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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ITALY

FROM 11 TO 20 MARCH 2013

IN ORDER TO EVALUATE IMPLEMENTATION OF ANIMAL HEALTH CONTROLS ON
AFRICAN SWINE FEVER AND THE OPERATION OF THE ERADICATION PROGRAMME
FOR THE DISEASE IN SARDINIA

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Italy, which took place between 11 and 20 March 2013.

The purpose of the audit was to evaluate the implementation of animal health control measures on African swine fever (ASF) in Sardinia and the objectives of the audit were:

- to assess compliance with specific provisions concerning minimum measures for the control of ASF laid down in Council Directive 2002/60/EC;*
- to assess the implementation and effectiveness of animal health protection measures against ASF in Sardinia, in accordance with provisions laid down in Commission Decision 2005/363/EC, and*
- to assess the implementation of the programmes for control and monitoring of ASF in Sardinia approved by the Commission for the last four months of 2012 (hereafter; revised programme for 2012) and for 2013.*

Overall, the competent authorities (CAs) have established a comprehensive legal environment and introduced a broad set of measures aimed at enhancing official controls on the pig population in Sardinia in order to control and eradicate ASF; however, they have not yet taken sufficiently decisive action to ensure the effective use of all those tools in accordance with EU requirements and as laid down in the approved control and monitoring programmes for the disease. The main shortcomings identified were:

- The inadequate functioning of coordination mechanisms between CAs and the lack of a clear and effective chain of command to ensure that all designated CAs fulfil their responsibilities. The main consequences are the lack of enforcement of basic legal requirements and the ineffective implementation of eradication and surveillance measures according to the evolution of the epidemiological situation of ASF in Sardinia.*
- Unsatisfactory management of well-known risk factors contributing to the transmission of the ASF virus in Sardinia, such as illegal farming of free-range pigs and non-compliance with basic requirements on holding registration, animal identification and notification and registration of animal movements. This is exacerbated by the fact that these factors occur mainly in ASF infected areas, where the free ranging pigs cohabit with infected populations of wild boars, which significantly raises the level of ASF virus circulation at local level, and represents the major contributing factor to the spread and endemicity of the disease in the island.*
- The inadequate targeting of surveillance efforts in infected areas, which significantly delays the detection of all infected epidemiological units where the ASF virus is circulating and prevents the CAs from cutting its transmission routes effectively. As a consequence, even well circumscribed infected areas remain as such for very long periods of time.*
- Insufficient awareness amongst the majority of pig farmers of the major importance for the control of ASF of both compliance with requirements on animal identification and movement of pigs, and application of basic biosecurity measures necessary to prevent exposure of the domestic pig population to the ASF virus.*

Official controls on food business operators (FBOs) availing of derogations laid down in Decision 2005/363/EC have been intensified during 2012 and should contribute to mitigate the risk of transmission of the ASF virus through products dispatched from Sardinia in accordance with the said Decision. However, some problems were still found in this area in respect of: a) some pig meat products produced before December 2011 with pig meat originating in Sardinia that have been allowed to be placed on the EU market with the explicit consent of the CCA, b) the approach used for the updating of the list of FBOs approved in this context, and c) the insufficient involvement of the Sardinian Veterinary Services in the planning and implementation of official controls on ports and airports so as to ensure that only authorised products of animal origin can leave the island.

The CAs had found evidence of non-compliance with the prohibition to transport animal by-products not for human consumption (ABP) containing material of porcine origin from Sardinia out of the island. The CAs took action to address the situation and further investigations were still ongoing at the time of the audit to determine responsibilities in that respect and confirm that the irregularities have been resolved.

The report makes a number of recommendations to the Italian competent authorities, 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
ADNS	Animal Disease Notification System
AISAS	Department for Hygiene and Health and for Social Assistance of the Autonomous Region of Sardinia (<i>Assessorato dell'Igiene e Sanità e dell'Assistenza Sociale</i>)
ASF	African swine fever
ASL	Local veterinary authority (<i>Azienda sanitaria locale</i>)
BDN	National database for porcine animals (<i>Anagrafe suina nella Banca Dati Nazionale</i>)
CA(s)	Competent authority(ies)
CCA	Central competent authority
CEREP	National reference laboratory for the diagnosis of ASF (<i>Centro di Riferenza per le pesti suine</i>)
CFVA	Forestry and Environmental Surveillance Service (<i>Corpo Forestale e di Vigilanza Ambientale</i>)
DAIS	Decree of the AISAS (<i>Decreto dell'Assessore dell'Igiene e Sanità e dell'Assistenza Sociale</i>)
DGS	Directorate General for Health (<i>Direzione Generale della Sanità</i>)
DGSAFV	Directorate General for Animal Health and Veterinary Medicinal Products (<i>Direzione Generale della Sanità Animale e dei Farmaci Veterinari</i>)
DIFT	Direct immuno-fluorescent test
ELISA	Enzyme linked immuno-sorbent assay
EU	European Union
FBO	Food business operator
FVO	Food and Veterinary Office
IZS	Regional laboratory responsible for diagnosis of ASF in the Autonomous Region of Sardinia (<i>Istituto Zooprofilattico Sperimentale della Sardegna</i>)
LDCC	Local disease crisis centre (<i>Unità di crisi locale</i>)
MdS	Ministry of Health (<i>Ministero della Salute</i>)
MS	Member States (of the EU)
NAS	Health protection Unit of the Italian police force (<i>Comando Carabinieri per la protezione della salute - Nuclei Antisofisticazioni e Sanità</i>)
OEVR	Epidemiology department of the IZS (<i>Osservatorio Epidemiologico Veterinario Regionale del' IZS</i>)
OIE	World Organisation for Animal Health
OV	Official veterinarian
PCR	Polymerase chain reaction

RDCC	Regional disease crisis centre (<i>Unità di crisi regionale</i>)
SIMAN	National Animal Diseases Notification System (<i>Sistema Informativo Malattie Animali Nazionale</i>)
SP	Regional Prevention Service (<i>Servizio Prevenzione</i>)
TI	Regional coordinating task force (<i>Tavolo Interassessoriale</i>)
UVAC	Veterinary offices of the MdS in charge of controls on intra-Union trade (<i>Uffici Veterinari per gli Adempimenti Comunitari</i>)

1 INTRODUCTION

This audit took place in Italy from 11 to 20 March 2013. The audit was undertaken as part of the planned audit programme of the FVO.

The audit team comprised two auditors from the FVO and, during the first week, two other officials from the Commission services in Brussels. The audit team was accompanied throughout the audit by:

- representatives of the Central Competent Authority (CCA), the Directorate General for Animal Health and Veterinary Medicinal Products (*Direzione Generale della Sanità Animale e dei Farmaci Veterinari* – DGSAFV) of the Department for Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection of the Ministry of Health (*Ministero della Salute* – MdS);
- representatives of the Regional Prevention Service of the Directorate General for Health of the Department for Hygiene and Health and for Social Assistance of the Autonomous Region of Sardinia (*Servizio Prevenzione* – SP – *della Direzione Generale della Sanità* – DGS – *del'Assessorato dell'Igiene e Sanità e dell'Assistenza Sociale* – AISAS), and
- representatives of the local veterinary authorities involved in the official controls covered by this audit in the provinces visited in the Autonomous Region of Sardinia (*Aziende Sanitarie Locali* – ASLs).

An opening meeting was held on 11 March 2013, with representatives of the DGSAFV, the SP, the national reference laboratory for the diagnosis of ASF (*Centro di Referenza per le pesti suine* – CEREP) and the epidemiology department of the regional laboratory responsible for diagnosis of ASF in the Autonomous Region of Sardinia (*Osservatorio Epidemiologico Veterinario Regionale* – OEVR – *del'Istituto Zooprofilattico Sperimentale della Sardegna* – IZS). At this meeting, the audit objectives and itinerary were confirmed, and additional information required for the satisfactory completion of the audit was requested.

2 OBJECTIVES

The objectives of the audit were:

- to assess compliance with specific provisions concerning minimum EU measures for the control of ASF laid down in Directive 2002/60/EC;
- to assess implementation and effectiveness of animal health protection measures against ASF in Sardinia, in accordance with provisions laid down in Decision 2005/363/EC, and
- to assess implementation of the programmes for control and monitoring of ASF in Sardinia approved for the periods:
 - from 1 January to 31 December 2012 by Commission Implementing Decision 2011/807/EU, in particular in respect of the last amendments contained in the version of the revised programme for 2012 sent to the Commission services on 2 October 2012, and
 - from 1 January to 31 December 2013, by Commission Implementing Decision 2012/761/EU.

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

- Organisation and implementation of official controls on, and enforcement of EU requirements on the identification and registration of pigs.
- Notification of suspect cases of ASF - awareness campaigns and cooperation of all relevant stakeholders.
- Specific measures taken in case of suspicion and confirmation of ASF.

- Laboratory diagnosis of ASF - diagnostic protocol followed to confirm or rule out the presence of the disease in domestic pigs and in wild boars.
- Use of epidemiological investigations to ascertain the routes of transmission of the disease and accelerate its control and eradication.
- Surveillance of ASF in the domestic pig population.
- Determination of herd health status in respect of ASF infection in domestic pig holdings – compliance with general bio-security principles and other ASF risk mitigation measures.
- Enforcement of measures on semi-enclosed pig holdings and on the illegal free-ranging pig population.
- Measures taken to monitor, control and eradicate ASF in the wild boar population.
- Measures to enforce the prohibition, and manage derogations thereof, on the dispatch by food business operators (FBOs) of pig meat, pig meat products and any other products containing pig meat from Sardinia.

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

Meetings/visits		Comments
Competent authorities	9	Opening and closing meetings with the DGSAFV and the AISAS. Additional meetings with the DGS in Cagliari, with the ASLs of the provinces visited (Cagliari, Ogliastra, Nuoro, Sassari and Olbia-Tempio) and with representatives of the CFVA. Meetings with OVAs during the visits to farms and FBOs
Animal holdings	2	Two pig holdings
Food business operators	2	Two FBOs authorised in the sense of Articles 5 and 6 of Decision 2005/363/EC
Laboratories	2	The IZS in Sassari and the local branch of the IZS in Nuoro
Other	1	One meeting with representatives of municipal authorities, of the meat industry and of farmers associations

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;
- Article 6(3) of Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption, and
- 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 texts quoted in this report are provided in Annex I, and refer, where applicable, to the latest amended version.

In addition to the standards established by the relevant EU legislation account was taken of other international standards, in particular the standards, guidelines and recommendations developed by the World Organisation for Animal Health (OIE).

4 BACKGROUND

4.1 ASF IN SARDINIA

ASF has been an endemic disease in the pig population in Sardinia since 1978. Epidemiologically, the disease has shown periodic recrudescence peaks with high incidence in domestic pigs and wild boars; the latest of which have occurred in 2004-2005, during 2007 and recently since mid-2011. The situation is considered to be the result of extensive pig farming that has been practised for centuries and of the presence of endemically infected wild boar.

Following the increase in reported outbreaks in 2011, that worsened during the first semester of 2012, revised control and monitoring programmes for ASF in Sardinia were submitted for approval by the Commission for the last four months of 2012 and for 2013. These programmes include targeted surveillance and control in high-risk areas for wild boar and domestic pigs, in particular for extensive pig farming, and stricter enforcement of biosecurity measures.

In addition, in December 2011, due to the significant increase in numbers and territorial extension of outbreaks of ASF, with more than 30 confirmed in domestic and feral pigs in seven of the eight provinces of Sardinia; Decision 2005/363/EC was amended in order to further mitigate the risk of transmission of the disease beyond the island. The amended Decision prohibits, with some derogations, the dispatch of pig meat, pig meat products and any other products containing meat from pigs originating from the island. A number of specifically approved FBOs have availed extensively of these derogations during 2012.

The Commission and the EU Member States (MS) have been kept informed of the ASF situation in Sardinia *inter alia* through several presentations made to the Standing Committee on the Food Chain and Animal Health - Section Animal Health & Animal Welfare. These presentations have been made available on the internet:

http://ec.europa.eu/food/committees/regulatory/scfcah/animal_health/index_en.htm

4.2 PREVIOUS FVO REPORTS

The last three audits carried out in Italy in order to evaluate official animal health controls in the context of the control and eradication programmes of ASF in Sardinia were carried out in 2004 (ref. DG(SANCO)/7369/2004 MR Final), 2005 (ref. DG(SANCO)/7706/2005 MR Final) and 2008 (ref. DG(SANCO)/2008-7801 MR Final). The reports of these audits (hereafter, the previous reports) can be found on the FVO Web site:

http://ec.europa.eu/food/fvo/index_en.cfm

The overall conclusions of the previous reports highlighted as the main weaknesses of the official control system in place, the following:

- the insufficient cooperation between all involved CAs;
- the lack of enforcement in relation to clandestine free-range pigs and illegal movement of domestic pigs, which highly contributed to the maintenance of an ecological niche for the ASF virus to persist in some areas of Sardinia, and
- the inadequate application of eradication measures in infected areas where outbreaks were detected, which were not sufficient to impede the further circulation of the ASF virus and the continuous infection of new holdings in the same area.

The CAs have since undertaken several times to address the shortcomings above mentioned, amongst others, and measures to be implemented in that respect have been part of the annual

eradication programmes for ASF implemented since 2004. More recently, actions aimed at addressing those problems have been further emphasised as pillars of the eradication programmes for the disease planned for 2012 and 2013.

5 FINDINGS AND CONCLUSIONS

5.1 PERFORMANCE OF THE COMPETENT AUTHORITIES

5.1.1 Legal requirements

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

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

5.1.2 Findings

5.1.2.1 Legislation

A number of legal texts have been introduced in Italy, and are applicable in Sardinia, in order to transpose and apply all relevant EU requirements concerning identification and registration of pigs, and control of ASF, in particular:

- In 2004, EU provisions concerning minimum measures for the control of ASF laid down in Directive 2002/60/EC were transposed into national legislation - *Decreto Legislativo 20 febbraio 2004, n. 54 di attuazione della Direttiva 2002/60*. In addition, on the same year, the DGSAFV asked the CEREP to prepare an updated contingency plan and a general guidance for the preparation of operational plans for the control of ASF in case of an outbreak.
- In line with EU requirements laid down in Articles 15 and 16 of the said Directive, the CAs prepared a specific eradication programme for ASF in feral pigs, which was approved by Commission Decision 2005/362/EC and remained valid until February 2009, when it was declared obsolete. The guidance for the preparation of operational plans prepared by the CEREP in 2004 indicates that a specific eradication programme must be ready within 90 days of the confirmation of the disease in feral pigs.
- In 2010, EU provisions concerning identification and registration of pigs laid down in Council Directive 2008/71/EC - *Decreto Legislativo 26 ottobre 2010, n. 200 di attuazione della direttiva 2008/71/CE relativa all'identificazione ed alla registrazione dei suini*. Previous EU requirements on the same subject laid down in Council Directive 92/102/EC, mainly in relation to registration of pig holdings and tattooing of animals, had been

transposed into national legislation in 1996.

- Moreover, since 1979, there are two Ministerial Orders which lay down, respectively, national provisions to prevent and control ASF in Sardinia and the rest of Italy, and the prohibition to dispatch any product of porcine origin, including ABP, from the island without approval by the MdS.
- Finally, according to the sentence 12/2004 of the Italian Constitutional Court, the Italian State, represented in this context by the MdS, has the exclusive power to legislate in cases of highly infectious animal diseases whose repercussions can go beyond the national borders. The same sentence gives the MdS also the exclusive possibility to call in the health protection Unit of the Italian police force (*Comando Carabinieri per la protezione della salute - Nuclei Antisofisticazioni e Sanità – NAS*) in the same cases so as to ensure that the situation does not escalate out of control.

In addition, there are several relevant legal texts that were introduced by the CAs in Sardinia during 2011 and 2012 in response to the worsening of the epidemiological situation of ASF:

- Measures were introduced at the end of 2011 in order to tackle the increase in the number of confirmed outbreaks of ASF and to implement the control and eradication programme approved by Commission Implementing Decision 2011/807/EU - *Decreto del Presidente della Giunta Regionale n. 154 del 21 dicembre 2011 relativo a 'Misure straordinarie di lotta alla Peste Suina Africana'* (hereafter, Decree n. 154).
- The President of the Sardinian Regional Authority issued a Decree on May 2012 (n. 56), laying down special measures to combat ASF and creating a regional coordinating task force for that purpose (*Tavolo Interassessoriale – TI*). The main points covered by Decree n. 56 are:
 - The TI is presided by the President of the Sardinian Regional Authority; nevertheless, since August 2012, another person has been delegated this responsibility on his behalf.
 - The TI includes representatives of the AISAS, and of the regional authorities for agriculture, rural development, the environment, including the Forestry and Environmental Surveillance Service (*Corpo Forestale e di Vigilanza Ambientale – CFVA*), and the industry.
 - Its main objective is to bring all illegal rearing of pigs in line with EU and national requirements on identification and registration of pigs in communal areas of nine municipalities situated in well-known ASF infected areas of the provinces of Ogliastra and Nuoro.
 - It includes estimates that in May 2012 there were some 700 illegal holdings rearing between 13 and 15 000 pigs in the areas covered by its scope.
 - It indicates that financial support is going to be provided by the regional authorities in order to facilitate the development by the municipalities of semi-enclosed facilities for the rearing of the newly registered pigs.
 - It lays down the responsibilities of all CAs, including those of municipal mayors and provincial prefects, and of animal keepers. The CFVA holds the main responsibility for the surveillance and detection of illegal free-ranging pigs in the areas covered by this DAIS. The municipalities are held responsible for the surveillance and proper functioning of the newly established semi-enclosed facilities for legalised pig holdings.
 - It includes prescriptions to enforce all relevant legal requirements in the context of ASF controls, including details on the level of sanctions to be imposed by the ASLs.
- Later on, measures were introduced in June 2012 in order to reinforce implementation of the

ASF control and eradication programme, due to the further increase of the incidence and spread of the disease in Sardinia – *Decreto dell'Assessore dell'Igiene e Sanità e dell'Assistenza Sociale n. 30 del 4 giugno 2012 relativo a 'Decreto attuativo del Piano di eradicazione della Peste Suina Africana. Anno 2012'* (hereafter, DAIS n. 30). Amongst other things, this DAIS:

- updated regional provisions defining the health status of ASF 'accredited' pig holdings according to a number of factors, such as compliance with identification and registration of animals, biosecurity measures in place and negative results to an annual serological test for ASF;
 - introduced measures, and further clarified responsibilities, in order to organise the semi-enclosed rearing of pigs in communal land (*pascolo semi-brado*) and to handle situations where illegal free-ranging pigs (*pascolo brado*) were found, as foreseen in the DAIS n. 56.
- Finally, in order to implement the control and eradication programme for 2013 approved by Commission Implementing Decision 2012/761/EU, while at the same time giving legal validity to actions already taken to modify the programme for 2012 since October; the AISAS introduced a new DAIS - *DAIS n. 69 del 18 dicembre 2012 relativo a 'Decreto attuativo del Piano di eradicazione della Peste Suina Africana. Anno 2012 e 2013'*. This DAIS introduces some modifications with respect to DAIS n. 30:
- It redefines the categories used to qualify the health status of pig holdings according to the number of ASF negative annual serological tests. After one negative test, the holding is considered a 'controlled holding', and after two, a 'controlled certified holding'. In addition, sampling for the serological tests is designed so that a prevalence of 5% of seropositive animals can be detected (with a 95% confidence level), instead of the 10% used before.
 - It fixes 30 June 2013 as the deadline for the legalisation of non registered pig holdings.
 - It limits the size of the semi-enclosed private pig rearing holdings to three hectares and requires for them additional biosecurity measures if situated in an ASF infected area.
 - It explicitly prohibits the activity of free-ranging of pigs and, therefore, does not contemplate any more the possibility to legalise these holdings (animals) when spotted by the CFVA, as they must be captured and killed under municipal mandate.
- In the same context, in 2009 the AISAS had introduced a DAIS laying down the details of the geographical areas in Sardinia to be considered infected with the ASF virus in respect of the population of feral pigs - *DAIS n. 67 del 23 dicembre 2009 relativo alla modifica della zona infetta per PSA nel cinghiale*:
- These areas were based on historical epidemiological data obtained during the epidemic occurred in 2004-2005 (see 5.3.2.3).
 - One of the areas defined therein was slightly amended in October 2012 after a meeting convening representatives of all relevant CAs at regional and national level, who sporadically play the role of expert group in the sense of Article 15 of Directive 2002/60/EC.

The audit team found that:

- All the above mentioned legal requirements currently in force give to all relevant CAs, whether at local, regional or national level, sufficient powers to enforce EU legislation concerning control and eradication of ASF and identification and registration of pigs. However, the spread of responsibilities in various pieces of legislation between a diversity

of CAs in an uncoordinated manner, which most of the time requires the intervention of two or three of them to enforce a basic piece of legislation, along with the limited enforcement of some of those legal requirements, has shown to be ineffective as further explained in the sections here below.

- According to documentation presented by the DGSAFV to the audit team, they had drawn the attention of higher instances of the MdS to the fact that regional measures introduced with Decree n. 154 at the end of 2011 were not fit for purpose and that the AISAS had not incorporated therein the recommendations that they had given in cooperation with the CEREP. The same documentation indicates that it was only in mid-2012, when the Commission intervened to request a decisive approach to eradicate ASF, that the AISAS started to consider those options, mainly focused on tackling the long-standing problems of illegal rearing of free-range pigs and the lack of enforcement of other provisions on identification and registration of pigs. It was not until December 2012, with DAIS n. 69, that the free-ranging of pigs was finally made illegal in Sardinia.

5.1.2.2 Organisation, operation and verification of effectiveness of official controls

A description of the animal health control system in place in Italy is included in the latest version of the country profile for this MS (May 2012), which is available through the following link:

http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=IT

In addition, it is worth mentioning that:

- At central level, Unit III of the DGSAFV is in charge of the national centre for animal disease control and eradication and of the national disease crisis centre. They are the operative Unit of the CCA in charge of coordinating all control and eradication efforts in case of outbreaks of highly contagious diseases.
- The CEREP keeps the overall responsibility as regards provision of all necessary scientific and technical advice in the context of control and eradication of ASF, in principle to the DGSAFV, but also directly to the regional CAs if requested. They also play the role of national reference laboratory for ASF in accordance with provisions laid down in Directive 2002/60/EC concerning supervision of the activities of the IZS in Sardinia (see 5.3.2.4).
- As indicated in the previous section, the health protection Unit of the Italian police force (*Comando Carabinieri per la protezione della salute - Nuclei Antisofisticazioni e Sanità – NAS*), with its regional and local offices, is available to perform specially targeted investigations upon request of the MdS in case of necessity in the areas of public or animal health.
- The AISAS keeps overall responsibility in the Autonomous Region of Sardinia for application of official controls in the veterinary field, including implementation of the approved control and eradication programmes for ASF:
 - The SP is responsible for planning, overall coordination and verification at regional level of those controls; this is done by three veterinary Units responsible, respectively, for controls on animal health, food safety and other issues such as identification and registration of animals.
 - Official controls are implemented at provincial level by eight ASLs, which are organised in three operational Units mirroring the distribution of responsibilities made by the SP at regional level.
- The OEVR is responsible for the regular epidemiological assessment of the ASF situation in

Sardinia, including evaluation of data derived from serological and virological monitoring of domestic and feral pigs, and from the investigations carried out in the context of outbreaks of the disease. In particular, they keep overall responsibility for updating the epidemiological situation as regards the ASF infected areas concerning the population of feral pigs. The OEVR reports and is directly accountable to the AISAS.

- The veterinary offices of the MdS in charge of controls on intra-Union trade in Sardinia (*Uffici Veterinari per gli Adempimenti Comunitari – UVAC*) are responsible for the on-the-spot verification of measures put in place by FBOs who have submitted an application to the MdS in order to avail of the derogations contemplated in Decision 2005/363/EC (see 5.4.2.1).
- The CFVA, as indicated in the previous section, has as its main responsibility detection and notification to the ASLs of illegal free-ranging pigs. Recently in 2013, as a result of shortcomings found both by inspections of the ASLs and by audits of the NAS (see below), the scope of their regular inspection activities on registered holidays farmhouses, which are mainly focused on verifying the exclusive use of Sardinian products, was extended by the president of the TI to include verification of ASF related aspects, such as proper traceability of all pigs reared or slaughtered, and meat used therein.

The audit team also found that:

- The planning made by the SP on the basis of the different components of the control programmes laid down in DAIS n. 30 and n. 69, for 2012 and 2013, respectively, lays down a number of monthly tasks for each ASL, which includes targets for various areas, such as numbers of holdings and of FBOs to be inspected. Each ASL plans and organises at provincial level the official controls allocated by the SP on a monthly basis. These controls are carried out by official veterinarians (OVs), who can be permanent officials or staff on temporary contracts; the latter have been hired since 2012 in order to increase the number of official controls, and their contracts are co-funded as part of the approved control and eradication programmes:
 - In all ASLs visited but one, numbers of staff were reasonable taking into account the standard tasks they have to carry out. Nevertheless, for some of the ASLs, and in particular for the one with less staff (Olbia-Tempio), the situation became more complicated during certain periods in 2012 due to the detection of numerous outbreaks of ASF and the additional tasks related to performance of checks on established protection and surveillance zones.
 - Temporary OVs must dedicate 18 hours per week to the official tasks (inspections and sampling) and the rest of the time they are allowed to perform other private activities in the veterinary field; they sign a contract where they acknowledge that there is no conflict of interest between both activities, but the ASLs visited had not put in place any verification system to ensure that this is the case. Those met by the audit team stressed the fact that their private activities were mostly related to other animal species, as keepers of small pig holdings hardly ever make use of their professional services.
 - Staff met in the ASLs were largely well prepared and competent to carry out their duties in the context of the official controls related to ASF.
- The ASLs must report monthly back to the SP indicating if the targets they had been allocated have been fulfilled:
 - Documentation on the planning process made by the SP for the second semester of 2012 and for the first one in 2013 could be verified by the audit team, as well as

details on the monthly reporting made by the ASLs. In general, ASLs fulfil their quantitative targets.

- Summarised accounts of the number of controls carried out are sent regularly to the DFSAFV who, insofar as this is possible on the basis of the quantitative data received, analyses them, in order to evaluate if verification activities could be necessary, and forwards them to the Commission.
- The summaries include data on the number of legal notices issued and sanctions imposed by the ASLs. In this respect:
 - There are big differences between the approach of the ASLs, as in some nearly all inspections find non-conformities and a lot of legal notices are issued (in Cagliari province, some 1 600 for around 2 100 holdings), whereas in other, with a well-known persistence of non-compliant holdings, there is nearly none (Ogliastra province, with some 25 for more than 700 registered holdings, and mostly related to holdings visited in relation to outbreaks of ASF).
 - Upon discussion on these discrepancies, it transpired that most OVAs consider this approach useless, as holding keepers do not get to perceive the seriousness of the legal requirements checked and their impact on prevention and control of ASF (see below, on the findings of the inspections).
 - Nearly no sanction has been imposed, only 44 for the whole of Sardinia out of more than 3 500 legal notices issued, and nearly all were related to holdings where the disease was detected.
- The AISAS organises several times per year, as necessary depending on the epidemiological situation of ASF, but mostly on a quarterly basis, meetings of the ASF regional disease crisis centre (*Unità di crisi regionale – RDCC*), where representatives of all involved CAs are convened, including on occasion the DGSAFV. From the minutes of several of these meetings held between March 2012 and the time of the audit, it was clear that some issues keep undermining the overall coordination of the actions needed to accelerate controls on ASF, namely:
 - The level of autonomy claimed by the AISAS and the TI in front of the DGSAFV and the CEREP, which has kept exclusively at regional level the power to take decisions on the level of enforcement to be applied to ensure implementation of the additional measures laid down in the approved ASF control and eradication programmes, as formalised in DAIS n. 30 of 2012, and Decree n. 56 and DAIS n. 69 of 2013.
 - One of the main problems frequently underlined is the reluctance by some CAs (mayors and prefects at local level, and the AISAS at regional level) to enforce all necessary legal requirements, as barely any action has been taken since the beginning of 2012 to stop the practice of illegal rearing of free-ranging pigs in some areas of the island, in particular in the provinces of Nuoro and Ogliastra, but also in some areas of the provinces of Olbia-Tempio, Sassari and Oristano (see 5.2.2). Despite the fact that Decree n. 56 of 2012 gives overall powers to the president of the TI to ensure application of all measures contained therein, this has not been used to ensure that those municipal and provincial CAs enforce those legal requirements.
 - Staff of the ASLs, as responsible in the field to manage the control and eradication programme, do not have any power to address the main risk factor related to transmission of the ASF virus; the presence of clandestine free-ranging pigs, as this

is the responsibility of majors and prefects. As witnessed by the audit team, and expressed on the minutes above mentioned, this has contributed to create an environment where more and more OV's working in the most problematic ASF infected areas, get frustrated as they cannot see any progress in that respect.

- Serious deficiencies identified by staff of the DGSAFV during their audits or by the NAS, in relation to the level of compliance of pig holdings and holidays farmhouses with basic requirements of paramount importance for the control of ASF, which were supposed to be guaranteed by the intensified official controls carried out in Sardinia since early 2012; are usually not well received by the AISAS or representatives of the TI.
- The SP has organised several initiatives in order to verify and audit the official controls carried out by the ASLs and the OV's working therein. These audits were carried out by a number of staff of the SP and some ASLs who had been specifically trained for that purpose. In 2012, the SP carried out:
 - An audit programme in June of the whole ASF official control system in place in three ASLs. In this case, the three operational Units of the ASL were audited and the few recommendations given included a variety of aspects, such as:
 - practical issues such as the need to get additional supplies of sampling material to be used in case of suspicion of ASF;
 - the need to better document regular controls and their supervision, including certification procedures. In this regard, for instance, in one ASL there were problems with the incomplete reporting by OV's of all non-conformities found during their on-farm inspections.
 - Actions to address some of those recommendations were followed up by the audit team; some had been addressed properly (e.g. new documented planning of inspections, preparation of a new certification protocol), but the one on the limited reporting by OV's was seen to persist as it was corroborated by the findings of other audits carried out by the SP and by the DGSAFV (see below).
 - An audit programme between September and October of the inspections carried out by all the ASLs on ASF 'accredited' pig holdings. The reason for this series of audits was the confirmation of an ASF outbreak in one of these (large) pig holdings in August, which raised doubts on the quality and the reliability of the controls carried out on this type of farms. This had also been stressed by the DGSAFV after an audit carried out on that holding once the disease was confirmed. 61 holdings were covered and 59 non-compliances were found in 34 of them; some related to very significant requirements for this type of farms:
 - no registration of births or deaths, and even of movements of individual animals, in the holding register;
 - no presence altogether or impossibility to read the tattoos in the ears of the pigs to verify the movement history of the animals, and
 - inadequate biosecurity measures in place and considerable lack of awareness in this regard.
- The SP sent a letter to the ASLs in October to request assurances that the non-conformities had been addressed; since no answer was provided, a reminder had been sent in February 2013, also to no avail yet.
- Finally, the SP organised an audit programme during the last quarter of 2012 in order

to verify the official controls performed by the ASLs on FBOs approved in the context of Decision 2005/363/EC (see 5.4.2.2).

- Concerning the involvement of the CCA in the overall verification of implementation of the control and eradication programmes; on top of their participation in the above mentioned meetings of the RDCC, staff of the DGSAFV has regularly carried out audits in this respect during 2012 and 2013. Moreover, a recent audit carried out by surprise by staff of the DGSAFV and the NAS has found a very high level of non-conformities in holidays farmhouses situated in ASF high risk areas (presence of infected feral pigs or protection zones established in case of outbreaks), in particular in relation to the absence of data on movements in and out of the establishment, but also specific serious situations, such as one place where 60 pigs were not registered in the holding registration and animal identification national database (*Anagrafe suina nella Banca Dati Nazionale – BDN*).
- Despite the result of all those audits, and the obvious worsening of the epidemiological situation during 2011 and 2012; the MdS has decided not to make full use of their powers to take over the command and overall coordination of the measures undertaken to guarantee that ASF is eradicated in Sardinia in accordance with EU, national and regional legal requirements.

5.1.3 Conclusions

Significant efforts have been made since October 2012 to facilitate implementation of the control and eradication programmes for ASF. Sufficient legal powers have been given to the CAs so that they can apply all necessary actions as required by the results of their official controls and the epidemiological situation of the disease in Sardinia. However, important weaknesses still persist undermining the overall functioning of the official control system as:

- coordination and cooperation mechanisms within and between CAs, both at national and regional level, have shown to be insufficient and ineffective;
- there is no clear and effective chain of command to ensure that all designated CAs fulfil their responsibilities, in particular as regards timely enforcement of legal requirements;
- implementation of official controls can not guarantee detection and resolution of all relevant non-conformities, and
- despite commendable improvements concerning verification of effectiveness of those controls, action taken upon their results has not yet translated into any amelioration of that effectiveness.

As a consequence:

- The official control system currently in place for ASF in Sardinia can not be considered in line with general rules laid down in Regulation (EC) No 882/2004 for the performance of official controls to verify compliance with rules aimed at preventing, eliminating or reducing to acceptable levels, risks related to the presence of this disease.
- The persistent lack of enforcement of basic legal requirements and the ineffective implementation of eradication and surveillance measures:
 - seriously questions the effective implementation during 2012 of the control and eradication programme for ASF in Sardinia approved by Decision 2011/807/EU, and
 - undermines the current implementation of the one approved for 2013 by Decision 2012/761/EU.

5.2 HOLDING REGISTRATION, ANIMAL IDENTIFICATION AND ANIMAL MOVEMENTS

5.2.1 *Legal requirements*

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

- keeping of lists of registered holdings by the CAs;
- identification marks to be applied on animals;
- keeping by animal keepers of holding registers recording all movements of pigs;
- provision by animal keepers of information on animal movements to the CAs;
- basic rules to ensure traceability of all animals moved to their holding of origin, and
- adoption by the CAs of the necessary administrative and/or penal measures to punish any non-conformity with the requirements of the said Directive.

The above mentioned EU requirements make integral part of the programmes for control and monitoring of ASF in Sardinia approved by:

- Commission Implementing Decision 2011/807/EU, for the period from 1 January to 31 December 2012, and posterior amendments contained in the version of the control and monitoring programme submitted by the CCA to the Commission services on 2 October 2012, and
- Commission Implementing Decision 2012/761/EU, for the period from 1 January to 31 December 2013.

5.2.2 *Findings*

As explained in section 5.1.2.1, since 2010 national legal requirements on identification and registration of pigs and in relation to registration of pig holdings and tattooing of animals, along with regional provisions laying down extraordinary measures for the control and eradication of ASF, enable the CAs to enforce all EU requirements in that respect and, if complied with, this would facilitate the effective application of other specific animal health control measures necessary for the eradication of the disease.

In addition to that:

- All data in respect of the identification and registration system for pigs are kept and regularly updated in the BDN. The BDN includes animal health data for all registered pig holdings, including their health status concerning ASF, and details on the type of holding, i.e. whether they are closed farms, semi-enclosed premises, etc..
- At the time of the audit, there were some 14 000 registered holdings in Sardinia with some 150 000 pigs. The majority of the holdings are of small size, with more than 4 000 with four or less animals, less than 200 holdings with more than 50 animals and some 500 with more than 25.
- The OEVR has georeferenced data for all registered pig holdings in Sardinia. All registered pig keepers must communicate annually by 30 March the census of animals in their holdings. This, together with the updated situation given by the BDN, is used as a reference by OVAs when they carry out their on-farm inspections.
- Most representatives of the ASLs met stressed the fact that without a new individual animal identification system for the pigs in Sardinia, which should use an individual identification device instead of tattoos; control and eradication of ASF will continue to be very difficult. Representatives of the AISAS informed the audit team that they were in the process of

studying that option and that a new system could be proposed shortly to all relevant stakeholders.

The audit team also found that:

- Representatives of all CAs met acknowledged that the major problem they have to confront is the presence of:
 - many clandestine pig holdings, whose owners add to their illegality risky practices such as liberation of the pigs in semi-enclosed premises of variable size with very basic and mostly inadequate fencing to prevent contacts with feral pigs or, simply, they turn temporarily their production into free-range in areas with high seasonal availability of acorns to feed them, and
 - groups of free-ranging animals belonging to a number of unknown owners which roam permanently around large extensions of forest and mountainous territories, and that can easily get in contact with wild boars.
- According to information provided by the president of the TI, more than 1 000 holdings had been newly registered in recent months (1 071, at the time of the audit, 267 in 2013) but, according to representatives of the CFVA and the ASLs visited, there is a significant level of uncertainty as to how many more could still be operating illegally. As mentioned in 5.1.2.1, the deadline for clandestine pig holdings to apply for registration is 30 June 2013. The recent increase in registration has occurred mainly in some provinces, such as Oristano (435 new holdings), Cagliari (224), Sassari (186) and Olbia-Tempio (152); with the high risk provinces of Nuoro (54) and, mainly, Ogliastra (3) contributing much less. The fact that clandestine holdings in the latter province do not get registered, when it is well-known by all CAs that they exist and even where they are; along with the questions raised on the reliability of the higher than average level of compliance resulting from the official inspections carried out in these areas (see 5.1.2.2), keep raising many doubts on the feasibility of controlling ASF in this area.
- Even though newly registered holdings are not required to provide accurate data on the origin of the animals kept, from the moment they are found, they must comply with relevant animal identification and registration requirements and put in place adequate biosecurity measures in accordance with DAIS n. 69. When this is not the case, keepers are given a legal notice and they have 15 days to ensure that any non-conformity is addressed; however, in most cases an on-the-spot follow-up to verify this had not been done yet.
- Concerning controls on illegal free-range pigs, as mentioned before, the CFVA is the main CA as regards detection and notification of these animals:
 - The relevant local Units of the CFVA, i.e. those operating in areas considered of a higher risk in this respect and mainly due to the recent confirmed circulation of the ASF virus in the area, had sent a comprehensive account of their findings to the AISAS in January 2012. Those notifications confirmed the well-known extension of the problem and the fact that those numerous animals were not identified or traceable to any owner, and that they were roaming in wide geographical areas which made difficult their regular tracking once initially spotted.
 - The president of the TI has intensified his activities over the last months as regards meeting municipal and provincial authorities, responsible for enforcing of legislation in this respect, and with local representatives of animal keepers, so as to inform them of the major importance that tackling this problem represents for the eradication of ASF and the overall economy of Sardinia.

- Data provided to the audit team on the situation as of March 2013 show that little has changed and that some 3 600 pigs (some 330 groups of animals) had been spotted by staff of the CFVA since October 2012. As expected, the majority of the groups of animals had been seen in the problematic provinces of Ogliastra (more than 1 400 pigs and more than 80 groups) and Nuoro (more than 1 200 in some 100 groups), with lower figures for Cagliari (some 350 pigs), Oristano (300) and Sassari (some 130). The majority of the animals are found in the municipalities targeted by the measures laid down in Decree n. 56 of 2012.
- As mentioned earlier in this report, staff of some of the ASLs met, representatives of the CFVA and even the president of the TI, acknowledged that these data just allow for a partial picture to be drawn, as more animals are likely to be found during the incoming months. According to the data above mentioned for the recent months, 15 sanctions had been imposed and six groups of pigs have been captured and killed:
 - Representatives of the CFVA informed the audit team that they were considering for the near future bringing more cases directly to Court, as municipal and provincial authorities were not fulfilling their responsibilities concerning enforcement of the prohibition laid down in DAIS n. 69.
 - Staff of the relevant ASLs stressed the fact that since these animals were not being captured, they could not test them or do anything to ascertain the risk they bear in relation to transmission of the ASF virus in the areas where they are spotted.
- According to representatives of all CAs met, the development of semi-enclosed communal holdings had been encouraging in a few cases, and this had reduced the number of groups of clandestine pigs found therein. However, staff of some ASLs and some municipal authorities met stressed that since the financial support to be provided by the regional authorities in order to facilitate the development by the municipalities of those facilities had not been granted to the extent initially undertaken, in some areas this added up to their historical reluctance to abide by rules on registration of holdings and animals (in one case the facilities just built up had been immediately vandalised), and the situation had not improved yet.
- Just before the end of this audit, representatives of the regional authorities for agriculture and rural development undertook to make the promised funds, six million Euros, available for the development of the semi-enclosed facilities in all the municipalities listed in Decree n. 56 of 2012.
- Illegal exchange of animals without respecting animal health and movement registration rules is still considered a common practice in many parts of the island. This happens between registered holdings, between the former and clandestine holdings or, in the case of piglets, from registered or clandestine holdings to holidays farmhouses and households, where they are slaughtered and consumed. Some extreme examples worth being highlighted are:
 - The common habit of exchanging boars for breeding purposes, mostly happening locally, but also in larger areas of the provinces. These animals are moved without any respect for rules on the official health status of the farms of origin and on notification and registration of the movements. A few cases detected in some ASLs were presented to the audit team, but representatives of all ASLs met stressed that this is still considered a major risk factor for the transmission of ASF in the island.
 - In the context of the under-notification of obvious or sub-clinical suspect cases of

ASF (see 5.3.2.1), according to representatives of the SP and the OEVR, in these cases farmers tend to sell some of the animals they know that have survived the disease in the farm, as they are considered valuable by the farming community as resistant to ASF.

- In areas where home-slaughtering is prohibited for long periods, for instance because they are in the territory covered by overlapping protection zones established after several confirmed outbreaks, an increase of the illegal rearing and clandestine slaughtering of the animals has been observed as a consequence.
- Representatives of the AISAS informed the audit team that they had intensified their campaigns in this respect to raise awareness amongst owners of small holdings in high risk areas, emphasising that unless they are fully compliant with requirements, animals would be seized and destroyed, and their owners penalised (see though 5.1.2.2, on enforcement in this respect).

5.2.3 Conclusions

Efforts have been made in recent months to verify compliance with requirements on animal identification and animal movement in registered pig holdings, and to bring illegal holdings and clandestine free-range rearing of pigs in line with legal requirements; however, verification of official controls carried out by the regional CAs and the CCA, evidence presented to, and observations made by the audit team, confirmed that they are still insufficient to ensure compliance with EU requirements on identification and registration of pigs laid down in Directive 2008/71/EC.

Moreover, the lack of effectiveness of official controls, coupled with insufficient awareness amongst animal keepers about the importance of these issues for the control and eradication of ASF, and the absence of adequate dissuasive action to enforce existing EU, national and regional legal requirements in that respect, keep seriously undermining efforts to:

- prevent and stop further transmission of the ASF virus by tackling illegal animal movements, and address the presence of clandestine animals with an uncertain health status in ASF infected areas, and
- obtain the accurate traceability information necessary in the context of epidemiological investigations aimed as ascertaining the routes of transmission of ASF in Sardinia.

5.3 MEASURES FOR THE CONTROL AND ERADICATION OF ASF

5.3.1 Legal requirements

Directive 2002/60/EC lays down specific provisions concerning minimum EU measures for the control of ASF, in particular as regards:

- Article 3 lays down requirements on the immediate and compulsory notification of any suspicion and confirmation of the presence of ASF. Annex I provides details on the format of the official notification to be provided through the EU Animal Disease Notification System (ADNS).
- Article 4 lays down measures to be taken in case of suspicion of the presence of ASF, including on the interim measures to be applied until the presence of the disease is confirmed or ruled out.
- Articles 5 to 14 lay down provisions on measures to be taken in cases where the presence of ASF is confirmed in domestic pigs, in particular as regards:
 - performance of epidemiological investigations;

- establishment of protection and surveillance zones (measures laid down in Articles 10 and 11);
- cleaning and disinfection protocols (principles and procedures laid down in Annex II), and
- re-population of pig holdings following ASF confirmed cases.
- Articles 21 and 22, and Annex VI, lay down principles and guidelines on contingency planning, emergency preparedness and early response in case of confirmation of an ASF outbreak.
- Articles 15 and 16 lay down provisions on measures to be taken in cases where ASF is suspected or confirmed in feral pigs.
- Article 17 and Annex III lay down principles and guidelines to investigate the possible involvement of vectors in the epidemiological cycle of ASF.

Commission Decision 2003/422/EC approves an ASF diagnostic manual laying down uniform diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation of the disease. Article 18 of Directive 2002/60/EC requires MS to carry out all necessary procedures to detect the presence of ASF in accordance with the diagnostic manual.

The above mentioned EU measures for the control of ASF make integral part of the programmes for control and monitoring of ASF in Sardinia approved by:

- Commission Implementing Decision 2011/807/EU, for the period from 1 January to 31 December 2012, and posterior amendments contained in the version of the control and monitoring programme submitted by the CCA to the Commission services on 2 October 2012, and
- Commission Implementing Decision 2012/761/EU, for the period from 1 January to 31 December 2013.

5.3.2 Findings

5.3.2.1 Specific measures in case of suspicion and confirmation of ASF

The audit team found that:

- According to data provided by the OEVR, in 2012 there were 74 cases of ASF confirmed in domestic pigs. Details on all these cases have been reported by the ASLs and the SP to the National Animal Diseases Notification System (*Sistema Informativo Malattie Animali Nazionale* – SIMAN). This information is used by the DGSAFV for the official notification to be provided through the ADNS. In this respect, considerable discrepancies were present between data as present in the ADNS and the reality of what had happened in particular cases:
 - Very often details on the number of animals considered present in the holding, those found dead or those killed once the disease was confirmed were very different from data kept on their own files by the ASLs responsible for the study and notification of the case. The main explanation was that data for the ADNS were often preliminary and approximative, and as the situation evolved the picture of the outbreak had changed.
 - In other cases, dates of suspicion, confirmation and resolution of the outbreaks, which is considered the date of cleaning and disinfection, had been communicated in an inconsistent manner and did not correspond to the reality. For instance, in some cases the latter date is the same day or just one day after the day of confirmation.

- According to representatives of all the CAs met, the epidemiological evolution of the disease since 2011 and the scattered detection of cases and seropositive animals in problematic infected areas through a long period of time (see 5.3.2.2), supports the idea that under-notification of ASF suspect cases is still a problem:
 - They added that new rules on compensation in case of detection of the disease, that mostly do not compensate farmers if the OVs suspect any illegal practice or find any non-compliance in the farm, could well be contributing to exacerbate this undernotification.
 - In addition, quite often presence of seropositive animals is not considered by the CAs as sufficient demonstration that suspicions of ASF have not been notified. Even if conceding that in normal circumstances there should have been sick and/or dead animals in the farm, staff of the SP and the ASLs underlined that in many cases this has not been necessarily the case in the holding where the animal is found, as the animals could have come from another holding (see 5.2.2 on illegal movements) or the animals could have gone through a sub-clinical form of the disease and the keeper had not seen any abnormal situation. As a consequence, there has been hardly any sanction imposed on animal keepers in this respect.
 - According to all representatives of the ASLs and the SP, they could not remember any suspect case of ASF ever reported by OVs carrying out ante or post-mortem inspections in the pig slaughterhouses of Sardinia.
 - Representatives of the AISAS emphasized that they had increased their efforts to organise more awareness campaigns in that regard in order to get additional cooperation from all relevant stakeholders. Some proof in this respect could be seen by the audit team, but limited, if any, written options, such as posters and leaflets, were available at the ASLs visited, and they were mostly outdated.
- Within the limits described in other sections concerning levels of compliance with identification and registration of animals, notification and registration of animal movements and biosecurity; measures taken by the ASLs visited in case of suspicion of the presence of ASF, including those to be applied until the presence of the disease is confirmed or ruled out and, since December 2012, the diagnostic approach (see 5.3.2.4), were largely adequate. The average amount of time spanned between the notification and the confirmation, or exclusion, of the disease was mostly of one or two days, but on a few cases it went as far as seven days.
- Concerning detected outbreaks of ASF:
 - Establishment of protection and surveillance zones by the ASLs largely follows provisions laid down in Directive 2002/60/EC and takes usually good advantage of the georeferenced data available on all registered farms.
 - Particular problems could be identified in relation to performance of epidemiological inquiries in case of confirmed cases of ASF. In this respect:
 - The contingency plan prepared by the CEREP contains a comprehensive and well designed form to be filled out by the OV responsible for the investigation, which has also been incorporated as an Annex to DAIS n. 69 of 2012.
 - However, the main problem encountered by OVs when they have to fill out the form is that most of the information received, if any, is inaccurate (see 5.1.2.2 and 5.2.2) and adds little if anything to the understanding of the epidemiology of the disease in the infected area. As a consequence, hardly any targeting can be done of additional investigations to detect the disease in

neighbouring holdings or other epidemiologically linked areas at risk.

- In addition, OVs met in several ASLs had a particular understanding of provisions laid down in Article 11(3) of Directive 2002/60/EC on the minimum time span necessary (40 days from the date cleaning and disinfection takes place in the infected holding) before serological testing can be carried out on holdings within a surveillance zone, so that absence of the ASF virus can be demonstrated and movement restrictions lifted. Their understanding was that serological testing in those farms cannot be carried out at all for at least those 40 days. Therefore, there was no proactive or targeted sampling to try and accelerate detection of other infected holdings in those zones.
- As a consequence of the weaknesses above mentioned, reappearance of new outbreaks in the same area has occurred during long periods (more than a year and a half) which, as exacerbated by the non-compliances described in other sections (e.g. clandestine animals, illegal movements, limited biosecurity, illegal disposal of carcasses), increases the risk of further spreading the disease and impedes the dedication of available human resources to more effective preventative tasks than to manage these outbreaks.
- No shortcoming was observed in relation to cleaning and disinfection protocols used in case of outbreaks and concerning re-population of pig holdings following ASF confirmed cases.
- According to representatives of the CEREP, they have recently initiated in the context of a EU funded research project studies to investigate the possible involvement of vectors in the epidemiological cycle of ASF in Sardinia. They acknowledged that this aspect may have not received sufficient attention to unequivocally exclude it as another contributing factor to the persistence of the ASF virus in the island.

5.3.2.2 Official controls and surveillance on the domestic pig population

The audit team found that:

- As explained in previous sections, the number of inspections carried out during the last quarter of 2012 on pig holdings increased significantly. At the time of the audit, all the approximately 14 000 registered pig holdings had been inspected and tested at least once since January 2012, with the higher percentage carried out during the last quarter of the year.
- On-farm inspections include checks on identification and registration issues, animal health status of the animals (clinical evaluation) and compliance with biosecurity requirements according to the type of holding (e.g. closed or semi-enclosed, in an infected area for feral pigs or not, etc.), and sampling for serological testing and detection of antibodies against ASF. Both the checks and the serological testing were also carried out on any new registered holding (see 5.2.2). Concerning the outcome of these inspections, please see sections 5.1.2.2 and 5.2.2. The audit team could corroborate on-the-spot the type of deficiencies found by the inspections of the ASLs, and the audits of the SP and the DGSAFV, in relation to issues such as the individual tattooing as an identification system that makes very difficult checking traceability of individual animals, the limited compliance with requirements on holding registers and animal movements, and the low levels of biosecurity in the visited farms.
- As laid down in DAIS n. 69 of 2012, special checks need to be carried out in pig holdings that want to be considered ASF controlled certified holdings; the main one being the bi-annual serological test. In the ASLs visited, very few of the previously considered 'accredited' holdings had been retested (in one, for instance, only four out of 180) and,

therefore, at the time of the audit, the majority of these holdings were not yet allowed to dispatch animals to other holdings in Sardinia. Staff of the ASLs acknowledged that this may contribute to increase the number of illegal movements between holdings of lower health status.

- Serological surveillance of domestic pigs has detected positive animals in some 100 small holdings since the beginning of 2012, with a much higher number being detected since October 2012. Detection of seropositive animals is spatially clustered in some geographical areas of the provinces of Sassari, Olbia-Tempio, Nuoro and Ogliastra, but a few seropositive animals were also found in Oristano and Cagliari. In relation to this:
 - Positive results in the serological testing have been mainly found in samples taken due to the situation of the holding in a protection or surveillance zone, stamping out of a confirmed outbreak and in case of newly registered holdings; and to a lesser extent in the context of the annual on-farm inspections, rechecks for ASF 'accredited' holdings and compulsory testing in case of on-farm slaughtering.
 - In relation to sampling of animals in the context of on-farm slaughtering, according to staff of one of the ASLs met, some 3 000 animals are slaughtered annually in their territory. In 2011, some 190 samples had been taken, in 2012, in excess of 800, whereas so far in 2013, they had already sampled more than 600 pigs.
 - Most of the time, epidemiological investigation of these cases does not allow the ASLs to ascertain the causes behind the presence of the disease, as most cases are found much later than the time when the pigs could have been exposed to the ASF virus (see previous section for further details on this).
 - Finally, holdings where seropositive animals are found are hardly ever considered as an outbreak and, in many cases, no further follow up is done once the seropositive animals are killed and no remaining animal shows any clinical sign compatible with ASF.

5.3.2.3 *Surveillance on the wild boar population*

As indicated in section 5.1.2.1, DAIS n. 67 of 2009, lays down the delimitation of geographical areas considered ASF infected in respect of the population of feral pigs, i.e. where circulation of the ASF virus has been confirmed, mostly on the basis of historical data. A description in this respect can be seen in the document accessible through the following link:

http://www.izs.it/vet_italiana/2007/43_3/463.pdf

This delimitation has an impact on ASF surveillance, as:

- virological testing of wild boars is done only in areas considered already infected;
- the number of wild boars shot during the hunting season that need to be sampled for serological testing is lower in the non-infected areas (at least 59) than in the infected ones (at least 96), and
- many of the defined geographical areas overlap territories and municipalities that are the responsibility of more than one ASL, which makes the supervision of the surveillance activities more difficult.

According to representatives of the CEREP, during the recent year there had been some controversy in that respect as they had proposed the AISAS to consider the island as a single infected territory, rather than keeping the historical delimitation of infected areas. Representatives of the OEVR added that, as indicated in the approved control and eradication programme for 2013, once all information for the 2012-13 hunting campaign is carefully analysed, surveillance in this population will be reorganised in order to render it more sensitive, and better target additional controls on domestic pig

holdings in accordance with the environmental risks present in the area. Nevertheless, on the basis of preliminary analysis, they reiterated that they do not expect that the geographical distribution of the infected areas will change much.

According to data provided by the OEVR:

- At the time of the audit, of the 32 pre-defined surveillance areas, 14 were considered infected. They cover some 4 000 holdings (mostly backyard holdings) with some 40 000 animals.
- The hunting bag in Sardinia is estimated around 45-50% of the total population of 75 to 100 000 wild boars.
- During the 2011-12 hunting season, more than 9 000 samples, tissues and blood, were examined with virological and serological tests (the majority). 148 seropositive animals were found and the presence of the ASF virus was confirmed in 31.
- In 2012 there were 17 cases of ASF confirmed in feral pigs; nine detected in wild boars shot during the hunting seasons, five in wild boars found dead and three in feral pigs found dead.
- At the time of the audit, four more cases had been confirmed this far in 2013, three in wild boars shot during the hunting season and one in a feral pig found dead.
- The geographical distribution of the confirmed cases covers four provinces, namely, Sassari (eight in 2012), Olbia-Tempio (four in 2012), Nuoro (three in 2012 and two in 2013) and Ogliastra (two each year). They cover five of the pre-defined infected areas.
- Since the beginning of 2012, 168 seropositive wild boars have been found in 14 of the 32 pre-defined surveillance areas. Nearly 5 700 animals were tested, mostly evenly throughout those areas, but in six of them the number of samples collected were lower than the established target. Seropositive animals are found in all age categories, but rarely amongst feral pigs younger than six months of age.

The audit team also found that:

- As indicated in section 5.1.2.1, no specific eradication plan for feral pigs is any more in place in the sense of requirements laid down in Article 16 of Directive 2002/60/EC. The main measures taken in cases where ASF is confirmed in wild boars are intensification of clinical and serological surveillance in surrounding domestic pig holdings; as a result of this, outbreaks, or simply the presence of seropositive animals, were eventually confirmed in many of the infected areas. In addition, additional restrictions apply to any movement of domestic pigs.
- Hunting is, in principle, forbidden in the infected areas, but derogations are granted by the ASLs provided all hunted animals are brought to the attention of OVs for comprehensive sampling and testing. Very limited verification of compliance with this requirements was observed in the relevant ASLs visited.
- In addition to checks for ASF, depending on the area of the island, wild boars hunted must be compulsorily checked for trichinellosis in order to be considered fit for human consumption. According to data provided to the audit team by the SP, some 23 000 wild boars had been tested during the 2012-13 campaign; they acknowledged that there may be a 25 to 40% of the hunting bag which is not tested in this respect, and that consequently is not sampled either for ASF testing.
- In some areas of the island, mostly outside the ASF problematic areas, there has been an increase in the notification of feral pigs found dead that are sampled by staff of the ASLs and tested at the IZS, but according to representatives of the former, there are still many cases that cannot be investigated due to the impossibility to obtain samples of good quality

when the animals are found.

- Deficiencies mentioned before in relation to the levels of awareness amongst keepers of small pig holdings in Sardinia in respect of ASF virus transmission routes and the necessary (basic) biosecurity measures to apply on farm, are exacerbated by the fact that many farmers are also hunters. Insufficient consciousness was observed in respect of risk factors derived from the likely contact of hunters with infected wild boars and feral pigs, or fomites related thereto, and limited initiatives had been taken by the CAs to improve application of preventive measures in order to mitigate them.
- In relation to the expert group theoretically in place in compliance with Article 15 of Directive 2002/60/EC, very sparse evidence was present of any meeting they have held, any advice given to the AISAS, or any analysis they have carried out of the epidemiological data available on the outbreaks confirmed and the results of ASF surveillance.

5.3.2.4 *Laboratory diagnosis of ASF*

The audit team found that:

- The CEREP provides test methods and standards for ASF diagnostics and handles all analyses of samples from suspect cases of ASF in Italy, with the exception of samples from Sardinia. The IZS has a network of four laboratories, with the one in Sassari acting as the regional reference laboratory (see below).
- Concerning the role of the CEREP as national reference laboratory for ASF:
 - It has carried out audits of the IZS in 2011 and in 2012. A number of deficiencies which had been noted in 2011 had been addressed in 2012, but some minor issues, mostly related to communication of the results, had not been addressed and remained open in 2012.
 - In 2012, it organised its first comparative test for ASF in domestic pigs for the four branches of the IZS in Sardinia. This included the ELISA test for detection of antibodies, the direct immuno-fluorescence test (DIFT) and PCR methods; the results were mostly satisfactory.
- Both the CEREP and the laboratory of the IZS in Sassari have direct communication with the EU reference laboratory for ASF and have participated since 2010 with satisfactory results in the comparative tests for ASF diagnostic techniques they organised.
- The IZS network has a common quality assurance system, common standard operating procedures and one quality manager for the network, located in Sassari. The IZS network is accredited in accordance with standard EN ISO/IEC 17025.
- Concerning use of diagnostic techniques for ASF:
 - The laboratory of the IZS in Sassari can perform the broadest range of tests, including ELISA tests for detection of antibodies and the ASF virus, the DIFT, immunoblotting for detection of antibodies (only one in the network, the test is within the scope of accreditation), PCR (including real-time PCR - RT-PCR) and virus isolation (also accredited).
 - All the other laboratories in the IZS network can perform ELISA testing for detection of antibodies (all but one accredited) and RT-PCR. All but one laboratory can perform DIFT, and three of the four have this technique included in their scope of accreditation.
 - None of the laboratories of the IZS, or the CEREP, has any PCR technique for the diagnosis of ASF included in the scope of accreditation.

- There was no timetable in place indicating when the currently used non-accredited methods would be submitted for inclusion in the accreditation scopes, but according to representatives of the IZS in Sassari, PCR techniques are a priority and they expect to accelerate this process shortly.
- Until December 2012 samples from domestic pigs and wild boar submitted for detection of ASF virus were first analysed by DIFT. A negative result was considered final, whilst all DIFT-positive samples were analysed in Sassari by PCR. The PCR result was considered final. Since December 2012, the three other laboratories of the IZS carry out DIFT and RT-PCR tests in parallel and if one or both methods come up with positive results, that sample is re-tested by PCR in Sassari. Representatives of the CEREP stated that this change of procedure had been made to increase the sensitivity of the testing since, as it is underlined in the EU diagnostic manual for ASF laid down in Decision 2003/422/EC, DIFT is less suitable for autolytic samples and may give false negative results in sub-acute and chronic cases.
- Serum samples from wild boars and domestic pigs are first analysed for antibodies to ASF by ELISA. A negative ELISA result is considered final. Samples with positive or inconclusive ELISA results are analysed in Sassari by immunoblotting, the result of which is considered final. These methods have been validated using material from domestic pigs:
 - Staff from the CEREP stated that although there was good correlation between the serological results by ELISA and immunoblotting for domestic pigs, only around 40% of the ELISA-positive samples from wild boar were positive in immunoblotting.
 - According to them, these problems may originate in the poor quality of the wild boar serum samples or intrinsic factors present in their blood; they added that they were in the process of evaluating the performance of serological methods for wild boar samples in order to validate a more robust method. They conceded that, consequently, without additional validation data it was difficult to estimate what proportion of the tested samples was likely to be false positives or false negatives.
- During the visits to the laboratories of the IZS network, the audit team could verify that:
 - Procedures were in place describing the choice of methods and the diagnostic pathways for samples within the ASF programme;
 - no maximum turnaround times for sample analysis had been set for the IZS. The sample reports studied by the audit team confirmed, as described in 5.3.2.1, that suspect samples had regularly been analysed within 24 hours of being registered in the laboratory;
 - results were reported in a way which clearly identified those methods which were within the scope of accreditation of the laboratory;
 - positive results for serological or virological testing of domestic pigs were communicated immediately to the relevant ASL, before results of confirmatory analyses carried out by the IZS in Sassari were available. Evidence was seen that ASLs had taken action based on these initial results; however, according to representatives of the DGSAFV, during 2012 they had not received prompt information on all those situations as soon as the initial positive results were known. They added that this had been solved recently. Concerning confirmatory analyses, once results were available, this information was timely provided to all relevant regional CAs and to the CEREP and the DGSAFV.

5.3.3 Conclusions

Concerning application of EU specific provisions for the control of ASF laid down in Directive 2002/60/EC, the CAs have made important efforts to:

- Follow principles and guidelines laid down therein in relation to contingency planning, emergency preparedness and early response in case of confirmation of an ASF outbreak.
- Take largely adequate measures both in case of suspicion of the presence of ASF, until the presence of the disease is confirmed or ruled out, and when the presence of ASF is confirmed in domestic pigs, in particular as regards:
 - establishment of protection and surveillance zones;
 - cleaning and disinfection protocols, in line with principles and procedures laid down in Annex II to the said Directive, and
 - re-population of pig holdings following ASF confirmed cases.

However, application of some measures cannot be considered full in compliance with requirements laid down in the said Directive, namely:

- The CAs have not taken effective steps to ensure that all suspect cases of ASF are immediately notified to them, which is not in line with Article 3 of the said Directive.
- Inaccurate data are provided too often to the ADNS in the context of immediate and compulsory notification of any suspicion and confirmation of the presence of ASF. This is not in line with requirements of Article 3 of and Annex I to the said Directive.
- Performance of epidemiological inquiries does not contribute effectively to provide accurate and timely information necessary to ascertain the origin of the disease, the length of its presence in the holding and all the possible factors and contacts that could contribute to its spread beyond the investigated holding. This is not in line with Article 8 of the said Directive.

Progress has been made in relation to some of the specific measures addressed to registered pig holdings included in the approved control and eradication programmes for 2012 and 2013, and a significant increase of on-farm inspections and controls has taken place; however:

- these controls has shown to be largely insufficient to ensure adequate levels of biosecurity in these holdings;
- there is a very significant delay in implementing statutory control measures on high ASF health status holdings, which further restricts internal movement of animals and, consequently, increases the risk of illegal movements; and
- serological surveillance is not fully implemented in all targeted sub-populations and, in case of positive findings, the reasons for the previous infection of the animals are rarely ascertained and the health status of the holding is not appropriately follow-up.

Additional efforts have also been made in recent months with regard to ASF surveillance in wild boars, and measures are taken in case of confirmation of the disease in feral pigs with respect to domestic pig holdings; however, some shortcomings still prevent the control system from being fully in line with EU requirements laid down in Articles 15 and 16 of Directive 2002/60/EC, in particular:

- Until data on the recently finished hunting season are epidemiologically analysed, there is still considerable uncertainty concerning the geographical spread of the ASF virus in this population. This undermines the preparation of a tailor-made eradication programme for feral pigs in accordance with Article 16 of the said Directive, and limits the options of the CAs to provide appropriate and accurate reporting to the Commission and the other MS on

the evolution of the disease in that population.

- The expert group seemingly operational in accordance with Article 15 of the said Directive, has had very limited impact on the recent evolution of ASF surveillance and control activities and very little evidence was present of their verification and analysis of the effectiveness of the measures applied.
- Despite additional measures taken recently to further regulate hunting activities, very little has been made concerning verification of compliance with the new rules and in respect of increasing hunters' awareness of the measures they have to adopt in the framework of the ASF control and eradication plan.

The use of standardised diagnostic methods for the ASF programme ensures that results provided by all the laboratories of the IZS are comparable and the reliability of the majority of test methods is regularly checked by participation in international and national comparative tests, which can be considered largely in accordance with the EU diagnostic manual for ASF laid down in Decision 2003/422/EC. However, some weaknesses remain as regards:

- Certain important diagnostic methods, such as PCR, have not been included in the scopes of accreditation of the IZS, which is not in line with requirements of Article 12 of Regulation (EC) No 882/2004. It is of particular concern that this deficiency also affects the methods used in the CEREP.
- Unresolved uncertainty concerning sensitivity and specificity of serological diagnosis of ASF in wild boars undermines the reliability of surveillance results and the accurate identification of animals which have been exposed to the ASF virus; this could be interfering with the adequate delimitation of ASF infected areas.
- Similar problems occurred until recently with virological diagnosis in both domestic pigs and wild boars, but changes made to diagnostic protocols should have since increased the reliability of results and contribute to obtain a more accurate picture of the epidemiological situation of ASF in Sardinia.

All in all, the shortcomings identified:

- seriously question the effective implementation during 2012 of the control and eradication programme for ASF in Sardinia approved by Decision 2011/807/EU;
- if unresolved, will keep undermining the current implementation of the one approved for 2013 by Decision 2012/761/EU, and
- contribute to increase the uncertainty around the real epidemiological situation of ASF in Sardinia and raise serious concerns concerning the capacity of the CAs to stop further transmission of the ASF virus in the domestic and wild populations of pigs and to eventually eradicate the disease.

5.4 ANIMAL HEALTH RULES ON THE DISPATCH OF PIG MEAT AND PIG MEAT PRODUCTS FROM SARDINIA

5.4.1 Legal requirements

Decision 2005/363/EC, as last amended in December 2011, establishes animal health protection measures against ASF in Sardinia, in particular:

- Article 3 of the said Decision lays down the prohibition on the movement of live pigs, pig semen, ova and embryos and on the dispatch of pig meat, pig meat products and any other products containing pig meat from Sardinia;
- Article 4 of the said Decision introduces measures to ensure special health or identification marking of pig meat, pig meat products and any other products containing pig meat

originating from pigs slaughtered in Sardinia, and

- Articles 5 and 6 of, and Annex II to the said Decision lay down provisions concerning:
 - specific conditions for derogating from the prohibition and the special marking requirements indicated above for pig meat, pig meat products and any other products containing pig meat from Sardinia, including the requirement that FBOs availing of those possibilities must be approved for that purpose by the CAs, and
 - certification conditions for intra-Union trade of those products in accordance with Article 5 of Directive 2002/99/EC.
- Article 7 of the said Decision lays down obligations for Italy concerning communication to the Commission and the other MS of:
 - the updated list of FBOs approved in accordance with Articles 5 and 6, and
 - the list of consignments that have been certified as provided for in the said Articles.

Council Regulation (EC) No 1099/2009 lays down health rules as regards ABP. In particular, Article 6 therein lays down general animal health restrictions, and thereby MS should continue to take the necessary measures to prevent the dispatch of ABP from restricted areas or establishments, in particular in the event of an outbreak of a disease listed in Annex I to Council Directive 92/119/EEC, such as ASF.

Commission Regulation (EC) No 142/2011 lays down implementing measures for the public and animal health rules for ABP and derived products laid down in Regulation (EC) No 1069/2009.

5.4.2 Findings

5.4.2.1 Establishments operating according to Decision 2005/363/EC

The audit team found that:

- The approval process for FBOs had been established years ago by the DGSAFV and included a comprehensive set of rules which, as amended to apply further restrictions introduced by Decision 2005/363/EC and implemented locally by the food safety Unit of the SP, were mainly:
 - An application to be sent to the MdS by the FBO with detailed indications on the measures to be put in place to ensure management of any possible risk of contamination of the products with any meat from pigs originating from pig holdings in Sardinia, a list of all suppliers, an adequate system to ensure traceability of all products, and the favourable opinion of the food safety Unit of the SP. In this respect, following provisions emanated from the MdS, the SP requires since November 2011:
 - approved slaughterhouses, to exclusively slaughter pigs not originating from pig holdings in Sardinia on separate days to those from Sardinia;
 - cutting plants, to cut meat from pigs not originating from pig holdings in Sardinia on separate days to that from pigs from Sardinia, and always in the presence of an OV, and
 - FBO producing meat products and other products containing pig meat, to operate exclusively with meat from pigs not originating from pig holdings in Sardinia.
 - Once the file is considered fit for purpose by the SP, including checks and simulations performed at the FBO, the MdS asks the UVAC in Sardinia to verify on-

the-spot the feasibility of all risk management and traceability measures; if this is considered satisfactory, the FBO is approved.

- Meat from pigs transported from other MS to be slaughtered in Sardinia in any of the four authorised slaughterhouses represent a very small percentage of the meat processed by authorised cutting plants and FBOs producing meat products and meat preparations.
- Due to the significant increase in numbers and territorial extension of outbreaks of ASF, in November 2011, the CCA had temporarily suspended the authorisation to avail of the derogations laid down in Decision 2005/363/EC, before its latest amendment. On a note addressed to the AISAS issued on 17 November 2011, the DGSAFV explicitly indicated that despite this prohibition, to be one month later formalised by the amendment to the said Decision, it was still allowed to place on the EU market products that have been produced with pig meat from pigs originating from pig holdings in Sardinia before the prohibition.
- The audit team could confirm in one of the FBOs visited that this was still happening; some cured hams that were remaining from some batches that had started to be produced before 2011. The FBO had received the fresh pig meat originating from pig holdings in Sardinia when this was still allowed (before December 2011). The understanding of the FBO was that, since the production of those batches had started before the entering into force of the prohibition, and the process (salting, drying, curing) is so long (24, 30 months, or even longer), placing them on the market nowadays is still in accordance with the Decision. This wrong interpretation by both the CCA and the FBO was clarified by the audit team, as the scope of the last amendment of the said Decision made in December 2011, suspended the previous derogation that permitted the dispatch of such products if derived from pigs originating in holdings situated outside the risk areas defined in Annex I to the Decision, before the amendment. Thereafter, that Annex I covers the whole island of Sardinia and, consequently, no such product can be dispatched if derived from any pig originating in any holding in Sardinia.
- At the time of this audit there were 24 FBOs in operation authorised to place on the market pig meat and meat products in accordance with provisions laid down in Articles 5 and 6 of Decision 2005/363/EC. They are situated in six of the provinces of Sardinia (none in Olbia-Tempio and Ogliastra) and four of them are slaughterhouses. In accordance with Article 7 of Decision 2005/363/EC:
 - The SP submitted on 6 March 2013 to the MdS an updated list with details of the 24 approved FBOs, and of 21 and two FBOs who, respectively, had requested a temporary suspension or the withdrawal of the authorisation. Upon careful checking of this updated list, of related documentation, and of the requirements laid down by the CCA and the food safety Unit of the SP on the requisites for FBOs to keep availing of the derogations, the audit team found that:
 - The requisites above mentioned include a provision for the FBO to actually avail of the derogation, or otherwise the approval would be temporarily or definitively withdrawn after six months without any dispatching of meat or meat products. According to representatives of the SP, this occurs very rarely and in any case it is a prerogative of the MdS to do that. Nevertheless, the SP is responsible for making the CCA aware of the situation regularly, as they had just done in early March 2013.
 - In the annual report transmitted by the AISAS to the DGSAFV on January 2013 including the number of official controls carried out on approved FBOs, there were 41 FBOs, including five slaughterhouses. In September 2012,

when the SP was planning verification of the official controls carried out by the ASLs on the approved FBOs, they indicated that there were 43 approved FBOs.

- Inconsistencies between the above mentioned lists of FBOs were found with respect to some of the provinces; for instance, in the province of Cagliari, there were 10 FBOs reported as approved and under official control in January 2013, but on the update provided in March, there are seven still approved and seven are indicated to have requested a temporary suspension of the approval.
- The SP submits regularly to the MdS detailed data on all consignments dispatched from authorised FBOs to other parts of Italy or to other MS.
- The MdS forwards timely all that information to the Commission.
- Concerning official controls on the approved FBOs, data provided by the SP on the number of checks carried out during 2012 show that there was an extensive presence of OVAs in the establishments and, in addition to daily controls carried out in slaughterhouses and cutting plants, and proof of checks carried out in relation to certification of consignments to be dispatched out of the island; reports of more detailed inspections could be seen in the FBOs visited. The latter are carried out without previous notice to the FBO and the aspects checked target the main areas to be addressed by the FBO in the context of general food safety and, in particular, concerning their approval in the context of Decision 2005/363/EC. The main issues evaluated concerning that approval are arrangements to guarantee the origin of the raw material (including the pigs, in the case of the slaughterhouses) and the effective and accurate traceability back and forward of all meat and meat products. In the reports seen by the audit team, only minor findings had been underlined and none which could bear any risk in relation to dispatch of non-compliant products out of Sardinia.
- As mentioned in section 5.1.2.2, the SP has organised during the last quarter of 2012 an audit and verification programme aimed at ensuring that the ASLs were performing their official controls on approved FBOs as planned. Some issues worth being underlined in this respect are:
 - These audits targeted 20 FBOs. The programme was planned to cover some 23 more FBOs during 2013.
 - The audits were carried out with a seven days notification period to the FBO and the OVAs of the ASL responsible for the regular inspections were present during the audits.
 - The results presented by the SP to the audit team show a detailed account of all the areas checked, which were adequately targeted taking into account the objective of the auditing process. In 14 of the FBOs audited there was at least one recommendation issued to improve the type of official controls applied on them; in three of them three to four recommendations had been issued, and even though most of the recommendations were related to minor problems, in a couple of cases problems were found in relation to inadequate proof of a proper certification process, such as absence of certification for the raw material to demonstrate their origin from outside Sardinia, or problems related to registers of incoming or outgoing products that undermined traceability in some of the batches checked.
 - The SP, and some of the ASLs audited, showed proof of the measures taken to address some of the recommendations and, in the case of the former, undertook to

improve the consistency of the certification process by redrafting the instructions available to OVs.

- The AISAS informed the audit team that they had increased the level of communication and made more information available to the public concerning restrictions related to ASF that apply to both personal goods and commercial consignments than can be transported out of the island. The main focus was to ensure that sufficient and clear visual information is present in all ports and airports, which could be verified by the audit team, and to enhance the preparation of staff of the CAs responsible for standard security and customs controls therein.
- The AISAS provided data on the number of inspections carried out by the ASLs during 2012 on the five ports and three airports in that respect, ranging from one to two on a monthly basis, with the main ports not being necessarily targeted, as those in Cagliari (14 inspections) and Porto Torres (11), were visited less frequently than smaller ones. The reasoning for the frequency of inspections could not be explained by the AISAS, as it is the responsibility of the relevant ASL depending on their perception of the risk. The latter did not have either any particular risk-based approach to decide on those inspections. The summary provided with the results of the inspections just shows that in a few cases the ASL had found minor problems with the availability of clear signs describing the current restrictions related to ASF. Very little information could be provided on how frequently, and on what amounts, illegal products had been found and seized at ports and airports, as the audit team was informed that this barely happens. Interestingly, weaknesses in this respect had already been found during the previous FVO audit of 2005 (see 4.2).
- The AISAS informed the audit team that regular controls carried out daily at ports and airports are the responsibility of staff of other CAs in charge of standard security and customs controls for all types of goods. Upon the questioning of the audit team, they acknowledged that there is still an inadequate attribution of responsibilities in respect of those official controls as there is hardly any involvement of staff from the ASLs. The ASLs had not been given powers to perform checks on means of transportation or personal goods (trucks with commercial consignments, car boots, personal luggage) and, thus far, there has not been any operational coordination between them and other CAs with powers to carry out checks so that their effective targeting can be organised and implemented. Representatives of the AISAS advised the audit team that they were in the process of reorganising this area as new working protocols were being worked out, in particular with the regional airport authority, so as to ensure that staff from the ASLs will have a more active role in the targeting of checks and will be helped by other CAs in order to detect and destroy products transported illegally.

5.4.2.2 *Official controls on the ABP chain*

In Sardinia, there is only one ABP processing plant that is approved for processing category 1 material and has been historically also in charge of the processing of ABP of porcine origin due to the animal health risks involved. This plant processes some 60% of the ABP produced annually in Sardinia. In addition, there is an incineration plant which is also authorised to receive those ABP. Apart from the ABP collection carried out by the category 1 processing plant, since 2008 there is one intermediate plant approved to collect and store category 1 and 3 ABP, which regularly dispatches the latter to a sister intermediate plant situated in another region of Italy.

As mentioned in section 5.1.2.1, apart from general animal health restrictions derived from EU legislation on ABP, that are applicable to the situation in Sardinia due to the presence of ASF; national provisions in force since 1979 prohibit for the same reason the dispatch of any ABP of

porcine origin from the island without approval by the MdS of any possible derogation there from. According to representatives of both the MdS and the AISAS, no derogation has ever been approved by the CCA.

The audit team found that:

- According to several representatives of the CAs met, mainly staff of the ASLs visited, there is still a significant level of non-compliance with requirements on disposal of ABP at local level by farmers and small FBOs. The main problems, as confirmed by the audit team, are related to:
 - very limited awareness and lack of understanding of the impact that inadequate disposal of ABP may have on transmission of the ASF virus;
 - disposal of ABP in case of on-farm slaughter, including catering waste, which are mostly fed to local dogs, but also dumped in the vicinity of the households or the forest nearby;
 - slaughtering of illegal free-range pigs, which even happens on-site, with the ABP left behind in the field or the forest, and
 - ABP resulting both from local slaughtering of pigs (mostly piglets) and catering waste in the numerous holiday farmhouses operating in Sardinia. This particular problem has been confirmed recently by audits and inspections carried out by staff of the DGSAFV and by the NAS, respectively (see also 5.3.2.2).
- Since 2011, there have been several investigations promoted jointly by the CCA, the SP and the NAS in order to check whether category 3 ABP containing material of porcine origin from Sardinia was being sent from the intermediate plant in the island to the sister plant in another region of Italy in order to be further distributed to processing plants.
- The initial approval of the intermediate plant was amended in June 2008 to restrict the type of category 3 ABP that could be handled therein. The plant was authorised to handle material of porcine origin derived from FBOs authorised in the sense of the derogations laid down in Articles 5 and 6 of Decision 2005/363/EC and derived from the retail sector, provided these ABP originated from pig meat or meat products from outside of Sardinia.
- According to reports of the investigation carried out by the NAS during 2011, they could not find any non-compliance and they concluded that material of porcine origin was being sent for incineration in Sardinia and that only category 3 ABP of other species were dispatched from that plant to other parts of Italy.
- The NAS informed the MdS in January 2013 that on the basis of additional evidence found afterwards, they had taken the case to Court in July 2012 and that since then they had intensified their investigations to better ascertain the situation in the plant. They added that those investigations confirmed that category 3 ABP of porcine origin was being dispatched from the plant in Sardinia to the sister intermediate plant in Campania.
- Reports of investigations carried out in January 2013 by the NAS in the sister intermediate plant mentioned above indicate that some category 3 ABP of porcine origin (fat and bones) had been sent from Sardinia, but also that the majority of the ABP of porcine origin collected by the plant in Sardinia had been processed in the island.
- In September 2012, the AISAS had requested clarification from the MdS concerning the possibility that the plant could dispatch the ABP of porcine origin that they were authorised to handle (see above) out of the island. In response to this, the CCA informed the AISAS in January 2013 of the risk involved in the activities of the intermediate ABP plant, but they

did not mention any of the findings of the investigations carried out by the NAS. They advised the regional CAs:

- Since this was now their responsibility, to re-approve the plant in accordance with new provisions laid down in Article 24 of Regulation (EC) No 1099/2009 and Article 19 of Regulation (EC) No 142/2011. In doing so, the AISAS should take into account that, according to the interpretation of the CCA, the existing approval of the plant did not cover handling category 3 ABP of porcine origin since November 2011, but only of other animal species. No official communication in respect of this restriction, amending the scope of the original approval, could be seen by the audit team.
- To put measures in place to mitigate all possible risks derived from the fact that this plant was still collecting ABP from various animal species in Sardinia, including of porcine origin, and that it was regularly dispatching ABP to other regions of Italy for processing purposes.
- Later in January 2013, the AISAS informed the plant of the advice given by the CCA and about the fact that they were not allowed to handle together ABP of porcine origin and other ABP intended to be sent to other parts of Italy. Nevertheless, the plant was still authorised to handle ABP of porcine origin provided the plant's own-checks system could ensure separation from any other ABP. In addition, the plant was informed about their upcoming re-approval, including an inspection to be carried out by the relevant ASL to verify the plant's own-checks system.
- In February 2013, the CCA reiterated to the AISAS the need to ensure that the intermediate plant was respecting the general animal health restrictions derived from Article 6 of Regulation (EC) No 1099/2009 and Decision 2005/363/EC.
- According to representatives of the SP, on the basis of the reinforced official controls they had been carrying out recently, they were in a position to ensure that this plant was no longer dispatching any ABP of porcine origin out of Sardinia. However, in March 2013, the CCA, upon suspicion that illegal activities could still occur, had asked the NAS in Sardinia to intensify again their investigations on the activities of the intermediate plant. At the time of this audit, these investigations were still ongoing and done following restrictive Court orders as regards releasing of information concerning their outcome; therefore, no additional information could yet be provided to the audit team.

5.4.3 Conclusions

Official controls on FBOs availing of derogations laid down in Decision 2005/363/EC have been intensified during 2012 and convincingly contribute to mitigate the risk of transmission of the ASF virus through products dispatched from Sardinia in accordance with the said Decision. However, some related areas whose effective management should complement the above mentioned official controls had not been given adequate attention by the CAs and, as a consequence:

- Procedures for updating the list of FBOs approved in the context of derogations laid down in Articles 5 and 6 of the said Decision are not applied effectively so as to ensure that the CAs can provide accurate information to the Commission and the other MS in accordance with Article 7 therein.
- Pig meat products produced before December 2011 with meat originating from pig holdings in Sardinia were still allowed to be placed on the EU market in accordance with an incorrect interpretation by the CCA of the scope of the last amendment of the said Decision, which effectively suspended from that month previous derogations contemplating that possibility.

- The CAs have not yet put in place adequate arrangements to ensure that effective official controls on ports and airports can guarantee that only authorised products of animal origin can leave the island, in accordance with Articles 5 and 6 of the said Decision.

Evidence has been found since 2012 of non-compliance with the prohibition to transport ABP of porcine origin from Sardinia to any destination out of the island; this, together with the reported persistence of widespread non-conformities in relation to disposal of ABP by farmers and small FBOs, indicate that:

- The approval process for the ABP intermediate plant under investigation can not be considered fit for purpose so that risks to animal health arising from the process used will be adequately contained, as required by Article 27 of Regulation (EC) No 1099/2009.
- The system of official controls to be implemented by the CAs along the ABP chain in line with Article 45 of Regulation (EC) No 1099/2009 has not been sufficiently effective to ensure compliance with:
 - general animal health restrictions applicable to the situation in Sardinia in accordance with Article 6 of the said Regulation due to the presence of ASF, and
 - basic requirements concerning disposal of ABP by all operators in accordance with Article 4 of Regulation (EC) No 1099/2009, so that adequate control of risks to animal health is ensured, in particular as regards transmission of the ASF virus.

Undertakings given by the CAs in respect of the reinforcement of the approval process and the official controls may be sufficient to address the deficiencies; however: a) the situation of the ABP plant was still unclear and under investigation, and b) compliance with requirements on disposal of ABP is not ensured in backyard holdings and concerning the clandestine rearing of pigs. Therefore, a level of uncertainty remains as to the adequate management by the CAs of risks derived from those shortcomings in the current epidemiological situation of ASF in Sardinia.

6 OVERALL CONCLUSIONS

The CAs have established a comprehensive legal environment and introduced a broad set of measures aimed at enhancing official controls on the pig population in Sardinia in order to control and eradicate ASF; however, they have not yet taken sufficiently decisive action to ensure the effective use of all those tools in accordance with EU requirements and as laid down in the approved control and monitoring programmes for the disease. The main shortcomings identified were:

- The inadequate functioning of coordination mechanisms between CAs and the lack of a clear and effective chain of command to ensure that all designated CAs fulfil their responsibilities. The main consequences are the lack of enforcement of basic legal requirements and the ineffective implementation of eradication and surveillance measures according to the evolution of the epidemiological situation of ASF in Sardinia.
- Unsatisfactory management of well-known risk factors contributing to the transmission of the ASF virus in Sardinia, such as illegal farming of free-range pigs and non-compliance with basic requirements on holding registration, animal identification and notification and registration of animal movements. This is exacerbated by the fact that these factors occur mainly in ASF infected areas, where the free ranging pigs cohabit with infected populations of wild boars, which significantly raises the level of ASF virus circulation at local level, and represents the major contributing factor to the spread and endemicity of the disease in the island.
- The inadequate targeting of surveillance efforts in infected areas, which significantly delays

the detection of all infected epidemiological units where the ASF virus is circulating and prevents the CAs from cutting its transmission routes effectively. As a consequence, even well circumscribed infected areas remain as such for very long periods of time.

- Insufficient awareness amongst the majority of pig farmers of the major importance for the control of ASF of both compliance with requirements on animal identification and movement of pigs, and application of basic biosecurity measures necessary to prevent exposure of the domestic pig population to the ASF virus.

Official controls on FBOs availing of derogations laid down in Decision 2005/363/EC have been intensified during 2012 and should contribute to mitigate the risk of transmission of the ASF virus through products dispatched from Sardinia in accordance with the said Decision. However, some problems were still found in this area in respect of: a) some pig meat products produced before December 2011 with pig meat originating in Sardinia that have been allowed to be placed on the EU market with the explicit consent of the CCA, b) the approach used for the updating of the list of FBOs approved in this context, and c) the insufficient involvement of the Sardinian Veterinary Services in the planning and implementation of official controls on ports and airports so as to ensure that only authorised products of animal origin can leave the island.

The CAs had found evidence of non-compliance with the prohibition to transport ABP containing material of porcine origin from Sardinia out of the island. The CAs took action to address the situation and further investigations were still ongoing at the time of the audit to determine responsibilities in that respect and confirm that the irregularities have been resolved.

7 CLOSING MEETING

A closing meeting was held on 20 March with representatives of the CAs. At this meeting, the main findings and preliminary conclusions of the audit were presented by the audit team. During the meeting the representatives of the CAs did not indicate any major disagreement with the findings and preliminary conclusions.

8 RECOMMENDATIONS

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

N°.	Recommendation
1.	To ensure that the official control system currently in place for ASF in Sardinia operate fully in line with general rules laid down in Regulation (EC) No 882/2004 for the performance of official controls to verify compliance with rules aimed at preventing, eliminating or reducing to acceptable levels, risks related to that disease for the pig population in the island and the rest of the EU, in particular as regards: coordination and cooperation within and between all relevant CAs; fulfilment by all relevant CAs of all allocated responsibilities; detection and resolution of all non-conformities with EU legislation that keep undermining control and eradication of the disease, and taken appropriate dissuasive action and enforce all legal requirements, as necessary.
2.	To ensure that all requirements on identification and registration of pigs laid down in Directive 2008/71/EC and the additional measures in that respect included in the ASF control and eradication programme approved by Decision 2012/761/EU, are complied

N°.	Recommendation
	with, in particular as regards: registration of all pig holdings present in Sardinia; adequate and timely individual identification of animals; notification to the CAs and adequate keeping of records in the holding registers of all movements of pigs, and effective enforcement of the prohibition to rear free-range pigs out of registered semi-enclosed or enclosed premises.
3.	To ensure that all suspect cases of ASF are immediately notified in accordance with Article 3 of Directive 2002/60/EC.
4.	To ensure that accurate data are provided to the ADNS in the context of immediate and compulsory notification of any suspicion and confirmation of the presence of ASF in accordance with requirements of Article 3 of and Annex I to Directive 2002/60/EC.
5.	To ensure performance of epidemiological inquiries in case of confirmation of ASF in line with Article 8 of Directive 2002/60/EC so that they contribute effectively to provide accurate and timely information necessary to ascertain the origin of the disease, the length of its presence in the affected holding and all possible factors and contacts that could contribute to its spread beyond the investigated holding.
6.	To ensure that specific controls and serological surveillance done in the context of the control and eradication programme approved for 2013 by Decision 2012/761/EU: can guarantee compliance with adequate levels of biosecurity in pig holdings; are implemented as required on high ASF health status holdings, so that they can avail of the possibility to move animals to other holdings of lower health status and, thereby, diminish the risk of illegal movements, and are adequately investigated and followed up, in case of positive serological results, in order to ascertain both the reasons behind the infection of the animals and the health status of the holding.
7.	To ensure that EU requirements laid down in Articles 15 and 16 of Directive 2002/60/EC, in relation to the confirmation of ASF in feral pigs, and specific measures in respect of ASF surveillance in this population laid down in the control and eradication programme approved for 2013 by Decision 2012/761/EU, are fully complied with, in particular as regards: make effective use of the expert group indicated in Article 15; preparation of an adequate updated eradication plan in accordance with provisions laid down in Article 16; verification of compliance with notification responsibilities of hunted wild boars and of feral pigs found dead, so that they can be sampled and tested, and increasing hunters' awareness of the measures they have to adopt in the framework of the ASF control and eradication programme.
8.	To ensure that all analytical methods used for official samples are included in the scope of accreditation in order to meet the requirements of Article 12 of Regulation (EC) No 882/2004.
9.	To ensure that all diagnostic methods used in the ASF eradication programme have

N°.	Recommendation
	been satisfactorily validated for the type of samples and species covered by the programme so that they can offer technically valid results in accordance with the EU diagnostic manual for ASF laid down in Decision 2003/422/EC.
10.	To ensure that procedures for updating the list of FBOs approved in the context of derogations laid down in Articles 5 and 6 of Decision 2005/363/EC are applied effectively so as to ensure that the CAs can provide accurate information to the Commission and the other MS in accordance with Article 7 therein.
11.	To ensure that all FBOs approved in the context of Decision 2005/363/EC cannot place on the market out of the Autonomous Region of Sardinia pig meat, pig meat products or any other product containing pig meat, from pigs originating in the island, so as to comply with the prohibition laid down in Article 3 of the said Decision.
12.	To ensure that all necessary arrangements are in place so that official controls on ports and airports are effective and can guarantee that only authorised products of animal origin can leave the Autonomous Region of Sardinia, in accordance with Articles 5 and 6 of Decision 2005/363/EC.
13.	To ensure that the approval process for the ABP intermediate plant under investigation is fit for purpose so that risks to animal health arising from the process used will be adequately contained, as required by Article 27 of Regulation (EC) No 1099/2009.
14.	To ensure that the system of official controls to be implemented by the CAs along the ABP chain in line with Article 45 of Regulation (EC) No 1099/2009 is sufficiently effective to ensure compliance with: general animal health restrictions applicable to the situation in Sardinia in accordance with Article 6 of the said Regulation due to the presence of ASF, and basic requirements concerning disposal of ABP by all operators in accordance with Article 4 of Regulation (EC) No 1099/2009, so that adequate control of risks to animal health is ensured, in particular as regards transmission of the ASF virus.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6788

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. 2002/99/EC	OJ L 18, 23.1.2003, p. 11-20	Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption
Dec. 2009/470/EC	OJ L 155, 18.6.2009, p. 30-45	2009/470/EC: Council Decision of 25 May 2009 on expenditure in the veterinary field (Codified version)
Dir. 2002/60/EC	OJ L 192, 20.7.2002, p. 27-46	Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever
Dec. 2003/422/EC	OJ L 143, 11.6.2003, p. 35-49	2003/422/EC: Commission Decision of 26 May 2003 approving an African swine fever diagnostic manual
Dec. 2005/363/EC	OJ L 118, 5.5.2005, p. 39-46	2005/363/EC: Commission Decision of 2 May 2005 concerning animal health protection measures against African swine fever in Sardinia, Italy
Dec. 2005/362/EC	OJ L 118, 5.5.2005, p. 37-38	2005/362/EC: Commission Decision of 2 May 2005 approving the plan for the eradication of African swine fever in feral pigs in Sardinia, Italy

Legal Reference	Official Journal	Title
Dec. 2011/807/EU	OJ L 322, 6.12.2011, p. 11-22	2011/807/EU: Commission Implementing Decision of 30 November 2011 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2012 and following years
Dec. 2012/761/EU	OJ L336, 8.12.2012, p.83-93	2012/761/EU: Commission Implementing Decision of 30 November 2012 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2013
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)
Dir. 92/102/EEC	OJ L 355, 5.12.1992, p. 32-36	Council Directive 92/102/EEC of 27 November 1992 on the identification and registration of animals
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)
Reg. 142/2011	OJ L 54, 26.2.2011, p. 1-254	Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive