changes in the numbers of pigs present on holdings means that the information in the system regarding the inventory of pigs on holdings is not accurate.

Hardware and design problems continue to dog the central database, making it difficult to use and limiting the amount of useful epidemiological information that can be extracted at municipal level.

### **6.3 SURVEILLANCE OF DOMESTIC PIGS**

The health status of pigs on industrial holdings and type A family farms is monitored rigorously. Biosecurity measures in place on these holdings provide valuable protection from the potential introduction of disease from neighbouring domestic and feral pigs. The situation regarding type B family farms and East Balkan pig herds, which also supply pigs to slaughterhouses, is less well controlled. The lack of biosecurity measures on these holdings and the difficulties experienced by the CCA in maintaining the surveillance of type B family farm holdings up to date means that the health status of pigs coming from these holdings is uncertain.

The CCA generally takes appropriate measures to restrict and investigate holdings on

which the presence of CSF is suspected, in accordance with Article 4 of the CSF directive, and there is no evidence of active infection on any of the holdings involved. However, the investigation of seropositive animals is not conducted according to the guidance provided in Chapter VII (C) of the CSF Diagnostic Manual.

#### **6.4 CSF ERADICATION IN WILD BOARS**

The survey of samples collected from wild boars shot and found dead during 2007 demonstrates that the CSF virus is not circulating widely within Bulgaria. However, the survey's design does not take account of the location of separate wild boar subpopulations and ensure that an adequate number of samples is collected from each. As a result, no conclusions can be reached on whether or not the virus is absent from all hunting areas.

The vaccination of wild boars is generally carried out according to plan. However, decisions were made to exclude some hunting territories from vaccination and to reduce the number of baits distributed in others, which lacked a sound veterinary justification. Furthermore, the absence of reliable information on the level of immunity to CSF among wild boars means that it is not possible to conclude on the overall efficacy of the vaccination programme.

#### **6.5 DISEASE OUTBREAK CONTROL**

The CAs took prompt action to control an outbreak of CSF on a type B family farm in May 2008. They established protection and surveillance zones and generally applied the control measures foreseen in the national contingency plan and in Council Directive 2001/89/EC, thereby preventing the dissemination of the disease from the restricted zone. However, epidemiological enquiries to determine the possible source of the outbreak were incomplete.

#### **6.6 NATIONAL DISEASE CONTROL CENTRE AND EXPERT GROUP**

Although the recent disease outbreak in domestic pigs was brought under control rapidly, this was achieved with limited involvement of the NDCC and Expert Group. In particular, the NDCC was not made responsible for the activities listed in Article 23(2) of the CSF Directive. As a result, an opportunity to confirm the central role of these bodies and to develop their capacity to direct and monitor the operations of Local Disease Control Centres was missed, which could undermine their ability to control of future outbreaks, particularly in areas of more intensive pig production.

#### **6.7 LABORATORIES**

Considerable work has been done to strengthen the National Reference Laboratory (NRL) since the previous FVO mission. The introduction of testing capacity at two regional laboratories has reduced the burden on the NRL, allowing it to develop its role as a reference laboratory. The process of assessing and accrediting these laboratories in accordance with European standards is under way.

## 6.8 OVERALL CONCLUSION

Progress has been made in practically all aspects of the CSF control system since the previous mission. 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 programme remain.

## 7 CLOSING MEETING

The FVO team held a closing meeting with the CCA and representatives from the NRL on 26 June 2008, at which the main observations and preliminary conclusion of the mission were presented. The CCA provided clarification on a number of observations, which are reflected above, and proposed to provide additional comments and clarification upon receipt of the draft report.

## 8 RECOMMENDATIONS

The following recommendations are made to the Bulgarian CCA:

No.	Recommendation
1	To use the newly-developed reporting tools as a means to verify that CSF control activities are effective, as required by Article 8 of Regulation (EC) No. 882/2004 of the European Parliament and of the Council.
2	To further develop the central database, particularly facilities for the extraction of animal movement data, and to address the causes for delayed notifications, so that the database can supply the particulars of their last holding for groups of pigs at any time, as required by Article 14(3) of Council Directive 64/432/EEC, and may be used effectively in the control of CSF.
3	To ensure that holdings meet biosecurity standards and are subject to regular supervision, as foreseen in the national CSF programme established to implement the requirements of Council Directive 2001/89/EC, before they may dispatch pigs to slaughterhouses, in order to prevent the potential dissemination of CSF virus within Bulgaria and to other Member States.
4	To establish targets for the surveillance and vaccination of wild boar subpopulations, based on hunting zones defined according to the migration patterns of these animals and other epidemiological factors rather than administrative or organisational boundaries, in accordance with Chapter IV(H) of the Annex to Commission Decision 2002/106/EC.
5	To review the CSF Contingency Plan and to further develop the role of the National Disease Control Centre and Expert Group, in light of experience gained during the recent CSF outbreak and in accordance with Articles 22 and 23 of Council Directive 2001/89/EC.

<b>No.</b>	<b>Recommendation</b>
6	To ensure that all laboratories performing diagnostic tests for CSF have been assessed and are accredited in relation to these analytical methods, as required by Article 12 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

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

[http://ec.europa.eu/food/fvo/ap/ap\\_bulgaria\\_7800\\_2008.pdf](http://ec.europa.eu/food/fvo/ap/ap_bulgaria_7800_2008.pdf)

## ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Regulation (EC) No 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
Directive 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
Directive 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
Directive 92/102/EEC	OJ L 355, 5.12.1992, p. 32–36	Council Directive 92/102/EEC of 27 November 1992 on the identification and registration of animals
Decision 2006/805/EC	OJ L 329, 25.11.2006, p. 67–73	2006/805/EC: Commission Decision of 24 November 2006 concerning animal health control measures relating to classical swine fever in certain Member States
Decision 2008/77/EC	OJ L 23, 26.1.2008, p. 28–29	2008/77/EC: Commission Decision of 25 January 2008 approving the plans for 2008 for the eradication of classical swine fever in feral pigs and the emergency vaccination of those pigs against that disease in Bulgaria
Decision 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
Decision 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
Decision 2007/19/EC	OJ L 7, 12.1.2007, p. 38–40	2007/19/EC: Commission Decision of 22 December 2006 approving contingency plans for the control of classical swine fever pursuant to Council Directive 2001/89/EC