



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6789 - MR FINAL

FINAL REPORT OF AN AUDIT  
CARRIED OUT IN  
ROMANIA  
FROM 10 TO 13 SEPTEMBER 2013  
IN ORDER TO EVALUATE THE IMPLEMENTATION OF THE CLASSICAL SWINE FEVER  
ERADICATION PROGRAMME

## ***Executive Summary***

*This report describes the outcome of an audit carried out by the Food and Veterinary Office (FVO) in Romania from 10 to 13 September 2013.*

*The objectives of the audit were:*

- to assess compliance with specific EU requirements for the control of classical swine fever (CSF) laid down in Council Directive 2001/89/EC;*
- to assess the level of preparation of the Romanian competent authorities (CAs) in order to ensure the effective implementation of control measures against CSF laid down in Article 6 of Commission Decision 2008/855/EC, in case the territory of Romania was listed in part II of the Annex to the said Decision, and*
- to assess implementation of the programmes for control and monitoring of CSF in Romania approved by the Commission for 2012 and 2013.*

*The scope of the audit included verification of the effectiveness of measures put in place by the Romanian CAs in the context of the objectives above mentioned.*

*According to data provided by the CAs, the cumulative results obtained during 2012 and so far in 2013 from the implemented CSF control and monitoring programmes indicate that it is highly unlikely that the CSF virus has circulated in the domestic and wild pig populations in Romania for at least the last 12 months. In relation to commercial pig holdings, the CAs can ensure that as a result of both their targeted control efforts, which have been found to be fit for purpose and largely effective, and the high levels of bio-security consistently applied in these holdings; the risks of infection with the CSF virus and, if that happened, of transmission of the disease from them, are negligible.*

*However, deficiencies in the implementation of the CSF control and monitoring programmes approved for 2012 and 2013 still undermine the effectiveness of the control system put in place by the CAs in order to fulfil the overall objectives of those programmes and, thereby, decrease the reliability of the epidemiological picture that can be drawn from results of that implementation.*

*The main deficiencies are:*

- The limited effectiveness of official controls on identification of animals and their movements in back-yard holdings and the absence of enforcement of legal requirements in that respect.*
- Information obtained from the epidemiological surveys designed for surveillance for CSF in back-yard holdings is not robust enough because of a number of design faults and implementation gaps.*
- The very limited passive surveillance in numerous counties with a fairly large pig population, which casts doubt on the effectiveness of the early warning system for CSF in those areas.*
- The lack of legal powers to ensure that surveillance for CSF is effectively carried out in all privately run wild boar hunting areas.*

*As a consequence, the measures to verify the CSF free status of the non-commercial domestic pig herd and the wild boar population in Romania could be improved.*

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

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**ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT**

<b>Abbreviation</b>	<b>Explanation</b>
CA	Competent authority
CCA	Central competent authority
CSF	Classical swine fever
CV	Concessionary veterinarian
ELISA	Enzyme Linked Immuno-Sorbent Assay
EU	European Union
FAT	Fluorescent antibody test
FVO	Food and Veterinary Office
MS	Member States (of the EU)
NRL	National reference laboratory
NSVFSA	National Sanitary Veterinary and Food Safety Authority
OIE	World Organization for Animal Health
OV	Official veterinarian
PCR	Polymerase chain reaction
SCoFCAH	Standing Committee on the Food Chain and Animal Health
SVFSD	Sanitary Veterinary and Food Safety Directorate (county level)

## 1 INTRODUCTION

This audit took place in Romania from 10 to 13 September 2013. 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 10 September 2013, 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 compliance with specific provisions concerning EU measures for the control of CSF laid down in Council Directive 2001/89/EC;
- to assess the level of preparation of the CAs in order to ensure the effective implementation of control measures against CSF laid down in Article 6 of Commission Decision 2008/855/EC, in case the territory of Romania was listed in part II of the Annex to the said Decision, and
- to assess implementation of the programmes for control and monitoring of CSF in Romania approved for the periods:
  - from 1 January to 31 December 2012 by Commission Implementing Decision 2011/807/EU, and
  - from 1 January to 31 December 2013, by Commission Implementing Decision 2012/761/EU.

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

- In relation to the assessment of compliance with EU measures for the control of CSF, the evaluation focused on:
  - Emergency preparedness, contingency planning and local operational programmes to be implemented in case of suspected and confirmed cases of CSF.
  - Notification of the suspected presence of CSF – awareness campaigns and cooperation of all relevant stakeholders.
  - Official investigation of the suspected presence of CSF in domestic and feral pigs, and interim measures taken until the presence of the disease is confirmed or ruled out.
  - Diagnostic protocol followed to confirm or rule out the presence of CSF, in accordance with diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests laid down in Commission Decision 2002/106/EC.
- With regard to the assessment of the level of preparation of the official control system in place to ensure compliance with requirements laid down in Article 6 of Commission Decision 2008/855/EC, the evaluation focused, in particular, on:
  - health status and effective risk management of participating holdings in relation to CSF, including application of adequate bio-security measures;
  - compliance with minimum residency periods and movement control for pigs in the

- participating holdings;
- frequency and effective implementation of official inspections, and
- effective implementation of official check and sampling procedures before pigs are dispatched to slaughterhouses, in order to exclude the presence of CSF.
- With respect to the implementing measures to give effect to the approved programmes for the control and monitoring of CSF for 2012 and 2013, the evaluation focused on:
  - Compliance with provisions on registration of pig holdings, identification and movement of pigs, including organisation and implementation of official controls, in particular on-the-spot inspections and enforcement measures in case of non-compliance.
  - Implementation of CSF surveillance in the domestic pig population – commercial farms and backyard holdings.
  - CSF surveillance in wild boars and feral pigs.
  - Laboratory diagnosis of CSF - Diagnostic preparedness, laboratory capability and accreditation status.

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

Meetings/Visits		Comments
Competent authorities	7	Opening and closing (debriefing) meetings with the NSVFSA. Additional meetings with staff of the SVFSD in the counties visited (Prahova, Arges, Olt, Suceava and Iasi). Meetings with OV's and CV's during the visits to the animal holdings.
Animal holdings	3	Two commercial pig holdings; one fattening unit and one breeding farm, and one back-yard holding.
Laboratories	2	One county veterinary laboratory and meeting with representatives of the NRL.

### 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 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 and
- Article 27(9) of Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field.

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>

In addition to the standards established by the relevant EU legislation in the context of the objectives and scope of this audit, account has been taken of other international standards, in particular the standards, guidelines and recommendations developed by the World Organisation for Animal Health (OIE).

## 4 BACKGROUND

### 4.1 CSF IN ROMANIA

The following features are worth being highlighted:

- There has not been any confirmed case of CSF in Romania since 2007.
- Molecular epidemiological and phylogenetic studies of the strains of the CSF virus detected in Romania confirmed that all belonged to one homogeneous genetic cluster of wild virus showing nearly no genotypic, antigenic, and virulence variability.
- Due to the persistent uncertainties around the health status of both the pig population kept in the numerous backyard holdings and in the wild boar population, Romania is not recognised as free from the disease and, therefore, it is currently listed in Part III of the Annex to Decision 2008/855/EC.
- Article 8(a) of that Decision lays down provisions permitting the dispatch to other Member States (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 channelling system proposed by the CA is in place. This derogation only applies to a number of pig holdings situated in four counties in Western Romania (Arad, Timis, Caras-Severin and Bihor).
- Co-financed programmes for the control and monitoring of CSF in Romania were approved for 2012 by Decision 2011/807/EU and for 2013 by Decision 2012/761/EU.

The Commission and the EU Member States (MS) have been kept informed of the CSF situation in Romania *inter alia* through several presentations made to the Standing Committee on the Food Chain and Animal Health (SCoFCAH) - Section Animal Health & Animal Welfare. The latest update was provided by the NSVFSA during the SCoFCAH meeting held on 2 July 2013; these presentations have been made available on the internet:

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

In addition, there has been a task force meeting of the CSF subgroup in Bucharest in April 2013. During that meeting, the task force experts and the Commission got detailed information on all aspects related to the eradication, monitoring and control programme in the whole territory of Romania and they provided expert advice on how to improve the programme so that its implementation produces robust and reliable results to prove that the CSF virus is not circulating in Romania. The report of the task force can be found on the internet:

[http://ec.europa.eu/food/animal/diseases/eradication/csfs\\_report\\_romania\\_042013\\_en.pdf](http://ec.europa.eu/food/animal/diseases/eradication/csfs_report_romania_042013_en.pdf)

The outcome of the task force meeting was largely positive and its conclusions reflect the significant progress made recently by the Romania CA with implementation of the CSF control and monitoring programmes. Nevertheless, some room for improvement was found in relation to some issues and a number of recommendations were provided to the NSVFSA. Amongst them, the following points are of major relevance in the context of the objectives and scope of this audit:

- As the number of back-yard holdings is still very high, there is a need for more information on location, size and census of those holdings in order to better and more accurately present data on surveillance for CSF on that part of the domestic pig population;
- passive surveillance in backyard operations should be carried out systematically to be able to detect any re-introduction of the CSF virus as early as possible, and
- more efforts should be put into gathering information about the actual status, dynamics and geographical distribution of the wild boar population. In addition, age-related serology of

wild boar samples should be introduced in order to allow better evaluation of data from surveillance for CSF.

## **4.2 PREVIOUS FVO REPORTS**

Two FVO audits verified in July 2011 and September 2012 the development and proper functioning of the channelling system mentioned in the previous section (ref.: DG(SANCO)/2011-6046 – MR Final, and DG(SANCO)/2012-6585 – MR Final; hereafter, previous FVO reports). Those audits also verified the fitness for purpose and implementation of surveillance for CSF, and covered many topics included in the scope of this audit; though usually within a restricted geographical scope determined by the proposal for the channelling system (see 4.1, for details on the extent of this system). The reports of those audits are available at the FVO Web site:

[http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_id=3023](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=3023)

[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)

## **5 FINDINGS AND CONCLUSIONS**

### **5.1 PERFORMANCE OF THE COMPETENT AUTHORITIES**

#### *5.1.1 Legal requirements*

Regulation (EC) No 882/2004 lays down general rules for the performance of official controls to verify compliance with rules aimed at preventing, eliminating or reducing to acceptable levels, risks to humans and animals. In particular, this includes:

- Article 3 on the general obligations with regard to the risk-based, regular, unannounced official controls;
- Article 4 on the designation of CAs, who shall ensure the availability of legal powers to carry out official controls, the effectiveness and appropriateness of those official controls, including adequate coordination and cooperation within and between all designated CAs, and the performance of audits to ensure that they are achieving the objectives of the said Regulation;
- Article 6 on training and updating of professional competence;
- Article 8 on documented procedures and verification of effectiveness;
- Article 9 on reporting on official controls, and
- Articles 54 and 55 on actions in case of non-compliance and sanctions, respectively.

#### *5.1.2 Findings*

##### *5.1.2.1 Legislation*

An extensive body of legislation is in force in Romania in order to transpose and apply nearly all relevant EU requirements concerning identification and registration of pigs, and control of CSF. However, specific weaknesses were identified by the audit team, and acknowledged by the CCA, in relation to one particular area:

- A description of the organisation of surveillance for CSF in the wild boar population is provided in section 5.3.2.2. In that context, it is considered of paramount importance for the adequate and unbiased implementation of that surveillance, that the CA are timely notified about all wild boars that are hunted in Romania during the hunting season in order to take a

geographically representative sufficient number of samples from them.

- According to representatives of the NSVFSA and of the SVFSD visited, that is not always possible as they do not have legal powers to make it compulsory for privately run hunting grounds to notify of their hunting activities to official veterinarians (OVs). As a consequence, OVs cannot decide, in accordance with planned sampling activities submitted by the NSVFSA, on whether samples need to be taken from available wild boars depending on their geographical situation and the sampling numbers already fulfilled for a particular area or hunting ground. For further details, please refer to section 5.3.2.2.
- Representatives of the NSVFSA informed the audit team that they had already started negotiations and discussions with representatives of the environmental authorities at central level in order to prepare as a matter of urgency new legal provisions to address the above mentioned deficiency.

#### *5.1.2.2 Organisation, operation and verification of effectiveness of official controls*

A description of the animal health control system in place in Romania is included in the latest version of the country profile for this MS (valid as of March 2013), which is available through the following link:

[http://ec.europa.eu/food/fvo/controlsystems\\_en.cfm?co\\_id=RO](http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=RO)

Additional details on the activities carried out by the NSVFSA and the SVFSD in the context of CSF controls and surveillance activities, is provided in the previous FVO reports. Descriptions given therein on the activities of OVs working at the SVFSD and of concessionary veterinarians (CVs) involved in official control activities and surveillance for CSF in back-yard holdings are still applicable.

In addition, it is worth mentioning that:

- All OVs and CVs met were well aware of their control responsibilities and had sufficient knowledge to fulfil their tasks in the context of the CSF control and monitoring programme. In addition, planning of official controls was found to be fit for purpose; however:
  - implementation of planned sampling activities in back-yard holdings was not adequately verified at local level to ensure that sampling principles and targets were always respected by CVs (see 5.3.2.1.2), and
  - as a consequence of political and managerial decisions at central and county level, OVs cannot enforce the necessary legal provisions with regard to back-yard holdings (see 5.2.2) and private hunting grounds.
- The internal audit Unit of the NSVFSA has organised a series of audits in order to verify official controls and implementation of the CSF control and monitoring programmes carried out by the SVFSD. These audits are carried out by staff who has been specifically trained for that purpose. They have covered all counties in Romania and they have issued, or were in the process of drafting, individual reports for each of them. The audit team had access to a number of them, including for some on the counties visited, and could verify the comprehensive evaluation carried out by the NSVFSA auditors, who had detected most of the weaknesses eventually confirmed by the FVO audit team.
- According to representatives of the NSVFSA and of the SVFSD visited, many issues had been addressed immediately, such as the presence of illegal pig markets or unidentified animals found in the back-yard holdings visited by the auditors. Ongoing control activities in that respect could be checked by the audit team.

- As indicated in previous FVO reports, local auditors at the SVFSD are responsible for the regular follow-up of the national audits and for updating the internal audit Unit on the progress with implementation of the action plans submitted by the SVFSD. In general, evidence was available of the progress made with implementation of the action plans submitted by the counties visited, but addressing of recommendations related to compliance of back-yard holdings with provisions on animal identification and movement, and requirements on notification of sick and dead pigs, were still in progress. Representatives of the SVFSD visited acknowledged that implementation of action plans to address those recommendations will take time and additional efforts to raise awareness on those requirements amongst animal keepers, before they can be resolved. They added that strict enforcement of legal requirements, including sanctions or seizing of animals, were not a possibility as there was no political willingness to do so.

### 5.1.3 Conclusions

Significant efforts have been made during 2012 and this far in 2013 to implement the control and eradication programmes for CSF. Largely sufficient legal powers have been given to the different levels of the CA so that they can apply most of the necessary actions as required by the results of their official controls and the epidemiological situation of the disease in Romania.

However, some weaknesses still persist undermining the overall effectiveness of the official control system, such as:

- The CA do not have adequate legal powers to ensure that surveillance for CSF in wild boars can be fully implemented in accordance with the control and monitoring programmes approved for 2012 by Decision 2011/807/EU and for 2013 by Decision 2012/761/EU. This is not in line with provisions laid down in point (e) of article 4(2) of Regulation (EC) No 882/2004.
- The CAs are still fairly reluctant to enforce legal requirements on identification of animals and their movements, which is conducive to the persistence of non-conformities among keepers of animals in back-yard holdings. This is not in line with provisions laid down in articles 54 and 55 of Regulation (EC) No 882/2004.
- Despite commendable improvements concerning verification of effectiveness of those controls, action taken upon their results has not yet conclusively translated into amelioration of that effectiveness, which is not fully in line with provisions laid down in article 8 of Regulation (EC) No 882/2004.

## 5.2 HOLDING REGISTRATION, ANIMAL IDENTIFICATION AND ANIMAL MOVEMENTS

### 5.2.1 Legal requirements

Article 18 of Council Directive 64/432/EEC obliges all MS to establish a computer database for porcine animals comprising *inter alia* holding registration details, holding numbers of origin for all groups of pigs on each holding and details of each separate movement of the animals.

Council Directive 2008/71/EC lays down provisions on the identification and registration of pigs, including requirements on:

- keeping of lists of registered holdings by the CAs;
- identification marks to be applied on animals;
- maintaining by animal keepers of holding registers recording all movements of pigs;

- provision by animal keepers of information on animal movements to the CAs;
- basic rules to ensure traceability of all animals to their holding of origin, and
- adoption by the CAs of the necessary administrative and/or penal measures to punish any non-conformity with the requirements of the said Directive.

The above mentioned EU requirements are implicitly embedded into the programmes for control and monitoring of CSF in Romania approved by:

- Decision 2011/807/EU, for the period from 1 January to 31 December 2012, and
- Decision 2012/761/EU, for the period from 1 January to 31 December 2013.

### 5.2.2 Findings

The previous FVO reports provide information in relation to this area, in addition, it is worth being highlighted that:

- the CA have access to a fully operational holding registration and pig identification central database;
- significant efforts made since 2011 largely guarantee that the CA can keep full coverage and registration of all back-yard holdings where animals are kept at any time during the year;
- requirements are in place on compulsory individual identification (ear-tagging) of pigs kept in back-yard holdings;
- provisions are in place prohibiting movements of unidentified pigs, and all movements must be reported to the central database, and
- animal keepers are required to keep updated holding registers containing all information on the animals present in the holding, on all pig movements in and out, and on all other relevant events such as deaths and own-farm slaughter of pigs.

The audit team also found that:

- The NSVFSA can provide comprehensive information from the central database on each and every registered back-yard holding, with indication of the individual identification numbers of the pigs present therein and details on the movements that occurred since the set up of the database.
- The central database is fit for purpose and enables the CA to perform all sorts of checks and studies on animal movements, in particular in relation to traceability of individual pigs. In addition, the database is an excellent tool for the planning, follow-up and verification of all activities, including epidemiological surveys' design and sampling, related to surveillance for CSF (see though 5.3.2.1.2).
- Holding registers kept by the commercial pig holdings visited were comprehensive and well up-to-date; the keepers inform the CA each time pigs are going to arrive or to be dispatched to other farms or to slaughterhouses. Pigs in commercial holdings are identified with tattoos indicating the holding registration number of their holding of origin and, on occasion, additional ones in case they have been moved from that to another holding. In all cases checked, movement documents and veterinary certificates had adequate information to facilitate traceability of movements, and the central database had been updated accordingly.
- As indicated in section 5.3.2.1.2 below, there is widespread non-compliance amongst back-yard holdings with requirements on identification and registration of pigs and notification and registration of animal movements. The audit team could verify by checking on several occasions the database, and on-the-spot in the back-yard holding visited, that this is a very

serious problem. Levels of non-notification of movements and life-events by the keepers checked in the database, and by the keeper of the holding visited, were numerous and very frequent. Official inspections and their verification by the CCA consistently confirm these problems, but no enforcement measure is taken by the CA (see also section 5.1.2).

### 5.2.3 *Conclusions*

The efforts made by the NSVFSA to set up a pig identification and registration system in accordance with EU requirements, including the availability of a fully operational central database, and that can be considered fairly reliable with regard to its implementation in commercial pig holdings, are nonetheless significantly undermined by:

- the persistent non-compliance by keepers of back-yard holdings with basic requirements on animal identification and notification and registration of animal movements, and
- ineffective enforcement by the CAs of EU requirements on identification and registration of pigs laid down in Directive 2008/71/EC, despite the frequent unfavourable outcome of official controls carried out to check compliance with them.

## 5.3 MEASURES FOR THE CONTROL AND SURVEILLANCE OF CSF

### 5.3.1 *Legal requirements*

Directive 2001/89/EC lays down specific provisions concerning minimum EU measures for the control of CSF.

Decision 2002/106/EC approves a CSF diagnostic manual laying down uniform diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation of the disease. Article 17 of Directive 2001/89/EC requires MS to carry out all necessary procedures to detect the presence of CSF in accordance with the diagnostic manual.

The above mentioned EU measures for the control of CSF are implicitly embedded in the programmes for control and monitoring of the disease in Romania approved by:

- Decision 2011/807/EU, for the period from 1 January to 31 December 2012, and
- Decision 2012/761/EU, for the period from 1 January to 31 December 2013.

### 5.3.2 *Findings*

#### 5.3.2.1 *Official controls and surveillance for CSF in the domestic pig population*

##### 5.3.2.1.1 *Commercial holdings*

According to information provided by the NSVFSA, at the time of the audit there were 332 commercial holdings in Romania keeping some 1.6 million pigs. There is significant variation in respect of their operation as, up until now, 30 to 40% of these holdings are often not populated; therefore, according to representatives of the pig industry met, there is considerable potential for growth and the industry is ready, and eagerly awaiting for participating in EU trade.

In addition, there are some 250 'type A' holdings keeping some 12 000 pigs, 25% of which are situated in just one county (county Arad). Representatives of the NSVFSA stressed the fact that meat from pigs originating in these holdings is not going to be authorised yet for EU trade, as this type of holdings cannot ensure the same levels of bio-security present in the commercial holdings.

In addition, the audit team found that:

- OV's of the SVFSD are responsible for performing monthly official inspections on all commercial and 'type A' holdings. Reports of these inspections were available at the holdings visited and they included details on clinical checks, done both randomly and targeted on sick animals, on evaluation of mortality and health records, on verification of animal movements and on evaluation of implementation of on-site bio-security measures. In addition, the reports sometimes provided recommendations to the animal keeper in order to improve the situation in the holding, in particular in relation to bio-security measures. Usually, action taken by the animal keeper had been followed-up in the following monthly inspections.
- All commercial and 'type A' holdings have to be sampled for serological testing as part of the CSF control and monitoring programme. This epidemiological survey is aimed at detecting a 5% within-herd prevalence rate in each holding and it is carried out by OV's twice a year; in March/April and in October/November. The first sampling performed in 2013 collected some 23 000 samples, largely as planned, which had all given negative results.
- In addition, surveillance for CSF in these holdings also includes sampling of all sows and boars slaughtered from commercial holdings during the above mentioned time periods and of all sows and boars present in the 'type A' holdings at the time of sampling. During the first sampling period in 2013, 6 349 samples have been taken. According to detailed data provided by the NSVFSA, and as checked by the audit team in the holdings visited, this sampling has been done in accordance with the rules and largely as planned in the CSF control and monitoring programme for 2013.
- With regard to passive surveillance in commercial and 'type A' holdings, detailed data provided by the NSVFSA show that so far in 2013, samples have been taken from sick animals, when the presence of CSF could not be excluded (some 500 samples), in situations where abnormal mortality rates had been detected (some 2 000 samples) and as part of abortion investigations (some 1 500 samples). Samples (whole blood and animal tissues) are mostly tested with PCR, but serological testing was also carried out in part of the cases.
- Close analysis of data on passive surveillance shows that this sampling varies significantly between counties, as there are some counties where nearly no sample has been taken, even if numerous holdings are present. This was confirmed by the audit team during the visits to the commercial holdings where, according to the animal keepers and the OV's, no dead or sick animal had been sampled for years. The audit team underlined the fact that taking into account both the average size of the holdings (2 to 3 000 thousand pigs) and the production cycles (at least two fattening cycles per year, in one of the holdings, and two litters in the breeding farm), it would be logical to expect that, given the high sensitivity of the CSF passive surveillance claimed by the CA, some targeted investigations to exclude the presence of CSF would have been carried out in these holdings, as it was the case in many other similar holdings in other parts of Romania.

#### 5.3.2.1.2 *Back-yard holdings*

According to information provided by the NSVFSA, at the time of the audit:

- There were some 680 000 registered back-yard holdings in Romania keeping in excess of 2.2 million pigs.
- These holdings are distributed throughout the 13 743 localities of the 42 counties, but the number of holdings per county varies between 1 000 and 40 000, with an average of 15 000 to 20 000 per county.

- The majority of these holdings usually keeps less than three pigs, with very few with more than ten. These numbers vary considerably throughout the year.

In addition, the audit team found that:

- In accordance with plans set up by SVFSD, CVs carry out twice a year on-the-spot official inspections in all back-yard holdings. These inspections check compliance with pig identification and registration requirements, and also verify application of general principles of biosecurity; however, the latter is not a legal requirement. On top of those inspections, further checks are requested on occasion by some SVFSD in order to update information contained in the central database before sampling activities are implemented (see below).
- According to representatives of the NSVFSA, surveillance for CSF in this sub-population, as included in the approved control and monitoring programmes, is based on a random epidemiological survey that, on top of being aimed at detecting 5% between and within-herd prevalence rates in each county; it adds another level of aggregation that selects a number of localities in order to detect a 5% rate of affected localities also at county level.
- However, according to data presented by the NSVFSA, the selection of the localities is initially not random, but rather risk-based. The first selection steps target in all counties localities situated within the 3 km area surrounding all commercial holdings, and also those situated along the borders with some neighbouring countries (Ukraine, Serbia and Moldova). As a result:
  - Out of the 2 197 localities selected for sampling in Romania in 2013; 719 and 131 are, respectively, targeted for those two reasons.
  - For most counties, 25 to 50% of the localities selected are in the 3 km area surrounding commercial holdings.
  - For some counties, that have a significant number of localities selected as described in the previous point; since they are also situated along the border with neighbouring countries, in the end, most localities are not selected at random.
- Therefore, the underlying basic assumption made by the CCA for this design, as included in the approved control and monitoring programme for 2013; i.e. that all epidemiological units in Romania have the same probability of being infected with the CSF virus and, therefore, that a random sample of the population was used for surveillance for CSF; has not been respected.
- In practice, an algorithm has been incorporated to the central database whereby, once the initial targeted localities have been selected, the remaining number of holdings and pigs to be sampled is randomly selected. In the end, for each selected locality, those targeted and the balance selected at random; the database produces a list with the holding registration numbers and the individual identification numbers of the pigs to be sampled in each of them.
- The list of localities, holdings and pigs to be part of the survey was submitted to the SVFSD, and eventually to the CVs, for the sampling to be carried out in the period March/April 2013 (once a year). In total, 170 000 samples have been taken from some 60 000 holdings.
- Upon close scrutiny of the outcome of the official inspections carried out on all back-yard holdings in the autumn of 2012, and from May to July 2013, it was obvious that the level of compliance amongst back-yard holdings with requirements on identification and registration of pigs and notification and registration of animal movements, was very low; as there was a very high percentage of cases where data retrieved from the database did not coincide with the reality encountered by the CVs in the field. The main findings were:

- presence of pigs not-born in the back-yard holding that were not identified and whose holding of origin, and the date when they had arrived in the new holding, could not be ascertained, and
- disappearance of pigs that were still registered in the database as present in the visited holding, but whose destination, death or slaughter, could not be proved by the animal keeper or verified by the CV.
- The main reasons explained by the CAs for both phenomena were:
  - Many animals had just been purchased; those found during the inspection in autumn, were due to be fattened for Christmas, and those found during springtime-early summer, because they had been purchased after home-slaughtering during the Orthodox Easter festivities (early May 2013). In either case, most of them had not been identified before leaving the holding of origin or notified to the database by the holding of destination, and
  - Animal home-slaughtered during Christmas or the Orthodox Easter were not notified to the database.
- As a consequence of the above mentioned deficiencies, and the fact that the sample for the epidemiological survey to be carried out in 2013 was drawn during the autumn 2012; the following discrepancies were found with data resulting from implementation of the sampling:
  - Some 67 000 pigs of the 170 000 randomly selected from the central database during the autumn 2012 could not be found during the recent sampling campaign carried out in March/April 2013.
  - In some 10 000 of the 60 000 holdings selected to be sampled there was no pig present at the time of sampling.
  - The process of selection by CVs of substitute holdings and pigs, as recommended by the CCA, is not verified by the SVFSD to ensure that this process is carried out appropriately in order to ensure that no clustering occurs and that the initial sampling principles are respected.
- With regard to implementation of passive surveillance, some 12 000 samples have been tested so far in 2013 (mostly virological testing in blood samples and tissues with PCR). They were taken from sick animals, aborted sows (foetuses) and emergency slaughtered pigs. As indicated for the commercial holdings, there is a very significant variation between counties, with some with a high number of back-yard holdings investigating very few cases (169 animals each from two counties with more than 35 000 and 40 000 holdings, respectively, or 75 and 135 animals from two counties with some 15 000 holdings each). In addition, this sampling is usually clustered geographically within the counties, as it depends on the willingness and clinical approach of the CV involved, who is usually responsible for a certain geographical area.

#### 5.3.2.2 *Surveillance for CSF in the wild boar population*

According to information provided by the CCA, in Romania there are some 70 000 wild boars distributed all over the country. The audit team found that:

- There is a good cooperation between the NSVFSA, the SVFSD and the environmental authorities so that reliable estimates of the dynamics of the wild boar population in each hunting ground are available to the former in order to plan and implement, respectively, the

surveillance for CSF;

- The hunting bag is determined for each hunting season (August one year to February the following one) and every authorised hunting ground; this means that in excess of 20 000 wild boars could, and can be hunted in Romania during the previous and the current hunting seasons, respectively. As a result of that, the CA has detailed data on the number of wild boars expected to be hunted in each hunting ground and the target number of wild boars to be sampled for surveillance for CSF has been fixed for each of them. Moreover, county representatives of the environmental authorities usually share data on progress and fulfilment of hunting quotas for each hunting ground with the SVFSD.
- Sampling is carried out by OVs, who are informed by hunters of the wild boars hunted, and samples (blood and tissues) are immediately dispatched to the relevant county laboratory.
- Targeted surveillance efforts have been made to verify the health status of the wild boar populations situated in areas neighbouring countries with an uncertain CSF status in their wild boar populations, such as Ukraine, Serbia and Moldova.
- According to data provided by the NSVFSA on the hunting season running from August 2012 to the end of February 2013:
  - Some 12 000 wild boars have been sampled and tested. Tests carried out included serological (ELISA) and virological testing (PCR and fluorescent antibody test - FAT). This sampling has been carried out consistently all along the hunting season and samples have been taken from all counties in Romania.
  - However, a closer look to data on fulfilment of targets by individual hunting grounds in a number of counties, shows that a limited number of samples have been taken from some of them, and sometimes they represent a large geographical area in the particular county. As explained in section 5.1.2.1, there is no legal requirement for the numerous privately run hunting grounds to cooperate in the implementation of surveillance for CSF by submitting hunted wild boars for official testing. As further confirmed during discussions held with representatives of the NSVFSA and some SVFSD; the above mentioned weakness affects the outcome of the surveillance for CSF in those counties, which cannot be implemented as planned, and prevents the CAs from drawing an accurate epidemiological picture of the situation of the wild boar population in those parts of Romania.
  - Twelve wild boars were found positive to serological testing:
    - Except one, all of them were clustered in one county where vaccination against CSF was implemented until November 2011. The situations had been comprehensively investigated by the NSVFSA and no additional serological or virological evidence of virus circulation was found afterwards in either area.
    - According to representatives of the NSVFSA, the most plausible explanation for most of the animals (those older than one year) was the presence of antibodies derived from vaccination. In addition, persistent maternal immunity was considered the reason of the positive findings in a few tested young wild boars.

### 5.3.2.3 *Laboratory diagnosis of CSF*

The audit team found that:

- The national reference laboratory (NRL) maintains good supervision on the county

diagnostic laboratories, including organisation of annual inter-laboratory comparison tests for serological (ELISA) and virological (FAT) diagnosis of CSF. Extensive evidence in that respect was available and presented to the audit team for evaluation. The level of satisfactory results obtained by participating county laboratories is consistently high and the few occasions when one laboratory had failed in any of the comparison tests; follow-up investigations had been done and corrective measures provided by staff of the NRL, as appropriate.

- county laboratories share a common quality assurance system and common standard operating procedures for diagnosis of CSF (ELISA and FAT), as provided by the NRL. Moreover, county laboratories participating in CSF diagnosis must have their testing procedures included within their scope of accreditation in accordance with standard EN ISO/IEC 17025.
- As already indicated in the previous FVO reports and further acknowledged by the EU experts who participated in the task force meeting mentioned in section 4.2; the network of county diagnostic laboratories guarantees good testing capacity and timely processing of samples.
- The audit team could verify in the county laboratory visited the good quality management system in place and the satisfactory results of their participation in comparison tests organised by the NRL.

### 5.3.3 Conclusions

The Romanian CAs are making significant efforts to implement the surveillance for CSF in accordance with the provisions laid down in the control and monitoring programme approved by Decision 2012/761/EU, in particular in commercial pig holdings. The frequent and largely effective official controls applied by the CA on these holdings, along with the high level of bio-security they consistently ensure, dramatically diminish their risk of infection with the CSF virus.

The laboratory network responsible for CSF diagnosis in Romania can be considered capable of producing technically valid results in the context of CSF serological and virological surveillance because:

- all participating laboratories use standardised accredited diagnostic methods in accordance with the EU diagnostic manual for the disease laid down in Decision 2002/106/EC, that ensures that results provided by all county laboratories are robust and comparable, and
- the reliability of the test methods is periodically checked by participation in inter-laboratory comparative tests organised by the NRL in accordance with Annex III to Decision 2001/89/EC.

Results of surveillance for CSF indicate at first sight that it is very unlikely that the CSF virus has circulated in the domestic pig herd or in the wild boar population in Romania for at least the last 12 months. However, a closer analysis of the situation shows that there are a number of faults in the design of, and deficiencies in the implementation of some components of the CSF control and monitoring programme, that cast doubt on:

- the reliability of the epidemiological picture that can be drawn from results of active surveillance for CSF in back-yard holdings and wild boars, and
- the operation of the disease early warning system in place in accordance with the guidelines laid down in Chapter III of the Annex to Decision 2002/106/EC on the findings, criteria and grounds to be used to recognise CSF suspected holdings.

As a consequence, implementation of the CSF control and monitoring programme approved by Decision 2012/761/EU in back-yard holdings and wild boars cannot be considered sufficiently effective to provide a robust epidemiological picture of the CSF situation in these sub-populations for the CAs to offer definitive assurances in respect of their CSF health status.

## **6 OVERALL CONCLUSIONS**

According to data provided by the CAs, the cumulative results obtained during 2012 and so far in 2013 from the implemented CSF control and monitoring programmes indicate that it is highly unlikely that the CSF virus has circulated in the domestic and wild pig populations in Romania for at least the last 12 months. In relation to commercial pig holdings, the CAs can ensure that as a result of both their targeted control efforts, which have been found to be fit for purpose and largely effective, and the high levels of bio-security consistently applied in these holdings; the risks of infection with the CSF virus and, if that happened, of transmission of the disease from them, are negligible.

However, deficiencies in the implementation of the CSF control and monitoring programmes approved for 2012 and 2013 still undermine the effectiveness of the control system put in place by the CAs in order to fulfil the overall objectives of those programmes and, thereby, decrease the reliability of the epidemiological picture that can be drawn from results of that implementation.

The main deficiencies found are:

- The limited effectiveness of official controls on identification of animals and their movements in back-yard holdings and the absence of enforcement of legal requirements in that respect.
- Information obtained from the epidemiological surveys designed for surveillance for CSF in back-yard holdings is not robust enough because of a number of design faults and implementation gaps.
- The very limited passive surveillance in numerous counties with a fairly large pig population, which casts doubt on the effectiveness of the early warning system for CSF in those areas.
- The lack of legal powers to ensure that surveillance for CSF is effectively carried out in all privately run wild boar hunting areas.

As a consequence, the measures to verify the CSF free status of the non-commercial domestic pig herd and the wild boar population in Romania could be improved.

## **7 CLOSING MEETING**

A closing meeting was held on 13 September 2013 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 immediately review the situation, in particular the organisation of the CSF surveillance surveys in the back-yard pig population, in order to render them fit for purpose from the epidemiological point of view, so that the proposal for a co-financed control and monitoring programme for 2014 could contribute unequivocally to obtain the necessary information to demonstrate the CSF free health status of the pig population in Romania.

## **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:

<b>Nº.</b>	<b>Recommendation</b>
1.	To ensure in accordance with point (e) of article 4(2) of Regulation (EC) No 882/2004, that the CAs have adequate legal powers to fully implement measures for surveillance for CSF in wild boars in accordance with provisions laid down in the CSF control and monitoring programme approved for 2013 by Decision 2012/761/EU.
2.	To ensure in accordance with articles 54 and 55 of Regulation (EC) No 882/2004, that action is taken, and effective, proportionate and dissuasive sanctions applied, as appropriate, to ensure that non-compliances with legal requirements on identification of animals and their movements laid down in Directive 2008/71/EC, are remedied among keepers of animals in back-yard holdings.
3.	To ensure in accordance with articles 8(3) and 4(6) of Regulation (EC) No 882/2004, that corrective action is taken without delay upon results of the verification activities and internal audits aimed at improving the effectiveness of official controls.
4.	To ensure that adequate measures are taken in the context of the control and monitoring programme approved for 2013 by Decision 2012/761/EU, and any future one approved and co-funded within the same EU framework, to design and implement active surveillance in back-yard holdings so that it can be considered fit for purpose from the epidemiological point of view and can yield robust results that accurately reflect the epidemiological situation in the whole population under study.
5.	To ensure that adequate measures are taken in the context of the control and monitoring programme approved for 2013 by Decision 2012/761/EU, and any future one approved and co-funded within the same EU framework, so that an effective early warning system that reports and investigates suspect cases of CSF from commercial and back-yard pig holdings is functioning throughout the country, in accordance with the guidelines laid down in Chapter III of the Annex to Decision 2002/106/EC on the findings, criteria and grounds to be used to recognise CSF suspected holdings.

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=2013-6789](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6789)

## 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
Dec. 2009/470/EC	OJ L 155, 18.6.2009, p. 30-45	2009/470/EC: Council Decision of 25 May 2009 on expenditure in the veterinary field (Codified version)
Dir. 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. 2001/89/EC	OJ L 316, 1.12.2001, p. 5-35	Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever
Dec. 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
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. 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

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
Dec. 2012/761/EU	OJ L336, 8.12.2012, p.83-93	2012/761/EU: Commission Implementing Decision of 30 November 2012 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2013