



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL  
Directorate F - Food and Veterinary Office

DG(SANCO) 2010-8417 - MR FINAL

FINAL REPORT OF A SPECIFIC AUDIT

CARRIED OUT IN

ROMANIA

FROM 16 TO 26 MARCH 2010

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

IN THE CONTEXT OF A GENERAL AUDIT

### ***Executive Summary***

*This report describes the outcome of a Food and Veterinary Office (FVO) specific audit in Romania, which took place between 16 and 26 March 2010, as part of the general audit of Romania carried out under the provisions of Regulation (EC) No 882/2004 on official food and feed controls. The specific audit evaluated the implementation of the approved Classical swine fever (CSF) control and monitoring programme (CMP) and the application of requirements established by Commission Decision 2008/855/EC concerning intra-Community trade (ICT) in fresh pig meat, meat products and preparations.*

*The roles and responsibilities of the competent authorities (CAs) are clearly defined and they have adequate resources to carry out official controls. However, limited progress has been made regarding the development of legal texts and procedures needed for the implementation of national plans. CSF laboratories operate quality systems and are making progress towards accreditation. The CAs take appropriate measures to ensure that non-compliant food business operators bring their operations in line with legal requirements. Regional CAs and inspection services perform frequent checks and audits to verify the effectiveness of official controls.*

*The CSF laboratory network in Romania is well-organized, operates in accordance with Community diagnostic requirements and is competent to diagnose both CSF and African swine fever (ASF). Animal identification and registration systems are generally reliable. However, there are technical problems with the computer database and the measures taken to prevent the unauthorized transfer of pigs from backyard holdings are not entirely effective. These weaknesses would impede the prompt investigation of possible disease outbreaks. Biosecurity measures on commercial farms and slaughter premises are officially supervised and generally acceptable. However, the layout and construction of backyard holdings makes them difficult to protect from the introduction of disease agents. The CAs are generally well-prepared to deal with possible CSF outbreaks. As in previous years, the CAs did not achieve the surveillance and vaccination targets established in the CMP during 2009. Nevertheless, the analysis that was performed revealed no evidence of the disease and the risk that CSF virus is circulating undetected in domestic pigs or in wild boars is low. The CAs did not achieve the vaccination targets in the CMP for 2009 and vaccination in wild boars was not performed consistently.*

*Systems for the control of ICT in pig meat, meat preparations and meat products are generally reliable. However, official instructions do not require health certification of products dispatched in accordance with the provisions of Article 8a of Commission Decision 2008/855.*

*In conclusion, the CAs are well-organised and systems to verify the effectiveness of official controls are operational. Systems in place for the detection and control of CSF and for the dispatch of products containing pork meat to other Member States are generally functional. However, the capacity of the CAs to implement new animal health policies is limited, which is particularly significant in light of the planned changes to the CSF control and monitoring systems.*

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

# Table of Contents

<b>1</b>	<b><u>INTRODUCTION</u></b> .....	<b>1</b>
<b>2</b>	<b><u>OBJECTIVES OF THE MISSION</u></b> .....	<b>1</b>
<b>3</b>	<b><u>LEGAL BASIS FOR THE MISSION</u></b> .....	<b>1</b>
<b>4</b>	<b><u>BACKGROUND</u></b> .....	<b>2</b>
4.1	<u>CONTRIBUTION TO THE GENERAL AUDIT</u> .....	2
4.2	<u>SUMMARY OF PREVIOUS FVO MISSION RESULTS</u> .....	2
<b>5</b>	<b><u>FINDINGS AND CONCLUSIONS RELATED TO IMPLEMENTATION OF REGULATION (EC) no 882/2004</u></b> .....	<b>2</b>
5.1	<u>COMPETENT AUTHORITIES</u> .....	2
5.1.1	<u>DESIGNATION OF COMPETENT AUTHORITIES</u> .....	2
5.1.2	<u>CO-OPERATION BETWEEN COMPETENT AUTHORITIES</u> .....	2
5.1.3	<u>CO-OPERATION WITHIN COMPETENT AUTHORITIES</u> .....	2
5.1.4	<u>DELEGATION OF SPECIFIC TASKS RELATED TO OFFICIAL CONTROLS</u> .....	3
5.1.5	<u>CONTINGENCY PLANNING</u> .....	3
5.2	<u>RESOURCES FOR PERFORMANCE OF CONTROLS</u> .....	3
5.2.1	<u>LEGAL BASIS FOR CONTROLS</u> .....	3
5.2.2	<u>STAFFING PROVISION AND FACILITIES</u> .....	3
5.2.3	<u>STAFF QUALIFICATIONS AND TRAINING</u> .....	4
5.3	<u>ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS</u> .....	4
5.3.1	<u>REGISTRATION / APPROVAL OF FOOD BUSINESS OPERATORS</u> .....	4
5.3.2	<u>PRIORITISATION OF OFFICIAL CONTROLS</u> .....	4
5.3.3	<u>CONTROL ACTIVITIES, METHODS AND TECHNIQUES</u> .....	4
5.3.4	<u>SAMPLING AND LABORATORY ANALYSIS</u> .....	5
5.3.5	<u>PROCEDURES FOR PERFORMANCE AND REPORTING OF CONTROL ACTIVITIES</u> .....	5
5.3.6	<u>TRANSPARENCY AND CONFIDENTIALLY</u> .....	5
5.4	<u>ENFORCEMENT MEASURES</u> .....	5
5.4.1	<u>MEASURES IN THE CASE OF NON-COMPLIANCE</u> .....	5
5.4.2	<u>SANCTIONS</u> .....	6
5.5	<u>VERIFICATION AND REVIEW OF OFFICIAL CONTROLS AND PROCEDURES</u> .....	6
5.5.1	<u>VERIFICATION PROCEDURES</u> .....	6
5.5.2	<u>AUDIT</u> .....	6
5.6	<u>MULTI ANNUAL NATIONAL CONTROL PLAN</u> .....	6
<b>6</b>	<b><u>SECTOR SPECIFIC FINDINGS AND CONCLUSIONS</u></b> .....	<b>7</b>
6.1	<u>SECTOR SPECIFIC HEADING</u> .....	7
6.1.1	<u>SECTOR SPECIFIC SUB-HEADING</u> .....	7
6.1.2	<u>SECTOR SPECIFIC SUB-HEADING</u> .....	7
6.2	<u>SECTOR SPECIFIC SUB-HEADING</u> .....	7
6.2.1	<u>SECTOR SPECIFIC SUB-HEADING</u> .....	7
<b>7</b>	<b><u>OVERALL CONCLUSION</u></b> .....	<b>8</b>
<b>8</b>	<b><u>CLOSING MEETING</u></b> .....	<b>8</b>
<b>9</b>	<b><u>RECOMMENDATIONS</u></b> .....	<b>8</b>
	<b><u>ANNEX 1 - LEGAL REFERENCES</u></b> .....	<b>9</b>

## ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

<b>Abbreviation</b>	<b>Explanation</b>
ASF	African Swine Fever
AV	Authorized Veterinarian
CA	Competent Authority
CCA	Central Competent Authority
CDb	Computer Database for animal identification
CMP	Control and Monitoring Programme
CRL	Community Reference Laboratory
CSF	Classical Swine Fever
CV	Contract Veterinarian
DG(SANCO)	Health and Consumers Directorate-General
EC	European Community
ELISA	Enzyme Linked Immunosorbent Assay
EU	European Union
FBO	Food Business Operator
FMD	Foot-and-mouth Disease
FVO	Food and Veterinary Office
GA	General Audit
ICT	Intra-Community Trade
IF	Immuno-fluorescent
IP	Immuno-peroxidase
Lohn system	Arrangements to control the receipt of raw materials originating in other Member States, the separate handling of these materials and the re-dispatch of final products to other Member States
MANCP	Single Integrated Multi-Annual National Control Plan
MARD	Ministry of Agriculture and Rural Development ( <i>Ministrul agriculturii și dezvoltării rurale</i> )
MS	Member State
NSVFSA	National Sanitary Veterinary and Food Safety Authority ( <i>Autoritatea Națională Sanitare Veterinare și pentru Siguranța Alimentelor</i> )
OIE	World Organisation for Animal Health.
OV	Official Veterinarian
PCR	Polymerase Chain Reaction
SA	Specific Audit
VNT	Virus Neutralization Test

## 1 INTRODUCTION

The Specific Audit (SA) formed part of the Food and Veterinary Office's (FVO's) planned mission programme. It took place in Romania from 16 to 26 March 2010. The FVO audit team comprised two inspector(s) from the FVO and one expert from a European Union (EU) Member State (MS). An opening meeting was held on 16 March with the National Sanitary Veterinary and Food Safety Authority (NSVFSA), which is the central competent authority (CCA) within the scope of this mission, and the Ministry of Agriculture and Rural Development (MARD). At this meeting, the objectives of, and itinerary for, the SA were confirmed by the FVO audit team and the control systems were described by the authorities. Representatives from the CCA accompanied the FVO audit team for the duration of the audit.

## 2 OBJECTIVES OF THE MISSION

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

- verify that official controls are organised and carried out in accordance with relevant provisions of Regulation (EC) No 882/2004, and the multi-annual national control plan (MANCP) prepared by the competent authorities (CAs) in Romania.
- to evaluate the official control systems in place to give effect to EU requirements concerning:
  - surveillance, control and eradication measures against classical swine fever (CSF) in domestic and feral pigs;
  - measures to control the dispatch of live pigs, fresh pig meat and certain meat preparations and meat products to other MS.

In terms of **scope**, the audit concentrated primarily on:

- As regards Regulation (EC) No 882/2004, the organisation of official controls (Artt. 3-7), control and verification procedures and methods (Artt. 8-10), registration and approval of establishments (Art. 31), enforcement (Artt. 54-55) and MANCP (Artt. 41-42);
- Reviewing the actions taken by the CAs to address the recommendations made in FVO inspection report DG(SANCO)/2009-8250.
- Evaluating the systems implemented for official control on fresh meat and meat products dispatched to other MS.

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

MEETINGS/VISITS		n	COMMENTS
COMPETENT AUTHORITIES	Central	3	- initial and final meetings; meeting with the Institute for the control of biological products and veterinary medicines - visits to two regional CA offices
	Regional	2	
LABORATORIES		3	National reference laboratory (NRL); two regional laboratories
FARMS		4	Two commercial farms; two backyard holdings
ESTABLISHMENTS		5	Three establishments approved for dispatch of fresh meat; one establishment approved for dispatch of meat products; one establishment approved for slaughter of domestic pigs
OTHER SITES		3	Two wild boar hunting areas; office of an authorized veterinarian (AV)

### 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 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

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

### 4 BACKGROUND

#### 4.1 CONTRIBUTION TO THE GENERAL AUDIT

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

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

#### 4.2 ANIMAL HEALTH SITUATION AND PREVIOUS FVO MISSION RESULTS

Sporadic outbreaks of CSF were reported in Romania until 2007, both in domestic pigs and wild boars. Taking account of the history of the disease and the progress made to control it, Commission Decision 2008/855/EC establishes certain animal health control measures for Romania:

- the introduction into intra-Community trade (ICT) of live pigs, reproductive materials and fresh pig meat produced from pigs of Romanian origin is prohibited;
- meat products produced from domestically reared pigs may enter ICT provided that they undergo treatment ensuring the elimination of the disease agent;

- fresh meat produced from pigs originating on holdings within the EU but outside Romania may be processed in the country and re-dispatched subject to strict separation requirements.

National programmes for the control and monitoring of CSF in Romania were approved for 2009 and 2010 by Commission Decisions 2008/897/EC and 2009/883/EC respectively. The programme for 2009 included plans for the vaccination of domestic pigs on backyard holdings and of wild boars. In 2010, the CAs intend to suspend the vaccination of domestic pigs entirely and to confine campaigns for the vaccination of wild boars to regions located close to Third Country borders.

Two FVO missions relevant to the scope of this SA were carried out during 2008 and 2009:

- Mission DG(SANCO)/ 2008-7997, which was carried out in August 2008 in order to evaluate official controls in relation to a proposed system to authorise trade of fresh pig meat and pig meat products from Romania (hereafter referred to as the 'previous FVO mission concerning meat and meat products'). The overall conclusion of the mission was that arrangements to control the receipt, processing and re-dispatch of fresh meat (the so-called "Lohn" system) were incomplete and did not guarantee that this trade would not lead to the spread of CSF to other MSs. The reliability of the official controls at establishment level was considered to be weak, particularly with regard to the verification of relevant requirements and certification. Food business operators (FBOs) had not yet implemented reliable systems and major deficiencies were found in relation to the identification of raw materials, which made traceability systems unreliable. As this was a fact-finding mission, the report did not contain any recommendations to the CAs;
- Mission DG(SANCO)/ 2009-8250, which was carried out in March 2009 in order to evaluate the implementation of control and monitoring programmes for CSF in domestic pigs and wild boars in Romania (hereafter referred to as the 'previous FVO mission concerning live animals'). The overall conclusion of the mission was that the situation had improved and veterinary structures were being changed to ensure more direct line management. Nevertheless, certain issues remained unsatisfactory, in particular the fact that certain corrective actions were not fully implemented 18 months after FVO mission DG(SANCO)/ 2007-7618, which had a similar scope. The provision of inaccurate information to the Commission undermined confidence in the Romanian authorities. However, in view of the safeguard measures in place preventing ICT in live pigs and untreated pork from Romania, there was no immediate risk for the pig health situation in the other MSs.

Copies of the above-mentioned FVO mission reports are available for download at:

[http://ec.europa.eu/food/fvo/ir\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm)

## **5 FINDINGS AND CONCLUSIONS RELATED TO IMPLEMENTATION OF REGULATION (EC) NO 882/2004**

### **5.1 COMPETENT AUTHORITIES**

#### *5.1.1 Designation of Competent Authorities*

#### **Legal Requirements**

Article 4(1) of Regulation (EC) No 882/2004 requires MSs to designate the CAs responsible for official controls.

## **Findings**

▶ Government Decision no. 1415/2009, on the organization and functioning of the National Sanitary Veterinary and Food Safety and its subordinated units, establishes the roles and responsibilities of the CCA and regional CAs. The responsibilities of authorized veterinarians (AVs) performing official activities at district level are defined in formal contracts (concessionary agreements). Private contract veterinarians (CVs), who provide veterinary services to commercial farms, must receive a mandate from the CAs defining their official obligations.

▶ The report of the previous FVO mission concerning live animals noted that the position of the CCA within the government executive had changed: it reports directly to the office of the Prime Minister and is no longer part of the MARD. The report included a recommendation (# 1) to demonstrate the impact of the new structures on the efficacy of the system of official control. No formal evaluation of the change was conducted. However, the CCA informed the FVO audit team that their experience of the new reporting arrangements during the foot-and-mouth disease simulation exercise in 2009 and the recent AI outbreak was favorable. The CAs at regional level stated that the new structure required them to work more closely with the County Prefects, which helped them to develop and implement veterinary controls more coherently and effectively.

▶ Since the previous FVO mission concerning live animals, the General Inspection Service of the CCA has been split into General Inspection and Border Inspection Directorates. The General Inspection Directorate is responsible for evaluating the technical performance of official controls at each stage of the production process. It is supported by Inspection and Control Services in each region. Further details are provided below in Section 5.5.

### *5.1.2 Co-operation between Competent Authorities*

#### **Legal Requirements**

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

#### **Findings**

▶ Written protocols have been established between the CAs and the police and hunting authorities at national and regional levels. These protocols set out criteria for cooperation and joint working in order to deliver effective veterinary controls.

▶ The FVO audit team noted the good working relationships between CAs at regional level and their counterparts in the Hunting Inspectorate of the Ministry of the Environment and the National Forestry Authority (ROMSILVA).

### *5.1.3 Co-operation within Competent Authorities*

#### **Legal Requirements**

Article 4(5) of Regulation (EC) No 882/2004 requires that, when, within a CA, more than

one unit is competent to carry out official controls, efficient and effective co-ordination and co-operation shall be ensured between the different units.

## **Findings**

► Since the previous FVO mission concerning live animals, the CCA modified its plans for the National CSF Monitoring Network and formally dropped the proposal, which was included in its plans for 2009, to appoint regional coordinators. The network now includes the officials responsible for CSF at central level and representatives from each regional CA. Its objective is to improve the coordination and reporting of surveillance and vaccination activities. The FVO audit team met the network representatives appointed in each of the regions visited, who explained that their focus was on ensuring the effective bidirectional flow of information between CCA and the counties. Although the network appeared to meet its objective, the FVO audit team noted that it was not being used as a means to ensure inter-county collaboration and communication in the event of a disease outbreak.

### *5.1.4 Delegation of specific tasks related to official controls*

## **Legal Requirements**

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

## **Findings**

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

### *5.1.5 Contingency planning*

## **Legal Requirements**

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

## **Findings**

► In the event of a disease emergency, the provisions of Law no. 1 of 8 January 2008, which amended the legal status of the CCA, require the National Disease Control Centre (NDCC) to be activated and administered by the Minister of the Interior. The NDCC is an intra-governmental structure composed of:

- Central Decision Making Unit, which is headed by the Minister of the Interior and Administrative Reform and comprised of the members of the National Committee for Emergency Situations;

- Central Operational Unit, which is constituted at the level of the CCA under the leadership of its president;
- Central Support Unit, which supports the Central Operational Unit and is comprised of experts and specialists from government and the private sector.

Similar structures exist at regional level, with the prefecture representing the Ministry of the Interior and Administrative Reform in the Local Disease Control Centre.

► The arrangements in place to prepare for possible outbreaks of CSF are considered in more detail in section 6.3 below.

### **Conclusions on Competent Authorities**

Responsibilities for official controls within the scope of this SA are clearly defined and arrangements have been made to coordinate official activities within and between the CAs. The establishment of the CCA as an independent authority better prepares it to deal with possible disease outbreaks.

## **5.2 RESOURCES FOR PERFORMANCE OF CONTROLS**

### *5.2.1 Legal basis for controls*

#### **Legal Requirements**

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

Article 45(5)(a) of the same Regulation requires the CAs to take appropriate follow-up action in the light of the recommendations resulting from Community controls

#### **Findings**

► The powers of official veterinarians (OVs) are established by Government Decision no. 1415/2009 (see also in Section 5.1) and Government Decision no. 1492/2009 for the implementation of activities listed in the 'Programme of activities for surveillance, prevention, control and eradication of animal diseases and zoonoses, animal welfare and environmental protection' (hereafter referred to in this report as the 'annual animal health and welfare programme'), and other actions provided for in other national programmes for which the NSVFSA is responsible. Presidential Order 83/2008 establishes their duties and powers in the context of the animal identification programme.

► The previous FVO mission report concerning live animals concluded that the late adoption and publication of some legal texts related to the control of CSF, together with budgetary issues, reduced the effectiveness of the system. It recommended (# 5) that the CAs should further adopt necessary legal texts and seek to accelerate the adoption of future texts. Detailed arrangements for the implementation of the approved control and monitoring programme (CMP) during 2009 were formally finalized in April that year, with the publication of Presidential Order 24 of 28.04.2009 establishing the annual animal health and

welfare programme for that year. The annex to that Order set out detailed instructions covering the diagnosis, surveillance and vaccination against CSF. Although these instructions were not available for the first quarter of the year, officials in the regions visited carried out some surveillance and vaccination activities before April, based on the instructions received during preceding years. However, by the end of the year some of the control activities foreseen in the plan had not been completed (see Sections 6.4 and 6.5).

► Presidential Order 2 of 20.01.2010 established the annual animal health and welfare programme for 2010. However, it did not contain detailed instructions for surveillance or vaccination. Chapter II of the Order indicated that detailed instructions would be circulated to the regional CA in the form of Service Notes issued by the President of NSVFSA. Although vaccination of domestic pigs on backyard holdings was suspended at the start of the year, no Service Notes had been issued three months later to instruct officials on how surveillance of these holdings should be carried out. This is contrary to the requirement established in Article 19 of Commission Decision 2009/883/EC approving the Romanian CSF CMP, which required the MSs to introduce the laws, regulations and administrative provisions necessary for implementing the approved programme by 1 January 2010 at the latest. It was not clear whether other instructions established for the 2009 animal health and welfare programme, concerning the supervision of commercial farms and the implementation of emergency vaccination in wild boars were still valid. During the mission, the CAs explained that they intended to resolve this problem shortly.

### 5.2.2 *Staffing provision and facilities*

#### **Legal Requirements**

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

#### **Findings**

► In line with government policy, the recruitment of staff to fill vacant posts within the CCA has been suspended. However, the directors of the regional offices visited considered that they had adequate numbers of staff.

► The report of the previous FVO mission concerning live animals included a recommendation (# 2) to take action to reduce the risk for conflict of interest for veterinarians carrying out official controls. In conjunction with the College of Veterinarians, the CCA has developed conflict of interest declarations that must be signed by AVs and CVs. It requires them to declare that they are neither owners nor shareholders of the holdings and farms on which they perform official duties. This requirement was introduced recently and had not yet been implemented at regional level.

► The CA offices and laboratories visited were adequately equipped to enable the CAs to perform routine official control activities. The CAs were taking action to ensure that they have access to the facilities and equipment needed to deal with disease outbreaks (see section 6.4).

### 5.2.3 *Staff qualifications and training*

#### **Legal Requirements**

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

#### **Findings**

- ▶ Annual training programmes were established at national and regional levels and included training courses relevant to the scope of this audit.
- ▶ The CAs organized training for officials in the animal health domain within a cascade system: CCA experts trained representatives from each regional CA, who in turn trained OVs at district level. District OVs were then responsible for providing training to AVs and CVs. The CCA did not receive any feedback from the districts and regions on the delivery of this training. However, the completion of the annual training programmes was monitored during audits by the General Inspection Directorate and Inspection and Control Services at regional level.
- ▶ Similar cascade training was organized within the food safety domain. However, shortcomings were detected by the CCA in the level of expertise among OVs. As a result, targeted training courses in priority areas were also provided to these officials directly by experts from the CCA.
- ▶ The CAs also used twinning programmes to organize training events during 2009, including training in the field of animal welfare and the destruction of carcasses.
- ▶ The officials at central level and in the regions visited by the FVO audit team were familiar with their technical duties and demonstrated their competence to perform them.

#### **Conclusions on Resources for Performance of Controls**

The CAs generally have adequate legal and physical resources and sufficient numbers of qualified staff to carry out official controls. However, limited progress has been made regarding the development of legal texts and procedures needed for the implementation of national plans.

## **5.3 ORGANISATION AND IMPLEMENTATION OF OFFICIAL CONTROLS**

### **5.3.1 *Registration / approval of food business operators***

#### **Legal Requirements**

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

## **Findings**

► The CAs implemented procedures for the registration and approval of food businesses within the context of this report. Approval requirements have been established for commercial farms and for food processing establishments. These requirements had generally been implemented correctly on the sites visited by the FVO audit team. However, some shortcomings were noted with regard to the manner in which compliance with these requirements was monitored and reviewed on commercial farm (see Section 6.2).

### *5.3.2 Prioritisation of official controls*

#### **Legal Requirements**

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. Controls shall be carried out at any of the stages of the production and processing chain and, in general, are to be carried out without prior warning. Controls shall be applied with the same care to exports from the Community, imports into the Community and to product placed on the Community market.

#### **Findings:**

► The CAs put a high priority on official controls performed on food business operators (FBOs) involved in the CSF CMP. For example, commercial farms were subject to monthly visits by OVAs, who checked that they complied with animal health, identification and registration requirements (see Sections 6.2 and 6.4). Food processing establishments involved in the Lohn system were subject to full time supervision by OVAs (see Section 6.6).

### *5.3.3 Control activities, methods and techniques*

#### **Legal Requirements**

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

#### **Findings**

► The CAs used combinations of all of the methods listed in Article 10 when performing official controls on FBOs involved in the CSF CMP, including the inspection of installations, animals, raw materials and labels and the examination of records and measured values.

### *5.3.4 Sampling and Laboratory analysis*

#### **Legal Requirements**

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

## **Findings**

- ▶ The national laboratory network for CSF in Romania includes the Institute for Diagnosis and Animal Health, which has been designated as the National Reference Laboratory (NRL) for the disease, and regional laboratories in each county. Shortage of laboratory capacity was not considered to be a factor limiting the CAs from completing planned diagnostic and surveillance activities.
- ▶ The NRL is accredited according to the ISO/IEC 17025 international standard for all of the CSF diagnostic tests that it performs. Several of the regional laboratories are also accredited according to this standard for some or all of the test methods that they perform. The CCA expressed the intention to ensure that all laboratories achieve accreditation for all official test methods.
- ▶ The FVO audit team's findings and conclusions on the technical performance of the laboratory network are set out in Section 6.1 below.

### *5.3.5 Procedures for performance and reporting of control activities*

#### **Legal Requirements**

Article 8 of Regulation (EC) No 882/2004 requires that CAs carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Article 9 of the above Regulation requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

#### **Findings**

- ▶ As indicated in Section 5.2 above, the Annex to Presidential Order 24 of 28.04.2009 established detailed instructions for the implementation of the CSF CMP in 2009. These were supplemented by standard inspection and report forms. As mentioned in section 5.2, the procedures to be adopted during 2010 had not been documented.
- ▶ Detailed Service Notes were prepared for OVs in meat processing establishments supplying pig meat and meat products to other MSs (see Section 6.6).
- ▶ Officials responsible for official controls submitted regular reports, copies of which were available in each of the holdings and establishments visited. These were summarized in each region and reported to the central level.

### *5.3.6 Transparency and confidentiality*

#### **Legal Requirements**

Article 7 of Regulation (EC) No 882/2004 requires that CAs carry out their activities with a high degree of transparency, in particular by giving relevant information to the public as soon as possible. However, information covered by professional secrecy and personal data

protection is not to be disclosed.

### **Findings**

- ▶ The annual reports for 2009 from each region are available on the CCA website. These provide details of the nature and number of official controls conducted.
- ▶ The Director of the CA in one region visited organized regular press conferences to provide information on the animal health control system. The CAs were mentioned regularly in articles published in the national and regional press.
- ▶ The FVO audit team did not encounter any case in which the CAs had neglected their duty to protect confidential information pertaining to FBOs.

### **Conclusions on Organisation and Implementation of Official Controls**

Official controls are prioritized according to risk and appropriate control methods are employed. CSF laboratories operate according to quality systems and the CAs are making progress towards accreditation. Where procedures have been documented, they provide a basis for harmonized controls and transparent reporting.

## **5.4 ENFORCEMENT MEASURES**

### *5.4.1 Measures in the case of non-compliance*

#### **Legal Requirements**

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies a non-compliance to take appropriate action to ensure that the operator remedies the situation.

#### **Findings**

- ▶ When official controls performed by OVs detected non-compliances in the animal health and food safety domains, formal notes were issued to the FBOs, requiring them to take corrective action. The FVO audit team noted that OVs generally followed up these notes to ensure that the underlying shortcomings had been rectified.

### *5.4.2 Sanctions*

#### **Legal Requirements**

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

#### **Findings**

- ▶ The FVO audit team was presented with records of cases where pig keepers were

fined for breaches in animal identification and movement control requirements. The CAs explained that amendments to national rules in December 2009 led to a fivefold increase in the maximum fines that could be imposed in such cases. However, data received from the CCA indicated that high levels of noncompliance with animal movement requirements were detected during roadside checks performed in 2009 and 2010. There was no evidence that the CAs had imposed more stringent penalties during 2010 (see section 6.2).

### **Conclusions on Enforcement Measures**

The CAs take measures to ensure that non-compliant FBOs bring their operations in line with national and Community requirements. However, controls and sanctions in place to ensure compliance with animal movement requirements are not effective.

## **5.5 VERIFICATION AND REVIEW OF OFFICIAL CONTROLS AND PROCEDURES**

### *5.5.1 Verification procedures*

#### **Legal Requirements**

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

#### **Findings**

- ▶ The CAs had measures in place for the supervision of official controls and other official activities performed by CVs and AVs responsible for the supervision of domestic pig holdings (see Section 6.4) and OVs supervising meat processing establishments (see Section 6.6).

### *5.5.2 Audit*

#### **Legal Requirements**

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

#### **Findings**

- ▶ As mentioned in Section 5.1, the General Inspection Directorate and Inspection and Control Services audit the technical performance of officials at each level, including concessionary veterinarians. They periodically audit each operational unit, including regional and district CAs. In addition, they frequently carry out thematic audits focusing on particular policy areas or production sectors. For example, thematic audits evaluating the implementation of CSF requirements were to be conducted in each region during 2010.
- ▶ Inspection procedures have been developed, which establish templates and checklists

tailored to the nature of the food business or CA unit being audited and the scope of the audit. These procedures have been revised regularly, most recently in February 2010.

► The FVO audit team reviewed the records of a thematic audit on CSF, which had recently been performed in one of the regions visited. The audit included evaluations of the regional and district CA units, of OVs in meat processing establishments and AVs working on pig holdings. The scope of the audit covered nearly all aspects of the CSF control system. It detected several operational and documentary deficiencies and recommended corrective actions.

► No external audits were conducted within the scope of the CSF CMP or ICT in pork and pork meat products.

### **Conclusions on Verification Procedures**

Regional CAs and inspection services perform regular checks and audits to verify the effectiveness of official controls.

## **5.6 MULTI ANNUAL NATIONAL CONTROL PLAN**

### **Legal Requirements**

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

### **Findings**

► The MANCP for the period 2007-2011 was updated in April 2009 and describes how controls within the animal health domain are organized. However, the revised version does not include information on the organizational arrangements mentioned in Section 5.1 above

► As mentioned in Section 5.2, more detailed information on the strategic objectives and nature of the official controls carried out within the animal health domain is provided each year in the annual animal health and welfare programme.

### **Conclusions on Multi-Annual National Control Plan**

The MANCP provides information on the structure and organization of official controls and is supplemented by more detailed operational plans each year.

## 6 SECTOR SPECIFIC FINDINGS AND CONCLUSIONS

### 6.1 LABORATORIES

#### Legal Requirements

Article 17 of Council Directive 2001/89/EC requires MSs to perform diagnostic tests for CSF in accordance with the diagnostic manual, which is established by Commission Decision 2002/106/EC. Article 17 also obliges MSs to establish a national laboratory responsible for the diagnosis of the disease, which should liaise with the Community Reference Laboratory (CRL) for CSF.

Annex III of the Directive establishes the role for the NRL in controlling the quality of the reagents used in national laboratories, in organising proficiency tests for the participants in the network and for holding isolates of viruses recovered from confirmed cases of the disease.

Chapter IX of Commission Decision 2002/106/EC establishes minimum safety requirements for CSF laboratories.

#### Findings

- ▶ The NRL performs the following CSF test methods: virus isolation and genome sequencing, for the characterization of the disease agent; immuno-fluorescent (IF) and immuno-peroxidase (IP) assays and the polymerase chain reaction (PCR) methods (conventional and real time) for the detection of viral antigen; enzyme linked immunosorbent assay (ELISA) and the virus neutralization test (VNT) for the detection of antibodies. In each case, the test methods used are based on the recommendations and methods established in Commission Decision 2002/106/EC.
- ▶ The CAs considered that all regional labs met the biosafety standards and had the technical capability and competence to perform IF and IP assays and ELISA tests. Eight regional laboratories were also equipped to perform PCR tests and were authorized to perform confirmatory tests for CSF. The laboratories visited by the FVO audit team were well-equipped.
- ▶ The NRL participated in all of the comparative trials organised by the CRL. In turn, it organized inter-laboratory proficiency testing (for IF assays, PCR methods, ELISA tests, but not for IP assays) for regional laboratories, with satisfactory results overall.
- ▶ The NRL had sophisticated automated test equipment enabling it to handle large numbers of samples in case of emergency. Although the equipment was functional, it had not been used routinely and its capacity in the event of an emergency had not been tested in practice.
- ▶ The report of the previous FVO mission concerning live animals noted that the NRL had no records of ever having rejected samples that could not be tested. It recommended (# 4) the CA to ensure that doubtful laboratory test result and samples that could not be tested should be notified properly so that the CA could take the necessary measures in order to meet surveillance targets. The FVO audit team noted that the NRL had not revised

procedures to address the recommendation or to carry out training. However, there was no evidence that the receipt of non-conforming or inconclusive samples was a significant impediment to the delivery of the approved CMP. Furthermore, checks performed in one of the regional laboratories visited showed that the regional CAs had been notified of cases where samples submitted within the surveillance programme for CSF were unsuitable for testing.

► The report of the previous FVO mission concerning live animals noted insufficient training was provided for certain officials on the differential diagnosis of CSF. It included a recommendation (# 3) that all diagnostic laboratories should be reminded of the need to send samples to the NRL for analysis for African Swine Fever (ASF) when this disease cannot be ruled out otherwise. The annual animal health and welfare programme for 2010 included the provision that all samples collected from suspected cases of CSF that turn out to be negative for that disease should be retested for ASF. The diagnostic flow chart used by the laboratories for the investigation of CSF suspect cases was amended accordingly. The staff in the laboratories visited by the FVO audit team were also aware of the need to consider ASF as a differential diagnosis for CSF.

## **Conclusion**

The CSF laboratory network in Romania is well-organized, operates in accordance with Community diagnostic requirements and is competent to diagnose both CSF and ASF.

## **6.2 ANIMAL IDENTIFICATION AND MOVEMENT CONTROL, HOLDING REGISTRATION AND APPROVAL**

### **Legal Requirements**

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

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

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

Council Directive 2008/71/EC establishes requirements for:

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

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

- geographic coordinates of each holding or other geographical indicator of its location;

- a field in which data on the health status of the holding may be entered.

## **Findings**

### *6.2.1 Commercial farms*

- ▶ There were 287 registered commercial farms in Romania when the SA was carried out.
- ▶ Movement and inventory data for commercial farms had not been entered on the CDb since 2008, when national legislation was changed and the requirement to identify each pig on commercial farm with a unique individual number was dropped. Since then, keepers were permitted to identify these pigs with a tattoo or slap mark linked to the holding number. Keepers continued to notify the regional CAs of the number of pigs moved to or from their holdings but this information could not be entered into the CDb, which cannot process batch movement data. Each regional CA maintained its own archive of these movement notifications and also received monthly reports from CVs on the current inventory of animals on each commercial farm. The CCA explained that they were planning to oblige regional CAs to keep this information in the form of electronic spreadsheets. The CCA was unable to provide a deadline by when the underlying CDb problem would be resolved.
- ▶ The report of the previous FVO mission concerning live animals concluded that non-compliances in the register of commercial farms undermined the system's reliability. It recommended (# 6) that stricter controls should be applied to the holding registers on commercial farms. During 2009 and 2010, all commercial holdings continued to be subject to monthly inspections by the regional CAs. In addition, selected holdings were audited by the regional Inspection and Control Services, in order to verify that holding registers were maintained correctly. The records for movements to and from the commercial farms visited, and for the movements of pigs within these farms, were consistent.
- ▶ The FVO audit team noted that animal identification requirements were routinely checked at the slaughterhouse visited. The pigs observed on the premises were clearly identified and it was possible to determine their holding of origin.
- ▶ At the final meeting, the CA announced that an official would be appointed at central level to supervise all aspects of commercial farm operations, including the approval of premises, the appointment of CVs, the completion of conflict of interest declarations by these veterinarians and maintenance of on-farm records.

### *6.2.2 Backyard holdings*

- ▶ Article 5 of Presidential Order No. 85 of 06.10.2008 requires all keepers to maintain up-to-date holding registers conforming to the requirements of Article 4 of Council Directive 2008/71/EC. A holding register was maintained on one of the two backyard holdings visited. Although official vaccination records were present on the other holding, there was no holding register, which meant that it was not possible to determine the date of movement and destination holding of piglets sold within the locality.
- ▶ The report of the previous FVO mission concerning live animals included a recommendation (# 7) to properly enforce the movement ban on unidentified pigs,

particularly in relation to backyard holdings. The CAs carry out joint roadside checks with the Romanian Roads Authority to ensure that live pigs, fresh pig meat and meat products are transported in accordance with animal health requirements. Data provided by the Inspection and Control Directorate at the final meeting showed that during 2009, 1 776 controls were performed and infractions were detected in 677 cases (approximately 40% of the controls). Fines totaling approximately 300 000 euros were imposed (more than 400 euros on average per infraction). During the first quarter of 2010, 259 controls were performed, infractions were detected in 185 cases (approximately 70% of the controls) and fines of approximately 30 000 euros were imposed (approximately 160 euros per infraction). Officials at regional level confirmed that it was extremely difficult to control the movement of backyard pigs within the village environment. The FVO audit team noted a number of cases where such movements occurred:

- on one backyard holdings visited, official vaccination records indicated that approximately 20 piglets had been sold between October 2009 and March 2010. However, no information on their destination or dates of movement could be provided;
  - information available in the office of one of the concessionary veterinarians visited indicated that a small number of five-week old piglets had been moved between backyard holdings before they were identified or vaccinated.
- ▶ The animal identification and vaccination records were well-maintained in the office of the AV visited by the FVO team. The AV was also responsible for performing trichinosis testing on pigs slaughtered on backyard holdings for home consumption. However, the AV did not routinely crosscheck that the owners of slaughtered pigs had complied with animal identification, movement notification or vaccination requirements.
- ▶ During the SA, the CCA outlined its proposals for modifications to the holding registration and movement control systems during 2010. They anticipated that, with the cessation of vaccination on backyard holdings, they could permit unvaccinated pigs from semi-commercial backyard holdings to be slaughtered in approved slaughter establishments. These holdings would have to register with the local Chamber of Commerce and could benefit from MARD grants to enhance their animal health and welfare standards. Pigs from these holdings would be subject to sampling and laboratory testing at slaughter. Pigs from smaller backyard holdings could be sold locally through officially supervised livestock markets. Keepers of pigs on all backyard holdings would be obliged to notify the regional CAs whenever the number of animals present on their holdings changed (including births or deaths) and this information would be entered into the CDb.

## **Conclusion**

Animal identification and registration systems are generally reliable. However, there are technical problems with the CDb and the measures taken to prevent the unauthorized transfer of pigs from backyard holdings are not entirely effective. These weaknesses would impede the prompt investigation of possible disease outbreaks.

## 6.3 BIOSECURITY OF HOLDINGS

### Legal Requirements

Article 22 of Regulation (EC) No 1774/2002 prohibits the feeding of farmed animals other than fur animals with catering waste or feed material containing or derived from catering waste.

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

- all pigs on the holding be kept in their living quarters or some other place where they can be isolated from feral pigs. The feral pigs must not have access to any material which may subsequently come in contact with the pigs on the holding;
- appropriate means of disinfection be used at the entrance and exits of buildings housing pigs and of the holding itself;
- appropriate hygienic measures be applied by all persons coming in contact with feral pigs, to reduce the risk of spread of CSF virus, which measures may include a temporary ban on persons having been in contact with feral pigs from entering a pig holding;
- all dead or diseased pigs with CSF symptoms on a holding be tested for the presence of CSF;
- no part of any feral pig, whether shot or found dead, as well as any material or equipment which could be contaminated with CSF virus shall be brought into a pig holding;
- vehicles used to transport pigs from holdings within Romania must be cleaned and disinfected immediately following such operations.

### Findings

► The report of the previous FVO mission concerning live animals included a recommendation (# 15) to enhance the collaboration with keepers of pigs on backyard holdings, in particular regarding the ban on the use of catering waste for feeding pigs. The CCA did not introduce new measures to ensure the correct disposal of waste food produced by restaurants, retail outlets or domestically. AVs were not required to verify whether pigs were being fed kitchen waste. However, the keepers and veterinarians interviewed declared that the feeding of waste food to domestic pigs was not a common practice.

► The commercial farms visited were fenced and biosecurity measures were applied to vehicles and personnel entering the premises. On one of the holdings, loading facilities for dispatched pigs were not maintained hygienically. The registration of visitors on one of the commercial farms visited was not in accordance with national requirements.

► There were adequate cleaning and disinfection facilities in place at the slaughterhouse visited by the FVO audit team and the records for cleaning and disinfection of vehicles that left the slaughterhouse were generally complete and under official supervision.

► The backyard holdings visited and observed by the FVO audit team were in close

contact and provided little separation between the animal pens and public areas. In these circumstances it was impossible to establish disease control barriers between visitors and the animals.

## **Conclusion**

Biosecurity measures on commercial farms and slaughter premises are officially supervised and generally acceptable. However, the layout and construction of backyard holdings makes them difficult to protect from the introduction of disease agents.

## **6.4 DISEASE CONTROL IN THE EVENT OF EMERGENCIES**

### **Legal Requirements**

Article 22 of Council Directive 2001/89/EC obliges MSs to draw up contingency plans. The criteria and requirements for drawing up these plans are set out in Annex VII to that Directive, including the need for twice yearly alarm drills, training of staff on the diagnosis and control of the disease and on communication).

Article 23 establishes a requirement for a permanently operational expert group, responsible for maintaining technical expertise in the area of disease control and to assist the CAs in ensuring disease preparedness.

### **Findings**

#### *6.4.1 Contingency plans and disease preparedness*

- ▶ The report of the previous FVO mission concerning live animals included a number of findings and recommendations related to contingency plans and disease preparedness:
  - The CAs were recommended (# 8) to apply proper documentation procedures with regard to updated versions of the CSF contingency plan and operational manual. During this SA, the FVO audit team noted that the revised national CP included a version control number. Records kept at regional level demonstrated that supporting information (including contact lists) were updated during the previous 12 months.
  - The report noted that no contingency plan or operational manual for ASF existed and concluded that this was not in compliance with Article 2 of Directive 2002/60/EC. The FVO audit team received a draft copy of the newly developed contingency plan for ASF. The CCA indicated that the final version would be sent to the EC once it has been approved for official use.
  - The CAs were recommended (# 13) to take the necessary action to deal with large scale outbreaks, taking into account animal welfare requirements. Presidential Order No 74 of 29 December 2009 established requirements for all practising veterinarians to purchase the instruments necessary for the humane slaughter and killing of animals and required the regional CAs to retain a stock of five captive bolt pistols for use in emergencies. The Order was published in the Official Journal of Romania on 12 March 2010 and was notified to the Regional CAs by a Service Note on 23 March 2010. Consequently, this instruction had not been implemented at the time of the FVO audit. However, the CCA reported that 393 stunning devices were

available to veterinarians throughout Romania and that a further 2 264 devices would be purchased. Training for veterinarians in the use of these devices was included in the national training plan for 2010.

– The CAs were recommended ( # 14) to reconsider the use of certain substances for the killing of small quantities of pigs, taking account of the provision of Article 3 of Council Directive 93/119/EC. The official animal welfare guidance on killing pigs had been redrafted but had not been circulated to field staff. It listed the relevant substance as a possible alternative method but included a statement that the European Commission had prohibited its use for killing pigs.

– The CAs were recommended ( # 9) to ensure that in the event of a CSF outbreak all possible ways of destroying dead pigs are rapidly accessible to the CA including the use of incinerators if needed. It was noted during this SA that the CCA has entered into lease arrangements allowing them emergency access to fixed and mobile incineration equipment owned by private companies.

► The CAs in one of the regions visited had a large mobile unit at their disposal. This consisted of a number of containers, which contained the materials needed to equip a team to deal with an outbreak of epizootic disease. The CCA explained that similar containers were distributed strategically around the country. They were purchased in preparation for a possible outbreak of avian influenza but were available to whichever regional CA that might need them.

#### *6.4.2 Disease control centres and expert groups*

► One of the recommendations of the CSF subgroup of the EU Task Force for Monitoring Disease Eradication, which met in Bucharest in November 2009, was that the expert groups should meet regularly. It was noted during this SA that expert groups had been established in each region but that they did not meet regularly. The CCA explained that its objective was to ensure that the groups could provide practical advice in the case of outbreaks rather than to act as fora for esoteric discussions.

#### *6.4.3 Suspect cases and simulation exercises*

► No official cases of clinical disease suspicion were reported during 2009 or 2010. However, refresher courses for CSF had been conducted in most counties during the early part of 2010. The CCA anticipated that such an exercise would be completed in all counties by the end of March 2010. In the regions visited, the training courses were targeted at veterinarians (OVs and AVs). The materials used included videos, slide presentations and written materials covering each stage of the control of a disease outbreak. The knowledge of participants following training was evaluated. More than 90 veterinarians participated in the exercise organized in one of the counties visited.

► The report of the previous FVO mission concerning live animals included a recommendation (# 10) to keep the Commission Services informed about the outcome of the foot-and-mouth disease (FMD) real time exercise that was planned for 2009. In October 2009, the CCA sent the FVO a copy of the report of an FMD seminar and simulation exercise, which took place during September. The CCA considered the exercise a useful test of the revised organizational arrangements for dealing with disease outbreaks and that it helped them to sort out communication and responsibilities issues between central and regional levels. Although the NRL did not participate in this exercise, the CCA expressed the intention to involve it in a future exercise planned for later in 2010.

## Conclusion

The CAs are generally well-prepared to deal with possible CSF outbreaks. Although progress has been made to address previous FVO recommendations, corrective measures in respect of the national ASF contingency plan and the humane slaughter of pigs have not been fully implemented.

## 6.5 SURVEILLANCE

### Legal Requirements

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

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

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

Commission Decisions 2008/897/EC and 2009/883/EC approved the Romanian CSF control and monitoring programmes for 2009 and 2010 respectively. These programmes include measures for disease surveillance in domestic pigs and wild boars.

### Findings

► The report of the previous FVO mission concerning live animals included a recommendation (# 11) to carry out the CSF surveillance as foreseen in the approved CMP. The extent to which this recommendation was addressed was evaluated during this SA:

#### 6.5.1 Commercial farms:

► The surveillance plan for commercial farms in 2009 included:

– Passive surveillance: CVs on each commercial farm were obliged to perform daily clinical and *post mortem* inspections on representative numbers of pigs. Additional clinical inspections were also to be performed by OVVs during routine monthly official controls that assessed compliance with relevant record keeping and biosecurity requirements.

– Active surveillance: Laboratory tests (PCR and IF assays) to detect the presence of field virus antigens were to be performed on representative numbers of blood and organ samples collected from each commercial farm twice annually. In addition, serological tests (ELISA) were to be performed on breeding pigs (four times per year; sufficient samples to detect the presence of CSF with 95% confidence, assuming a prevalence of 5%) and fattening pigs (twice per year; sufficient samples to detect the presence of CSF with 95% confidence, assuming a prevalence of 10%)

► Records of the daily clinical inspections by CVs and of the monthly official controls

by OVVs were available on both commercial farms visited.

► Mortality records and the results of necropsies were maintained on both farms visited. However, on one of the farms the mortality figures for farrowing houses were not kept after each batch of piglets had been transferred to the weaner accommodation. Chronically sick and recumbent pigs on this farm were kept in a separate shed. The pigs in this shed that were examined by the FVO audit team in poor condition and there were sufficient animal health and animal welfare reasons for destroying them humanely. However, both the CV and OV defended the practice of keeping them alive. Insufficient records were kept of the clinical and necropsy inspections performed on these pigs.

► The following table summarizes the national targets and outputs for active surveillance achieved on commercial farms during 2009:

Test method	Target (n)	Samples submitted (n)
IF assay	27 400	8 818
PCR	4 000	12 510
ELISA	31 372	28 371

This laboratory analysis detected no evidence of virus circulation.

► Significant inter-regional variation was noted in the extent to which surveillance targets were achieved during 2009. In many regions, adequate numbers of samples were collected. However, in others, including three regions visited, significant shortfalls were reported, with less than 10% of the antigen detection targets and 25% of the serological testing targets being achieved. For example, an analysis of the surveillance records in one of the regions visited showed that:

- not all of the commercial farms were surveyed (samples were collected from 10 of the 13 farms on which pigs were kept);
- the frequency of testing foreseen in the CMP was not respected (there was a breeding farm on which samples were collected twice rather than four times and six fatter farms on which samples were collected once rather than twice);
- the number of samples collected was insufficient (a single organ sample rather than samples from 10 animals was submitted on one occasion from one of the farms visited).

► The frequency and range of samples collected during 2010 in the regions visited by the FVO audit team was in accordance with the requirements established in the CMP for 2009.

### 6.5.2 Backyard holdings

► The surveillance plan for backyard holdings in 2009 included:

- Passive surveillance: AVs were to perform clinical inspections on all pigs kept on backyard holdings twice, during CSF vaccination campaigns. OVVs also visited a selection of these holdings to collect samples from vaccinated pigs (see Section 6.6). In addition, pigs from backyard holdings were inspected regularly by AVs for other purposes, such as during the collection of samples for trichinosis testing from home-slaughtered animals.

– Active surveillance: Samples were to be submitted for laboratory testing (IF and IP assays, PCR) from all live and dead pigs showing clinical or *post mortem* signs of CSF.

▶ The FVO audit team visited the offices of an AV and noted that records of vaccination visits were well maintained and indicated that passive surveillance targets in that district had been met.

▶ The following table summarizes the national targets and outputs for active surveillance achieved on backyard holdings during 2009:

Test method	Target (n)	Samples submitted (n)
IF assay	18 900	876
PCR	6 400	186

This laboratory analysis detected no evidence of virus circulation.

▶ In seven of the 42 regions, no samples were collected for surveillance purposes from backyard holdings.

▶ As indicated in Section 5.2 above, procedures for recording and monitoring surveillance activities during 2010 have not yet been established. The CCA had not received any reports on the number of such inspections that had been carried out prior to the SA.

### 6.5.3 *Wild boar*

▶ The surveillance plan for wild boars in 2009 included the collection of organ and blood samples from all shot and 'found dead' animals. These samples were to be tested for the presence of viral antigen (using PCR and IF assay) and antibodies (using ELISA and VNT). At least 59 samples were to be collected from each hunting area. Representative numbers of samples were to be collected from each age group, with a higher proportion of samples coming from young pigs (i.e. less than 1 year old). The estimated wild boar population during 2009 was approximately 50,000 animals.

▶ The following table summarizes the national targets and outputs for active surveillance achieved for wild boars during 2009:

Test method	Target (n)	Samples submitted (n)
PCR and IF assay	18 093	11 806
ELISA and VNT	18 093	10 686

This laboratory analysis detected no evidence of virus antigen. A small number of seropositive wild boars were detected in regions that had not completed emergency vaccination campaigns during 2009. Investigations conducted in these cases revealed that the animals had most likely been vaccinated in previous years.

▶ Records were available in both hunting funds visited indicating that samples were collected from wild boar shot throughout 2009 and were generally submitted to the

laboratory within a couple of days. These were accompanied by details of the time and place of hunting, the gender and age estimate of the animal, the name of the hunter and a description of the animal's clinical condition. In one hunting area visited the zonal veterinarian signed the submission forms but the name of the veterinarian who took the samples from the wild boar was not recorded.

## **Conclusion**

As in previous years, the CAs did not achieve the surveillance targets established in the approved CSF CMP during 2009, particularly in the case of surveys to detect viral antigens in domestic pigs. Nevertheless, the analysis that was performed revealed no evidence of the disease and the risk that CSF virus is circulating undetected in domestic pigs or in wild boars is low.

## **6.6 VACCINATION**

### **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.

Commission Decision 2008/897/EC approved the Romanian CSF CMP for 2009, which included emergency vaccination measures for domestic pigs and wild boars. Commission Decision 2009/883/EC approved the Romanian CSF CMP for 2010, which included emergency vaccination measures for wild boars.

### **Findings**

► The report of the previous FVO mission concerning live animals included a recommendation (# 12) to take action in order to achieve the targets set for emergency vaccination against CSF, in particular for wild boars. The extent to which this recommendation was addressed was evaluated during this SA:

#### *6.6.1 Backyard farms*

► The plan for 2009 was to vaccinate all pigs over seven weeks of age twice (in Spring and Autumn), with monthly follow up vaccinations being carried out on pigs that had been omitted from the main campaigns. Estimating the backyard pig population to be 4.8 million pigs for the purposes of the plan, the CAs calculated that 5.5 million doses would be used during the Spring campaign and 6.0 million doses in Autumn. Post vaccination testing by OV's was planned in order to verify that vaccination was effective. Samples were to be collected 28 days post vaccination from 15 vaccinated pigs selected at random in each village or commune. The CCA estimated that 86 000 samples would be collected.

According to information provided by the CAs, 6.1 million doses of vaccine had been used by the end of November 2009. 94 802 post vaccination tests were analyzed and indicated that 96% of the animals had seroconverted. Records available in the regions visited demonstrated that the collection of samples from vaccinated animals was performed as planned.

### 6.6.2 *Wild boar*

► The plan was to vaccinate in all hunting areas during three separate campaigns (in Spring, Summer and Autumn). Each campaign would consist of initial and booster vaccination phases. In calculating the number of doses to use, the CAs planned to distribute two doses for each of the approximately 55 000 wild boars in the country during each phase. In total, 660 000 vaccine baits would be distributed. The efficacy of vaccination would be determined by performing serological tests on blood samples collected from shot wild boars. The CAs estimated that 18 093 samples would be analyzed.

According to information provided by the CAs, slightly more than 300 000 baits had been distributed by the end of November 2009. They explained that they had experienced difficulties in obtaining the required stocks of vaccine in many regions but that some vaccination was carried out in 35 of the 42 counties. Serological tests performed on 10 686 shot wild boar revealed highly variable seroconversion rates (10-90%) between different hunting areas. The CAs accept that these differences may be related to poor vaccinator performance in some areas.

► The CSF CMP for 2010 defined a 20km band stretching along the borders with Moldova and Ukraine in which the risk of possible introduction of CSF in wild boar was considered to be high. Vaccination of wild boar was scheduled to be carried out in this area during two campaigns in 2010. Sufficient doses of vaccine to complete this exercise had been procured in five of the eight counties affected. One other county had adequate stocks of vaccine for the completion of the Spring campaign. The other three counties were in the process of tendering for the vaccine.

### 6.6.3 *Control on vaccines*

► Each batch of CSF vaccine used in the official vaccination campaigns must undergo tests for sterility, innocuity and efficacy, which is assessed by determining the concentration of virus in the vaccine. These tests are performed by the manufacturer. Each year, the Institute for Control of Biological Products and Medicines for Veterinary Use is required to perform its own tests to verify the safety and efficacy of the vaccine on two batches of each vaccine marketed. The FVO audit team noted that the results of the official tests performed on one batch of vaccine detected non-conformities in respect of the sterility and viral concentration of one of the batches tested. The CAs had informed the manufacturer and a formal order seizing the affected batch was issued.

### **Conclusion**

The CAs did not achieve the vaccination targets in the approved CMP for 2009 and vaccination in wild boars was not performed consistently.

## 6.7 ANIMAL HEALTH CONTROLS ON THE PRODUCTION OF MEAT AND MEAT PRODUCTS

### **Legal Requirements**

Article 7 of Commission Decision 2008/855/EC permits the dispatch of meat products that have been processed in compliance with Article 4(1) of Council Directive 2002/99, which establishes conditions for the placing on the market of animal products coming from

territories subject to animal health restrictions. In this case they include:

- separation between eligible and ineligible raw materials and products;
- clear identification of products at all times;
- inclusion of processes (heat treatment or fermentation and maturation) to eliminate CSF virus that may be present.

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

Article 8a of Commission Decision 2008/855/EC permits the dispatch to other MSs of fresh meat, meat preparations and meat products that have not undergone processes intended to eliminate CSF virus provided that:

- the meat is derived from pigs coming from holdings in other MSs;
- the establishments in which the meat is processed are approved for the purposes of this trade;
- production, storage and processing is carried out separately from other products containing ineligible meat.

Article 10 of Commission Decision 2008/855/EC requires fresh meat, meat preparations and meat products produced from meat derived from pigs coming from holdings outside Romania to be accompanied by the appropriate intra-Community health certificate as laid down in Commission Regulation (EC) No 599/2004.

## **Findings**

► Conditions for the approval, operation and official supervision of meat processing establishments, including slaughterhouses and cutting plants, were set out in ANSVSA Service Note 8487 of 04.12.2009. These included requirements for the registration and traceability of incoming and outgoing raw materials and products; a prohibition on the receipt of fresh meat from intermediary stores; permanent supervision by specially trained OVs; monthly audits by regional CAs. This Service Note covered the requirements set out in Articles 7 and 8a of Commission Decision 2008/855/EC but did not include instructions on the certification of meat dispatched within the Lohn system, which is required by Article 10 of the Decision.

### *6.7.1 Meat products produced from domestically produced meat (Article 7 of Commission Decision 2008/855/EC)*

► Following the previous FVO mission on meat, the CCA carried out checks in a number of meat processing establishments and detected instances where meat products containing pork were dispatched without health certificates or where these products bore the oval health mark although it could not be demonstrated that they had undergone the necessary heat treatment. ANSVSA Service Note 7931 of 07.08.2009 instructed all OVs responsible for processing and storage establishments to check these points and to report to the NVSFSa by mid September 2009.

- ▶ Records were available in the establishments visited to demonstrate that meat products had been heat-treated in accordance with the animal health requirements established in 2002L0099.

- ▶ Certificates were issued on TRACES for each consignment of meat products dispatched to other MSs. However, in one case there was a delay of more than two weeks between the date of dispatch and the date when the certificate was signed.

#### 6.7.2 *Lohn system (Article 8a of Commission Decision 2008/855/EC)*

- ▶ 21 meat processing establishments applied for official approval to operate the Lohn system. At the time of the FVO audit, three establishments had been approved and all were visited by the FVO audit team. One of the three establishments had already consigned fresh meat to other MS, while the others were prepared to do so.

- ▶ All three establishments handled meat originating in other MSs exclusively and had no plans to develop channeling procedures that would allow them to process meat of Romanian origin as well. The traceability systems in place could demonstrate that all meat handled in these establishments came directly from other MSs.

- ▶ The official staff responsible for the supervision of these establishments were familiar with the approval conditions and had participated in training organized by the regional CAs.

- ▶ The CCA explained that the monthly audits by the regional CAs would be conducted by regional Hygiene Departments (to cover FBO obligations) and Inspection and Control Services (to assess OV performance).

### **Conclusion**

Systems for the control of ICT in pig meat, meat preparations and meat products are generally reliable. However, official instructions do not require health certification of products dispatched in accordance with the provisions of Article 8a of Commission Decision 2008/855/EC.

## **7 OVERALL CONCLUSION**

The CAs are well-organised and systems to verify the effectiveness of official controls are operational. Systems in place for the detection and control of CSF and for the dispatch of products containing pork meat to other MSs are generally functional and no clinical disease outbreaks have been recorded in recent years. However, the capacity of the CAs to implement new animal health policies is limited, which is a particular concern in light of the fundamental changes to the CSF control and surveillance systems being introduced this year.

## **8 CLOSING MEETING**

A closing meeting was held on 26 March with representatives of the CCA. At this meeting, the FVO audit team presented the main findings and preliminary conclusions of the mission. The authorities did not express disagreement with the FVO audit team's preliminary conclusions and clarified some of the observations made by the team. The CCA also provided additional information, which has

been included in this report.

## 9 RECOMMENDATIONS

The CAs 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 SA report.

N°.	Recommendation
1.	To urgently put in place operational instructions and other arrangements for the implementation of the surveillance plans outlined in the control and monitoring programme approved for 2010, as required by Article 19(1)(b) of Commission Decision 2009/883/EC.
2.	To complete the actions undertaken in response to recommendations made in the report of FVO mission DG(SANCO)/2009-8250 concerning the prevention of possible conflicts of interest, the national contingency plan for African swine fever and the humane slaughter of pigs, as required by Article 45(5)(a) of Regulation (EC) No 882/2004.
3.	To ensure that the computer database for pigs is made operational and contains data on each separate movement of pigs, as required by Article 18 of Council Directive 64/432/EEC.
4.	To establish documented procedures in order to verify that keepers of backyard holdings comply with the requirements of Article 22 of Regulation (EC) No 1774/2002 and Article 11 of Commission Decision 2008/855/EC
5.	To take concerted action at all levels in order to meet the surveillance and vaccination targets established in the CSF control and monitoring programme approved by Commission Decision 2009/883/EC.
6.	To ensure that meat dispatched in accordance with Articles 7 and 8a of Commission Decision 2008/855/EC is accompanied by the appropriate health certificate and that the relevant information is entered promptly into the TRACES database.

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

[http://ec.europa.eu/food/fvo/ap/ap\\_ro\\_2010-8417.pdf](http://ec.europa.eu/food/fvo/ap/ap_ro_2010-8417.pdf)

## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 1774/2002	OJ L 273, 10.10.2002, p. 1-95	Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption
Reg. 599/2004	OJ L 94, 31.3.2004, p. 44-56	Commission Regulation (EC) No 599/2004 of 30 March 2004 concerning the adoption of a harmonised model certificate and inspection report linked to intra-Community trade in animals and products of animal origin
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Dir. 64/432/EEC	OJ 121, 29.7.1964, p. 1977-2012	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine
Dir. 93/119/EC	OJ L 340, 31.12.1993, p. 21-34	Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing
Dir. 2001/89/EC	OJ L 316, 1.12.2001, p. 5-35	Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever
Dir. 2002/60/EC	OJ L 192, 20.7.2002, p. 27-46	Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever
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,	2000/678/EC: Commission Decision of 23 October 2000 laying down detailed rules for registration of

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
	p. 16-17	holdings in national databases for porcine animals as foreseen by Council Directive 64/432/EEC
Dec. 2002/106/EC	OJ L 39, 9.2.2002, p. 71-88	2002/106/EC: Commission Decision of 1 February 2002 approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever
Dec. 2008/855/EC	OJ L 302, 13.11.2008, p. 19-25	2008/855/EC: Commission Decision of 3 November 2008 concerning animal health control measures relating to classical swine fever in certain Member States
Dec. 2008/897/EC	OJ L 322, 2.12.2008, p. 39-49	2008/897/EC: Commission Decision of 28 November 2008 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2009 and following years
Dec. 2009/470/EC	OJ L 155, 18.6.2009, p. 30-45	2009/470/EC: Council Decision of 25 May 2009 on expenditure in the veterinary field (Codified version)
Dec. 2009/883/EC	OJ L 317, 3.12.2009, p. 36-45	2009/883/EC: Commission Decision of 26 November 2009 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2010 and following years