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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
ITALY
FROM 13 OCTOBER 2015 TO 23 OCTOBER 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

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 carried out in Italy from 13 to 23 October 2015 as part of the audit programme of the Directorate General for Health and Food Safety 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 animal health emergency preparedness system in place in Italy has the technical and material resources available to be effective. The systems evaluated at regional and local level are largely adequate to manage the early response to a localised disease outbreak.

The level of preparedness for avian influenza is satisfactory and stems from the excellent technical advice and experience provided by the national reference centre for the disease and from the enhancement of the emergency response systems in the regions visited (which is the result of lessons learnt from managing frequent outbreaks in recent years).

Although the national reference centre for foot-and-mouth disease guarantees an excellent level of expertise, there are doubts as to whether the regions visited would be able to respond rapidly to, and contain effectively a large outbreak of the disease, as:

There is insufficient coordination and verification at national and regional level of the development and potential operability of the emergency preparedness systems for this disease.

Limited attention has been paid to address interlinked factors that will play a major role in the event of a widespread disease outbreak; e.g. options to cope with those situations in high densely populated areas, arrangements for emergency vaccination and operational options for animal depopulation and disposal of a large number of animal carcasses.

The organisation of real-time exercises has been inadequate and has not contributed effectively to verify the fitness-for-purpose of the arrangements in place for contingency planning for the disease.

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

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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
ASL	Local Veterinary Services – <i>Azienda Sanitaria Locale</i>
CA	Competent Authority
CCA	Central Competent Authority
DG SANTE	Directorate General for Health and Food Safety
EU	European Union
FMD	Foot-and-mouth disease
(HP)AI	(Highly pathogenic) avian influenza
MS	Member State of the EU
NDCC	National disease control centre
NRL	National reference laboratory
R/LDCC	Regional/Local disease control centre
RVS	Regional Veterinary Services
SIMAN	National Animal Diseases Notification System (<i>Sistema Informativo Malattie Animali Nazionale</i>)

1 INTRODUCTION

This audit took place in Italy from 13 to 23 October 2015 and was undertaken as part of the planned audit programme of the Directorate General for Health and Food Safety (DG SANTE). The audit team comprised two auditors from DG SANTE.

The audit team was accompanied throughout the audit by representatives of the Central Competent Authority (CCA), the Directorate General for Animal Health and Veterinary Medicinal Products of the Department for Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection of the Ministry of Health.

In addition, during the visits at regional and provincial level, the audit team was accompanied by representatives of the competent authorities (CAs) responsible for the preparedness for, and early response to animal disease outbreaks at those levels; i.e. the Regional Veterinary Services (RVS), and the Local Veterinary Services (Azienda Sanitaria Locale – ASL).

2 OBJECTIVES AND SCOPE

The objective was 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 outbreaks of foot-and-mouth disease (FMD) and highly pathogenic avian influenza (HPAI):

- FMD is one of the most difficult diseases to contain and affects several livestock species.
- 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 and other associated advisory bodies and institutions.
	Regional	3	Meetings were held with the RVS of Veneto, Lombardy and Tuscany.
	Provincial	6	Meetings were held in three ASLs. In addition, staff of another three ASLs was met during the on-the-spot visits.
Laboratories/reference centres		4	The national reference laboratories/centres for FMD and AI, and the national reference centre for exotic animal diseases, epidemiology and risk analysis. One regional laboratory involved in serological diagnosis of AI and in active and passive surveillance for other exotic animal diseases.
Holdings		2	One cattle and one sheep farm.
Markets & assembly centres		1	One assembly centre for cattle.
Slaughterhouses		1	One pig and cattle 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. In addition, 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 Member States (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 Italy 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 1993. A few sporadic suspect cases of the disease have been investigated, and the presence of the disease was excluded, in recent years.
- The most recent cases of HPAI occurred in 2013 (subtype H7N7, in laying hens and turkeys) and 2014 (subtype H5N8, in turkeys). Several cases of low pathogenic Avian Influenza (AI) (H5 and H7 subtypes) are detected each year in various species of poultry; nine in 2013, five in 2014, and three so far in 2015.

Information on the structures of the Italian CAs can be found in the country profile, which is available through the following link:

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

The country profile (valid from April 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 last audit carried out in Italy covering the area of contingency planning for exotic animal diseases took place in 2003 (ref.: DG(SANCO)/9078/2003 – MR Final). The report of that audit can be accessed through the following link:

http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=908

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 insufficient involvement of the CCA in the coordination and verification of the preparation and application of the contingency plans and operation manuals by the regional and local CAs. In addition, insufficient attention had been paid to ensure the operability of the regional and local disease control centres and to the organisation of real-time alert exercises for FMD.

The three regions visited by the audit team comprise nearly half of the 139 ASLs in operation in Italy, have the most densely animal-populated areas in the country, and keep a very high share of all livestock populations and of the animal production industry in Italy.

5 FINDINGS AND CONCLUSIONS

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 has been evaluated, are listed on the Appendix to this report. In addition, the general and specific legal requirements listed 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. The CCA updated arrangements for contingency planning for a number of major exotic animal diseases, including FMD and AI, which is in line with requirements laid down in Council Directives 2003/85/EC (Art. 72) and 2005/94/EC (Art. 62). Inadequate arrangements were in place in relation to other diseases, which is not in line with provisions laid down in Council Directive 92/119/EEC (Art. 20).
 - Before 2014, the contingency plan system was based on individual plans for a number of exotic animal diseases. As a result of a review, from 2010, the CCA developed a unique generic national contingency plan that can be used for all those diseases. The CCA's intention is to complete the plan with specific operational manuals for each disease, as required by EU legislation. The reviewing process is carried out in cooperation with a specific standing strategic committee where all 21 RVS in the country are represented.
 - The generic plan covers a description of the chain of command and general aspects such as management of suspicions and confirmations, financial arrangements, options for animal depopulation, etc. It also has a number of technical annexes and pre-set harmonised documents and forms that can be used in the event of any disease outbreak.
2. At the time of the audit, the CCA had prepared specific operational manuals for FMD, AI, classical and African swine fever, African horse sickness, Newcastle disease and bluetongue. These manuals incorporate tailor-made tools adapted to each disease (e.g. epidemiological enquiries, diagnostic criteria, specific provisions on cleaning and disinfection and options for the setting out of restriction zones and vaccination). The generic national contingency plan and the specific operational manuals are available on the CCA official webpage to all staff of the CAs and to the general public.
3. The specific operational manuals for FMD and AI were updated in cooperation with the respective national reference laboratories (NRLs), which also play the role of national reference centres for their epidemiology and control. The manual for AI is under continuous review to adapt it to the lessons learned during outbreaks of the disease. The audit team saw examples of updates done according to that policy.

4. Manuals for other diseases included in Council Directive 92/119/EEC were not available. The CCA stated its intention to develop specific manuals for other diseases required by EU legislation in the near future. The RVS and the ASLs developed their own contingency plans and operational manuals following the principles and measures contained in the national one. These plans were available in the regions and ASLs visited. In general, they were adapted to the local conditions and, in some cases, there were considerable additional details that go beyond the baseline documents in the national plans. In particular, these plans included specific details on the structure and composition of the local disease control centres (LDCCs), and the allocation of staff
5. According to all representatives of the RVS and the ASLs met, the CCA had a limited involvement in coordinating and verifying the level of preparedness of the RVS and the ASLs (e.g. they do not facilitate or encourage the sharing of experience and expertise gained from this exercise between the RVS and the ASLs). As a consequence, the CCA is not sufficiently aware of whether those plans are fully fit for purpose and applicable. 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. In the regions visited, the RVS have also paid insufficient attention to those responsibilities with respect to the ASLs. One of the regions visited acknowledged that gap and the RVS had incorporated that task as a major priority for the next few years.
 - In the Lombardy region more attention had been paid to the coordination of the levels of preparedness in the ASLs, whilst in Veneto and Tuscany coordination in that area has been largely neglected.
 - The CCA informed that no specific verification activity has been carried out on the RVS and the ASLs in recent years in relation to their level of emergency preparedness, including on the availability of adequate contingency plans and staff operation manuals. However, their internal audit service carried out some targeted audits to verify the response of some RVS to outbreaks of exotic diseases (e.g. in 2007, including Veneto and Tuscany).

5.1.2 Addressing the main EU criteria and requirements for contingency plans

Findings

6. In accordance with EU legislation, the generic national contingency plan includes a well-defined chain of command for the national disease control centre (NDCC) aimed at guaranteeing a rapid and effective decision-making process in the event of an outbreak of an exotic disease. In addition, it incorporates similar guidance for the deployment and operation of disease control centres by the regions (RDCCs) and the ASLs (LDCCs).
 - A national crisis management centre for animal diseases was created at the end of 2005 (by the same Law that set out the structure of the CCA). This centre is operational in "peace time" (when no outbreaks are present) and when an exotic disease outbreak occurs (as the NDCC). The distribution of tasks and responsibilities

is based on a well-defined structure and instructions that are laid down in the generic national contingency plan. The activities of the centre are ensured by a dedicated unit within the structure of the CCA that has permanent staff and it is operational permanently.

- The RVS and the ASLs visited had developed detailed chains of command to adapt the requirements of the generic national contingency plan to their local conditions.
7. The national contingency plan includes references to the options available to cooperate with many other CAs (e.g. the police, civil protection services, the fire brigade, etc.) and underlines the importance of the general crisis management systems established at local, regional and national level, which could be availed of easily by the RVS and the ASLs in case of necessity.
- All contingency plans seen in the regions and ASLs visited had arrangements in this respect and staff from these CAs had been nominated, and participated regularly in a activities carried out in the context of those regional and local crisis management systems.
 - The CCA and the RVS were preparing national and regional general crisis management plans which, amongst other areas will incorporate specific arrangements to improve the level of preparedness for animal health crisis.
8. The RVS and the ASLs visited have drawn up a variety of staff operation manuals that describe the actions, procedures, instructions and control measures to be employed in handling outbreaks of exotic animal diseases, with the exception of those covered by Directive 92/119/EEC. This last point is not in line with provisions laid down in Annex IV to that Directive.
- In general, the staff operation manuals drafted by the RVS and further developed and adapted by each ASL, cover all basic practical arrangements needed to deploy an early response to an exotic disease. They include a clear indication of who must do what, while providing details on the human resources and specific equipment available at local level.
 - In all cases, CAs have put high emphasis on preparing practical arrangements to respond to an outbreak of AI, as they had frequent and recent experiences with the disease, but more limited arrangements were in place for FMD and other exotic diseases.
 - Those staff operation manuals had taken into account, in most cases and mainly for AI, the details included in the national specific operational manuals prepared by the CCA. Thus, in most ASLs visited there were no specific arrangements in place to adapt the staff operation manuals to the specific epidemiological conditions derived from outbreaks of the diseases included in Directive 92/119/EEC (such as lumpy skin disease or sheep and goats pox), despite the increased risk associated with the recent incursions of those diseases in the EU.

9. The generic national contingency plan and the specific operational manuals include templates and forms that can be used in the outbreak scenario (e.g. templates for epidemiological investigations adapted to each disease, forms to be used for sampling purposes, forms to communicate within the CAs or to stakeholders, measures to be taken). The audit team observed that those tools were available to staff of the ASLs and, in some cases, they have been incorporated as annexes in the regional and local staff operation manuals.
10. Operations manuals available to ASLs staff included instructions on how to perform a number of tasks and activities related to the investigation of the suspicion of exotic diseases. Those for AI and FMD have been updated recently, and in the case of AI, they include all relevant provisions of the current EU Diagnostic Manual for the disease:
 - The specific operational manuals developed by the CCA for FMD and AI with the technical support of the national reference centres included a clear description of the responsibilities for staff of the RVS and the ASLs in case of suspicion and confirmation of either disease.
 - For AI, the new specific operational manual that has been used for the update of the staff operation manuals makes specific reference to the procedures described in the current EU Diagnostic Manual for this disease.
 - In general, the manuals seen for FMD contain adequate information for staff of the ASLs to investigate a suspicion of the disease, including extensive details on how to evaluate the ageing of lesions and on specific sampling procedures to optimise the diagnostic activities of the NRL.
11. The generic national contingency plan and the specific operational manuals for AI and FMD include instructions on application of control and restriction measures once the outbreak has been confirmed in order to accelerate eradication of the diseases. In general they are in line with EU requirements and they have been incorporated in the staff operation manuals present in the ASLs visited.
 - The documents propose adequate measures to apply movement restrictions for the affected holding(s) and in the protection and surveillance zones. They also have options for granting derogations in surveillance zones to allow movement of animals to slaughter for animal welfare reasons.
 - Specific provisions underline the importance of collaborating with other crisis management services (e.g. police, civil protection services) to apply measures in the protection and surveillance zones (e.g. installation of signs and roadside warnings to demarcate those zones visibly, setting up checkpoints for road controls).
 - The specific operational manuals prepared by the CCA include guidelines on how cleansing and disinfection of vehicles in the restricted zones should be checked. These were translated into staff instructions by some RVS and ASLs, on how, when and by whom those would be done.

12. There is an extensive network of laboratories and associated diagnostic centres which includes NRLs for all the exotic diseases covered by EU legislation. They are under regional administration but operationally coordinated by the Ministry of Health. The laboratory in Veneto (Padova) has been designated as NRL for AI and the one in Lombardy (Brescia) and NRL for FMD. The national contingency plan and specific operational manuals for both diseases include provisions for them to fulfil their role in accordance with EU legislation, in particular with regard to: a) the confirmatory diagnosis of AI and FMD, b) coordination of other laboratories involved in the serological and virological diagnosis of those diseases, and c) regular cooperation with the relevant EU reference laboratories.
13. The generic national contingency plan has a specific chapter containing measures to safeguard animal welfare when killing of animals is performed for the purpose of depopulation. They are in line with the requirements of Article 18 of Council Regulation (EC) No 1099/2009.
 - The guidance on animal welfare in the generic national contingency plan was drawn up with the national reference centre for animal welfare and with representatives of the RVS. ASLs, under coordination of the relevant RVS, have to use the standard depopulation procedures contained therein to develop action plans taking into account the specific regional conditions and their available resources.
 - The guidance contains extensive criteria for selection of the most appropriate method for stunning and killing and, on the basis of that, the staff operation manuals seen in the ASLs visited contained details on the key parameters for those methods and options for adapting them to the size and location of suspected outbreaks.
14. The information given on the methods provides guidance on their estimated maximum kill rates. This would provide support for granting possible derogations to some provisions envisaged in Article 18 (3) to the said Regulation under exceptional circumstances. However, neither the generic national contingency plan, nor the staff operation manuals seen in the regions and ASLs visited contained details on the way CAs could evaluate the exceptional circumstances that would permit derogation from certain provisions of Regulation (EC) No 1099/2009.
15. The generic national contingency plan includes rules for disposal of animals killed for disease control purposes in order to prevent and minimise risks to public and animal health in accordance with Regulation (EC) No 1069/2009 and with Article 72 of Directive 2003/85/EC (with respect to FMD). Staff operation manuals developed by the RVS and the ASLs have identified undertakings for the treatment of animal carcasses and animal waste in the event of a disease outbreak in the geographical areas under their responsibility, and in some cases have evaluated the options for the use of burial sites for that purpose.
 - The generic national contingency plan indicates approved ABP processing plants and -in exceptional cases - burial sites as the methods of choice for disposal of carcasses in the event of an outbreak of an exotic disease. It also includes how to select the areas

intended for burial of carcasses and describes in detail how to perform that activity to manage associated environmental risks.

- Authorities met indicated that they have legal powers to request the use of the ABP processing plants to facilitate the quick confinement and eradication of the disease in the event of a disease outbreak.
- CAs met indicated they would only resort to burial in exceptional cases; e.g. when transport of carcasses to the ABP processing plants is problematic, in a large outbreak that exhausts their processing capacity, or when the affected area is remote and the animal population is small.
- In some of the ASLs visited, the CAs carried out very detailed investigations to identify suitable sites for burial of carcasses and made arrangements with the environmental CAs in order to identify and address possible environmental risks related to the use of those disposal methods.
- In line with EU requirements, the generic national contingency plan, the specific operational manuals for FMD and AI, and the staff operation manuals for those diseases at RVS and ASLs, include information on the procedures to follow to ensure a proper cleaning and disinfection of all materials bearing possible risk of transmitting the diseases. The audit team verified examples of cleaning and disinfection guidance and instructions available to staff. In the case of AI, these had been used in response to outbreaks of HPAI (in Veneto) and low pathogenic AI (in all the visited regions).

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

Findings

16. The specific operational manual for FMD includes instructions on how to apply protective and emergency vaccination against the disease. These incorporate the provisions laid down in Directive 2003/85/EC (Art. 49 to 58), and indicate that the criteria laid down in points 1 and 2 of Annex X to the said Directive have to be taken into account in order to decide on, and apply those disease control options.
17. 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) is not adequately taken into account in the generic national contingency plan, in the specific operational manual for FMD, and in the staff operation manuals seen in the RVS visited.
 - None of the three regions visited had any analysis taking into account information on the densely populated animal areas, as required by point 3 of Annex X to the said Directive, or on the possible scenarios in the event of a large outbreak of the disease. This was also not done at national level. Thus, there was no formal protocol to adequately provide information for the decision making process and properly weigh up the criteria laid down in points 1 and 2 of the same Annex, and thereby anticipate options for pre-emptive culling and/or emergency vaccination.

- 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 the experts at the national reference centre for the disease in Brescia.
 - There were no arrangements at national level to ascertain the overcapacity available in the operating ABP processing plants, nor was it discussed or agreed with the RVS and the operators of those plants procedures for the up-scaling of their activities to anticipate the need to dispose of a significant amount of carcasses in the event of an outbreak of FMD. Some RVS and ASLs had discussed these issues with the representatives of the ABP processing plants operating in their areas and even agreed on some basic operational principles to speed up the mobilisation of all available rendering and incineration capacity in the event of an FMD outbreak.
18. The generic national contingency plan and the specific operational manual for AI mention the option of resorting to emergency vaccination to respond to an outbreak of HPAI. No specific vaccination plan has been prepared to do that, which is not in line with requirements laid down in Directive 2005/94/EC (Art. 62). Documents indicate that the NDCC in cooperation with the national reference centre for AI would evaluate and weigh up the options for that purpose; there was no evidence of analysis indicating which populations of poultry or other captive birds may be vaccinated, or whether the CAs have obtained an updated estimate of the amount of vaccine that may be required, and of its availability.

Conclusions on the policy for contingency planning

19. The CCA set out a largely satisfactory crisis management policy in relation to exotic animal diseases and had taken action to establish a potentially effective system for animal health emergency preparedness. The system relies on a well-defined chain of command and on the existence of generic arrangements on contingency planning and sufficient technical guidance and advice to enable all relevant CAs to deploy an early response to the incursion of most exotic animal diseases.
20. The availability of updated contingency planning tools and staff operation manuals in all RVS and ASLs visited and the fact that they are adapted to the local conditions (dynamics of a disease outbreak and to the availability of human and material resources in the geographical areas under their responsibility) should facilitate the early and effective containment of localised outbreaks of FMD and AI.
21. Although all CAs can resort to the generic emergency preparedness tools, the absence of specific arrangements to consider the particular epidemiological conditions surrounding outbreaks of the diseases covered by Directive 92/119/EEC could significantly undermine the effectiveness of the measures to quickly contain those outbreaks.
22. In case of large outbreaks of exotic animal diseases affecting several regions - in particular with regard to FMD- it is uncertain whether Italy could offer a swift and harmonised response, as there is no coordination of the development and no verification of the readiness of the animal health emergency preparedness systems at regional and local level. This absence of coordination also hinders regional and local authorities to incorporate lessons learned from recent outbreaks by their peers.
23. CAs have the necessary information on the generic plan to make adequate arrangements in the event of a localised exotic disease outbreak to spare animals any unnecessary pain, suffering and distress during depopulation. However, the absence of details on how CAs would evaluate exceptional circumstances in this context, the fact that training and practical guidance for this are deficient at local level (see paragraph 53) and the different levels of preparedness observed on the resources to carry out stunning (see paragraph 55) will make it difficult to prepare action plans for depopulation that safeguard the welfare of the animals.
24. The effective response to cope with the exceptional circumstances related to large outbreaks of exotic diseases, in particular FMD is undermined by the limited specific arrangements that have been made to anticipate them (e.g. identification of risky densely populated livestock areas, additional arrangements related to depopulation, availability of sufficient carcass disposal capacity, clear vaccination strategies for FMD and AI).
25. The powers to require the use of ABP processing and incineration plants in the event of an outbreak, together with the efforts to ensure that alternative means of disposal, such as burial, can be used in accordance with environmental rules would facilitate the disposal and containment of the disease in case of outbreaks.

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

26. The generic national contingency plan and the specific operational manuals address the suspicion and confirmation of the exotic diseases they cover in a satisfactory manner. During the meetings with staff of the ASLs the audit team confirmed that they were well instructed in this area. The staff operation manuals seen at local level adequately reflected the procedures to follow in the event of a suspicion of an exotic disease. There were clear details laid down in those manuals describing all the steps to follow, and who to contact, in those cases.
27. For AI, the manuals provide detailed references to the EU diagnostic manual to describe in practical terms the diagnostic pathway to follow to confirm or exclude its presence in case of suspicion. This is in compliance with requirements laid down in Directive 2005/94/EC (Art. 7). The national reference centre for FMD has prepared for the specific operational manual a case definition and a diagnostic pathway for the disease that complies with specific provisions laid down in Directive 2003/85/EC.
 - Numerous suspicions of AI in domestic poultry have been notified to the CAs between 2013 and 2015. In all cases the presence of either HPAI or low pathogenic AI was swiftly confirmed or ruled out after the investigations carried out in the NRL following the criteria laid down in the EU diagnostic manual for the disease.
 - A few suspect cases of FMD have been investigated in 2014 and 2015 by the NRL in accordance with the diagnostic pathway laid down in the specific operational manual. The audit team reviewed some of them and concluded that the diagnostic techniques followed to exclude the presence of FMD were performed quickly and were well adapted to the type of sample received from the field while taking into account the information contained in the epidemiological inquiries carried out by the relevant CA (e.g. ageing of the lesions).
28. The audit team evaluated additional evidence of suspect cases of AI and FMD, and determined that in all those situations adequate precautionary measures had been taken in accordance with EU requirements, e.g:
 - Suspicions had been immediately evaluated by staff of the ASL and by specialised staff of the relevant laboratory, who contributed to the epidemiological evaluation of the situation and to the drafting of the initial epidemiological inquiry that accompanied the samples to the relevant NRL.

- There was evidence that staff of the ASL informed the animal keepers without delay of the necessary official restrictions applied on the animals as a result of the suspicions.
- The suspicions of HPAI and FMD had been communicated immediately to the CCA and to all the other RVS and ASLs in the country through the National Animal Diseases Notification System (Sistema Informativo Malattie Animali Nazionale – SIMAN). Backward and forward tracing exercises were carried out straightaway to identify possibly connected holdings or establishments where immediate action could be necessary. Data on those exercises were still available in detail in the SIMAN.

5.2.1.2 Quality of the disease diagnostic system

Findings

29. The NRLs for FMD and AI use validated and fit-for-purpose tests which are accredited according to norm ISO:17025. In all cases, the diagnostic techniques used by those NRLs have been validated either by the relevant EU reference laboratory or by internal validation procedures carried out in accordance with appropriate international standards. Both laboratories participate regularly with satisfactory results in inter-laboratory comparison tests organised by the respective EU reference laboratories.
30. Updated standard operating procedures are in place for the relevant tests in the context of the quality management system set up in the NRLs for FMD and AI. Those procedures follow the provisions laid down in EU diagnostic manuals, when available, or in other relevant EU and international standards, as appropriate (e.g. those of the EU reference laboratories). Both NRLs are also FAO and OIE reference laboratories for their respective disease.
31. Both NRLs for AI and FMD organise regularly national inter-laboratory comparison tests to verify the reliability of serological and virological testing (only PCR, in the case of FMD) carried out by other regional and provincial laboratories. Participating laboratories are involved in regular surveillance for AI (national annual surveillance programme), or they have been selected by the NRL for FMD to be ready to provide help in the event of a large outbreak of the disease. In the few occasions where some laboratories did not reach the expected standards, specific follow-up initiatives were implemented (e.g. targeted training and on-the-spot visits by experts from the NRL).

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

32. The generic national contingency plan describes in detail the operation of the NDCC and of the R/LDCCs in the context of the responsibilities of the national crisis management centre for animal diseases. The NDCC operates under the command of the Chief Veterinary Officer of the Ministry of Health. The R/LDCCs operate under the

responsibility of the respective top veterinary managers at regional and local level. In line with specific EU requirements, the CCA and the R/LDCCs visited during the audit had arrangements to establish at short notice those operational centres in the event of a disease outbreak.

33. There are clear arrangements defining that the LDCCs must coordinate the activities for the initial containment of the exotic animal disease in the geographical area under their responsibility. For situations when the disease affects more than one ASL in the same region, the RVS visited had arrangements so the RDCCs would coordinate those situations. When the outbreak affects several regions, or it has potentially a large impact (e.g. FMD), the generic national contingency plan clearly stipulates that the NDCC will take over the general coordination of the situation.
 - The audit team saw examples of the activity of those centres in relation to recent outbreaks of AI. In those cases, the national reference centre for the disease played a major role, acting largely as a NDCC, in coordinating the operation of the R/LDCCs. The national reference centre planned, and accompanied in many cases, all investigations related to the outbreaks, while coordinating the organisation and timing of all additional sampling and diagnostic activities necessary to accelerate the verification of the eradication of the disease.
 - In the RVS and ASLs visited, the CAs had made arrangements to ensure the availability of the necessary infrastructure and equipment for the operability of the crisis centres under their responsibility. In the case of the RDCCs, special attention had been paid to facilitate the coordination of, and the communication with the ASLs of the region.
34. At all levels of the organization of the CAs, the existing arrangements include provisions to facilitate that all the necessary activities can be done in cooperation with other services responsible for general crisis management at national, regional and local level.
 - The NDCC incorporates representatives from other relevant services (e.g. army, civil protection services). The audit team saw examples of decisions taken with the support of those representatives, which led to additional availability of resources to the RVS: e.g. in one case, the army was quickly deployed to accelerate the depopulation of poultry, and the quick cleaning and disinfection of poultry farms, in order to stop the extension of an outbreak of HPAI.
 - The audit team noted the significant involvement of at least one senior member of staff from the RVS, and of at least one member of staff from each of the ASLs visited, in the general crisis management services available at regional and local level, respectively: e.g. those members of staff were actively involved in the organisation, implementation and evaluation of real-time exercises related to natural disasters and public health emergencies.

35. There is evidence and records (in SIMAN and on paper) of the activities carried out during recent outbreaks of HPAI and in case of suspicion of FMD that allow for reconciling all the steps taken during the investigations and, when appropriate, the containment of the outbreaks of HPAI. Thus, current arrangements in this respect ensure that the NDCC and the R/LDCCs can record in chronological order all the events associated with a disease outbreak allowing different activities to be linked and coordinated. This is in line with Directive 2003/85/EC (Art. 75).

5.2.2.2 Access to data analysis and information management tools

Findings

36. The activities of the NDCC and the R/LDCCs are facilitated by the integrated information management system available in the SIMAN which is in line with general EU provisions for contingency planning and can contribute decisively to the prompt analysis of information in order to facilitate the implementation of disease control and eradication measures.
37. The SIMAN brings together several animal health information retrieval systems, including diagnostic data from the NRLs, and the national databases for animal identification, holding registration and animal movements. The system is suitable to provide information quickly and accurately to the CAs decision-making process in the event of a disease outbreak.
- The SIMAN allows for exchange of a number of predefined types of information between, and within, all relevant CAs for animal health in Italy. The results of all epidemiological inquiries are available on a special module in the SIMAN, as well as details of other official activities related to the implementation of disease eradication measures, such as sampling activities, animal depopulation and cleaning and disinfection.
 - The SIMAN has additional features that enable staff of all CAs to carry out extensive forward and back-tracing of animal movements and to quickly identify all possible epidemiological connections with the affected herds/flocks.
38. The SIMAN has integrated geographical information systems, which can interplay with the other sources of information in and outside the system, such as meteorological data. Those capabilities together with the support of epidemiologists from the relevant laboratory enables the CAs at all levels, to anticipate the evolution of the disease spread and to delimit and adapt accordingly the boundaries of protection and surveillance zones. The audit team got examples in relation to recent outbreaks of HPAI.
39. In addition to the SIMAN, the RVS have developed, or were in the process of developing, their own animal health information management systems. In the case of Lombardy and Tuscany, they went beyond the capabilities currently available in the SIMAN. The development of those systems had not been coordinated and there was no evidence that their operation in the event of an outbreak affecting several regions would

facilitate adequate levels of cooperation and coordination, in particular in relation to the regular exchange of epidemiological information.

40. The operation of the existing national animal identification and registration system seems to be fit-for-purpose so as to allow the CAs to both keep a reasonable overview of the level of compliance ensured by the operators and perform the animal traceability exercises needed in the event of animal disease outbreaks, in particular in high animal density areas.
 - The national reference centre for animal identification, responsible for the operation of the national database, informs monthly the RVS of the delays on notifiable events (e.g. animal movements) and of other possible inconsistencies based on a number of standard queries that they run regularly in the database. The RVS pass this information to the ASL responsible, who in turn liaise with the operator to address the situation. In the areas visited by the audit team, this activity was done regularly at the ASLs, who target their control activities on those herds that show recurrent non-compliances in various consecutive monthly reports.

5.2.2.3 Communication strategy

Findings

41. The generic national contingency plan includes basic instructions on communication in the event of a disease outbreak. In addition, the RVS have made arrangements to ensure that the media and the general public are kept informed in those situations. This is in line with general EU arrangements for contingency planning.
 - The main principle, as verified on-the-spot by the audit team, is that the RVS, the ASLs, and even the NDCC, must ensure that there is a unique line of communication with the media and with other stakeholders during the acute phase of an outbreak. It also makes reference to standard sources of information, e.g. Websites with fit-for-purpose questions & answers about the specific disease and the possible consequences of its outbreaks.
 - All communication is managed by the one in charge of the relevant control centre, who should count on staff with expertise on media communication. The audit team saw examples of it in the three regions visited in relation to recent outbreaks of HPAI and low pathogenic AI, and to past outbreaks of swine vesicular disease.

5.2.3 Technical and epidemiological expertise

5.2.3.1 Availability of expert groups

Findings

42. In accordance with EU requirements, both the CCA, notably the national crisis management centre for animal diseases, and the RVS can receive support from expert groups on exotic animal diseases.

- A number of national reference centres for all exotic diseases covered by EU legislation, as well as a national reference centre for the epidemiology of animal diseases, have been designated to operate on a permanent basis in order to provide expertise and advice on disease preparedness, and assistance to all CAs in the event of an outbreak.
 - The Websites of those centres offer an enormous array of information on the diseases under their responsibility and they organise frequent training sessions for the various CAs in Italy.
43. In accordance with EU requirements, the national reference centres for AI and FMD can provide expert knowledge on all possible dimensions of the epidemiology and diagnosis of those diseases. Their staff have confronted numerous outbreaks of those diseases nationally and internationally and ensure a vast experience on the adaptation and selection of the most suitable control and eradication measures to the various epidemiological situations that may be found in the different regions of Italy. This was verified by the audit team during the visit to the centre.
44. In all the ASLs visited, at least one member of the staff, along with some staff of the relevant RVS, has extensive epidemiological expertise that would enable them to address the situation in case of minor disease outbreaks. In the event of outbreaks of AI and FMD, the CAs indicated they would always involve the national reference centres.

5.2.3.2 Epidemiological inquiries and surveys

45. Official veterinarians of the ASLs, on their own or with the support of epidemiologists from the regional or provincial laboratory, are responsible for performing the epidemiological inquiries related to the suspicion or confirmation of an exotic disease. The audit team saw a few excellent examples of training on how to carry out epidemiological inquiries provided by staff of some ASLs to other staff of the same or other ASL (see 5.2.4.2).
46. The audit team reviewed some examples of epidemiological investigations carried out in the context of suspicions of AI and FMD, and after HPAI had been confirmed. They were comprehensive and in line with requirements laid down in Directives 2005/94/EC (AI) and 2003/85/EC (FMD).

5.2.4 Availability of human resources and training of staff

5.2.4.1 Personnel – availability and distribution of responsibilities

Findings

47. Staff met who had been given responsibilities in the context of the operation of the NDCC and the R/LDCCs in the event of an exotic disease outbreak were, in general, very capable of performing the associated tasks in accordance with the instructions provided in the generic national contingency plan, in the specific operational manuals and in the staff operation manuals.

48. In the three regions visited there were arrangements in place to ensure that in case of need, staff from other ASLs and also other external personnel with basic and specialised technical qualifications- who had been identified and their details listed by the RVS or the ASLs- could be called in to assist in the disease containment and eradication activities (e.g. private veterinary practitioners, competent personnel for animal depopulation, operators of machinery for the burial sites, etc.). This is in line with specific EU provisions on contingency planning.
49. The staff operation manuals seen in the ASLs visited contained details describing how the specific tasks had been assigned to individual members of the LDCC; e.g. the various managerial responsibilities, the administrative tasks, tasks related to coordination of animal depopulation, to verification of cleaning and disinfection activities, etc.

5.2.4.2 Staff training

Findings

50. Staff of all the ASLs visited are regularly involved in training courses focusing on the clinical signs and generic control measures of the main exotic diseases.
 - The audit team saw examples of a wide variety of training courses on animal exotic diseases that were organised and/or attended by their staff. They were delivered by the CCA, or relevant laboratories for the diseases, the University and other ASLs. There was also evidence of staff who had attended specific courses organised by the European Commission for the control of FMD and contingency plans.
 - Only a few of those training courses focused on the operational side of the emergency preparedness systems at local, regional or national level, and they rarely went beyond generic material on the specific diseases. Only in a few cases they did include training on how to perform epidemiological enquiries or animal depopulation.
51. The CCA, in cooperation with the national reference centre for animal welfare, had organised a generic training activity in November 2013 to enhance the level of preparedness of the RVS with the intention to cascade the knowledge to ASLs, in relation to animal depopulation. The objective was to enable them to use properly the standard operating procedures laid down in the generic national contingency plan and, a) select the method for stunning and killing taking 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.
52. Various ASLs in the regions visited were involved in outbreaks of HPAI and low pathogenic AI since 2013. The reports on those activities were sent to the Commission with all the information required by Article 18 (4) of Regulation (EC) No 1099/2009. Those reports had been uploaded onto the SIMAN and were accessible to all ASLs in Italy. In all cases, limited attention had been paid to them and to the experience gained with the killing methods and other depopulation practices used in those situations.

53. Despite the national training organised in 2013, hardly any training and absence of practical guidance on how to draft action plans before the animals are killed were the realities found in most of the ASLs visited.

5.2.5 Access to facilities, equipment and other materials

5.2.5.1 General arrangements

Findings

54. Most of the RVS and the ASLs visited had general arrangements in accordance with specific EU requirements on contingency planning to ensure the availability of the equipment necessary to facilitate the rapid deployment of disease containment and eradication measures in the event of an exotic disease outbreak. There was no overview of the level of preparedness nationwide.

- A number of wide-ranging emergency packages were available in the premises of all the ASLs visited in order to ensure rapid deployment of staff to farms could be done (containing, for example, protective clothing, sampling and necropsy equipment or material for personal disinfection).
- The availability of sufficient equipment relies also on the mobilisation of resources accessible at local and regional level under general crisis management provisions. The RDCC has the powers to reallocate the necessary equipment from non-affected ASLs to the affected ones.
- Representatives of the CCA confirmed that there is no provision in place at national level for them to have an overview of the level of equipment available in all RVS and ASLs in Italy in the context of their animal health emergency preparedness systems.

55. The RVS and the ASLs visited had different levels of preparedness regarding the material resources necessary to carry out stunning and killing operations during animal depopulation in the event of a disease outbreak required in Regulation (EC) No 1099/2009.

- Some of the RVS and ASLs have contracts and arrangements with private companies, who would take care of animal depopulation and disposal of animal carcasses. Others stated that they would find solutions when the problem occurs.
- The instructions in the generic national contingency plan require the ASLs to identify all material resources needed for each stunning and killing method that could be used in the event of a localised disease outbreak. The audit team noted that this had been done in general in relation to some equipment, such as captive bolts for animal stunning, but not in relation to other resources such as options to use gas in the event of disease outbreaks affecting poultry and pigs.

5.2.5.2 *Diagnostic capabilities and capacity in case of emergency*

Findings

56. The NRLs for AI and FMD have developed their own laboratory contingency plans, which include an evaluation of their capacity, and that of other regional and provincial laboratories included in their diagnostic network, 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

57. The animal health emergency preparedness systems in place in the regions visited have profited from past outbreaks of AI. The audit team observed signs of lessons learnt from those events in the current arrangements for contingency planning for the disease in that part of Italy; e.g. in the Veneto region. Likewise, in Lombardy, the system has evolved as a result of the lessons learned from past outbreaks of swine vesicular disease, which were eradicated successfully despite the high density of pig herds and animals in the affected areas. However, no policy has been set out at any level of the CAs in relation to the organisation with certain frequency of real-time exercises or alarm drills for exotic animal diseases in accordance with requirements laid down in EU legislation, in particular on FMD.
- The audit team saw evidence on some small scale exercises organised by ASLs. The results had not been shared with other ASLs and they did not contribute to improving the general preparedness at regional and national level. One of those exercises underlined the difficulties inherent to deal with outbreaks of a highly contagious exotic disease such as FMD, and important steps had to be taken by the ASL that organised it to address the deficiencies found.
 - There is no overview of the organisation of those exercises by the ASLs, or by the RVS.
 - None of the relevant national reference centres for exotic animal diseases and their epidemiology has studied the dynamics and impact of possible outbreaks in order to prioritise attention to the weaker components of the emergency preparedness system (e.g. through modelling getting information from the actual organisation of the various CAs, by taking into account the possible involvement of several regions, etc.).
 - In the last five years two minor, or geographically localised, real-time regional or national simulation exercises were organised: one organised in 2010 by the RVS in Sardinia on African horse sickness and one in 2011 for FMD, with the involvement of the NDCC, but with a reduced geographical scope (one cattle herd in one University).
58. The organisation of real-time alert exercises for FMD in Italy cannot be considered in compliance with requirements laid down in Directive 2003/85/EC (Art. 73 and Annex

XVII, point 11.2): The national real-time alert exercise organised in relation to FMD in 2011 had very limited scope, there were a significant number of high densely populated livestock areas with many FMD susceptible animals in the regions visited, there is a new set of contingency planning tools available to all CAs in recent years, the local real-time exercises uncovered deficiencies in the level of preparedness in some ASLs during, and the CCA does not have a good overview of that level of preparedness nationwide.

Conclusions on the readiness and operation of the emergency preparedness system

59. The operation of the NDCC and R/LDCCs is well defined and supported by largely sufficient human and material resources which will contribute to the effective control of outbreaks.
60. The ability of the NRLs for AI and FMD to provide CAs with rapid and reliable results for the diagnosis of those diseases and the existence of internal contingency plans ensures that feasible options to cope with diagnostics are in place in unexpected emergency situations.
61. The available operational expert groups for AI and FMD assist the CAs in ensuring adequate preparedness against those diseases and in the effective early containment of outbreaks.
62. The animal health information management systems available to the CAs are largely adequate to facilitate the effective deployment of an early response to a disease outbreak and to speed its follow-up. They will also ease up the selection of actions, particularly in the event of disease outbreaks happening within one region. As the interaction and effective compatibility of the systems in place at regional and national level has not been verified, it is not clear whether they will facilitate or undermine, the necessary coordination between all RVS involved and with the NDCC in the event of an outbreak affecting various regions.
63. The integration of the existing national database for animal identification and registration in the animal health information management systems should contribute effectively to provide quickly reliable data on animal traceability, facilitating the correct targeting of actions to contain diseases (particularly in a widespread disease outbreak).
64. The fact that official staff is in general appropriately trained for their tasks, will ease the deployment of contingency activities. The exceptions in this respect relate to the implementation of animal depopulation, where the absence of adequate training may undermine the protection of the welfare of animals.
65. The CAs have not taken sufficient action to organise adequate and frequent real-time exercises to test the fitness for purpose of the arrangements for contingency planning available for FMD at regional and national level and where they were organised, they do not have an adequate overview (number, scope and quality of the exercises). This limits the possibility for the CCA to coordinate, review and update the level of national animal health emergency preparedness, in particular for FMD.

6 OVERALL CONCLUSIONS

The animal health emergency preparedness system in place in Italy has the technical and material resources available to be effective. The systems evaluated at regional and local level are largely adequate to manage the early response to a localised disease outbreak.

The level of preparedness for avian influenza is satisfactory and stems from the excellent technical advice and experience provided by the national reference centre for the disease and from the enhancement of the emergency response systems in the regions visited (which is the result of lessons learnt from managing frequent outbreaks in recent years).

Although the national reference centre for foot-and-mouth disease guarantees an excellent level of expertise, there are doubts as to whether the regions visited would be able to respond rapidly to, and contain effectively a large outbreak of the disease, as:

- There is insufficient coordination and verification at national and regional level of the development and potential operability of the emergency preparedness systems for this disease.
- Limited attention has been paid to address interlinked factors that will play a major role in the event of a widespread disease outbreak; e.g. options to cope with those situations in high densely populated areas, arrangements for emergency vaccination and operational options for animal depopulation and disposal of a large number of animal carcasses.
- The organisation of real-time exercises has been inadequate and has not contributed effectively to verify the fitness-for-purpose of the arrangements in place for contingency planning for the disease.

7 CLOSING MEETING

A closing meeting was held on 23 October 2015 with representatives of the CAs. At this meeting, the main findings and conclusions of the audit were presented by the audit team. The representatives of the CAs did not indicate any major disagreement with the findings and preliminary conclusions.

8 RECOMMENDATIONS

The CAs are invited to provide, within 25 working days of receipt of the report, an action plan containing details of the actions taken and planned, including deadlines for their completion, aimed at addressing the recommendation set out below:

No.	Recommendation
1.	<p>To ensure that contingency plans and staff operation manuals are drawn up and kept updated for the diseases listed in Annex I to Council Directive 92/119/EEC as required by EU legislation.</p> <p>Specific EU legal requirements laid down for each exotic disease listed in Appendix to this report (specifically those related to chapters 5.1.1 and 5.1.2).</p> <p>Based on conclusions (21) and associated findings (1), (4) and (8).</p>
2.	<p>To ensure that a swift and coordinated response could be given in the event of a widespread disease outbreak of FMD or AI affecting more than one region by having an overview of the level of preparedness available in all RVS and ASLs – i.e. that their plans and manuals are fully fit for purpose and applicable.</p> <p>Article 4 (2)(f) of Regulation (EC) No 882/2004; criteria for contingency planning listed in Appendix to this report.</p> <p>Based on conclusions (22) and (62), and associated findings (5), (39), (54) and (55).</p>
3.	<p>To identify and analyse the epidemiological factors and operational criteria (e.g. identification of risk areas with high density of susceptible animal populations, availability of sufficient carcass disposal capacity, clear vaccination strategy for FMD and AI) that would allow CAs to take a well-informed decision on the application of additional eradication measures – such as pre-emptive animal depopulation and emergency vaccination – in the event of a large outbreak of FMD, and to a lesser extent, of HPAI.</p> <p>Article 72 (3) of, and Annexes XVII (point 12) and X to Directive 2003/85/EC. Article 62 (2) of, and Annex X (point 9) to Directive 2005/94/EC.</p> <p>Based on conclusions (22) and (24) and associated findings (14), (15), (17), (18) and (58).</p>
4.	<p>To ensure that, on the basis of the various possible scenarios for the size and location of exotic disease outbreaks, staff at the RVS and ASLs are capable of preparing adequate action plans for depopulation operations in order to safeguard the welfare of the animals.</p> <p>Article 18 of Regulation (EC) No 1099/2009.</p> <p>Based on conclusions (23), and associated findings (14), (15) (53) and (55).</p>

No.	Recommendation
5.	<p>To ensure that the requirements for real-time alert exercises for FMD (minimum frequency and scope) laid down in EU legislation are met. Thus, the real-time exercises could effectively contribute to: a) training personnel designated to be involved in an emergency situation, and b) testing, critically reviewing and up-dating contingency plans, emergency preparedness arrangements in general and disease eradication strategies at national, regional and local level.</p> <p>Article 73 and Annex XVII (point 11.2) to Directive 2003/85/EC.</p> <p>Based on conclusion (65), and associated findings (57) and (58).</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 OPERATION 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)							
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	

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	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=2015-7569

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

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

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