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FINAL REPORT OF A FACT-FINDING MISSION

CARRIED OUT IN

ITALY

FROM 24 JUNE 2019 TO 28 JUNE 2019

IN ORDER TO

EVALUATE THE IMPLEMENTATION OF ANIMAL HEALTH CONTROLS IN RELATION TO AFRICAN SWINE FEVER

Executive summary

This report describes the outcome of a fact-finding mission in Sardinia, Italy, carried out from 24 to 28 June 2019, which was added to the DG Health and Food Safety programme in agreement with the Italian authorities.

The main objectives of the fact-finding mission were to evaluate the suitability of planned arrangements in achieving the objective of eradicating African swine fever (ASF) and to verify the extent to which the guarantees and corrective actions submitted to the Commission services in response to the recommendations included in the report of the latest Commission audit on this subject in October 2016 have been implemented and enforced by the competent authorities.

*In the last two years, the Project Unit for the eradication of ASF (*Unita di Progetto*) established by the Regional Government of Sardinia to direct and coordinate the ASF control and eradication programme has substantially re-organized the veterinary structures responsible for its delivery. Key milestones include:*

- *the establishment of a single coordination unit;*
- *the rationalisation of provincial veterinary services;*
- *the creation of a veterinary intervention group;*
- *the systematic rotation of district veterinary inspectors.*

The report concludes that the epidemiological situation in domestic pigs has improved significantly over the last 18 months. During this time, there have been no disease outbreaks in registered pig holdings. The veterinary authorities mainly attribute this to improved control of free-ranging (illegal) pigs and better biosecurity on pig holdings.

The dense wild boar population, particularly in northern Sardinia, presents a serious risk to the eradication of ASF. Since 2016, controls on hunting activities performed by the veterinary authorities and forestry inspectors have been reinforced to ensure the safe disposal of animal by-products and to check compliance with wild boar sampling requirements. On the other hand, some hunting practices in Sardinia do not conform to the EU strategic approach. The veterinary authorities consider that more rigorous requirements would risk alienating hunters.

The veterinary authorities report a change in attitude among local people, who are more willing to inform them about suspected disease and possible illegal activities. This is partly thanks to the extensive communications campaign directed at farmers, hunters and the public. It also reflects growing public confidence in the commitment and ability of the veterinary authorities to eradicate the disease. Representatives of the hunters' and pig producers' associations are in favour of maintaining the Project Unit for the eradication of ASF and continuing to implement the regional eradication programme.

The measures in place to prevent the dispatch of potentially infected pig meat and products from Sardinia, either in commercial consignments or carried in personal luggage, are well-established and well-understood. Official controls in meat establishments and at the air and sea ports to apply these measures are effective.

There has been significant progress bringing ASF under control in Sardinia. The problem of free-ranging (illegal) pigs has improved but has not yet been solved and the risk of disease from wild boars continues to be a threat. As the number of infected animals decreases, the veterinary authorities have to make additional efforts and use more of their resources in order to stamp out the remaining pockets of this persistent disease. For this, they rely on the continued commitment of their political leaders and on the support from farming and hunting organisations.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ASF	African swine fever
ASL	*Azienda sanitaria locale* Local health unit
ATS	*Azienda tutela della salute* Health protection unit
GIV	*Gruppo di Intervento Veterinario* Veterinary intervention group
IZS	*Istituto Zooprofilattico Sperimentale* Experimental zooprophylactic institute – the regional reference for ASF
LAORE	Agency for the implementation of regional programmes in agriculture and rural development.
SIMAN	System for the Notification of Infectious Animal Disease
UdP	*Unita di Progetto* Project Unit for the eradication of ASF
UVAC	*Uffici Veterinari per gli Adempimenti Comunitari* Veterinary Offices for Compliance with EU Requirements, responsible for controls on intra-Union trade

1 INTRODUCTION

The fact-finding mission took place in Sardinia, Italy from 24 to 28 June 2019. The mission was added to the DG Health and Food Safety programme for 2019 in agreement with the Italian authorities.

The mission team comprised two officials from the Commission services. The team was accompanied throughout the mission by representatives of the central competent authority.

2 OBJECTIVES AND SCOPE

The purpose of this fact-finding mission was to collect up-to-date information on the current epidemiological situation in Sardinia and on the progress that the veterinary authorities have made to overcome issues identified previously. The main objectives were:

- To evaluate the suitability of planned arrangements in achieving the objective of eradicating African swine fever (ASF);
- To verify the extent to which the guarantees and corrective actions submitted to the Commission services in response to the recommendations included in the report of the latest Commission audit[1] on this subject in October 2016 have been implemented and enforced by the competent authorities.

The scope of the mission covered all aspects of the regional ASF eradication programme for 2018-19. It did not include the draft national programme for the control and eradication of ASF for 2020, which was still under evaluation by the Commission at the time of this mission.

The mission was conducted by review of documentation, interviews and inspections.

In pursuit of the objectives, the following sites were visited:

Meetings/Visits		**No.**	**Comments**
Competent authorities	Central	2	Opening and closing meetings with representatives of the relevant services of the competent authorities
	Local	2	Health protection unit (ATS) Local health unit (ASL) Ogliastra, Nuoro
Laboratories		1	Experimental zooprophylactic institute (IZS) - Cagliari
Pig farms		2	One backyard, one commercial
Processing plant		1	Meat processing establishment
Hunting ground		1	Dog training facility
Port		1	Cagliari

1 http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3825

3 LEGAL BASIS

The fact-finding mission was carried out under the general provisions of EU legislation, in agreement with the competent authority of the country, and in particular under:

- 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 20 of Council Directive 2002/60/EC laying down specific provisions for the control of ASF and amending Directive 92/119/EEC as regards Teschen disease and ASF.

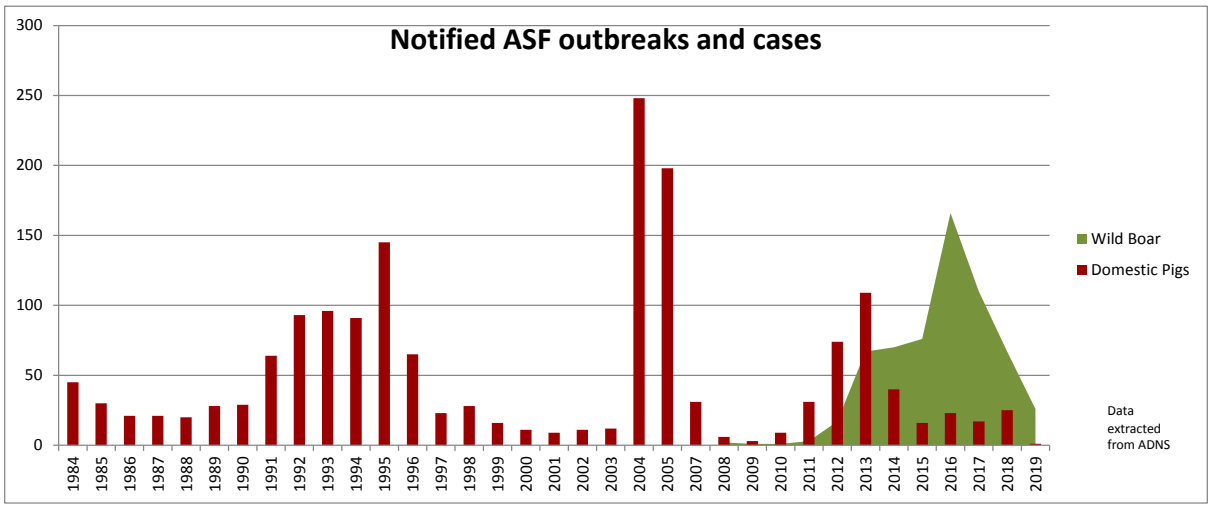
The evaluation criteria included:

- EU legislative requirements concerning the keeping of pigs and the control and eradication of ASF (the full legal references are provided in Annex 1);
- The Strategic approach to the management of ASF for the EU (SANTE/7113/2015 - Rev 10[(2)]) – hereafter referred to as the EU Strategic approach;
- The Regional Government of Sardinia's programme for the control and eradication of ASF (Delib G.R 6/12 of 6 February 2019).

4 BACKGROUND

4.1 HISTORY OF THE DISEASE

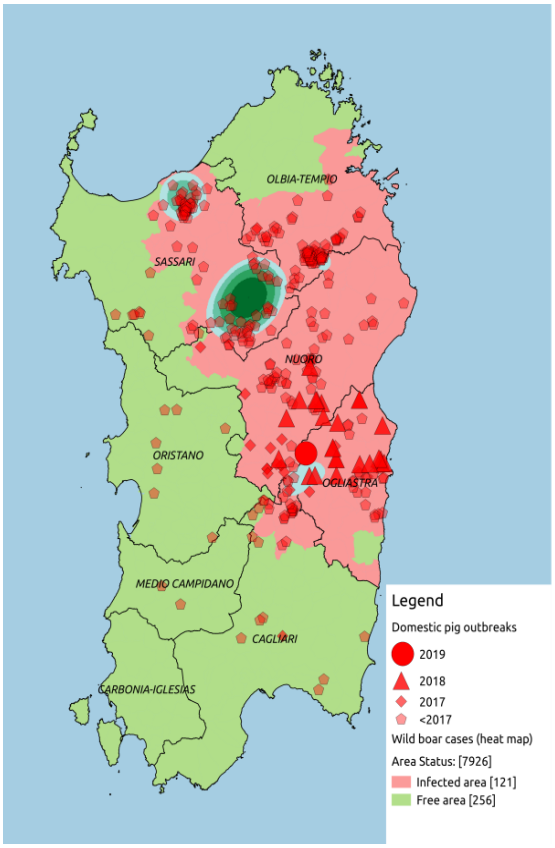
ASF first occurred in Sardinia in 1978. Since then it has persisted despite numerous campaigns to eradicate the disease. The following chart summarises data held on the Animal Disease Notification System (ADNS) database for all ASF outbreaks in domestic pigs and cases in wild boar (data available since 2011) in Sardinia:



Since 1982, the disease incidence has fallen to low levels on a number of occasions. However, any hopes that the disease might be eradicated were short-lived as the disease recovered its dominance over the pig population on the island.

[2] https://ec.europa.eu/food/sites/food/files/animals/docs/ad_control-measures_asf_wrk-doc-sante-2015-7113.pdf

For most of this period, the provinces of Nuoro and, to a lesser extent, Oristano were worst affected. The upsurge of outbreaks observed during 2012 and 2013 was particularly alarming because outbreaks began to occur in Sassari and Cagliari provinces. In more recent years, the disease has only been observed in Ogliastra and Nuoro. It is significant that these are not the areas with the highest pig population densities.



Local researchers[3] identified a number of factors involved in the persistence of the disease:

- unregistered (illegal) free-ranging pigs ('brado');
- high density of wild boar;
- large proportion of non-professional farms;
- counter-productive compensation policies.

4.2 DOMESTIC PIG PRODUCTION

Pig production in Sardinia is a secondary but important agricultural activity, particularly in mountainous areas where grazing for other livestock is not available. It provides a source of income and employment for rural dwellers with little or no land.

Historically, a considerable part of the region (more than 400,000 hectares, distributed across the island) is held in communal ownership. The public has access to this land and is free to make use of its resources. The communal ownership of land is an important part of the Sardinian cultural identity. Much of this communal territory is covered by oak forest and most of the illegal pig rearing has occurred in these areas. Not alone is this land well-suited to the extensive rearing of pigs, its cultural importance has made it extremely difficult for the authorities to enforce holding registration requirements.

4.3 WILD BOAR MANAGEMENT

The estimated wild boar population in Sardinia is 90,000. This represents an average population density of approximately 3.7 wild boar/km^2 across the entire territory of the island. This is high when compared with other parts of Europe. In fact, studies conducted by the Wildlife Observatory in the University of Pavia during 2013[4] concluded that the wildlife

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3 Mur L, Atzeni M, Martinez-Lopez B, Feliziani F, Rolesu S, Sánchez-Vizcaíno J. (2014). "Thirty-Five-Year Presence of African Swine Fever in Sardinia: History, Evolution and Risk Factors for Disease Maintenance" *Transboundary and Emerging Diseases* 63. 10.1111/tbed.12264.

4 Piano di Controllo e Gestione del Cinghiale nel territorio di Buddusò http://www.regione.sardegna.it/documenti/1_82_20151118100609.pdf

density in the north-eastern part of Sardinia varied from 1,5 wild boar/km^2 to more than 45 wild boar/km^2, with a mean density in managed hunting grounds, communal areas and nature reserves of 14,4 ± 3,1 wild boar/km^2. These studies also highlighted the important role that nature reserves play in this region as a refuge for breeding animals. By extending their home range into surrounding intensively farmed areas, which provide a rich source of feed for much of the year, wild boar are able to sustain the high population densities observed.

The European Food Safety Authority (EFSA)[5] has concluded that it is currently not possible to determine a density threshold below which ASF will not persist in a wild boar population. This is because the ecology of the disease is complex and there are many external factors (including the behaviour of hunters and farmers) that can contribute to the maintenance and spread of disease. Nevertheless, the likelihood of disease transmission does increase as the population density increases. For this reason, the large wild boar population represents a significant obstacle to the eradication of ASF from Sardinia.

4.4 ERADICATION PROGRAMMES

Eradication programmes began in 1982 and have continued every year since then. Following the upsurge of outbreaks observed in 2012-2013, the Ministry of Health in Rome and the Regional Government of Sardinia agreed on a new approach that would place authority and responsibility for all ASF eradication measures in the hands of the Regional Government.

With this mandate, the Regional Government established a Presidential Steering Committee to oversee the development and implementation of the first regional programme for the eradication of ASF. A Project Unit (*Unita di Progetto* - UdP) was established under the direction of the Director General of the Regional Presidency. The first regional eradication programme, covering the period 2015-2017, was published in December 2014 and launched the following spring. The programme has been extended and modified during the subsequent period. The latest version of the programme covers the period 2019-2020[6].

Between 2017 and 2019, the Regional Government has invested approximately € 5 million of the regional budget on the ASF programme. Most of these funds were dedicated to funding and resourcing the field operations undertaken by the veterinary intervention group (*Gruppo di Intervento Veterinario* - GIV) and the Forestry Corp. 2015 was the last year for which an ASF eradication programme in Italy was approved by the Commission for the purposes of technical assurance and financial support.

The most recent Commission audit in Sardinia to evaluate the implementation of animal health controls in relation to ASF was carried out in October 2016. The audit report (see footnote 1) highlighted the value of the UdP as a means to ensure effective management, coordination and cooperation among different authorities (at central, regional and local levels). However, insufficient progress had been made to tackle the significant number of uncontrolled pigs on the island. Delays in the imposition of restrictions following disease

5 EFSA Scientific Opinion 'African swine fever in wild boar' EFSA Journal Volume 16, Issue 7, July 2018 https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5344

6 Regional Government decisions: 50/17 of 16 December 2014; 46/4 of 10 August 2016; 52/12 of 23 October 2018; 6/12 of 5 February 2019

outbreaks and insufficient official surveillance on pig holdings were also identified as factors that undermined the effectiveness of disease prevention and control measures. The table presented in section 5.6 summarises the open audit recommendations and the measures being taken to address them.

5 FINDINGS AND CONCLUSIONS

5.1 ORGANISATION

Legal requirements

Article 21 of Directive 2002/60/EC

Articles 4 and 8 of Regulation (EC) No 882/2004

Findings

1. The UdP led by the Director-General of the Regional Presidency coordinates the activities of the regional veterinary, agricultural agencies, and forestry agencies. It has the authority to directly mobilise all regional resources needed for disease control purposes. This ensures that measures can be taken promptly, without undue bureaucratic delay. It also reduces considerably the political pressure exerted on the local authorities by interest groups.

2. Since its establishment, the UdP has taken a series of measures to rationalise and strengthen the organisation and implementation of the ASF eradication programme.

5.1.1 Reorganisation of the provincial veterinary authorities

3. Prior to the reform, each of the existing eight provinces possessed its own local health unit (*Azienda Sanitaria Locale* - ASL) with a department dedicated to the prevention of animal diseases. These were supported by 24 veterinary services, which perform the on-farm measures and controls required for the implementation of the eradication programme.

4. This organizational structure was formally replaced[7] with a single health protection unit (*Azienda Tutela della Salute* - ATS) covering the entire region. This ATS is subdivided into three areas: Northern, Central and Southern.

5. Each area has its own prevention department. The Central area is further subdivided into two parts: the eastern part comprises the area previously covered by the ASLs for Nuoro and Lanusei. The western part comprises the area previously covered by the Oristano ASL.

6. The ATS is supported by four veterinary services responsible for animal health controls (separate veterinary services are also responsible for food safety and farm hygiene).

7. In practice, the transition to the unified structure was implemented progressively. At the time of the fact-finding mission, the planned centralisation of the administration of

[7] Legge Regional n.17 of 27 July 2016

sanctions had not yet been achieved. Otherwise, the unified structure is now in operation.

5.1.2 Veterinary intervention group

8. The GIV, which is comprised of 12 veterinarians and 12 auxiliaries, was established in 2017[8] and commenced activities in June that year.

9. This is a team of dynamic, highly-trained and committed individuals responsible for:
   a. measures taken against illegal pigs (see section 5.2.2);
   b. checks on pigs holdings (covering biosecurity and animal identification and registration requirements) (see section 5.2.3);
   c. controls during the hunting season (see section 5.3.1);
   d. controls on regional investigation of seropositive animals (see section 5.3.2);
   e. epidemiological investigation (see section 5.4.1);
   f. emergency sanitary measures in the event of an outbreak (see section 5.4.2).

5.1.3 Rotation of official veterinarians

10. One of the weaknesses that the UdP identified in the implementation of previous eradication programmes was the exposure of official veterinarians to potential conflicts of interest. Having worked, and often lived, in the same communes for many years, official veterinarians often found themselves enforcing unpopular animal health control measures on neighbours, friends and even family members. On occasion, this led to situations where animal health requirements were not enforced consistently and fairly. In turn, this tarnished the reputation of the veterinary authorities and limited their ability to prosecute the eradication programme.

11. In order to address this issue, the ATS ordered[9] each Prevention Department to ensure that all veterinarians and managers working in the Department and in associated veterinary services completed an official conflict of interest declaration. Where potential conflicts were identified, the personnel were moved to different duties. At the same time, a pilot programme was launched to systematically rotate staff, preferably to neighbouring communes, in order to avoid situations where staff carrying out official duties are subject to intimidation. By the time of the fact-finding mission, more than 300 veterinarians had been rotated to different communes or duties.

5.1.4 ASF coordinator

12. In June 2018 the UdP appointed[10] an experienced veterinarian to the role of ASF coordinator with responsibility for the coordination and supervision of all actions taken to implement the Regional programme for the eradication of ASF. The ASF coordinator plays a key leadership role for the veterinary authorities, using professional judgement to

8 DG decision 238 of 27 April 2017

9 ATS Prot. Nr PG 241 268 of 5 July 2017

10 DG decision 724 of 1 June 2018

direct the eradication programme taking account of available epidemiological data and technical operational information.

5.1.5 Epidemiological observatory

13. The epidemiological observatory provides expert data analysis to support decision making. By analysing field and laboratory data held in the System for the Notification of Infectious Animal Disease (SIMAN) database, the observatory assists the UdP to plan and coordinate its activities. For example, its work on the risk categorisation of communes and holdings is central to the planning of official controls on pig holdings (see section 5.2.3).

5.1.6 Communications & public awareness

14. The organisation responsible for the communications exercises is the agency for the implementation of regional programs in agriculture and rural development (LAORE) *Sardegna*, the Government agency responsible for the implementation of rural development policy on the territory.

15. The public awareness campaign has a budget of approximately € 40,000 per year and is delivered across all media channels including print, television, radio, on line and using posters displayed throughout the high risk area. The campaign is delivered through the Italian and Sardinian languages. It aims to raise the awareness of the public by debunking commonly held beliefs. The economic benefits of disease eradication are highlighted regularly, with frequent references to Spain, where there was a five-fold increase in production following the eradication of ASF.

16. Different messages are targeted at three distinct groups:
    a. the legal pig farmers;
    b. the illegal but willing pig farmers;
    c. the unwilling pig farmers.

17. The mission team met representatives of the Sardinian hunters' and pig producers' associations, who confirmed their support for the ASF eradication programme spoke strongly in favour of maintaining the UdP and continuing its activities.

5.1.7 Laboratory performance

18. The regional reference laboratory for ASF in Sardinia is the *Istituto Zooprofilattico Sperimentale* (IZS). The institute's headquarters are located in Sassari and there are three provincial diagnostic laboratories in Cagliari, Nuoro and Oristano. All four IZS laboratories are involved in the ASF diagnostic network.

19. The laboratory in Sassari coordinates the activities of the network and performs confirmatory tests on positive samples detected by the provincial laboratories. Sassari also performs genetic sequencing on new viral isolates. The three provincial diagnostic laboratories perform serological tests and real time PCR.

20. All laboratories apply the same diagnostic and quality assurance procedures and operate

within a single laboratory information management system. Laboratory reports are made available to field veterinarians in real time through the SIMAN information system.

21. *IZS Sardegna* is competent to officially declare ASF outbreaks without seeking confirmation from the Italian National Reference Laboratory for ASF.

22. *IZS Sardegna* participates directly in the EURL ring tests. It also participates in the proficiency trials organized by the National Reference Laboratory. The results from all of these trials are consistently satisfactory. In addition, veterinarians and technicians from *IZS Sardegna* regularly collaborate and exchange information with both reference laboratories.

23. All laboratories within the *IZS Sardegna* hold ISO 17025 accreditation certificates issued by the national accreditation body.

24. The laboratory reports reviewed during this mission indicated that samples obtained from suspect cases and during routine surveillance were analysed promptly and in accordance with established procedures.

Conclusions on organisation

25. The rationalisation and reorganisation of veterinary control structures establishes the authority and responsibilities of the component teams and structures. It has eliminated important conflicts of interest (both real and perceived) and improved the effectiveness of the ASF eradication programme.

26. The appointment of experienced and well-respected officials to lead the UdP, coordinate veterinary activities, lead the GIV and to provide expert advice has undoubtedly facilitated the smooth implementation changes. As many of these lead officials are now approaching retirement, the veterinary authorities will need to plan for their succession.

5.2 CONTROLS ON SWINE PRODUCTION

Legal requirements

Articles 3, 4 and 5 of Council Directive 2008/71/EC

Article 18(c) of Council Directive 64/432/EEC

Articles 10 and 15(2)(b) of Directive 2002/60/EC

Article 17 of Commission Implementing Decision 2014/709/EU

Findings

5.2.1 Registration and categorisation of holdings (including biosecurity requirements)

27. There are approximately 13,000 registered pig holdings keeping 178,000 domestic pigs. For biosecurity purposes these are classified in three categories based on risk:

a. non-commercial or backyard farms: pigs are only kept for fattening and are intended for self-consumption; neither live animals nor pig products are transported outside the farm.

b. commercial farms (breeding farms and fattening farms): farms dispatching pigs intended for breeding and slaughter, and transporting pig products outside the farm.

c. farms where pigs are kept in outdoor structures temporarily or permanently: these pigs are not free-ranging as the grazing of pigs outside the holding and holding pens is prohibited throughout the territory of Sardinia.

28. The regional biosecurity requirements for swine holdings establish progressively more stringent measures depending on the size of the holding. The requirements are in line with, and in some respects go beyond, the measures established in the EU strategic approach.

29. Although they have been in place since 1998, the biosecurity rules have not been enforced until recently. The task force veterinarians now systematically follow up non-conformities and the payment of compensation for animals culled for animal disease reasons is linked to compliance with biosecurity rules.

5.2.2 Measures taken against free-ranging (illegal) pigs

30. The previous Commission audit (see footnote 1) concluded that the existence of uncontrolled pigs undermined the traceability of pig movements in the region. Since then the UdP has made concerted efforts to tackle the problem.

31. Since 2016, there has been a 90% reduction in the free-ranging pig population as result of joint action taken by the GIV and the forestry inspectors, often working in difficult and sometimes dangerous circumstances. By June 2019, the veterinary authorities estimated that the remaining illegal pig population was between 500 and 700 animals.

32. Where free-ranging pigs have been removed they apparently have not been replaced. The veterinary task force reports a change in the attitude of local communities, with local people now being willing to inform them about the presence of illegal pigs in their area.

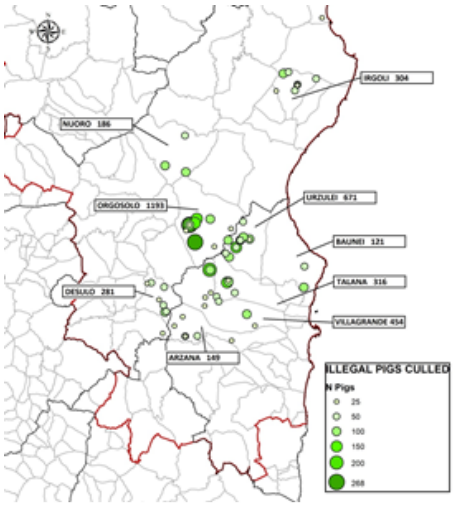
33. Since 2015, the veterinary authorities have undertaken 79 separate exercises to identify, seize and destroy free-ranging (illegal) pigs. These exercises are undertaken jointly by the GIV (see section 5.1.2) and the Forestry Corps (the regional environmental protection service).

34. Following initial exercises undertaken in 2015 and 2016, the depopulation campaign began in earnest in December 2017. During this campaign, stable teams were organized involving more than 100 personnel. Beginning at the edges of the area where free-ranging (illegal) pigs were kept they progressively worked inwards to tackle the more difficult cases.

35. The campaign was suspended temporarily during the dry season in the summer of 2017, when the Forestry Corp was fully occupied dealing with the risk of forest fires. For this reason, depopulation activities were also suspended at the time of the fact-finding

mission.

Year	Pigs culled	Cumulative total
2015	58	58
2016	420	478
2017	616	1,094
2018 (1st half)	1,792	2,886
2018 (2nd half)	860	3,746
2019 (1st half)	551	4,297



36. During the fact-finding mission, depopulation activities were temporarily suspended to allow the Forestry Corps to concentrate on fire-watch activities during the dry season.

37. So far, there have been no cases where free ranging pigs have reappeared in areas from which they were removed. Apparently, local communities are no longer willing to tolerate the illegal activities of a few self-interested individuals.

38. Although all of the culled animals appeared to be clinically healthy, the GIV routinely collected samples to investigate their ASF status. 1,861 animals were tested, of which 46% possessed ASF antibodies (indicating that they had previously been exposed to the disease, perhaps months or even years previously) and 2.8% were virus positive (indicating that they were actively infected when killed).

5.2.3 Official controls and surveillance on registered pig holdings

39. The veterinary authorities implement a systematic programme of on-the-spot controls on domestic pig holdings across the entire region. The purpose of these controls is fourfold:

    a. verification of compliance with animal identification and registration requirement (including cross checks on reproductive performance);

    b. verification of compliance with national biosecurity requirements (including the safe disposal of animal by-products);

    c. verification of compliance with animal welfare requirements;

    d. disease surveillance, based on clinical examination and, in certain cases, serological analysis.

40. Based on the outcome of these controls, the holdings are classified as:

    a. **certified** – the results of the clinical and serological examination are favourable and the holding complies with animal identification and registration, animal welfare and biosecurity requirements;

    b. **controlled** – the results of the clinical and serological examination are favourable but breaches in compliance with animal identification and registration, animal welfare or biosecurity requirements were detected.

41. The latest Commission audit (see footnote 1) recognised the value of this approach but observed that it was not being fully implemented. For example, more than 20% of the holdings located in the infected area had not been checked by the veterinary authorities that year. This was an improvement on the situation in 2015, when more than 50% of the holdings had not undergone an annual inspection.

42. By the end of 2018, there were 8,488 (63%) certified holdings, 4,627 (34%) controlled holdings and 57 (3%) uncontrolled holdings. The veterinary authorities explained that there is a regular annual turnover of holdings, with new holdings being established while others cease operations. As a result, some uncontrolled holdings are encountered each year. They believe that most of the uncontrolled holdings in 2018 can be accounted for in this way.

43. The frequency and extent of these controls is determined based on the risk profile of the holding and of the commune in which it is located. Each commune is assessed taking account of factors that have been shown to either reduce or increase the likelihood of infection:

    a. **protective factors**: including level of compliance with biosecurity requirements; compliance with animal identification, registration requirements;

    b. **risk factors**: including the presence of infected wild boar (virologically or serologically positive) and the presence of illegal free-ranging pigs.

44. There are five risk categories, ranging from 1 (low risk) to 5 (highest risk). Farms in the higher risk categories are checked twice each year and serological samples are routinely collected to check for possible ASF virus circulation. Samples are also collected from farms that were not checked during the previous year (regardless of the risk level).

45. The GIV generally performs the official controls on high-risk holdings within the infected area. They collected blood samples from 77% of the holdings that they inspected.

46. The risk profile is updated each year and a progressive improvement in the profile of the municipalities has been observed. The following table summarises the risk categorisation at the start of 2019:

Risk level	No. of holdings	Inspection target
1,2	11,815	7,926
3	980	723
4	534	471
5	361	361
Total	**13,690**	**9,481**

Note: 5,641 of these holdings are located in the Infected Area

47. In cases where biosecurity deficiencies are detected, keepers are ordered to correct them within a maximum of two months. If the holdings do not meet the requirements within that period they are de-stocked and closed, under the supervision of the ATS. The mission team was informed that many holdings had been closed on this basis.

48. The mission team checked the records of official controls performed on domestic pig holdings. They were well-documented and reached clear conclusions on the level of compliance with biosecurity, animal identification and health requirements. Keepers are required to sign the checklist used during these controls. They are given the right to appeal if with they disagree with the inspectors' conclusions.

49. Several cases were reviewed where the inspectors had found breaches with biosecurity requirements. These were recorded accurately and were followed up within the prescribed time limit for corrective action.

50. On the other hand, the mission team observed that the follow up of non-compliances related to the holding registers (e.g. discrepancies in the notification of births and on-farm deaths/slaughter) was insufficient. In one case, where GIV officials detected under-reporting of on-farm births, no sanctions or other written warnings were issued to the keeper. The veterinary authorities explained that their initial focus had been on improving biosecurity but that they are now pursuing more diligently cases in which keepers under-report births and deaths on their holdings.

5.2.4 Disease surveillance on domestic pig holdings

51. In addition to the collection of active surveillance samples during official controls, the veterinary authorities also treat all domestic pigs that die on-farm as suspect cases. As a result, the number of suspect outbreak cases investigated by the veterinary authorities has increased significantly during this period. This measure is coupled to the communications campaign undertaken to maintain public awareness about the signs and significance of the disease (see Section 5.1.6).

5.2.5 Incentives for farmers

52. The regional Rural development programme for 2014-2020 includes a range of incentives and initiatives for registered farm holdings. The measures, which are valued at € 50 million over 5 years, include the establishment of:

a. funds allowing farmers to access business consultancy service and to join farm quality schemes;

b. grants promoting farm modernisation and diversification as well as the conservation of local breeds (*Suino Sardo*);

c. grants supporting additional structural improvements to promote animal welfare;

d. support for the establishment of producer organisations and local groups to promote knowledge transfer, innovative practices and community participation;

e. additional disadvantaged area payments.

53. Among these measures, the investment in additional animal welfare improvements has proved to be particularly successful in achieving improvements in the overall biosecurity standards, especially on pig holdings with controlled status (see section 5.2.3).

54. The regional government is also supporting artificial insemination and breeding training courses for pig keepers. By using artificial insemination, keepers of small holdings can avoid the disease risks associated with boar-sharing.

Conclusions on swine production

55. By simultaneously tackling the illegal pig problem and rolling out systematic checks on registered domestic pig holdings, the veterinary authorities have secured widespread acceptance of, and compliance with, pig identification, registration and biosecurity requirements. The deployment of rural development funds to support pig keepers who are willing to improve the biosecurity conditions on their holdings has undoubtedly reduced the risk of disease circulation and supports sustainable and responsible pig ownership.

5.3 MANAGEMENT AND SURVEILLANCE OF WILD BOAR

Legal requirements

Article 15 and 16 of Directive 2002/60/EC

Chapter VI, Section H of Commission Decision 2003/422/EC

Findings

5.3.1 ASF eradication plan for wild boar

56. In May 2019, the Regional Government announced measures to combat ASF in wild boar during the 2019-2020 hunting season. This replaced the previous programme, which had operated from 2015 (with several amendments). Key elements of the programme include:

a. The obligation on the environmental and agricultural authorities and Forestry Corps to provide each year updated information on registered hunting grounds and

places where wild boar are kept (including organisations keeping wild boar for hunting or other purposes) and on registered hunters.

b. Each hunting group must register with their local veterinary authorities, notifying the names of the responsible hunter and the arrangements for hygienic and safe handling and storage of wild boar carcases and for the disposal of animal by-products. 663 hunting groups were approved last year.

c. The responsible hunters must participate in paraprofessional training courses organised by LAORE under the direction of the UdP. Between 2016 and 2018, more than 7,000 hunters were trained (from an estimated 40,000 hunters in Sardinia).

d. The hunters and Forestry Corps are obliged to notify each dead wild boar they encounter. For this purpose, the veterinary authorities have organised joint patrols with them to look for dead animals in more than 6,000 hectares of forest.

e. In the non-infected area, hunters must collect at least 59 blood samples from each defined macro-area every hunting season. These are tested for the possible presence of antibodies to ASF virus. Carcases must be stored securely and intact until the results of the analysis are available.

f. Within the infected area, hunting is generally prohibited. However, hunting groups may be authorised to do so by the local veterinary authorities, specifying the hunting areas and responsible hunters. In order to be authorised the hunting groups must demonstrate that they have appropriate facilities for evisceration and handling of carcases. Hunters authorised to hunt in the infected area may not participate in hunts in the uninfected area.

g. Wild boar shot within the infected area are tested for the possible presence of ASF virus. Carcases may not be split or moved until the results of these tests are known.

h. The Forestry Corps is responsible for enforcing compliance with the above requirements. If any hunting group is found to be in breach of their obligations, their authorisation to hunt may be suspended immediately and for a period of at least 30 days.

i. All holdings where wild boar are kept, including breeding and rearing holdings, agri-tourist hunting holdings and dog training facilities, must be securely fenced. They must be registered as pig holdings and comply with the same identification and movement recording requirements as domestic pig holdings and all hunting activities must be authorised by the local veterinary authorities. The keepers of these holdings must participate in the training referred to in point (b) above.

57. In several respects the arrangements in place to tackle the problem of ASF in wild boars are less rigorous than the recommendations in the EU strategic approach:

a. hunting with dogs is not prohibited – indeed, it is the only method of hunting permitted for wild boar (see section 5.3.2);

b. hunting is not suspended in areas where cases of ASF in wild boar have been confirmed;

c. there are no initiatives to target adult and sub-adult females during hunting;

d. hunting for consumption continues within the infected area, in circumstances where culling by trained hunters is recommended, with all culled animals being rendered;

e. there is no agreed strategy to reduce significantly the density of the wild boar population outside the infected area.

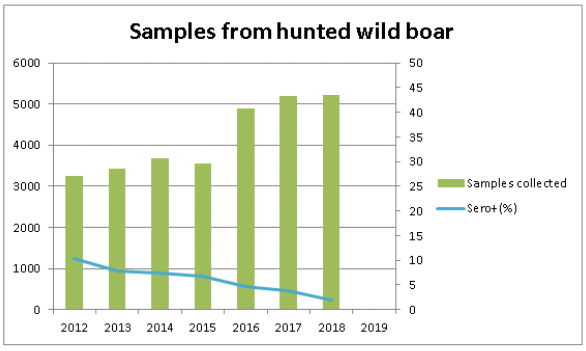
5.3.2 Population estimation and hunting control

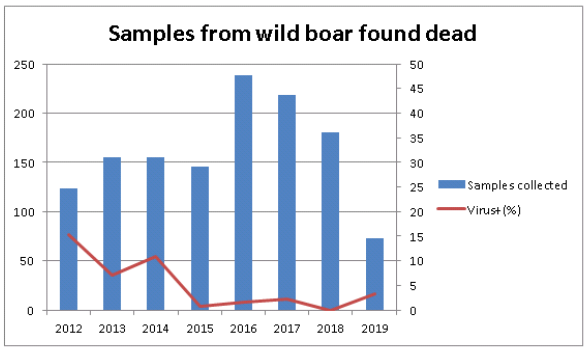
58. Each year the Minister for the protection of the environment announces the official hunting calendar. For the 2019/2020 hunting season, 27 hunting days are planned (between 3 November and 30 January). The means of hunting authorised is using dogs.

59. Responsibility for managing and protecting wildlife, including the establishment of hunting quotas and targets, is delegated to the provincial authorities. Currently there is no regional plan for the management of the wild boar population. However, the Regional Department of Environmental Protection is currently consulting on proposals for a regional wildlife hunting plan which would include wild boar. The proposal is to develop this plan taking account of the hunting plans in each of the provinces. The aim is to achieve sustainable wildlife populations in which carnivorous species are not overly abundant.

5.3.3 Disease surveillance

60. Surveillance was carried during 2018 and 2019 in accordance with the provisions of the regional eradication programme (see Section 5.3.1). In total, 12,716 samples collected from wild boar were tested (including samples from hunted and found dead animals). The results are summarised below:





61. Key points to note include:

a. The upward trend in the number of samples (passive and active) collected each year contributes to increasing the likelihood that new cases of the disease in wild boar are likely to be detected at an earlier stage;

b. The downward trend in the likelihood of detecting seropositive animals. When coupled with an observed increase in the average age of seropositive animals, downward trend in seroprevalence suggests a decrease in the incidence of the disease in the wild boar population over the last seven years.

62. As indicated above, wildlife disease hotspots in the infected area are subject to additional surveillance, including patrols to find carcasses of dead wild boar. Two positive carcasses were in fact found in April of this year.

63. Where positive serology or virology results are obtained from wild boar, the GIV carries out a follow up investigation to decide whether a case of the disease may be confirmed (see paragraph 62) and to determine the additional measures required.

64. The IZS provided information on recent studies to evaluate and validate an experimental pen-side test based on molecular biological probes that simultaneously detect antibodies and antigens specific to ASF virus. The intention is to develop this test for use in the field as a means to rapidly and reliably determine the ASF status of hunted wild boars.

65. The veterinary authorities provided information about a pilot ASF surveillance project in Sassari during 2017, which involved the killing of wild boars by trained hunters outside the normal hunting season and on privately owned land. This project yielded surveillance samples from 246 animals killed outside the infected territory in areas of woodland and shrubs surrounded by agricultural land. None of the samples analysed revealed signs of previous exposure to ASF virus.

Conclusions on management and surveillance of wild boar

66. The increased segregation of the domestic pig and wild boar population reduces the risk of disease transmission between the populations. However, it is likely that the disease will persist due to the existing high wild boar population densities. For this reason, the continuation of practices not aligned with the EU Strategic approach increases the risk that the disease will persist in the wild boar population.

5.4 DETECTION AND CONTAINMENT OF OUTBREAKS

Legal requirements

Articles 4, 5, 8, 9 and 11 of Directive 2002/60/EC

Chapters III and IV of Annex to Commission Decision 2003/422/EC

Findings

5.4.1 Confirmation of disease

67. As indicated above, the veterinary authorities have established surveillance requirements to actively (see Section 5.2.3) and passively (see Section 5.2.4) detect ASF on domestic pig holdings. GIV veterinarians have received epidemiological training and are deployed to investigate any suspect cases detected.

68. The routine collection of surveillance samples during official controls on holdings located in high-risk areas provides assurance that the disease would be detected if present. It is significant that between July 2018 and June 2019 there were six outbreaks on domestic pig holdings. One of these outbreaks occurred in a commune categorised at

risk level 3 (moderate) (see Section 5.2.3). The other five outbreaks occurred in communes at risk level 4 or 5 (high or very high). No outbreaks were confirmed in domestic pig holdings located outside the infected area for more than two years.

69. The ASF eradication programme for Sardinia during 2018-2019 includes revised case definitions for ASF in wild boar. The following table compares these definitions with the guidance on the evaluation of the results of virological and serological tests provided in Chapter VI (Section D) of the ASF diagnostic manual:

Outside the infected area	**Primary case**
ASF case confirmed if: • At least one virological (virus isolation, genome test) is positive *Or* • At least two positive antibody test results in wild boar *Or* • A single positive antibody test result plus o At least one outbreak on a domestic pig holding *Or* o The presence of free ranging (illegal) pigs	ASF case confirmed if: • Virus isolation is positive *Or* • At least two positive results from: o Antigen test o Genome test o Antibody test
Within the infected area	**Secondary case**
ASF case confirmed if: • At least one virological (virus isolation, genome test) is positive *Or* • At least two positive antibody test results in wild boar *Or* • A single positive antibody test result plus o Positive virological test results from wild boar *Or* o Free ranging (illegal pigs) in the same area in the last two years	ASF case confirmed if: • Epidemiological link with a confirmed case *And* • At least one positive result from: o Antigen test o Genome test o Antibody test

70. No cases of active infection in wild boar have been detected in the last five years, although some seropositive results were obtained (indicating previous exposure to the disease).

71. During the fact-finding mission, the Italian authorities reported a discrepancy between the numbers of outbreaks reported on ADNS and the information held on the SIMAN database for the period from November 2018 to January 2019.

ASF Outbreaks

	Wild Boar		Domestic pigs	
	2018	2019	2018	2019
ADNS	64	17	10	1
SIMAN	80	25	12	1

72. The discrepancy apparently arose due to an administrative error that was detected during preparations for the mission. The veterinary authorities provided assurances that all of the outbreaks and cases were correctly registered in SIMAN and that protection measures were routinely applied on each occasion.

5.4.2 Control measures

73. Following confirmation of disease in domestic pig holding or free-ranging (illegal) pigs, the veterinary authorities immediately establish restrictions on affected holdings and in the surrounding protection and surveillance zones, in accordance with the requirements set out in Directive 2002/60/EC.

74. The previous Commission audit (see footnote 1) concluded that frequent delays in establishing protection and surveillance zones and delays in checking holdings in the protection zone compromise the fast detection of other infected holdings and constrain the effectiveness of the measure in preventing further spread of the infection. In response to this recommendation, the GIV is routinely deployed to assist the local veterinary authorities to establish restrictive measures on and around confirmed outbreak holdings. An enforcement cell, comprised of GIV personnel and officials from the Forestry Corps, is established for each outbreak and is responsible for carrying out surveillance visits and patrols within the area to ensure that the restrictions are respected.

Conclusions on detection and containment of outbreaks

75. Measures taken to improve the quality and timeliness of suspect case investigations and the application of restrictive measures following disease confirmation significantly reduce the possible secondary spread of disease to neighbouring and contact holdings.

76. The modified case definitions provided in the regional ASF eradication programme are likely to increase the number of confirmed ASF cases in the infected area and to reduce the likelihood that measures will be applied when occasional seropositive results are obtained from wild boar shot outside the infected area. This approach can be justified, taking into account the ecology of the disease in Sardinia.

5.5 TRACEABILITY OF MEAT PRODUCTS

Legal requirements

Articles 2, 6 and 12 of Commission Implementing Decision 2014/709/EU

Findings

5.5.1 Controls on meat establishments

77. Arrangements for the approval of food business operators to dispatch consignments of pig meat and its products from Sardinia are set out in operational guidelines([11]) published by the Regional Government. They are also described in the previous Commission audit report (see footnote 1).

78. In summary, food business operators seeking to dispatch pig meat products from Sardinia must be approved to do so by the Italian authorities. In order to maintain their approval the establishments are subject to risk-based official controls by ASL officials and receive an annual re-approval audit from the Ministry of Health Veterinary Offices for Compliance with EU Requirements (*Uffici veterinari per gli adempimenti comunitari* - UVAC), responsible for controls on intra-Union trade.

79. An updated list of the establishments approved in accordance with Article 12 of Decision 2014/709/EU was provided to the Commission prior to the fact finding mission. However, this information is not included in the official lists([12]) of establishments approved for products of animal origin, which the Italian Ministry of Health maintains on line.

80. The mission team visited one meat establishment approved to use swine meat that originated from within and outside Sardinia.

81. The food business operator presented:

    a. documented procedures for each stage in the production process, including the separation of eligible and ineligible raw materials and products and the preparation of the cooked products using pig meat originating in Sardinia;

    b. traceability records demonstrating that all pig meat coming from Sardinia originated on certified pig holdings (see section 5.2.3). It had also been produced in establishments that were approved in accordance with Article 12 of Decision 2014/709/EU.

82. ASL officials provided information about the official controls carried out on the establishment, including completed checklists. The outcome of these controls was satisfactory. However, no records were available to verify that the cooking process satisfied the relevant treatment requirement (that a minimum temperature of 80°C is reached throughout the meat([13])).

83. The annual audit performed by UVAC officials included operational and documentary checks. However, the audit records did not indicate whether or how compliance with traceability and heat treatment requirements had been assessed.

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[11] www.regione.sardegna.it/documenti/1_5_20170102165641.pdf

[12] www.salute.gov.it/portale/temi/trasferimento_PROD.jsp

[13] Council Directive 2002/99/EC, Annex III, Treatment (c)

84. Following the mission, the Italian central competent authorities advised that the checklists used to audit establishments in accordance with Article 12 of Decision 2014/709/EU are under revision, with more specific and detailed checks being added. In addition, the Sardinian veterinary authorities are also validating the establishment's cooking process against legal requirements.

5.5.2 Controls on personal luggage

85. The veterinary authorities routinely carry out on-the-spot checks on the personal luggage accompanying passengers arriving in, and leaving from, Sardinia through the ports and airports. The following tables summarise the outcome of the veterinary controls performed during 2018:

Ports	Sassari	Olbia	Cagliari	Lanusei	**Total**
Vehicle checks	1,849	1,802	1,036	52	**4,739**
Products seized	19	11	0	9	**39**

Airports	Sassari	Olbia	Cagliari	**Total**
Passenger checks	1,992	1,750	1,511	**5,253**
Products seized	1	0	23	**24**

86. The mission team visited a ferry port (Cagliari) with connections to continental Italy. Notices were clearly visible informing travellers that they may not carry Sardinian pig products. Although they are not permanently present, veterinary officials visit the port on a daily basis to carry out spot checks.

87. In addition to the veterinary spot checks, passengers and vehicles passing through the port also undergo routine security checks. For this purpose, the security staff use an x-ray scanner. They have clear instructions on how to check identification and health marks to determine the eligibility of meat products leaving Sardinia.

88. If non-compliant products are detected, the passengers are asked to dispose of them. In case of doubt or if the passengers refuse, the security staff consults the veterinary authorities. Most of the controls on personal luggage performed during routine security checks are not included in the table above, which records checks performed by veterinary officials.

Conclusions on traceability of meat products

89. Well-established and well-understood arrangements are in place to prevent the dispatch of pig meat products, either commercially or accompanying travellers, that are potentially contaminated with ASF virus. However, the veterinary authorities need to take additional steps to ensure that these arrangements are regularly and critically assessed in order to ensure that any deviation from the requirements is detected.

5.6 FOLLOW-UP OF PREVIOUS AUDIT

The table below summarizes the follow-up of five of the nine recommendations made in the report DG(SANTE)/2016-8764-MR (recommendations 1 to 4 and 9, as numbered in the report). At the time of this fact-finding mission, these five recommendations remained open as follow-up actions by the Italian authorities were still in progress:

No.	Previous recommendations	Assessment
1	To ensure that all requirements on identification and registration of pigs laid down in Directive 2008/71/EC, are complied with and updated in the national pig database as required in Article 18(c) of Directive 64/432/EEC	Partially addressed (see section 5.2.2 of this report)
2	To ensure adequate implementation of official health surveillance on all pig holdings in the infected area. Article 15(2)(b) of Directive 2002/60/EC.	Addressed (see section 5.2.3 of this report)
3	To carry out effective epidemiological investigation in the case of confirmation of ASF. Article 8 of Directive 2002/60/EC and Chapter IV(B)(2) of Decision 2003/422/EC.	Partially addressed (see section 5.4.1) Additional assurance is required about how the investigations are conducted and the quality of these investigations is systematically ensured.
4	To ensure immediate establishment of protection and surveillance zones and associated measures in an occurrence of an ASF outbreak. Article 9 and Article 10(1)(a) of Directive 2002/60/EC.	Partially addressed (see section 5.4.2 of this report) Additional assurance is required concerning the timely implementation of measures (official visits and clinical examinations on pig holdings) in the restricted zones surrounding confirmed ASF outbreaks.
9	To ensure that the list of establishments approved according to Article 12 of Decision 2014/709/EU is communicated to the Commission. Article 14 of Decision 2014/709/EU.	Addressed (see section 5.5.1 of this report)

6 OVERALL CONCLUSIONS

The epidemiological situation in domestic pigs has improved significantly over the last 18 months. During this time, there have been no disease outbreaks in registered pig holdings. The veterinary authorities mainly attribute this to improved control of free-ranging (illegal) pigs and better biosecurity on pig holdings.

The dense wild boar population, particularly in northern Sardinia, presents a serious risk to

the eradication of ASF. Since 2016, controls on hunting activities performed by the veterinary authorities and forestry inspectors have been reinforced to ensure the safe disposal of animal by-products and to check compliance with wild boar sampling requirements. On the other hand, some hunting practices in Sardinia do not conform to the EU strategic approach. The veterinary authorities consider that more rigorous requirements would risk alienating hunters.

The veterinary authorities report a change in attitude among local people, who are more willing to inform them about suspected disease and possible illegal activities. This is partly thanks to the extensive communications campaign directed at farmers, hunters and the public. It also reflects growing public confidence in the commitment and ability of the veterinary authorities to eradicate the disease. Representatives of the hunters' and pig producers' associations are in favour of maintaining the Project Unit for the eradication of ASF and continuing to implement the regional eradication programme.

The measures in place to prevent the dispatch of potentially infected pig meat and products from Sardinia, either in commercial consignments or carried in personal luggage, are well-established and well-understood. Official controls in meat establishments and at the air and sea ports to apply these measures are effective.

There has been significant progress bringing ASF under control in Sardinia. The problem of free-ranging (illegal) pigs has improved but has not yet been solved and the risk of disease from wild boars continues to be a threat. As the number of infected animals decreases, the veterinary authorities have to make additional efforts and use more of their resources in order to stamp out the remaining pockets of this persistent disease. For this they rely on the continued commitment of their political leaders and on the support from farming and hunting organisations.

7 CLOSING MEETING

A closing meeting was held with the central competent authority on 28 June 2019 during which the audit team presented the main findings and preliminary conclusions of the audit.

During this meeting the competent authority provided certain clarifications and did not indicate any major disagreement with the findings and preliminary conclusions.

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
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. 64/432/EEC	OJ 121, 29.7.1964, p. 1977-2012	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine
Dec. 2014/709/EU	OJ L 295, 11.10.2014, p. 63–78	2014/709/EU: Commission Implementing Decision of 9 October 2014 concerning animal health control measures relating to African swine fever in certain Member States and repealing Implementing Decision 2014/178/EU
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