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**FINAL REPORT OF AN AUDIT
CARRIED OUT IN
HUNGARY
FROM 08 SEPTEMBER 2015 TO 17 SEPTEMBER 2015
IN ORDER TO
EVALUATE THE IMPLEMENTATION OF CONTINGENCY PLANS IN RELATION TO
ANIMAL HEALTH, INCLUDING PROVISIONS ON THE PROTECTION OF ANIMALS
DURING DEPOPULATION FOR DISEASE CONTROL**

Executive Summary

This report describes the outcome of a Food and Veterinary Office audit in Hungary carried out between 8 and 17 September 2015 as part of the Food and Veterinary Office audit programme for 2015. The objective was to evaluate the competent authorities' preparedness to deal effectively with outbreaks of exotic animal diseases and to protect animals from unnecessary pain, suffering and distress during depopulation.

The report concludes that the current setting out of the animal health emergency preparedness system in Hungary can be considered mostly capable to manage the situation in the event of a geographically restricted disease outbreak. However, in the event of a large disease outbreak, its effective and swift containment may be undermined by:

- *The uncertain level of coordination that can be expected between the central competent authority and the counties.*
- *The limited availability and use of adequate expertise to evaluate the epidemiological situation and adapt the eradication measures accordingly.*
- *The insufficient anticipation and analysis of the factors that will play a major role in the event of a widespread disease outbreak, in particular with regard to FMD, which is of major importance in order to reach well-informed decisions on the most effective measures to apply in those exceptional circumstances.*
- *The less than adequate tools provided and the insufficient verification of emergency preparedness to ensure the early containment and eradication of the disease.*

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

Table of Contents

| | |
|--|----|
| 1. Introduction | 1 |
| 2. Objectives and scope | 1 |
| 3. Legal Basis | 2 |
| 4. Background | 2 |
| 5. Findings and Conclusions | 3 |
| 5.1 Policy for contingency planning..... | 3 |
| 5.1.1 <i>Preparation and updating of contingency plans</i> | 3 |
| 5.1.2 <i>Addressing of the main EU criteria and requirements for contingency plans</i> | 5 |
| 5.1.3 <i>Anticipation of large animal health crises - Worst-case scenario for FMD and emergency vaccination for AI</i> | 8 |
| 5.2 Readiness and operation of the animal health emergency preparedness system..... | 10 |
| 5.2.1 <i>Suspicion and confirmation of the diseases</i> | 10 |
| 5.2.1.1 <i>General arrangements</i> | 10 |
| 5.2.1.2 <i>Quality of the disease diagnostic system</i> | 11 |
| 5.2.2 <i>The chain of command – Tasks and responsibilities in the NDCC and the LDCC</i> | 11 |
| 5.2.2.1 <i>Establishment and operation of the NDCC / LDCC</i> | 11 |
| 5.2.2.2 <i>Access to data analysis and information management tools</i> | 12 |
| 5.2.2.3 <i>Communication strategy</i> | 14 |
| 5.2.3 <i>Technical and epidemiological expertise</i> | 14 |
| 5.2.3.1 <i>Availability of expert groups</i> | 14 |
| 5.2.3.2 <i>Epidemiological inquiries and surveys</i> | 15 |
| 5.2.4 <i>Availability of human resources and training of staff</i> | 16 |
| 5.2.4.1 <i>Personnel – availability and distribution of responsibilities</i> | 16 |
| 5.2.4.2 <i>Staff training</i> | 17 |
| 5.2.5 <i>Access to facilities, equipment and other materials</i> | 18 |
| 5.2.5.1 <i>General arrangements</i> | 18 |
| 5.2.5.2 <i>Diagnostic capabilities and capacity in case of emergency</i> | 19 |
| 5.2.6 <i>Organisation of real-time exercises and alarm drills</i> | 19 |
| 6. Overall Conclusions | 20 |
| 7. Closing Meeting | 21 |
| 8. Recommendations | 22 |
| Appendix – Specific legal requirements related to specific provisions and measures | 25 |

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

| Abbreviation | Explanation |
|---------------------|--|
| ABP | Animal by-products not for human consumption, as defined in Regulation (EC) No 1069/2009 |
| AHS | African horse sickness |
| ASF | African Swine Fever |
| BT | Bluetongue |
| CA | Competent Authority |
| CCA | Central Competent Authority |
| CSF | Classical swine fever |
| EU | European Union |
| FMD | Foot-and-mouth disease |
| FVO | Food and Veterinary Office |
| (HP)AI | (Highly pathogenic) avian influenza |
| MS | Member State |
| NRL | National reference laboratory |

1. INTRODUCTION

This audit took place in Hungary from 8 to 17 September 2015 and was undertaken as part of the Food and Veterinary Office (FVO) planned audit programme. The audit team comprised two auditors from the FVO.

The audit team was accompanied throughout the audit by representatives of the Central Competent Authority (CCA), the National Food Chain Safety Office Directorate, in particular by representatives of the Directorate for Animal Health and Animal Welfare.

In addition, during the visits at local level, the audit team was accompanied by representatives of the relevant competent authorities (CAs) of the counties, the Department of Food Chain Safety and Agriculture/Plant Protection and Soil Conservation of the County Government Offices (hereafter, county CAs).

2. OBJECTIVES AND SCOPE

The objective is to evaluate the CAs' preparedness to deal effectively with outbreaks of exotic animal diseases and to protect animals from unnecessary pain, suffering and distress during depopulation.

The audit mainly concentrated on the evaluation of emergency preparedness in the event of an outbreak of African swine fever (ASF), foot-and-mouth disease (FMD) and highly pathogenic avian influenza (HPAI):

- ASF currently represents a serious animal health risk for the pig population in the European Union (EU) due to the presence of the disease in some Member States (MSs) and in the Russian Federation, Ukraine and Belarus;
- FMD is one of the most difficult diseases to contain and affects several livestock species, and
- HPAI is chosen as an example of a poultry disease where specific requirements for contingency planning are laid down in EU legislation.

As the requirements of Council Regulation (EC) No 1099/2009 apply from 1 January 2013, the audit team carried out an evaluation of the current state of implementation of the requirements of Article 18 (1), (2) and (3) of this Regulation.

In pursuit of this objective, the following sites were visited and meetings held:

| MEETINGS / VISITS | | no. | COMMENTS |
|-----------------------|---------|-----|---|
| Competent Authorities | Central | 2 | Opening and closing meetings with representatives of the relevant services of the CCA |
| | County | 3 | The meetings were held with the CAs of three counties |
| Laboratories | | 2 | The national reference laboratory for ASF, FMD and AI. One regional laboratory involved in serological diagnosis of some of the diseases covered by the scope of the audit. |

| | | |
|----------------------------|---|--|
| Holdings | 3 | One pig, one cattle and one sheep farm |
| Markets & assembly centres | 1 | One assembly centre for cattle, pigs and sheep |
| Slaughterhouses | 1 | One pig slaughterhouse |
| Other establishments | 1 | One processing plant for animal by-products. |

3. LEGAL BASIS

The audit was carried out under the general provisions of EU legislation and, in particular:

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council 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.

Full legal references to EU legal acts quoted in this report are provided in Annex 1 and refer, where applicable, to the last amended version. Besides, a table is included as an Appendix to this report summarising the main legal requirements related to the specific provisions and measures laid down in the body of EU legislation pertaining to the control of exotic animal diseases.

4. BACKGROUND

Given the potential impact of outbreaks of exotic diseases, it is important that MS can react immediately and effectively in a co-ordinated manner and in co-operation with neighbouring countries. EU legislation requires MS to have contingency plans in place to contain such outbreaks so as to reduce their adverse consequences.

Of critical importance to the effective containment of an outbreak of an exotic animal disease, are the swiftness of the initial diagnosis and the early deployment of the measures contained in the contingency plans.

With regard to the historical situation in Hungary as regards occurrence of exotic animal diseases within the scope of this audit, the following is worth mentioning:

- The last outbreak of FMD occurred in 1973. There has been no suspect case of the disease in recent years.
- Hungary has never reported outbreaks of ASF. The last case of classical swine fever (CSF) in wild boars was confirmed in October 2009 and the last outbreak of the same disease in domestic pigs was confirmed in 1993.
- The most recent case of HPAI occurred in February 2015 (subtype H5N8) and it was detected in ducks.

Information on the structures of the Hungarian CAs can be found in the country profile, which is published on the FVO Website at:

http://ec.europa.eu/food/fvo/country_profiles/details.cfm?co_id=HU

The country profile (valid as of March 2014) provides detailed information on the responsibilities of the CAs under normal circumstances and a brief description of their activities in the event of a disease outbreak.

The latest audit carried out in Hungary covering the area of contingency planning for exotic animal diseases took place in 2005 (ref.: DG(SANCO)/7619/2005 – MR Final). The report of that audit is also published on the FVO Website at:

http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=1560

The outcome of the previous audit highlighted a number of important weaknesses in the animal health emergency preparedness system, in particular in relation to the availability, and adequacy, of contingency plans, the operability of the disease control centres and the chain of command in the event of an animal health crisis, the levels of training, and the organisation of real-time alert exercises for all relevant exotic animal diseases.

5. FINDINGS AND CONCLUSIONS

Legal requirements

The legal requirements applicable to the findings included in each chapter and subchapter, as related to the provisions and measures specific for each exotic disease that have been evaluated, are listed on the Appendix to this report. In addition, the general and specific legal requirements listed here below, which are applicable within the scope of this audit regardless of the disease involved, are laid down in Annex 1, and referred to in the findings, as appropriate:

- General requirements on official controls performed to ensure the verification of compliance with animal health and animal welfare rules laid down in Regulation (EC) No 882/2004, in particular, specific provisions on availability and applicability of contingency plans laid down in Article 4 (2)(f).
- General requirements laid down in EU legislation on identification and registration of bovines, sheep and goats, and pigs, and on intra-EU trade of those animal species.
- Specific animal welfare requirements related to animal depopulation in the event of an animal health crisis laid down in Council Regulation (EC) No 1099/2009.
- Specific requirements applying to disposal of animal by-products not intended for human consumption (ABP) in the event of a disease outbreak, which are laid down in Regulation (EC) No 1069/2009 of the European Parliament and of the Council and in Commission Regulation (EU) 142/2011.

5.1 POLICY FOR CONTINGENCY PLANNING

5.1.1 Preparation and updating of contingency plans

Findings

1. National and county contingency plans have been drawn by the CAs for FMD, ASF and

AI, as well as for bluetongue and CSF. But none has been drawn for the other exotic diseases in contradiction with Directives 92/35/EEC (Art. 17), 92/66/EEC (Art. 21) and 92/119/EEC (Art. 20):

- The CCA has prepared separated national contingency plans for exotic diseases, e.g. FMD, Bluetongue (BT), CSF, ASF and AI. The national plans are available on the CCA official webpage to all staff of the CAs and to the general public.
 - The county CAs developed their own county contingency plans following the principles and measures contained in national plans. In the Counties visited they were more detailed than national plans as they had been adapted to the local conditions, in particular as regards the structure and composition of the local diseases control centres (LDCCs), and the allocation of staff responsibilities and tasks.
 - The CA did not present to the audit team any specific reason behind the absence of arrangements for contingency planning for other diseases, required by EU legislation. No contingency plan has been drawn up for Newcastle Disease, African Horse Sickness and Swine Vesicular Disease and a number of other diseases required under Council Directive 92/119/EEC.
2. The national plan for African swine fever (ASF) has been recently updated. Strategy in relation to the update of other national contingency plans and implementation of this strategy has not been fully in line with EU legal requirements for FMD and AI. As a result, the national contingency plans for FMD and AI have not been updated for more than five years, which is not in line with requirements laid down in Directives 2003/85/EC (Art. 72) and 2005/94/EC (Art. 62):
- The CCA informed the audit team that updating of contingency plans is prioritised by the perceived level of threat from each disease, as it was the case with the increased risk related to the presence of ASF in Ukraine, but also by the availability of suitable human resources who can perform the task.
 - A new version of the national contingency plan for ASF was approved in September 2013 and further updated in February 2014 after a real-time exercise and its evaluation by the expert group on the disease.
 - No national contingency plan other than the one for ASF has been regularly updated. The one for AI was last updated in 2006, the one for FMD in 2004, the one for CSF in 2004, and the one for BT only in 2001. As a result, several sections of these national contingency plans are outdated and obsolete, e.g. aspects related to the current distribution of legal powers and to the organisation of the chain of command, details with regard to vaccine stocks for FMD and AI, the chapter on diagnostic capacity for FMD, or various forms annexed to the contingency plan for FMD.
 - The CCA has not yet updated the contingency plan for AI, in particular in the light of the lessons learned from the recent outbreak of HPAI in February 2015 in Hungary.

3. The CCA informed the audit team that no specific verification activity has been carried out on the county CAs in relation to their level of emergency preparedness, including on the availability of adequate county contingency plans and staff operations manuals.
4. The CCA does not play any role in coordinating the adaptation of the national contingency plans to the local conditions in the counties, neither do they facilitate or encourage the sharing of experience and expertise gained from this exercise between the counties. As a consequence, the CCA is not sufficiently aware of the full fitness for purpose and applicability of those plans. This is not in line with general EU requirements for the preparation of contingency plans (see Appendix 2 section 5.1.1) and with provisions laid down in Article 4 (2)(f) of Regulation (EC) No 882/2004.

5.1.2 Addressing of the main EU criteria and requirements for contingency plans

Findings

5. In accordance with EU legislation, the contingency plans include a well-defined chain of command for the national and local (county) disease control centres (NDCC and LDCCs) aimed at guaranteeing a rapid and effective decision-making process in the event of an outbreak of an exotic disease.
 - The distribution in practice of tasks and responsibilities is based on a well-defined structure and instructions laid down in the contingency plans.
 - Contingency plans include references to the options available to collaborate with many other CAs (e.g. the police, civil protection services, the fire brigade, etc.) and underline the importance of the general crisis management systems established at local, county and national level, which could be availed of easily by the veterinary services in case of necessity.
6. The staff operation manuals, that describe all the actions procedures, instructions and control measures to be employed in handling an outbreak of epizootic diseases, are drawn up. However, they cover only those epizootic diseases for which the contingency plan are available. Therefore there are no manuals for Newcastle Disease, African Horse Sickness and Swine Vesicular Disease and a number of other diseases required under Council Directive 92/119/EEC which is not in line with EU requirements (see appendix for specific applicable legal references).
7. The staff operation manuals are incorporated in each contingency plan as annex to the main document. The audit team noted that official staff, and additional staff called in for the outbreak, would have to identify and extract the part(s) of the relevant contingency plan that is relevant for their particular tasks. This is not very practical and user friendly and may result to higher frequency of individual errors (e.g. incomplete instructions, not relevant instructions).
8. The contingency plans include templates for forms, which can be copied and used in the outbreak scenario, e.g. for the epidemiological investigation and for the measures to be

taken. The audit team noted that most forms included in the national contingency plans are outdated. This has been compensated in the Counties visited where the forms in their county contingency plans have been recently updated to take into account the amended legislation and changes in CA organisation.

9. Contingency plans/staff operation manuals include instructions on how to perform a number of tasks and activities related to the investigation of the suspicion of exotic diseases. Those for AI have been outdated and not having included all provisions of current EU Diagnostic Manual for AI:
 - The contingency plans include a clear description of the responsibilities for staff of the county CAs in case of suspicion and confirmation of an exotic disease.
 - For ASF the contingency plan/operational staff manual makes specific reference to the procedures described in the current Diagnostic Manual for this disease.
 - Neither contingency plan nor operational staff manual for AI includes any reference to the current Diagnostic manual for AI. The procedures included are not completely in line with this Diagnostic manual, in particular a section on sampling of birds in case of suspicion.

10. Contingency plans include instructions on application of the necessary control and restriction measures once the outbreak has been confirmed in order to accelerate eradication of the disease. In general they are in line with EU requirements. Some instructions still need to be developed:
 - Adequate measures are proposed in relation to application of movement restrictions for the affected holding(s) and in the protection and surveillance zones.
 - Consideration has been given to options for granting derogations in surveillance zones to allow movement of animals to slaughter for animal welfare reasons.
 - Measures to be taken in the protection and surveillance zones include the installation of noticeable signs and roadside warnings in order to visible demarcate those zones. But no further instructions, e.g. criteria for siting of checkpoints for road controls to verify compliance with movement restrictions are provided for in the contingency plans.
 - There are no guidelines or staff instructions on how, when and by whom cleansing and disinfection of vehicles in the restricted zone should be checked.

11. One laboratory (that makes part of the organisation of the CCA) has been designated as the national reference laboratory (NRL) for all the exotic diseases covered by the scope of this audit. The contingency plans include provisions for it to fulfil its role in accordance with EU legislation, in particular with regard to: a) the confirmatory diagnosis of the diseases, b) coordination of other county laboratories involved in the diagnosis of some of those diseases, and c) regular cooperation with the relevant EU reference laboratories.

12. Measures to safeguard animal welfare when killing of animals is performed for the

purpose of depopulation are drawn up. They are being currently updated bringing them in line with the requirements of Article 18 of Council Regulation (EC) No 1099/2009:

- The CCA informed the audit team that the chapter of the contingency plans on animal depopulation in the event of a disease outbreak is currently under revision to include the provisions laid down on a recently produced national guidance on the topic. That guidance was drawn up in September 2015 and made available immediately to the county CAs. The county CAs have to use the standard depopulation procedures contained in the guidance to develop action plans taking into account the specific regional conditions and their available resources.
 - The guidance contains some criteria for selection of the most appropriate method for stunning and killing, but:
 - It does not cover options for adapting them to the size and location of suspected outbreaks, and it lacks some details on key parameters for certain stunning methods, as required by Article 18 (1) of, and Annex I to Regulation (EC) No 1099/2009.
 - The methods mentioned therein do not identify all respective estimated maximum kill rates which would provide support for granting the possible derogations to some provisions envisaged in Article 18 (3) to the said Regulation for exceptional circumstances.
 - The guidance does not contain any reference to the way the CAs can evaluate the exceptional circumstances that would permit to derogate from certain provisions of Regulation (EC) No 1099/2009.
13. Rules for disposal of animals killed for disease control purposes in order to prevent and minimise risks to public and animal health have been prepared in accordance with Regulation (EC) No 1069/2009. They include the identification of undertakings for the treatment of animal carcasses and animal waste in the event of a disease outbreak.
- All contingency plans, except the one for FMD, indicate that the method of choice for disposal of carcasses in the event of an outbreak of an exotic disease would be in ABP processing plants approved in accordance with Regulation (EC) No 1069/2009.
 - According to representatives of the CAs met, in the event of a disease outbreak, they have the legal powers to require the use of the ABP processing plants to facilitate the confinement and eradication of the disease.
14. The methods of choice included in the contingency plan for FMD for the disposal of carcasses have not been updated to reflect the current position of the CCA; the CAs have not made any arrangement to manage the environmental risks associated with the use of burial or burning methods in the event of an outbreak of the disease. This is not in line with requirements laid down in Directive 2003/85/EC (Art. 72):
- The contingency plan for FMD includes as the methods of choice burial or burning on site in order to reduce the risk of spreading the disease. However, the CCA

informed the audit team that those methods of disposal are no longer considered as the first choice, and that they would resort to them only in exceptional cases; e.g. in cases when the transport of carcasses to the rendering plants would be problematic, the affected area is remote, or the animal population is small.

- The county CAs met informed the audit team that they had not identified any suitable sites for burial or burning of carcasses. The CCA have not prepared any guidelines or instructions on how to proceed to identify those suitable sites and no specific arrangement have been made yet with the environmental CAs in order to identify, and address, possible environmental risks related to the use of those disposal methods.

5.1.3 Anticipation of large animal health crises - Worst-case scenario for FMD and emergency vaccination for AI

Findings

15. Limited attention has been paid in the FMD contingency plan to anticipate the possible occurrence of a worst case scenario related to an outbreak of the disease, as required by Directive 2003/85/EC (point 12 of Annex XVII).
16. Although a plan is available for emergency vaccination against FMD, no analysis has been carried out of the possible scenarios in the event of a large outbreak of the disease in order to better inform the decision making process and weighing up of the criteria laid down in Annex X to Directive 2003/85/EC, and thereby anticipate options for pre-emptive culling and/or emergency vaccination.
17. The CCA stated that the decision whether to vaccinate or not will be highly dependent on the particular circumstances during the outbreak. Any decision on the vaccination will be taken after consultation with an expert group on the disease.
18. Neither the CCA nor the county CAs met have identified the geographical areas with a high animal population density as defined in Directive 2003/85/EC, or evaluated the vaccination requirements considered necessary if FMD emergency vaccination was to be applied in those areas.
19. There is no arrangement made yet to ascertain the overcapacity available in the operating ABP processing plants, or defined procedures for the up-scaling of their activities. Nevertheless, representatives of the CCA informed the audit team that they had recently started to discuss these issues with the representatives of the ABP processing plants and that they had reached a preliminary agreement to ensure the mobilisation of all available rendering and incineration capacity in the event of a larger disease outbreak.
20. The vaccination plan for AI prepared by the CCA has not giving an indication of which populations of poultry or other captive birds may be vaccinated depending on different scenarios for the spread of the disease, nor have they given an updated estimate of the amount of vaccine required and its availability. This is not in line with requirements laid

down in Directive 2005/94/EC (Art. 62).

Conclusions on the policy for contingency planning

21. The CAs put in place the system for the animal health emergency preparedness and established crisis management policy. The system relies on a well-defined chain of command, the existence of national and county contingency plans, and on the several additional instructions to control epizootic diseases.
22. Contingency plans/staff operation manuals available are largely in line with EU requirements. But they have not been prepared for all relevant exotic diseases. Other than for ASF they have not been regularly updated. Although the CA can resort to the generic parts of the existing contingency plans, the specific epidemiological conditions, with potential impact on the effectiveness of disease containment, have not been taken into account.
23. There is no verification of availability of adequate county contingency plans by the CCA and the central authority exercises only limited coordination of animal health emergency preparedness at county level. Therefore, in case of larger outbreaks affecting several counties, it is uncertain whether Hungary could offer a swift and harmonised response.
24. The new central guidance for animal welfare during depopulation represents an important step forward to ensure sparing animals unnecessary pain, suffering and distress during depopulation. This development needs to be further ensured by availability of adequate standard operating procedures and action plans accordingly, in particular when a large disease outbreak occurs and it affects several animal species in a high animal density area.
25. Only limited specific arrangement has been made to anticipate, and cope with the exceptional circumstances related to large outbreaks of exotic diseases, in particular FMD (e.g. identification of risky areas with higher susceptible animal density population, availability of sufficient carcass disposal capacity, clear vaccination strategy and sufficient number of vaccination doses). Therefore the effective response in those exceptional circumstances may be potentially undermined.
26. The CCA has the legal powers to ensure that the ABP processing and incineration capacity available in the country could be used in the event of a disease outbreak. Insufficient efforts have been made so far to make use of alternative means of disposal, such as burial or burning, in accordance with environmental rules.

5.2 READINESS AND OPERATION OF THE ANIMAL HEALTH EMERGENCY PREPAREDNESS SYSTEM

5.2.1 Suspicion and confirmation of the diseases

5.2.1.1 General arrangements

Findings

27. Practical arrangements to address the suspicion and confirmation of an exotic disease follow the general principles laid down in the available contingency plans.
28. In relation to ASF further detailed references to the EU diagnostic manual for the disease have been provided to describe in practical terms the diagnostic pathway to follow in order to confirm or exclude its presence in case of suspicion. The fact that this has not been done in the case of AI is not in compliance with requirements laid down in Directive 2005/94/EC (Art. 7). In addition the absence of a clear-cut case definition or a diagnostic pathway for FMD do not comply either with specific provisions laid down in Directive 2003/85/EC:
 - Several suspicions of CSF in domestic pigs have been notified to the CAs between 2013 and 2015. In all cases the presence of both CSF and ASF was ruled out after the investigations carried out in the NRL for both diseases following the criteria laid down in the EU diagnostic manuals for both diseases.
 - The contingency plan for AI does not include any reference to the current EU diagnostic manual and the procedures laid down therein are not fully in line with it, in particular with regard to the criteria to be followed to organise and carry out the sampling necessary to investigate the possible presence of the disease.
 - Neither the contingency plan for FMD, nor the procedures in place in the NRL for the diagnostic of the disease describe the various possible steps of the diagnostic pathway to be followed to confirm, or exclude, the presence of the disease depending on the type of sample received, the diagnostic techniques used and the information contained in the epidemiological inquiries carried out by the relevant CA.
29. Information provided on the suspect case of AI confirmed in February 2015 showed that the lack of a formalised diagnostic pathway for the disease could mean that those situations are not always followed by a proper laboratory diagnosis and by the taking of adequate precautionary measures in accordance with EU requirements. Documentation provided on the case showed that:
 - The private veterinary practitioner who notified of the suspicion provided an excellent account of the situation, did suspect of the disease, and submitted samples for diagnostic analysis to the county laboratory.
 - The official veterinarian that first visited the holding, after having been notified of the suspicion, produced very poor records of that visit that were not

in accordance with procedures established in the contingency plan. Unclear and confusing information was provided on whether official samples had been taken, on what type of samples, on the time when they had been taken, or on what initial investigations were performed on them as part of the official investigation (e.g. pathology in the county laboratory or not), as no record of the epidemiological inquiry carried out could be evaluated.

- No record on the interaction and coordinated evaluation of the case between the members of the CAs involved (or with the private practitioner) could be shown, before a laboratory diagnosis was reached 24 hours after the first samples had been taken.
- The laboratory diagnosis was comprehensive and fast once it started, which was early in the morning of the day following the initial suspicion.

5.2.1.2 Quality of the disease diagnostic system

Findings

30. The NRL uses validated and fit-for-purpose tests which have been, or are in the process of being accredited according to norm ISO:17025. In all cases, the diagnostic techniques used by the NRL for exotic diseases have been validated either by the relevant EU reference laboratory or by internal validation procedures carried out in accordance with appropriate international standards.
31. Well updated standard operating procedures are in place for the relevant tests in the context of the quality management system set up in the NRL. Those procedures follow the provisions laid down in EU diagnostic manuals, when available, or in other relevant EU and international standards, as appropriate.
32. The NRL participates regularly with satisfactory results in inter-laboratory comparison tests organised by the network of EU reference laboratories for FMD, ASF / CSF and AI.
33. The only national inter-laboratory comparison test that needs to be organised by the NRL in relation to exotic diseases verifies the reliability of serological testing carried out by two county laboratories for ASF / CSF in hunted wild boars (as part of the active surveillance for the disease). The first of the tests organised with that purpose was done in March 2015, and the results were not yet available at the time of this audit.

5.2.2 The chain of command – Tasks and responsibilities in the NDCC and the LDCC

5.2.2.1 Establishment and operation of the NDCC / LDCC

Findings

34. Provisions laid down in the contingency plans established that the Chief Veterinary Officer in the CCA directs the eradication of the disease through the NDCC.
35. The NDCC directly manages the work of the LDCCs, which must coordinate the

activities for the containment and eradication of the disease in the geographical area under the responsibility of the relevant county CA.

36. In line with specific EU requirements, the CCA and the county CAs visited had made general arrangements in accordance with the contingency plans to establish at short notice an operational NDCC and LDCCs, in the event of a disease outbreak.
37. The NDCC will be established at the NRL premises where a room is available for that purpose with all the necessary infrastructure and equipment to make feasible the management of a disease outbreak. This is of major importance when an outbreak involves more than one county, as the NDCC will have to ensure timely coordination between the relevant LDCCs.
38. The existing arrangements include provisions to facilitate coordination of the necessary activities in cooperation with other services responsible for general crisis management at county level. The audit team noted the involvement of staff from the county general crisis management services in the organisation of the animal health preparedness system, in particular in relation to the organisation, implementation and evaluation of a real-time exercise for ASF.
39. Available evidence and records of the activities carried out during the 2015 AI outbreak did not allow reconciling all the steps taken during the early containment of the disease. No arrangement had been put in place to ensure that the NDCC has the means which is maintained to record in chronological order all the events associated with a disease outbreak and allowing different activities to be linked and coordinated. This is not in line with Directive 2003/85/EC (Art. 75).

5.2.2.2 Access to data analysis and information management tools

Findings

40. The activities of the LDCC and, as appropriate, the NDCC, are modulated by the availability of a number of information management systems and databases that aim to facilitate the CAs decision-making process in the event of a disease outbreak.
41. Tools available allow exchange of information between, and within, all relevant CAs and services. They contribute to the analysis of information in order to facilitate the implementation of disease control and eradication measures at county level.
42. While the systems in place are largely in line with general EU provisions for contingency planning, and some improvements were already underway, all tools are not yet fully computerised and interlinked. Therefore, they do not ensure the timely fulfilment of all the analytical needs of the decision making process, in particular in the case of large FMD outbreak:
 - All staff of the CAs has direct immediate access to information produced by the NRL on disease diagnosis in relation to suspicion and confirmation of exotic

diseases.

- The results of all epidemiological inquiries and official records of implemented measures are still only available in paper format. Current procedures indicate that they have to be faxed or E-mailed to the NDCC in order to facilitate their further evaluation. As explained earlier in the context of the recent outbreak of AI, the lack of formalisation and computerisation of these procedures may considerably delay and hinder the integrity of this process.
 - Staff in charge of the activities of the NDCC has access to basic geographical information systems that enable them to delimitate and adapt the boundaries of protection and surveillance zones, as it was done during the recent outbreak of HPAI. However, their integration with the central database of the system for identification and registration of animals has not been finalised yet, which makes still cumbersome and slow the interplay between the various types of data available.
 - According to representatives of the CCA, the potential of the available analytical tools is being improved with the ongoing computerisation of all CAs' official control activities, including arrangements related to the streamlining of data management in case of disease emergency situations.
43. Both the NDCC and the LDCCs have access to information on animal traceability in order to target disease control actions. LDCC has access to data restricted geographically to the area under their responsibility. That may limit the options to quickly investigate disease suspicions and also the performance of the epidemiological investigations by staff of the LDCCs.
44. The operation of the existing national animal identification and registration system has a number of weaknesses that could hinder the reliability and speed of the animal traceability exercises needed, in particular in the event of a larger disease outbreak in higher animal density area:
- One holding can have more than one keeping place. Those keeping places are registered under unique individual registration number and linked to holding registration number. Most of keeping places are exclusive but some are shared among different keepers (e.g. seasonal pastures).
 - Under certain circumstances the movement notification to the central database is not required, in particular in case of movements of bovines and sheep to a pasture. Although this practice is under the CA control to make sure that epidemiological link between the keeping places is always well known, any tracing back and forward exercise needed in outbreak scenario will become more complex than in normal circumstances.
 - The timing of all those (numerous) seasonal movements should be kept on the holding registers. For instance, in the sheep farm visited the audit team noted that at the beginning of the grazing period, records kept on the holding register indicated the number of sheep originally moved to the various pieces of land used for pasture.

However, no other details had been recorded in relation to the additional movements that occurred during the grazing season, and no updated number or list of (individually identified) animals present on the different keeping places at the various periods of time used was available either. This is not in line with the EU requirements.

- The census carried out in two villages in the framework of a real-time exercise for ASF in October 2013 showed a high level of non-compliance with obligations on registration of backyard holdings, and on identification and movement notification of pigs in general. Out of the 80 holdings found with pigs during that census, only 32 had been registered in the central database. The CCA and staff from the county CAs visited informed the audit team about the actions taken to address this issue. But no evidence could be shown on any verification activity carried out by any of those CAs, or at national level, to prove that those actions had been effective and that the level of compliance with registration of backyard holdings had improved.

5.2.2.3 Communication strategy

Findings

45. The arrangements contained in the contingency plans in relation to communication in the event of a disease outbreak were followed during the most recent AI outbreak (February 2015), as the NDCC included staff with expertise on media communication from the Ministry of Agriculture.
46. The staff coordinated all messages circulated outside of the CAs, mainly in the affected counties, to inform the media and the general public about the evolution of the disease. This is in line with general EU arrangements for contingency planning.

5.2.3 Technical and epidemiological expertise

5.2.3.1 Availability of expert groups

Findings

47. In accordance with EU requirements, both the CCA and the county CAs can receive support from expert groups on some exotic diseases that operate on a permanent basis in order to provide advice on disease preparedness and assistance in the event of an outbreak.
48. The CCA stated that, as laid down in the contingency plans, expert knowledge on disease detection and transmission is provided by experts from the relevant NRL and by senior veterinarians who have confronted outbreaks of the specific disease before or who have experience in general with control and eradication of exotic animal diseases.
49. The audit team was provided with a list of experts for the permanent groups established for AI, CSF and ASF, and for BT, and with some evidence of their activities and meetings.

50. According to the representatives of the CAs met, since some staff of the county CAs have extensive epidemiological expertise enabling them to address the situation in case of minor disease outbreaks, the involvement of the national expert groups is not considered necessary. In one of the counties visited, the county CA had established a permanent expert group in relation to ASF in wild boars.
51. The CAs have not maintained an expert group with regard to FMD. This is not in compliance with requirements laid down in Directive 2003/85/EC (Art. 78). No evidence was available to prove the advisory role played by the expert group for AI during a recent disease outbreak.
- Unlike the provisions laid down in the specific contingency plan, the CCA informed the audit team that no expert group has been established for FMD and that this group will be set up only upon appearance of a high risk of the disease for Hungary.
 - The audit team did not receive any evidence of the involvement of any member of the expert groups on the performance of epidemiological inquiries during the outbreak of HPAI in February 2015:
 - The CCA acknowledged that no additional expert or member of the NDCC provided assistance on-the-spot to the county CA in that case because of the small scale of the outbreak and of the effective control measures taken to prevent further spread of the infection (see also section 5.2.1.1).
 - The AI expert group only convened in March 2015 to discuss the course of the outbreak and the actions taken. Thus, this group did not participate in the earlier stages of the outbreak, when the source of the infection and the possible spread of the disease were not known yet, or later during the application of eradication and surveillance measures in the protection and surveillance zones in order to verify and confirm that they were the best suited for the epidemiological situation.

5.2.3.2 Epidemiological inquiries and surveys

52. The CCA has developed generic instructions and questionnaires for the performance of epidemiological inquiries and surveys in the context of suspicions of exotic diseases and confirmation of disease outbreaks.
53. Official veterinarians of the county CAs are responsible for performing the epidemiological inquiries related to the suspicion or confirmation of an exotic disease. The generic questionnaires for the epidemiological inquiries were available at the offices of the county CAs visited and staff met there were familiar with their use.
54. The expert group on ASF has recently contributed to the update and further tailoring of the available questionnaires to the specific epidemiological features of ASF. The CCA informed the audit team that they were in the process of adapting the generic epidemiological questionnaire to the needs of inquiries related to FMD suspicions and outbreaks (e.g. in order to better ascertain the length of time the disease could have been

present in the holding, etc.).

55. During the HPAI outbreak experienced in February 2015, the epidemiological inquiry was performed by an official veterinarian of the county CA (see 5.2.1.1). Although requested by the FVO team, the questionnaire from this inquiry was not available. This is not in line with Article 6 of Directive 2005/94/EC.
56. No specific questionnaire was used during the epidemiological inquiries carried out at the time of the suspicion, or during the outbreak of AI in 2015, and the information collected was scattered through several consecutive reports sent from the LDCC to the NRL and the NDCC. While traceability of direct contacts with the affected holding could be established for further investigation, the information collected was insufficient to find out the source and the duration of the infection in that holding. No additional samples were taken during killing of animals in the adjacent stables. As a result of insufficient inquiry and the slow decision-making process, poultry from the immediate vicinity of the affected holding (closely related epidemiologically, as they were part of the same production entity and at first sight very likely to be related) were sent to a slaughterhouse, which caused a complex (partial) recall of the meat produced later on.

5.2.4 Availability of human resources and training of staff

5.2.4.1 Personnel – availability and distribution of responsibilities

Findings

57. Staff of the CCA and of the county CAs visited who had been given responsibilities in the context of the operation of the NDCC and the LDCCs in the event of an exotic disease outbreak were largely capable of performing the associated tasks in accordance with the instructions provided in the available contingency plans.
58. Arrangements were in place to ensure that in case of necessity, both staff from other CAs and services, including from other county CAs, and other external personnel with basic and specialised technical qualifications, could be called in to assist in the disease containment and eradication activities. This is in line with specific EU provisions on contingency planning.
59. Both in the CCA and in the county CAs visited, documentation was available describing in detail how the specific tasks had been assigned to individual members of the NDCC and of the LDCCs; e.g. the various managerial responsibilities, the administrative tasks, tasks related to coordination of animal depopulation, to verification of cleaning and disinfection activities, etc.
60. Specific arrangements were in place at both national and local level to ensure the cooperation of the police forces, of the civil protection services, and of other CAs and services involved in the general crisis management systems, when it is considered necessary by any of the CAs in charge of the animal health crisis.

61. In the counties visited, documentation from the operation of the LDCCs includes lists with contact details of available competent personnel to be called in to cooperate with the killing of animals (e.g. staff from slaughterhouses specifically trained on animal welfare aspects, professional hunters to be used in specific difficult cases).
62. National legislation lays down provisions for private veterinary practitioners to abide by the request from the CAs to provide help in case of a large disease outbreak, and it further stipulates that those activities need to be properly paid.
63. While options for the participation of other personnel, such as private veterinary practitioners, are considered in the contingency plans; details on the nature of the tasks that will be given to them is not further elaborated. According to representatives of the CAs met, their role will be decided by the head of the LDCC on the basis of the particular conditions of the outbreak, the level of official resources available, and the specific expertise needed. The specific examples given were situations where intensive sampling or vaccination campaigns would need to be carried out.

5.2.4.2 Staff training

Findings

64. Staff of all CAs, as well as private veterinary practitioners, are regularly involved in training courses focusing on the clinical signs and generic control measures of the main exotic diseases.
65. All CAs provided the audit team with evidence and examples of a wide variety of training courses on animal exotic diseases that had been organised and/or attended by their staff. They had been delivered by staff of the CCA, of the NRL, of the University and of some county CAs. Likewise, examples were provided of staff who had attended specific courses organised by the Commission on contingency planning or of courses organised by the European Commission for the control of FMD.
66. In the counties visited, examples were also provided of the frequent training activities organised to maintain the awareness among private veterinary practitioners about exotic animal diseases. Those trainings focused in particular on the early recognition of clinical signs of the exotic diseases. Similar initiatives have been organised by the national chamber of veterinarians; e.g. on ASF, FMD and lumpy skin disease.
67. The audit team noted that no specific training has been recently provided on the performance of epidemiological inquiries. This is not in line with specific EU provisions on contingency planning, in particular Article 13 of Directive 2003/85/EC which stipulates that epidemiological inquiry are carried out by specifically trained veterinarians. In the counties visited, official veterinarians met and responsible for epidemiological inquiry did not recall any special training provided on how to perform epidemiological inquiries.
68. Neither the CCA, nor any of the county CAs visited had organised training activities to

ensure that staff responsible for animal depopulation in the LDCCs could make adequate use of the standard operating procedures laid down for all animal species in the new national guidance on this topic in order to comply with requirements laid down in Article 18 of Regulation (EC) No 1099/2009 and: a) select the method for stunning and killing taken into account the species involved, the number of animals on the farm and the epidemiological constraints, b) prepare the required action plans before any depopulation operation is implemented, and c) supervise those activities accordingly.

69. Representatives of the CCA noted that two culling/depopulation exercises had been carried out since 2013. In that year, the killing of a few pigs was carried out during a real-time exercise for ASF, and in February 2015 depopulation of the poultry flock affected by HPAI was carried out with a standard gas method. The report on the latter activity was sent to the Commission with all the information required by Article 18 (4) of Regulation (EC) No 1099/2009. In either case, limited if any sharing of the experience gained with those methods had been done nationwide.
70. In addition to the very few staff involved directly in the two cases mentioned above, some other staff of a few county CAs has been specifically trained on the use in practice of a well-formalised killing methodology for depopulation of poultry and pigs in small disease outbreaks. However, staff responsible for this task met in one of the county CAs visited had not been trained to use that methodology.

5.2.5 Access to facilities, equipment and other materials

5.2.5.1 General arrangements

Findings

71. Both the CCA and, in particular, the county CAs have made arrangements in accordance with specific EU requirements on contingency planning to ensure the availability of adequate equipment to facilitate the rapid deployment of disease containment and eradication measures in the event of an exotic disease outbreak.
72. With some minor exceptions, logistical arrangements were in place in the county CAs visited to ensure that the equipment and resources necessary in the event of a small disease outbreak could be readily available to staff of the LDCCs. As an example, a number of wide-ranging emergency packages were available in the premises of all the county CAs visited in order to ensure that a rapid deployment of staff to the suspected or confirmed farm(s) could be done (containing, for example, protective clothing, sampling and necropsy equipment or material for personal disinfection).
73. The availability of sufficient equipment to react effectively in the event of a widespread outbreak relies on the mobilisation of resources accessible under general crisis management provisions and on the reallocation by the NDCC of the necessary equipment from non-affected counties to the affected ones. For instance, 19 county CAs own 21 disinfection vehicles which can be re-allocated by the NDCC according to the needs and geographical spread of the particular disease outbreak.

74. Both the CCA and the county CAs visited have identified in accordance with EU requirements laid down in Regulation (EC) No 1099/2009 the material resources necessary to carry out stunning and killing operations during animal depopulation in the event of disease outbreak.

- The county CAs have to follow the recently prepared national guidance to identify all material resources needed for each stunning and killing method that could be used in the event of a small disease outbreak. The audit team noted that this had been done in all the counties visited, although not all equipment available; e.g. the captive bolts kept by one county CA, was subject to regular maintenance.
- As a particular example, five county CAs own six mobile units with gas chamber to be used in the event of disease outbreaks affecting poultry and pigs. These units can be shared by all counties in Hungary upon the decision of the NDCC.

5.2.5.2 Diagnostic capabilities and capacity in case of emergency

Findings

75. The NRL has developed its own laboratory contingency plan, which includes an evaluation of their capacity to adapt and respond to the diagnostic demands of a larger disease outbreak, upon which action will be taken to enhance their preparedness. This is in accordance with EU requirements.

5.2.6 Organisation of real-time exercises and alarm drills

Findings

76. In last five years one real-time national simulation exercise was organised in October 2013, exercising emergency response to ASF outbreak. Participants from County and District Offices, National Reference Laboratory and ASF expert group exercised sampling and on-the-spot killing of pigs. After the simulation exercise, organised, and on the basis of the lessons learnt and the outcome of a meeting of the ASF expert group; the contingency plan for ASF was further updated. This is in line with requirements laid down in Directive 2002/60/EC.

77. In addition to the national simulation exercise mentioned above, the CCA informed the audit team that during the last five years four county CAs had organised alarm drills focused on diseases such as FMD, ASF and AI. They added that another eight counties had carried out similar exercises on CSF. However, by reviewing available documentation in one county visited, the audit team noted that the initiative referred to as a county real-time alert exercise had been rather a series of study sessions. It included issues such as the development of scenarios for specific situations related to a disease outbreak in order to update available documentation for the county contingency plans, and literature searching initiatives used to further discuss the information collected. But this activity cannot be considered as real-time alert exercise.

78. No national real-time alert exercise has been organised during the last five years for

FMD. This is not in accordance with requirements laid down in Directive 2003/85/EC (Art. 73 and Annex XVII, point 11.2).

Conclusions on the readiness and operation of the emergency preparedness system

79. The operation of the NDCC and the LDCCs is well defined and supported by largely sufficient human and material resources.
80. The NRL is able to provide the CAs with rapid and reliable results for the diagnosis of the epizootic diseases covered by the audit. Besides, the availability of an internal CP to be used in the event of a large disease outbreak ensures that arrangements will be in place to adapt to unexpected emergency situations.
81. The performance of epidemiological investigations in case of suspicion and confirmation of disease outbreaks is weakened by the lack of some arrangements (e.g. no specific training provided, only generic questionnaire available, limited expert group involvement) to ensure that adequate expertise is always available at local level, in particular for FMD and AI. This may compromise the capacity of the NDCC and the LDCC to fine tune the actions taken to control a disease outbreak.
82. No operational expert group for FMD in place limits maintenance of expertise required to assist the CA in ensuring preparedness against an outbreak of FMD.
83. Several data recording and sharing systems and the information management tools are currently available to the CAs. Their further development (e.g. full computerisation and overall integration) will result in an increase of their effectiveness. Therefore they will further facilitate the coordination of the early response to the outbreak and to speed and ease up the selection of actions, particularly in the event of larger disease outbreaks.
84. The deficiencies found with regard to the incompleteness and unreliability of the data on pig holding registration and animal movements (mainly bovines and sheep to seasonal pasture), may delay the quick availability of information on animal traceability. This is of major importance for the targeting of actions to contain rapidly outbreaks of exotic animal diseases, particularly in the event of widespread disease outbreak.
85. Official staff is in general appropriately trained for their tasks and the authorities have regular contacts with veterinary practitioners, farmers, hunters and other stakeholders. But the staff allocated with the responsibilities for animal depopulation in the event of a disease outbreak has not received yet adequate training in order to safeguard the welfare of the animals during the depopulation.
86. During the last five years, the CAs have tested the fitness for purpose of the CP for ASF with the organisation of a real-time exercise in 2013. No similar initiative has been carried out for FMD, although it is required by EU legislation. This limits the possibility for the CCA to review and update the level of animal health emergency preparedness, in particular for FMD.

6. OVERALL CONCLUSIONS

The current setting out of the animal health emergency preparedness system in Hungary can be considered mostly capable to manage the situation in the event of a geographically restricted disease outbreak. However, in the event of a large disease outbreak, its effective and swift containment may be undermined by:

- The uncertain level of coordination that can be expected between the central competent authority and the counties.
- The limited availability and use of adequate expertise to evaluate the epidemiological situation and adapt the eradication measures accordingly.
- The insufficient anticipation and analysis of the factors that will play a major role in the event of a widespread disease outbreak, in particular with regard to FMD, which is of major importance in order to reach well-informed decisions on the most effective measures to apply in those exceptional circumstances.
- The less than adequate tools provided and the insufficient verification of emergency preparedness to ensure the early containment and eradication of the disease.

7. CLOSING MEETING

A closing meeting was held on 17 September 2015 with representatives of the CCA. At this meeting, the main findings and conclusions of the audit were presented by the audit team. The representatives of the CCA did not indicate any major disagreement with the findings and preliminary conclusions.

8. RECOMMENDATIONS

| No. | Recommendation |
|-----|---|
| 1. | <p>To ensure that contingency plans and staff operation manuals are drawn up for Newcastle Disease, African Horse Sickness and Swine Vesicular Disease and a number of other diseases listed in Annex I to Council Directive 92/119/EEC as required by EU legislation, and that in particular the ones for FMD and AI are regularly updated.</p> <p><i>Specific EU legal requirements laid down for each exotic disease listed in Appendix to this report (and specifically those related to chapter 5.1.1 and 5.1.2).</i></p> <p><i>Based on conclusions (22) and associated findings (1), (2), (6), (9), (10), (28), (29) and (39).</i></p> |
| 2. | <p>To ensure in accordance with the national policy for emergency preparedness availability of adequate county contingency plans and staff operation manuals (based on the national plans) in order to ascertain swift and harmonised response, particularly in the event of widespread disease outbreak, affecting more than one county.</p> <p><i>Article 4 (2)(f) of Regulation (EC) No 882/2004; criteria for contingency planning listed in Appendix to this report.</i></p> <p><i>Based on conclusions (23), and associated findings (3) and (4).</i></p> |
| 3. | <p>To provide for measures to be implemented under the exceptional circumstances related to large number of outbreaks of FMD. In particular, to identify and analyse the epidemiological factors and the operational criteria (e.g. identification of risk areas with high susceptible animal density population, availability of sufficient carcass disposal capacity, clear vaccination strategy and sufficient number of vaccination doses, etc.) that would allow taking a well-informed decision on the application of additional eradication measures, e.g. pre-emptive animal depopulation and emergency vaccination.</p> <p><i>Article 72 (3) of, and Annexes XVII (point 12) and X to Directive 2003/85/EC.</i></p> <p><i>Based on conclusions (25), and associated findings (16), (17), (19), and (20).</i></p> |
| 4. | <p>To ensure that, on the basis of the various possible scenarios for the size and location of exotic disease outbreaks, the action plans for depopulation operations are available at the county level in order to safeguard the welfare of the animals.</p> <p><i>Article 18 of Regulation (EC) No 1099/2009.</i></p> <p><i>Based on conclusions (24) and (85), and associated findings (12), (68) and (70).</i></p> |

| No. | Recommendation |
|------------|--|
| 5. | <p>To ensure that the expert group is available to maintain expertise and to assist the CA in ensuring preparedness against an outbreak of FMD.</p> <p><i>Article 78 of, and Annex XVII (point 7) to Directive 2003/85/EC.</i></p> <p><i>Based on conclusion (82), and associated finding (51).</i></p> |
| 6. | <p>To ensure that standardised, speedy and targeted epidemiological inquiries in relation to outbreaks of exotic animal diseases are carried out by specifically trained personnel on the basis of instructions and documentation and standardised questionnaires that make part of contingency plans and/or operations manuals.</p> <p><i>Article 13 of, and Annex XVII (points 9 and 11.1) to Directive 2003/85/EC; Article 6 of, and Annex X (points 6 and 7) to Directive 2005/94/EC.</i></p> <p><i>Based on conclusion (81), and associated findings (54), (55), (56) and (67).</i></p> |
| 7. | <p>To ensure that, in cooperation with the environmental authorities and in accordance with the FMD national contingency plan, sites that can be used in case of an outbreak are identified for deep burial or burning of carcasses as required by the EU requirements.</p> <p><i>Article 72 (1), (4) and (5) of, and Annex XVII (points 13 and 14) to Directive 2003/85/EC; Article 19 (1)(e) of Regulation (EC) No 1069/2009; Article 15 (a) of Regulation (EU) No 142/2011.</i></p> <p><i>Based on conclusion (26), and associated finding (14).</i></p> |
| 8. | <p>To verify that activities carried out in order to improve the level of compliance with registration of backyard holdings keeping pig at national level had been effective.</p> <p><i>Articles 3 of Directive 2008/71/EC and Article 4 (2)(a) of Regulation (EC) No 882/2004.</i></p> <p><i>Based on conclusion (84), and associated finding (44).</i></p> |
| 9. | <p>To ensure that movements of animals (sheep, goats and bovines) are timely and accurately on-farm registered and notified to the central database, in particular in the context of seasonal grazing, in order to improve the traceability of animals in case of widespread epizootic disease outbreak.</p> <p><i>Articles 7 and 22 of Regulation (EC) No 1760/2000 (cattle), Articles 5, 8, 12 of Regulation (EC) No 21/2004 (sheep).</i></p> <p><i>Based on conclusion (84), and associated finding (44).</i></p> |

| No. | Recommendation |
|------------|---|
| 10. | <p>To ensure that the requirements for real-time alert exercise for FMD (minimum frequency) laid down in EU legislation are met. Therefore the real-time exercises can effectively contribute to: a) train personnel designated to be involved in an emergency situation, and b) testing, critically reviewing and updating contingency plans, emergency preparedness arrangements in general and disease eradication strategies at national and county level.</p> <p><i>Article 73 of, and Annex XVII (point 11.2) to Directive 2003/85/EC.</i></p> <p><i>Based on conclusion (86), and associated findings (77) and (78).</i></p> |

APPENDIX – SPECIFIC LEGAL REQUIREMENTS RELATED TO SPECIFIC PROVISIONS AND MEASURES

| Specific chapter in the report | Specific provisions and measures | Applicable legislation for each disease – legal requirements corresponding to the specific provisions and measures ¹ | | | | | | | |
|--------------------------------|---|---|---|--------------------------------------|--------------------------------------|---|-------------------|-------------------------------------|------------------|
| | | FMD Dir. 2003/85 | BT Dir. 2000/75 Reg. 1266/2007 | CSF Dir. 2001/89 Dec. 2002/106 | ASF Dir. 2002/60 Dec. 2003/422 | SVD and other Dir. 92/119 Dec. 2000/428 | AHS Dir. 92/35 | AI Dir. 2005/94 Dec. 2006/437 | ND Dir. 92/66 |
| 5.1.1 | Availability of contingency plans | Art. 72 | Art. 18 | Art. 22 | Art. 21 | Art. 20 | Art. 17 | Art. 62 | Art. 21 |
| 5.1.1 | Updating of contingency plans every five years | Art. 72 (10) | | Art. 22 (3) | Art 21 (3) | | | Art. 62 (5) | |
| 5.1.2 | Criteria for drawing contingency plans | Annex XVII | Annex III | Annex VII | Annex VI | Annex IV | Annex IV | Annex X | Annex VII |
| 5.1.2 | Preparation of operations manuals / instructions available to staff | Annex XVII (9) | Annex III (6) | Annex VII (e) | Annex VI (e) | Annex IV (6) | Annex IV (6) | Annex X (6) | Annex VII (6) |
| 5.1.2 | Disposal of carcasses – environmental conditions ² | Art. 72 (1), (4), (5) Annex XVII (13) and (14) | Annex III (6) | | | Annex IV (6) | Annex IV (6) | Annex X (6) | |
| 5.1.3 | Definition of worst-case scenario | Annex XVII (12) | | | | | | | |

¹ For further clarification on the animal diseases and details on the specific legislation, please refer to the table of acronyms and abbreviations, and to Annex 1, respectively. The animal welfare requirements related to animal depopulation in the event of an animal health crisis are laid down in Council Regulation (EC) No 1099/2009, in particular in its Article 18, and apply to outbreaks of all the diseases covered by the scope of this audit.

² General legal requirements in relation to disposal of ABP in the event of a disease outbreak are laid down in Regulation (EC) No 1069/2009 of the European Parliament and of the Council, in particular on Article 19 (1)(e), and on Article 15 (a) of, and Annex VI (Section I of Chapter III) to Commission Regulation (EU) 142/2011.

| | | | | | | | | | |
|----------------------------|---|--|---|---|---|---|---------------------|--|------------------------------|
| 5.1.3 | Areas of high population density identified | Art. 72 (3)(b) Regions with high densely populated areas. Definition: Annex X (3) | | Art. 22 (1)(b) Regions with high density of pigs. Definition: Art. 2(u) | Art. 21 (1) | | | Annex X (12) Art. 62 (2) Annex X (10) Registration of commercial poultry holdings | |
| 5.1.3 | Vaccination requirements identified | Art. 72 (3)(a) | Annex III (9) | Art. 22 (1)(a) | | | Annex IV (9) | Art. 59 (1) Art 62 (2) | Art. 21 (1) Annex VII (9) |
| 5.1.3 | Availability of vaccine identified | | | | | Annex IV (9) | | Annex X (9) | |
| 5.1.3 | Plans & procedures for emergency vaccination | Conditions and criteria specified in Art. 49 to 58, and Annex X | Conditions and criteria specified in Art. 5 and 6 (as amended by Dir. 2012/5) | Annex VII (f) Annex VI (criteria for deployment of emergency vaccination) | | | | Annex X (9) | |
| 5.2.1.1 | Handling of suspicion / confirmation | Art. 4 to 9, 10, 12, 14 to 16, 18 and 19 | Art. 4 and 6 | Art. 4 to 7 | Art. 4 to 7 | Art. 4 to 7 | Art. 4 and 6 | Art. 7 to 9, and 11 to 15 | Art. 4 and 5 |
| 5.2.1.2 | Diagnostic methods specified | Art. 71 Annex XIII | | Diagnostic manual: Decision 2002/106/EC | Diagnostic manual: Decision 2003/422/EC | Diagnostic manual: Decision 2000/428/EC | | Diagnostic manual: Decision 2006/437/EC | |
| 5.2.2.1 and 5.2.2.2 | Establishment and operation of NDCC / LDCC | Art. 74 to 77 Annex XVII (3) to (5) | Annex III | Art. 23 | Art. 22 | Annex IV | Annex IV | Art. 62 (6) Annex X | Annex VII |
| 5.2.2.3 | Communication strategy | Annex XVII (11.3) and (15) | Art. 14 | Art. 23 (6) Annex VII (g)(iii) | Annex VI (f)(iii) | Annex IV (4) | Annex IV (4) | Annex X (4) | Annex VII (4) Art. 13 |
| 5.2.3.1 | Availability of a permanent expert group | Art. 78 Annex XVII (7) | | Art. 23 (5) | Art. 22 (5) | | | Art. 62 (6) | |
| 5.2.3.2 | Epidemiological enquiry / survey | Art. 13 | Art. 6 (1)(e) and 7 | Art. 5 (1)(i) and 8 | Art. 5 (1)(i) and 8 | Art. 5 (1)(d) and 8 | Art. 6 (1)(e) and 7 | Art. 6 (1) Annex X (3) | Art. 5 (1)(g) and 7 |
| 5.2.4.1 | Personnel - qualifications and responsibilities | | Annex III (3) | | | Annex IV (3) | Annex IV (3) | Annex X (3) | Annex VII (3) |

| | | | | | | | | | |
|----------------|--|------------------------------------|---------------------------|---------------------------|------------------------------|--------------|----------------------|-------------------------|--------------------------|
| 5.2.4.2 | Staff training | Annex XVII (11.1) and (11.3) | Annex III (7) | Annex VII (g)(i) | Annex VI (f)(i) and (f)(iii) | Annex IV (7) | Annex IV (7) | Annex X (7) | Annex VII (7) |
| 5.2.5.1 | Availability of equipment and materials | Art. 72 (2) Annex XVII (2) and (8) | Art. 18 (1) Annex III (5) | Art. 22 (1) Annex VII (d) | Art. 21 (1) Annex VI (d) | Art. 20 (1) | Art. 17 Annex IV (5) | Art. 62 (2) Annex X (5) | Art. 21 (1) Annex VII(5) |
| 5.2.5.2 | Diagnostic capacity | Art. 71 Annex XVII (8) | Annex III (8) | Art. 17 (d) Annex VII (d) | Annex VI (d) | Annex IV (8) | Annex IV (8) | Annex X (8) | Annex VII (8) |
| 5.2.6 | Organisation of real-time alert exercises / frequency | Art. 73 Annex XVII (11.2) | | | | | | | |
| 5.2.6 | Organisation of alarm drills / frequency | Annex XVII (11.2.4) | | Annex VII (g)(ii) | Annex VI (f)(ii) | | | | |

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2015-7568

ANNEX 1 – LEGAL REFERENCES

| Legal Reference | Official Journal | Title |
|------------------------|--|---|
| Reg. 882/2004 | OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1 | Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules |
| Dir. 2005/94/EC | OJ L 10, 14.1.2006, p. 16-65 | Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC |
| Dir. 2003/85/EC | OJ L 306, 22.11.2003, p. 1-87 | Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC |
| Reg. 1099/2009 | OJ L 303, 18.11.2009, p. 1-30 | Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing |
| Dir. 2000/75/EC | OJ L 327, 22.12.2000, p. 74-83 | Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue |
| Dir. 2001/89/EC | OJ L 316, 1.12.2001, p. 5-35 | Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever |
| 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 |

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| Dir. 92/35/EEC | OJ L 157, 10.6.1992, p. 19-27 | Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness |
| Dir. 92/66/EEC | OJ L 260, 5.9.1992, p. 1-20 | Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease |
| 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) |
| Reg. 21/2004 | OJ L 5, 9.1.2004, p. 8-17 | Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC |
| Reg. 1266/2007 | OJ L 283, 27.10.2007, p. 37-52 | Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue |
| Dec. 2002/106/EC | OJ L 39, 9.2.2002, p. 71-88 | 2002/106/EC: Commission Decision of 1 February 2002 approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever |
| Dec. 2003/422/EC | OJ L 143, 11.6.2003, p. 35-49 | 2003/422/EC: Commission Decision of 26 May 2003 approving an African swine fever diagnostic manual |
| Dec. 2000/428/EC | OJ L 167, 7.7.2000, p. 22-32 | 2000/428/EC: Commission Decision of 4 July 2000 establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of swine vesicular disease |
| 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 |

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| Reg. 1069/2009 | OJ L 300, 14.11.2009, p. 1-33 | Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) |
| Reg. 142/2011 | OJ L 54, 26.2.2011, p. 1-254 | Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive |