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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
CROATIA
FROM 18 APRIL 2016 TO 22 APRIL 2016
IN ORDER TO
EVALUATE THE IMPLEMENTATION OF THE PROGRAMME FOR THE CONTROL
AND MONITORING OF CLASSICAL SWINE FEVER

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

Executive Summary

This report describes the outcome of an audit in Croatia, carried out from 18 to 22 April 2016, as part of the published Directorate-General Health and Food Safety audit programme.

The objective of the audit was to evaluate:

- the implementation of the programme for the control and monitoring of classical swine fever in Croatia and in particular to evaluate whether the surveillance system is effective in:
 - providing an adequate and reliable picture of the classical swine fever status of the country;
 - early detection of classical swine fever outbreaks in the domestic pig population as well as classical swine fever cases in feral pigs;
- the effectiveness of the official controls over the implementation of the programme, and in particular over movements and traceability.

Overall, the report concludes that the system for active surveillance in domestic pigs is well organised for all registered pig holdings. Its weaknesses do not significantly affect the confidence in the status of the country for classical swine fever in domestic pigs (where the last classical swine fever case reported was in 2008).

In wild boars, the active surveillance coverage and the implementation and monitoring of surveillance on an annual basis (during the hunting season), support the absence of the circulation of the classical swine fever virus in this population in audited years.

The capacity for early detection of classical swine fever in wild boars is affected by low submission of samples from dead wild boars. This combined with weak passive surveillance on small-scale pig holdings (with less than five pigs), raises some questions in relation to the competent authority's ability to detect the disease at an early stage, should it be reintroduced into the country.

The structure and organisation of the competent authority allows them to perform their control tasks on classical swine fever adequately in most circumstances but the control system in place had not prevented underperformance of certain counties in the implementation of the programme in audited years.

The national system for pig holding registration and pig identification provides the competent authority with a solid basis to implement the programme and control classical swine fever for registered farms. The use of a derogation for one pig holding not authorised in the Commission Decision is to some extent mitigated by the comprehensive movement registration system.

The preventive movement control and biosecurity measures in place give additional assurances, that should the disease re-emerge, its further spread will be limited before being detected.

The report makes recommendations to the competent authorities aimed at addressing areas in which further improvements are required.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ASF	African Swine Fever
AV(s)	Authorised Veterinarian(s)
AVO(s)	Authorised Veterinary Organisation(s)
CA	Competent Authority
CSF	Classical Swine Fever
ELISA	Enzyme Linked ImmunoSorbent Assay (serological test to detect CSF antibodies)
EU	European Union
NRL	National Reference Laboratory
PCR	Polymerase Chain Reaction (virological test to detect CSF genes)
VFSD	Veterinary and Food Safety Directorate
VI(s)	Veterinary Inspector(s)

1 INTRODUCTION

The audit took place in Croatia from 18 to 22 April 2016. The audit team comprised three auditors from the Commission services.

An opening meeting was held on 18 April 2016 with the central Competent Authority (CA). At this meeting the objectives of, and itinerary for the mission were confirmed by the audit team and the control systems were described by the authorities. The audit team was accompanied throughout the audit by the representatives of the central CA.

2 OBJECTIVES, SCOPE AND AUDIT CRITERIA

The objective of the audit was to evaluate:

- The implementation of the programme for the control and monitoring of classical swine fever (CSF) (the programme) in Croatia and in particular to evaluate whether the surveillance system is effective in:
 - providing an adequate and reliable picture of the CSF status of the country;
 - early detection of CSF outbreaks in the domestic pig population as well as CSF cases in feral pigs;
- The effectiveness of the official controls over the implementation of the programme, and in particular over movements and traceability.

The scope of the audit covered:

- The programme in Croatia approved by the Commission for 2014 (Commission Implementing Decision 2013/722/EU), 2015 (Grant Decision approving national programmes and associated funding of 30 January 2015 - Decision Number SANTE/VP/2015/HR/SI2.700784) and 2016 (Grant Decision approving national programmes and associated funding of 29 January 2016 - Decision Number SANTE/2016/HR/SI2.726011);
- Pigs holdings (e.g. commercial, backyard, markets);
- Feral pigs (e.g. areas where feral pigs are kept, hunting grounds);
- Central level and selected regions.

The main audit criteria are listed in the Annex. Legal acts quoted in this report refer, where applicable, to the last amended version. Please note that any implementing legislation or derogations falling under those main audit criteria were also applicable to this audit.

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

Visits / meetings	No.	Description
Central CA	2	Opening and closing meetings
Regional CA offices	3	
Laboratory	1	
Hunter association	2	
Pig holdings	3	
Pig market	1	

3 LEGAL BASIS

The audit was carried out under the general provisions of 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.

4 BACKGROUND

Part of the territory of Croatia is subject to specific animal health control measures relating to CSF, laid down in Commission Implementing Decision 2013/764/EU.

The last cases of CSF reported from Croatia in domestic or feral pigs date back to 2008. An active surveillance system of domestic pigs and the wild boar population has been in place since 2005, when vaccination in domestic pigs was prohibited. Vaccination in wild boars was never carried out in Croatia.

Since its accession to the European Union (EU), the programmes for control and monitoring of CSF in Croatia have been approved and the subject of financial support from the European Commission.

Croatia presented a request to the Commission in February 2016 for the restrictions laid down in Commission Implementing Decision 2013/764/EU to be lifted.

An audit of the CSF control measures was performed by the Commission services in 2010 (with a view to authorising imports to the EU at the time). Some elements from this audit were followed-up during a general animal health pre-accession audit performed in April 2013.

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

http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=2581 .

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

Legal requirements

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

Findings

1. Information on the organisation of the Croatian CA can be found in the country profile (http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=HR) and in previous Commission services audit reports.
2. The Veterinary and Food Safety Directorate of the Ministry of Agriculture (VFSD) is the national CA responsible for supervision and coordination of implementation of the programme.
3. The VFSD is also the CA for identification and registration of pigs. The maintenance of the Central Register of Domestic Animals (electronic database) has been delegated by Ministry of Agriculture to the Croatian Agricultural Agency.
4. The Animal Health Protection Sector of VFSD is responsible for developing the programme in Croatia in coordination with the National Reference Laboratory (NRL) for CSF and also responsible for the drafting and updating of contingency plans, including the contingency plan for CSF. Furthermore, the Animal Health Protection Sector collates and analyses the data from the implementation of the programme and notifies the occurrence of infectious diseases, including CSF, to the World Organisation for Animal Health (OIE) and Animal Disease Notification System.
5. The Veterinary Inspection Sector within the VFSD has 13 regional veterinary departments (veterinary offices) and their 65 branch offices are responsible for supervising the implementation of the programme as well as other legislation on pig animal health and pig identification. Its Veterinary Inspectors (VIs) implement the national legislation and disease control programmes, assisted by the work of the Authorised Veterinarians (AVs) working in Authorised Veterinary Organisations (AVOs).
6. The sector for hunting of the Ministry of Agriculture plays an important role during the drafting and implementation of the programme. It provides information on wild boars population size and structure, spatial references for each hunting ground and, when needed, issues licences for increased hunting in a specific hunting area. Together with VFSD they are responsible for supervision of hunting activities implemented within the framework of the programme.
7. AVOs (131 contracted by the CA in 2016) as delegated control bodies (veterinary organisation accredited to ISO 17020:1998) carry out several official tasks under the programme, e.g. official checks on pig farms, sampling within CSF surveillance in

domestic pigs, both at farms and slaughterhouses, collection and transfer of samples to the laboratory within the surveillance programme for wild boars, certification for movement of pigs in general, and movement of pigs and pig meat from the restricted counties in Croatia, including certification for intra EU trade.

8. Administrative measures in the case of non-compliance detected are not delegated., When the AV finds non-compliance while performing delegated tasks, he must then notify the VI.
9. Hunters are responsible for sampling of wild boars and for completion of sampling forms that accompany samples to the laboratory.

5.1.1 Monitoring of the CSF programme:

10. The monitoring of the implementation of the programme is carried out at central and regional/local branches level. Data on sampling are collated and transmitted on a monthly/semi-annual and annual basis by the NRL to the central CA. The data are good quality and detailed enough to enable spatial and temporal analyses when needed. In addition, the regional/local branch offices carry out their inspections to verify the implementation of the programme by the AVOs and hunters, i.e. their compliance with the existing rules.
11. Evidence was seen that data collected were analysed at central level in order to identify non-compliances with the programme and causes of underperformance of certain counties, and to initiate corrective actions. The central CA activities resulted in amendments to the programme over the years with the aim of making it more effective, aligned with EU requirements and achievable targets of the programme. Despite the actions taken, the existing variations between counties in implementation of the programme and in some instances constant underperforming by certain counties have not yet been addressed (see points 48, 51, 87, 88, 91-93).

5.1.2 Supervision and Internal audit programme

12. In 2015 the Veterinary Inspection Sector had implemented a new Procedure for verifying the effectiveness of the official controls. The purpose of verification was to assess work of VIs in the veterinary offices, the quality of the inspection performed with the goal of improving and harmonizing their work.
13. The verification consisted of an administrative supervision (in respect of procedures and deadlines) carried out by the heads of department and technical/expert supervision, including on-the-spot visits, performed by the senior VIs from the central CA.
14. In 2015, in total 130 supervisions were carried out by the senior VIs from the central level and they covered the work of 109 VIs (some of them were inspected more than once). Out of those 130 supervisions, 21 included some aspects relevant for this audit (eleven were carried out in the AVOs and ten in other premises). The reports from supervisions were available to the audit team.

15. Official controls carried out by VIs are performed according to the annual working plan of the veterinary inspection service. All AVOs in Croatia, in line with the annual working plan, are to be controlled at least four times per year. The scope of these controls varies; some of them cover implementation of the animal health measures, including implementation of the CSF rules and the programme. More information on the objective, scope and number of these controls per year is available under points 65-67 and 94.
16. The last national audit on the CSF programme was performed in 2011. The recommendations concerned, e.g. a lack of supervision by senior VIs, lack of participation in CSF training by different stakeholders, not meeting targets for planned official activities and flaws in the system for recording of official controls. All recommendations from the audit were addressed and their implementation was verified during follow up audits in 2012. However, the targets for some official controls were not achieved in subsequent years (for more information see point 30) showing that this weakness still exists. The central CA informed the audit team that in 2016 they will carry out an internal audit on crisis plans, including the contingency plan for CSF.

5.1.3 Training

17. Formal training of VIs and AVs is organised at central level. The central CA held the training courses on CSF in both audited years (2014 and 2015). They covered implementation of measures laid down in Commission Implementing Decision 2013/764/EU and implementation of measures laid down in the national Order on measures to protect animals from infectious and parasitic diseases and their financing - the annual working plan. All heads of regional offices were involved in it, and many VIs participated as well. Those VIs that did not attend the courses were trained through cascade training organised at regional level. A list of attendees and agendas of the courses were available.

Conclusions on Competent authorities

18. The structure and organisation of the CA allows them to perform their control tasks on CSF adequately. Control of CSF is a priority for the CA. The system of extensive use of AVs for completion of official tasks within the programme is well organised. However, underperformance of certain counties in implementation of the programme in audited years (2014 and 2015) has not been adequately addressed.
19. The new procedures introduced in 2015 have strengthened verification of the effectiveness of controls and consistency across regional/local branch units. The regular verification and evaluation activities by senior inspectors allows earlier detection of potential weaknesses in implementation of the programme and CSF controls.
20. Training provided to staff helps ensure uniform implementation of official controls.

5.2 HOLDING REGISTRATION, ANIMAL IDENTIFICATION, MOVEMENT CONTROLS

Legal requirements

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

Findings

5.2.1 Production holdings

21. Using the derogation provided for in Article 3(2) of Directive 2008/71/EC, the CA keeps an up-to-date list of all holdings, except those with one single pig. Croatia is not listed in Commission Decision 2006/80/EC, as a Member State authorised to use this derogation. The central CA claimed that they informed the Commission services of the derogation used during the accession negotiations, and the relevant chapter on pig identification and registration in Croatia was found fully compliant with *Acquis Communautaire*.
22. A uniform pig central register is fully operational. It contains information on pig holdings (including its geographic coordinates) and pig (group) movements but no data field where it is possible for the CA to enter sanitary information, for example restrictions on movements, status or other relevant information in the context of EU or national programmes, in contradiction to Article 1(e) of Commission Decision 2000/678/EC.
23. According to the information provided from the pig database, there are around 1.5 million pigs kept on 97,412 registered holdings. Holdings of 50 pigs or less represent 98% of holdings registered in the pig database and 45.4% of pigs. Holdings of five pigs or less represent 53.2% of holdings registered in the pig database.
24. All pigs must be identified before leaving the farm of birth (as required under the EU legislation), or at the latest at two months old in areas under restriction. They are generally identified with an ear-tag displaying a unique farm number, with an additional three-digit serial number. Some farms are authorised to use instead a tattoo of a code linked to each farm. This special number is recorded in the central database and the farm register.
25. When pigs leave their subsequent residence holdings, they are not marked/identified with the holding number of the second holding. They are accompanied by a movement document that includes the original identification number of the pigs involved and the holding number of departure. This information is also recorded in porcine database and in the register on the holding. This in the opinion of the CA allows the holding from which an animal came to be determined and therefore satisfies the objective of Article 5(2) of Council Directive 2008/71/EC.

26. Maintaining a register on each holding is compulsory for all registered pig farms. A hard copy (harmonised) has to be kept on the farm and updated continuously by recording movements of pigs (including pig identification number), as well as births and deaths. The template is fully in line with the EU requirements.
27. On the farms visited, farm registers were available and with one exception regularly updated. A register was reliable: movements were registered on an aggregate form, referring to the pig identification code. Destinations of pigs were indicated in the register. The movements matched the information in the central database. In one instance reviewed, the farm register was not updated with information in 2016. But other records available (e.g. data in the central database and movement documents on the farm) enabled traceability of the pigs to be established.
28. The keeper of the pigs has to declare annually (in December) the number of pigs present at the farm to the Agricultural Agency using a census form. On the farm visited the census was entered into the farm register and the data from the census on the farm tallied with the data in the central database.
29. Between 2008 and 2010 all registered holdings were subjected to annual checks carried out by the AVs. The objectives were to help farmers with the implementation of EU requirements in the pre-accession period and make the central database fully operational. After this period and based on analyses or results of previous checks the central CA identified the priorities for selection of farms for annual checks to address the problems detected, thus making the annual checks become more targeted.
30. In addition, official controls on registered pig holdings are planned on 3% of all pig holdings in Croatia, selected using some risk criteria (e.g. in 2015 size of holdings – farms with five or more sows, ten or more pigs, holding location, biosecurity measures applied, previous non-compliances, etc.). The official controls have different objectives and scope (currently with priority on Animal Welfare issues), but they always cover, to a certain extent, pig identification and registration data on the farm and in the central database. In 2015 the target for the number of official controls on the pig farms was not met; 78 % of planned controls were carried out.
31. The number of sanctions applied for non-compliance with pig identification and movement rules at national and regional level was available. In general the data showed a good compliance with existing rules.
32. Carcasses of hunted wild boar get a tag with a unique number referring to the hunting season, the hunter and the species. This system is run by the Forestry Department of the Ministry of Agriculture. It allows traceability, including to the area in which the animal was shot.

5.2.2 *Markets*

33. A list of registered and approved pig markets and assembly centres is publicly available on the official web site of the Ministry of Agriculture:
<http://www.veterinarstvo.hr/default.aspx?id=72>.
34. Official controls which indirectly cover implementation of CSF measures (mainly identification and registration, biosecurity measures in place, and pig traceability) are performed on animal markets by AVs and VIs. A specific checklist, harmonizing the scope of the controls, is used.
35. One authorised market was visited by the audit team. It had basic infrastructure, and biosecurity measures in place. The pig market register was well maintained and the data matched those in the central database. The market was under the supervision of the AV. It operated twice per month. The catchment area was not restricted in the approval document but from data available it operates as a small local market - the pigs going through market originated from holdings located in the same county. The evidence of cleaning and disinfection of premises before and after operation was available, but the surface on the market was unpaved and therefore it limits the efficacy of cleaning and disinfection. The pigs were not unloaded from the trailers and kept in available pens; instead, based on movement documents available, in the majority of cases they were directly shipped on the same vehicle to the place of destination. Only in some instances, were the pigs (category of piglets and weaners according to pig market operator) directly transferred from trailers to new vehicles.

5.2.3 *Movement controls*

36. According to Croatian legislation, all national pig movements need to be accompanied by:
 - A health certificate issued by an AV after a visit to the farm of origin and after he or she has checked the animal health status and the identification of the pigs as well as the records kept on the farm. A visit to the farm is not necessary for issuing health certificates regarding consecutive movements within 30 days of a previous farm visit.
 - A movement document issued by the keeper of the pigs, stating the ear tags or tattoo numbers used to identify the pigs, as well as the holding of destination and information regarding the transport vehicle. While the original document accompanies the pigs to their destination, a copy must be provided to the AVO within a three day deadline (the latter has, in turn, three days to download the information into the database) and one stub remains at the farm of origin.
37. All movements of pigs must be notified to the central database by the receiver (pig keeper at place of destination) by providing a movement document to the AVO and subsequently by the AVO to the database (also see point 36). Movement to holdings under derogations (single pig holdings) must also be notified as a movement from a registered farm to a pig holder identified by a personal identification number; the

notification is made by the receiver. In 2015 more than 15,000 such movements were recorded in the central database. No evidence was provided on the verification by the CA on the fulfilment of this notification obligation by single pig holding owners.

38. The movement documents were present at the pig farms/pig market visited. Control of movement documents in the central database revealed no discrepancies. Tracing back the pig farm by eartags was possible; movements of pigs were correctly introduced into the database.
39. In order to implement the Commission Decision 2013/764/EU, the central CA put in place several additional requirements for movements of live pigs from holdings located in a restricted area to holdings outside of the restricted area. In general, in the instances reviewed, they were well implemented, apart from one case where the 90 day residency period for pigs dispatched was not observed (a consignment was authorised by the AV despite the fact that a couple of pigs had been sent to a pig market and returned back unsold to the holding of origin 30 days beforehand).
40. In 2015, the pig receivers notified to the central database 35,250 pig movements from holding to holding, representing 730,047 animals moved. Additionally, 24,271 movements to slaughterhouses were notified, encompassing 827,902 pigs, and 663 imports (244,917 pigs) and 869 exports (125,773 pigs) were registered. 6,512 records were linked to slaughter on the farm (for personal consumption) of 18,068 pigs.

Conclusions on holding registration, animal identification and movement controls

41. The national system for pig holding registration, pig identification and movement controls is largely well implemented and provides the CA with a solid basis to implement the programme and control CSF on registered holdings. The existing deficiency regarding the missing data field for entering sanitary information in the pig database is mitigated by well organised movement controls and pig movement notification to the central database.
42. The use of a derogation for one pig holding which is not authorised in the Commission Decision is in contravention with EU requirements. Its impact could be mitigated by the implementation of the comprehensive movement registration system, but evidence of such implementation in all holding segments is lacking.

5.3 SURVEILLANCE, CONTROLS IN DOMESTIC PIGS AND AWARENESS

Legal requirements

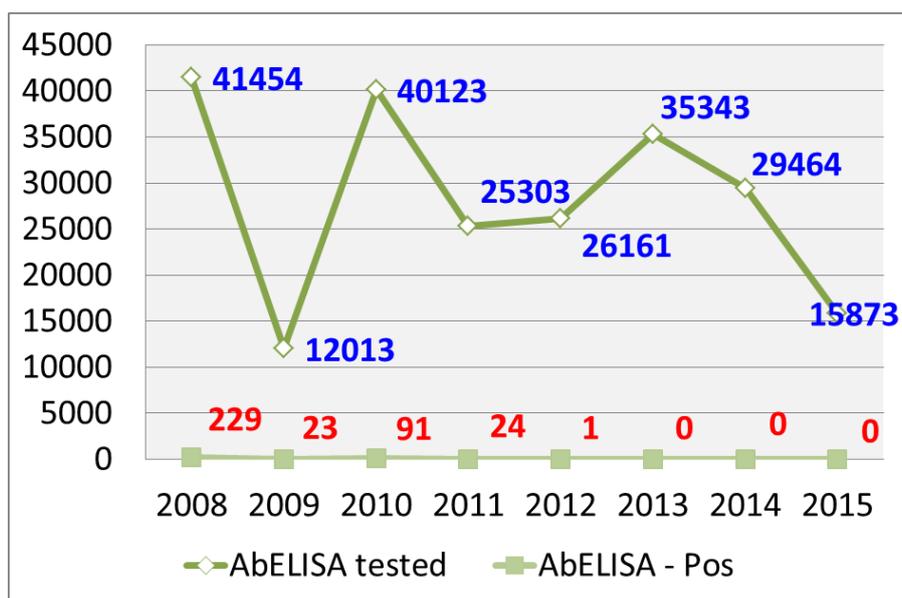
Council Directive 2001/89/EC; Commission Decision 2002/160/EC; Commission Decision 2013/722/EU.

Findings

5.3.1 Active surveillance

43. Since 2005, Croatia has implemented the CSF control policy without preventive vaccination, including surveillance in domestic pigs. The last confirmed case of CSF in domestic pigs occurred in March 2008.
44. In accordance with CSF programmes for 2014 and 2015 the CA had decided to carry out serological surveillance. The aim of the surveillance was mainly to detect possible illegal use of vaccines against CSF and keep awareness among pig keepers and veterinarians on CSF risks and prevention. In addition, the data collected contribute to demonstrating freedom from CSF.
45. The surveillance programme implemented in 2014 included a random survey of domestic pig holdings all over the country, grouped into three groups as follows: commercial pig farms containing 100 or more fattening pigs, farms keeping five or more sows, and mixed herds with ten or more pigs.
46. Sampling was planned to achieve the expected between-herd and within-herd estimated prevalence. The selection of holdings and number of sampled pigs was performed at central level, using information available in the central database.
47. In addition, more intensive targeted surveillance was designed in the restricted areas, implying settlements situated in the vicinity of the hunting grounds where direct or indirect evidence of CSF virus circulation was detected in wild boars in the past and localities bordering non-Member States. In these 60 settlements sampling was planned on 20 holdings/per settlement, keeping from five to 50 pigs. Only pigs older than four months were eligible for sampling and CSF serological testing.
48. Although the overall targets for the number of farms and animals tested for the whole territory in 2014 had been achieved, an analysis of collected surveillance data shows that the sampling varied between counties. 14 out of 21 counties did not meet their target and they sampled fewer farms than originally planned. But those counties with higher CSF-related risk (under restrictions) performed very well. The central CA did not carry out or was not aware of more epidemiological/statistical analysis of the results in 2014, in particular in terms of disease detection/sensitivity of surveillance achieved at the level of individual counties/how the planned sensitivity was affected by an undersampling in some counties.
49. In 2015 the design of the sampling campaign was modified and the target population of CSF serological surveillance had changed with the aim of focusing more on farms located in restricted areas (farms keeping 5 or more sows, farms with 100 or more fattening pigs and mixed herds keeping 10 or more pigs). Outside restricted areas mixed herds keeping ten or more pigs with unsatisfactory results as regards the biosecurity measures implemented were selected.

50. Sampling was, as in 2014, planned to achieve the expected between-herd and within-herd estimated prevalence for each of target populations. Only pigs older than four months were eligible for CSF serological testing. Holdings included in the study were randomly selected from the list of all holdings in each group.
51. The target for the number of farms tested for whole territory in 2015 had been achieved (1304 farms tested with 15,873 pigs sampled and tested compared to 765 farms with approximately 18,500 samples planned). Data shows that between-counties the variation of the implemented sampling had diminished compared to the situation in 2014. But still seven out of 21 counties did not meet their target and sampled fewer farms than planned. Furthermore, two out of seven counties with higher CSF-related risk in 2015 (one part of restricted area and another county with seropositive wild boar in 2015) underperformed and were well below their targets (in one instance 25 farms were tested out of the 76 planned; in a second instance no farm was tested out of the four planned).
52. During both audited years 2014 and 2015 the small farms keeping less than five pigs were not included in any selected sub-populations; therefore they were not targeted in the active CSF surveillance plan.
53. CSF serological surveillance in domestic pigs 2008 – 2015 is shown in the table below:



54. Positive ELISA results were obtained from three holdings in the same county in 2014, and from one holding in 2015, all being located in the restricted area. The holdings were subject to an epidemiological investigation, clinical examination, additional sampling and laboratory tests, both for antibodies and the CSF virus, in order to rule out the presence of the disease (and vaccination).

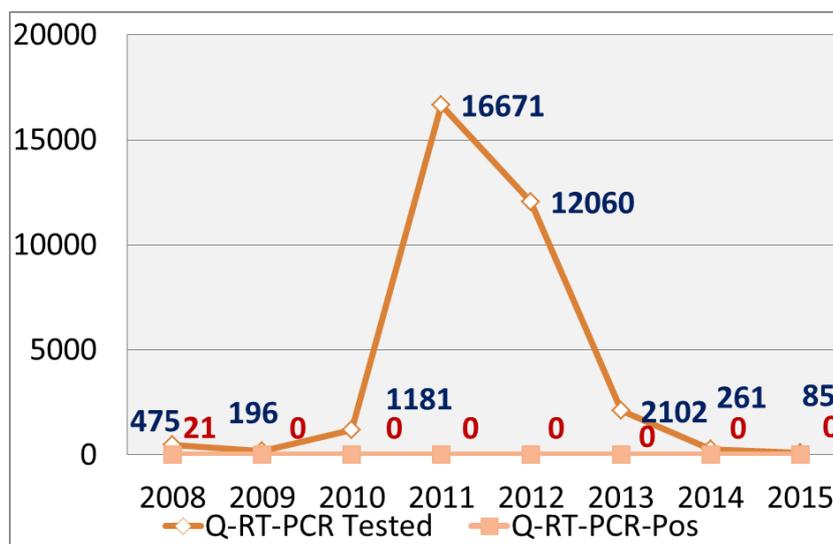
5.3.2 *Passive surveillance*

55. A passive CSF surveillance programme is in place in order to provide for an early detection of CSF infection. The main feature of the 2014 and 2015 programme included

monitoring and sampling of pigs with CSF compatible clinical signs or lesions compatible with CSF.

56. One clinical suspicion was reported in 2014 (from the restricted area), and another one in 2015 (from outside the restricted area).
57. In both cases reviewed, the measures taken were in line with the EU requirements and included epidemiological investigation, clinical examination of pigs on the farm, additional sampling, movement restrictions and laboratory tests. CSF was ruled out only after getting negative results of laboratory tests (serological and virological) carried out by the NRL for both CSF and African swine fever (ASF), following the criteria laid down in the EU diagnostic manuals for both diseases.
58. In addition to the compulsory notification system in place, another feature of the programme is to investigate cases where the presence of CSF (and ASF), cannot be easily excluded. This can be done, e.g. by monitoring and sampling holdings where no CSF signs are observed but antibacterial treatment of pigs failed to lower body temperature and to improve the health of pigs in five days (or resulted only in a temporary drop in body temperature of the pig, after which it increased again), or by monitoring of sudden pig deaths with no clinical signs or pat-anatomical lesions compatible with CSF, or other epidemiological reason to suspect CSF. The central CA claimed that, this approach increases the sensitivity of the surveillance system and should contribute to the early detection of the incursion of an exotic or emerging disease. The occurrences were not considered as clinical suspicion nor legally notified as such (and therefore also not under official movement restriction). The tests used for CSF were real time PCR and Antigen ELISA, simultaneously.
59. In 2014 42 holdings were tested under this scheme, and a further 38 holdings were tested in 2015. For 2016, at the time of the audit, this scheme had been applied on two pigs. The data obtained under this scheme indicate an uneven geographical distribution of the samples; they were taken from twelve out of 21 counties. Furthermore, 52.5 % of holdings sampled (42 out of 80) in both years are located in one county (outside the restricted area). During the audit the central CA presented its new initiative to widen the concept by increasing the number of conditions triggering CSF testing. This initiative will promote testing of samples from pigs sent to laboratories for other diagnostics reasons and will be implemented once the financial resources become available.
60. Although the small-scale farms of up to five pigs represent 53.2% of registered pig holdings in Croatia (with approximately 9% of the registered pig population), they were not represented either in cases of suspicion or in samples tested for CSF under exclusion diagnosis.

61. CSF virological surveillance in domestic pigs 2008 – 2015 is shown in the following table:



5.3.3 Biosecurity on pig farms and controls over implementation of the surveillance in domestic pigs

62. According to national legislation, all pig holdings are required to implement specific biosafety measures to prevent an introduction of infectious diseases.
63. Biosecurity checks of farms are performed by AVs according to the programme. In 2014, controls were carried out mainly on farms located in four restricted counties. In 2015, in addition, all farms included in the CSF programme (selected for CSF active surveillance) were checked.
64. On one farm visited, located in the restricted area, the report of the AV inspection indicated two deficiencies related to the disinfection barrier for vehicles entering the premises and related record keeping. Despite those deficiencies, the farm was considered by the AV as compliant with biosecurity rules. No recommendations were included in the report. The farm was authorised to send pigs to holdings located outside of the restricted area. The farmer addressed the deficiencies but the action taken - installing a temporary disinfection barrier in the form of a carpet soaked with disinfectant - cannot be considered as an adequate correction.
65. The implementation of the programme, in particular the sampling plan is checked during supervision visits carried out by VIs to assess the work of AVOs. In the counties visited the reports showed the stage of implementation of the sampling plan at the time of inspection and listed all farms which still need to be sampled and tested in order to achieve the target. In one county, in 2015 the VIs decided (based on some deficiencies previously detected) to increase the frequency of the inspections to monthly. But this target was not met (due to a shortage of human resources) and for 2016 the frequency reverted back to the minimum required (4x/year).

66. In addition, various official controls carried out by VIs which also cover implementation of the CSF programme and related requirements and measures (e.g. pig identification and registration, traceability and other topics) are performed also on pig farms, transporters, dealers, animal markets, and slaughterhouses. The table below summarises the results of those controls:

Official controls in relation to CSF programme (domestic pigs) 2014					
Subject of control (authorised veterinary organisation, slaughterhouse, farm, transporter, dealer, market)	No. of controls	No of controls with non-compliances	Description of non-compliances	Measures taken (decision issued)	Follow up
Farm	461 (4)	70 (4)	biosecurity, I&R, record keeping, animal health, movements of animals, suspicion	Yes	Yes
Authorised veterinary organisation	124	1	animal health measures		
Slaughterhouse	43	0			
Transporter	34	1	record keeping	Yes	Yes
Dealer	7	0			
Market	18	4	biosecurity, record keeping	Yes	Yes
Official controls in relation to CSF programme (domestic pigs) 2015					
Subject of control (authorised veterinary organisation, slaughterhouse, farm, transporter, dealer, market)	No. of controls	No of controls with non-compliances	Description of non-compliances	Measures taken (decision issued)	Follow up
Farm	921 (2)	137 (2)	biosecurity, I&R, record keeping, animal health, movements of animals, suspicion	Yes	Yes
Authorised veterinary organisation	233	5	animal health measures	Yes	Yes
Slaughterhouse	40	1	I&R	Yes	Yes
Transporter	42	7	record keeping	Yes	Yes
Dealer	8	1	record keeping	Yes	Yes
Market	26	1	biosecurity, record keeping	Yes	Yes
Official controls in relation to CSF programme (domestic pigs) 2016					
Subject of control (authorised veterinary organisation, slaughterhouse, farm, transporter, dealer, market)	No. of controls	No of controls with non-compliances	Description of non-compliances	Measures taken (decision issued)	Follow up
Farm	139	15	biosecurity, I&R, record keeping, animal health, movements of animals	Yes	Yes
Authorised veterinary organisation	17	0			
Slaughterhouse	4	0			
Transporter	5	2	record keeping	Yes	Yes
Dealer	0	0			
Market	3	0			

67. Two pig holdings visited (both in a restricted area) by the audit team were subjected to official control by VIs in 2015. The main objective was to verify compliance with biosecurity measures. The harmonised checklist was used to guide the VI during inspection. Deficiencies noted were corrected by the owner and well verified by the VI during a follow-up inspection.
68. Furthermore, clinical inspections are carried out by the AVs on pig farms before movements of pigs (see point 36), and also in the framework of the national Aujeszky's disease programme: these activities cover all types of farms, including the small-scale ones (in 2015 up to 85 % of small-scale farms were visited in restricted area within this programme).

5.3.4 Awareness programmes

69. Information on the CSF situation and preventive measures (including legislation, guidelines, and instructions) are regularly published on the website of the VFSD.

70. In addition, the central CA stated that other modes of information dissemination (e.g. TV, local radio, state and local press/local newspapers, public gatherings) were used in the past in order to inform the general public and stakeholders about areas under restrictions, the disease status, preventive measures, current and future actions, predictions on possible further spread as well as results of eradication efforts and measures to be implemented in order to lift the restrictions.
71. According to the CA, in recent years the various leaflets have been used to raise awareness amongst all stakeholders, e.g. veterinarians, pig keepers and hunters.
72. Workshops have also been used to communicate information on animal disease prevention and eradication measures, e.g. training for pig farmers organised by the Croatian Agricultural Agency and the CA on topics related to CSF.
73. In the farms visited, the farmers had not received/presented any CSF-related leaflet. But they appeared to be informed of their obligations regarding notification of CSF suspicion and the identification of their pigs, as well as on the requirements regarding the keeping and updating of the farm register and the use of the movement documents.
74. The CSF situation in domestic pigs and wild boars as well as measures implemented to eradicate CSF infection were discussed with neighbouring non-Member States on several occasions, organised at both central and local levels.

Conclusions on surveillance, controls on domestic pigs and awareness

75. The CA monitors the effective CSF surveillance applied to the registered pig population. No evidence of virus circulation in domestic pigs has been identified during the audited period 2014 - 2016.
76. Active serological surveillance in domestic pigs had been implemented in both audited years - 2014 and 2015. Although the programme was not completely implemented as approved, and suffered from some regional variations, the coverage brings a reliable picture, in particular for pig holdings located in restricted areas.
77. The approved programmes for 2014 and 2015 did not include any active CSF surveillance for small farms (less than five pigs) which represent approximately 53 % of all registered farms. The passive surveillance of domestic pigs remains weak, mainly for those small-scale holdings and, as such, is not effective in providing a sufficient level of confidence that CSF is being continuously ruled out as a potential cause of pig illness/mortality. This results in uncertainty regarding the effectiveness of the CSF early detection system for those small-scale farms.
78. The component of the early detection system increases the sensitivity of the surveillance system and, when further widened, this will contribute even more to the early detection of a possible re-incursion of the CSF virus.
79. The preventive measures in place provide assurances that should the disease re-emerge, its further spread will be limited before being detected. Measures are taken to prevent CSF from being transmitted from wild boars to pig holdings, in particular in the infected area and from being further spread to other parts of Croatia.
80. All farmers met demonstrated a good level of knowledge in relation to the impact of CSF, clinical signs, actions to be taken and precautionary measures commensurate with their role in the disease control system.

5.4 SURVEILLANCE IN WILD BOARS

Legal requirements

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

Findings

81. Currently, in Croatia, a total of 1,065 hunting grounds (319 state-owned and 746 common hunting grounds) have been geographically demarcated. In a certain number of hunting grounds wild boars have not been the resident species. The overall size of the hunting area in the country is around 36,000 km². In the hunting season 2015/2016, 792 hunting grounds were included in the programme.

82. According to the data obtained from the Directorate for Forestry, Hunting and Wood Industry of the Ministry of Agriculture, the estimated number of wild boars, permanently present in active hunting grounds is around 27,000, while the estimated number of these animals at the peak of the hunting season is around 55,000. The hunting season starts on 1 April and ends on 31 March, of the following year. Hunting bag size is around 26,000 wild boars. Hunters have an obligation to report the number of hunted wild game by 31 May.
83. The objective of the programme in the hunting season 2013/2014 and 2014/2015 was to support the claim that Croatia is free from CSF infection in wild boars and to allow for early detection of a reintroduction of the virus in areas bordering non EU countries.
84. In the hunting season 2013/2014 the programme required sampling, for serological and virological testing, in two distinguishable zones:
- Zone 1 which covered a 20 km belt along the border with non-Member States where all hunted wild boars (up to max. 340 per hunting ground) were planned to be sampled and subjected to serological and virological tests.
 - Zone 2 - rest of the country, divided into 60 sampling areas, where serological testing (with a detection limit of one seropositive if seroprevalence is 2 % with 95% confidential interval) was envisaged.
- All wild boars found dead and sick were to be sampled and virologically tested for the CSF virus irrespective of the zones.
85. For the purpose of this programme, the sample size was calculated based on one hunting year. Majority (70-80%) of samples were taken during the main hunting season for wild boars - from November until the end of January.
86. Data available for the hunting season 2013/2014 (Table 1) show that the total number of samples tested for the whole territory of Croatia (7,709) was above the target (7,680). However, only two counties achieved their target and took even more samples than planned. The majority of counties (19) underperformed, including two counties under restriction.
87. The sampling performance in the hunting season 2013/2014 varied between counties and in one county (located outside the restricted area) the number of samples taken achieved only 20% of the sampling plan, therefore decreasing the sensitivity/detection limit from 0.02 to 0.1 (the value for detection of one seropositive wild boar if seroprevalence is higher than 10%). Most recent data available (hunting season 2014/2015) shows that the hunting plan/bag in this county reached only 48% of the sampling plan, and therefore indicating that the sampling plan for this county did not correlate well with the hunting plan. The identical issue (incorrect correlation of sampling and hunting plan) was identified for two other counties with a lower number of samples taken.

Table1 *The number of samples for serological surveillance planned and taken in the hunting season 2013/2014*

County	Samples planned	Samples taken
Zagreb	384	294
Krapina-zagorje	128	39
Sisak-Moslavina	640	3065
Karlovac	640	1082
Varaždin	128	77
Koprivnica-Križevci	128	114
Bjelovar-Bilogora	512	305
Primorje-Gorski Kotar	384	241
Lika-Senj	512	264
Virovitica-Podravina	384	125
Požega-Slavonia	256	231
Brod-Posavina	512	259
Zadar	512	155
Osijek-Baranja	512	274
Šibenik-Knin	256	144
Vukovar-Srijem	768	599
Split-Dalmatia	512	227
Istra	128	106
Dubrovnik-Neretva	128	42
Međimurje	128	41
The City of Zagreb	128	25
Total	7680	7709

88. In the counties under restriction area the detection limit in the hunting season 2013/2014 was at least 0.05 (allowing detection of 5 % seroprevalence with 95 % confidence); therefore compliant with the value laid down in point 3, Part H, Chapter IV of Annex to Commission Decision 2002/106/EC. In seven counties (outside the restricted area) this detection limit was not achieved; three of those counties border a non EU country (with a limited/unknown CSF situation).
89. For hunting season 2015/2016 the surveillance programme in wild boars had been amended and aligned with CSF risk and rules laid down in the Commission Implementing Decision (EU) No 2013/764. The country had been divided into two new zones:
- Zone 1 covering territory of five counties (four under restrictions and one with higher CSF risk identified by the central CA due to proximity of serologically positive wild boars detected in neighbouring non EU country).
 - Zone 2 - rest of the country covering 16 counties.

The country had been divided into 65 sampling areas according to the county and number of wild boars at the peak of hunting season.

90. The programme envisaged sampling:

- In Zone 1 - hunted wild boars for serological and virological testing. In every sampling area 138 samples were planned in order to achieve a set detection limit (of at least one seropositive wild boar if CSF seroprevalence in the area is 2% or more, with 95% confidence).
- In Zone 2 hunted wild boars for serological testing. In every sampling area 59 blood samples were planned in order to reach a set target (detection of at least one seropositive wild boar if CSF seroprevalence in an area is 5%, with 95% confidence).

In addition, it was planned to sample all wild boars found dead or sick for virological investigation.

91. Data available for the hunting season 2014/2015 (Table 2) show that the total number of samples tested for the whole territory of Croatia (8,501) was above the target (5,968). Four counties performed well and achieved their target. Ten counties did not reach their target, including one county under restriction (with 98.5% fulfilment of the sampling plan).
92. In comparison with the previous hunting season, the variation between counties in sampling performance diminished, however, one county (located outside the restricted area) achieved less than 50 % of the sampling plan. The same county also underperformed in the previous hunting season 2013/2014 (a county with a low hunting plan/bag).

Table 2. *The number of wild boars tested for serological surveillance in the hunting season 2014/2015 per county is shown in the table below*

County	Number of samples planned	Number of wild boar serologically tested	Tested organs/ PCR
Zagreb	177	256	2
Krapina-zagorje	59	49	0
Sisak-Moslavina	1242	3141	2991
Karlovac	690	1480	1346
Varaždin	59	102	0
Koprivnica-Križevci	118	138	2
Bjelovar-Bilogora	354	286	1
Primorje-Gorski Kotar	118	299	1
Lika-Senj	354	229	19
Virovitica-Podravina	236	163	0
Požega-Slavonia	177	238	63
Brod-Posavina	414	405	335
Zadar	118	110	61
Osijek-Baranja	966	267	136
Šibenik-Knin	59	165	155
Vukovar-Srijem	414	721	686
Split-Dalmatia	118	206	122
Istra	118	130	2
Dubrovnik-Neretva	59	35	15
Međimurje	59	55	0
The City of Zagreb	59	26	1
Total	5968	8501	5938

93. In the counties under the restriction area the detection limit in the hunting season 2014/2015 was at least 0.05, similar to the previous hunting season 2013/2014 (see point 88). However, in nine counties (outside the restricted area) this detection limit was not achieved; three of those counties border a non EU country (with a limited/unknown CSF situation), the same counties as in the previous hunting season 2013/2014.
94. Similar to active surveillance in domestic pigs, the central CA did not carry out or was not aware of more epidemiological/statistical analysis of the results in the hunting seasons 2013/2014 and 2014/2015, in particular in terms of disease detection/sensitivity of surveillance achieved at the level of individual counties/how the planned sensitivity was affected by undersampling in some counties.

95. At the time of the audit, data for the hunting season 2015/2016 were not yet available. But the number of samples for CSF surveillance in wild boars taken in the calendar year 2015 was already provided and is shown in the table below:

Table- Number of wild boar tested by age structure for 2015_final results

Counties	Zone	Number of wild boar tested	In total number of seropositive	Number of positives (%)	VN-test	6 month to 1 year Elisa tested	6 month to 1 year(number of seropositive)	1 to 2 years Elisa tested	1 to 2 years(number of seropositive)	>2 years Elisa tested	>2 years(number of seropositive)	Tested organs/P CR
Zagreb	2	247	0	0		113	0	53	0	81	0	0
Krapina-zagorje	2	96	0	0		54	0	25	0	17	0	0
Sisak-Moslavina	1	2964	1	0,03	1	1556	0	727	1	681	0	2902
Karlovac	1	1420	0	0		698	0	355	0	367	0	1332
Varaždin	2	77	0	0		43	0	17	0	17	0	0
Koprivnica-Križevci	2	120	0	0		62	0	15	0	43	0	3
Bjelovar-Bilogora	2	288	0	0		119	0	63	0	106	0	7
Primorje-Gorski Kotar	2	195	0	0		87	0	61	0	47	0	0
Lika-Senj	2	291	0	0		97	0	77	0	117	0	12
Virovitica-Posravina	2	136	0	0		86	0	19	0	31	0	0
Požega-Slavonia	2	263	0	0		171	0	33	0	59	0	1
Brod-Posavina	1	647	0	0		363	0	123	0	161	0	613
Zadar	2	74	0	0		43	0	7	0	24	0	11
Osijek-Baranja	1	337	0	0		170	0	73	0	94	0	91
Šibenik-Knin	2	126	1	0,79	1	30	0	35	0	61	1	47
Vukovar-Srijem	1	1196	0	0		583	0	268	0	345	0	1174
Split-Dalmatia	2	366	1	0,27	1	114	0	136	1	116	0	41
Istra	2	107	0	0		49	0	26	0	32	0	0
Dubrovnik-Neratva	2	73	0	0		12	0	17	0	44	0	0
Međimurje	2	84	0	0		42	0	21	0	21	0	0
The City of Zagreb	2	32	1	3,12	1	13	1	7	0	12	0	9
Total		9139	4	0,04%	4	4505	1	2158	2	2476	1	6243

96. In 2014, one wild boar older than two years was found serologically positive in one hunting ground located in an area under restriction. For confirmation, a virus neutralization test was carried out with a positive result. The sample was also subjected to a virological (molecular) method (QRT-PCR) with a negative result. In this hunting ground all wild boars shot were sampled and laboratory investigated by serological and PCR methods and all other (223) samples in the same hunting season were negative.
97. In 2015, four wild boars tested serologically positive in four different counties, three cases outside current restricted areas. For confirmation, a virus neutralization test was carried out with a positive result. The sample was also subjected to a virological (molecular) method (QRT-PCR) with a negative result. Based on analysis of data available and the epidemiological situation the central CA investigations concluded that seropositivity was due to non-specific reactions as a result of the lower quality (cytotoxic effect) of blood samples taken.
98. In hunting grounds in a restricted area or in which the presence of antibodies against CSF had been detected in one or more wild boars, all wild boar shot or wild boar carcasses are kept until the negative results (serological and virological) are available. In one instance reviewed, following the positive result for CSF antibodies in the virus neutralisation test, increased hunting was ordered in the affected hunting ground in accordance with the programme. The aim was to obtain additional samples from at least 60 wild boar during a short time period. In two other instances in 2015 reviewed by the audit team, this very intensive sampling was not ordered and applied. The CA pointed out that in both hunting grounds affected all hunted wild boars were already being sampled and tested for CSF. But in one instance, the audit team noted that the

seropositive case was detected right at the end of main hunting season (beginning of February) and in the following three months only 34 samples were tested, therefore not reaching the target of 60 samples.

99. Reviewing files related to one seropositive case, the audit team noted that additional clinical examination and sampling of domestic pigs were carried out on farms located in close vicinity to the case in order to rule out the risk of transmission of infection into those farms. All results of tests were negative.
100. In order to tackle the poor submission rate of samples from wild boars found dead, the central CA developed a financial incentive and sent in 2013 a letter reminding all hunting licensed bodies, AVOs and CA offices of the importance of passive surveillance. No improvement was observed in subsequent years: since 2014 only one sample of a wild boar found dead was submitted to a laboratory for investigation. In two instances the hunters interviewed by the audit team had only limited knowledge of financial incentives put in place for sampling wild boars found dead, although they were very well aware of the incentives provided for sampling hunted wild boar (free trichinella testing). The hunters met indicated the increased population of wolves/jackals as the main reason for no suitable samples being available for the passive surveillance. No practical arrangements had been put in place between the CA and border guards patrolling along the border with third countries to increase the chance of finding and sampling of dead wild boars.
101. The implementation of the programme is subject to official controls carried out by the CA. Those controls are performed by VIs of AVOs and hunters' associations and data are presented in the following tables:

Official controls on CSF (wild boar) 2014					
Subject of control	No. Of controls	No of controls with non-compliances	Description of non-compliances (biosecurity, traceability, animal health)	Measures taken	Follow up
Authorised veterinary organisatio	43	0			
Hunters associations	15 (1)	2 (1)	sampling according to CSF surveillance program,	Yes	Yes
Official controls on CSF (wild boar) 2015					
Subject of control	No. Of controls	No of controls with non-compliances	Description of non-compliances (biosecurity, traceability, animal health)	Measures taken	Follow up
Authorised veterinary organisatio	102	0			
Hunters associations	27 (4)	1 (1)	suspicion		
Official controls on CSF (wild boar) 2016					
Subject of control	No. Of controls	No of controls with non-compliances	Description of non-compliances (biosecurity, traceability, animal health)	Measures taken	Follow up
Authorised veterinary organisatio	11	0			

Conclusions on surveillance in wild boars

102. The active surveillance system in wild boars is implemented. Despite regional variations it supports the absence of the circulation of the CSF virus in this population. In areas under restrictions it allows adequate sensitivity for quick detection of the changes in the CSF status of wild boars in the period November-January (main hunting season for wild boars). Outside this period the lower sampling rates decrease the sensitivity of the surveillance system and therefore the ability to quickly detect changes in a CSF epidemiological situation.
103. The early warning system in wild boars is severely underperforming, despite the financial incentives. This affects the ability of the CA to identify at an early stage the possible introduction of the CSF virus through wild boars, particularly in areas with lower active surveillance or in periods other than the main hunting season.

5.5 LABORATORIES

Legal requirements

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

Findings

104. The Croatian Veterinary Institute is the NRL for CSF, responsible for testing samples for CSF, either in the framework of disease suspicion or for active surveillance. For the latter, two of its branches, in Vinkovci and in Križevci, carry out serological testing (antibody ELISA) in domestic pigs. In the case of positive results, the sera are to be immediately sent and re-tested in the NRL.
105. The NRL is accredited for CSF testing in accordance with the ISO 17025:2005. Serological test methods are included in the scope of accreditation of the NRL, but not virological tests (virus isolation, PCR).
106. In recent years the NRL has successfully participated in several proficiency tests organised by the EU Reference Laboratory for CSF using all methods (two PCRs, virus isolation, Ab ELISA, Ag Elisa, virus neutralisation test), including those methods not within the accreditation scope.
107. The NRL organises annual proficiency tests for the antibody ELISA test in domestic pigs for the other two laboratories involved. In all instances evaluated (years 2014 and 2015), their results showed a good performance by the laboratories involved. The NRL also visits the branches and assists them when needed. All experts must be trained in the NRL prior to conducting the antibody ELISA test for CSF.

108. The NRL has an active role in planning the eradication programme and in evaluating the effectiveness of the programme. The electronic data maintained in the laboratory and provided to the central CA are suitable for monitoring of the implementation of the sampling plan.
109. Standard protocols for the CSF diagnosis are validated. Information was also available to the team regarding the capacity calculation, both when there is no outbreak and in the event of a major outbreak. A laboratory contingency plan was available.
110. A protocol for the procedure to follow when unfit samples are received was available and its application documented. Figures on unsuitable samples are regularly provided to the central CA for intervention when needed.

Conclusions on laboratories

111. The laboratories (central and two branches) have the appropriate validated methods for detection of virus and CSF antibodies and regularly participate in proficiency tests with satisfactory results. In general, they provide timely and reliable results. The reliability of non-accredited methods used in the NRL is demonstrated by regular participation in proficiency tests with satisfactory results and a well implemented quality control system.

6 OVERALL CONCLUSIONS

The system for active surveillance in domestic pigs is well organised for all registered pig holdings. Its weaknesses do not significantly affect the confidence in the status of the country for CSF in domestic pigs (where the last CSF case reported was in 2008).

In wild boars, the active surveillance coverage and the implementation and monitoring of surveillance on an annual basis (during the hunting season), support the absence of the circulation of the CSF virus in this population in audited years.

The capacity for early detection of CSF in wild boars is affected by low submission of samples from dead wild boars. This combined with weak passive surveillance on small-scale pig holdings (with less than five pigs), causes some concerns about the CA's ability to detect the disease at an early stage, should it be reintroduced into the country.

The structure and organisation of the CA allows them to perform their control tasks on CSF in most circumstances adequately but the control system in place had not prevented underperformance of certain counties in implementation of the programme in audited years.

The national system for pig holding registration and pig identification provides the CA with a solid basis to implement the programme and control CSF for registered farms. The use of a derogation for one pig holding not authorised in the Commission Decision is to some extent mitigated by the comprehensive movement registration system.

The preventive movement control and biosecurity measures in place give additional assurances that should the disease re-emerge, its further spread will be limited before being detected.

7 CLOSING MEETING

A closing meeting was held on 22 April 2016 with the central CA. At this meeting the audit team presented the findings and preliminary conclusions of the audit. During this meeting, the competent authority did not indicate any major disagreement with the findings and preliminary conclusions.

8 RECOMMENDATIONS

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

No.	Recommendation
1.	<p>Ensure that the database for porcine animals contains on each holding a data field to enter sanitary information (for example restrictions on movements, status or other relevant information in the context of EU or national programmes) as required by Article 1(e) of Commission Decision 2000/678/EC.</p> <p>Based on conclusion (41), and associated finding (22).</p>
2.	<p>Ensure the full compliance of pig holding registration with EU requirements (Article 3 Directive 2008/71/EC).</p> <p>Either all pig holdings, including single pig holdings, are registered ((as required under Article 3 (1)) or Croatia is authorised in accordance with procedures referred to in Article 18 of Directive 90/425/EEC to avail of a derogation for non-registration of single pig holdings ((as stated in Article 3(2)).</p> <p>Based on conclusion (42), and associated finding (21).</p>
3.	<p>Improve implementation of active surveillance in domestic pigs and wild boars by underperforming counties in order to achieve targets set out in the programme.</p> <p>Grant Decision Number SANTE/ 2016/HR/SI2.726011 (programme for 2016).</p> <p>Based on conclusions (77) and (102) and associated findings (48), (51), (86-88) and (91-93).</p>

<p>4.</p>	<p>Improve robustness of surveillance in small-scale pig holdings in order to provide for early CSF warning in all segments of the pig population.</p> <p>Grant Decision Number SANTE/ 2016/HR/SI2.726011 (programme for 2016).</p> <p>Based on conclusion (77), and associated findings (59) and (60).</p>
<p>5.</p>	<p>Improve the early warning system in wild boars by increasing the number of laboratory analysis carried out on wild boars found dead and road killed, in particular by raising awareness of the hunters and other relevant stakeholders of the need to report any feral pig found dead (including road kill). Any incentive should be coupled with an adequate information campaign.</p> <p>Grant Decision Number SANTE/ 2016/HR/SI2.726011 (programme for 2016).</p> <p>Based on conclusion (103), and associated finding (100).</p>
<p>6.</p>	<p>Ensure that all confirmation virological tests used for CSF are within the scope of ISO 17025 accreditation.</p> <p>Article 12(2)(a) of Regulation (EC) No 882/2004.</p> <p>Based on conclusion (111), and associated finding (105).</p>

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

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2016-8974

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 652/2014	OJ L 189, 27.06.2014, p. 1-32	Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC
Dec. 2013/722/EU	OJ L 328, 7.12.2013, p. 101-117	2013/722/EU: Commission Implementing Decision of 29 November 2013 approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2014 and the following years
Dec. 2008/341/EC	OJ L 115, 29.4.2008, p. 44-46	2008/341/EC: Commission Decision of 25 April 2008 laying down Community criteria for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses
Dir. 2008/71/EC	OJ L 213, 8.8.2008, p. 31-36	Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (Codified version)
Dec. 2000/678/EC	OJ L 281, 7.11.2000, p. 16-17	2000/678/EC: Commission Decision of 23 October 2000 laying down detailed rules for registration of holdings in national databases for porcine animals as foreseen by Council Directive 64/432/EEC
Dec. 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)

