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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
HUNGARY
FROM 04 SEPTEMBER 2017 TO 08 SEPTEMBER 2017
IN ORDER TO
EVALUATE THE IMPLEMENTATION OF THE PROGRAMME FOR THE
SURVEILLANCE AND EMERGENCY PREPAREDNESS IN RELATION TO AFRICAN
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 Hungary, carried out from 4 to 8 September 2017, as part of the published Directorate-General for Health and Food Safety audit programme.

The objectives of the audit were to evaluate whether:

- the programme for surveillance of African swine fever for the years 2015, 2016 and to the date of the audit in 2017 in domestic pigs and wild boars in Hungary has been implemented effectively to achieve the objective of early detection of the disease;*
- the measures in place to prevent the disease from spreading into the domestic pig population, if it appears in wild boars, are effective;*
- emergency preparedness in the event of an outbreak of African swine fever in domestic pigs and cases of African swine fever in wild boar is effective.*

Overall, the report concludes that legal measures aimed at the gradual reduction of the wild boar population have been recently issued at national level and reinforced in the High Risk Area.

The competent authority has raised the awareness of African swine fever with veterinarians, hunters, pig owners and local municipalities for its prevention and early detection.

The competent authority did not carry out official controls of hunting grounds to date in the High Risk Area, in order to verify the correct implementation of specific preventive biosecurity measures that have entered into force since the beginning of this year. In addition, driven hunts using dogs and movements of carcasses within this area before test results are available are still allowed, therefore increasing the risk of uncontrolled spread of disease, in the event of a positive case in wild boar.

The likelihood of the introduction of the disease and spread of infection in domestic pig population is being reduced due to adequate biosecurity measures in place and regular inspection of domestic pig holdings.

Despite a slight improvement in the African swine fever passive surveillance in wild boars in 2017, the current passive surveillance in wild boars across the whole territory of Hungary, combined with weaknesses in passive surveillance in the domestic pig population, does not provide confidence that African swine fever would be detected at an early stage following its introduction.

The reserved rendering capacity should allow Hungary to cope with depopulation in an outbreak situation. However, the need to perform a more time consuming census of pigs combined with the lack of supervision of county contingency plans by the central authorities may delay containment of disease in an outbreak scenario.

While generic supervisory procedures are in place, regular cross-checks of data to verify the correct implementation of the surveillance programme are not carried out.

The report contains recommendations aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.

Table of Contents

1	Introduction.....	1
2	Objectives and scope.....	1
3	Legal basis.....	2
4	Background.....	3
5	Findings and conclusions.....	4
5.1	Preventive measures.....	4
5.1.1	Wild boar management and biosecurity.....	4
5.1.2	Biosecurity measures applied on pig holdings.....	8
5.2	Early detection.....	10
5.2.1	Training and awareness programmes.....	11
5.2.2	Surveillance in wild boar.....	11
5.2.3	Surveillance in pig holdings.....	14
5.2.4	Laboratory testing.....	15
5.3	Emergency preparedness for ASF.....	16
5.3.1	National plan and operations manual.....	16
5.3.2	Simulation exercises.....	17
5.4	Verification, supervision and expert group.....	17
5.4.1	Supervision by line management.....	18
5.4.2	Internal audits.....	18
5.4.3	Evaluation(s) by the expert group.....	18
6	Overall conclusions.....	20
7	Closing meeting.....	20
8	Recommendations.....	20

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AHAW	Animal Health and Animal Welfare
ASF	African swine fever
CA	Competent authority
CGO	County Government Office
CVET	Community Veterinary Emergency Team
CVO	Chief Veterinary Officer
DGO	District Government Office
ELISA	Enzyme-linked immunosorbent assay
EU	European Union
EURL	European Union Reference Laboratory
HRA	High Risk Area
IPT	Immuno-peroxidase test
LDCC	Local disease control centre
LRA	Low Risk Area
MA	Ministry of Agriculture
MRA	Medium Risk Area
NDCC	National disease control centre
NFCSO	National Food Chain Safety Office
NRL	National Reference Laboratory
PCR	Polymerase chain reaction
PVP	Private Veterinary Practitioner
SOP	Standard operating procedure
SV	Supervision ~ Visit

1 INTRODUCTION

This audit took place in Hungary from from 4 to 8 September 2017 as part of the DG Health and Food Safety audit programme. The audit team comprised two auditors from the Commission services.

At the opening meeting on 4 September 2017 the team confirmed the objectives and scope of the audit as well as the itinerary.

The audit team was accompanied by representatives from the central competent authority (CCA) throughout the audit.

2 OBJECTIVES AND SCOPE

The objectives of the audit were to evaluate whether:

- The programme for surveillance of African swine fever (ASF) for the years 2015, 2016 and to the date of the audit in 2017 in domestic pigs and wild boars in Hungary has been implemented effectively to achieve the objectives of early detection of ASF;
- The measures in place to prevent the disease from spreading from wild boars into the domestic pig population and between pig holdings are effective;
- Emergency preparedness for an outbreak in domestic pigs and for cases in wild boar is effective.

The scope of the audit included:

- The surveillance programme for the years 2015, 2016 and to the date of the audit in 2017.
- Preventive measures and contingency planning (wild boar population management, biosecurity measures in hunting grounds, biosecurity measures on pig holdings, active and passive surveillance for ASF in domestic pigs and wild boars, ASF contingency plan and ASF operational manual);
- Competent authority processes (controls, supervision, verification and analyses of results, audits, use of expert groups, cooperation between authorities involved, coordination between Member States and neighbouring non-EU countries);
- Infrastructure (ASF laboratories, information technology systems for animal health management, pig traceability).

The audit team met/visited the following:

Site visited/Authority met	Number	Comments
Central Competent Authority	2	Opening and closing meetings
County Government Office	1	Local Disease Control Centre located in the MRA
Pig holding	4	One commercial holding, three non-commercial farms located in the HRA
Hunting ground	1	Including one meeting with hunting association located in the HRA
Low capacity slaughterhouse	1	
Game collection centre	1	Collecting wild game from different hunting grounds located in the HRA
Laboratory	1	NRL for ASF

3 LEGAL BASIS

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

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;
- Article 20 of Council Directive 2002/60/EC laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever.
- Article 37 of Regulation of the European Parliament and of the Council (EU) No 2014/652 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.

Other relevant legislation for this audit is mentioned in the Annex to this report.

4 BACKGROUND

Since January 2014, ASF has spread in Estonia, Latvia, Lithuania and Poland. In response to this development, the Commission audited these Member States.

In 2015, the Commission developed an ASF strategy¹ for the affected Member States and for those with a higher risk of introduction of the disease. This strategy aims to prevent further spread of the disease and eventually lead to its eradication from the affected territories. The strategy was developed and updated taking into account the latest opinions from the European Food Safety Authority. To support this strategy, Member States at risk of introduction of ASF have been invited to develop surveillance and control programmes, co-funded by the Commission.

Hungary is considered to have a high risk of introduction of ASF from the bordering non-EU country, Ukraine. Since 2015, a programme for surveillance of ASF in Hungary has been approved and subject to financial support from the European Commission. Grant Decision SANTE/VP/2015/HU/SI2.700811 approves the programme for 2015, Grant Decision SANTE/2016/HU/SI2.726013 for 2016 and Grant Decision SANTE/VP/2017/HU/SI2.749861 for 2017.

This was the third audit, to a non-affected Member State, to evaluate preventive measures, the implementation of surveillance for early detection of ASF and emergency preparedness arrangements for dealing with cases/outbreaks of the disease.

Currently, Hungary is divided into three areas for ASF surveillance purposes:

- A High Risk Area (HRA), 10 km wide along the Eastern border of Hungary with Ukraine, was established after the Ukrainian outbreak of December 2016. The HRA has been further extended following the Romanian outbreak of July 2017. The current HRA delineation has not been substantiated by a specific risk assessment as requested by the Community Veterinary Emergency Team (CVET) in June 2016.
- A Medium Risk Area (MRA) consisting of three counties in the north-eastern part of Hungary, excluding the HRA, where an enhanced active surveillance is implemented. Prior to establishment of HRA, this was considered as the high risk area (2014 – 2016).
- A Low Risk Area (LRA), consisting of the rest of the country.

In December 2016, the Ukrainian authorities reported an ASF outbreak located 18 km from the Hungarian border. Subsequently, based on the recommendations of the ASF expert group the CA imposed specific measures for 6 hunting grounds and 30 settlements along the Ukrainian border, so called HRA. (Internal instruction of the Chief Veterinary Officer (CVO) No ÉFHÁT/114-2/2016).

In January 2017, the HRA was extended and totally encompassed 22 hunting grounds and 56 settlements along the Ukrainian border. The specific measures applied in the HRA were

¹ SANTE/7113/2015 – Rev 7 ASF Strategy for Eastern Part of the EU

published in the Official Journal of the MA - Decision No 2/2017 of the CVO (hereinafter "CVO Decision").

In March 2017 the CVO Decision was supplemented with an implementing guideline (State Secretary instruction No ÉFHÁT/1-20/2017) and in April 2017, the CVO ordered additional measures for the HRA (Internal instruction of the CVO No ÉFHÁT/1-21/2017).

At the end of July 2017, an ASF outbreak was reported by the Romanian authorities ~15 km away from the Hungarian border with Romania. Consequently, the HRA has been extended to include a further 19 hunting grounds and 30 settlements along the Hungarian border with Romania².

5 FINDINGS AND CONCLUSIONS

5.1 PREVENTIVE MEASURES

5.1.1 Wild boar management and biosecurity

Legal requirements

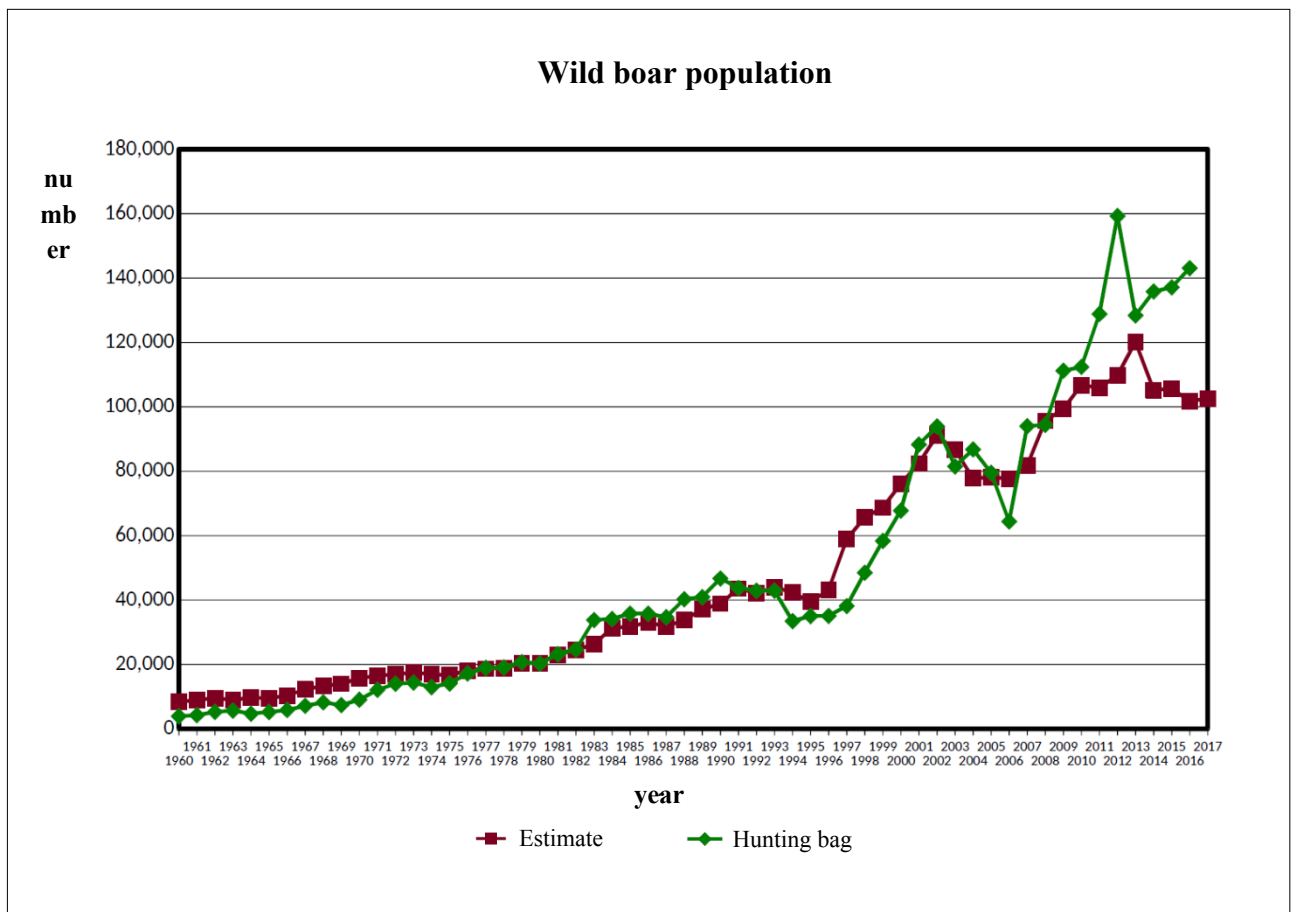
Articles 15 of Directive 2002/60/EC; the approved national programme (based on ASF strategy for Eastern Part of the EU (SANTE/7113/2015-Rev 7).

Findings

1. The Ministry of Agriculture (MA) is responsible for the drafting of relevant legislation and the management of hunting activities. The main national legislation for hunting is Act LV of 1996 and implementing Decree No 79/2004 of 29 May 2004. In addition, the MA operates a national database used for planning, controlling and supervising game management activities in conformity with the Hunting Act.
2. At county level, the hunting authority is responsible, inter alia, for the approval of hunting quotas for wild game and mapping of hunting grounds. Hunting ground managers draw up their annual hunting plans (based on the spring census and desired density of population of wild game) and submit those to the county hunting authority for approval by 15 February of each year. The Hunting Act empowers the hunting authority to modify the proposed hunting plan (e.g. increased hunting of female stock or in general increase the proposed hunting quota) in its decision approving the plan. Compliance with the plan is checked on an ongoing basis by the county hunting authority.
3. Currently, there are 1,445 hunting grounds in Hungary, covering 87,270 km². These hunting grounds are distributed between 52 hunting regions, each of them managed by a regional chief hunter. Regional chief hunters serve as hunters' advisors and provide information/training for hunters including information on preventive measures related to ASF.

² After the audit, following an internal instruction of the CVO No ÉFHÁT/70/2017 issued on 28 September 2017, the HRA has been extended to a zone (20-25 km wide) along the Ukrainian border and (10 km wide) along the Romanian border, which includes 59 hunting grounds and 162 settlements in total.

4. Approximately 12 to 15% of hunting grounds are state owned. The rest of the hunting grounds are run by private hunting ground managers. One hunting manager can be responsible for more than one hunting ground. There is an obligation to employ at least one professional hunter per hunting ground. Hunting is performed by professional and licensed ("non-professional) hunters. Hunting tourism is largely practiced for economic reasons.
5. In February 2017, according to data provided by the CA:
 - In the whole territory of Hungary, the total number of wild boars was estimated at 98,068 including 20,999 boars, 25,865 sows and 51,204 young adult females.
 - In the county where the HRA is located (hereinafter "the County"), the total number of wild boars was estimated at 4,165 including 883 boars, 1,078 sows and 2,204 young adult females.
 - In the HRA (22 hunting grounds), the total number of wild boars was estimated at 1,920 including 405 boars, 500 sows and 1,015 young adult females.
6. There had been a significant increase in the wild boar population over the last 20 years. However, the trend provided by the CA shows a slight decrease in the wild boar population during the last three years.



7. The table below shows spring census data on wild boar population for 2014, 2015, 2016 and 2017 in Hungary as provided by the CA.

	February 2014				February 2015			
	Boar	Sow	Young adult female	Total	Boar	Sow	Young adult female	Total
Whole country	22,461	28,726	52,028	105,215	23,896	28,300	53,458	105,654
MRA: 3 counties	-	-	-	-	3,868	4,416	8,552	16,836
The County visited	1,306	1,348	2,487	5,141	1,120	1,257	2,390	4,767

	February 2016				February 2017			
	Boar	Sow	Young adult female	Total	Boar	Sow	Young adult female	Total
Whole country	22,614	27,265	51,803	101,682	20,999	25,865	51,204	98,068
MRA: 3 counties	3,697	4,299	8,386	16,382	-	-	-	-
The County visited	1,056	1,197	2,360	4,613	883	1,078	2,204	4,165
HRA: 22 Hunting Grounds	-	-	-	-	405	500	1015	1,920

8. Following the estimate of the wild boar population which is carried out every year in February (spring census), a wild boar density (number of wild boar per km²) is set for each county by the MA. Wild boar densities are calculated on the area of suitable biotope for wild boar (forest and agricultural land) within the county. The average density per county is 1.2/km², range interval between 0.23/ km² up to 2.54/ km². The wild boar density in the County is estimated (February 2017) at 0.76 wild boars/km².
9. The hunting season for wild boar runs from 1 March through to 28 February of the following year. Wild boar hunting is carried out from hunting towers all year long. Driven hunts are regularly carried out during autumn-winter when 70-80% of the whole hunting bag is achieved (from November to January). In the HRA, the hunting authority confirmed that driven hunts using dogs are still used.
10. The CA adopted several activities/measures aimed at non-disruptive and gradual reduction of the wild boar population, in particular in the HRA. The team noted that:
- The implementing Decree has been recently amended in order to take account of measures aimed at reducing the big game population size, and in particular wild boars:

- under Section 30(2), the quota of female large game species, including wild boar, may be exceeded without special permission from the hunting authority;
 - Section 69(2) allows the hunting authority to authorise the night-time hunting, of wild boar where warranted on animal health grounds;
 - under Annex 5/I, there is no hunting season anymore for wild boar, so they qualify as a species that may be hunted all year round without any restriction on species or sex;
- In the County visited, the hunting authority confirmed that the current hunting quotas were set up using a coefficient of 1.20 to 1.30 to the estimated wild boar population (spring census), in an attempt to decrease it.
 - In the HRA, official measures for controlling the wild boar population were issued in the CVO Decision in line with the ASF strategy for the Eastern Part of the EU (hereinafter "ASF strategy"), e.g. sustained feeding prohibited, only baiting allowed (10 kg/km²/month), targeted hunting of female wild boar, etc.
11. In the County visited the regional chief hunter instructed hunting grounds located in the HRA to perform targeted hunting of adult and sub-adult wild boar females. His note highlighted the fact that this measure was the best method to reduce wild boar population and to prevent propagation of the disease. However, the team noted that currently there is no incentive for selective hunting of female wild boar.
12. Regarding biosecurity in the HRA, specific measures were imposed by the CVO Decision in line with the ASF strategy, e.g. burial of all found dead wild boar on site (a fee of 50 Euro is available for this task), the safe disposal of offal (to be buried on the spot or collected), etc. In addition, wild boar carcasses (or any part of them) must not be used or sold until laboratory results are obtained. However, the team noted that:
- In one hunting ground visited located in the HRA, wild boar carcasses were allowed to be taken home by hunters, at least two of whom kept domestic pigs, before test results are available. The CA confirmed that there were no dedicated dressing facilities and only one refrigerator among the 22 hunting grounds located in the HRA.
 - In one game collection centre located in the HRA, wild boar carcasses from five different hunting grounds in the HRA were stored pending laboratory results after transport at a distance up to 25 km. Therefore, these carcasses did not remain in the premises of the hunting ground until tested as required by the ASF strategy.
13. In the County visited, the CVO Decision and related instructions have been relayed and communicated to the relevant District Government offices (DGO) and hunting grounds for implementation. However, the CA confirmed that they had not yet verified the correct implementation of these measures in the HRA. This does not take into account the objective of the ASF strategy.

5.1.2 Biosecurity measures applied on pig holdings

Legal requirements

Articles 15 of Directive 2002/60/EC; the approved national programmes for surveillance of ASF in Hungary for 2015 - 2017.

Findings

14. According to the national legislation, there are two types of pig holdings: small scale holdings and large scale holdings, where the number of animals is at least 100 pigs.
15. Following the CVO Decision, a new classification of pig holdings, in line with the current ASF strategy for the eastern part of the EU, has been implemented across the whole territory of Hungary:
 - Large scale commercial holding: large farm (>100 pigs), which sell pigs, send pigs to a slaughterhouse or move pig products off the holding;
 - Small scale commercial holding: small farm (<100 pigs), which sell pigs, send pigs to a slaughterhouse or move pig products off the holding;
 - Small scale non-commercial holdings: small farms where pigs are kept only for fattening for own consumption and neither pigs nor any of their products leave the holding;
 - Outdoor holdings: where pigs are kept temporarily or permanently outdoor.
16. The CA explained to the team how the census of pig holdings took place when the HRA was first established following the Ukrainian outbreak of December 2016. During the exercise, all the pig farms located in the HRA were visited by either an official veterinarian from the DGO or a Private Veterinary Practitioner (PVP). In parallel to the census, an assessment was made of biosecurity measures in each holding, using a checklist. Additionally, leaflets were distributed to pig keepers informing them about the characteristics of ASF and their own responsibilities, including preventive biosecurity measures to be taken in their holdings. The census was carried out over two months in 56 settlements.

Number of pig farms in the whole country / HRA

Category	Number of pig farms in the whole country	Number of pig farms in HRA
Large scale, commercial	870	2
Small scale, commercial	6,691	17
Small scale, non-commercial	30,299	667

17. In the whole country, a census of holdings where animals are permanently or temporarily kept in an open-air area was also carried out. Owners of such holdings were obliged to prevent the possibility of any contact with wild boars.

Number of outdoor pig farms in the whole country / HRA

Category	Number of outdoor pig farms in whole country	Number of outdoor pig farms in HRA
large scale, commercial	35	0
small scale, commercial	62	0
small scale, non-commercial	23	0

18. The main biosecurity requirements for pig holdings are laid down in the national legislation (Decree No. 41/1997. of the MA), e.g. fences around large scale farm, disinfection at entry points, control of movements of vehicles and people, prevention of direct or indirect contact with other pigs or wild boars, etc.
19. In the HRA, specific measures in line with the current ASF strategy have been issued in the CVO Decision: e.g. ban of outdoor pig keeping; disposal of dead pigs in a rendering plant; controls over feeding fresh grass or grains to pigs or using straw for bedding of pigs, etc.
20. Pig holdings are regularly inspected on the basis of an annual risk based monitoring programme. The programme takes into account the evaluation of the risk at local level: e.g. for 2017, the inspection of 200 holdings has been allocated to the county where the HRA is established, of which 100 are pig holdings.
21. The team visited one large scale commercial holding and three small scale non-commercial holdings and noted in general that biosecurity was adequate. The large scale commercial holding was inspected in the framework of the 2017 monitoring programme, using a checklist. The scope of inspection was quite broad and included, inter alia, checks on biosecurity and health status of pigs. Reporting and follow-up procedures were adequately implemented.

Conclusions on preventive measures

22. Legal measures aimed at the gradual reduction of the wild boar population have been recently issued and implemented, resulting in a slight decrease in the number of wild boars. More targeted measures have been introduced in the High Risk Area to further decrease the wild boar population.
23. In the High Risk Area, although specific preventive (biosecurity) measures in line with the current ASF strategy for the eastern part of the EU have entered into force by the end of January 2017, the Competent Authority did not carry out official controls of hunting grounds to date, in order to verify their correct implementation. Certain activities e.g.

driven hunts using dogs and movements of carcasses within this area before test results are available are still allowed, therefore increasing the risk of the uncontrolled spread of disease, in the event of a positive case in wild boar.

24. The national legislation contains the main biosecurity requirements for pig holdings and these have been further strengthened in the high risk area. Pig holdings are regularly inspected on the basis of an annual risk based monitoring programme. Therefore, the likelihood of introduction of the disease and spread of infection in domestic pig farms is being gradually reduced.

5.2 EARLY DETECTION

Legal requirements

Articles 4, 14, 15, and 18 of Directive 2002/60/EC, Commission Decision 2003/422/EC; Articles 4 to 10 and 12 of Regulation (EC) No 882/2004; the approved national programme (based on ASF strategy for Eastern Part of the EU (SANTE/7113/2015-Rev 4³)

Findings

5.2.1 Training and awareness programmes

25. The CA has taken measures to increase stakeholders awareness to ASF including:
- Leaflets were widely distributed to pig keepers informing them about the characteristics of ASF and their own responsibilities, including preventive biosecurity measures to be taken in their holdings. Pig keepers are also regularly informed by official veterinarians and PVP, via professional organisations, national or local media, etc.
 - Raising awareness of hunters has been constantly organised through different channels: e.g. hunters' representatives (national/county Hunting Chamber, national association of game management), wild life experts, officials (chief regional hunter, hunter authority, etc.), various trainings and conferences organised at national or local level, hunting magazines, TV, etc.
 - Copies of leaflets, training presentations, magazine articles and attendance records were provided to the team during the audit.
 - Information on ASF is also available on the National Food Chain Safety Office (NFCSO) website.
26. CA staff participated in regular ASF trainings. In addition, some of them participated in international meetings on ASF.

³ Current version is SANTE/7113/2015-Rev 7 (as of 08/06/17)

5.2.2 *Surveillance in wild boar*

27. In 2015 and 2016, although the surveillance programme covered the whole territory of Hungary, three eastern counties (see map below) were considered as a higher risk area for the introduction of ASF, mainly due to their proximity with Ukraine. In this area, the national programmes for the control and surveillance of ASF required a more intensive surveillance programme compared to the rest of the country.

Hungary map: 19 counties; 3 counties at higher risk due to proximity of Ukraine



28. As already mentioned, Hungary is divided into three areas (HRA, MRA and LRA) for ASF surveillance purposes. The CA acknowledged that the current HRA delineation has not been substantiated by a specific risk assessment as requested by the CVET in June 2016.
29. The 2015, 2016 and 2017 surveillance programmes, which have been approved by the Commission services, include both passive and active surveillance. The 2017 surveillance programme has been updated in November 2016 to take into account the recommendations of the CVET team.

Passive surveillance

30. The current programme for the control and surveillance of ASF requires sampling and laboratory analysis of all wild boars from the entire territory of Hungary found dead or shot because of abnormal behaviour. Samples are analysed by polymerase chain reaction (PCR) and for confirmation of positive or doubtful results virus isolation (haemadsorption test) is used.
31. Across the territory of Hungary, the CA incentivises reporting of wild boar found dead – 50 Euro paid for each wild boar found dead – and the sampling carried out by qualified samplers – 33 Euro paid for this activity.
32. Additionally, to strengthen passive surveillance in the HRA, specific measures have been included in the CVO Decision:
 - An obligatory organised and systematic search for dead wild boar in each hunting ground.
 - The requirement for a written report of every found dead wild boar within 24 hours of finding.

- The obligation for veterinarians appointed by the CA/other qualified persons for the sampling of all reported found dead wild boar.
33. In a hunting ground visited, the team noted that searches for dead wild boars had taken place and were on-going. Moreover, samples were taken by qualified samplers.
 34. In order to provide a meaningful passive surveillance and early detection of ASF, the minimum number of found dead wild boar sampled in a given area should be about 1% of the wild boar population at risk. Therefore, the minimum number of wild boars sampled in the MRA throughout 2015/2016 and 2016/ 2017 hunting seasons should have been around 165, based on an estimated wild boar population of respectively 16,836 and 16,382 animals in 2015 and 2016. The number of wild boar sampled for ASF falls short of the target, as a total of 33 and 64 found dead wild boars were respectively sampled in 2015 and 2016 across the entire territory of Hungary.
 35. For the first six months of the 2017/2018 hunting season (to 31 August 2017) the number of tested found dead wild boars still remains low as only 72 wild boars have been tested for ASF in the whole country, of which were 13 wild boars in the HRA.
 36. For the 2015/2016 and 2016/2017 hunting seasons, the team noted that a large number of found dead wild boars were reported (respectively 2,432 and 2,036) to the hunting authority at the end of each hunting season with only a small number of them being tested for ASF (see Point 34 above). The CA didn't perform any check to assess correlation between these data and the number of tests results. These findings (34, 35 and 36) do not fulfil the objectives of early detection of ASF as outlined in the ASF strategy.

Active surveillance

37. The strategy of active surveillance is based on theoretical sampling units, each one consisting of 700 wild boars. In practice, the entire wild boar population of a county is divided by 700 to obtain the number of sampling units. For each sampling unit a certain number of samples have to be collected and tested for ASF antigen and ASF antibodies. For the three counties of the MRA, a higher number of samples are requested to reach a detection limit of one positive wild boar if prevalence is 5% with a 95% confidence limit. For the counties of the LRA, a lower number of samples are requested to reach a detection limit of one positive wild boar if prevalence is 10% with 95% confidence.
38. With regard to 2015/2016 and 2016/2017 hunting seasons, respectively 8546 and 8949 PCR tests together with 8082 and 8877 ELISA tests were performed on wild boar samples, achieving the estimated targets in both years.
39. In the HRA, according to the CVO Decision, all shot wild boars have to be sampled and tested (PCR on clotted blood samples) for ASF. In addition, wild boar carcasses (or any part of it) must not be used or sold until laboratory results are available.

5.2.3 *Surveillance in pig holdings*

40. The CA carries out passive surveillance for ASF in the domestic pig population. Measures are in place nationally, requiring reporting of suspicions of ASF, including domestic pigs found dead following transit from another MS. The CA also called for an increased number of samples of domestic pigs dead for other reasons to be sent to the laboratory from the whole territory of Hungary.
41. Additional measures have been issued in the CVO Decision:
 - For the whole territory of Hungary
 - Pig owners must report to the PVP any suspicion of ASF as well as dead or sick pigs (even if they don't suspect ASF) within 24 hours after observing.
 - When the PVP cannot exclude the suspicion of ASF, he must report the suspicion of the disease to the District, which carries out investigations, and in the case of a confirmed suspicion orders official movement restrictions for the holding and starts taking samples for laboratory testing.
 - If the examination of the dead pigs does not suggest a suspicion of ASF, samples for ASF testing should also be taken when: pigs died suddenly without clinical signs; or pigs had fever > 40°C after 3 days treatment; or pigs had fever > 40°C and died during the treatment.
 - In large scale holdings, pig owners and the PVP should report to the District any case of increased mortality > 20% in piglets, > 10% in weaners and > 5% in fattening or breeding pigs.
 - Additionally in the HRA:
 - All dead domestic pigs from all holdings (small or large scale) should be sampled and tested to exclude ASF, irrespective of the estimated cause of death
 - Sampling of all reported dead domestic pigs has to be carried out by a PVP appointed by the CGO. 12 Euro is paid to the PVP for this activity.
 - All dead domestic pigs should be disposed in a rendering plant (measure to be organised by the CGO and to be implemented by the pig owner).
42. In the county visited, the team noted that two ASF suspicions were recorded. Appropriate measures including movement restrictions, sampling and laboratory testing and lifting of movement restrictions were implemented and enforced by the CA in line with EU requirements.
43. The team noted that, from January to July 2017, in the HRA only 17 PCR tests were completed on dead domestic pigs. This is very low number compared to the estimated number of dead pigs in the HRA during the same period of time, e.g. in one large scale holding located in the HRA and visited by the team, more than 30 dead pigs were recorded in the herd register for the previous four week period which were not sampled for ASF. The CA informed the team during the final meeting that this requirement would normally apply to small scale holdings; consequently, the CVO Decision, as regards

passive surveillance in large scale holdings would be amended accordingly. This does not fulfil the objective of early detection of ASF as outlined in the ASF strategy.

5.2.4 Laboratory testing

44. Currently, all ASF testing is carried out at the National Reference Laboratory (NRL) in Budapest.
45. For the 2017 EU co-financed programme, subsequent to recommendations of the CVET team, tonsils are no longer sampled from hunted wild boars: PCR testing is carried out only from clotted blood samples⁴. In addition, based on the experience of infected countries, serology (antibody ELISA) will not be performed as long as there are no changes in the epidemiological situation.
46. The team noted the following:
 - EURL ASF inter-laboratory tests for 2015, 2016 and 2017 found assay systems for detecting antibodies to ASF and ASF virus in field samples performed in the NRL Budapest to be fit for purpose.
 - Recent turnaround time for ASF active surveillance in wild boar was very short with rapid reporting of results; in contrast, several recent results for passive surveillance in wild boars were seen to take 12+ days to report. The laboratory explained to the team that such turnaround time was due to additional testing for other diseases, and in the case of a positive result, the information would have been immediately forwarded to the CA. The laboratory confirmed to the team that this discrepancy will be immediately corrected.
 - For one inconclusive ASF test result, the laboratory had carried out an additional three conventional PCR tests and one virus isolation test, all with negative results;
 - The NRL has organised a daily courier service exclusively for ASF samples operating seven days a week.

Conclusions on early detection

47. The competent authority has raised the awareness of ASF with veterinarians, hunters, pig owners and local municipalities for prevention and early detection.
48. Since the beginning of 2017, there has been a slight improvement in the ASF passive surveillance in wild boars, especially in the High Risk Area. However, the current passive surveillance in wild boars across the whole territory of Hungary combined with weaknesses in passive surveillance in domestic pig population does not provide confidence that ASF would be detected at an early stage following ASF introduction.

⁴ In their comments to the draft report, the competent authority stated that: "the sampling of tonsils is not finished, but the virological testing from hunted wild boars for ASF is no longer performed from tonsils, but primarily from blood samples".

5.3 EMERGENCY PREPAREDNESS FOR ASF

Legal requirements

Articles 4, 5, 8, 21, 22, Annex VI of Dir. 2002/60, Dec. 2003/422, Dir.92/119

Findings

5.3.1 National plan and operations manual

49. The competent authority has a contingency plan for ASF (Version 1.1, 30 September 2013) as required by Article 21 of Directive 2002/60/EC and an instruction manual for ASF as required by Annex VI(e) of Directive 2002/60/EC. CA confirmed these documents were last updated in February 2014.
50. Each CGO is responsible for preparing and implementing a contingency plan at county level based on the national plan. The CA confirmed that they had no capacity to check implementation of contingency plans at county level. In one CGO visited by the audit team, a local ASF contingency plan was available. The plan contained e.g. named persons available to perform duties but certain practical aspects were missing e.g. link to a guide for stunning and killing animals and an indication of killing rates.
51. There are two main rendering plants in Hungary (state owned) - CA confirmed they can instruct these establishments to accept carcasses in the event of a disease outbreak requiring depopulation. The CA provided data to demonstrate that the two establishments have reserve capacity to deal with emergency situations and further capacity could be created by suspending movement of animal by-products from other member states.
52. Competent authorities confirmed that the national database for animals does not contain a record of geographic co-ordinates for registered pig holdings as required by Article 1 (1) (d) to Commission Decision 2000/678/EC.
53. Furthermore, the database does not have a field where the competent authority could enter sanitary information (e.g. restrictions on movements) which is not in line with Article 1(e) to Commission Decision 2000/678/EC. Consequently, the database cannot be used for implementation and verification of ASF movement restrictions. The CA indicated that work was underway to update the database with a completion date of 2019 which should address the shortcomings noted.
54. Breeding pigs are identified with a transponder and an ear tag bearing a unique identification number. Production pigs are identified with either a single ear tag with a unique identification number or a slap mark with holding number (holdings with more than 100 pigs).
55. Under national rules, movement of pigs between registered keepers must be accompanied by a health attestation issued by a private veterinarian and a movement document. All

movements must be notified to the national database for animals within 7 days of the event. This goes beyond EU requirements.

56. All holdings visited had an up-to-date record of movements (number of animals concerned by each entering and leaving operation) stating their origin or destination and the date of such movements as required by Article 4(1) of Directive 2008/71/EC. This should allow tracing of batches of animals in an outbreak situation.
57. In one large pig holding visited, pigs moved (up to 30km) between 4 holdings in same ownership without being identified. This practice, allowed by the CA does not comply with the provision laid down in Article 5(2) of Directive 2008/71/EC.
58. The establishment of protection zone and surveillance zone requires liaison between County and Central veterinary authorities. If an outbreak is confirmed, the CA run a Geographical Information System query, using location provided by County, to determine which municipalities are in the respective zones. It is then up to the DGO to establish manually which holdings are included in these zones. The CA confirmed this exercise may take several days. The CA informed audit team that a project was currently underway to link the animal health database with GIS and this project was due to complete by 2019.

5.3.2 *Simulation exercises*

59. The most recent ASF simulation exercise was held in 2015 in one county. At the time of the audit, the CCA was unsighted on the outcome of the exercise.

Conclusions on emergency preparedness

60. The reserved rendering capacity should allow Hungary to cope with depopulation in an outbreak situation. However, in the event of confirmation of ASF, due to limitations of the database performing a census of pigs will be more time consuming and demand increased resources to localise holdings in restricted areas. In addition, there is no verification of the availability of adequate county contingency plans by the CCA. This may delay containment of disease in an outbreak scenario.

5.4 VERIFICATION, SUPERVISION AND EXPERT GROUP

Legal requirements

Articles 4 and 8 of Regulation No 882/2004; Directive 2002/60/EC (Articles 15, 16 and 22, Annex VI)

Findings

5.4.1 Supervision by line management

61. Within the NFCSO, the Department of Epidemiology under the Animal Health and Animal Welfare (AHAW) Directorate, supervises at central level the correct implementation of the ASF surveillance programme and prepares all reports for the Commission services. At county level, the CGO is responsible for organising and controlling the monitoring activities that are performed at district level. In addition, the Veterinary Diagnostic Directorate regularly informs the AHAW Directorate about the state of play of ASF analyses/tests performed.
62. From 1 January 2016, technical audits carried out by the sectorial directorates of NFCSO are organised and supervised by the Office of the Prime Minister. Compliance with vertical EU legislation across different CAs (central, regional and local level) and sectors are verified during these audits. The Prime Minister's Office issues an annual control plan for the CGO as laid down in Government Decree No 66/2015.
63. In the County visited, the team noted that regular cross-checks of information to verify the correct implementation of the surveillance programme are not carried out: e.g. correlation between the number of wild boars found dead (passive surveillance) notified to the hunting authority and the number of PCR tests performed by the laboratory; correlation between the number of dead domestic pigs in HRA and the number of tests performed; correlation between the number of hunted wild boars (active surveillance) in the HRA and the number of PCR tests performed, etc.

5.4.2 Internal audits

64. Within the NFCSO, the Supervision Unit (SU) within the System Management and Supervision Directorate is responsible for internal audits in accordance with the requirements laid down in Regulation (EC) No 882/2004. The SU has been operating under EN ISO 9001:2008 since 2013. The transition towards ISO 9001:2015 is ongoing. The scope of the quality management system is “the audit of food chain control authorities and other bodies, and the agricultural administration bodies”. The SU comprises a head of unit and five auditors with university degrees, who have undergone specific training in public administration. According to the Quality Manual, an audit programme is drafted every year and issued after approval of the president of NFCSO. Compliance with requirements laid down in Regulation (EC) No 882/2004 and verification of the effective implementation and suitability of planned arrangements across different CA (central, regional and local level) and sectors are verified during these internal audits.
65. Regarding ASF, the CA informed the team that no internal audit has yet taken place.

5.4.3 Evaluation(s) by the expert group

66. The composition, structure and competencies of the ASF Expert Group are described in the national ASF contingency plan. This Group has historically provided advice on ASF.

67. The ASF Expert Group held a meeting on 28 September 2016 to propose a road map to the CA. The following issues were discussed and addressed:
- ASF awareness programme for veterinarians, hunters and pig owners, e.g. a guideline for veterinarians in case of suspicion of ASF, information sheets on ASF for pig owners, etc.
 - Incentives to strengthen passive surveillance in wild boars: e.g. incentives for finding and sampling of dead wild boar, burial of found dead wild boar, etc.
 - Biosecurity measures in line with certain provisions mentioned in the ASF strategy for the eastern part of the EU were approved, e.g. targeted hunting of adult and sub-adult females, ban of sustained feeding, baiting, requirements for outdoor farms, etc.
 - Surveillance in the wild boar population: e.g. active surveillance in wild boars to be maintained as long as the number of wild boars tested in the frame of passive surveillance will reach approximately 1% of the estimated wild boar population, PCR tests from clotted blood samples instead of tonsils, serological testing (antibody ELISA) of wild boar samples not performed anymore, etc.
 - Surveillance in domestic pig population: e.g. incentive for sampling domestic pig, sampling and testing of all dead domestic pigs in the "Specific Risk Area", etc.
68. Following the Ukrainian outbreak of December 2016, most of the measures discussed during the Expert Group meeting were included in the CVO Decision. However, the Expert Group has not yet carried out checks to verify the effectiveness of the measures adopted for the prevention and early detection of the disease in HRA.

Conclusions on verification, supervision and expert group

69. Although generic supervision procedures are in place at different levels, regular cross-checks of information to verify the correct implementation of the surveillance programme are not carried out. Regarding ASF, no internal audit has yet taken place.
70. Although an ASF Expert Group has been established and is operational, this Group has not yet carried out checks to verify the effectiveness of the measures adopted for the prevention and early detection of the disease in the High Risk Area.

6 OVERALL CONCLUSIONS

Legal measures aimed at the gradual reduction of the wild boar population have been recently issued at national level and reinforced in the High Risk Area.

The competent authority has raised the awareness of ASF with veterinarians, hunters, pig owners and local municipalities for prevention and early detection.

The Competent Authority did not carry out official controls of hunting grounds to date in the High Risk Area, in order to verify the correct implementation of specific preventive biosecurity measures that have entered into force since the beginning of this year. In addition, driven hunts using dogs and movements of carcasses within this area before test results are available are still allowed, therefore increasing the risk of an uncontrolled spread of disease, in the event of a positive case in wild boar.

The likelihood of introduction of the disease and spread of infection in domestic pig population is being reduced due to adequate biosecurity measures in place and regular inspection of domestic pig holdings.

Despite a slight improvement in the ASF passive surveillance in wild boars in 2017, the current passive surveillance in wild boars across the whole territory of Hungary combined with weaknesses in passive surveillance in domestic pig population does not provide confidence that ASF would be detected at an early stage following ASF introduction.

The reserved rendering capacity should allow Hungary to cope with depopulation in an outbreak situation. However, the need to perform a more time consuming census of pigs combined with the lack of supervision of county contingency plans by the CCA may delay containment of disease in an outbreak scenario.

While generic supervisory procedures are in place, regular cross-checks of data to verify the correct implementation of the surveillance programme are not carried out.

7 CLOSING MEETING

A closing meeting was held with the central competent authority on 8 September 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.

No.	Recommendation
1.	<p>To ensure that official controls are regularly carried out in hunting grounds located in the High Risk Area in order to verify the correct implementation of specific measures.</p> <p>SANTE/7113/2015-Rev 7 – ASF Strategy for Eastern Part of the EU.</p> <p>Recommendation based on conclusion No. 23</p> <p>Associated finding Nos. 13</p>
2.	<p>To ensure that hunted wild boar do not leave the hunting ground in High Risk Area before test results are available.</p> <p>SANTE/7113/2015-Rev 7 – ASF Strategy for Eastern Part of the EU.</p> <p>Recommendation based on conclusion No. 23</p> <p>Associated finding No. 12</p>
3.	<p>Practical arrangements should be put in place to increase the number of found dead wild boar samples across the whole territory of Hungary and in particular in the High Risk Area.</p> <p>SANTE/7113/2015-Rev 7 – ASF Strategy for Eastern Part of the EU.</p> <p>Recommendation based on conclusion No. 48</p> <p>Associated finding Nos. 34, 35 and 36</p>
4.	<p>Practical arrangements should be put in place to increase the number of dead domestic pigs sampled in particular in the High Risk Area.</p> <p>2017 EU co-financed veterinary programme.</p> <p>Recommendation based on conclusion No. 48</p> <p>Associated finding No. 43</p>
5.	<p>To ensure that the national database for animals contains all required information including the geographic co-ordinates of all registered pig holdings and a field where sanitary information can be recorded as required by Article 1 (1)(d) to Commission Decision 2000/678/EC.</p> <p>Recommendation based on conclusion No. 60</p> <p>Associated finding No. 52</p>
6.	<p>To ensure that domestic pigs are identified before leaving a holding making it possible to determine the holding from which they came, as required by Article 5(2) of Directive 2008/71/EC.</p>

	Recommendation based on conclusion No. 60 Associated finding No. 57
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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=2017-6115

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 882/2004 - Article 45 (MS)	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Dir. 64/432/EEC	OJ 121, 29.7.1964, p. 1977-2012	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine
Dir. 2008/71/EC	OJ L 213, 8.8.2008, p. 31-36	Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (Codified version)
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Dir. 2002/60/EC	OJ L 192, 20.7.2002, p. 27-46	Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever
Dir. 92/119/EEC	OJ L 62, 15.3.1993, p. 69-85	Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease

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
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption