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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ROMANIA

FROM 03 TO 10 NOVEMBER 2014

IN ORDER TO EVALUATE THE IMPLEMENTATION OF THE CLASSICAL SWINE FEVER
CONTROL AND MONITORING PROGRAMME

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Romania carried out between 03 and 10 November 2014, as part of the FVO audit programme for 2014. The objective was to evaluate the implementation of the programme for control and monitoring of classical swine fever (CSF) in Romania approved for 2014.

Overall, the report concludes that:

The well organised and elaborate system for active surveillance in domestic pigs is auditable. Its weaknesses do not significantly affect the confidence in the status of the country for CSF in domestic pigs (where the last CSF case reported was in 2007), which is supported also by a passive surveillance system in a largely susceptible (non-vaccinated) pig population.

In wild boars, the intense active surveillance coverage and the implementation and monitoring of surveillance, give a reliable picture supporting the absence of the circulation of CSF virus in the populations investigated. However, the absence of corrective actions in certain areas with consistently low surveillance prevents drawing conclusions for the whole territory.

The capacity for early detection of CSF in domestic pigs is hampered by the largely uncontrolled movements of pigs in the non-commercial sector. The lack of a (geographically) risk-based strategy for surveillance and the general lower grade of investigation in commercial holdings also represent factors hindering the capacity of the competent authorities for early detection of resurgence of CSF (or incidentally, of introduction of African swine fever). The capacity for early detection of CSF in wild boars is affected by the low number of dead wild boars analysed and by the dismissal of the few suspect cases without sufficient epidemiological evidence.

The general lack of enforcement of movement conditions for pigs in the backyard sector (including market operations), already identified in previous reports, has not been addressed. This undermines the capacity of the CA to perform efficient surveillance (including for detection of illegal imports of pigs from third countries) and to control the situation in cases of introduction of the disease.

The report makes recommendations to the Competent Authorities of Romania aimed at addressing areas in which further improvements are required.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ASF	African Swine Fever
CA	Competent Authority
CCA	Central Competent Authority
CSF	Classical Swine Fever
CV	Contracted (private) veterinarian
DG(SANCO)	Health and Consumers Directorate General
ELISA	Enzyme Linked ImmunoSorbent Assay (serological test to detect CSF antibodies)
EU	European Union
FAT	Fluorescence antibody test (virological test to detect CSF antigen)
FVO	Food and Veterinary Office
MS	Member State
NRL	National Reference Laboratory
OV	Official Veterinarian
PCR	Polymerase Chain Reaction (virological test to detect CSF genes)
RCA	Regional competent authority (county level)
TRACES	Trade Control and Expert System, database including notification of movement of live animals between Member States

1 INTRODUCTION

The audit took place in Romania from 03 to 10 November 2014 and was undertaken as part of the FVO (Food and Veterinary Office) audit programme. The audit team was comprised of two auditors from the FVO and a National Expert . The team was accompanied throughout the audit by representatives of the National Sanitary Veterinary and Food Safety Authority, which is the Central Competent Authority (CCA) within the scope of this audit.

2 OBJECTIVES

The objectives of the audit were:

- to evaluate implementation of the programme for control and monitoring of Classical swine fever (CSF) in Romania approved for 2014 by Commission Decision 2013/722/EC, and in particular, to evaluate whether the surveillance system is effective in:
 - providing an adequate and reliable picture on the CSF status in the country,
 - early detection of CSF outbreaks in the domestic pig population as well as CSF cases in feral pigs;
- to evaluate the effectiveness of the official controls over the implementation of the programme and, in particular, over movements and traceability.
- to verify on the spot the implementation of the corrective actions in response to the recommendations of FVO audit report SG(SANCO) 2013-6789.

In pursuit of this objective, the following sites were visited:

MEETINGS / VISITS		no.	COMMENTS
Competent Authorities	Central	1	
	Regional	3	<i>Iasi, Botosani, Suceava</i>
Laboratories		2	
Holdings		7	4 backyard, 1 “type A”, 2 industrial holding
Markets & Assembly centres		1	
Slaughterhouse		1	

3 LEGAL BASIS

The audit was carried out under the general provisions of European Union (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;
- Article 27(9) of Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field.

Full legal references to EU legal acts quoted in this report are provided in Annex 1 and refer, where applicable, to the last amended version. EU legislation can be found following the link:

<http://eur-lex.europa.eu/homepage.html>

4 BACKGROUND

4.1 CSF IN ROMANIA

Romania is listed in the Annex to Commission implementing Decision 2013/764/EU concerning animal health control measures relating to CSF in certain Member States (MSs). This Decision prohibits the dispatch of live pigs, semen, ova or embryos from Romania to other Member States. Pig-meat, meat preparations and meat products may be dispatched to other MSs if they have been treated (in compliance with Article 4(1) of Directive 2002/99/EC), or if the pigs originate from holdings subject to bio-security, surveillance, inspections, residence and standstill rules (Article 4a of the Decision).

The last cases of CSF reported from Romania in domestic or feral pigs date back to 2007. A programme of control and monitoring CSF has been in place since, which included vaccination in industrial holdings (with an inactivated marker vaccine) until 2008, vaccination in backyard holdings (with attenuated vaccine) until 2009, and vaccination (attenuated vaccine) in wild boars until 2011. The European Commission has approved and co-financed the programme on an annual basis. The programme is still on-going, with an exclusive focus on active and passive surveillance of both feral and domestic pig populations since 2012.

Romania shares borders with two other Member States (Bulgaria and Hungary) and three third countries (Serbia, Ukraine and Moldova). None of these countries have reported any CSF since at least 2011 (Serbia) or much longer. However, CSF vaccination of domestic pigs is still routinely practiced in neighboring third countries. Bulgaria is also listed in the Annex to Decision 2013/764/EU and also runs an approved control and monitoring programme.

The European Commission and MSs have been kept informed of the CSF situation in Romania through regular presentations made at the Plant, Animals, Feed and Food Committee. The latest update was provided during a meeting held in September 2014. These presentations can be consulted at: http://ec.europa.eu/food/committees/regulatory/scfcah/animal_health/index_en.htm.

4.2 PREVIOUS FVO AUDITS

The FVO has conducted audits related to CSF in Romania every year since 2009. Enforcement of identification and movement rules of pigs, in particular between backyard holdings, has been identified as an issue from the first audit. Recommendations from previous reports have received adequate action or have been integrated into more recent recommendations. Five recommendations of the last FVO audit (DG(SANCO)2013-6789) were still considered in progress at the time of the present audit. They related to:

- enforcement of legal requirements on identification and movement of animals among backyard holdings (Recommendation 2);
- follow-up of the internal audits (Recommendation 3)
- implementation of active surveillance of backyard holdings (Recommendation 4)
- passive surveillance in commercial and backyard holdings (Recommendation 5).

The report and the action plan proposed by the Romanian CA can be accessed at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=3213

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

Legal requirements

Article 3 to 9, 54 and 55 of Regulation (EC) No 882/2004.

Findings

Information on the organisation of the Romanian CA can be found in the country profile (http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=RO), in previous FVO audit reports, in particular regarding the roles and performance of the CCA and the Regional competent authorities (RCAs) at county level, and the delegation to private concessionary veterinarians (CVs) of some official tasks related to surveillance of CSF, identification and movement controls of pigs.

The newly established Directorate for Official Controls had been effectively in operation for a month prior to the audit and its operation was not reviewed during this audit.

Use of CVs for official tasks:

The audit team noted that:

- Formal training of CVs was organised at county level (including a test at the end of the training). The RCAs planned activities at circumscription level, and sent instructions (and list of holdings and pigs registered in the database) via email to the CV for the execution of the programme. As indicated in response to Recommendation 2 of FVO report 2013-6789, the CA informed the CVs early in 2014 that the payment of their activities would be linked to the upload of updated information collected during their visits to the holdings into the pig database, which has led to better updating of the information in the database (see chapter 5.3.1.).
- The RCA performed 5% spot-controls of the backyard holdings visited by the CVs, checking the reliability of the information. In addition, official veterinarians (OVs) visited twice a year all industrial and type A holdings, where they checked the activities of the CVs.
- In addition to financial sanctions, the CA can also terminate contracts in cases of insufficient performance of CV.
- The concessions of official duties to CVs are not necessarily nominal: contracts can be given to a veterinary practice and all veterinarians working for this practice can perform the official duties (as long as they are registered to practice in Romania). Industrial holdings must inform the CA of the initial contract that they have with a CV (or practice) but are not required to notify any ulterior change. In one industrial holding visited, the operator had changed his veterinarian who was not a practitioner (and therefore not a concessionary veterinarian), but an employee of the feeding company and provider of the holding.

Monitoring of the CSF programme:

The audit team noted that:

- A CSF monitoring network was organised at central and regional level. Data on activities were collected and transmitted on a monthly basis, and quarterly reports were issued. The network also received data on laboratory analyses (number of tests, results) through a dedicated epidemiological team from the National reference laboratory (NRL).
- As indicated in subsequent chapters (5.3, 5.4), these data showed some significant variation

of performance among the counties, with some counties consistently performing very poorly. No evidence was seen that critical analysis of these data was performed at regional or central level, in order to identify causes of poor performance or initiate corrective action. This is contrary to the action proposed in response to Recommendation 3 of audit report 2013-6789.

Internal audit programme

The last audit on official controls related to classical (and African) swine fever was performed in 2013 by the national audit team. The audit led to recommendations related to:

- human resources at county level and availability of testing kits in laboratories,
- clarification of biosecurity feature for type A holdings,
- legal basis for health marks for pigs from backyard or type-A holdings slaughtered in slaughterhouses,
- revision of the contingency plan,
- movement notification and control in backyard holdings,
- surveillance in backyard holdings and official sampling in commercial holdings,
- authorisation of markets,
- clarification of list of industrial holdings approved for EU market, and
- clarification over assessment of CVs.

The audit team noted that:

- The audit file included the action plan from the CCA but no assessment of its adequacy by the national audit team. In particular, the responses in relation to the identification and movement controls in backyard holdings and to the authorisation and supervision of markets did not address the structural and systemic causes at the root of the non-conformity.
- The conclusions of the audit were presented to all counties at an arranged meeting and further audits are planned for 2015, visiting five counties.
- The CCA indicated that some of the counties performing poorly in the CSF control and monitoring programme would be included in the 2015 audit series.

Conclusions

The system for extensive use of private CVs for completion of official tasks is well organised and its effectiveness has been improved in 2014 by linking their retribution to the completion of tasks. However, as the CA does not have a systematic, complete and updated knowledge of individuals performing official tasks. They may be performed by veterinarians who do not meet the standards established.

The structured system for monitoring the implementation of the programme is not used to its full capacity, in particular as the absence of critical analysis prevents from identifying and analysing the causes of regional or local performance, in order to initiate timely and adequate corrective actions. The inclusion of poorly performing counties in future national audits may contribute to uncover causes at the origin of shortcomings, but the usefulness of national audits is limited by the lack of assessment of the measures proposed to solve some of the highlighted shortcomings.

While actions in response to Recommendation No 3 of FVO report 2013-6789 were in principle

satisfactory, this recommendation has not been addressed because actions implemented to tackle markets and traceability in backyard holdings were inadequate, and those related to the poor performance during monitoring by the CCA were insufficient.

5.2 HOLDING REGISTRATION, ANIMAL IDENTIFICATION, MOVEMENT CONTROLS

Legal requirements

Council Directive 2008/71/EC; Council Directive 64/432/EEC; Commission Decision 2000/678/EC; Commission Decision 2013/764/EU.

Findings

5.2.1 Production holdings

All holdings must be registered in Romania, under one of the three following categories:

- Industrial holdings
- “Type A” holdings
- Backyard holdings (for traditional family consumption)

The number of pig holdings and pigs in each category is as follows:

Year	number of holdings			Number of pigs (x1,000)		
	Industrial	Type A	Backyard	Industrial	Type A	Backyard
2012	323	158	810,000	1,740	?	2,766
2013	331	272	670,000	1,890	?	2,571
2014	348	713	750,000	1,910	19	2,217

(source: annual CSF control and monitoring programmes)

In order to be registered, type A holdings must present a technical file, including a description of basic generic bio-security features (established in Order 63 of 2008). Industrial holdings also need to present a file with more elaborate bio-security features and their infrastructures are subject to official inspections before registration.

Pig-meat can only be dispatched to other MSs if it originates from industrial holdings with a specific additional approval. This approval is granted following an inspection of the holding in operation by an OV. Around one third of industrial holdings were approved for dispatch of pig-meat to other MSs at the time of the audit.

Requirements for pig identification and movements are laid down in Orders 85 of 2008, 40 of 2010, and 67 of 2012. Pigs from industrial holdings must be identified with a holding identification number when leaving the holding. Pigs from Type A and backyard holdings must be identified with individual ear-tag numbers within 60 days of birth (or at first movement if occurring earlier). Pigs from backyard holdings can be moved to other backyard holdings, markets, or slaughterhouses but not to commercial holdings.

Pigs to be moved from any holding must be inspected by a CV who issues a health certificate; he must also complete a check-list on CSF surveillance for pigs moving from commercial holdings. All movements and individual identification must be notified to the national database, either directly by the operators (slaughterhouses and industrial holdings) or indirectly (through CVs).

A standstill of 30 days is to be applied to holdings introducing pigs from another holding unless these are kept separately. All keepers must have an updated register (containing information detailed in Section A of Annex 2 to Order 85 of 2008). A model of register is specifically set for type A and industrial holdings.

As noted by the previous audits, the system is supported by an fully operational national database, which represents an excellent tool for planning, follow-up and verification of activities related to surveillance for CSF.

The audit team noted that:

- The system requires notification of movements of pigs in the database both from operator of the dispatching holding and of the receiving one. A CV met (at a market) indicated that he did not enter confirmation of arrival of the pigs but only their dispatch to the declared holdings of destination. The audit team requested the number of pigs which had been notified in the database as having left a holding with no confirmation of arrival from the holding of destination (“floating movements”). This information was not provided;
- Around one million pigs have been registered in the database in 2014 as having moved to a “virtual holding”, a code assigned to pigs which are no longer present in holdings during inspections and the destination of which is undocumented (including on-farm slaughter);
- Holding registers were available and updated in the industrial holdings visited. A register was also kept at the type A holding, but was unreliable: movements were registered on aggregate form, not referring to batches or individuals (as pigs are individually identified in such holdings). Destinations of pigs were not indicated in the register. Movement documents issued by the CV indicated that they were systematically sent to an unapproved market independent of their actual destination, as many buyers buying directly from the type A holding had no holding registration number;
- The owner of this type A holding stated that pigs were transported to their destinations in his vehicle which was impossible to clean and disinfect. The CA indicated that no legislation could be applied on this means of transport as it was used for distances of less than 50 km but as the destinations were not recorded, this was impossible to check;
- Most pigs seen during the audit in backyard holdings were identified and information had been entered into the database. Many of them had been identified and registered during the spring surveillance campaign. Movement documents were in most cases unavailable in such holdings. The CA stated that many movements occur within a village, and that it would be unrealistic to have movement documents for them. Holding registers were usually not kept in backyard holdings nor requested by CVs or OVs during their inspections; the CCA indicated that backyard holdings were allowed to keep a collection of movement documents instead of a register;
- No instructions were available for CVs on how to proceed when pigs were found on backyard holdings without identification or movement documents. These occurrences are not reported as such; in these cases identification of the animals is done at the expense of the owner (instead of the State), as indicated in response to Recommendation 2 of audit report 2013-6789. No further sanctions were imposed, despite observation of deficiencies and contrary to the response to Recommendation 2 of audit report 2013-6789;
- The number of sanctions applied for non-compliance with pig identification and movement rules were requested by the audit team at national and regional level but were not provided. The CA does not keep a record of sanctions related to identification and movement control per species;

- The CCA indicated that sanctions were also applied to non-compliant pig keepers in the framework of cross-compliance inspections performed or coordinated by the Agency for Payment and Intervention in Agriculture with 12,000 holdings visited per year. The number of holdings with pigs, and the number of pig holdings that failed to comply with statutory minimum requirements for identification of pigs (SMR6), were not available at the time of the audit. Cross-compliance checks usually do not verify compliance with additional national rules. At a village visited, the CV indicated that farmers tended to be more compliant with bovine identification and movement rules as otherwise they were subject to sanctions in the framework of cross-compliance checks;
- The CA organised in 2014 a two-week exercise of roadblocks to check movement of animals, resulting in the issuance of 70 sanctions. The CA indicated that these checks were of limited efficacy as information on the presence of roadblocks spread rapidly.

5.2.2 Markets

Markets must be registered and approved. The CCA indicated that they must comply with conditions laid down in Order 45 of 2010. Pigs from markets can only be sent to backyard holdings.

The audit team noted that:

- Order 45 of 2010 does not apply to pigs and the CA could not indicate which other legal requirements would apply to sanitary conditions for registration/approval of pig markets.
- Lists of markets were kept at county level and were not publicly available. The lists in two counties contained, in one case six “non authorised” markets and in the other, 14 non-authorised and two authorised markets. None was recorded in these lists with a holding registration number.
- One authorised market was visited by the audit team. It had basic infrastructure, a register, access to the pig database and was under the supervision of a CV. Although the RCA indicated that it operated on a weekly basis, it was non-operational (the last pig movement registered occurred more than a year before the visit of the audit team).
- Non-authorised markets were indicated by several keepers interviewed (both backyard and type A farms) as the source or destination of their pigs. The CA stated that these markets are not under veterinary supervision.
- The CV of the type A holding issued movement documents and health certificates with destination to a non-approved market which had a holding registration number. The audit team requested the CA to provide the number of pigs in the database which were recorded as being sent to this market in 2014 and those that were declared as moved from this market, but did not receive this information.

5.2.3 Slaughter for dispatch of fresh pig-meat to other Member States

The channelling conditions set in Commission Decision 2008/855/EC were amended (and eased) by Commission Decision 2013/764/EU in December 2013. In order for pig-meat to be eligible for the EU market, pigs need to be resident of the holding of origin for at least 90 days with no introduction of pigs for the last 30 days. Holdings shall implement a bio-security plan and be subject to bi-annual inspections. In addition, the holdings are either subject to sampling and laboratory testing at least every three months, or they are subject to such sampling at least once a year, in which case a clinical examination following procedures laid down in points 1 and 3 of Part D of Chapter IV of

the annex to Decision 2002/206/EC must be performed by an OV.

Although the audit did not focus on this aspect, the audit team noted that:

- An instruction was issued by the CCA to the RCAs on the requirements of Decision 2013/764/EU, for their transmission to the relevant stakeholders.
- The control and monitoring programme for Romania does not foresee quarterly sampling and testing of industrial holdings. Therefore clinical inspections were performed as foreseen by Decision 2013/764/EU. These were delegated to CVs . Their performance was not reviewed in the context of the bi-annual official inspection of the holdings by the OV. In the industrial holding approved for the EU market, the CV was not complying with the standard requirements (no temperature taken, number and location of pigs checked was not recorded);
- The certificates arriving at the slaughterhouse visited did not indicate if the holdings of origin were approved for the EU market. The OV indicated that she could check this on-line if she needed it; however, these checks were not documented and internet access was only available at the operator's directorial office;
- The certificates arriving at this slaughterhouse did not indicate whether the batches arriving had been subject to the required clinical inspection intended for animals the meat of which is destined to the EU market;
- The slaughterhouse received animals both from EU approved and non-approved holdings. The OV indicated that they had two type of health marks and had time-separation protocols for each category. No supervision or verification of the official controls performed on checks of origin, traceability and separation of both standards was organised by the RCA; no instruction from the CCA was issued on this aspect.
- The CCA indicated that they recently performed targeted inspections on general traceability in two slaughterhouses. They resulted in the suspension of approval of one of them, and prosecution of the owner. The experience would be used for controls at national level.

Conclusions

The ambitious system for traceability of pigs established by the CA in the context of an important tradition of backyard rearing in Romania (with individual identification at a young age) is undermined by the absence of routine observation and enforcement of the rules for movement of pigs.

The identification of pigs during compulsory visits of CVs to backyard holdings had limited impact on the improvement of traceability (no investigation of the origin of pigs present) and none on the observance of movement rules (no sanctions). The operation of markets that are known but not authorised by the CA and the unclear legal basis for sanitary requirements in markets indicate that these are not effectively controlled. The enforcement exercised through roadblocks is not only of limited impact but useless if the baseline causes are not addressed.

Recommendation 2 of the FVO report 2013-6789 (on sanctions in case of non-compliance on identification and movements in backyard holdings) has not been satisfactorily addressed.

The system in place concerning the conditions of eligibility of pig-meat for the EU markets does not guarantee that these conditions are met. The development of a plan of inspections and investigations

on traceability in slaughterhouses may uncover fraudulent practices but does not address the structural deficiencies of this system.

5.3 SURVEILLANCE IN DOMESTIC PIGS

Legal requirements

Council Directive 2001/89/EC; Commission Decision 2002/160/EC; Commission Decision 2013/722/EU.

Findings

5.3.1 Active surveillance

The elaborate system for active surveillance was described in previous audit reports.

The 2014 control and monitoring programme included:

- in backyard holdings: sampling of breeding sows in all holdings in spring, targeted sampling in summer in a selection of holdings around industrial holdings along the border with Ukraine and Serbia, as well as areas surrounding cross-border posts with Moldova and in randomly selected holdings in each county in autumn;
- in type A holdings: all breeding sows and boars and a proportion of other categories of pigs;
- in industrial holdings: a proportion of all categories of pigs.

The audit team noted that:

- The CCA restricted sampling of breeding sows to those of less than 48 months in order to avoid possible interference with vaccine-induced antibodies. Only sows either pregnant or with piglets were sampled: this represented around 50,000 sampling out of around 150,000 eligible animals (between 14 and 48 months). At the time of the audit, around 50,000 sows over 48 months were registered in backyard holdings ;
- Data showed that many more sows were sampled compared to the number of registered eligible sows in six counties. In five other counties, the rate of sampling was only between five and ten per cent;
- In line with the response to recommendation 4 from 2013-6789 FVO report, the design of the summer sampling campaign in backyard holdings was modified: the selection of holdings and pigs was still performed at central level, using information available in the database, but when the CV did not find the selected animals, no replacement was sought (in line with indications in the report). The result was that 92% of selected holdings and 89% of selected pigs were effectively sampled; only one county had low performance (46% and 44% respectively for holdings and pigs). More than 118,000 pigs were sampled during this campaign.
- In the case of seropositive results, restriction of movements were applied and documented. Further epidemiological and laboratory investigations were performed, leading to a conclusion that the results were not due to CSF.

5.3.2 *Passive surveillance*

The main features of the 2014 control and monitoring programme for passive surveillance of domestic pigs included:

- Monitoring of sick or dead pigs and sampling of pigs with compatible clinical signs or sent to emergency slaughter; sampling of all sows which have aborted (or for industrial holdings, only when the abortion rate is above their average rate);
- Visit and formal clinical inspections of all backyard holdings by a CV in spring and autumn;
- Clinical monitoring of pigs in type A and industrial holdings prior to certification of movement of pigs;
- Clinical inspection by an OV twice a year of type A and industrial holdings.

In order to illustrate the effectiveness of passive surveillance throughout the country (recommendation 5 of FVO report 2013-6789), data were collected on samples submitted from each category of holdings to demonstrate how it functioned.

The audit team noted that:

- In addition to the surveillance present in the programme, surveillance at slaughterhouses (through *ante mortem* and *post mortem* inspections) was documented and subject to recent reminders from the RCA at the place visited.
- On the other hand, the large number of pigs from backyard holdings, the fate of which is unaccounted for (see section 5.2.1. on pigs sent to virtual holding), includes pigs which are not slaughtered in slaughterhouse, and for which no *ante mortem* and *post mortem* inspections is required by national legislation.
- The programme did not include clinical inspection in backyard holdings prior to movement of pigs as an element for passive surveillance.
- 87% of all registered holdings (with or without pigs) were subject to a documented visit by a CV in 2014 (995,130 out of 1,143,841). Five counties had a rate of visit below 70%. The report did not take into consideration the number of holdings in which pigs were effectively found and for which a clinical report was effectively issued. Nevertheless, the high rate of active surveillance performed in summer (high percentage of pigs identified from the database actually found in the holdings visited) gives an indirect indication of the effectiveness of these visits. The county of Bucharest has few holdings but none was subject to visit (or surveillance).
- Close to 4,500 samples were submitted from backyard or type A holdings in the framework of passive surveillance for the first semester of 2014, which are less than in 2013 (where 12,000 samples had been submitted in the first 8 months). These came from all counties except Bucharest. No differential surveillance strategy had been developed by the CCA. A relatively more intense surveillance was performed in counties bordering Serbia.
- For the same period, samples were taken from 290 industrial holdings (202 abortions, 1,369 sick pigs, 1,157 dead pigs). Most counties with industrial holdings had samples analysed in the framework of passive surveillance, but two counties, with 10 and 13 industrial holdings, had no sample submission from these holdings.
- The operator of the type A holding visited by the audit team indicated that he never had any sick or dead pigs in his holding of 268 pigs. This was not challenged by the CV or the OV who performed inspections and controls of the registers despite the very poor sanitary

conditions in which the pigs were kept.

- The CCA indicated that instructions for passive surveillance in commercial holdings were modified in 2014: increased mortality was to be subject to sampling and testing only in case of clinical signs compatible with CSF. One industrial holding visited experienced sustained mortality over several days. The veterinarian in charge did not perform any necropsy nor sent any sample for analysis; mortality was attributed to the poor condition of pigs brought from another MS three weeks earlier.
- None of the samples sent on the basis of passive surveillance in 2014 was subject to differential diagnosis with African swine fever. The CA explained that the increased focused surveillance for CSF triggered laboratory investigations while the occurrences were not considered as clinical suspicion nor legally notified as such (and therefore also not under official movement restriction), thus in contradiction with the instructions to restrict investigations to clinical signs compatible with CSF.

Conclusions

The elaborate active surveillance programme in domestic pigs is implemented and monitored so that it can demonstrate its effectiveness. No evidence of virus circulation was identified. Although the programme was not completely implemented as approved, and suffered from regional variations, the intense coverage and improved performance in backyard holdings bring a reliable picture; recommendation 4 of FVO report 2013-6789 has been addressed.

The capacity of early detection in commercial holdings is affected by the low standard of submission of samples and the insufficient veterinary supervision and investigations in some holdings visited. The adoption and verification of a clear strategy for surveillance is lacking, as demonstrated by the inconsistency between the focus of investigations to cases with compatible clinical signs and the absence of differential diagnosis with African swine fever (and absence of official restrictions measures).

Passive surveillance in backyard holdings, which is structurally of a lower grade (because of the absence of veterinary inspection for on-farm slaughter), suffers also from the lack of traceability of pigs in this sector and the lack of controls at markets. In this context, the reduced submission of samples from these holdings affects the chances of early detection of the introduction of the disease.

While the early warning system reporting suspect cases of CSF is functioning throughout the country, its effectiveness is impaired by the above conclusions: recommendation 5 of FVO report 2013-6789 was only partially addressed.

5.4 SURVEILLANCE IN WILD BOARS

Legal requirements

Council Directive 2001/89/EC; Commission Decision 2002/160/EC; Commission Decision 2013/722/EU.

Findings

The programme requires sampling, for serological and virological testing of all hunted wild boars in the country. Dead wild boars must also be reported to the CA. Surveillance is concentrated during the hunting season (from October to March), and few samples are submitted outside this period.

The formal framework for implementation of the surveillance programme in wild boars has been further strengthened by Order No.359/2014, obliging the managers of hunting grounds to provide

assistance to the territorial sanitary veterinary authority for sampling, packing and submission of samples for laboratory testing as well as notification of wild boars found dead (thus addressing recommendation 1 of FVO report 2013-6789).

The results of the sampling during the last two hunting seasons are as follows:

Season	Population	Wild boars hunted	Wild boars sampled	Serology	FAT	PCR
2012/2013	77,700	20,200	12,200	6,900	11,700	11,900
2013/2014	77,800	22,300	14,200	10,500	14,000	14,100

(source: CCA)

During the 2013/2014 hunting season, three CSF seropositive wild boars were identified in two hunting grounds in two counties at the border of Ukraine and Moldova.

Since the beginning of 2014, six samples of wild boars found dead were submitted for analysis; they were seven such samples submitted for the whole year 2013.

The audit team noted that:

- Representatives of the hunting grounds visited were aware of legal requirements and their responsibility in relation to the sampling of wild boars and submission of samples to the laboratory. Evidence of their training by the RCA was available.
- Since the start of the 2014/2015 hunting season sampling forms have been amended. The new sampling form allows for grouping the hunted wild boars into three age categories (<1 year, 1 to 2 years, >2 years). This allows for more specific age categorization of hunted wild boars compared to descriptive categories (young, mature, adult) in sampling forms used during the past hunting season.
- Around 60 to 65% of the hunted wild boars were subject to sampling (tissues and/or serum), with a great variation among counties. Serological analysis was performed on 34% and 47% of the wild boars hunted for 2013/2013 and 2013/2014 season respectively. In 2013/2014, no wild boars were serologically tested in one county and limited information on the serological status of the wild boar population was available in four other counties. The same counties also had very poor rates of serological analysis for the previous year.
- Less variation was observed in implementation of virological testing. The county which did no serology tests had only one sample tested for virus detection (for a total of 219 wild boars hunted).
- The implementation of the program at hunting ground level level is monitored by the RCAs, which provide quarterly reports to the CCA. No active monitoring is in place: the RCAs are not required by the CCA to compare the number of samples submitted with the number of hunted wild boars during the campaign (which would allow corrective actions if required) and the CCA does not investigate the counties with poor performances at the end of the season.
- No plan was in place to improve the monitoring of the compliance with the obligation of sampling during the current hunting season and there was no coordination with the authority responsible for Order 259/2014 (Forestry Department) in place for a control of sampling during the hunting season.
- A documented epidemiological investigation was carried out in the three seropositive cases and samples were further analysed by the NRL. The epidemiological investigations concluded that seropositivity was due to vaccination carried out in 2011 or earlier. The

hypothesis that seropositivity could be due to another factor was not debated and no additional sampling and testing was required in order to evaluate the CSF status in the whole habitat of these wild boar meta-populations. All three seropositive animals were described as being mature (1 to 2 years) at the time of the sample submissions. Following the seropositive results, their age category was reviewed by an OV and they were declared as being older than 4 years. The CA explained that this re-categorisation was made following further examination of the carcasses when seropositive results were obtained; however, in one case, the carcass of the wild boar had been released by the hunting ground three days before completion of the serological analysis (on the day of the negative virological analysis).

- All samples from dead wild boars were submitted to the NRL for diagnosis of classical and African swine fever. The CCA explained that there were very few reports of wild boars found dead because of the presence of predators (wolves, bears) making it difficult to find them. Wild boars killed (e.g. road accidents) are not explicitly considered for sampling in the approved programme or the Order 359/2014.

Conclusions

The current level of implementation of CSF surveillance in wild boars provides for an adequate and reliable picture of CSF status in wild boar populations in major parts of the country.

However, the conclusion of the absence of virus circulation in wild boars at the country level suffered from the lack of timely investigation and effective corrective actions to remedy consistent under-sampling in certain areas. No system is in place to effectively use the newly adopted legal powers to enforce cooperation of hunters during the hunting season: if not quickly corrected, the implementation of surveillance during the on-going hunting season will be a missed opportunity to address these remaining uncertainties.

The capacity of early detection of recurrence or new introduction of CSF is reduced by the low numbers of dead wild boars reported (together with the unclear requirement of the reporting of killed animals) and the concentration of hunting activities during half of the year. It is also undermined by the current procedure of attributing seropositive results to former vaccination without investigating alternative possibilities.

5.5 LABORATORIES

Legal requirements

Articles 11 & 12 of Regulation (EC) No 882/2004; Article 17 of Council Directive 2001/89/EC

Findings

At the time of the audit, the laboratory network for testing for CSF in Romania consisted in county laboratories (37 for ELISA testing, 38 for fluorescence antibody tests (FAT) and 15 for PCR) and a NRL. County laboratories are appointed by the CCA, taking into account the requirement for them to be accredited according to ISO/EN 17025 (using the methods under the scope of accreditation).

Diagnostic kits are validated by the NRL. County laboratories manage their orders of kits independently (the centralisation of orders was considered but eventually rejected as it would have been less flexible); the kit provider must supply the laboratory with a certificate of validation from the NRL.

All samples for passive or active surveillance can be sent to any county laboratory, except for samples from wild boars found dead. These are sent to the NRL, for their concurrent testing for African swine fever. The laboratory performs the tests for which it is accredited and if need be, sends the samples to another accredited laboratory for further testing. All samples giving positive ELISA results are sent to the NRL which performs virus neutralisation tests, including differential analysis for other pestiviruses.

The audit team noted that:

- The NRL organises annual ring tests for PCR, FAT and ELISA; in 2013, all results were satisfactory for the country laboratories.
- 105 serological samples from domestic pigs gave positive ELISA results; these were sent to the NRL which followed the diagnostic pathway (virus neutralisation test), .
- The process of validation of kits was adequately documented; a case of shortage of kits from one county laboratory did not trigger major disruption, as other county laboratories took over the task, and the network reports to an integrated laboratory information management system.
- None of the county laboratories which received samples of domestic pigs with clinical signs compatible with CSF sent samples to the NRL for further differential diagnosis with African swine fever.

Conclusions

Laboratory support for official activities in the framework of the control and monitoring programme for CSF is well organised and delivers reliable results. Analyses of clinical suspicions of CSF in domestic pigs did not consider African swine fever as a differential diagnosis.

6 OVERALL CONCLUSIONS

The well organised and elaborate system for active surveillance in domestic pigs is auditable. Its weaknesses do not significantly affect the confidence in the status of the country for CSF in domestic pigs (where the last CSF case reported was in 2007), which is supported also by a passive surveillance system in a largely susceptible (non-vaccinated) pig population.

In wild boars, the intense active surveillance coverage and the implementation and monitoring of surveillance, give a reliable picture supporting the absence of the circulation of CSF virus in the populations investigated. However, the absence of corrective actions in certain areas with consistently low surveillance prevents drawing conclusions for the whole territory.

The capacity for early detection of CSF in domestic pigs is hampered by the largely uncontrolled movements of pigs in the non-commercial sector. The lack of a (geographically) risk-based strategy for surveillance and the general lower grade of investigation in commercial holdings also represent factors hindering the capacity of the competent authorities for early detection of resurgence of CSF (or incidentally, of introduction of African swine fever). The capacity for early detection of CSF in wild boars is affected by the low number of dead wild boars analysed and by the dismissal of the few suspect cases without sufficient epidemiological evidence.

The general lack of enforcement of movement conditions for pigs in the backyard sector (including market operations), already identified in previous reports, has not been addressed. This undermines

the capacity of the CA to perform efficient surveillance (including for detection of illegal imports of pigs from third countries) and to control the situation in cases of introduction of the disease.

7 CLOSING MEETING

The closing meeting was held on 10 November 2014 with representatives of the CCA. At this meeting, the main findings and conclusions of the audit were presented by the audit team. The representatives of the CCA agreed with the description and findings. They indicated that had submitted an African swine fever surveillance strategy (in a buffer zone with third countries) to the Commission and pending its approval, were considering starting it on wild boars. They also mentioned that in the future they would review the requirements of compulsory visits of CVs to backyard holdings as according to them, it had a deterrent effect on notification of suspect cases.

8 RECOMMENDATIONS

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

N°.	Recommendation
1.	In order to ensure that all feral pigs shot or found dead are reported and inspected by an official veterinarian and examined for classical swine fever, as required by Article 15(2)(c) of Council Directive 2001/89/EC, and proposed in the monitoring and control programme approved by Commission Decision 2013/722/EU; to urgently review the supervision system for submission of samples from wild boar shots, so that corrective action can be taken when needed; to develop awareness of the relevant stakeholders on the need to report any feral pig found dead (including road kill).
2.	To ensure that all veterinarians performing official tasks are known by the Competent Authorities, in order for them to ensure that requirements for staff are met (i.e. they are free from conflict of interest and they receive training, information and instruction).Articles 4(2)(b), (6) and 8(1) of Regulation (EC) No. 882/2004
3.	To ensure that Order no. 16/2010, referred to in the approved control and monitoring programme approved by Commission Decision 2013/722/EU, is applicable to pigs, and is enforced; to clarify the supervision of “unapproved” registered markets, and to ensure that traceability requirements are known, applied and enforced for all markets (including at least: an updated list of all markets, specifying the keeper; presence of an up-to-date register of movements, including origin and destination with documents provided from the keepers of origin and destination).Article 3(1)(a), 4(1) and 4(2)(b) of Council Directive 2008/71/EC; Articles 54 and 55 of Regulation (EC) No. 882/2004.
4.	To enforce the requirement of identification marks being applied before animals leave their holding of origin, and the requirement of an up-to-date register of movements

N°.	Recommendation
	(including the date, the origin or the destination, and the identification marks) in backyard and type A holdings. Article 4(1) and 5(1)(a) of Directive 2008/71/EC; Articles 54 and 55 of Regulation (EC) No. 882/2004.
5.	To review the certification system and its supervision in order to ensure that the conditions laid down in Article 4 of Commission Decision 2013/764/EU are respected for fresh meat dispatched to other Member States.
6.	To review the passive surveillance strategy in order to ensure that suspicions of CSF, in line with the main criteria described in Chapter III of Annex to Decision 2002/160/EC, lead to adequate investigations and control.
7.	To ensure further that investigations are carried out as quickly as possible to confirm or rule out CSF in case of detection of antibodies in feral pigs. Point C(4) second indent of Chapter VII of the Annex to Commission Decision 2002/106/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=2014-7045

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 1069/2009	OJ L 300, 14.11.2009, p. 1-33	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
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
Dir. 2008/71/EC	OJ L 213, 8.8.2008, p. 31-36	Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (Codified version)
Dec. 2000/678/EC	OJ L 281, 7.11.2000, p. 16-17	2000/678/EC: Commission Decision of 23 October 2000 laying down detailed rules for registration of holdings in national databases for porcine animals as foreseen by Council Directive 64/432/EEC
Dec. 2002/106/EC	OJ L 39, 9.2.2002, p. 71-88	2002/106/EC: Commission Decision of 1 February 2002 approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever
Dec. 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. 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)

Legal Reference	Official Journal	Title
Dec. 2013/722/EU	OJ L 328, 7.12.2013, p. 101-117	2013/722/EU: Commission Implementing Decision of 29 November 2013 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 2014 and the following years
Dec. 2013/764/EU	OJ L 338, 17.12.2013, p. 102-106	2013/764/EU: Commission Implementing Decision of 13 December 2013 concerning animal health control measures relating to classical swine fever in certain Member States