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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ROMANIA

FROM 18 TO 22 JULY 2011

IN ORDER TO AUDIT THE PROPOSED CHANNELLED SYSTEM FOR THE PRODUCTION
OF PIG MEAT

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

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Romania, which took place between 18 and 22 July 2010

The purpose of the audit was to evaluate the implementation of a proposed channelled system for the production of pig meat. The objective of this is to provide a reliable basis for the official certification of pig meat and meat products, derived from within the system, to allow them to be placed on the EU market. The conclusions of this audit are as follows:

The proposed channelled system, as specified in the Position Paper, has the potential to function effectively, given some relatively minor amendments. Insufficient time has been available to the CA to devise, implement and verify the correct functioning of the system.

The initial preparatory work and the initial audits of the system were professionally carried out. However, the follow-up audits, aimed at verifying correction of the deficiencies identified in the system, are unreliable.

Recent changes to the national CSF eradication programme and the fact that the new programme has not been formally submitted to the Commission, coupled with the poor implementation of the programme in 2010 and the first semester of 2011, undermine confidence in this prerequisite for the channelled system.

The well developed biosecurity and traceability systems in the proposed channelled system provide a high level of protection for these establishments. However, while the Position Paper envisages enhancement of official controls in the channelled system farms, this had not been fully implemented at the time of this audit and official controls were insufficient, with an almost total delegation of competence to the private operator, with very little official oversight.

Significant efforts have been made to enhance official controls in backyard holdings. However, it is not yet possible to determine the effectiveness of these efforts and significant difficulties remain, particularly in relation to ensuring the impartiality of concessionary veterinarians when performing official tasks.

Overall, the poor implementation of the national CSF eradication programme, particularly in the wild boar population and backyard holdings in the months prior to implementation of the channelled system, coupled with the deficiencies in official controls, reduce the reliability of the proposed channelled system at this time, despite the effectiveness of biosecurity and traceability systems in channelled system establishments.

The report makes a number of recommendations to the Romanian competent authorities, both in relation to general official controls and to controls of the proposed channelled systems, 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

Abbreviation	Explanation
CA	Competent Authority
CCA	Central Competent Authority
CSF	Classical Swine Fever
CV	Concessionary Veterinarian
EDTA	Ethylenediaminetetraacetic acid
ELISA	Enzyme Linked Immuno-Sorbent Assay
EU	European Union
FAT	Fluorescent Antibody Test
FVO	Food & Veterinary Office
MS	Member State (of the EU)
NSVFSA	National Sanitary Veterinary and Food Safety Authority
RT-PCR	Reverse Transferase-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 18 to 22 July 2011. The audit was added to the Food and Veterinary Office (FVO) planned programme on the request of the Romanian authorities. The audit team comprised two auditors from the FVO.

The FVO team was accompanied throughout the audit by representatives from the central competent authority (CCA), the National Sanitary Veterinary and Food Safety Authority (NSVFSA).

An opening meeting was held on 18 July 2011, with the central competent authority. 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 objective of the the audit was to assess the implementation and effectiveness of the proposed channelled system for pig meat and meat products production in Romania, intended for placing on the EU market (as outlined in the Position Paper of 30 March 2011, submitted by the Romanian authorities to the European Commission – see section 4 below; hereinafter referred to as the Position Paper).

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

MEETINGS / VISITS			COMMENTS
COMPETENT AUTHORITIES	CENTRAL	2	OPENING AND CLOSING MEETINGS
	COUNTY	2	SVFSD: ARAD & TIMIS
	LOCAL (ZONAL)	2	1 ZONAL OFFICE: ARAD MEETING WITH ZONAL & OFFICIAL VETS: TIMIS
PIG FARMS		2	CHANNELLED SYSTEM
SLAUGHTERHOUSE		1	CHANNELLED SYSTEM

3 LEGAL BASIS

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

In addition, the audit was carried out on request of, and with the agreement of the Romanian authorities.

EU legislation of relevance to this audit is listed in the Annex to this report and refers, where applicable, to the last amended version.

4 BACKGROUND

Romania is not recognised as free from Classical Swine Fever (CSF) and is currently listed in Part III of the Annex to Commission Decision 2008/855/EC. As a consequence, pig meat and meat products derived from pigs reared in Romania may not be dispatched to other Member States.

There has been no recorded case of CSF in Romania since 2007. There is an annual programme of surveillance for CSF (the national Programme for the Eradication, Monitoring and Control of Classical Swine Fever in Romania – hereinafter “the National CSF programme) which is co-financed by the European Union under Council Decision 2009/470/EC, and which aims to demonstrate freedom from CSF in Romania. The programme for 2011 has been approved by the EU by Commission Decision 2010/712/EU.

The pig industry in Romania comprises two main sectors: commercial farms and non-professional farms (backyard holdings). In addition, there is a significant population of wild boar in Romania. CSF vaccination of domestic pigs in commercial farms was banned in April 2007. Vaccination of pigs in non-professional holdings and of wild boar ceased in December 2009.

On 30 March 2011, the Romanian authorities submitted a “Position Paper” (a copy of which is annexed to this report), laying down animal and public health criteria for the approval of a channelled system from which Romania may place fresh pig meat and pig meat products on the European market. This paper was presented at a SCoFCAH meeting on 4 April 2011. The channelled system is intended to be a temporary measure.

The Position Paper provides an undertaking that Romania will “implement active and passive CSF surveillance ... in accordance with the programs for disease surveillance, control and eradication, annually approved through Commission Decisions”. The strategy outlined in the Position Paper envisages additional controls in channelled system establishments and the reinforcement of controls in the non-professional farms in their vicinity. Pigs, originating in Romania, intended for slaughter for production of meat and meat products to be placed on the EU market would be derived, only, from commercial herds meeting the additional conditions specified in the Position Paper.

On 2 June 2011, the Romanian authorities wrote to the Commission, indicating that a documentary check of establishments (commercial farms and slaughterhouse) applying for inclusion in the channelled system had been completed and that audits of the establishments, by teams from central and local level, were in progress. The letter foresaw the completion of audits by 1 July, stated that the audit reports would be sent to the Commission services and requested an FVO audit be carried out when this had been done.

A further letter was sent on 9 June 2011. This letter informed the Commission that audits had been completed, by twelve teams, consisting of specialists from the NSVFSA and the County Sanitary Veterinary & Food Safety Directorates (SVFSD), during the period 30 May to 3 June 2011. It further stated that, while most of the criteria had been fulfilled, some non-compliances had been found; the company concerned had provided plans of corrective actions intended to remedy non-compliances by 19 June. The Romanian authorities further informed the Commission that, from 20 June 2011, “an audit team of NSVFSA will go on the spot in order to check the implementing of the corrective actions ...” and that the results of this audit would be sent “up to 27.06.2011”. The letter also stated that some non-compliances had been found regarding the official control activities performed by the veterinary services from local and regional levels, that these had been communicated to the County SVFSD audited, and that these non-compliances would be remedied “within the deadline established”.

A third letter was sent on 28 June 2011, stating that, in the period 20 – 23 June, an audit team consisting of specialists from the NSVFSA and County SVFSDs had carried out the follow-up audit in pig farms and the pig slaughterhouse and that “the non-compliances ... had been remedied up to 19 June 2011”. The Romanian authorities informed the Commission that “those units are fully in

compliance with the veterinary criteria and requirements provided for in the Position Paper”, and requested that an FVO audit of the system be organised in July 2011.

5 FINDINGS AND CONCLUSIONS

The channelled system is based on a number of essential elements: the National CSF Programme, CA audits of the channelled system establishments, official controls in channelled system establishments and in the 10Km zones around these establishments, biosecurity in channelled system establishments and traceability of live pigs and meat within the system.

5.1 NATIONAL PROGRAMME FOR THE ERADICATION, MONITORING AND CONTROL OF CSF

5.1.1 Recent amendments to the Programme

The Romanian authorities have recently made significant changes to the approved programme. The revised programme has been enshrined in Romanian legislation, by Order 31 of 8 July 2011, but it has not yet been officially submitted to the Commission for approval.

The stated objective of the revised programme is to increase the sensitivity of the surveillance in backyard holdings in the 10 Km radius around all commercial farms in Romania, including the farms proposed for the channelling system.

The FVO team found the following in relation to the design and implementation of this new approach:

- All backyard holdings have been identified, and animals therein accounted for, within the areas around the 304 commercial farms all over Romania;
- Two types of blood samples (with and without anticoagulant) are planned to be taken at the same time in order to carry out:
 - serological testing with an ELISA, targeting detection of antibodies against the E2 protein of the CSF virus, and
 - whole blood testing with RT-PCR to detect the presence of the CSF virus.
- The NSVFSD has provided each county SVFSD with a detailed table indicating how many samples need to be taken in each commune/village (considered as an epidemiological unit) during the second half of 2011. For instance, in the case of the areas around the farms proposed for the channelling system in county Arad:
 - The number of holdings identified per epidemiological unit varies between eight and 887, with the vast majority having between 20 and 200;
 - The number of animals per epidemiological unit shows a very broad range. A small proportion have 20 to 100 animals, the majority have between 100 and 700, and a small number have between 1 000 and 5 000 animals;
 - The number of samples planned to be taken per epidemiological unit varies between 38 and 60. These samples will not be collected contemporaneously, but will be divided into monthly collections for the remaining six months of 2011. On average between five and ten samples will be collected monthly from each epidemiological unit.
 - Planned sampling targets have been allocated for the areas around other commercial farms (not included in the proposed channelled system) in the same county. Examples include: 19 samples over six months for an epidemiological unit with 22 animals; and 30 for epidemiological units with 1 200 to 4 300 animals.

- According to the NSVFSD, the number of samples mentioned above has been calculated so that the surveillance system could detect an animal-level prevalence of 10% with a 95% level of confidence in each epidemiological unit. However, while the total number of samples planned could, in principle, support this level of assurance, the manner in which implementation is envisaged would not:
 - The revised programme does not take into account the diversion from the design caused by the breaking down in time of the sampling numbers, which does not allow detection of the estimated prevalence of the disease within the studied population. For example, a sample size of five animals taken from a population of 250, would allow detection of a 50% prevalence estimate at a certain time, but not of 10%. Likewise, a sample size of ten animals taken from a population of 1400, would allow detection of a 30% prevalence estimate, but not of 10%;
 - The programme assumes a homogeneous distribution of the risk of acquiring CSF within the epidemiological units, which given the varied range of the number of holdings per epidemiological unit and the geographical spread of some of them, seems to be questionable. This factor needs to be better incorporated into the epidemiological design by using two different estimates of prevalence, one for between-holding prevalence (estimate for the number of holdings that would most likely be infected in each epidemiological unit) and another one (the one used) for within-holding prevalence (estimate for the number of animals that would most likely be infected in each holding);
 - All above mentioned calculations need to take into account estimates for the sensitivity and specificity of the diagnostic systems, both at holding and individual animal levels. Initial scrutiny of the revised plan indicates that these factors have not been thoroughly evaluated and determined.
 - Selection of holdings and animals to be sampled, if used to complement all the above mentioned calculations, needs to be done randomly as this is a pre-requisite for the validity of the survey as a whole. According to the explanations given by representatives of the county veterinary services and both of zonal and concessionary veterinarians, sampling is largely risk-based and targets certain holdings according to a perceived higher risk of CSF based on factors such as their size, number of movements and proximity to areas with wild boars or commercial farms. This, despite being very appropriate to enhance the sensitivity of the surveillance system as a whole, completely biases the performance of this specific survey, limits the validity of the results obtained and raises questions on the cost-effectiveness of the initiative.
- Surveillance on backyard holdings has been delegated to Concessionary Veterinarians (CV – private veterinarians approved for the performance of some official tasks) responsible for the commune/village where they are situated as this is considered the epidemiological unit for the surveillance. Given the possible conflict of interest, it is essential that supervision by the zonal veterinarian is effective (see section 5.3.2 below).

Some of the CSF testing in the 10Km zones around commercial pig farms, described as “additional” in the Position Paper on the Channelled System, has been subsumed into the revised programme.

Given that the revised programme came into effect on 8 July 2011, it was not possible to evaluate implementation of this programme.

5.1.2 Implementation of the National CSF Programme 2010 and 2011 (first semester)

The implementation of the programme for 2010 and 2011 (first semester) was evaluated for the two counties (Arad and Timis) in which the majority of channelled system farms are located (there is one channelled system farm in each of two other counties: Bihor and Caras-Severin).

The figures provided for 2010 for Bihor and Caras-Severin are identical for all categories, both in relation to targets and actual samples collected.

5.1.2.1 Commercial Farms

The strategy outlined in the eradication programme for 2010 contains two main elements:

1. Active surveillance: Sampling of fattening pigs and non-vaccinated sows for the detection of antibodies to CSF virus. These samples to be tested using an Enzyme Linked Immuno-Sorbent Assay (ELISA).
2. Passive surveillance: Collection of samples from:
 - diseased pigs exhibiting clinical signs compatible with CSF,
 - dead pigs with lesions compatible with CSF and
 - other dead pigs.

Initial testing of these samples to be tested using Fluorescent Antibody Test (FAT) for detection of viral antigen and/or Reverse Transferase – Polymerase Chain Reaction (RT-PCR) for detection of viral RNA.

The 2010 programme set targets for each of the tests to be applied. Data were provided by the NSVFSA to the FVO team on the out-turn of the 2010 programme in Arad and Timis counties (within this data, targets were provided for Arad which differed slightly from those in the programme). The following table summarises the data provided:

Samples collected: 2010		Number of samples		
County		ELISA	FAT	RT-PCR
Arad	Planned (2010 programme)	2704	2280	812
	Planned (data provided to FVO team)	1826	2096	598
	<i>Collected</i>	<i>1807</i>	<i>2091</i>	<i>138</i>
Timis	Planned (2010 programme)	4900	4200	1392
	<i>Collected</i>	<i>3807</i>	<i>6353</i>	<i>33</i>

The following table provides data on the implementation of the 2011 plan to date:

Samples collected: 2011 (1 st semester)		Number of samples		
County		ELISA	FAT	RT-PCR
Arad	Planned (2011 programme)	700	2500	350
	Planned (data provided to FVO team)	845	1670	93
	<i>Collected (1st semester)</i>	<i>941</i>	<i>2171</i>	<i>62</i>
Timis	Planned (2011 programme)	5000	4900	2500
	<i>Collected (1st semester)</i>	<i>2031</i>	<i>257</i>	<i>0</i>

Within commercial (including Channelled System) farms, all official eradication programme samples, both active and passive, are collected by veterinarians employed by the farms. There is no official supervision or verification that samples have been collected in accordance with requirements.

5.1.2.2 *Non-professional farms (backyard holdings)*

The strategy outlined in the 2010 eradication programme for backyard farms is similar to that for commercial farms. Each village is considered as an epidemiological unit:

1. Active surveillance: Sampling of non-vaccinated pigs over six months of age (sampling scheduled for the second semester of 2010) for the detection of antibodies to CSF virus. using the ELISA test.
2. Passive surveillance: Collection of samples from:
 - diseased pigs detected during regular clinical examinations, showing signs compatible with CSF. Blood samples to be tested by RT-PCR.
 - dead pigs with lesions compatible with CSF (organs and sternum for testing by RT-PCR and FAT) and
 - other dead pigs (organs and sternum for FAT).

The following table provides data on the implementation of the 2010 and 2011 (1st semester) programmes:

County	Year		No. of samples		
			ELISA	FAT	RT-PCR
Arad	2010	Target (Approved programme)	7830	620	120
		Target (data provided to FVO team)	0	648	614
		Collected	0	282	12
	2011	Target (Approved programme)	0	820	120
		Target (data provided to FVO team)	295	115	9
		Collected	298	179	0
Timis	2010	Target (Approved programme)	9077	860	200
		Target (data provided to FVO team)	-	-	-
		Collected	0	197	0
	2011	Target (Approved programme)	0	1060	200
		Target (data provided to FVO team)	-	-	-
		Collected	0	0	0

5.1.2.3 Wild boar

In relation to sampling of wild boar, the 2010 and 2011 programmes are the same. The main elements of the programmes are:

1. Virological surveillance:

- RT-PCR and FAT testing of all wild boars found dead or injured;
- RT-PCR testing of all hunted wild boar below 1 year of age and of all hunted wild boar over 1 year of age showing lesions suspicious of CSF;
- FAT of all hunted wild boar (irrespective of age).

2. Serological surveillance:

- ELISA testing of samples from animals less than 1 year old (sampling strategy varies between counties depending on when vaccination for CSF was terminated; the

criteria specified here apply to Arad and Timis counties where vaccination ceased in late 2009).

During the visit to the SVFSD in Arad, the FVO team met with a representative of a hunting association who explained:

- All hunting is organised by the hunting associations, usually at weekends;
- Each hunting party is supervised to ensure that hunting quotas are respected;
- All carcasses are brought to a wild game collection centre where they may be sampled (both for Trichinella and for CSF);
- Hunters are aware of requirements and there is good co-operation between the hunting associations and the veterinary services in Arad.

The following table summarises the implementation of wild boar surveillance for CSF in Arad and Timis counties:

County	Year	Age	ELISA			FAT			RT-PCR		
			< 1 yr	1 – 2 yrs	> 2 yrs	< 1 yr	1 – 2 yrs	> 2 yrs	< 1 yr	1 – 2 yrs	> 2 yrs
Arad	2010	Target (Approved programme)	130	652		0	652		130	0	0
		Target (data provided to FVO team)	560	310	302	560	310	302	100	25	25
		Collected	586	244	207	586	244	207	0	0	0
	2011	Target (Approved programme)	150	1172	0	0	1172	0	150	0	0
		Target (data provided to FVO team)	400	150	50	400	150	50	300	0	0
		Collected	396	135	75	396	135	75	16	0	0
Timis	2010	Target (Approved programme)	150	712		0	712		150	0	0
		Target (data provided to FVO team)	-	-	-	-	-	-	-	-	-
		Collected	87	95	44	87	95	44	0	0	0
	2011	Target (Approved programme)	150	712		0	712		150	0	0
		Target (data provided to FVO team)	-	-	-	-	-	-	-	-	-
		Collected	113	16	55	113	17	55	0	0	0

In most cases, samples collected from hunted wild boar have been of sternum only, without other organs, such as tonsil, which are more suitable for testing. In addition, samples are usually frozen.

To date, no samples have been collected from wild boar found dead in either Timis or Arad.

Timis county borders on Serbia where CSF is present in the wild boar population. However, no additional risk mitigation measures have been put in place along this border, despite the fact that a number of commercial pigs farms, proposed for inclusion in the channelled system, are situated close to the border (the 10Km zones around these farms straddle the border).

Conclusions on National Programme for the Eradication, Monitoring and Control of CSF

The programme currently being implemented differs significantly from that approved by Commission Decision 2010/712/EU under Council Decision 2009/470/EC. It is not clear whether this programme has the capacity to demonstrate freedom from CSF in Romania.

In relation to active, sero-surveillance, there has been significant under sampling in 2010 and 2011, both in commercial and backyard holdings.

In relation to backyard pig holdings, during 2010 and the first 6 months of 2011, the programme was poorly implemented with sampling targets not met and an almost total absence of passive surveillance activity (particularly important in this sub-population). There was also a shortfall in passive surveillance in commercial farms during this period, in particular in relation to the collection of EDTA blood samples for RT-PCR testing from pigs showing signs compatible with CSF.

The collection of samples from wild boar in Arad was well organised, nevertheless sampling targets were not met. In Timis, there was significant undersampling, in particular, no samples for RT-PCR analysis were collected in 2010 or 2011 to date. No risk mitigating measures have been applied along the border with Serbia. Given that they represent the potential source of CSF for domestic pigs, the under implementation of the surveillance programme in wild boar undermines the effectiveness of the programme as a whole.

The National CSF Programme provides a foundation for the additional controls applied to the channelled system. The deficiencies in the implementation of the programme reduce the level of protection provided in relation to the channelled system and weaken the level of guarantee that could be provided in relation to it.

5.2 COMPETENT AUTHORITY (CA) AUDITS OF THE CHANNELLED SYSTEM

5.2.1 Initial audits

A number of applications were received from companies wishing to establish channelled systems and seeking approval. In most cases, pre-existing supply contracts, with farms that would not meet the requirements of the system, prevented companies from pursuing the issue further. One company was considered suitable for inclusion in the system. This company included a slaughterhouse, two feedmills and 48 pig farms, including breeding and fattening facilities. The slaughterhouse has undertaken to slaughter and process pigs and pig meat exclusively sourced from within the channelled system or imported from other Member States (MS).

Following a documentary check of submitted applications, an initial round of audits of establishments was carried out between 30 May and 3 June 2011. These audits were performed by teams made up of staff from NSVFSA central level and from local (SVFSD) veterinary services. A standard checklist was used and a standardised format of report produced. Reports, containing conclusions and recommendations, were produced promptly following each audit.

These audits were thorough and were carried out in a professional manner. The company concerned

provided action plans for the establishments with an undertaking that deficiencies would be rectified by 19 June 2011.

In addition to the audits of the establishments applying for inclusion in the channelled system, the NSVFSA also carried out audits of the local (SVFSD) veterinary services in Arad and Timis. These audits clearly identified the deficiencies in the implementation of the National CSF Programme described above. In addition, the official controls in backyard holdings and commercial farms were assessed. Virtually all of the difficulties and discrepancies subsequently found by the FVO team (see section 5.3 below) were identified in these audits.

5.2.2 Follow-up audits

Contrary to the statement made in the letter of 28 June 2011 from the Romanian to the Commission service that: “in the period 20 – 23 June, an audit team consisting of specialists from the NSVFSA and County SVFSDs had carried out the follow-up audit in pig farms and the pig slaughterhouse and that “the non-compliances ... had been remedied up to 19 June 2011”, the FVO team found the following:

- A small number of follow-up audits had been performed with the involvement of NSVFSA staff. The rest had been delegated to staff in the local veterinary authorities;
- Approximately two thirds of follow-up audit reports had not been received at central level;
- Many audit reports were not officially received at local level until 20 July;
- One zonal veterinary officer, who had carried out a follow-up audit on a channelled system farm, had not been requested to submit his report, either to the local or central CA.
- On one channelled system farm there was no record, in the well maintained visitors log, of the auditor having visited the farm on the day specified in the follow-up audit report.
- While the initial audits and the follow-up audits involving NSVFSA officials followed a defined format and structure based on the standard checklist, the majority of other follow-up audit reports did not.
- A small number of the follow-up audit reports indicated that some non-compliances remained outstanding.

Conclusions on CA audits of the channelled system:

The initial audits of the establishments applying for inclusion in the proposed channelled system were competently performed and demonstrate the capacity of the central competent authorities (CCA), as do the audits of the local veterinary services. From these audits, the Romanian authorities were aware of significant deficiencies in the implementation of the National Programme for the Eradication, Monitoring and Control of CSF in Arad and Timis and in the implementation of controls in backyard holdings.

The follow-up audits were not completed within the timeframe notified to the Commission services, were not systematic and their outcomes were not available to the CCA at the time the Commission services were informed that all deficiencies had been corrected. The findings in relation to one follow-up audit cast doubt on whether it was actually carried out.

5.3 OFFICIAL CONTROLS

At county level, the SVFSD is responsible, *inter alia*, for implementation of animal health controls. Under the SVFSD manager, one of three co-ordination managers is in charge of the County Animal Health Service. A number of official veterinarians are employed at county level. Each county is divided into zones, each headed by a Zonal Veterinarian. In addition, private veterinarians are appointed as Concessionary Veterinarians (CV) who, in addition to their private work on clients' farms, perform and are paid for official duties.

The FVO team examined files relating to a suspect case of CSF in 2010. This case had been efficiently and effectively dealt with in accordance with EU requirements.

5.3.1 Channelled system establishments

Within Timis, two official veterinarians have been appointed as Zonal Veterinarians, dealing exclusively with channelled system establishments.

In channelled system farms, official active sampling (for ELISA detection of antibodies to CSF) for the National CSF Programme, which should be performed as an official task, is carried out by veterinarians employed by the company which owns the farms.

In addition, there is no system in place to supervise these company veterinarians or to verify their compliance with requirements when carrying out passive surveillance sampling (blood and organs from cadavers and pigs showing signs compatible with CSF) and the additional sampling required for the channelled system.

The forms accompanying samples, collected in channelled system farms, to the laboratory are stamped by the official Zonal veterinarian.

Additional sampling in channelled system farms: for farms operating a continuous production system, 30 samples (EDTA blood for RT-PCR) should be collected per month; for farms operating on an all-in-all-out basis, 30 samples should be collected 7 to 10 days prior to the start of slaughter (results should be available before any of the pigs are sent for slaughter). In all cases, it was seen that these samples were collected as required.

5.3.2 10Km zones around channelled system establishments

Official controls focus on sampling (active and passive) for the National CSF Programme; on registration of holdings; and on identification of pigs and control of movements of live pigs. The majority of these controls are performed by CVs whose work is generally unsupervised.

As described above (section 5.1.2.2), sampling targets in this sector were not met.

In Timis, nine official veterinarians have recently been redeployed from other duties at county level to help bolster controls in the 10Km zones around channelled system farms. A major effort has been made to identify and register all backyard holdings in these zones.

Data was provided, in relation to Timis and other counties, demonstrating that more systematic sampling of backyard holdings commenced on 7 July 2011: on 7 & 8 July, a total of 372 samples for ELISA were collected from 12 villages in Timis, 2 in Arad, 2 in Caras-Severin and 1 in Bihor. The audits of Timis and Arad SVFSD carried out on 27 & 28 June 2011 by the NSVFSD found that sampling of backyard pigs within the 10Km radius of channelled system farms had not started at that time.

Zonal vets are responsible for performance of regular checks on backyard holdings and use a standard report in the form of a checklist for this purpose. The report includes sections on

identification of pigs, compliance with movement requirements, deaths within the previous 90 days and the health of pigs present on the holding. The FVO team examined numerous reports: in no case seen were any anomalies of any kind recorded. The veterinary service estimate that up to 30% of pig movements between backyard holdings are unreported and unrecorded. The NSVFSD audit of the county veterinary services identified deficiencies in animal identification and movement recording.

Conclusions on Official Controls:

In relation to the channelled system farms, the collection of official sero-surveillance samples for the National CSF Programme by private veterinarians, employed by the farms, jeopardises the objectivity of the programme. The lack of official supervision of these private veterinarians when collecting samples for passive surveillance under the programme and the additional samples required by the channelling system, represents a potential conflict of interest and undermines the ability of the official services to certify meat produced within the system as having met the system conditions.

Since the beginning of July, a significant effort has been made to improve controls in backyard holdings. The lack of supervision of CVs results in weak passive surveillance for CSF and deficiencies in the implementation of animal identification and movement controls.

The manner in which a CSF suspect case was handled in 2010 indicates a satisfactory level of expertise at SVFSD level.

The NSVFSA audits of Timis and Arad SVFSD demonstrate their knowledge of requirements and competence to operate and oversee the channelled system.

5.4 BIOSECURITY AND TRACEABILITY IN CHANNELLED SYSTEM ESTABLISHMENTS

Biosecurity

Biosecurity plans are in place for all farms and for the slaughterhouse. The farms checked operate as virtually closed units in that all deliveries (live pigs, feed, etc.) are made from outside the perimeter without the need for vehicle access inside the farm premises. The farms had on-site rendering facilities. All personnel access was via a sanitary barrier which included shower facilities and changing of clothing.

Protocols are in place for disinfection of premises and vehicles, for recording of births and deaths, management of slurry, etc.

Most of the channelled system farms are situated away from villages and access to the vicinity of the farms is controlled.

The Position Paper places an obligation on channelled system farms to perform a risk analysis in the 10Km zone surrounding each farm. The initial series of audits performed by the NSVFSA identified that this had not been done. However, this is an official task and the channelled system farms do not have the necessary powers to carry out such an analysis.

Traceability

All establishments proposed for inclusion in the channelled system are under the control of a vertically integrated company which includes breeding and fattening farms, two feedmills and a slaughterhouse, which processes only pigs from within the channelled system (slaughter of pigs from other MS is an option). The company employs a number of veterinarians responsible for

oversight of the operation of the farms.

All breeding animals are individually identified by ear tags. At weaning, piglets are identified by tattoo on the left shoulder (the tattoo indicates the farm of birth). Prior to dispatch to slaughter, fattening pigs are identified by tattoo on the right rump with the code of the fattening farm. Examination of slaughtered carcasses indicated that this system was fully applied.

Movement documents were available on farms for all movements on and off.

At the slaughterhouse, all necessary movement documentation, including food chain information, was available.

Each lot arriving is assigned a lot number which is retained throughout the slaughter process. Microchips in the gambrels and the tattoos are also used to identify carcasses to their arriving lot. All cut meat carries a code on the packaging which identifies the day of slaughter and is therefore traceable to one of the farms supplying pigs on that day.

Conclusions on biosecurity and traceability in channelled system establishments

Biosecurity measures in place in the proposed channelled system establishments provide a high level of protection and minimise the risk of introduction of CSF into these establishments.

Effective forward and backward traceability mechanisms are in place both in relation to live animals and to meat.

There is, however, insufficient official supervision and verification of the effectiveness of these systems.

The proposed channelled system imposes unworkable obligations on channelled system farms in relation to neighbourhood risk analysis.

6 OVERALL CONCLUSIONS

The proposed channelled system, as specified in the Position Paper, has the potential to function effectively, given some relatively minor amendments. Insufficient time has been available to the CA to devise, implement and verify the correct functioning of the system.

The initial preparatory work and the initial audits of the system were professionally carried out. However, the follow-up audits, aimed at verifying correction of the deficiencies identified in the system, are unreliable.

Recent changes to the National Programme for the Eradication, Monitoring and Control of CSF and the fact that the new programme has not been formally submitted to the Commission, coupled with the poor implementation of the programme in 2010 and the first semester of 2011, undermine confidence in this prerequisite for the channelled system.

The well developed biosecurity and traceability systems in the proposed channelled system provide a high level of protection for these establishments. However, while the Position Paper envisages enhancement of official controls in the channelled system farms, this had not been fully implemented at the time of this audit and official controls were insufficient, with an almost total delegation of competence to the private operator, with very little official oversight.

Significant efforts have been made to enhance official controls in backyard holdings. However, it is not yet possible to determine the effectiveness of these efforts and significant difficulties remain, particularly in relation to ensuring the impartiality of concessionary veterinarians when performing official tasks.

Overall, the poor implementation of the national CSF eradication programme, particularly in the wild boar population and backyard holdings in the months prior to implementation of the channelled system, coupled with the deficiencies in official controls, reduce the reliability of the proposed channelled system at this time, despite the effectiveness of biosecurity and traceability systems in channelled system establishments.

7 CLOSING MEETING

A closing meeting was held on 22 July 2011 with the CCA. At this meeting, the main findings and preliminary conclusions of the mission were presented by the FVO team. The representatives of the CCA did not express disagreement with the findings and conclusions presented. They stated their conviction that the channelled system could operate effectively and that their overall objective was to demonstrate freedom from CSF in Romania, particularly in light of the absence of any case of CSF in the last 3 years.

8 RECOMMENDATIONS

The CAs 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:

Nº.	Recommendation
1.	To re-evaluate the revised National Programme for the Eradication, Monitoring and Control of CSF in order to ensure that it can fulfil the objective of demonstrating freedom from CSF in Romania and to submit the revised plan to the Commission services for approval, in accordance with Article 16 § 1 of Council Directive 2001/89/EC and Article 27 § 6 of Council Decision 2009/470/EC. In this re-evaluation, consideration should be given to the implementation of additional measures on the border with Serbia.
2.	To ensure that the National Programme for the Eradication, Monitoring and Control of CSF (current or modified as appropriate) is fully implemented, in particular in relation to wild boar and backyard holdings, in accordance with Article 16 of Council Directive 2001/89/EC.
3.	To replicate the NSVFSA audits of Timis and Arad in all other counties so as to identify and rectify any deficiencies found in the effectiveness of official controls, as required by Article 8 § 3 of Regulation (EC) No 882/2004.
4.	As envisaged in the Position Paper, to carry out audits of channelled system establishments on a regular basis and to ensure that these are performed with the same rigour and procedures and similar team composition as the initial series of audits.
5.	To ensure that official tasks are performed by officials, in particular the collection of samples for serological surveillance for CSF, in accordance with the requirements of

N°.	Recommendation
	Regulation (EC) 882/2004.
6.	In accordance with Article 8 § 3 and 4 § 2(b) of Regulation (EC) No 882/2004, to ensure that control tasks performed by private veterinarians in channelled system farms (passive surveillance and additional sampling for the channelled system) are subject to effective official supervision and verification.
7.	To continue the process of reinforcement of controls in backyard holdings and to ensure that measures are in place to counter any possible conflict of interest on the part of the Concessionary Veterinarians, as required by Article 4 § 2(b) of Regulation (EC) No 882/2004.
8.	To revise the Position Paper on the channelled system, taking into account the findings, conclusions and recommendations of this report.

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

http://ec.europa.eu/food/fvo/ap/ap_ro_2011-6046.pdf

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
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. 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)
Dec. 2010/712/EU	OJ L 309, 25.11.2010, p. 18-30	2010/712/EU: Commission Decision of 23 November 2010 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 2011 and following years
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