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FINAL REPORT OF AN AUDIT

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FROM 24 TO 28 SEPTEMBER 2012

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 a Food and Veterinary Office audit in Portugal carried out between 24 and 28 September 2012, as part of the FVO audit programme. The objective was to evaluate the resources and arrangements put in place to implement the European Union requirements for contingency planning, including provisions on the protection of animals during depopulation, in the event of one or more outbreaks of epizootic diseases.

Overall the report concludes that:

CAs have been designated and sufficient legal powers are available to develop CPs and control epizootic outbreaks in accordance with the requirements of Regulation (EC) No 882/2004.

With the recent updating of the Common Core and MOs the CA have provided themselves with the necessary instruments to operate in a case of an animal health emergency. The provisions in those documents, along with the capacity to swiftly set up a NDCC and/or a LDCC would allow the CA to become quickly operative to act in an emergency. The unfinished geo-referencing of holdings, and lack of completeness concerning identification of high livestock density areas and vaccination, and some cases of insufficient integration (e.g. sampling in case of suspicion) or clarity (e.g. interface with civil defence services, instructions on killing methods) are not likely to impede significantly the possibility of the CA to adequately face an animal health emergency.

Active monitoring is performed for BT, AI and CSF/ASF, with risks assessed and measures taken accordingly. All other diseases are under passive surveillance.

The NRL has the capacity to diagnose the main epizootic diseases, and its grade of preparedness in case of contingency is being improved with the development of its own CP. However, it has not secured or adequately documented the alternative path for diseases it cannot confirm. Despite the fact that none of the methods used have been accredited, important elements of quality assurance are in place, but they are still incomplete, and the tests lack formal validation.

The CA has dedicated a significant amount of work to adapting its systems and procedures to bring them into compliance with the requirements of Regulation (EC) No 1099/2009. That work has succeeded in bringing the existing system already close to full compliance prior to that Regulation applying from 1st January 2013. Nevertheless the lack of identification of a maximum estimated kill rate for the killing methods, clear SOP, and a better separation and clarification of tasks between reference documents are areas that can still be improved

The systems in place provides adequate provisions to ensure that carcass disposal does not cause environmental damage and that carcasses would be processed in line with requirements.

The report makes recommendations to the Competent Authorities aimed at rectifying the shortcomings identified and addressing areas in which further improvements are required.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

| | |
|-----------|---|
| ABP | Animal by-products |
| AHS | African Horse Sickness |
| AI | Avian Influenza |
| ASF | African Swine Fever |
| BT | Bluetongue |
| CA | Competent Authorities |
| CDOS | Civil defence services, district level |
| CNOS | Civil defence services, national level |
| CP | Contingency Plan |
| CSF | Classical Swine Fever |
| DG(SANCO) | Health and Consumers Directorate General |
| DGADR | Directorate-General for Agricultural and Rural Development (<i>Direcção-Geral de Agricultura e Desenvolvimento Rural</i>) |
| DGAV | Directorate-General for Food and Veterinary issues (<i>Direcção-Geral de Alimentação e Veterinária</i>) |
| EHD | Epizootic Hemorrhagic Disease |
| EU-RL | European Union Reference Laboratory |
| FMD | Foot-and-Mouth Disease |
| FVO | Food and Veterinary Office |
| HPAI | High Pathogenic Avian Influenza |
| INIAV | <i>Instituto Nacional de Investigação Agrária e Veterinária</i> , the national reference laboratory |
| LDCC | Local Disease Control Centre |
| LPAI | Low Pathogenic Avian Influenza |
| MO | Manual of Operations |
| MS | Member State |
| ND | Newcastle Disease |
| NDCC | National Disease Control Centre |
| NRL | National Reference Laboratory |
| OIE | World Organisation for Animal Health |
| OV | Official Veterinarian |
| SOP | Standard Operating Procedure |
| SVD | Swine Vesicular Disease |

1 INTRODUCTION

This audit took place in Portugal from 24 to 28 September 2012 and was undertaken as part of the Food and Veterinary Office (FVO) planned audit programme. The audit team comprised three auditors from the FVO and a National Expert. The team was accompanied throughout the audit by representatives of the Directorate-General for Food and Veterinary issues which is the Competent Authority within the scope of this audit.

2 OBJECTIVES

The principal objective of this audit was to evaluate the resources and arrangements put in place to implement the European Union requirements for contingency planning, including provisions on the protection of animals during depopulation, in the event of one or more outbreaks of the following epizootic diseases: Foot & Mouth Disease (FMD), Bluetongue (BT), Classical Swine Fever (CSF), African Swine Fever (ASF), Swine Vesicular Disease (SVD), African Horse Sickness (AHS), Avian Influenza (AI), Newcastle Disease (ND) and a number of other diseases.

A secondary objective was to gather information and to identify areas of best practice in relation to a number of issues relevant to epizootic disease control but not explicitly specified in EU legislation. Such issues include routine monitoring for epizootic disease, the deployment of risk analysis with subsequent determination of alert levels and Member State (MS) requirements for biosecurity measures on farms.

Whilst contingency planning for all of these diseases is included within the scope of this audit, the audit will concentrate on FMD, AI and BT. FMD is one of the most difficult diseases to contain and affects several livestock species. AI is chosen as an example of a poultry disease where specific requirements for contingency plans (CP) are laid down in European legislation. BT is a disease which has frequently occurred in Portugal in recent years. This evaluation will include a follow-up of the actions taken by the competent authorities following the recommendations of certain previous audits as far as contingency plan issues are concerned (audit DG(SANCO)/2003-9102 and DG(SANCO)/2006-8197).

Although the requirements of Council Regulation (EC) No 1099/2009 will only come into force in 1 January 2013 the FVO team carried out a preliminary evaluation of the current state of preparedness of the competent authorities (hereafter: CA) to comply with the requirements of its Article 18 (1), (2) and (3).

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

| Visits | | | Comments |
|-------------------------|----------|---|--|
| Competent authority | Central | 2 | Opening and closing meetings, representatives from civil defence, police forces and laboratory staff were also present. The NDCC was also visited. |
| | Regional | 2 | Alentejo and Lisboa Vale do Tejo regions. Respective LDCC sites were also visited. |
| Laboratory | | 1 | The national reference laboratory. |
| Other official services | | 1 | District command for relief operations (Civil Defence) |

| Visits | | Comments |
|-------------------------------|---|--|
| Holdings | 3 | One each for poultry, pigs and sheep. |
| Markets / Live animal auction | 2 | One of each, dealing mainly in bovine animals and sheep. |
| Slaughterhouses | 2 | One for poultry and another for ruminants and pigs |
| ABP processing plant | 1 | Location where in some cases carcasses would be disposed of in the event of an epizootic outbreak. |

The sites were selected by the FVO team.

3 LEGAL BASIS

The audit was carried out under the general provisions of Community legislation, and in particular Article 45 of Regulation (EC) 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.

4 BACKGROUND

Given the potential impact of outbreaks of epizootic disease, 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 CPs in place to combat such outbreaks so as to reduce their adverse consequences.

Of critical importance to the suppression of an outbreak of epizootic disease, is the swiftness of initial diagnosis and the deployment of the first stages of the CP.

| Disease | Year of last occurrence |
|---------|---------------------------|
| FMD | 1984 |
| CSF | 1985 |
| AHS | 1989 |
| ND | 1997 |
| ASF | 1999 |
| SVD | 2007 |
| AI | HPAI: never LPAI: 2008 |
| BT | BTV4: 2008 BTV1: 2012 |

(source: OIE, ADNS)

Previous audits in 2003 and 2006 also covered CP issues (audit DG(SANCO)/2003-9102 and DG(SANCO)/2006-8197). The CA indicated that certain actions had been taken in response to the recommendations, and the effectiveness of some of these actions was also assessed during the current audit.

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITY

Legal requirements

Regulation (EC) No 882/2004 lays down rules for the performance of official controls; in particular Article 4 requires the designation of competent authorities; co-ordination and co-operation between and within competent authorities and that sufficient legal powers are available to the competent authorities. The availability of sufficient legal powers for the implementation of contingency plan is specified in most of the relevant Directives (see Annex 2). In addition Council Directive 2003/85/EC (Article 74 (3)(d), and (i)) requires close cooperation with other authorities and enforcement bodies in relation to FMD control and Council Directive 2005/94/EC on the control of avian influenza (Article 62 (3)) requires close cooperation between the competent authorities responsible for the different sectors, particularly those in charge of animal health, public health, environmental matters and health and safety of workers.

Article 18 (1) of Regulation (EC) No 1099/2009 requires that the stunning and killing methods planned and the corresponding standard operating procedures for ensuring compliance with the rules laid down in the Regulation shall be included in the contingency plans required under Union law on animal health, on the basis of the hypothesis established in the contingency plan concerning the size and location of suspected outbreaks.

Findings

5.1.1 *Competent authority structure*

The organisation of the CA is described in the country profile of Portugal on control systems over food and feed safety, animal health, animal welfare and plant health which is accessible at: http://ec.europa.eu/food/fvo/country_profiles_en.cfm. This provides information on the responsibilities of the competent authorities under normal circumstances.

There have been some changes in the CA structures since the country profile was last updated and the lead authority for animal health control and protection of animals at the time of killing has gained some additional responsibilities in new areas and has changed name. It is now the Directorate-General for Food and Veterinary issues (*Direcção-Geral de Alimentação e Veterinária*, DGAV), instead of Directorate-General for Veterinary issues (DGV) as referenced in the country profile. Not all organisational changes caused by the reorganisation of the services have been implemented yet. Nevertheless the system of controls over animal health and protection of animals at the time of killing remains basically the same.

The development of CPs requires extensive cooperation within and between competent authorities and responsibilities of the various CAs when dealing with an outbreak of epizootic disease to be formally defined and agreed in advance. Section 5.2.3 below, outlines the responsibilities of the various CAs for dealing with an epizootic outbreak, as designated in the CP.

5.1.2 *Legal powers available to the competent authorities*

- The legislation in place (Decree Law 39209) provides adequate legal powers to the CA namely regarding power of entry, imposition of movement restrictions, establishment and

enforcement of protection and surveillance zones, order immediate slaughter or killing, impose cleaning and disinfection, destruction of carcasses and animal products, etc.

5.1.3 Cooperation between and within competent authorities in development of contingency plans

- The CPs in Portugal have been developed with a main shared part for all diseases, the "Common Core CP", supported by disease specific detailed Manuals of Operations (MOs) for all the relevant diseases.
- There was a meeting between the central level and the regions in December 2011 in which the updating of the CP were discussed. In addition to that meeting all the regions designated representatives to deal with updating of the CP and were given the opportunity to comment on its drafts.
- Evidence was provided to the FVO team of contacts and agreements established by DGAV with other relevant institutions (e.g. civil defence, police) that could need to be involved in controlling outbreaks, as required by Directives 2003/85/EC and 2005/94/EC (see also section 5.2.3).
- The national reference laboratory was not formally involved in the revision process of the CPs and MOs, in particular for the revision of information related to sampling and transport media¹, or procedures for contacting the laboratory. However, DGAV indicated that they had the necessary contact numbers to reach the virology department at any time.
- Specific "Depopulation Guidelines" (*Guia prático de manejo e despovoamento de espécies pecuárias em situações de emergência*) applicable to all relevant species were also developed in order to prepare for compliance with the animal welfare requirements of Regulation (EC) No 1099/2009 which will apply from 1st January 2013.
- The Depopulation Guidelines were issued in July 2012. Guidelines are established for depopulation operations, defining the slaughter methods most appropriate to each species, animal behaviour characteristics, etc, clearly showing quite an extensive amount of work dedicated to them. However, no hypothesis is established in the Common Core (or in the MOs) on the size and location of suspected outbreaks.
- Under the Multi-annual National Control Plan the DGAV has control procedures to verify the implementation of the provisions for contingency planning at regional and local levels. Reports of two such controls (one in 2010 another in 2011) were provided to the FVO team. In both cases only minor non-compliances concerning equipment and supplies storage had been detected (see also section 5.2.11).

Conclusions

CAs have been designated and sufficient legal powers are available to develop CPs and control epizootic outbreaks in accordance with the requirements of Regulation (EC) No 882/2004. The cooperation with other authorities is also in place as required.

However, the requirement of Art. 18 (1) of Regulation (EC) No 1099/2009 to establish in the contingency plan an hypothesis concerning the size and location of suspected outbreaks has not been complied with yet.

¹ In their response to the draft report the Competent Authority noted that after the national reference laboratory finalises its own contingency plan the CPs and MOs will be brought into line with it in the relevant areas.

5.2 CONTINGENCY PLANS

Legal requirements

Requirements for Member States to have contingency plans to control disease outbreaks are in place for the following diseases: Foot & Mouth Disease (Council Directive 2003/85/EC), Bluetongue (Council Directive 2000/75/EC), Classical Swine Fever (Council Directive 2001/89/EC), African Swine Fever (Council Directive 2002/60/EC), Swine Vesicular Disease and a number of other diseases (Council Directive 92/119/EEC), African Horse Sickness (Council Directive 92/35/EEC), Avian Influenza (Council Directive 2005/94/EC) and Newcastle Disease (Council Directive 92/66/EEC). A summary of some specific requirements of each is provided in Annex 2.

Article 18 of Council Regulation (EC) No 1099/2009 requires that the stunning and killing methods planned and the corresponding standard operating procedures for ensuring compliance with the rules laid down in the Regulation shall be included in the contingency plans required under Union law on animal health.

Requirements relating to holding registration, animal identification and movement controls for cattle, sheep and pigs are laid down in Regulation (EC) No 1760/2000, Council Regulation (EC) No 21/2004 and Council Directive 2008/71/EC respectively, and associated implementing measures.

Findings

5.2.1 Coverage and approval

- DGAV has recently published a “Common Core CP” for all diseases for which a CP is required by EU legislation. The Common Core is complemented by MOs for each disease and they were sent to the Commission services for approval in September 2012.
- The Common Core and MOs are published on the intranet as well as in the internet in order for officials and external persons or entities to be able to access them. The DGAV website shows exclusively the current versions, each with a 2012 indication in the cover page.
- The FVO team saw that printed copies of the relevant updated MOs were available in all premises visited.
- The Common Core and/or relevant MOs include provisions to take into consideration activities concerning wildlife in cases where wild species would be part of the epidemiological cycle of a particular disease. The provisions concerning AI in wild birds allowed for immediate issuance of guidelines to strengthen bio-security measures in poultry farms in 2007. Furthermore in the case of a contingency situation of an emerging disease in big game, the DGAV can amend the existing "Edict no. 1 - Tuberculosis in big game" as needed, in conjunction with hunting management bodies.

5.2.2 Documentation

5.2.2.1 Operational manuals & instructions

- The Common Core and MOs follow in general the criteria defined in EU legislation and OIE for suspicion or confirmation of any disease.
- The FVO team was informed that the implementation of measures on the ground for any suspicion or confirmation of a new emerging disease for which MOs are not defined, would follow the procedures laid down in the Common Core, in accordance with requirements of the relevant EU legislation and the applicable chapter of the OIE Sanitary Code for Terrestrial Animals. Furthermore, it was also explained that in case of a suspicion or

confirmation of a new emerging disease a specific Edict will always be published with the precise details of all procedures to be implemented.

- The Common Core contains the required information, in the form of lists, of the different people and organisations that would be affected by an outbreak of infectious disease.
- The FVO team analysed the Common Core and MOs and confirmed that these documents have sufficient provisions to effectively activate a suspicion and confirmation procedure in the presence of a known infectious disease or in case of an emerging disease. However, it was also noted that the MOs can vary in the level of details given for similar procedures. Examples of this are the details given in the FMD and AI manuals on sampling methods, specifically concerning the medium to be used to send pathological material to the laboratory in case of suspicion of an infectious disease. Instructions on killing methods in case of outbreaks are another example (see also section 5.5.1, bullet points 4 and 5).

5.2.2.2 System for reviewing/updating

- Nobody has been formally designated at central level as responsible for ensuring that the Common Core and MOs are revised periodically and kept updated and there is also no formalised frequency established to review and update the manuals.
- DGAV explained that in general an updating of the CP can happen to incorporate new lessons learned while dealing with outbreaks of infectious diseases and in the event of structural re-organisations within the CAs structure. DGAV stated that for example during the 2012 update it took into account the results and experience from dealing with the 2007 outbreak of low pathogenic avian influenza (LPAI).
- The updating of CPs is done in conjunction with the regional veterinary services and evidence of this was provided to the FVO team. In 2012 the Common Core and all the revised MOs were issued and placed in the publicly available part of the DGAV web page. DGAV stated that it is intended to have another meeting with the regions before the end of 2012 to discuss these recent updates.
- The regions have the possibility of drafting their own CPs and during the audit it was seen that one of the regions visited had drafted its own CP.

5.2.3 Competent authority command structure during an epizootic outbreak

- The chain of command regarding control of epizootic disease outbreaks within the structure of the CA has two levels: national and regional. The DGAV Director General as the head of the National Disease Control Centre (NDCC) is ultimately responsible for disease control at national level. At regional level the operations will be under the command of a local disease control centre (LDCC) which can be set up at the regional or district office.
- The FVO team was informed that in case of an outbreak, the veterinary authorities will also work in collaboration with the Civil Defence services at national level, the “CNOS” (*Comando Nacional de Operações de Socorro*), and district level, the “CDOS” (*Comando Distrital de Operações de Socorro*), which are responsible for coordinating relief operations due to all types of emergencies such as earthquakes, floods, fires, etc. The Civil Defence services have the competence, and all the contacts established and maintained, to provide quick logistical support, link up with police authorities to block roads, and other authorities to obtain diggers, portable toilets, tents, food, lighting equipment, generators, etc.
- Although the CDOS was involved already in dealing with the LPAI outbreak in 2007 this important interface with CNOS/CDOS, that allows the NDCC (or LDCC) to focus on

addressing the animal health and welfare aspects of the operations and not also all the essential support activities, is not clear in the Common Core or MOs.

- In 2005 with the appearance of a zoonotic disease, AI, in some countries in Europe an “AI Monitoring Committee” was nominated in Portugal with the DGAV Director General designated as president and with participation from the NRL and the Directorate General for Health (*Direcção-Geral de Saúde*). Evidence was provided that even in the case of an AI outbreak with possible human health implications DGAV is ultimately responsible for dealing with outbreaks.

5.2.4 National disease control centre

- The Director General of DGAV is in permanence the coordinator of the NDCC even if such a structure is not activated in peacetime. Nevertheless the CA always carries out a series of activities that would allow an immediate activation of the structure, if the need arises:
 - a particular room has been defined that could quickly and easily be adapted as needed to convert it into the NDCC headquarters. The room allows for mapping and communication tools to be used immediately;
 - an updated list of international and national contacts is maintained;
 - regular contact via phone is maintained with all the veterinary hierarchy throughout the country;
 - there is permanent access to the various database used to manage the registration of holdings and movements of animals;
 - updated lists of the veterinary officials operating throughout the country are maintained;
 - acquisition of materials and equipment to be used in routine veterinary activities, as well as in emergency situations, with regular contact maintained with regions to assess their needs;
 - a list of facilities for cleaning, disinfection and applying insecticides to means of transport used for the carriage of live animals is available on the DGAV website, as well as a list of approved disinfectants;
 - records of people that have attended training relevant to emergency situations and people that have operated in cases of outbreaks in the past are kept, and were provided to the FVO team.
- The FVO team noted also that, although DGAV has access to software to map areas where infection is present (or into which it could spread) some information concerning localisation of holdings and in particular the areas of high density of livestock are not readily defined as required by EU legislation concerning FMD and CSF (Art. 72 (3) (b) of Dir. 2003/85 and Art. 22 (1) (b) of Dir. 2001/89, respectively).
- The mapping of infected and surveillance areas can also be done, in collaboration with the regional offices, although geo-referencing of holdings is not yet finalised. If no further delays occur the geo-referencing of holdings should be finalised by March 2013.
- The localisation of holdings, and the definition of their health status, would also imply at present the use of different databases (and even other types of records) at the same time, which could be cumbersome in certain cases and in particular for holdings that have only a “mark” since they are not licensed (see also section 5.2.5).

- At present no definition is done at national level of suitable burial sites. The policy of the CA is that in case of an outbreak fallen animals should not be moved from the place of killing or death and that burial sites would only be defined case by case, by a regional service, in the area where an outbreak would arise (see also section 5.6).

5.2.5 Local disease control centre

- The LDCC can also be quickly set up, at regional or district level. Both regions visited had singled out a room where the headquarters of the LDCC would be located in case of emergency and necessary basic equipment was readily available, including communication and mapping equipment.
- CAs have access in their regional or district offices to the databases needed to identify holdings in and around infected zones. This allows listing holdings in those zones relatively swiftly, with the exception of holdings which only have a “mark” but no license (e.g. locations with only one pig for own consumption). Identification of which of these holdings would be in and around infected zones would be a bit more laborious, although still possible.
- Lists complete with all relevant information were available concerning veterinary staff (official or private), slaughterhouses and transporters. The lists are similar to those available at central level, but are more complete and informative. However, in one region visited the lists were not updated.
- Evidence of formal contacts, in the form of e-mails exchanged between CAs and local slaughterhouses were found in one of the regions visited. The slaughterhouses confirmed their availability, in case of emergency killing of animals, to provide both stunning equipment and staff to the LDCC. It was however not clear to what extent these intentions of collaboration would be binding in a case of widespread or long lasting outbreaks.

5.2.6 Financial provisions

- The DGAV has its own operating budget and in addition the Decrees-Law No 327/2007 and 199/2012 would also allow financing for urgent or exceptional expenditures.
- If compensation has to be paid because of an outbreak there is an official bulletin, updated weekly, that details the current market price for the usual species (including laying hens according to their age) that would be used to establish the compensation to be paid.
- The procedure above was common knowledge among the officials supposed to use them, and seems to have been already consistently applied, but is not described in the CP.
- One practical example of a case of urgent need of funds for a specific localised situation happened in 2007 with the need to buy CO₂ for depopulation. The DGAV gave a delegation to the LDCC veterinarian in charge and CO₂ was ordered directly from the supplier without having to go through the usual slower process.

5.2.7 Establishment and enforcement of protection and surveillance zones

- Provisions for the establishment of protection and surveillance zone are outlined in the Common Core and in the MOs. The provisions were established providing flexibility at the moment of deciding the zones. The CA can extend or reduce the area of the zones, according to the appreciation of the epidemiological situation. Thus the provisions allow adjusting the radius of the zone according to the disease (1 km instead of 3 in case of LPAI) although in the Common Core only the “standard” 3 and 10 Km areas are mentioned.

- For the sake of better containing a disease, of practicality and to facilitate the identification of zones the CA stated that administrative borders would be considered also and not only the 1-3 or 10 Km radius.
- As already mentioned (see also sections 5.2.4 and 5.2.5) the identification of holdings within the zones is to some degree still influenced by the lack of a complete geo-referencing of all holdings, but still feasible.

5.2.8 Communication to the public during an outbreak

- DGAV informed the FVO team that:
 - although a specific communication chapter is not developed in the Common Core, it is understood by every official that only one entity is allowed to communicate with the public in case of emergency situation in the veterinary field, the secretary of state;
 - communication to the media of slaughter methods and their implications on animal welfare is assumed by the coordinator of the NDCC;
 - the establishment of helplines is also foreseen in case of emergencies. In this case any information provided needs to be first endorsed by the CA.

5.2.9 Availability of epidemiological expertise

- In 2011 an expert from DGAV and one member of the Faculty of Veterinary Medicine (Technical University of Lisbon), an epidemiologist, were appointed to be included in the "Community Veterinary Emergency Team" and are now part of the list published in the DG(SANCO) website at http://ec.europa.eu/food/animal/cvet_en.htm.
- In 2012 these same two experts together with one more expert from the laboratory INIAV, a virologist, were officially designated as the permanent expert group, necessary according to EU requirements, appointed for all diseases for which a CP is needed. One of these experts, namely the member from the DGAV, would also in principle be one of the main NDCC staff responsible for the management of an outbreak.
- Standard epidemiological enquiry forms are part of the MOs.

5.2.10 Animal identification and movement control

- The movement controls in case of emergency situations are based on the same databases used to control animal movement in peace times. The CA effectively controls in real time any movement of livestock by the issuance of movement documents from a holding to another holding or any other premise such as a slaughterhouse.
- The issuance of the movement documents is based on the database used to identify the holdings (SNIRA). By March 2013 this database should include all licensed holdings for all species. The same database allows the CA to check that movement of cattle is concluded within the required time of 7 days.
- Currently SNIRA is set up to automatically issue template "Auto-de-Noticia" (infringement notices) to either dispatchers or receivers of live animals that have not registered adequately (missing exit or arrival notification) a animal movement within 30 days of it being notified by the other party. If the fine is paid voluntarily the case is closed, if not then it would move into subsequent legal process.
- The CA informed that when this automatic process was initiated (2006) there was a marked

drop in non-compliances. Now the number of non compliances is stable and concerns mainly occasional non-professional activities.

- Specific software is being used in one of the regions to trace pig movements. The FVO team was informed that it is intended (with a draft proposal already drafted) to use this same software in the future for the whole country.

5.2.11 Availability of equipment

- DGAV maintains a central storage from where equipment and materials can be dispatched immediately to the local storage in the regions.
- A detailed and comprehensive inventory of stock is maintained at central level of stock held at both central and regional level.
- The central storage was well stocked and out of date stock seen was properly identified as such.
- DGAV has a long established working relationship with a certain number of private companies for the delivery of material and equipment. However, there is no supply contract in place that would guarantee priority to DGAV over other buyers when acquiring material or equipment.

LDCC

- The two LDCC stores visited had an adequate space for storage of equipment and materials. Likewise they were adequately stocked with materials and equipment, although in certain cases only limited materials were available for sampling. In one store some materials and products were found to be out-of-date and not all identified as such.
- Both LDCC had killing equipment available but it was not maintained (see also section 5.5.1).
- The LDCC visited did not have ready-to-use kits to be carried on the field by veterinarians or technicians, but lists of kits to be used in different situation are available, allowing appropriate kits to be compiled quickly.
- Materials to signal infected areas (posters etc) were readily available; likewise for printed copies of epidemiological enquires forms and labels to identify samples.
- One of the LDCC stores visited had been the object of a control by the central level. Evidence was seen that recommendations to address shortcomings had been dealt with in a positive way.

5.2.12 Vaccination policy and vaccine availability

- General provisions for emergency vaccination are provided both in the Common Core and in the MOs for those diseases for which emergency vaccination can be implemented. Furthermore the Portuguese CAs have an established experience in applying vaccination in emergency situations such as in the BT epidemic, or in the LPAI outbreak of 2007 for which extraordinary vaccination against AI is still implemented in one holding.
- Concerning the above described cases the emergency vaccination decisions were taken at meetings of the Technical Board of DGAV and communicated to the European Commission. The vaccination requirements as well as all measures for disease control were publicized through edicts published in the website and publicized to the representative entities of the sector .

- However in spite of the provisions included in the Common Core and MOs and in spite of the experience acquired in the past, contrary to EU requirements (Art. 72 (3) (a) of Dir. 2003/85 and Art. 62 (2) of Dir. 2005/94) the estimates of vaccine quantities needed in emergency situations are not included in the Common Core or in the MOs.

Conclusions on Contingency Plans

With the recent updating of the Common Core and MOs the CA have provided themselves with the necessary instruments to operate in a case of an emergency in the animal health sector. The provisions in those documents, along with the capacity to swiftly set up a NDCC and/or a LDCC would allow the CA to become quickly operative to act in an emergency.

The unfinished geo-referencing of holdings, and lack of completeness concerning identification of high livestock density areas and vaccination, and some cases of insufficient integration (e.g. sampling in case of suspicion) or clarity (e.g. interface with civil defence services, instructions on killing methods) are not likely to impede significantly the possibility of the CA to adequately face an animal health emergency.

5.3 PREPAREDNESS AND AWARENESS

Legal requirements

For all epizootic diseases relevant to this audit, there is a requirement that any occurrence of the disease is notified to the competent authority. With the exception of AHS, notification to the European Commission is mandatory. Surveillance programmes and systems for early detection of disease are required for BT and AI. For some diseases, risk factors (e.g. areas of high animal density, worst cases scenarios) must be identified within the contingency plan. Specific preparedness and awareness criteria are specified for FMD; for most other relevant diseases, a communications strategy and appropriate communications training are required.

The organisation of real-time alert exercises is required for FMD and AI. Alarm drills are required for CSF and ASF.

Annex 2 to this report summarises relevant legislative requirements.

Findings

5.3.1 Epizootic disease risk analysis and alert levels

- After BT was notified in Spain in 2004 an assessment of high risk areas for BT due to vector presence was performed. Subsequently actions were taken by the CA to divulge to professionals the evolution of BT and respective control measures.
- Airports were identified as a risk for introduction of ASF/CSF and as a result information for travellers was provided at the airports.
- After a low pathogenic AI outbreak in a big duck holding in 2007 the breeding ducks of that same holding are now vaccinated for AI, under a derogation allowed by EU legislation, for prevention/protection of surrounding poultry farms.

5.3.2 Notification requirements “peacetime”

- Decree Law 39209 provides the legal basis for mandatory notification of all relevant diseases by the animal owners and veterinarians to the local veterinary authority and for this authority to inform the central level.
- The DGAV website includes three lists of notifiable diseases, one for diseases notifiable at national level, another for EU level notifications and another for international level (OIE)

notifications. The diseases relevant to this audit are included in all three lists.

5.3.3 Reporting and follow-up of suspicions

- If a livestock producer or private veterinarian notifies a suspicion an official veterinarian (OV) visits the holding, takes samples if necessary, and performs an epidemiological enquiry which is sent to the head of the regional services; the decision on whether to consider it a formal suspicion (with immediate imposition of all the relevant restrictions) is taken by the head of the regional services in possession of all the necessary information.
- Since 2009 and until August 2012 there have been a total of seven notifications of suspicions of SVD (two), BT (four, with in one case a differential diagnosis for FMD) or AI (one). All results of the investigations were negative.
- The FVO team visited one holding where the owner had notified some dead domestic ducks two years earlier (the AI suspicion mentioned above). The regional office had sent an OV to perform an epidemiological enquiry, which was made available also to the FVO team. However, the OV did not report in the epidemiological enquiry the presence of a lake beside the holding, information which is expressly requested in the report template used, and that could be of relevance in the decision to be taken by the regional services.
- The FVO team was informed by an OV that in case of suspicion in a slaughterhouse, the OV does not have the power to stop access to and movements in the slaughterhouse: only the CVO may do so. Theoretically this can cause a delay in the onset of movement restrictions.

5.3.4 Monitoring and surveillance systems

- The national programme for eradication, control and surveillance of BT in 2012 is approved and co-financed by the European Commission and is available at: http://ec.europa.eu/food/animal/diseases/eradication/programme2012/bt_pt.pdf
- In a slaughterhouse visited the FVO team was informed that in certain months sampling of cattle was performed, in accordance with the above mentioned BT 2012 programme.
- A case of BT was detected and notified at the end of September 2012.
- The national surveillance programme for AI 2012 is also approved and co-financed by the European Commission, it includes poultry and wild birds and is available at: http://ec.europa.eu/food/animal/diseases/eradication/programme2012/AI_PT.pdf
- The AI sampling in 2009 included 958 of 239716 holdings (of which approximately 3000 are commercial holdings), and in 2010 it covered 719 of 239364 holdings. No positive results were detected in either year.
- Monitoring of wild boars for CSF/ASF was performed in cooperation with the hunters association under the Epidemiosurveillance Plan and Normative for CSF and ASF for the hunting season 2011-2012. During 2012 wild boar are actively monitored and domestic pigs are under passive surveillance. All results are also negative until August 2012.
- The other relevant diseases are under passive surveillance.

5.3.5 Public awareness activities in “peacetime”

- The website of DGAV plays a particular role in enhancing awareness both within the CA and any external interested parties. It contains detailed information on relevant animal diseases and both private and official veterinarians informed the FVO team that they used the website frequently. It was generally appreciated as good and informative.

- Outbreaks and/or general information of infectious diseases in Member States or third countries can be divulged via the DGAV website as happened with the Schmallenberg disease cases. If the risk increases faxes are sent to the regional contact points and ultimately direct requests will be done for tracing and/or sampling if the risk is assessed as sufficiently high.
- Leaflets for many relevant diseases (e.g. AI, FMD, BT, CSF, ASF, etc.) and also a 62 page vade mecum (manual) on FMD are available at the website. A vade mecum is foreseen also for ASF/CSF
- In 2009, following the H1N1 pandemic, the DGAV carried out 8 clarification sessions throughout the country.

5.3.6 Bio-security measures in place on animal holdings and other sites

- The Decree-Law No. 214/2008 of 10 November 2008 establishes the general legal requirements for livestock producers on holdings to ensure, amongst others, compliance with standards of animal welfare, hygiene and health of herds.
- Bio-security and health measures are established in individual specific regulations applicable respectively to: horses - rabbits and hares - bovine animals, sheep and goats - swine - and poultry.
- Art. 6 of Decree-Law 214/2008 prescribes a risk categorisation of the holdings from 1, higher risk, to 3, lowest risk. DGAV in cooperation with other services carries out licensing of holdings in categories 1 and 2. All new holdings and holdings already in operation need to apply for licensing under this legislation. DGAV explained that the original licensing deadline has been extended a few times already and is currently set for March 2013.
- The FVO team observed a well documented bio-security plan on a pig holding. The plan was developed by the private veterinarian and the manager of the holding and reviewed by the CA during licensing. In addition bio-security measures can also covered during cross-compliance checks.
- A live animal auction market visited had not been licensed yet according to bio-security legislation, and there was no approval documentation available on site for the live animal market visited. Both of these had been visited for official controls of either animal welfare or of their cleaning and disinfection facilities for means of transport.
- Some Good Practices Manuals have been developed in Portugal (with variable levels of involvement of professional associations, academia and CA) that also include some bio-security indications for different activities and which DGAV has made available via hyperlinks in its website. These are the: "Code of Practice on Livestock Farming" - "Best Practice Guidebook from Farm to Meadow " - "Guide to good practice in hygiene in big game".
- A licensing system is also in place for facilities for cleaning and disinfection of means of transport for live animals: this licence must be renewed, with an inspection visit, at intervals of a maximum of five years.
- Some shortcomings were noted with regards to cleaning and disinfection of means of transport of live animals in two sites visited:
 - In one the registers of cleaning and disinfection of the trucks, if performed at the prescribed concentration, would require the use of a quantity of disinfectant higher than that consumed when compared with the amount of disinfectant declared in the

purchase invoices.

- In another the operator did not have the cleaning and disinfection equipment's instructions on site and was not aware if it was possible to make any adjustment to the equipment to modify the amount of disinfectant automatically injected. Therefore it was not possible to demonstrate that the desired concentration of disinfectant was reached.

5.3.7 *Staff training*

- A yearly training plan is available and was provided to the FVO team. Training priorities are set at central level while the regional level determines the needs of training of individual staff. From 2007-2009 the training focused on the OV's in slaughterhouses. In 2010 training in epidemiological enquiries was set as a priority.
- Individual staff attended international courses on contingency plan training for CSF in Hannover (2006) and for AI in Budapest (2007), as well as on FMD in Turkey (2009).
- Individual staff also attended international courses in the framework of Better Training for Safer Food (DG SANCO) on killing for disease control in 2007, 2009, 2010, with two staff attending in 2012.
- In 2008 three half-day courses on contingency planning were organised with the participation of 17 staff in total. In 2009 18 participants attended a course for contingency plans combined with a desktop simulation exercise.
- A workshop for BT organised in 2010 had 44 staff attending from both central level and the regions.
- During visits to regional offices, holdings, and slaughterhouses the official and private veterinarians met were well informed and adequately identified initial measures to take in case of suspicion of an outbreak.

5.3.8 *Simulation exercises*

- Desktop simulation exercises for FMD (2008, 2009) and AI (2006 and 2007) were organised and staff attended from both the central level and the regions.
- In addition the CA also used the four outbreaks of AI and SVD (and subsequent control and depopulation measures) in 2007 as opportunities to provide real time exercises to official staff from regions outside those directly involved.

Conclusions on preparedness and awareness

The legislation in place provides an adequate legal basis to ensure that relevant diseases are compulsorily notifiable.

Active monitoring is performed for BT, AI and CSF/ASF, with risks assessed and measures taken accordingly. All other diseases are under passive surveillance.

CA staff have attended relevant training and simulation desktop exercises have been regularly held. However, no real-time alert exercise has been performed for FMD contrary to the requirements of Art. 73 and Annex XVII of Council Directive 2003/85/EC.

5.4 LABORATORIES

Legal requirements:

Articles 11 and 12 of Regulation (EC) No 882/2004 set out requirements in relation to sampling,

analysis and official laboratories, including that laboratories must be accredited to and operate in accordance with ISO 17025.

Specific requirements relating to laboratories are laid down in the various Directives on epizootic disease control including the designation and functions of National Reference Laboratories, the tests and criteria to be applied, and the provision of adequate diagnostic capabilities and capacity. Member States shall maintain up-to-date lists of national reference laboratories for all epizootic diseases, except for vesicular diseases, for which the list is published in Annex XI, part A to Directive 2003/85/EC.

Diagnostic manuals or procedures are defined for CSF (Commission Decision 2002/106/EC), ASF (Commission Decision 2003/422/EC), SVD (Commission Decision 2000/428/EC), AI (Commission Decision 2006/437/EC), ND (Annex III to Council Directive 92/66/EEC), FMD (Annex XIII to Council Directive 2003/85/EC), and AHS (Annex IV to Council Directive 2009/156/EC).

Findings

The National Reference Laboratory (NRL) for epizootic diseases is the same as indicated in FVO report 2003-9102, and is still the only laboratory authorised for their diagnosis. Its name has recently been changed from LNIV (*Laboratorio Nacional de Investigação Veterinária*) to INIAV (*Instituto Nacional de Investigação Agrária e Veterinária*), as the agricultural and veterinary laboratory services have been integrated. The NRL is independent from DGAV, but reports to the same Ministry.

- All tests for epizootic diseases are performed in the Virology department of the INIAV, which has seven scientists and eight technicians. This department does not hold any ISO 17025 accreditation, but the LNIV has been accredited in other sectors (residues, transmissible spongiform encephalopathies, bacteriology).
- The laboratory has had a long-standing plan to move to new premises (first mentioned in the FVO report DG(SANCO)/1245/2000) where bio-safety conditions will be improved. The current expected date for the move is mid-2013.
- The INIAV is developing its own CP, and a draft, including flow charts and systematic differential diagnosis, was available. The laboratory had not yet identified its maximum capacity, but is confident to have sufficient analytical equipment in case of crisis; it identified a possible bottleneck in the reception and preparation of serological samples.
- The list of NRLs is provided by the Portuguese CA to the public but it contains some inaccuracies, e.g. incorrect reference to Directive 64/432/EEC for some diseases, such as CSF and ASF.
- Annex XI to Dir. 2003/85 does not list any laboratory acting as NRL for Portugal. The laboratory staff indicated that they had a contract for 2 years with the European Union Reference Laboratory (EU-RL) for it to act as NRL for Portugal, but this contract expired a few years ago and has not been renewed.
- The INIAV does not stock reagents or have documented diagnostic methods for diagnosis of the epizootic diseases listed in Directive 92/119/EEC, other than SVD, yet it is listed as LNR for these diseases. No formal agreement is in place either with NRL of other Member State for diagnosis of these diseases.
- The INIAV indicated that it had participated in EU proficiency testing for epizootic hemorrhagic disease (EHD) diagnosis, but did not stock reagents for this disease. Differential diagnosis of EHD was not included in the draft flow-charts developed for the NRL CP, and the staff indicated that they would only consider testing for this disease in case

of suspicion in deer.

- The quality management system of the laboratory also applies to the virology department. Specific standard operating procedures (SOPs) were in place for serological tests. General SOPs were drafted for molecular tests, but were incomplete: no specific elements or references were made to reagents (missing annex for primers, probes, controls) to be used for each specific test. Some primers used in the laboratory were modified compared to the primers recommended by the EU-RL. Pooling of samples was used in some instances, but not described in SOPs. No SOP was available for nucleotide sequencing (used as confirmation methods for HPAI or ND) or virus isolation.
- EU diagnostic manuals or procedures were available at the working stations, but were not referred to in the internal procedures. Adequate documentation of the performance of the tests was available.
- The LNR participates in most EU-proficiency tests (with the exception of FMD and CSF virus isolation). Actions were taken in case of deficiencies detected, and were adequately documented. The LNR was satisfied that the methods were validated thanks to proficiency testing and the fact that most methods are the ones used by the EU-RL but they were not formally validated.
- Calibration of equipment in the virology department was identified via labelling and records. The records showed that laminar-flow cabinets were subject to insufficient maintenance: this was explained as due to financial restriction, but the laboratory indicated during the closing meeting of the FVO audit that maintenance had been approved and would be performed Monday 1/10/2012.

Conclusions on laboratories

The NRL has the capacity to diagnose the main epizootic diseases, and its grade of preparedness in case of contingency is being improved with the development of its own CP. However, it has not secured or adequately documented the alternative path for diseases it cannot confirm.

Despite the fact that none of the methods used have been accredited, important elements of quality assurance are in place, but they are still incomplete, and the tests lack formal validation, which affects the assessment of the reliability of the laboratory performance.

5.5 DEPOPULATION FOR EPIZOOTIC DISEASE CONTROL

Legal requirements

Council Directive 93/119/EC lays down rules on the protection of animals at the time of slaughter or killing, including when this is performed for the purpose of disease control. In particular Article 10.1 and Annex E apply to the killing of animals for this purpose.

From 1st January 2013 the rules for the killing of animals laid down in Council Regulation (EC) No 1099/2009 must be followed. These rules include killing for the purpose of depopulation. In particular, Article 18 of the Regulation requires that the stunning and killing methods planned and the corresponding standard operating procedures for ensuring compliance with the rules laid down in the Regulation shall be included in the contingency plans required under Union law on animal health and that, when implementing depopulation, the competent authority shall take any appropriate action to safeguard the welfare of the animals in the best available conditions.

Findings

5.5.1 Slaughter/killing

- The recently developed Depopulation Guidelines provide guidance for depopulation operations, defining the slaughter methods most appropriate to each species, animal behaviour characteristics, etc., demonstrating that quite an extensive amount of work was dedicated to them.
- The methods proposed in the Depopulation Guidelines as being adequate for a “high number” and a “low number” do not identify the respective maximum kill rates which would provide support for granting the possible derogations to some provisions of Reg. 1099/2009 as envisaged in its Art. 18(3).
- Some of the indications concerning killing methods in the Depopulation Guidelines diverge from what is prescribed in Annex I of Reg. 1099/2009. Namely it envisages the use of non-penetrative captive bolt device for, amongst others, piglets of less than 10kg. While other differences were explained to be typographical mistakes this one was explained to be taken from OIE. Nevertheless, even if OIE based, this method is not allowed for pigs by this Regulation.
- The advantages, disadvantages and guidance for each possible killing method are covered in the Depopulation Guidelines. The MOs include killing methods but sometimes with relevant methods missing (e.g. FMD manual does not mention stunning with penetrative captive bolt device nor with CO₂) when compared with the Depopulation Guidelines. This could cause confusion when/if during an outbreak it becomes necessary to perform depopulation and select a killing method.
- The Depopulation Guidelines are the main reference that should be used when selecting a killing method for depopulation. However, at the moment the Common Core mentions these guidelines only in its section 9 in connection with selection of equipment, not as a reference to be used to help select a killing method, while the MOs do not mention it at all.
- The FVO team was informed that the final decision about the method of slaughter to be chosen is always taken at central level, by the NDCC, based on the data collected and made available in the action plan proposed by the LDCC regional coordinator. However, this is not clear in either the Common Core, the MOs or the Depopulation Guidelines.
- The SOPs required by Art. 18(1) of Reg. 1099/2009, are not clearly defined. The Depopulation Guidelines have framework guidance for them but not SOP as such. In the case of the MO for AI its Annex X does include an SOP for the method identified as being of election (depopulation with CO₂) but even in this case the SOP includes only two of the four relevant key parameters indicated in table 3 of Annex I to Reg. 1099/2009. The MO for FMD does not include an SOP for any depopulation method.
- Both LDCC visited had penetrative captive bolt devices in storage but these had not been maintained and therefore their effectiveness for dealing with an outbreak is questionable. The live animal market visited also had penetrative captive bolt devices available and in this case they had been maintained recently.
- The purchase of equipment or material for purposes of implementing depopulation is carried out according to Decree-Law n. 155/92 of July 28, which establishes the financial administration of the State and Law No. 8/2012 of February 21, approving the rules for public institutions to establish commitments with third parties.
- A list of ruminant slaughterhouses, pre-approved for killing animals in the case of an outbreak or during eradication programmes, was published in the official journal No 177 of

29 July 2004. Nevertheless DGAV has no agreed contracts in place at the moment with those slaughterhouses to accept animals in case of an outbreak.

- Lists of possible suppliers of necessary equipment for depopulation and associated activities are updated and published in the DGAV web site.
- One LDCC visited had established contacts with two slaughterhouses that had confirmed they would make their penetrative captive bolt devices and respective operators available to the LDCC in case of need.

5.5.2 *Protection of animal welfare*

- DGAV together with the Directorate-General for Agricultural and Rural Development (*Direcção-Geral de Agricultura e Desenvolvimento Rural*, DGADR) have developed the training programmes to provide the levels and certificate of competence, required by Art. 7 of Reg. 1099/2009, for persons carrying out killing and related operations. The training programmes cover ruminants, swine, equine, poultry and rabbits and there are also specific programmes for the animal welfare officers mentioned in Art. 17 of this same regulation.
- Those training programmes were issued by DGADR as part of the administrative “Standards No 11/2012” (*Norma Orientadora*) dated 28/08/2012 which provides all the additional details concerning entities designated to carry out the training, qualifications of trainers, contents and modalities of examinations, etc., in line with the requirements of Art. 21 of Reg. 1099/2009. The DGAV web page provides a brief overview of the requirements and procedures and the standards themselves are already published in its web page as well as that of DGADR.
- The transitional provision of Art. 29 (2) of Reg. 1099/2009 allowing MS (until 8/12/2015) to issue the certificates of competence by way of a simplified procedure to persons demonstrating relevant professional experience of at least three years is adequately covered by section 5 of those standards.
- The Depopulation Guidelines provide guidance on how to prioritize the killing of the animals present at an outbreak site in order to minimise stress and enhance animal welfare. Namely the youngest animals always in first place if stocking density permits, as well as the accessibility and availability of food on site. In addition both the AI and FMD MOs foresee allowing, under specific conditions and authorisation, the movement of animals from holdings in the surveillance zone directly to designated slaughterhouses for immediate slaughter.
- DGAV produced and issued in August 2012 a template report (*Relatório de bem-estar animal relativo a ocisão de animais no âmbito de uma ação de despovoamento*) to be produced after depopulation operations. This template includes fields for all the information required by Art. 18(4) of Reg. 1099/2009.
- During an outbreak in 2007 in a big poultry holding the authorities quickly established an agreement with a private company to provide CO₂ and staff to provide instructions and guidance on how to depopulate the holding with CO₂.
- Descriptions provided to the FVO team of the depopulation exercise at the above mentioned holding showed a good system and operations carried out in line with the requirements of Dir. 93/113 with regards to killing performed for the purpose of disease control.
- A scientific support network (envisaged in Art. 20 of Reg. 1099/2009) which could provide opinions on guidance developed in Portugal for the purpose of Reg. 1099/2009 (such as the Depopulation Guidelines) and the corresponding national single contact point have not been

designated yet.

Conclusions on depopulation for epizootic disease control

The system in place complies with the requirements of Directive 93/119/EC.

The CA has dedicated a significant amount of work into adapting its systems and procedures to the requirements of Regulation (EC) No 1099/2009. That work has succeeded in bringing the existing system already near full compliance prior to that regulation applying from 1st January 2013. Nevertheless the lack of identification of a maximum estimated kill rate for the killing methods, clear SOP, and a better separation and clarification of tasks between the Depopulation Guidelines, the Common Core and the MOs are areas that can still be improved.

5.6 DISPOSAL OF CARCASSES

Legal requirements

Commission Regulation (EC) No 1069/2009 lays down public health and animal health rules for animal by-products (ABP) and derived products, in order to prevent and minimise risks to public and animal health. In particular, Article 8 (b) (ii) and 9 (f) (i) specify that animals and parts of animals killed for disease control purposes, shall be considered as Category 1 or Category 2 animal by-products and therefore subject to the disposal methods specified in the Regulation.

In relation to FMD controls, Directive 2003/85/EC requires close cooperation with environmental authorities (Article 74 (3) (g) and Annex XVII (6) and that the means of disposal of carcasses and animal waste does not cause environmental damage and that appropriate sites and undertakings for the treatment or disposal of animal carcasses and animal waste be identified in the contingency plan (Article 72 (1), (4) and (5) and Annex XVII (13) and (14)).

Findings

- The Common Core states that in case of depopulation for disease control at a holding the CA preferred options for disposal is either by burial or incineration on-site. If that is not possible then the animals can be transported, with the proper precautions, to a designated slaughterhouse for slaughter and subsequent disposal at an ABP processing plant.
- Any on-site burial or destruction has to be approved by a regional Coordinating Commission for Rural Development that includes an environmental representative. If this commission comes to the conclusion that on-site burial or destruction is not advisable then the carcasses are sent to an ABP processing plant.
- Both the MOs for FMD and AI include instructions on how to bury or burn poultry, ruminants and pigs on-site.
- The FVO team visited one Category 1 ABP processing plant and plant management informed that at the moment there are two Category 1 processing plants in Portugal. Combined they would have an estimated maximum daily capacity for processing 500 tonnes and from early 2013 for at least 20% more.
- ABP transport capacity (specifically approved leak-proof vehicles) of the establishment visited exceeds that of its current maximum processing capability. In addition plant management informed that it also owned some other additional vehicles that fully complied with all bio-security requirements and if the CA so authorised they could be used simply by modifying the external identification of category of ABP being transported in case of need.
- This ABP processing plant has previously disposed of animal carcasses, subsequent to depopulation, at the request of the CA and continues to be willing to do so. Nevertheless the previously existing contract between DGAV and ABP processing plants is being

renegotiated and there is no contract in place at the moment that would formally oblige the ABP processing plants to provide priority access to the CA during an outbreak. A tendering process in this regard was being planned at the time of the audit.

- The existence (and location) of both Category 1 ABP processing plants was well known to the official veterinarians but none of the two plants is included in the list of contacts established and published by DGAV as Annex VIII to the Common Core.

Conclusions on disposal of carcasses

The systems in place provides adequate cooperation with environmental authorities to ensure that carcass disposal does not cause environmental damage as required by Directive 2003/85/EC.

Together with the carcass burial or destruction there should be sufficient ABP processing capacity in Portugal to dispose of animals that would have to be killed to control epizootic disease outbreaks in all but the most severe epizootic crisis. The animals could be processed in line with the requirements of Regulation (EC) No 1069/2009.

6 OVERALL CONCLUSIONS

CAs have been designated and sufficient legal powers are available to develop CPs and control epizootic outbreaks in accordance with the requirements of Regulation (EC) No 882/2004.

With the recent updating of the Common Core and MOs the CA have provided themselves with the necessary instruments to operate in a case of an animal health emergency. The provisions in those documents, along with the capacity to swiftly set up a NDCC and/or a LDCC would allow the CA to become quickly operative to act in an emergency. The unfinished geo-referencing of holdings, and lack of completeness concerning identification of high livestock density areas and vaccination, and some cases of insufficient integration (e.g. sampling in case of suspicion) or clarity (e.g. interface with civil defence services, instructions on killing methods) are not likely to impede significantly the possibility of the CA to adequately face an animal health emergency.

Active monitoring is performed for BT, AI and CSF/ASF, with risks assessed and measures taken accordingly. All other diseases are under passive surveillance.

The NRL has the capacity to diagnose the main epizootic diseases, and its grade of preparedness in case of contingency is being improved with the development of its own CP. However, it has not secured or adequately documented the alternative path for diseases it cannot confirm. Despite the fact that none of the methods used have been accredited, important elements of quality assurance are in place, but they are still incomplete, and the tests lack formal validation.

The CA has dedicated a significant amount of work to adapting its systems and procedures to bring them into compliance with the requirements of Regulation (EC) No 1099/2009. That work has succeeded in bringing the existing system already close to full compliance prior to that Regulation applying from 1st January 2013. Nevertheless the lack of identification of a maximum estimated kill rate for the killing methods, clear SOP, and a better separation and clarification of tasks between reference documents are areas that can still be improved

The systems in place provides adequate provisions to ensure that carcass disposal does not cause environmental damage and that carcasses would be processed in line with requirements.

7 CLOSING MEETING

A closing meeting was held on 28 September with representatives of the CA. At this meeting, the main findings and preliminary conclusions of the audit were presented by the FVO team. The representatives of the CA did not indicate any major disagreement with the findings and preliminary

conclusions.

8 RECOMMENDATIONS

The CA is requested to provide the Commission services with an action plan, including a timetable for its completion, within one month of receipt of the report in order to address deficiencies identified in the report and, in particular, the following:

| N°. | Recommendation |
|-----|--|
| 1. | The CA should ensure that the contingency plans establish an hypothesis concerning the size and location of suspected outbreaks in order to be able to determine the stunning and killing methods and procedures required by Art. 18 of Regulation (EC) No 1099/2009. |
| 2. | The CA should ensure that the contingency plans indicate areas of high density of livestock, pigs and poultry as required respectively by Art. 72 (3) (b) of Directive 2003/85/EC, Art. 22 (1) (b) of Directive 2001/89/EC, and Art. 62 and Annex X of Directive 2005/94/EC. |
| 3. | The CA should ensure that the contingency plans indicate the vaccine requirements in the event of emergency vaccination of livestock, pigs and poultry as required respectively by Art. 72 (3) (a) of Directive 2003/85/EC, Art. 22 (1) (a) of Directive 2001/89/EC and Art. 62 (2) of Directive 2005/94/EC. |
| 4. | The CA should continue its revision work on updating the several Manuals of Operations to address the points identified as not fully clear or lacking detail, namely: sampling in case of suspicion, interface with civil defence services, instructions on killing methods. In order for them to describe in detail in a comprehensive and practical way all the actions procedures, instructions and control measures to be employed in handling an outbreak as required by Art. 72 (5) and Annex XVII of Directive 2003/85/EC, and Art. 22 (2) and Annex VII of Directive 2001/89/EC. |
| 5. | The CA should ensure that real-time alert exercises for FMD are conducted as required by Art. 73 and Annex XVII of Directive 2003/85/EC. |
| 6. | The CA should ensure that the use of the NRL of another member state for testing for vesicular diseases is formalised through a mutual agreement with the competent authorities of the Member State, as required by Article 68 (2) of Directive 2003/85/EC. |
| 7. | The CA should ensure that the list of NRL available to the public is accurate and up-to date indicating the laboratories competent as regards the diseases in question as indicated in particular in Article 17 (4) and (5) of Directive 92/119/EC. |
| 8. | The CA should ensure that while keeping on working toward ISO 17025 accreditation of the tests performed for epizootic diseases (as required by Article 12 of Regulation |

| N°. | Recommendation |
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| | (EC) No 882/2004) at the NRL, at short term is is also ensured that all tests are performed following complete and accurate standard operating procedures, in accordance with the European diagnostic manuals when available; Deviations from EU-reference laboratories protocols are adequately documented and validated; Equipment maintenance can guarantee compliance with relevant specifications. |
| 9. | The CA should ensure that estimated maximum kill rates for the proposed methods for depopulation are available, so that it can be properly informed to determine when derogations to one or more provisions to Regulation (EC) No 1099/2009 should be granted due to exceptional circumstances, as allowed by its Article 18 (3). |
| 10. | The CA should ensure that standard operating procedures, with the stunning and killing methods planned, ensuring compliance with the rules laid down in Regulation (EC) No 1099/2009, are drafted and included in all relevant contingency plans as required by its Art. 18 (1). |

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=2012-6402

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 |
| Dir. 93/119/EC | OJ L 340, 31.12.1993, p. 21-34 | Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing |
| 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 |

| Legal Reference | Official Journal | Title |
|------------------------|--------------------------------|--|
| 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. 1760/2000 | OJ L 204, 11.8.2000, p. 1-10 | Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 |
| 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 |

| Legal Reference | Official Journal | Title |
|------------------------|---------------------------------|---|
| 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 |
| Dec. 2006/437/EC | OJ L 237, 31.8.2006, p. 1-27 | 2006/437/EC: Commission Decision of 4 August 2006 approving a Diagnostic Manual for avian influenza as provided for in Council Directive 2005/94/EC |
| Dec. 2010/367/EU | OJ L 166, 01.07.2010, p. 22-32 | 2010/367/EU: Commission Decision of 25 June 2010 on the implementation by Member States of surveillance programmes for avian influenza in poultry and wild birds |
| Dir. 2009/156/EC | OJ L 192, 23.7.2010, p. 1-24 | Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae |
| 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) |
| Dir. 92/117/EEC | OJ L 62, 15.3.1993, p. 38-48 | Council Directive 92/117/EEC of 17 December 1992 concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications |