EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2017-6113

FINAL REPORT OF AN AUDIT CARRIED OUT IN BULGARIA FROM 07 NOVEMBER 2017 TO 15 NOVEMBER 2017 IN ORDER TO EVALUATE THE IMPLEMENTATION OF THE PROGRAMME FOR THE CONTROL AND MONITORING OF CLASSICAL SWINE FEVER
Executive Summary

This report describes the outcome of an audit in Bulgaria, carried out from 7 to 15 November 2017, 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 (CSF) in Bulgaria and in particular to evaluate whether the surveillance system is effective in providing an adequate and reliable picture of the disease status of the country; early detection of the disease outbreaks in the domestic pig population as well as 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 competent authority cannot properly assess the sensitivity of the surveillance programme. Although there is a system in place for verification and supervision of official controls, they do not carry out an epidemiological analysis of CSF data collected.

The central database offers a more accurate picture of the pig farming sector in Bulgaria than before. The authorities started to clean it up in 2016 and currently it provides an up-to-date list of pig holdings. The list showed there has been a significant reduction in the number of holdings with a low biosecurity level.

The active surveillance programme for domestic pigs – with regional variations- provides substantial guarantees that the CSF virus is not circulating in holdings with adequate biosecurity. However, passive surveillance in domestic pigs remains very weak and, as such, it does not provide sufficient level of confidence that CSF is being continuously ruled out as a potential cause of pig illness or mortality. Furthermore, differential diagnosis with African swine fever is not carried out in cases of suspicion of CSF in domestic pigs.

The active surveillance system for wild boars has significantly improved since 2013, when the authorities issued guidelines on the targeted sampling of wild boars for the CSF surveillance programme. The programme allows adequate sensitivity for confirming absence of CSF virus circulation in wild boars. Some regions at risk showed significant under-performance regarding testing of wild boards, which leads to uncertainty regarding CSF situation in these zones.

The absence of virological testing of wild boars since April 2017 seriously undermines the ability of the competent authority to identify at an early stage the possible introduction of the CSF virus through wild boars. Differential diagnosis with African swine fever was also not carried out in cases of wild boar found dead.

There are significant shortcomings in the CSF national reference laboratory and one regional laboratory. They are mainly due to a shortage of resources and inadequate organisation. These shortcomings impact mainly the ability to early detect the disease.

Live pigs, fresh pig meat, meat products and meat preparations are dispatched to other Member States and certified without fully meeting the requirements laid down in implementing Decision 2013/764/EU.

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

1 Introduction ....................................................................................................................................1

2 Objectives, scope and audit criteria ...............................................................................................1

3 Legal Basis .....................................................................................................................................2

4 Background ....................................................................................................................................2
   4.1 Summary of previous audit report ...........................................................................................2
   4.2 Classical swine fever situation in Bulgaria .............................................................................3

5 Findings and conclusions ...............................................................................................................3
   5.1 Competent Authorities.............................................................................................................3
   5.2 Holding registration, animal identification, movement controls .............................................4
   5.3 Biosecurity in pig holdings ......................................................................................................8
   5.4 Surveillance in domestic pigs ..................................................................................................8
   5.5 Monitoring in wild boars .......................................................................................................11
   5.6 Laboratories ...........................................................................................................................16
   5.7 Animal health controls on meat production and EU trade ....................................................18

6 Overall conclusions ......................................................................................................................20

7 Closing meeting ...........................................................................................................................21

8 Recommendations ........................................................................................................................21
### Abbreviations and Definitions Used in This Report

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASF</td>
<td>African Swine Fever</td>
</tr>
<tr>
<td>BFSA</td>
<td>Bulgarian Food Safety Directorate</td>
</tr>
<tr>
<td>CSF</td>
<td>Classical Swine Fever</td>
</tr>
<tr>
<td>ELISA</td>
<td>Enzyme Linked ImmunoSorbent Assay (serological test to detect CSF antibodies)</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>EURL</td>
<td>European Union Reference Laboratory</td>
</tr>
<tr>
<td>PCR</td>
<td>Polymerase Chain Reaction (virological test to detect CSF genes)</td>
</tr>
</tbody>
</table>
1 INTRODUCTION

The audit took place in Bulgaria from 7 to 15 November 2017. The audit team comprised two auditors from the Commission services and one national expert from a Member State.

An opening meeting was held on 7 November 2017 with the central competent authority, the Bulgarian Food Safety Agency (BFSA). 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 authority.

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 Bulgaria 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 Bulgaria approved by the Commission for 2015 (Grant Decision approving national programmes and associated funding of 30 January 2015 - Decision Number SANTE/VP/2015/BG/SI2.700760), 2016 (Grant Decision approving national programmes and associated funding of 29 January 2016 - Decision Number SANTE/2016/BG/SI2.725978) and 2017 (Grant Decision approving national programmes and associated funding of 29 January 2016 - Decision Number SANTE/VP/2017/BG/SI2.749826);
- 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:

<table>
<thead>
<tr>
<th>Visits / meetings</th>
<th>No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central authority competent</td>
<td>2</td>
<td>opening and closing meetings</td>
</tr>
<tr>
<td>Regional authority competent</td>
<td>3</td>
<td>Regional Food Safety Directorates</td>
</tr>
<tr>
<td>Laboratory</td>
<td>2</td>
<td>The National Reference Laboratory (NRL) and one regional laboratory</td>
</tr>
<tr>
<td>Hunting ground</td>
<td>1</td>
<td>State owned</td>
</tr>
<tr>
<td>Domestic pig holding</td>
<td>2</td>
<td>Industrial</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Type A</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Type B</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Backyard</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>East-Balkan (free roaming pigs)</td>
</tr>
</tbody>
</table>

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

4.1 Summary of Previous Audit Report

The last audit on CSF was carried out in Bulgaria from 19 to 26 November 2012 (DG (SANCO) 2012-6602).

The report concluded that extensive control measures are in place to monitor and control classical swine fever in domestic and wild pig populations. However, the failure to register all pig holdings and pig movements, the under-implementation of certain parts of the inspection and testing programme, the lack of epidemiological analysis of the results and the lack of targeting of wild boar sampling undermined the ability of the competent authority to verify the effectiveness of the vaccination programme and to demonstrate freedom from CSF.

The report and the action plan proposed by the Bulgarian authorities can be accessed at:

4.2 CLASSICAL SWINE FEVER SITUATION IN BULGARIA

The whole territory of Bulgaria is subject to specific animal health control measures relating to CSF, laid down in Commission Implementing Decision 2013/764/EU. This Decision imposes restrictions on the movements and transit of live pigs, dispatch of consignments of porcine semen and ova and embryos of swine, as well as on the dispatch of fresh pig meat and of certain meat preparations and meat products containing pig meat.

The last outbreak of CSF in domestic pigs has occurred in Bulgaria in 2008, at a family farm on the western border. The last eight cases of CSF in young wild boar were detected during the autumn of 2009 in a 25 km² forest area in the north-east part of the country.

The last vaccination campaign of domestic pigs took place in 2005. Oral vaccination campaigns for wild boar were carried out along Bulgaria's western (until 2015) and northern (until 2014) borders 2-3 times per year.

Since its accession to the European Union (EU), the programmes for control and monitoring of CSF in Bulgaria have been approved and the subject of financial support from the Commission. The last CSF programme approved by the Commission is multi-annual (2017-2018).

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

Legal requirements


Findings

1. The information on the organisation of the Bulgarian authorities is in the country profile (http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=BG) and in previous Commission services audit reports.

2. The team noted that different actors report data related to the implementation of the CSF programme according to standardised procedures. The authorised veterinary practitioners report the results of their official controls (e.g. clinical examinations, sampling, etc.) monthly to the municipal Official Veterinarian. The latter summarises the input from the authorised veterinarian and reports to the Regional Food Safety Directorate which in turn collates and transmits them on a monthly and annual basis to the Animal Health and Welfare (AHW) Directorate of BFSA.

3. There were significant variations between regions in the implementation of the programme. The audit team noted that significant underperformances in certain regions did not have an adequate adequately followed up and thus, they were not addressed. The authorities confirmed that, at central level, there was no expert group in charge of epidemiological analysis of CSF data collected in order to assess non-compliances with
the programme and underperformances in certain regions, and to prioritise corrective actions.

4. The Regional Directorates use standardised lists for checking the effectiveness of official controls carried out at municipal level. The internal audits cover the official controls performed by Regional Directorates. Since 2015, according to new organisational rules published in State Gazette (Issue No 29 of 21.04.2015), internal audits are performed by the "Verification of official controls" General Directorate, which is directly subordinated to the BFSA Executive Director.

5. The General Directorate, which includes two Departments "Audit of official controls" and "Verification and administrative control activities of Regional Food Safety Directorates", works based on a five-year programme, with new developed and updated procedures, responsibilities and documents in accordance with guidelines set out by EU legislation and in the standard BS EN ISO 19011: 2004.

6. The team noted that:
   - The number of internal audits planned (12 in total) for the years 2016 and 2017, to verify the effectiveness of official controls carried out at regional level, has significantly increased compared to the previous years (respectively eight and seven in 2014 and 2015).
   - There are also internal audits targeting the official surveillance programme of animal diseases: one on the implementation of the CSF surveillance programme was performed in 2015 in a region randomly selected. The report included findings useful for identifying root causes of underperformance and recommendations requesting corrective actions to both the regional and the central authorities.

Conclusions on competent authorities

7. The structure, organisation and competencies of the authorities involved in the CSF surveillance programme are well defined. There is a system in place for verification and supervision of official controls.
8. The absence of epidemiological analysis of CSF data collected does not allow the competent authority to properly assess the sensitivity of the surveillance programme.

5.2 HOLDING REGISTRATION, ANIMAL IDENTIFICATION, MOVEMENT CONTROLS

Legal requirements

Findings

9. Pig holdings are registered in the Central Database with a unique holding number. The database (World Vet System) is an internet-based system designed for multi-species functionality. Data are entered into the system by multiple users, including official and approved veterinarians, slaughterhouses, etc. The database is the main tool used for issuing movement documents.

10. National legislation (Ordinance No 44 of 20/04/2006) requests that pig holdings be categorised according to their size and biosecurity standards: high biosecurity holdings include industrial and family type “A” holdings, and low biosecurity holdings include family type “B” holdings (allowing up to two breeding sows) and backyard farms (allowing a maximum of 5 pigs and no breeding sow). In addition some outdoor farms in the Eastern part of the country raise free-roaming East-Balkan pigs.

11. Data in the database indicated a huge decrease in the total number of pig holdings with low biosecurity level over the last three years, in particular type B holdings and backyard holdings (see tables below). To date, holdings with a low biosecurity level represent 92.5% of holdings registered in the database and they hold 2.5% of the total number of pigs.

<table>
<thead>
<tr>
<th>Type of pig holdings</th>
<th>Total number of pig holdings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2015</td>
</tr>
<tr>
<td>Industrial</td>
<td>52</td>
</tr>
<tr>
<td>Type A</td>
<td>118</td>
</tr>
<tr>
<td>Type B</td>
<td>810</td>
</tr>
<tr>
<td>Backyard</td>
<td>25856</td>
</tr>
<tr>
<td>East-Balkan pig</td>
<td>68</td>
</tr>
<tr>
<td>Total</td>
<td>26904</td>
</tr>
</tbody>
</table>

12. According to the authorities, these figures are the result of a thorough clean-up process of the database initiated in 2016, following an Order (RD 11-1065/15.06.2016) of the Director of BFSA. The Order also requested the Regional Directorates to strengthen checks on pig holdings to enforce compliance with the requirements of Ordinance No 44 of 20/04/2006, i.e. to increase biosecurity standards of type B holdings. Following these checks, the database was updated accordingly.

13. In parallel, there had been a continuous decrease in the domestic pig population in Bulgaria over the last 12 years.
14. The Bulgarian Law on Veterinary Activities and national Ordinance No 61 of 9/05/2006 establishes the rules for the identification of animals: pigs have to be identified before they leave the holding of origin, either with an ear-tag bearing an individual number or a holding number (e.g. pigs dispatched to slaughterhouse).

15. The team noted that:

- Apart from industrial holdings, pigs are usually identified at weaning or when blood is taken from them as part of the CSF surveillance programme. They are re-tagged when tags are lost or not readable.
- Identification is carried out by the authorised veterinarian who is also responsible for entering data on animal identification onto the database.
- The audit team visited one family holding. The owner/keeper stated that he recently brought on to the farm non-identified pigs from a non-registered holding. The pigs were identified by the authorised veterinarian without investigating their origin.

16. The Bulgarian Law on Veterinary Activities requires that all livestock holdings are registered. In one Regional Directorate visited, the team noted that two pig holdings were registered in the central database as backyard farms instead of type B holdings. In both farms, the total number of pigs was 10 fattening pigs and one breeding sow or more. Furthermore, the checklists filled during the official control on both farms clearly mentioned the exact number of pigs and sows along with the wrong category of the holding.

17. All the holdings visited by the audit team had holding registers, in the format initially designed by the competent authority:

- In all family holdings visited, the holding register did not contain a section to record births and deaths. Therefore, the register did not necessarily state the exact number of animals present on the holding as requested by Article 4 of Directive 2008/71/EC. Traceability of movements of animals not yet identified
could not be ensured. The authorities informed the team that the owner/keeper should notify all births to the authorised veterinarian within three days. This requirement was not implemented, checked or enforced in the holdings visited during the audit.

- In one type B holding, with 22 sows, the number of offspring identified and recorded in the register (respectively 155 and 29 in 2016 and 2017) was very low.
- In two family holdings, a large number of pigs were slaughtered on farm (e.g. up to 50 pigs in six months in one type A holding; 15 pigs in four days in one type B holding); the slaughter was mentioned in the holding register, but no other evidence was available to substantiate this information.

18. Regarding movement controls, the team noted that:

- Prior to movement, pigs are subject to health inspection by the authorised veterinarian, who enters the details of movement into the database, which in turns generates the document which will accompany the pigs. This notification can be entered even if the holding of destination is not known. The movement needs to be confirmed in the database by the authorised veterinarian of the holding of destination.
- The competent authority regularly monitors the database, and sends lists of incomplete records of movements on a monthly basis to the Regional Directorates with an instruction to investigate the cases and to close the movements.

19. The audit team received the results of the official controls on pig identification, holding registration and movements carried out by official veterinarians: in 2016, 1313 checks were carried out in 985 holdings. Non-compliances found led to administrative penalties or fines.

Conclusions on animal identification, holding registration and movement control

20. An operational central database is in place. It contains an up-to-date list of pig holdings and thus provides an accurate picture of the pig farming sector in Bulgaria. Its data shows a significant reduction of holdings with a low biosecurity level during the last years.

21. Bulgaria can ensure adequate traceability of identified pigs. However, the lack of records of births and deaths in the holding registers do not allow the control of production parameters.
5.3 Biosecurity in Pig Holdings

Legal requirements


Findings

22. Ordinance No 44 of 20.04.2006 defines the minimum levels of biosecurity standards for pig holdings. The standards established for industrial and type A holdings allow this pig holdings to meet the minimum requirements laid down in Commission Decision 2013/764/EC and the second and fourth to seven indents of Article 15(2)(b) of Council Directive 2001/89/EC. This is not the case for type B holdings, backyard farms and East-Balkan pig farms.

23. Official veterinarians and approved ones perform controls on biosecurity measures on the different categories of holdings during their inspections. They use a checklist. The two industrial holdings visited by the audit team had a biosecurity plan approved by the competent authority.

24. The authorities stated that the BFSA sent instructions (letter No 5729 of 06/10/2017) to the Regional Directorates reminding them to check type B farms in order to either upgrade them (to type A farms) or downgrade them (to backyard farms) by the end of December 2017.

25. According to the central database, at the time of the audit, approximately 97.5% of the pig population was kept in 164 holdings with an adequate level of biosecurity (60 industrial holdings and 104 type A holdings), while the remaining 2.5% of the pigs were kept in approximately 2,208 farms with no or low biosecurity (178 type B, 1,804 backyard and 46 East-Balkan pig farms).

Conclusions on Biosecurity in Pig Holdings

26. The level of biosecurity requirements for pig holdings has improved over the last years and 97.5% of the pig population is now kept in holdings with an adequate level of biosecurity. The central authorities have recently issued instructions to other services to further improve biosecurity on pig holdings.

5.4 Surveillance in Domestic Pigs

Legal requirements

Findings

27. Active surveillance is carried out through clinical examinations and serological sampling in a proportion of the domestic pig population. The surveillance scheme includes regular inspections of holdings by official and approve veterinarians, with a pre-determined frequency depending on categorisation of the holding.

<table>
<thead>
<tr>
<th>Category</th>
<th>Clinical examinations: detection of fever at prevalence 5% with 95% confidence</th>
<th>Approved vet Sampling scheme to detect CSF Antibodies at 20 % prevalence with 95% confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Approved veterinarian</td>
<td>Official veterinarian</td>
</tr>
<tr>
<td>Industrial</td>
<td>each batch for slaughtering (SL)</td>
<td>every 6 months</td>
</tr>
<tr>
<td>Type A</td>
<td>each batch for SL</td>
<td>once a year</td>
</tr>
<tr>
<td>Type B</td>
<td>once a year: 50% of farms</td>
<td>once a year: 25% of farms</td>
</tr>
<tr>
<td>Backyard</td>
<td>once a year: 10% of backyards</td>
<td>once a year: 5% of backyards</td>
</tr>
<tr>
<td>East-Balkan</td>
<td>Once a year each batch for SL</td>
<td>Once a year</td>
</tr>
</tbody>
</table>

Results of the CSF surveillance in domestic pigs for 2015 and 2016

<table>
<thead>
<tr>
<th>Period</th>
<th>Type of holding</th>
<th>No Holdings</th>
<th>No Pigs</th>
<th>No Serological tests</th>
<th>No Virological tests</th>
<th>No Clinical examinations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Industrial</td>
<td>56</td>
<td>520765</td>
<td>975</td>
<td>0</td>
<td>9705</td>
</tr>
<tr>
<td></td>
<td>Type A</td>
<td>118</td>
<td>33487</td>
<td>1605</td>
<td>5</td>
<td>1479</td>
</tr>
<tr>
<td></td>
<td>Type B</td>
<td>452</td>
<td>8972</td>
<td>2193</td>
<td>0</td>
<td>677</td>
</tr>
<tr>
<td></td>
<td>Backyards</td>
<td>15578</td>
<td>21406</td>
<td>4</td>
<td>0</td>
<td>4547</td>
</tr>
<tr>
<td></td>
<td>East-Balkan</td>
<td>58</td>
<td>3877</td>
<td>1218</td>
<td>46</td>
<td>163</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>16262</td>
<td>588507</td>
<td>5995</td>
<td>49</td>
<td>16571</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Period</th>
<th>Type of holding</th>
<th>No Holdings</th>
<th>No Pigs</th>
<th>No Serological tests</th>
<th>No Virological tests</th>
<th>No Clinical examinations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Industrial</td>
<td>59</td>
<td>428917</td>
<td>591</td>
<td>0</td>
<td>10463</td>
</tr>
<tr>
<td></td>
<td>Type A</td>
<td>114</td>
<td>27303</td>
<td>1416</td>
<td>0</td>
<td>1486</td>
</tr>
<tr>
<td></td>
<td>Type B</td>
<td>449</td>
<td>10286</td>
<td>2043</td>
<td>1</td>
<td>442</td>
</tr>
<tr>
<td></td>
<td>Backyards</td>
<td>16911</td>
<td>27254</td>
<td>0</td>
<td>0</td>
<td>2491</td>
</tr>
<tr>
<td></td>
<td>East-Balkan</td>
<td>49</td>
<td>4908</td>
<td>1057</td>
<td>267</td>
<td>152</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>17582</td>
<td>498668</td>
<td>5107</td>
<td>268</td>
<td>15034</td>
</tr>
</tbody>
</table>
28. In accordance with the CSF programmes for 2015, 2016 and 2017:

- The minimum number of pigs to be clinically examined by the official veterinarian must allow for the detection of fever if it occurs at prevalence 5% with 95% confidence.
- The approved veterinarian carries out clinical examination of each batch of pigs dispatched to slaughterhouses (industrial and type A holdings). A check-list accompanies the pigs to the slaughterhouse.
- Sampling is done by the approved veterinarian with the aim of detecting at least a 20% prevalence of CSF antibodies with 95% confidence. In cases of suspicion, the level of detection is lower (10% for fattening pigs; 5% for breeding sows and East-Balkan pigs).

29. Based on the data provided by the competent authority, they surpassed the total target set for industrial and type A holdings where animals had to be clinically examined, but not all regions achieved the targets set for them. In 2015, authorised veterinarians had to inspect 100% and official veterinarians 10% of backyard farms; in 2016, the surveillance scheme changed to 10% and 5% respectively.

30. Sampling was planned to achieve the expected within-herd estimated prevalence. Overall targets for the number of holdings and animals tested in 2015 and 2016 had been achieved, but some regions did not meet their individual target.

31. At industrial holdings, the team noted that although there were significant number of pigs (e.g. sows, piglets, weaners, fattening pigs, etc.) kept in several distinct sub-units, sampling was always carried out considering the whole holding as one epidemiological unit; i.e. in this type of holding, 14 blood samples have to be taken every year in order to detect at least a 20% prevalence of CSF antibodies with 95% confidence. The wrong categorisation of pig holding (e.g. holding classified as backyard farm instead of type A or type B holding), as mentioned in paragraph 15 also affects the implementation of the CSF surveillance programme, as instructions for clinical examinations and sampling of pigs are significantly different between these two types of holding.

32. Pre-slaughter testing (PCR) is usually carried out for East-Balkan pigs; however, due to a shortage of PCR tests since April 2017, an alternative testing method (ELISA antigen) had been used.

33. Notification of African swine fever (ASF) and CSF is mandatory according to Article 50 of the Law on Veterinary activities. The surveillance scheme includes monitoring and sampling of pigs exhibiting clinical symptoms or showing lesions compatible with CSF.

34. The team noted that:

- According to the central authority, since 2015 to date, only two occurrences of suspicion of CSF in domestic pigs were subject to laboratory tests. CSF was ruled out after getting negative results from the National reference laboratory.
following the criteria laid down in the EU diagnostic manual for CSF. However, differential diagnosis with ASF was not carried out.

Conclusions on surveillance, controls on domestic pigs

35. Although with regional variations, the active surveillance programme for domestic pigs provides substantial guarantees that the CSF virus is not circulating in commercial holdings. The system gives more limited guarantees for holdings with low biosecurity, where shortcomings in holding registration and records undermine the ability to fully assess the CSF epidemiological situation but the sharp drop in the number of backyard holdings following comprehensive verification by the competent authority mitigates the significance of this weakness.

36. Passive surveillance in domestic pigs remains very weak and, as such, does not provide a sufficient level of confidence that CSF is being continuously ruled out as a potential cause of pig illness or mortality. This results in uncertainty regarding the effectiveness of the CSF early detection system. Furthermore, differential diagnosis with ASF is not carried out in cases of suspicion of CSF in domestic pigs.

5.5 Monitoring in wild boars

Legal requirements


Findings

37. The Ministry of Agriculture Food and Forestry is responsible for drafting relevant legislation and the management of hunting activities. The main national legislation is the law for hunting and protection of the game published in the State Gazette (SG. No 78/26 September 2000 at last amended).

38. The main partners involved with BFSA in the CSF surveillance programme in wild boars are the Executive Forestry Agency and its 16 Regional Forestry Directorates, the National Council of Hunters represented at Regional Forestry Directorates level by the hunting councils and the National Union of Hunters and Anglers.

39. Currently, in Bulgaria, there are 16 regional state hunting areas, including around 1,900 hunting grounds.

40. In 2016, according to data provided by the competent authority, the wild boar population in Bulgaria was estimated at 89,183 animals, including 29,830 wild boars in state hunting areas and 59,353 wild boars in hunting areas provided for the National Union of Hunters and Anglers (see table below).
<table>
<thead>
<tr>
<th>Regional state hunting areas</th>
<th>No of wild boars in state hunting areas</th>
<th>No of wild boars in hunting areas provided for the National Union of Hunters and Anglers</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berkovitsa</td>
<td>871</td>
<td>5005</td>
<td>5876</td>
</tr>
<tr>
<td>Burgas</td>
<td>4942</td>
<td>4867</td>
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<td>5344</td>
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<td>6290</td>
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<td>5764</td>
<td>7649</td>
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<tr>
<td>Kardzhali</td>
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<td>5419</td>
<td>6720</td>
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<td>Kyustendil</td>
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<td>3159</td>
<td>3786</td>
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<tr>
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<td>4000</td>
<td>5325</td>
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<tr>
<td>Pazardzhik</td>
<td>1591</td>
<td>2208</td>
<td>3799</td>
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<tr>
<td>Plovdiv</td>
<td>1979</td>
<td>2367</td>
<td>4346</td>
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<tr>
<td>Ruse</td>
<td>1757</td>
<td>1810</td>
<td>3567</td>
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<tr>
<td>Sliven</td>
<td>1300</td>
<td>2754</td>
<td>4054</td>
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<tr>
<td>Smolyan</td>
<td>1005</td>
<td>2317</td>
<td>3322</td>
</tr>
<tr>
<td>Sofia</td>
<td>2377</td>
<td>7739</td>
<td>10116</td>
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<tr>
<td>Stara Zagora</td>
<td>1175</td>
<td>3075</td>
<td>4250</td>
</tr>
<tr>
<td>Shumen</td>
<td>2484</td>
<td>2446</td>
<td>4930</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>29830</strong></td>
<td><strong>59353</strong></td>
<td><strong>89183</strong></td>
</tr>
</tbody>
</table>

41. The data from the competent authority shows a steady increase in the wild boar population over the last 15 years.

Density of wild boar population in Bulgaria
Trend of wild boar population in Bulgaria

42. The main hunting season for wild boar runs from the beginning of October to the first week(s) of January, when the vast majority of samples are collected.

43. Regarding biosecurity measures in hunting grounds, the team noted that specific guidelines had been issued by BFSA:

- Guidelines (Annex to Order No RD 11-881 of 29 September 2009) on hygiene requirements for collection and storage of wild boar carcasses, sampling and dispatch of samples for laboratory testing.
- Guidelines (Annex to Order No RD 11-1075 of 4 September 2012) on biosecurity measures to be applied by hunters.

44. With regard to the surveillance scheme, guidelines (No RD 11-349) on the targeted sampling of wild boars were issued on 20 March 2013. The strategy of the CSF surveillance is based on areas defined in line with Chapter IV, point H.2 of Annex to Decision 2002/106/EC, each of them having a wild boar population in the range of 350 to 1600 animals. The country has been divided into 80 areas, including 15 high-risk areas situated along the northern and western border and 65 low-risk areas. The 15 areas along Bulgaria’s northern and western borders have been determined as high-risk due to the lack of clarity as regards the epizootic situation in Romania, Serbia and the Former Yugoslav Republic of Macedonia. Up until the end of 2015, oral vaccination of wild boar against CFS had only been carried out in these areas.

45. According to the guidelines, for the purpose of CSF surveillance in wild boar, at least 59 animals from each area (1 to 80) must be sampled (serum and organs for serological and PCR testing) each calendar year in order to detect 5% infection with 95% confidence. Moreover, sampling of wild boar must conform to the requirements set out in Chapter IV of the Annex to Decision 2002/106/EC so that approximately 50 % of sampled animals belong to the up to the one year age class; 35% to the one to two years age class; and 15% to the more than two years age class.

46. The results of the last three years' surveillance programme in wild boars, which requires sampling for serological and virological testing, were provided to the team.
The team noted the following:

- The active surveillance system for wild boars has significantly improved since guidelines on the targeted sampling of wild boars have been issued and implemented.

- In 2016, 49 wild boars were tested seropositive: all seropositive animals were tested negative by PCR. Age and location (oral vaccination in previous years) of each seropositive wild boar were compatible with the assumption that seropositivity was due to previous vaccination. However, no procedures are in place to confirm this assertion and discard other possible hypothesis (circulation of virus in the area). Therefore, appropriate measures to confirm or rule out the presence of the disease in wild boar when the disease is suspected, were not taken according to the requirements laid down in Article 15 of Directive 2001/89/EC (taking into account the recommendations of the CSF diagnostic manual: point B (3) and (7) of Chapter VII of Annex to Decision 2002/106/EC).

- The authorities issued new instructions regarding surveillance in wild boars in 2016 (No 6106 of 17 October 2016) requesting the sampling and testing (ASF and CSF) of all shot wild boars (ASF strategy to prevent or detect early the introduction of ASF in Bulgaria) and the request was renewed for the 2017 hunting season (letter dated 11 October 2017). These instructions have not been taken into account in two Regional Directorates visited during the audit. In addition, the 2016 and 2017 programmes have not been updated to take into consideration this new strategy, which would have led to a significant increase in testing expenses (about 90,000 wild boars were tested in 2016). The testing capacity of the laboratory has not been checked and assessed beforehand. The competent authority stated that the intention of these instructions was to raise the

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### Serological surveillance

<table>
<thead>
<tr>
<th>Age of wild boar in months</th>
<th>Vaccination area</th>
<th>Non-vaccination area</th>
<th>Vaccination area</th>
<th>Non-vaccination area</th>
<th>Non-vaccination area</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Serologically tested</td>
<td>% sero positive</td>
<td>Serologically tested</td>
<td>% sero positive</td>
<td>Serologically tested</td>
</tr>
<tr>
<td>0 - 12</td>
<td>611</td>
<td>11.62</td>
<td>577</td>
<td>0</td>
<td>466</td>
</tr>
<tr>
<td>12-24</td>
<td>578</td>
<td>50.74</td>
<td>532</td>
<td>0</td>
<td>303</td>
</tr>
<tr>
<td>&gt; 24</td>
<td>627</td>
<td>63.31</td>
<td>904</td>
<td>0</td>
<td>175</td>
</tr>
<tr>
<td>Total No of WB tested</td>
<td>1816</td>
<td>2013</td>
<td>944</td>
<td>3077</td>
<td>5940</td>
</tr>
<tr>
<td></td>
<td>3829</td>
<td>4021</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Virological surveillance

| Total No of WB tested | 6506 | 4128 | 6114 |

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47. The team noted the following:
awareness of hunters and develop the habit of systematic sampling, but that they had no intention to test all samples.

- In one region visited, the audit team noted under-implementation of the active surveillance programme in wild boars: e.g. respectively in 2015 and 2016, only 63 and 20 shot wild boars were sampled and tested, while the planned number of samples was 147. The region, where a vaccination programme was implemented until the end of 2015, was considered at risk, as it border a country with an unknown CSF status. The competent authority had an explanation for this situation, but no corrective action was initiated.

- The laboratories did not perform PCR testing for CSF since April 2017, due to a lack of test kits. According to the National reference laboratory, samples have been frozen pending further testing.

48. According to information provided in the reply to the pre-audit questionnaire, respectively, 11, 13 and 18 wild boars found dead were tested for CSF/ASF in 2015, 2016 and 2017. During the audit, the team collected completely different data from different sources, which could not be verified.

49. Regarding passive surveillance, the audit team noted the following:

- Instructions for sampling of wild boars were not correctly implemented in two Regional Directorates visited, as the authorities did not understand that samples of wild boars killed on the road have to be sent to the laboratory.

- Since April 2017, no PCR testing for CSF has been performed in the framework of passive surveillance because of the lack of availability of test kits.

- ASF differential diagnosis was not performed on samples forwarded to the laboratory, even when requested by the competent authority.
Conclusions on surveillance in wild boars

50. The active surveillance system for wild boars has significantly improved since the authorities issued guidelines on the targeted sampling of wild boars for the CSF surveillance programme in 2013. The programme, as implemented, has adequate sensitivity for confirming absence of CSF virus circulation in wild boars. The significant under-performances in some regions lead to uncertainty regarding the disease status of these zones, especially for peripheral regions, where a vaccination programme has been implemented until recently. There are no procedures in place to confirm or rule out the presence of the disease when a wild boar is tested seropositive.

51. The absence of PCR testing of wild boars since April 2017 (due to a lack of test kits) seriously undermines the ability of the Bulgarian authorities to identify the possible introduction of the CSF virus through wild boars at an early stage. For wild boar found dead, Bulgaria is not performing differential diagnosis with ASF.

5.6 LABORATORIES

Legal requirements


Findings

52. For CSF, Bulgaria has a central laboratory located in Sofia that is also the National Reference Laboratory and two regional laboratories. In addition, private laboratories are authorised to run CSF testing.

53. All three laboratories are accredited ISO 17025. For the National reference laboratory, the scope is, since September 2017, CSF ELISA antibody and Real Time-PCR; for the two other laboratories, only ELISA antibody. The reference laboratory participates yearly in the proficiency test organised by the EU Reference Laboratory (EURL) in Hannover for ELISA antibody and PCR. The results for the 2017 proficiency testing were satisfactory. Sofia organised in 2015 an inter-laboratory test for the ELISA antibody with the two regional laboratories and one private laboratory. The results for the three official laboratories were satisfactory.

54. The National reference laboratory controlled the reagents of each batch used by any of the official laboratories, but did not check the batches or reagents purchased by the private laboratories, contrary to point 3(b) of Annex III to Directive 2001/89/EC.

55. PCR is only performed in Sofia. In the near future there are plans to include the PCR test in the scope of accreditation of the two regional laboratories. In 2014 an on-site training for PCR was organised by the EURL in Sofia. Since then the detection of CSF
by PCR improved. Pooling of up to 10 samples is used for CSF testing: the method has not yet been validated.

56. Since 2013, no ELISA test performed on sera of domestic pigs gave a positive or inconclusive result, despite the high number of samples tested (e.g. 4,000 in 2016, 6,000 in 2015). No follow-up at the time of the results of the positive and negative kit control was performed at the laboratories visited.

57. During the visit of the national reference laboratory, the team noted that:

- The laboratory has no laboratory information management system, and therefore it was rather difficult to find the requested documents. Moreover, the laboratory has no crisis management plan as it had been running under crisis mode for the past couple of years (lumpy skin disease, avian influenza outbreaks).

- At reception level, in the absence of specific instructions, certain requests for testing were deliberately modified or not taken into account: e.g. even when requested by the authorities, ASF testing was not performed; in 2016, following a request for differential diagnosis (CSF, ASF and foot-and-mouth disease) on a wild boar sample coming from a region neighbouring Turkey, only CSF testing was performed. Moreover, since April 2017, incoming samples from wild boars found dead were not registered at reception: the laboratory explained to the team that this was applied in order to avoid impact on the turn-around time, which could affect its accreditation.

- The laboratory had only two pieces of PCR testing equipment at the time of the audit, of which one was not operational; consequently, the testing capacity of the laboratory was clearly deficient. The laboratory informed the team that two additional PCR devices will be purchased by the end of 2017; so that ASF testing can be performed on a routine basis.

- The only certified test for CSF virus detection is PCR. From April 2017, the national reference laboratory has not performed any PCR test, due to a lack of availability of test kits. The laboratory explained to the team that this was due to issues related to public procurement.
  - An alternative method (ELISA antigen), for which the laboratory is no longer accredited, was used in the pre-slaughter surveillance of East Balkan pigs. The central authorities were orally informed.
  - Regarding wild boar, since April 2017, all samples have been frozen and they are kept in cold storage until the PCR test is available again.

- In 2017, serological ELISA testing has been performed according to the surveillance scheme. However, in 2016, an internal audit carried out on the implementation of the CSF programme clearly identified in one region that
serological ELISA testing was not performed because the reference laboratory had run out of kits.

- Virus isolation and virus neutralisation for CSF are no longer accredited tests, and the laboratory hasn’t been in a position to perform a virus neutralisation test since 2014. Currently, there is no agreement with the EURL for support in confirmation of positive samples by virus isolation and virus neutralisation. Virus neutralisation was not performed on ELISA seropositive wild boars. Therefore, appropriate measures to confirm or rule out the presence of the disease in wild boar when the disease is suspected, were not taken in accordance with EU requirements.

58. During the visit to one regional laboratory involved in CSF testing, the team noted that:
- The laboratory, which is ISO 17025 certified since 2008 for CSF ELISA Antibody detection, has a quality manager and a biosafety manager.
- The laboratory has a standard operating procedure based on the manual of the commercial kit. There was no operating procedure for numbering or document control. The templates of the working sheets used in the laboratory were not included in the standard operating procedure.
- It was difficult to make an irrefutable link between the working sheet with the sample disposal and the ELISA reader printout. On the working sheet the incubation time is mentioned but the room temperature is not measured.

Conclusions on laboratories

59. The significant shortcomings in the CSF national reference laboratory and one regional laboratory visited - mainly due to shortage of resources and inadequate organisation – impact negatively on the capacity of the authorities to early detect CSF.

5.7 ANIMAL HEALTH CONTROLS ON MEAT PRODUCTION AND EU TRADE

Legal requirements


Findings

60. Industrial and type A holdings (which meet the minimum EU biosecurity requirements and routinely implement the CSF surveillance scheme described in Chapter 5.4) can send pigs for slaughter to an EU approved establishment, where carcasses are stamped with an oval health mark. Pigs intended for dispatch to a slaughterhouse must be subjected to clinical examinations, including temperature checks, within 24 hours prior to the issuing of the movement certificate by the authorised veterinarian or by an official veterinarian. The movement certificate is valid for three days and must accompany the
pigs to the slaughterhouse, as must the clinical inspection check-list, an owner-declaration regarding treatments with veterinary medicinal products and the food-chain information.

61. Type B holdings and backyard farms are not authorised to send pigs for slaughter to an EU approved establishment. The authorities used derogation for slaughtering East Balkan pigs in an EU approved slaughterhouse provided that within 7 days of dispatch the pigs must be subject to PCR tests for CSF with negative results. The sample numbers should be sufficient to detect a 5% prevalence of CSF with 95% confidence. The audit team visited one EU approved slaughterhouse which was authorised for slaughter of bovine, ovine and porcine animals, including East Balkan pigs. The meat from East Balkan pigs was marked with a diamond stamp and the meat and meat products dispatch only on the domestic market.

62. Fresh pig meat, meat preparations and meat products are dispatched to other member States accompanied by the appropriate Intra-Union trade certificate, signed on the basis of the current surveillance scheme. This scheme does not fully meet the requirements laid down in Decision 2013/764/EU and in particular the one relating to the absence of introduction of live pigs into the holding, or separate production unit, during the 30-day period immediately prior to the date of dispatch to the slaughterhouse.

63. In two industrial holdings visited, the audit team noted that live pigs were introduced into the holdings on a daily basis, without confirmation by the official veterinarian that the absence of introduction would only apply to separate production units, contrary to the requirements in Decision 2013/764/EU (i.e. the structure, size and distance between the production units and the operations carried out are such that the production units provide completely separate facilities for housing, keeping and feeding, so that the virus cannot spread from one production unit to another). The annual sampling plan was performed on the basis of the whole holding and not for each separate production unit (see paragraph 23), which incurs that the official veterinarian actually considered that the virus could spread among production units.

64. Bulgaria sends live pigs to other Member States accompanied by the appropriate Intra-Union trade certificate, signed on the basis of the current surveillance scheme. No specific instruction had been issued when Decision 2013/764/EU was modified in 2016 to introduce this derogation, and no specific check-list was developed to verify compliance with the provisions of Article 2a of this Decision. Live pigs certified for trade did not meet the requirements of Decision 2013/764/EU, as:

- The holding was not subjected at least every four months to inspections by the competent authority.
- Live pigs were introduced into the holding during the 30-day period immediately prior to the date of dispatch.
- The sampling and testing of the pigs was not performed within one month prior to movement to the slaughterhouse;
- The testing was performed as per the annual plan, allowing for detection of 20% prevalence, while the requirement is that the testing should be performed according to the standard laid down in point F.2 of Chapter IV of the Annex to Decision 2002/106/EC (10% seroprevalence with 95% confidence (5% for sows) in pigs in each sub-unit in the holding).

Conclusions on Animal health controls on meat production and EU trade

65. The clinical examinations and serological sampling of pigs before they are sent to slaughter contributes to monitor the possible presence of CSF virus and ensure that meat will not be a mean of spreading the disease.

66. The authorities certify and dispatch to other Member States live pigs, fresh pig meat, meat products and meat preparations which do not comply with the requirements set for Bulgaria for intra-Union trade.

6 Overall conclusions

The competent authority cannot properly assess the sensitivity of the surveillance programme. Although there is a system in place for verification and supervision of official controls, they do not carry out an epidemiological analysis of CSF data collected.

The central database offers a more accurate picture of the pig farming sector in Bulgaria than before. The authorities started to clean it up in 2016 and currently it provides an up-to-date list of pig holdings. The list showed there has been a significant reduction in the number of holdings with a low biosecurity level.

The active surveillance programme for domestic pigs – with regional variations- provides substantial guarantees that the CSF virus is not circulating in holdings with adequate biosecurity. However, passive surveillance in domestic pigs remains very weak and, as such, it does not provide sufficient level of confidence that CSF is being continuously ruled out as a potential cause of pig illness or mortality. Furthermore, differential diagnosis with African swine fever is not carried out in cases of suspicion of CSF in domestic pigs.

The active surveillance system for wild boars has significantly improved since 2013, when the authorities issued guidelines on the targeted sampling of wild boars for the CSF surveillance programme. The programme allows adequate sensitivity for confirming absence of CSF virus circulation in wild boars. Some regions at risk showed significant under-performance regarding testing of wild boards, which leads to uncertainty regarding CSF situation in these zones.

The absence of virological testing of wild boars since April 2017 seriously undermines the ability of the competent authority to identify at an early stage the possible introduction of the CSF virus through wild boars. Differential diagnosis with African swine fever was also not carried out in cases of wild boar found dead.

There are significant shortcomings in the CSF national reference laboratory and one regional
laboratory. They are mainly due to a shortage of resources and inadequate organisation. These shortcomings impact mainly the ability to early detect the disease.

Live pigs, fresh pig meat, meat products and meat preparations are dispatched to other Member States and certified without fully meeting the requirements laid down in implementing Decision 2013/764/EU.

7 CLOSING MEETING

A closing meeting was held with the central competent authority on 15 November 2017 when the audit team presented the main findings and preliminary conclusions of the audit to the competent authority. During this meeting the competent authority provided certain clarifications and did not indicate any major disagreement with the findings and preliminary conclusions.

8 RECOMMENDATIONS

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

<table>
<thead>
<tr>
<th>No.</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>To ensure that an epidemiological analysis of CSF data collected is regularly carried out in order to assess non-compliances with the programme and underperformances of certain regions and to prioritise corrective actions in accordance with the requirements laid down in Directive 2001/89/EC.</td>
</tr>
<tr>
<td></td>
<td>Recommendation based on conclusion No.7</td>
</tr>
<tr>
<td></td>
<td>Associated finding Nos.3, 31 and 46</td>
</tr>
<tr>
<td>2.</td>
<td>To ensure that any owner/keeper of porcine animals keeps a register stating the number of animals present in the holding as required by Article 4 of Directive 2008/71/EC.</td>
</tr>
<tr>
<td></td>
<td>Recommendation based on conclusion No. 21</td>
</tr>
<tr>
<td></td>
<td>Associated finding No.17</td>
</tr>
<tr>
<td>3.</td>
<td>To improve implementation of active surveillance in domestic pigs and wild boars by underperforming counties in order to achieve targets set out in the EU co-financed veterinary programmes approved by the Commission for 2015, 2016 and 2017.</td>
</tr>
</tbody>
</table>
| Recommendation based on conclusion Nos. 35 and 50  
Associated finding Nos. 29 and 47 |
|---------------------------------------------------------------|
| 4. To enhance passive surveillance in domestic pigs in order to ensure that CSF is being continuously ruled out as a potential cause of pig illness or mortality in line with the main criteria described in Chapter III of Annex to Decision 2002/106/EC.  
Recommendation based on conclusion No. 36  
Associated finding No. 34 |
| 5. To ensure that measures are immediately taken to confirm or to rule out suspicion of ASF in domestic pigs and wild boars in accordance with requirements laid down in Article 4 and 15 of Directive 2002/60/EC.  
Recommendation based on conclusion Nos. 36 and 51  
Associated finding Nos. 34, 47 and 49 |
| 6. To take all appropriate measures to confirm or rule out the presence of CSF in wild boar when the disease is suspected in accordance with the requirements laid down in Article 15 of Directive 2001/89/EC (taking into account the recommendations of the CSF diagnostic manual: point B (3) and (7) of Chapter VII of Annex to Decision 2002/106/EC).  
Recommendation based on conclusions No. 50 and 59  
Associated finding Nos. 47, 49 and 57 |
| 7. To ensure that all laboratories analysing samples for the CSF surveillance programme have adequate resources for reliable testing of official samples for CSF virus and antigen as indicated in EU co-financed veterinary programmes approved by the Commission for 2015, 2016 and 2017.  
Recommendation based on conclusion No. 59  
Associated finding Nos. 57 and 58 |
| 8. To ensure that live pigs dispatched to other Member States with the appropriate Intra-Union trade certificate fulfil the requirements laid down in Article 2a of Decision 2013/764/EC.  
Recommendation based on conclusion No. 66  
Associated finding No. 64 |
| 9. To ensure that pig meat, meat preparations and meat products dispatched to other Member States with the appropriate Intra-Union trade certificate fulfil the |
requirements laid down in Article 4 of Decision 2013/764/EC.
Recommendation based on conclusion No. 66
Associated finding Nos. 62 and 63

The competent authority's response to the recommendations can be found at:
## ANNEX I – LEGAL REFERENCES

<table>
<thead>
<tr>
<th>Legal Reference</th>
<th>Official Journal</th>
<th>Title</th>
</tr>
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