



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

DG(SANCO) 2012-6585 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ROMANIA

FROM 17 TO 21 SEPTEMBER 2012

IN ORDER TO EVALUATE ANIMAL HEALTH CONTROLS ON CLASSICAL SWINE FEVER  
IN THE CONTEXT OF THE APPROVED CHANNELLED SYSTEM FOR THE PRODUCTION  
OF PIG MEAT TO BE PLACED ON THE EUROPEAN UNION MARKET

## ***Executive Summary***

*This report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Romania from 17 to 21 September 2012.*

*The objectives of the audit were:*

- to assess the implementation and effectiveness of the channelled system for pork production in Romania (hereafter, CS), that aims to ensure the safety in respect of classical swine fever (CSF) of fresh meat and meat preparations and meat products consisting of or containing such fresh meat that are produced from pigs kept in Romania and dispatched to other Member States (MS), as set out in article 8(c) of Commission Decision 2008/855/EC, and*
- to assess in the context of the CS the implementation of the programme for the control and monitoring of CSF in Romania approved for the period from 1 January to 31 December 2012 by Commission Implementing Decision 2011/807/EU.*

*The scope of the audit included verification of the effectiveness of measures put in place by the Romanian competent authority (CA) to address the recommendations of the previous FVO audit on the same subject carried out in July 2011.*

*Overall, the Romanian CA has addressed effectively most of the deficiencies identified during the audit carried out in 2011 and official controls on the CS and operation of the CSF surveillance plan in the Counties involved therein are implemented largely in an effective manner.*

*Additional efforts are still needed to reinforce the functioning and reliability of some outstanding areas, in particular as regards the certification chain for intra-Union trade; nevertheless, these weaknesses do not increase the risk of transmission of CSF to other MS, as:*

- data from the implemented surveillance plan show that it is highly unlikely that the CSF virus has circulated in this part of Romania for at least the last 12 months;*
- if the CSF virus re-infected the pig population in that area, the surveillance system in place should detect it quickly, before the disease gets widespread in back-yard holdings or the wild boar population;*
- even if a re-infection of the pig population outside the CS would occur, it is very improbable that the CSF virus could enter the holdings operating within the CS due to the high level of bio-security they consistently ensure, and*
- if necessary in the event of an outbreak of CSF, arrangements made by the slaughterhouse currently operating within the CS and placing fresh pig meat on the EU market, would ensure the immediate and effective back and forward traceability of all possibly infected products within a very short deadline.*

*The report makes a number of recommendations to the Romanian CA aimed at 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</u></b> .....	<b>1</b>
<b>3</b>	<b><u>LEGAL BASIS</u></b> .....	<b>2</b>
<b>4</b>	<b><u>BACKGROUND</u></b> .....	<b>2</b>
<b>5</b>	<b><u>FINDINGS AND CONCLUSIONS</u></b> .....	<b>3</b>
5.1	<b><u>OFFICIAL CONTROLS ON THE CHANNELLED SYSTEM</u></b> .....	<b>3</b>
5.1.1	<i><u>LEGAL REQUIREMENTS</u></i> .....	<b>3</b>
5.1.2	<i><u>FINDINGS</u></i> .....	<b>4</b>
5.1.3	<i><u>CONCLUSIONS</u></i> .....	<b>5</b>
5.2	<b><u>CSF SURVEILLANCE PLAN</u></b> .....	<b>5</b>
5.2.1	<i><u>LEGAL REQUIREMENTS</u></i> .....	<b>5</b>
5.2.2	<i><u>FINDINGS</u></i> .....	<b>6</b>
5.2.3	<i><u>CONCLUSIONS</u></i> .....	<b>8</b>
5.3	<b><u>HEALTH MARKING AND CERTIFICATION FOR INTRA-UNION TRADE</u></b> .....	<b>8</b>
5.3.1	<i><u>LEGAL REQUIREMENTS</u></i> .....	<b>8</b>
5.3.2	<i><u>FINDINGS</u></i> .....	<b>9</b>
5.3.3	<i><u>CONCLUSIONS</u></i> .....	<b>10</b>
<b>6</b>	<b><u>OVERALL CONCLUSIONS</u></b> .....	<b>11</b>
<b>7</b>	<b><u>CLOSING MEETING</u></b> .....	<b>11</b>
<b>8</b>	<b><u>RECOMMENDATIONS</u></b> .....	<b>12</b>
	<b><u>ANNEX 1 - LEGAL REFERENCES</u></b> .....	<b>13</b>

**ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT**

<b>Abbreviation</b>	<b>Explanation</b>
CA	Competent authority
CCA	Central competent authority
CS	Channelled system for pork production in Romania
CSF	Classical swine fever
CV	Concessionary veterinarian
ELISA	Enzyme Linked Immuno-Sorbent Assay
EU	European Union
FVO	Food and Veterinary Office
MS	Member States (of the EU)
NRL	National reference laboratory
NSVFSA	National Sanitary Veterinary and Food Safety Authority
OV	Official veterinarian
RT-PCR	Reverse Transcriptase-Polymerase Chain Reaction
SVFSD	Sanitary Veterinary and Food Safety Directorate (County level)

## 1 INTRODUCTION

This audit took place in Romania from 17 to 21 September 2012. The audit was undertaken as part of the planned audit programme of the FVO.

The audit team comprised two auditors from the FVO. The team was accompanied during the whole audit by representatives of the National Sanitary Veterinary and Food Safety Authority (NSVFSA), which is the central competent authority (CCA) within the scope of this audit, and by representatives of the relevant Sanitary Veterinary and Food Safety Directorates (SVFSD) in the Counties visited.

An opening meeting was held on 17 September 2012, with the CCA. At this meeting, the audit objectives and itinerary were confirmed, and additional information required for the satisfactory completion of the audit was requested.

## 2 OBJECTIVES

The objectives of the audit were:

- to assess the implementation and effectiveness of the CS, that aims to ensure the safety in respect of CSF of fresh pig meat and meat preparations and meat products consisting of or containing such fresh meat that are dispatched to other MS, as set out in article 8(c) of Commission Decision 2008/855/EC, and
- to assess in the context of the CS the implementation of the programme for the control and monitoring of CSF in Romania approved for the period from 1 January 2012 to 31 December 2012 by Commission Implementing Decision 2011/807/EU.

The scope of the audit included verification of the effectiveness of measures put in place by the CAs to address the recommendations of a previous FVO audit on the same subject carried out in July 2011 (ref. DG(SANCO) 2011-6046 – MR Final; hereafter, previous FVO report). The report of that audit is available at the FVO Web site:

[http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_id=2770](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2770)

The main topics covered by the scope of the audit were confined to:

- the assessment of the elements of the CS to be implemented by the CAs in accordance with article 8(c) of Decision 2008/855/EC, in particular:
  - approval of holdings or one or more epidemiological units operating a common bio-security management system, in particular in respect of the approval of bio-security plans by the CAs;
  - approval of establishments which are producing, storing and processing fresh pig meat and meat preparations and meat products consisting of or containing such meat;
  - measures in place to ensure application of the required surveillance, control and bio-security measures on approved holdings, including implementation of regular inspections and sampling by the CAs;
  - surveillance on the perimeter of holdings approved in the CS in an area of at least 10 km radius in which animals in the pig holdings have been subjected to laboratory testing for CSF;
  - the production, storage and processing of meat and meat preparations and meat products consisting of or containing such meat to ensure that these operations are carried out separately from those on other products consisting of or containing meat

derived from pigs from holdings outside the CS located in the areas listed in Part III of the Annex to Decision 2008/855/EC;

- the health marking of fresh meat, meat preparations and meat products consisting of or containing such meat to be placed on the EU market, in accordance with provisions laid down in Regulations (EC) No 854/2004 and No 853/2004 of the European Parliament and of the Council, as appropriate.
- the assessment of the programme for the control and monitoring of CSF in the Counties of Romania where, at the time of the audit, there are holdings or one or more epidemiological units operating a common bio-security management system that are involved in the CS, in particular as regards:
  - implementation of CSF surveillance in commercial pig farms, backyard holdings and the population of wild boars;
  - laboratory diagnosis of CSF, and
  - epidemiological evidence to demonstrate that the CSF virus has not circulated in the pig population of the relevant Counties in the last 12 months.

In pursuit of the audit objectives, the following sites were visited and meetings held:

Meetings/visits		Comments
Competent authorities	4	Opening and closing meetings with the CCA. Additional meetings with the SVFSD in Counties Timis and Arad. Meetings with official veterinarians at local level in both Counties
Farms	3	Two farms authorised within the CS (one breeding farm and one fattening farm) and one backyard holding
Food business operators	1	One slaughterhouse authorised within the CS
Laboratories	2	County laboratories in Timis and Arad

### 3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation and, in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Full legal references are provided in the Annex to this report. Legal acts quoted in this report refer, where applicable, to the last amended version. EU legislation can be found following the link:

<http://eur-lex.europa.eu/en/index.htm>

### 4 BACKGROUND

Further to the detailed description of the situation in Romania provided in the previous FVO report:

- Romania is not recognised as free from CSF and is currently listed in Part III of the Annex to Decision 2008/855/EC. Nevertheless, Commission Decision 2012/40/EU amended the said Decision by introducing article 8(c) laying down provisions permitting the dispatch to other MS of fresh pig meat and meat preparations and meat products consisting of or containing such meat from pigs kept in Romania, provided that a CS proposed by the

Romanian CAs is in place.

- In order to address the recommendations of the previous FVO report, the Romanian CAs submitted before the end of 2011 a new version of the “Position Paper”, laying down updated animal and public health criteria for the operation of the CS. This was considered adequate by the Commission services in order to ensure the effective functioning of the CS.
- The CS has been in operation during 2012 and Romania has dispatched pig meat to a number of MS and exports have also taken place to some third countries:
  - there are 49 holdings that have been approved to supply pigs within the CS. They include breeding and fattening farms, which are situated in Counties Timis (34), Arad (13), Bihor (1) and Caras-Severin (1);
  - since the CS began to operate, there is only one establishment that has been approved to place fresh pig meat, meat preparations or meat products on the EU market. This establishment has been producing and dispatching fresh meat from pigs exclusively reared in holdings authorised within the CS;
  - at the time of this audit, there was no establishment approved within the CS involved in production or storing of meat preparations or meat products consisting of or containing such fresh meat.
- There has been no recorded case of CSF in Romania since 2007. The programme for the control and monitoring of CSF in Romania was approved for the period from 1 January to 31 December 2012 by Decision 2011/807/EU. Effective implementation of this programme in the four Counties involved in the CS is considered a pre-requisite for the maintenance of the CS in operation so as to ensure that there is no evidence of circulation of the CSF virus in domestic and wild pig populations in this area.

## **5 FINDINGS AND CONCLUSIONS**

### **5.1 OFFICIAL CONTROLS ON THE CHANNELLED SYSTEM**

#### *5.1.1 Legal requirements*

Article 8(c)(1) of Decision 2008/855 lays down provisions governing the dispatch to other MS of fresh pig meat and meat preparations and meat products consisting of or containing such meat from the areas listed in Part III of the Annex to the said Decision. Those provisions include conditions related to:

1. the holdings of origin for the pigs whose fresh meat is used within the CS, including:
  - their approval by the CAs;
  - the bio-security conditions therein;
  - rules concerning introduction of pigs from other holdings, and
  - the inspection regime, including the frequency of inspections, to be put in place by the CAs to verify their operation.
2. the slaughterhouses, cutting plants and meat processing establishments, where the fresh pig meat and meat preparations and meat products consisting of or containing such meat are produced, including:
  - their approval by the CAs, and
  - assurances to be provided by the establishments concerning separation of products

within the CS from other products consisting of or containing fresh meat and meat preparations and meat products consisting of or containing meat derived from pigs originating in or coming from holdings other than those approved in the CS.

### 5.1.2 Findings

The recommendations of the previous FVO report stressed the importance of:

- as envisaged in the Position Paper, to carry out audits of CS establishments on a regular basis and to ensure that these are performed effectively;
- to ensure that control tasks performed by private veterinarians in CS holdings (passive surveillance and additional sampling for the CS) are subject to effective official supervision and verification;
- to ensure that measures are in place to counter any possible conflict of interest on the part of the Concessionary Veterinarians (CVs - private veterinarians approved for the performance of some official tasks) and thereby reinforce official controls in backyard holdings, and
- to keep implementing systematic auditing of the activities of the SVFSDs in order to identify and rectify any deficiencies found in the effectiveness of official controls.

The CAs had undertaken to address all the above mentioned issues in the action plan submitted in response to the recommendations. The audit team found in this respect that:

- As indicated in the previous FVO report, the holdings approved in the CS must set up and apply adequate bio-security measures to ensure effective prevention of contamination with the CSF virus. As had been the case during the previous FVO audit, at the holdings visited during this audit, largely well designed bio-security plans were in place and they were functioning in accordance with protocols described therein. In addition, the CAs have made significant efforts to improve implementation of regular inspections of those holdings aimed at verifying compliance with approval conditions, in particular concerning bio-security measures and provisions on introduction of pigs from other farms. This was found to be done according to plans on a monthly basis and in a satisfactory manner.
- During the above mentioned inspections, official veterinarians (OVs) of the SVFSDs evaluate the activities of the private veterinarians responsible for CS holdings. In the holdings visited, the audit team found that the latter carry out regular health checks on both live animals, including sick pigs and aborted sows, and dead ones. In general, records were available on all those events and both private veterinarians and OVs had a good overview of the health status of every batch of pigs. The only area where OVs were not seen to play a major role in respect of supervision was in relation to certification of pigs sent to slaughterhouses, which causes some minor problems (see 5.3.2).
- Official controls on the only slaughterhouse that operates within the CS were also done in a satisfactory manner. The establishment operates to very high and reliable standards; back and forward traceability arrangements are excellent and demonstrably effective to ensure immediate retrieval of all necessary information on each batch of pigs and of the details of the farm where they were reared.
- As explained in the previous FVO report, sampling in backyard holdings has been delegated to CVs who are responsible for the commune/village where they are situated as this is considered the main epidemiological unit for the CSF surveillance plan in this population (see 5.2.2). In order to address the concerns raised in the previous FVO report as regards the possible conflict of interest involved in this official task, the NSVFSA took the decision that this sampling was going to be carried out by the CVs accompanied by an OV from the

SVFSD. The audit team could verify several examples in that respect and confirm that this is now the practice for the CSF sampling programme.

- The internal audit team of the NSVFSA has continued with the implementation of the national audit programme covering the implementation of the CSF surveillance plan by the Counties involved in the CS. In addition, local auditors at the SVFSDs are responsible for the regular follow-up of the national audits and for updating the central audit Unit on the progress with implementation of the action plans submitted by the SVFSDs. In general, evidence was available of the progress made with implementation of the action plans submitted by those Counties, in particular in relation to improvements in the registration of backyard holdings and the identification of pigs kept therein, the increase in the numbers of staff available for the performance of official controls, in particular as regards inspections on backyard holdings, and implementation of the CSF surveillance plan.

### *5.1.3 Conclusions*

The CCA has made significant efforts to effectively address the recommendations of the previous FVO report and, as a result, is in a position to largely ensure that provisions laid down Article 8(c) (1) of Decision 2008/855 governing the dispatch to other MS of fresh pig meat from Romania are complied with, in particular as regards:

- approval of and official controls on the holdings of origin for the pigs whose fresh meat is used within the CS, and
- approval of and regular operation of official controls on the slaughterhouse and the cutting plant where that fresh pig meat is produced.

## **5.2 CSF SURVEILLANCE PLAN**

### *5.2.1 Legal requirements*

Article 8(c)(1) of Decision 2008/855 lays down provisions governing the dispatch to other MS of fresh pig meat and meat preparations and meat products consisting of or containing such meat from the areas listed in Part III of the Annex to the said Decision. Those provisions include conditions related to the surveillance plan designed and implemented by the CAs on the CS holdings in order to ensure that:

- animals from these holdings have been subjected to laboratory testing for CSF carried out with negative results for a period of at least 6 months prior to movement to the slaughterhouse, and
- these holdings are located in the centre of an area of at least 10 km radius in which animals in the pig holdings have been subjected to laboratory testing for CSF carried out with negative results for at least the last 3 months prior to movement to the slaughterhouse.
- those holdings are located in a County in which:
  - a programme for the control and monitoring of CSF approved by the Commission is implemented;
  - the incidence and prevalence of CSF in domestic and feral pigs has significantly decreased, and
  - no evidence of CSF virus circulation in pigs has been detected in the last 12 months.

Decision 2011/807/EU approves the programme for the control and monitoring of CSF in Romania for the period from 1 January to 31 December 2012.

### 5.2.2 Findings

The recommendations of the previous FVO report stressed the importance of:

- redesigning the programme for the control and monitoring of CSF in Romania so that its implementation could unequivocally demonstrate the CSF free health status of the domestic and wild pig populations in Romania;
- ensuring that this programme was fully implemented, in particular in relation to the sampling strategies designed for the wild boar population and in backyard holdings, and
- ensuring that official tasks are performed by officials, in particular the collection of samples for serological surveillance for CSF.

The CAs had undertaken to address all the above mentioned issues in the action plan submitted in response to the recommendations. The audit team found in this respect that:

- There has been a major improvement in respect of implementation of holding registration and identification of pigs in backyard holdings, as well as with the gradual development of a highly operational database that facilitates planning of animal health controls on the pig population.
- The NSVFSA took action to ensure that the number of samples to be taken for each population, as described in the previous FVO report, has been calculated so that the surveillance system could detect an animal-level prevalence of 5 or 10% with a 95% level of confidence in each epidemiological unit considered, whether the holdings approved in the CS or villages and backyard holdings included in their 3 and 10 km surrounding areas. Evaluation of the sampling plans designed showed that the number of samples planned is adequate to support this level of assurance for each type of epidemiological unit considered, as described in the programme for the control and monitoring of CSF in Romania for the period from 1 January to 31 December 2012 approved by Decision 2011/807/EU.
- Data on the implementation of the sampling plan by the four SVFSDs involved in the CS show that:
  - In general, in the context of the CSF passive surveillance, there has been limited official testing of dead or sick pigs, including aborted sows, from holdings approved in the CS and from backyard holdings. Nonetheless, concerning the former, at the initiative of the holdings themselves, the private veterinarians responsible for their health management take samples regularly from sick and dead animals, in particular from aborted sows. These samples are tested according to official protocols in line with EU requirements by the national reference laboratory for CSF (NRL). According to representatives of the CCA, the very small average size of backyard holdings and the special care provided to the animals by their owners, reduce considerably the number of animals that die or present any clinical symptom resembling CSF. In any case, variation in this respect was observed between areas in the same Counties which, according to representatives of the SVFSDs, may be due to the varied levels of awareness amongst farmers and to different approaches amongst CVs when it comes to sample these animals. The CCA undertook to review this area so that a higher sensitivity can be ensured for this component of the surveillance system.
  - Concerning serological sampling plans in the holdings approved in the CS:
    - Biannual sampling of fattening pigs had been implemented by OVs mostly as planned; however, in one of the Counties there had been a delay in

implementation of the first sampling regime in March/April 2012 as, according to representatives of the relevant SVFSD, there had been delays with the financial allocations needed for the implementation of the plan in the field. That sampling was carried out later on in May (see 5.3.2).

- Virological testing of batches of pigs before their dispatch to the slaughterhouse was regularly implemented as planned. Samples are tested with a reverse-transcriptase-polymerase chain reaction test (RT-PCR).
- However, one of the components of the surveillance in this sub-population, that covering sows and boars sent to the slaughterhouse from breeding farms, was seen to be implemented only partially, as examples were found of farms from which not all these animals had been sampled in the slaughterhouses, as planned, but only 50 to 70% of them. The explanation provided by the CCA was that since there is a significant number of animals coming from each farm monthly (between 250 and 500), there is no statistical reason to justify taking samples from all of them.
- Concerning serological sampling of backyard holdings in the 3 and 10 km areas surrounding approved CS holdings, the epidemiological design of the sampling plan assumes a homogeneous distribution of the risk of acquiring CSF amongst the backyard holding populations at village level (higher epidemiological unit), and also at animal level within each backyard holding. As a major step forward in comparison with the situation described in the previous FVO report, the NSVFSA has, according to that design, randomly allocated sampling regimes to each SVFSD for each and every village, including for each bi-annual or quarterly sampling period precise details of the backyard holdings to be sampled and the individual identification numbers of the pigs to be part of the survey. Implementation of this component of the CSF surveillance plan was found to be largely adequate and all data in that respect were available to the audit team for each and every back yard holding sampled and tested.
- Another component of the CSF surveillance plan targets sampling of tissues from pigs slaughtered for own consumption at the end of the year in backyard holdings. The samples are used for virological surveillance and tested with RT-PCR in order to verify that no CSF virus has been circulating in this population for the previous months. This sampling initiative has been adequately designed on the basis of the expected number of pigs to be slaughtered in each village; however, its implementation was not fulfilled as, according to representatives of all the CAs met, cooperation from the farmers is not yet fully ensured and notification to the OV's of the time when the pigs are slaughtered is not properly and timely done. The CCA undertook to make additional efforts to raise the awareness in the farming community of the importance of this surveillance component.
- In both Counties visited there has been an adequate planning of surveillance in the wild boar populations; this includes collection of a range of samples from hunted wild boars that are used for serological (ELISA) and virological testing (RT-PCR). The SVFSDs had co-operated with environmental authorities and hunting associations in order to get sufficient reliable data on the target population so that they could anticipate how many wild boars were going to be shot, and where (hunting grounds), so that the sampling could be organised and the OV's could be available for this activity. Data on implementation show that the surveillance goals have been accomplished in a satisfactory manner, as planned, and together with the

broad geographical distribution of the hunted wild boars tested, should be sufficient to have detected any evidence of virus circulation in this sub-population if it had occurred. The only minor gap in that respect is the fact that nearly no dead wild boar has been tested. According to representatives of the SVFSDs met, this is mainly due to the difficult topography of the areas where wild boars normally roam, which are difficult reach, and this makes it nearly impossible to find dead wild boars which are still in good enough condition to take samples from their carcasses with sufficient quality to be tested.

- The NRL maintains good supervision on the County diagnostic laboratories, including organisation of annual inter-laboratory comparison tests for serological and virological diagnosis of CSF. The County diagnostic laboratories visited have good quality management systems in place and can be considered capable of producing technically valid results in the context of CSF serological and virological surveillance.

### 5.2.3 *Conclusions*

The CCA has made significant efforts to effectively address the recommendations of the previous FVO report and, as a result, implementation of sampling strategies and testing in the context of the channelled system and as required by the programme for the control and monitoring of CSF have been, by and large, robust enough to provide assurances that it is very unlikely that the CSF virus has circulated during 2012 in the domestic and wild pig populations in Romania.

However, in order to further reinforce the sensitivity of the CSF surveillance system so that it can contribute to unequivocally demonstrate the CSF free status of the pig herd in Romania, additional measures should be taken to adequately fulfil implementation of all components of the approved programme for the control and monitoring of the disease as planned, in particular as regards:

- rendering CSF passive surveillance more effective throughout the country by further targeting official sampling and testing of sick and aborted animals in backyard holdings, and
- carrying out virological testing of animals slaughtered for own consumption in backyard holdings and serological monitoring of culled breeding animals sent to slaughterhouses.

Therefore, the CCA can largely ensure:

- that conditions related to the CSF surveillance plan required by Article 8(c)(1) of Decision 2008/855 in respect of the dispatch to other MS of fresh pig meat have been complied with, and
- conditional on addressing the weaknesses above mentioned, that the programme approved by Decision 2011/807/EU for the control and monitoring of CSF in Romania for the period from 1 January to 31 December 2012, can be implemented as planned in the Counties involved in the CS.

## **5.3 HEALTH MARKING AND CERTIFICATION FOR INTRA-UNION TRADE**

### 5.3.1 *Legal requirements*

Article 8(c)(2) of Decision 2008/855 lays down provisions governing the dispatch to other MS of fresh pig meat and meat preparations and meat products consisting of or containing such meat from the areas listed in Part III of the Annex to the said Decision. Those provisions require that:

- that fresh pig meat shall be marked as provided for in Chapter III of Section I of Annex I to Regulation (EC) No 854/2004, and

- the meat preparations and meat products consisting of or containing such fresh pig meat shall be marked as provided for in Section I of Annex II to Regulation (EC) No 853/2004.

Article 7(2)(c) of Decision 2008/855/EC requires that MS concerned with areas listed in Part III of the Annex may authorise the dispatch of fresh pig meat and meat products and preparations consisting of, or containing such meat, to other MS, if the products are accompanied by the appropriate intra-Union trade health certificate indicating that they have been produced in accordance with animal health control measures laid down in the said Decision.

Council Directive 96/93/EC lays down the standards to be observed in issuing the certificates required by veterinary legislation, including in particular rules and responsibilities for certifying officers.

### 5.3.2 Findings

During the visit to the establishment approved in the CS for the production of fresh pig meat to be placed on the EU market, the audit team found that:

- the fresh meat was marked as provided for in Chapter III of Section I of Annex I to Regulation (EC) No 854/2004, and
- the marking and labelling enabled the establishment and the OVs to quickly carry out any traceability exercise needed to identify the farm and batch of origin of the pigs, as well as their day and time of arrival at the slaughterhouse, and of their slaughter. They also made possible the identification of the day and time of cutting and packaging of the fresh meat ready to be dispatched to other MS.

The CA have set up a certification system in accordance with requirements of Decision 2008/855/EC; along the certification chain there are several people with responsibilities in relation to the attestations concerning the health status of the pigs and the fresh meat, and the operation of the holdings and establishments approved in the CS:

- The private veterinarians responsible for the animal health management of the holdings approved in the CS must sign the health certificate accompanying the pigs to the slaughterhouse. They must attest to the health status of the animals on the day of dispatch, on the basis of a clinical examination of the batch of animals to be delivered, and on the negative results of the RT-PCR testing of blood samples taken within a week before the delivery of that batch begins. These veterinarians are allegedly regularly updated by the SVFSD about the state of play of the implementation by the CAs of the CSF surveillance plan in the holding and in the 10 km surrounding area.
- The OV at the relevant SVFSD, who upon reception of the request for the delivery of the batch of pigs, must ensure that the holding is in compliance with all requirements laid down in the Position Paper and in Decision 2008/855/EC, before granting the authorisation for the delivery of the animals.
- The OVs at the slaughterhouse, who in addition to the *ante-* and *post-mortem* examinations, must sign the intra-Union certificate stating that the fresh meat has been produced in accordance with all requirements of Decision 2008/855/EC.

The audit team found that despite the availability of numerous and adequate sources of information that should allow for an effective communication between the various layers of the certification chain, there were some weaknesses that undermine the effective operation and reliability of this certification chain for intra-Union trade, in particular:

- there is no procedure for the OV certifying the fresh meat in the slaughterhouse, to get evidence of compliance with surveillance at the level of the CS holding and in the

surrounding area, as required by article 8(c)(1)(a)(v) and (vi) in Decision 2008/855/EC. According to representatives of the CCA, since CSF surveillance is so intensive and there are many layers of the CAs involved and active on that, they did not consider it necessary as this information is easily accessible to any OV; however:

- the health certificate issued at farm level by the private veterinarian does not include any attestation indicating that serological surveillance has taken place in the CS farm as planned by the CAs. The audit team found a couple of cases where farms had sent pigs to the slaughterhouse and no check was done to ensure that that surveillance had been carried out. Sampling that should have taken place in March/April 2012 had not been done and was delayed until May. No level of the CAs, including the SVFSD, noticed this as there is no formal arrangement to verify compliance with that requirement before the pigs are dispatched to the slaughterhouse;
- even if each CS farm must get at the beginning of each quarter confirmation that the planned surveillance has been implemented in the surrounding areas in backyard holdings, cases were found where that was missing both in relation to the serological surveys that are carried out quarterly and on fulfilment of the annual virological checks, normally done in December.
- in addition, examples were seen of situations where clinical examination of batches of around 7 000 pigs ready to be dispatched to the slaughterhouse had been done only on one day, when the delivery had been divided in five or six consignments sent for a period of a month since the date of the clinical check. All certificates indicated the date of the initial clinical examination even if the date of delivery was one month later.

Representatives of the CAs acknowledged the weaknesses mentioned above and, since they already had all the tools and sources of information to address them quickly, they undertook to immediately change the layout of the certificate accompanying the pigs to the slaughterhouse, and reorganise the communication between, and availability of information to all those involved in the certification chain, up to the OV in the slaughterhouse. Thus, they underlined that they will be in a better position to ensure that all information is available to the latter and it can be verified before issuing the final certificate for intra-Union trade.

### *5.3.3 Conclusions*

The CAs have introduced adequate measures to ensure compliance with provisions laid down in Article 8(c)(2) of Decision 2008/855 concerning marking of fresh pig meat to be dispatched to other MS from the areas listed in Part III of the Annex to the said Decision, as provided for in Chapter III of Section I of Annex I to Regulation (EC) No 854/2004.

The CAs have made largely adequate arrangements in line with provisions laid down in Article 7(2) (c) of Decision 2008/855/EC to ensure that consignments of fresh pig meat to be dispatched to other MS are accompanied by the appropriate intra-Union trade health certificate indicating that it has been produced in accordance with animal health control measures laid down in the said Decision. However, the functioning and reliability of the certification chain for intra-Union trade must be further reinforced to ensure that:

- appropriate, accurate and updated information is always available to certifying officers so that they can guarantee that the CSF surveillance plan has been implemented as appropriate in the holding of origin of pigs dispatched to the slaughterhouse and in the 10 km area surrounding them, as required by Article 8(c)(1)(v), (vi) and (vii) of Decision 2008/855/EC, and
- certifying officers can always ascertain the accuracy of all information needed for the

issuing of intra-Union certificates, in accordance with standards laid down in Directive 96/93/EC to be observed in issuing the certificates required by veterinary legislation.

## **6 OVERALL CONCLUSIONS**

The Romanian CA has addressed effectively most of the deficiencies identified during the audit carried out in 2011 and official controls on the CS and operation of the CSF surveillance plan in the Counties involved therein are implemented largely in an effective manner.

Additional efforts are still needed to reinforce the functioning and reliability of some outstanding areas, in particular as regards the certification chain for intra-Union trade; nevertheless, these weaknesses do not increase the risk of transmission of CSF to other MS, as:

- data from the implemented surveillance plan show that it is highly unlikely that the CSF virus has circulated in this part of Romania for at least the last 12 months;
- if the CSF virus re-infected the pig population in that area, the surveillance system in place should detect it quickly, before the disease gets widespread in back-yard holdings or the wild boar population;
- even if a re-infection of the pig population outside the CS would occur, it is very improbable that the CSF virus could enter the holdings operating within the CS due to the high level of bio-security they consistently ensure, and
- if necessary in the event of an outbreak of CSF, arrangements made by the slaughterhouse currently operating within the CS and placing fresh pig meat on the EU market, would ensure the immediate and effective back and forward traceability of all possibly infected products within a very short deadline.

## **7 CLOSING MEETING**

A closing meeting was held on 21 September 2012 with the Romanian CA. At this meeting, the main findings and preliminary conclusions of the audit were presented by the FVO team. The representatives of the CA did not express disagreement with the findings and conclusions presented, and they undertook to take immediate action to address the shortcomings identified by the audit team, in particular in relation to the chain of certification for intra-Union trade. They reiterated that their overall objective was to proceed with implementation of the current surveillance system so as to demonstrate that the pig herd in Romania is free from CSF, particularly in light of the absence of any case of CSF in the last five years.

## 8 RECOMMENDATIONS

The CAs are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), within 25 working days after receipt of the report, aimed at addressing the recommendations set out below:

N°.	Recommendation
1.	To ensure that additional measures are taken to adequately fulfil implementation of all components of the programme for the control and monitoring of CSF approved by Decision 2011/807/EU in the Counties involved in the CS, in particular as regards virological testing in the context of passive and active surveillance in backyard holdings.
2.	To ensure the effective functioning and reliability of the certification chain for intra-Union trade of fresh pig meat produced in the context of the CS, so that certifying officers can always ascertain the accuracy of all information needed for the issuing of intra-Union certificates in accordance with standards laid down in Directive 96/93/EC, in particular as regards implementation of the CSF surveillance plan in the holdings of origin of pigs dispatched to the slaughterhouse and in the area surrounding them, as required by Article 8(c)(1)(v), (vi) and (vii) of Decision 2008/855/EC.

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

[http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_inspection\\_ref=2012-6585](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6585)

## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
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. 2011/807/EU	OJ L 322, 6.12.2011, p. 11-22	2011/807/EU: Commission Implementing Decision of 30 November 2011 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2012 and following years
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products