



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

Ares(2014)1959989

DG(SANCO) 2013-6780 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SWEDEN

FROM 15 TO 24 OCTOBER 2013

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 (FVO) audit in Sweden carried out between 15 and 24 October 2013, as part of the FVO audit programme. The objective was to evaluate the resources and arrangements put in place to implement the European Union (EU) requirements for contingency planning in the event of one or more outbreaks of epizootic diseases.

As an overall conclusion, the combination of an excellent animal disease early warning system and largely satisfactory emergency preparedness measures and arrangements, make the system in place in Sweden robust and capable to manage epizootic disease outbreaks with limited geographic scope, in particular thanks to:

- a satisfactory level of animal health surveillance, that should contribute to the early detection of any unusual disease event in domestic and wild animal populations;*
- the availability of adequate legal powers and financial provisions to cope with a disease outbreak;*
- the availability of largely adequate contingency plans (CPs) and operations manuals (OMs) providing most of the necessary instructions and guidance for staff involved in managing a disease outbreak;*
- the very satisfactory levels of training and preparation amongst staff of all the CAs involved, and*
- the availability of adequate technical, diagnostic and epidemiological expertise and of effective data analysis and information management tools that facilitate the decision-making process.*

However, should an epizootic outbreak become geographically widespread or affect several domestic and wild animal species, a number of shortcomings identified by the audit team cast a shadow on the level of preparedness of the system in place, namely:

- the limited operational arrangements in place to ensure access by the competent authorities (CAs) to all necessary equipment and resources to cope with such a disease outbreak;*
- the CP for foot-and-mouth disease (FMD) does not provide for measures to be implemented in the event of a worst case scenario and it lacks detailed plans to enable the CAs to take well-informed decisions in relation to the need and extent of emergency vaccination against that disease;*
- the lack of preparedness to comply with EU animal welfare requirements in the context of animal depopulation;*
- the limited rendering and incineration capacity available, and the lack of arrangements in the CP for FMD in respect of alternatives to ensure proper and effective disposal of animal carcasses and other animal by-products not for human consumption (ABP), in particular if it is necessary to bury or burn the carcasses of dead or killed animals on site, and*
- the lack of data and the ineffective official controls on animal movements that will have a significant impact on the quick availability of information on animal traceability needed for the targeting of actions to control disease outbreaks.*

The report makes recommendations to the Swedish CAs aimed at addressing areas in which further improvements are required.

Table of Contents

1	<u>INTRODUCTION</u>	1
2	<u>OBJECTIVES</u>	1
3	<u>LEGAL BASIS</u>	2
4	<u>BACKGROUND</u>	2
5	<u>FINDINGS AND CONCLUSIONS</u>	3
5.1	<u>COMPETENT AUTHORITIES</u>	3
5.1.1	<i><u>COMPETENT AUTHORITY STRUCTURE</u></i>	4
5.1.2	<i><u>LEGAL POWERS AVAILABLE TO THE CAs</u></i>	4
5.1.3	<i><u>COOPERATION BETWEEN AND WITHIN CAs IN DEVELOPMENT OF CPs</u></i>	5
5.2	<u>CONTINGENCY PLANS</u>	6
5.2.1	<i><u>COVERAGE & APPROVAL</u></i>	6
5.2.2	<i><u>DOCUMENTATION</u></i>	7
5.2.3	<i><u>CA COMMAND STRUCTURE DURING AN EPIZOOTIC OUTBREAK – NDCC AND LDCCs</u></i>	7
5.2.4	<i><u>FINANCIAL PROVISIONS</u></i>	9
5.2.5	<i><u>ESTABLISHMENT AND ENFORCEMENT OF PROTECTION AND SURVEILLANCE ZONES</u></i>	10
5.2.6	<i><u>COMMUNICATION PROCEDURES DURING AN OUTBREAK</u></i>	10
5.2.7	<i><u>AVAILABILITY OF EPIDEMIOLOGICAL EXPERTISE</u></i>	11
5.2.8	<i><u>ANIMAL IDENTIFICATION AND MOVEMENT CONTROL</u></i>	11
5.2.9	<i><u>AVAILABILITY OF EQUIPMENT</u></i>	12
5.2.10	<i><u>VACCINATION POLICY AND AVAILABILITY OF VACCINE</u></i>	13
5.3	<u>PREPAREDNESS AND AWARENESS</u>	14
5.3.1	<i><u>EPIZOOTIC DISEASE RISK ANALYSIS AND ALERT LEVELS</u></i>	14
5.3.2	<i><u>NOTIFICATION REQUIREMENTS (PEACETIME)</u></i>	15
5.3.3	<i><u>MONITORING AND SURVEILLANCE SYSTEMS</u></i>	15
5.3.4	<i><u>PUBLIC AWARENESS ACTIVITIES IN “PEACETIME”</u></i>	17
5.3.5	<i><u>BIO-SECURITY MEASURES IN PLACE ON ANIMAL HOLDINGS</u></i>	17
5.3.6	<i><u>STAFF TRAINING</u></i>	18
5.3.7	<i><u>SIMULATION EXERCISES</u></i>	18
5.4	<u>LABORATORIES</u>	20
5.5	<u>DEPOPULATION FOR EPIZOOTIC DISEASE CONTROL</u>	21
5.5.1	<i><u>SLAUGHTER/KILLING</u></i>	21
5.5.2	<i><u>PROTECTION OF ANIMAL WELFARE</u></i>	23
5.6	<u>DISPOSAL OF CARCASSES</u>	23
6	<u>OVERALL CONCLUSIONS</u>	25
7	<u>CLOSING MEETING</u>	25
8	<u>RECOMMENDATIONS</u>	26
	<u>ANNEX 1 - LEGAL REFERENCES</u>	27
	<u>ANNEX 2 - SUMMARY OF LEGAL REQUIREMENTS</u>	30

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ABP	Animal by-products not for human consumption, as defined in Regulation (EC) No 1069/2009
AHS	African Horse Sickness
AI	Avian Influenza
ASF	African Swine Fever
BT	Bluetongue
CA(s)	Competent Authority(ies)
CAB	County Administrative Boards - <i>Länsstyrelserna</i>
CCA	Central Competent Authority
CP	Contingency Plan
CSF	Classical Swine Fever
DG(SANCO)	Health and Consumers Directorate General
DIACP	Division for International Affairs and Contingency Planning
DVS	District Veterinary Station
EDA	Epizootic Diseases Act - <i>Epizootilag</i>
EDH	Epizootic diseases handbook
EHD	Epizootic haemorrhagic disease
ELISA	Enzyme Linked ImmunoSorbent Assay
EU	European Union
FMD	Foot-and-Mouth Disease
FVO	Food and Veterinary Office
LDCC	Local Disease Control Centre
LEIF	Management and Information System - <i>Lednings- och informationssystem</i>
MS	Member States (of the EU)
MSB	Swedish Civil Contingencies Agency - <i>Myndigheten för samhällsskydd och beredskap</i>
ND	Newcastle Disease
NDCC	National Disease Control Centre
NFA	National Food Agency - <i>Livsmedelsverket</i>
NRL	National Reference Laboratory
OM	Operations manual
OV	Official Veterinarian
PCR	Polymerase Chain Reaction
PRRS	Porcine reproductive and respiratory syndrome

SBA	Swedish Board of Agriculture - <i>Jordbruksverket</i>
SCAHAW	Scientific Committee on Animal Health and Animal Welfare
SOP	Standard operating procedure
STUDS-DBS	Computer assisted decision support system for major outbreaks of epizootic diseases - <i>Datorstött beslutsstödsystem för större utbrott av smittsam djursjukdom</i>
SVA	National Veterinary Institute - <i>Statens Veterinärmedicinska Anstalt</i>
SVD	Swine Vesicular Disease
SVDHV	Swedish Animal Health Service - <i>Svenska Djurhälsovården AB</i>
WIS	Web-based Information System - <i>Webbaserat informationssystem</i>

1 INTRODUCTION

This audit took place in Sweden from 15 to 24 October 2013 and was undertaken as part of the FVO planned audit programme. The audit team comprised two auditors from the FVO.

The team was accompanied throughout the audit by representatives of the Swedish Board of Agriculture (*Jordbruksverket* – SBA) which is the Central Competent Authority (CCA) within the scope of this audit. In addition, representatives of the National Food Agency (*Livsmedelsverket* – NFA) and the County Administrative Boards (*Länsstyrelserna* – CAB) accompanied the audit team during some of the visits to food business operators and in the relevant geographical areas under their remit, respectively.

2 OBJECTIVES

The objective of this audit was to evaluate the resources and arrangements put in place to implement the EU 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: 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 concentrated, in particular, on the evaluation of emergency preparedness in the event of an outbreak of ASF, FMD, AI and with regard to the functioning of the disease early warning system in case of emerging vector-borne diseases (e.g. BT and AHS), in particular for epizootic haemorrhagic disease (EHD):

- ASF is an emerging risk in the EU due to the presence of the disease in wild boar populations in some areas of Lithuania and Poland neighbouring Russia and Belarus, countries where the evolution of the epidemiological situation of the disease remains uncertain;
- FMD is one of the most difficult diseases to contain and affects several livestock species;
- AI is the most relevant example of a poultry disease where specific requirements for contingency plans are laid down in EU legislation, and
- EHD is an exotic vector-borne emerging disease that is occurring in EU neighbouring countries in the Mediterranean basin and, in addition to the domestic population of ruminants, there is a large population of wild ungulates present in Sweden.

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

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

MEETINGS / VISITS		no.	COMMENTS
Competent Authorities	Central	3	Opening and closing meetings with the relevant Units of the SBA. Additional meeting on information managing systems and organisation of simulation exercises
	Regional	4	Meetings with representatives of four CAB
	Local	2	Visit to one DVS and meeting at the planned facilities of a LDCC
Laboratories		2	NRL for epizootic diseases within the scope of this audit (SVA) and one laboratory responsible for pathological examination of submissions in the context of surveillance for epizootic diseases
Holdings		1	One holding with pigs and goats
Markets & Assembly centres		1	One assembly centre operating with pigs destined for intra-Union trade
Slaughterhouses		1	One pig slaughterhouse
Other establishments/operators/organisations		3	One ABP intermediate plant and one operator responsible for collection and transport of ABP, as well as for killing of animals in case of depopulation. Meeting with representatives of the SVDHV

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.

4 BACKGROUND

According to information provided by the SBA, demographic data show that most farms are located in the southern and central parts of Sweden and meat and milk are the major lines of production. In the northern part of Sweden, farms are mainly small. During recent decades the number of holdings with livestock has decreased, but those remaining have increased in size. With regard to the main animal populations, the following data referring to 2012 (June, for census data) are worth being mentioned:

- There were 19 560 holdings keeping in excess of 1.5 cattle in Sweden, out of which some 348 500 cows were situated in 5 000 dairy herds and 192 500 were cows for calf production. In total, approximately 392 000 adult cattle and 29 000 calves were slaughtered during 2012.
- There were some 1.3 million pigs kept in Swedish holdings in June 2012, with some 2 500 000 slaughtered during the same year.
- Some 9 000 sheep holdings kept some 300 000 ewes and rams, and approximately the same amount of lambs. The reported number of goats and goat holders were 11 600 and 2 135, respectively.
- In relation to poultry, there were some 3 900 holdings keeping some 6.7 million hens and 217 holdings from which some 76.8 million broilers have been slaughtered during 2012. Populations of turkeys, geese and ducks were much smaller.

Apart from day-old chicks, little trade of live animals from or to Sweden has occurred during recent years; in general, only some pigs and a few cattle and sheep have been exchanged with neighbouring MS, such as Finland, Denmark and Norway, and with Germany.

Given the potential impact of outbreaks of epizootic disease, it is important that MS can react immediately and effectively in a coordinated manner and in co-operation with neighbouring countries. EU legislation requires MS to have contingency plans 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 contingency plan.

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

- FMD has not occurred since 1966, and CSF has not been confirmed in Sweden since 1944.
- The most recent case of Highly pathogenic AI (HPAI) occurred in spring 2006 (subtype H5N1) and it was first detected in wild birds. One infected farmed mallard was also detected later on in a game bird holding. No case of low pathogenic AI (LPAI) have ever been confirmed in Sweden as a result of the AI routine surveillance programme in place.
- The latest cases of ND in poultry were detected in spring 2011.
- Cases of BT (serotype 8 of the BT virus) were detected first in September 2008 and later up until February 2009; Sweden was declared free of the disease in December 2010.
- AHS and ASF, as well as other exotic diseases such as SVD, EHD, Peste des petits ruminants, Rift- Valley fever or vesicular stomatitis, have never been reported from Sweden.

The latest audit carried out in Sweden on the same topic took place in 2003 (ref.: DG(SANCO)/9197/2003 – MR Final). The report of that audit is published on the FVO website at:

http://ec.europa.eu/food/fvo/index_en.cfm

The outcome of the previous audit was largely satisfactory with some weaknesses highlighted, amongst which it is worth mentioning the insufficient preparation of the rendering system to cope with the demands of disposal of carcasses in the event of a disease outbreak. An updated situation in relation to that subject is described in section 5.6 of this report.

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

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), (g) & (i) and Annex XVII (6) requires close cooperation with environmental 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.

Findings:

5.1.1 Competent Authority structure

Information on the structures of the Swedish CAs can be found in the country profile that is available on the following Web link:

http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=SE

The country profile (valid as of May 2012) provides information on the responsibilities of the CAs under normal circumstances and a brief description of their activities in the event of a disease outbreak; in addition:

- The lead authority for animal health control is the SBA, which is responsible *inter alia* for overall coordination of the drawing up of CPs which are required under EU animal health legislation, and for policy making regarding animal disease outbreaks at national level. These activities are the responsibility of the Division for International Affairs and Contingency Planning (DIACP) within the Department for Animal Welfare and Health of the SBA.
- The District Veterinary Department of the SBA coordinates the activities of the 80 District Veterinary Stations (DVSs), organised in four operational regions and where some 340 official veterinarians (OVs) constitute the first line of alert and investigation of the early warning system for animal diseases.
- The 21 CAB play a major role in the event of a disease outbreak to provide assistance to the SBA and the DVSs situated in the geographical area under their remit (see 5.1.3 and 5.2.3). In peace time, CAB hold major responsibilities with regard to official controls on animal welfare and on compliance with requirements on animal identification and movement control.
- The SBA, and also other CAs in Sweden involved in animal health controls, receive expert epidemiological advice from the Department of Epidemiology of the National Veterinary Institute (SVA - *Statens Veterinärmedicinska Anstalt*). The SVA also includes all the national reference laboratories relevant for diagnosis of epizootic diseases (NRLs).
- The SBA coordinates development of the emergency preparedness and crisis management policy with the National Food Agency (*Livsmedelsverket* – NFA), which is the CA responsible for food safety in Sweden, and is always involved in crisis situations whenever the animal disease outbreak is caused by a zoonosis; e.g. AI, and also when investigations need to be carried out and actions taken along the food chain.

The development of CPs requires extensive cooperation within and between CAs and that responsibilities of the various CAs when dealing with an outbreak of epizootic disease are formally defined and agreed in advance. In most cases this entails a change in the command structures of the CAs. Section 5.2.3 below outlines any such changes.

5.1.2 Legal powers available to the CAs

The main overarching pieces of legislation that regulate animal health issues in Sweden, including in the event of an animal disease outbreak, are the Epizootic Diseases Act (*Epizootilag 1999:657* - EDA) and the Epizootic Diseases Ordinance (*Epizootiförordning 1999:659*). Some important points contained therein are:

- The SBA keeps the overall lead in the chain of command in the event of a disease outbreak;

the CBA and other CAs (e.g. police forces who are required to provide assistance, municipalities in relation to disposal of ABP) must follow instructions from staff of the SBA in charge of the national or a local disease control centre (NDCC and LDCC).

- CAB are required to prepare CPs and operational manuals (OMs) in cooperation with the SBA to respond in the event of a disease outbreak; the SBA evaluates them and provides advice to the CBA on their fitness for purpose. However, this legislation does not give the SBA powers to verify or carry out audits on the level of preparedness of the CAB or any other CA.

The audit team found that:

- In addition, the SBA has introduced additional legislation, through their own regulations (*Föreskrifter*), that add to the extensive powers conferred to the CAs by the Acts mentioned above and, in general, makes special emphasis on the application of animal health controls as a fundamental pillar of the early warning system for detection of epizootic diseases (e.g. regulating minimum health monitoring arrangements in poultry and pig farms) and sets out requirements with regard to surveillance, control and eradication measures for those diseases (e.g. on general requirements for sampling for surveillance purposes, on specific measures for surveillance of AI or on measures to control and eradicate bluetongue).
- Currently existing national requirements and recommendations laid down on the "Welfare of Animals at Slaughter and Killing" regulations (ref.: SJVFS 2012:27), together with the EDA, and the provisions and instructions contained in the epizootic diseases handbook (EDH – see section 5.2.1), adequately address the requirements previously in place under Council Directive 93/119/EC on the protection of animals at the time of slaughter and killing. However, some necessary adaptations or implementation measures necessary to enforce new requirements on animal depopulation as laid down in Article 18 of Regulation (EC) No 1099/2009, have not been made yet (see section 5.5).
- The body of legislation above mentioned ensures that CAs at all levels have sufficient powers to: enter into all premises possibly involved in a disease outbreak, impose restrictions on animal movements, require application of the necessary cleaning and disinfection measures, impose protection zones and surveillance zones according to the epidemiological evaluation of the situation, order the killing of animals, etc.

5.1.3 Cooperation between and within CAs in development of CPs

A number of initiatives are in place, both already operational and in the form of ongoing projects, that are aimed at facilitating cooperation between operational Units in the SBA (e.g. between the DIACP and the DVSs in order to develop guidance and instructions to operate the NDCC and the LDCCs) and between the SBA and other CAs, such as:

- the SVA, mostly through regular meetings, and on topics further described in sections 5.2.1, 5.2.7, 5.3.1 and 5.3.3;
- the CAB, with several ongoing projects to enhance cooperation and better definition of their role and the type of CPs and OMs they need (see also 5.2.1 and 5.2.3);
- the NFA, on a common crisis management protocol in the event of a food-borne disease; and
- other CAs, such as the armed forces or the Swedish Civil Contingencies Agency (*Myndigheten för samhällsskydd och beredskap* – MSB) on deployment and operation of LDCCs (see 5.2.3).

Section 5.2.3 below, outlines the responsibilities of the various CAs for dealing with an epizootic outbreak, as designated in the CPs.

Conclusions on Competent Authorities:

CAs have been designated and sufficient legal powers are available to develop CPs and to control epizootic outbreaks in accordance with the requirements of Regulation (EC) No 882/2004 and the disease-specific Directives. Those fundamental strengths of the system in place are further reinforced by:

- the well formalised cooperation arrangements in place between the various CAs, and
- the additional efforts made to involve many other CAs, that can provide the necessary technical and logistical support, and to ensure the cooperation and availability of numerous stakeholders, whose contribution is vital in complementing the activities of the animal health services in the event of an outbreak of an epizootic disease.

5.2 CONTINGENCY PLANS

Legal requirements:

Requirements for Member States to have contingency plans to control disease outbreaks are required 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.

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 & Approval

The audit team found that:

- In general, CPs have been drafted, and regularly updated for the major diseases as required by EU legislation. The SBA has decided to develop a generic CP, which is further developed with specific technical and operational areas for each epizootic disease, including provisions for FMD, CSF, ASF, AI and ND, and BT.
- The main operational tool available to the crisis management system, including all those responsible for implementation of measures in the field, is an EDH that contains, with some exceptions with regard to animal depopulation, all necessary guidance and instructions to handle disease outbreaks. The EDH has been prepared, and it is continuously updated by staff of the DIACP, who works in cooperation with representatives of other relevant internal departments of the SBA, in particular from the department coordinating the activities of the DVSSs, and with other CAs, mainly the SVA and the CAB.

- No specific CP has been drafted for diseases listed in Council Directive 92/119/EC, as the SBA considers that provisions laid down in the generic CP along with the EDH and the expertise ensured by the epidemiology and diagnostic departments of the SVA, would guarantee an adequate management of the particular issues specific to each type of disease outbreak.
- The SBA is in the process of further developing the existing basic CP for AHS, as a project is underway to study the best approaches for this disease and vector borne diseases in general.
- As mentioned in section 5.1.3, the SBA is spearheading an ambitious project, where all relevant CAs take part, that will be carried out for two years and has as the main objective assessing the fitness for purpose of all components of the current emergency preparedness and early warning systems in order to propose possible alternatives to enhance their effectiveness. According to representatives of the DIACP, one of the likely outcomes will be a significant updating of the CPs and of the EDH in order to render them more user-friendly and operational. This project should be finished before the end of 2015.

5.2.2 Documentation

The audit team found that:

- The EDH is the main document available to staff of the SBA, including staff of the DVSS in LDCCs, to proceed in the event of a disease outbreak. It is available on the Website of the SBA and dates of the latest updates are included for each chapter. All operational documentation on the online version of the EDH is always the most updated, for instance after modifications made as a result of simulation exercises or introduction of new legislation, and the only one operational for staff with access to it in case of an outbreak.
- The CAB had adapted their OMs to their particular circumstances following general rules laid down in the EDH and in agreement with the SBA. According to representatives of the CAB visited, this is the only way to make them really useful for their staff in case they are involved in a crisis situation. Documentation from those OMs checked by the audit team contained chapters drafted along the lines of the EDH that include generic operational instructions, lists of contacts, details on organization of cooperation arrangements with other CAs (police, civil protection, environmental authorities, etc.) and communication protocols with stakeholders and the general public (see also 5.2.3).

5.2.3 CA command structure during an epizootic outbreak – NDCC and LDCCs

The audit team found that:

- The SBA has recently restructured their animal health emergency management systems, in particular with regard to the chain of command and the role and activities of the NDCC and the LDCCs, which are now more streamlined and should be more operational and effective in the event of an outbreak owing to a better allocation of responsibilities and tasks, and the definition of clear communication protocols between the various operational levels.
- Nevertheless, representatives of the SBA acknowledged that the components of the new structure that relate to the activities of the LDCC were still under development, in particular with regard to specific operational training of district veterinarians who should be in command of local operations. The audit team could see that training activities were targeted for the future operational leaders of the LDCCs and for the other colleagues at the DVSS

who will have specific operational tasks under the command of the former.

- As mentioned previously, the CAB have their own CPs and OMs adapted to the local circumstances, in case they are delegated specific tasks by the SBA (NDCC) for the handling of an epizootic disease outbreak. However, unless there was a large outbreak requiring major logistical arrangements; the activities of the CAB would mostly be restricted to organization of information and communication campaigns at local level and, on occasion, enforcing of protection and surveillance zones, in order to support the activities of the LDCC.
- According to representatives of the DIACP, they were in the process of reviewing their relationship with, and the possible roles of the CAB in the context of their crisis management system, in particular in the event of major disease outbreaks, which should be finished by the end of 2013.
- During the meetings with the CAB and staff of the DVSSs visited, it could be verified that all of them had access to the available CPs and OMs available (CAB) and to the EDH (all of them), including in the case of staff of the DVSSs, to instructions and guidelines (sometimes in draft format) on the operation of the LDCCs. In all cases, staff met were well aware of arrangements on the chain of command in case of an animal health emergency situation.
- The activities of the LDCC and, as appropriate, the NDCC, are modulated by the availability of a number of interlinked information management systems and databases, that are aimed at easing up the CAs decision-making process in the event of a disease outbreak. The main tools are:
 - A computer assisted decision support system for major outbreaks of epizootic diseases (*Datorstött beslutsstödsystem för större utbrott av smittsam djursjukdom – STUDS-DBS*). The STUDS-DBS was originally conceived as the main tool to handle all components of the emergency preparedness system and the reaction to a disease outbreak; however, its use has eventually been restricted to handle the spatial epidemiological features of an outbreak, thanks to its potential as a geographical information management system, which includes delimitation of the zones on the basis of tracking of animal movements and other factors that could contribute to transmit the disease. The system can interact and easily retrieve information from the herd and animal identification and registration operational databases (see 5.2.8); moreover, the SVA has developed a computerised tool to speed up the tracing back and forward of cattle in the event of a disease outbreak.
 - A specific crisis management and information system (Management and Information System - *Lednings- och informationssystem – LEIF*) that enables the SBA (NDCC) to manage all necessary activities in real-time and that gathers all details and information on the daily progress with the control and eradication of the disease. The LEIF is the main tool used by staff in command of the NDCC to circulate instructions and allocate tasks to the decentralised operational teams of the SBA (mostly, but not exclusively, from the DVSSs), and to keep registered and verify that all these activities are timely done. The audit team could see examples of its effective use in relation to outbreaks of food-borne illnesses (e.g. infection with *Salmonella spp.*) and of the training and preparation carried out to optimise its use in the event of a major disease outbreak.
 - Another system, called Web-based Information System (*Webbaserat informationssystem – WIS*), which is used to exchange all sorts of information between all CAs in the event of a crisis situation. Its use is therefore not restricted to SBA staff, as it is the case with the LEIF, but it is opened to all those possibly involved in performing

the various tasks needed to cope with a disease outbreak. The WIS is used mainly for informative and communication purposes with all the other CAs possibly involved in a disease outbreak, for instance with the CAB in order to share press-releases for editing before they are jointly issued, or even with other governmental bodies not directly involved in a particular crisis situation.

- Even though for the time being the SBA keeps the organisation of the LDCCs largely according to the distribution of the DVSs in the field; since 2007, but mostly after a simulation exercise on an FMD outbreak carried out in a LDCC in 2010, they started to reconsider the deployment of premises to be used as LDCCs. Initially, the priority was to ensure a geographical distribution of sufficient places to cover an area of a 100 km radius all over the Swedish territory with a reasonably high animal population. This was later on (after the outcome of the exercise in 2010) modified and the current approach is to use four (already determined) places for those LDCCs in the event of large outbreaks that will require significantly higher amounts of resources to be coped with:
 - Those premises will be equipped with basic ready-to-use emergency resources and will have space for storing additional equipment that can be necessary depending on the dimension of the crisis;
 - expert groups were in the process of being trained to set them up, as they were, to operate them, a number of staff of the District Veterinary Department of the SBA and the DVSs. In addition, arrangements were already in place so that the SBA can count on specialised staff of the armed forces and of the MSB to speed up their deployment and operation within 48 hours. The audit team visited one of those premises, which potentially can fulfil the standards required by the SBA initiative but, as acknowledged by representatives of the SBA, it was still in the preparatory phase and it has not been involved yet in any real-time disease outbreak exercise.

5.2.4 *Financial provisions*

As part of the annual funds assigned by the Swedish Parliament to the SBA, there is an specific allocation to be used for epizootic disease control; this includes, amongst other things, funds for disease surveillance and emergency preparedness during peacetime. In accordance with provisions laid down in one section of the EDA, those specific funds can be used for compensation purposes in the event of an epizootic disease outbreak, as the State must compensate those who, as a result of the disease, or regulations or decisions adopted on the basis of the EDA or EU legal requirements to be complied with in the context of a disease outbreak; for instance:

- lose their animals (e.g. dead or destroyed as a result of the disease or a vaccination policy);
- incur in costs as a result of killing of animals and disposal of carcasses, or owing to disinfection and cleaning-up measures, and
- bear production losses or other related consequential losses of income.

The audit team could see some examples of provisions and administrative arrangements to be availed of in those situations by staff of the DVSs and the CAB. Even though no major outbreaks of epizootic diseases have occurred recently in Sweden, this staff was experienced with those procedures as they had used them in situations where minor outbreaks of other diseases had been dealt with (e.g. salmonellosis in poultry, porcine reproductive and respiratory syndrome, anthrax).

Representatives of the SBA advised the audit team that there is no insurance policy in Sweden aimed at covering expenses and losses related to epizootic disease outbreaks, and that the option of an animal disease fund with the same aim, and based on levies paid by the farming industry, has not been considered suitable for the animal production sectors in the country. Hence, the Swedish State

has decided to assume the financial responsibility of coping with those situations, that goes beyond the initially allocated funds mentioned above thanks to availability of emergency funds, and, once the emergency situation has been dealt with, they would seek for financial compensation, as appropriate, in accordance with EU rules in that respect.

5.2.5 Establishment and enforcement of protection and surveillance zones

The audit team found that:

- The relevant services of the SBA, at crisis management and implementing levels, and the SVA, have access to the computerised tools described above (section 5.2.3) that speed up the evaluation of the crisis situation and facilitate a spatial and temporal assessment that allows them to quickly define protection and surveillance zones in accordance with EU requirements.
- The zones are adapted to the production area thanks to the geographical accuracy of the information retrieved from and assessed with the STUDS-DBS. This system, along with other inter-linked databases, can provide immediately up-to-date details on all farms and other relevant stakeholders, including geographical coordinates and specific data on, for instance, animal movements registered in the Internet-based herd and animal identification and registration system (see 5.2.8).
- As mentioned earlier, the NDCC (sometimes through LDCCs) will manage the definition of the zones and decide on what actions need to be taken, including on the scope and reach of restriction measures of any type in the zones and on any animal culling that needs to be done quickly. In addition, enforcement of animal movement restrictions can mostly be delegated to the CAB or the police forces, which must provide support to the LDCC. The audit team could see that in the CAB visited there was a variety of arrangements in place with other CAs, such as municipalities or the police forces, and private stakeholders to set up road control measures, in order to reinforce application of movement restriction measures, and cleaning and disinfection facilities for vehicles entering or leaving the zones, as appropriate.
- Representatives of the DIACP advised the audit team that derogations with respect to permitting movement to slaughter for animal welfare purposes; e.g. overstocking on farms in the protection or surveillance zone during an outbreak, are always considered, as appropriate, but that the overall priority is always to eradicate the disease as a matter of urgency and prevent it from spreading further afield.

5.2.6 Communication procedures during an outbreak

As mentioned in previous sections, both the SBA, as overall manager of the NDCC, and the CAB, thanks to the close links to the municipalities in the area they cover and to the regional stakeholders, share responsibilities in relation to communication in the event of an outbreak.

The audit team found that:

- Examples of communication arrangements could be checked both through the LEIF and the WIS systems, that had facilitated exchange of information between departments in the SBA, mainly between the NDCC and the DVSs involved in the field activities, and with other CAs, such as the CAB; e.g. in relation to a recent case of ND, or the NFA, as in a recent outbreak of salmonellosis. The LEIF system did allow a detailed tracking of all exchanges of instructions and data on on-the-spot activities that took place between the various departments of the SBA.

- In addition, a specific agreement between the SBA and the MSB allows the former to resort to specialised staff and additional resources in order to increase the reach of the communication activities in case of a large outbreak.
- The CAB have a specific department dedicated to communication activities; apart from their usual activities during peace time, examples could be seen of their specific preparation to deal with crisis situations of all kinds, including in the event of an animal disease outbreak.

5.2.7 Availability of epidemiological expertise

The SVA can provide the SBA (NDCC) with a highly experienced epidemiology advisory group specially trained to provide technical support in the event of epizootic disease outbreaks. The audit team could see examples of their involvement in many activities related to prevention and control of epizootic diseases, such as:

- provision of training to staff of the DVSs, the CAB and to veterinary practitioners, including those working for the Swedish animal health service (*Svenska Djurhälsovården AB – SVDHV*; see 5.3.3);
- performance of risk analysis of introduction of some epizootic diseases in Sweden (e.g. ASF or BT), development of new passive surveillance initiatives to increase the sensitivity of the early warning system (e.g. syndromic surveillance; see 5.3.3) and evaluation of risks related to wild animals in order to adapt surveillance initiatives thereto;
- spatial epidemiological evaluations to inform delimitation of surveillance zones and participation in simulation exercises.

5.2.8 Animal identification and movement control

The audit team found that:

- Registration of holdings is done according to the pertinent EU legislation for the identification of bovine animals, sheep and goats as well as pigs. According to representatives of the CAs met, a holding generally constitutes an epidemiological unit; in addition, herds held on different locations are registered under different holding numbers even if they are situated in the same municipality. In these cases, movements of animals between these locations do not have to be notified to the database, but they have to be registered in the holding register. In addition, when animals are gathered together in common grazing areas, they usually become a single epidemiological unit and are registered as such.
- There are two identification and registration systems in place; there is one database for cattle, whereas sheep and goats, and pigs, share another common database. The cattle database has been recognised by the EU Commission as fully operational since 1998, with the other common database being considered fully operational by the SBA for pigs since 2002 and for sheep and goats since 2008.
- The CAB carry out annually risk-based on-the-spot inspections in accordance both with EU requirements and in the context of cross-compliance checks that include detailed evaluation of compliance with legal requirements on animal identification and registration and notification of animal movements:
 - In general, the number of inspections carried out in Sweden is higher than required by EU legislation on identification and registration of animals.

- According to summarised results provided to the audit team, more problems are still found in relation to compliance by keepers of sheep and goats; according to representatives of the SBA, they are not as professional as keepers of cattle and pigs, and they are more reluctant to identify the animals and to timely address their registration and reporting responsibilities in relation to animal movements. The audit team did not find though any problem in one of the farms visited keeping some goats.
- Representatives of the SBA advised the audit team that warning letters are issued immediately after any CBA inspection finds non-compliances and automatically by the system when the database detects any notification missing, but they acknowledged that some weaknesses still needed to be addressed.
- A number of shortcomings in relation to the operation of the animal identification and movement reporting systems, and with regard to the reliability of the animal identification databases were observed during the audit:
 - A significant number of dead cattle had not been notified to the database, even if they had been collected by ABP processing plants. According to representatives of the SBA, the problem is the type of information provided by the processing plants, which prevents the system from being timely updated. They added that:
 - Herd registers would be updated anyway, but they acknowledged that notification of the events to the database had been a problem for a few years due to the confusing arrangements in place on the responsibilities for reporting of those animals by their keepers, who should do that anyway, and by the processing plants, which must provide that information to the SBA.
 - Two different codes are available for keepers to notify the database, one for dead animals going to a rendering plant and one for animals not going to a rendering plant. However, rendering plants do not have holding numbers and do not submit data to the database. In the end, no mechanism is in place to ensure that both sources of information can be cross-checked in order to update the database.
 - During one of the visits to a pig farm, the audit team could see that the animal keeper was sending pigs to the slaughterhouse without using his official holding registration number for tattooing the animals, as required by national legislation, but rather a unique number allocated by the company purchasing the animals. According to the animal keeper, this is the normal practice for all suppliers of this company. Representatives of the SBA acknowledged that that was not in compliance with rules in force and that they were going to address the issue immediately.

5.2.9 *Availability of Equipment*

The audit team found that:

- According to representatives of the SBA and the CAB met, logistic arrangements are in place to ensure that all necessary equipment and resources necessary in the event of an outbreak will be readily available for all CAs involved, including arrangements with the MSB in the event of a major crisis. However, this has been rarely formalised in the form of agreements or contracts with specific suppliers or service providers. For instance, lists of possible suppliers of support equipment for personnel involved in depopulation and associated activities are supposed to be updated and maintained by each CAB. The audit

team could verify that the lists kept by the CAB are quite generic and no contracts are in place to guarantee that commercial suppliers would in fact provide, for example, heavy digging equipment and respective operators for carcass burial if needed.

- Examples of minor crisis situations that happened in recent years proved that there had not been any problem in respect of availability of equipment, but possible worst case scenarios in the event of a widespread disease outbreak have not been studied sufficiently to anticipate problems derived from those situations.

5.2.10 Vaccination policy and availability of vaccine

The audit team found that:

- The SBA has the possibility to ask for the expert advice of the SVA in order to inform any decision on the use of vaccination to control the spread of an epizootic disease. However, so far there has not been any request to study possible strategies for how the system would operate in the event of a large outbreak of FMD, in particular in relation to the decision-making process and weighing up of the criteria laid down in Annex X to Directive 2003/85/EC, so that options for pre-emptive culling and/or emergency vaccination can be anticipated in the context of a worst case scenario, as required by the said Directive. In addition, no national vaccine bank has been set up for FMD and, should it be necessary, the SBA would need to resort to the common one available to all EU MS.
- According to representatives of the SBA, vaccination is not considered either a priority for the control of CSF or AI. Therefore, even if the CPs contemplate the possibility that the SBA could ask for expert advice in that respect from the SVA in the event of an outbreak; practical scenarios for the use of vaccines against those diseases in accordance with EU requirements have not been studied and developed yet.
- According to representatives of the SVA, their analysis of the previous outbreaks of BT, including the evaluation of the possible availability and distribution of vaccines, concluded that only in a very (unlikely) extreme case they would resort again to that disease control option.

Conclusions on Contingency Plans:

Largely appropriate arrangements are in place in Sweden to ensure that adequate CPs are available to all CAs with responsibilities in coping with an outbreak of an epizootic disease in accordance with the body of EU legislation regulating this area. The main pillars of the system in place are:

- The development by the CCA in coordination with other relevant CAs of a comprehensive Web-based generic CP, which is further elaborated and regularly updated with specific technical and operational areas for each epizootic disease.
- Availability to the relevant CAs of OMs that already include the necessary generic instructions and guidance for staff, and that are in the process of being further adapted to the local circumstances of LDCCs, to render them fully functional, and the CAB, in order to better define command and control structures, and reinforce the effectiveness of their operations in the event of epizootic disease outbreaks.
- Access by all CAs to adequate information management tools that:
 - speed up the evaluation of the crisis situation, providing all the necessary data and facilitating a spatial and temporal assessment that allows them to quickly define

protection and surveillance zones in accordance with EU requirements, and

- enable the CA in command to manage all necessary activities in real-time and facilitate processing and compilation of all relevant data and information on the daily progress with the eradication of the disease.
- Availability of satisfactory technical expertise in all areas involved in managing epizootic disease outbreaks.
- Financial provisions in place that should adequately contribute to cope with compensation of affected animal keepers in case of disease outbreaks and also provide additional resources for animal health prevention and disease surveillance activities.

However, in the event of a large scale epizootic disease outbreak, a number of shortcomings still undermine the robustness of the emergency preparedness system in place, in particular:

- The absence of sufficient assurances that all necessary equipment and resources necessary in the event of an outbreak will be readily available to all CAs involved.
- The insufficient attention paid to study possible worst case scenarios for the application of emergency vaccination in the event of an outbreak of FMD. As a consequence, the currently available CP for FMD does not include detailed plans for the CAs to effectively apply this measure in accordance with provisions laid down in Articles 14(3) and 72(3) of, and Annex XVII to Directive 2003/85/EC.
- Both the lack of timely notified data and the ineffective official controls on animal movements that will hamper the quick availability of information on animal traceability needed for the targeting of actions to control disease outbreaks.

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 of 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

The audit team found that:

- A joint annual risk analysis is carried out by the SBA with the support of the SVA, the NFA and other associated CAs in order to prioritise control and surveillance activities all along the food chain, including risk identification in relation to epizootic diseases.
- In addition, the SVA is responsible for doing more specific risk analysis exercises in order to better inform SBA policies and to prioritise animal health prevention and surveillance

activities (see 5.3.3). As a direct consequence of these assessments, several initiatives have been organised over the recent years to raise awareness amongst all stakeholders of the importance of early detection and notification of diseases, such as ASF and FMD, and some policies have been modified, such as surveillance for ASF and AI, or vaccination against BT.

5.3.2 Notification requirements (peacetime)

As indicated in section 5.1.2, the EDA and the Epizootic Diseases Ordinance, alongside some additional regulations of the SBA listing all notifiable diseases, lay down obligations for all stakeholders in Sweden in respect of the notification of suspicion of animals diseases, including all those epizootic diseases covered by the scope of this audit.

The FVO audit team noted that:

- Farmers, food business operators, staff of the DVSs and the CAB, staff of the private laboratory visited, and veterinary practitioners met during the on-the-spot visits were fully aware of their obligations to report suspicions of epizootic diseases.
- OV's of the DVSs were well aware of their powers and responsibilities to impose restrictions on farms straight away in case of suspicion of any contagious disease, and veterinary practitioners of theirs in respect of notifying any suspicion of an epizootic disease to both the SBA and to the CAB, who will then notify the local DVS, the SVA and the municipalities possibly involved in the situation.
- The SVA could provide comprehensive details of all investigations carried out on suspicions and confirmed cases of notifiable diseases. See the next section for additional information on notification of suspect cases of epizootic diseases.

5.3.3 Monitoring and surveillance systems

In accordance with the outcome of the joint annual risk analysis carried out by the SBA with the support of the SVA, the NFA and other associated CAs, the SBA has planned a number of initiatives in the context of the early warning system for epizootic diseases:

- With regard to some diseases, such as FMD, ASF, AHS and EHD; surveillance is carried out by means of clinical surveillance. According to representatives of the CAs met, the pillars of this approach are the constant training of private veterinary practitioners and staff of the DVSs, the campaigns aimed at raising awareness amongst animal keepers, specific surveillance protocols targeted at wildlife and an specific initiative encouraging free of charge pathological examination of dead animals in order to exclude the presence of a number of diseases, including many of the exotic diseases covered by the scope of this audit (see below).
- After an specific risk analysis exercise carried out during 2012, the SVA advised the SBA that active serological surveillance in respect of ASF was no longer necessary, as arrangements for clinical and pathological surveillance should be sufficient to ensure early detection of a disease incursion.
- Surveillance for BT (including regular entomological surveillance), CSF, SVD, AI and ND also includes active targeted pathological, virological and serological surveys.

All those surveillance activities are described in the report 'Surveillance of infectious diseases in animals and humans in Sweden', which is published annually. The 2012 report is available at the following address:

In addition, the audit team found that:

- One of the main pillars of the passive surveillance system in Sweden is the cooperation of the SVDHV, as a private cooperative association of veterinary practitioners that provides preventive animal health care services to keepers of beef cattle, sheep and goats, and pigs. The SVDHV covers the majority of pig producers in Sweden (85 to 90%), and an smaller percentage of keepers of the other species. A similar organisation (*Växa Sverige*) covers nearly 100% of the dairy herds. These services keep very close cooperation with both the SBA and, fundamentally, the SVA, and their veterinary practitioners carry out frequent visits to animal holdings.
- According to representatives of all the CAs met, the long-standing good level of cooperation with stakeholders works out very well in the poultry and the pig sectors, where the sensitivity of the system has repeatedly proved that farmers and veterinary practitioners are quick at reporting suspicions of unexpected health and production events amongst their animals.
- The above mentioned initiative promoted by the SBA and the SVA to decentralised pathological examination of dead animals in order to exclude the presence of a number of diseases has had a big impact in the number of cases that have been thoroughly investigated since 2007 in order to exclude the presence of major epizootic diseases, such as FMD (BT), CSF and ASF, AI and ND, and even EHD.
- Cases where the presence of any of those diseases cannot be excluded by the veterinary practitioner, an OV of a DVS, or staff of the private laboratories responsible for carrying out the necropsies of dead animals (see below), are discussed with an expert of the SVA on the phone who, in liaison with staff of the DIACP, decides on the diagnostic pathway to follow in accordance with a well documented and fully recorded protocol. The exclusion diagnosis is carried out immediately, as demonstrated by examples checked by the audit team, where presence of diseases such as CSF/ASF, FMD and AI/ND had been ruled out in less than 24 hours. In a few cases, the DIACP had instructed the DSV to impose movement restriction measures on the farms under investigation due to a higher level of uncertainty as to the possible presence of an epizootic disease. During 2013, 221 of those cases were handled by the SVA according to this diagnostic protocol.
- One of the main private laboratories responsible for this activity visited by the audit team is performing some 1 000 to 1 200 necropsies annually on farm animals reported by farmers, veterinary practitioners and ABP processing plants. According to representatives of the SVDHV, they have submitted for study through this initiative some 3 000 animals nationwide during 2012. All costs are covered by the SVA, which is also processing all samples taken for pathological and virological examinations.
- In parallel to the initiative just described, and as part of a far reaching national surveillance plan under preparation, the SVA was in the process of refining an specific syndromic surveillance programme aimed at bringing together all possible sources of animal health surveillance in the country. The main pillar of this initiative is the frequent collection and quick analysis of data from laboratories and veterinary practitioners (mostly through the SVDHV and similar services), in order to further reinforce the early warning system for animal diseases.
- Representatives of the SVA and the SBA acknowledged that there is some room for improvement with regard to animal health surveillance in wildlife. Even though an specific targeted initiative is in place for surveillance for AI in wild birds and the SVA performs

routine analysis of other wild animals found dead and brought to their attention by hunters and other stakeholders; little is done, for instance, in relation to surveillance in wild boars, of which some 100 000 are hunted each year in Sweden.

5.3.4 Public awareness activities in “peacetime”

The audit team found that:

- There is a high level of disease awareness amongst veterinary practitioners, farmers and other stakeholders, such as staff responsible for diagnostic laboratories or ABP processing plants. This is regularly enhanced by all CAs through targeted campaigns and continuous training of veterinary practitioners and official staff, as well as by maintaining well updated Websites where extensive information and adequate guidance can be found in relation to all these diseases and to the actions to be taken in case of any suspicion. Some examples found were:
 - An specific Website specially dedicated to inform and advice on epizootic diseases that is aimed at veterinary practitioners and veterinary students (www.epiwebb.se). The SVA had recently carried out a survey to evaluate how useful this source of information is considered by the intended stakeholders and to further refine its contents.
 - The Website of the SVA, where very extensive information on all epizootic diseases can be found (www.sva.se), and where the State Epizootiologist frequently comments on a number of issues, including on any emerging animal health risk.
 - An specific training and awareness initiative co-organised by the SBA and the SVA between 2011 and 2013 called EPISAM, aimed mainly at keeping the network of veterinary practitioners aware of the initial clinical signs of the major epizootic diseases and of the procedures for notification and investigation of suspicions, as described in section 5.3.3.
 - A Website maintained by the MSB, that is aimed at the general public and contains information and frequently asked questions on ongoing crisis events, including outbreaks of epizootic diseases (www.krisinformation.se).
 - The Website of the SVDHV (www.svdhv.org), where specific details can be found on a number of preventive health issues, as well as information on a number of diseases.
 - The Swedish Veterinary Journal, aimed mainly at the veterinary profession, which has a dedicated section to describe and discuss disease cases investigated by the SVA and the SBA.

5.3.5 Bio-security measures in place on animal holdings

The audit team found that:

- There are extensive formalised farm biosecurity programmes in all production sectors; these are mostly driven by the industry, through the Swedish farmers association, the SVDHV and similar services, with some of a general nature and other mostly related to control and prevention of a number of infectious diseases (e.g. bovine viral diarrhoea, porcine respiratory and reproductive syndrome – PRRS).
- Some aspects of on-farm biosecurity are becoming compulsory as a result of new SBA regulations on general good practice on farm hygiene aimed at preventing transmission of

zoonoses and other infectious diseases, that was going to enter into force early in 2014. In addition, the SBA has introduced specific biosecurity regulations aimed at preventing transmission of HPAI between wild birds and domestic poultry.

- Besides, there are voluntary salmonellosis control programmes in place in poultry (nearly 100% of broiler flocks covered), cattle (50% of dairy herds covered) and pig farms (some 80%), that require very high levels of biosecurity and that are frequently checked by veterinary practitioners and by staff of the DVSs. According to representatives of the SBA, the programmes for cattle and pig farms were shortly going to become compulsory, under a general biosecurity programme to be introduced by the SBA, and that will add to the general biosecurity measures already in place, additional practical and educational aspects to further prevent the transmission of infectious diseases.
- Examples of the above mentioned programmes and initiatives could be seen by the audit team during some of the meetings and visits carried out, in particular with representatives of the SVDHV, with OV's of the DVSs and in the farms visited.

5.3.6 *Staff training*

As it has been mentioned in several sections of this report, the audit team found that, in general, staff of all CAs met demonstrated having received adequate training to be prepared to act in the event of an epizootic disease outbreak according to their responsibilities. During the meetings held with staff of the DIACP, the DVSs and the CAB, and in both the private laboratory and the SVA, they demonstrated a high level of awareness, in particular, and as appropriate to each of them, in relation to:

- the evaluation of symptomatology conducive to suspicion and early detection of epizootic diseases, including on how to handle the case and liaise with other colleagues or other CAs, or on how to perform preliminary epidemiological investigations before the disease is confirmed or ruled out by laboratory diagnosis. This included awareness on safe methods for collection and delivery of samples to the laboratories;
- the use of the available information management systems and databases in order to manage on a daily basis their activities in the event of an outbreak and to further investigate the epidemiological situation and set up an early response to speed up the detection of possible transmission routes of the disease beyond the suspected holding;
- the structure and content of both the EDH and their OMs. Specific training has been provided to some members of the staff in areas such as valuation related to compensation payments, communication with the media, organisation of depopulation activities or liaison with and supervision of the activities of ABP processing plants in case of larger disease outbreaks.

5.3.7 *Simulation exercises*

The audit team found that:

- Simulation and real-time exercises in dealing with epizootic disease outbreaks take place regularly involving all or just some of the CAs and levels of the crisis management system; i.e. the NDCC, one LDCC, involvement of just some DVS, some CAB, and the SVA. Some of these exercises involve co-operation with other MS of the EU in the context of the Nordic-Baltic memorandum of understanding in this area, such as one that was organised on ASF in 2011. For instance, one exercise was organised in 2010 to check the readiness of the

LDCCs in case of an outbreak of FMD, and another one focused in 2012 on the role and availability of the veterinary network external to the CAs in case of outbreaks of FMD, ASF or CSF.

- The SBA has set up a system to review and evaluate the outcome of all these exercises; it involves both an internal and an external evaluation. The former is more technical and focused on the particular disease that has been used for the exercise and it is carried out by the specific working group established for the exercise in the SBA; the latter is done by experts on general aspects of the crisis management system, beyond the specific animal health dimension of the situation.
- According to representatives of the DIACP, the lessons learned from the exercises carried out since 2006, covering a variety of diseases (AI, FMD, BT, CSF and ASF, West Nile fever), were used to gradually strengthen the emergency preparedness system during recent years, and are some of the reasons why the SBA decided to modify their crisis management system (see 5.2.1). Some of the conclusions highlighted by staff of the DIACP, some already addressed and some still under review, were:
 - To increase preparation of staff, in particular those in charge of a LDCC, to better use the information management resources available, in particular the LEIF system.
 - To better define the strategic decision making process by the NDCC, in order to speed up the impact and consequences of the various scenarios drawn for each specific situation.
 - To review the crisis management system in cooperation with other CAs in the event of a zoonosis outbreak, including further development of specific tools for entomological surveillance.
 - To improve the reliability of, and speed up the tracing back and forward of animals, and of risk-bearing co-involved products in the feed and food chain.
 - To reinforce communication links with the farming community in emergency situations and to speed up the interaction with, and technical support provided to veterinary practitioners in case of suspicion
 - To increase the number of table-top exercises to target specific components of the early response to a disease outbreak; e.g. in case of incursion of a disease in the wild boar population in a restricted geographical area.

Conclusions on Preparedness and Awareness:

The multi-component early warning system in place in Sweden can effectively contribute to the prevention and prompt detection, control and eradication of outbreaks of epizootic diseases, in particular thanks to:

- Availability to the SBA of regularly updated disease risk analyses and epidemiological advice that are used to:
 - prioritise allocation of resources to animal health prevention and risk targeting of disease surveillance systems, and
 - plan well-focussed training initiatives for veterinary staff and raise awareness amongst all stakeholders of the importance of early detection and notification of these diseases.
- A high level of awareness amongst stakeholders in the animal production sector of the

importance of preventive health care and biosecurity measures as the main pillars of the high health status of the animal populations in Sweden.

- The very satisfactory collaboration between the industry, including animal keepers and private veterinary practitioners, and private and official laboratories and staff of the CAs at all levels. This system facilitates prompt investigations in case of disease situations whose cause can not be easily ascertained and thereby allow the CAs to adequately investigate the possible presence of epizootic diseases.
- Organisation of simulation and real-time exercises in dealing with epizootic disease outbreaks that take place regularly, often involving cooperation with other MS, and that effectively contribute to:
 - train personnel designated to be involved in an emergency situation related to the control of potentially rapid spreading animal diseases, and
 - testing, critically reviewing and up-dating CPs, emergency preparedness arrangements in general and disease eradication strategies at national and local level.

5.4 LABORATORIES

Legal requirements:

Articles 11 & 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. Diagnostic manuals are provided for FMD, CSF, ASF, SVD and AI (see Annex 2).

Findings:

As indicated above, the SVA plays the role of NRL for all epizootic diseases relevant in the scope of this audit:

- General procedures in the NRL are accredited according to norm ISO:17025, but not all the specific diagnostic tests for all epizootic diseases have been accredited as, according to staff of the SVA, the Swedish accreditation body requires their frequent use in order to do that, which in many cases (e.g. CSF/ASF, FMD, BT or AHS) has not been possible due to the very limited number of tests performed annually. Nevertheless, according to representatives of the SVA, the accreditation process for all these tests is in their final stages and they were expecting most of them to be accredited before the end of 2013 or shortly afterwards.
- Well updated standard operating procedures (SOP) were in place for all those tests in the context of the quality management system set up by the quality department of the SVA, as well as an adequate and reliable laboratory information management system. The former follow the provisions laid down on EU diagnostic manuals, when available, or in other relevant international standards, as appropriate.
- All NRLs participate regularly with satisfactory results in inter-laboratory comparison tests organised by the network of EU reference laboratories for all relevant infectious diseases.
- The laboratory has its own laboratory CP, which has been regularly updated as a result of a

very comprehensive evaluation of the outcome of, and the weaknesses found during the simulation exercises carried out during recent years, in particular after the exercise on ASF carried out in 2011 (see 5.3.7). The whole crisis management structure of the SVA has been reorganised after that exercise and this has included an evaluation of their capacity to adapt and respond to the diagnostic demands of a large disease outbreak, upon which action had been taken to enhance their preparedness.

Conclusions on Laboratories:

The SVA can guarantee that a reliable diagnosis can be carried out in accordance with relevant EU legislation for all the epizootic diseases covered by the scope of this audit. In addition, adequate arrangements and diagnostic overcapacity are also in place to ensure that this laboratory network can effectively adapt to and cope with unexpected large scale outbreaks of those diseases.

5.5 DEPOPULATION FOR EPIZOOTIC DISEASE CONTROL

Legal requirements:

Council Regulation (EC) No 1099/2009 lays down rules for the killing of animals, including when this is performed 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, on the basis of the hypothesis established in the contingency plan concerning the size and location of suspected outbreaks, 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 audit team found that:

- Although several CPs have been recently updated, those updates did not yet take into account the requirements of Regulation (EC) No 1099/2009. The CCA informed the audit team that additional revision and updating in order to incorporate those requirements was expected to be finalised by the end of 2013. In the meantime, most of the requirements of the said Regulation are not addressed by the existing CPs, namely:
 - As indicated in previous sections, the SBA is still in the process of developing options to deal with specific (worst) case-scenarios in the event of epizootic disease outbreaks. As a consequence, the lack of detailed hypothesis on the possible size and location of suspected outbreaks has so far prevented the inclusion in the CPs of the stunning and killing methods to be used in each case and the development of SOP for killing for depopulation, as required by Article 18 (1) of the said Regulation.
 - Current provisions for reporting on depopulation procedures do not include all the information required by Article 18(4) of the said Regulation.
- At the time of the audit, the CAs had not made any arrangements yet to ensure that adequate independent scientific support was available to them in accordance with Article 20 of Regulation (EC) No 1099/2009. As a consequence, no formal advisory system was in

place yet for the purpose of that Regulation (e.g. on drafting depopulation guidelines) and, in addition, the nomination of a national single contact point required in that respect by the same Article has not been done either.

- General instructions in relation to depopulation in the event of a disease outbreak are included in a specific section of the EDH:
 - It states that an OV (of a DSV) will be designated by the SBA as responsible for ensuring compliance with the relevant animal health and animal welfare requirements during depopulation.
 - It mentions some general principles to be followed with regard to valuation of the animals and it has an annex with additional details concerning depopulation methods. That annex contains general guidance for staff involved in killing for depopulation and some additional information on stunning methods that can be used (e.g. indications about advantages and disadvantages of a few of them) but even if combined with requirements laid down in the "Welfare of Animals at Slaughter and Killing" regulations, it still cannot be considered an SOP as required by Article 18 (1) of Regulation (EC) No 1099/2009.
 - The methods mentioned in that annex also do not identify the respective estimated maximum kill rates which would provide support for granting the possible derogations to some provisions of Regulation (EC) No 1099/2009 in exceptional circumstances as envisaged in Article 18 (3).
 - Finally, the EDH states that the final decision about the stunning and killing method to be used during a depopulation operation is taken by the SBA.
- There are two entities recognised in Sweden by the SBA as qualified to carry out depopulation procedures. One for poultry and another for other livestock with different possible methods. According to national requirements, it is the responsibility of the animal keeper to provide for one of those entities to come and perform the depopulation. Nevertheless, the SBA also has sufficient legal powers under the EDA to directly impose depopulation measures, which would be undertaken by those same entities.
- Both of the recognised depopulation entities would provide the qualified staff and relevant stunning and killing equipment for depopulation. The EDA also entitles the SBA to make use of any necessary additional staff and equipment, from slaughterhouses or other relevant equipment suppliers, to provide the support needed to carry out depopulation operations.
- A sub-contractor of one such entity was visited and could show some stunning equipment immediately available (penetrative captive bolt pistols) and informed the audit team that additional such equipment, as well as electrical stunning equipment, was also available in storage. The sub-contractor also informed:
 - about the frequency of on-farm killing routinely performed (four or five animals per month) due to accidents and/or old age, for mostly cattle and horses respectively;
 - that during a depopulation procedure the killing step itself would usually be either by pithing or by cardiac arrest, and presented a certificate of training issued by the SBA for performing pithing;
 - that neither the entity or the sub-contractor have prepared any SOP for stunning and killing during depopulation, and no estimated maximum stunning and killing rates have been established.
- In addition, representatives of the SBA informed the audit team that if there is a substantial need for resources, the Nordic countries may help each other in accordance with an existing

memorandum of understanding.

5.5.2 *Protection of animal welfare*

The audit team found that:

- In principle the preferred options for stunning and killing during depopulation would be with gas (carbon dioxide) for poultry, and captive bolt stunning followed by pithing or electric cardiac arrest for killing of other species.
- For large new chicken and turkey houses, SBA regulations require new livestock buildings to have an in-built gas supply system that can be connected to an external source of gas. The SBA informed the audit team that in practice it is common for spent laying hens to be killed by means of gas. This procedure is allowed by the said regulations after previous notification to the CAB, and in the presence of an OV who must approve the operation and amount of gas to be used as well as draft a report of that operation and send it to the SBA.
- The SBA has established a national list of slaughterhouse staff qualified (per method and species) for performing stunning and killing. The SBA informed the audit team that certificates of competence for these staff had been issued already in line with the requirements of Article 21 of Regulation (EC) No 1099/2009. The training, and respective final examination, is provided by the Swedish University of Agricultural Sciences and the certificates are issued by the SBA. The SBA has issued certificates after successful final examination as well as under the simplified procedure envisaged by Article 29 of the said Regulation.

Conclusions on depopulation for epizootic disease control:

General practical arrangements are in place in case animal depopulation had to be carried out in the event of an epizootic disease outbreak, and training for stunning and killing, and the respective certificates of competence, are already in line with requirements laid down in Regulation (EC) No 1099/2009. However, most of the new requirements introduced by that Regulation in order to anticipate and increase the planning necessary to properly integrate animal welfare aspects into the existing CPs have not been addressed yet and, therefore, the system in place cannot be considered yet in line with provisions laid down in Article 18 of the said Regulation.

5.6 DISPOSAL OF CARCASSES

Legal requirements:

Commission Regulation (EC) No 1069/2009 lays down health rules for ABP and derived products, in order to prevent and minimise risks to public and animal health. In particular, Article 9 (f)(i) specifies that animals and parts of animals killed for disease control purposes, shall be considered in principle, and provided Category 1 material is not present, as Category 2 animal by-products and therefore subject to the disposal methods specified in the Regulation. Ruminants from which specified risk material has not been removed must be disposed of as Category 1.

In relation to FMD controls, Directive 2003/85/EC (Article 72 (1), (4) and (5) and Annex XVII Points 13 and 14) requires 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 CP.

Findings:

The audit team found that:

- There is a centralised system set up at national level for farmers to notify of animals dead at the farm by either phone call, text message or online at a dedicated Website. The carcasses are then collected by local sub-contractors for disposal. The notification, after introduced into the system, is automatically routed to the relevant sub-contractor for the locality in question.
- All the sub-contractors must have mobile broadband in their ABP collection trucks to receive these notifications directly and organise their collection route accordingly. All such trucks must also comply with certain other minimal requirements (e.g. inbuilt cleaning equipment and spillage prevention facilities). The standard truck seen by the audit team was well equipped to handle containers designed specifically for collecting ABP.
- After collection, the sealed containers are transported to approved regional intermediate collection points where the, still sealed, containers are unloaded. The containers are later picked up here by bigger trucks with trailer, capable of transporting up to four containers simultaneously, and taken to one of the two ABP processing plants.
- The collected ABP are processed as category 1 material and then transported to incineration plants. According to evaluations carried out by the SBA; the capacity of the ABP processing plants could be doubled in the event of a crisis situation.
- Adequate general principles were explained to the audit team of what adaptations would be needed in order for this collection and disposal system to safely dispose of possibly infectious carcasses in case of an outbreak. However, the described adaptations were not included in the current CPs.
- The SBA owns a mobile incinerator that can incinerate up to one tonne per hour and could also be used for disposal of carcasses in case of outbreaks, as was the case recently with a small anthrax outbreak.
- Representatives of the SBA informed the audit team that there are formal agreements in place with both Denmark and Norway to provide support for disposal of ABP if needed. Nevertheless, these agreements do not necessarily apply in the event of an outbreak of a major epizootic disease.
- Carcass disposal during an outbreak would in principle be performed either by processing and incinerating or by on-site burial. On-site burial can be done after approval by the municipality and no sites have been identified in the CPs for that disposal (either at national level or by the CAB). If needed, and on the basis of the powers conferred by the EDA, the SBA has legal powers to override the municipalities and decide on the necessary burial locations. Representatives of the SBA advised the audit team that if a major outbreak occurred, in the absence of sufficient carcass processing capacity, or in order to avoid moving infected material around the country; burial on site is the preferred option for disposal of carcasses of animals killed in the affected holdings.

Conclusions on disposal of carcasses:

The CAs have a well set up system for carcass disposal during peace time that should be able to deal adequately with carcass disposal in case of small disease outbreaks. On the contrary, in the event of a major disease outbreak, that carcass disposal system may be quickly overwhelmed by the volume of ABP to be disposed of, and burial on site has been chosen by the CAs as the most likely alternative method to be used in order to avoid the risks of moving infected material. However, the fact that no specific sites have been approved for that purpose indicates that sufficient consideration

has not been given yet to anticipate any adverse environmental impact that may arise from such operations. This is not in compliance with the relevant requirements laid down in Directive 2003/85/EC in relation to FMD, or with the requirements laid down in Article 19(1)(e) of Regulation (EC) No 1069/2009 and Article 15(a) of Regulation (EU) No 142/2011, with regard to outbreaks of any epizootic disease.

6 OVERALL CONCLUSIONS

The combination of an excellent animal disease early warning system and largely satisfactory emergency preparedness measures and arrangements, make the system in place in Sweden robust and capable to manage epizootic disease outbreaks with limited geographic scope, in particular thanks to:

- a satisfactory level of animal health surveillance, that should contribute to the early detection of any unusual disease event in domestic and wild animal populations;
- the availability of adequate legal powers and financial provisions to cope with a disease outbreak;
- the availability of largely adequate CPs and OMs providing most of the necessary instructions and guidance for staff involved in managing a disease outbreak;
- the very satisfactory levels of training and preparation amongst staff of all the CAs involved, and
- the availability of adequate technical, diagnostic and epidemiological expertise and of effective data analysis and information management tools that facilitate the decision-making process.

However, should an epizootic outbreak become geographically widespread or affect several domestic and wild animal species, a number of shortcomings identified by the audit team cast a shadow on the level of preparedness of the system in place, namely:

- the limited operational arrangements in place to ensure access by the CAs to all necessary equipment and resources to cope with such a disease outbreak;
- the CP for FMD does not provide for measures to be implemented in the event of a worst case scenario and it lacks detailed plans to enable the CAs to take well-informed decisions in relation to the need and extent of emergency vaccination against that disease;
- the lack of preparedness to comply with EU animal welfare requirements in the context of animal depopulation;
- the limited rendering and incineration capacity available, and the lack of arrangements in the CP for FMD in respect of alternatives to ensure proper and effective disposal of animal carcasses and other ABP, in particular if it is necessary to bury or burn the carcasses of dead or killed animals on site, and
- the lack of data and the ineffective official controls on animal movements that will have a significant impact on the quick availability of information on animal traceability needed for the targeting of actions to control disease outbreaks.

7 CLOSING MEETING

A closing meeting was held on 24 October 2013 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 preliminary findings and conclusions, and provided additional clarification on a number of issues.

8 RECOMMENDATIONS

The CAs are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), within one month after receipt of the report, aimed at addressing the recommendations set out below

N°.	Recommendation
1.	To ensure in accordance with EU legal requirements on control of epizootic diseases that CPs allow access to facilities, equipment, personnel and all other appropriate materials necessary for the rapid and efficient eradication of a geographically widespread epizootic disease outbreak.
2.	To ensure that the CP for FMD provides for measures to be implemented in the event of a worst case scenario and it includes detailed plans to enable the CAs to take well-informed decisions in relation to the need and extent of emergency vaccination against that disease in accordance with provisions laid down in Articles 14(3) and 72(3) of, and Annex XVII to Directive 2003/85/EC.
3.	To ensure completeness and reliability of data on animal movements available to the CAs and that effective official controls are implemented in that respect, in order to guarantee both compliance with EU requirements on identification and registration of animals and quick availability of information on animal traceability needed for the targeting of actions to control animal disease outbreaks.
4.	To ensure in accordance with Article 18 of Regulation (EC) No 1099/2009 that on the basis of the various possible scenarios for the size and location of animal disease outbreaks, CPs include details on: a) the stunning and killing methods planned and the corresponding SOPs for ensuring compliance with the rules laid down in the said Regulation, and b) exceptional circumstances that would permit to derogate from certain provisions of the said Regulation.
5.	To ensure that reports on depopulation operations include all the information specified in and required by Article 18(4) of Regulation (EC) No 1099/2009.
6.	To ensure that, in cooperation with the environmental authorities, sites are identified that can be used, in case of an outbreak of an epizootic disease, for deep burial of carcasses as required by Directive 2003/85/EC (Article 72 (1), (4) and (5) and points 13 and 14 of Annex XVII) and Article 15(a) of Regulation (EU) No 142/2011.

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=2013-6780

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
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. 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. 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
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

Legal Reference	Official Journal	Title
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
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
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)

Legal Reference	Official Journal	Title
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. 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
Dir. 2008/71/EC	OJ L 213, 8.8.2008, p. 31-36	Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (Codified version)
Dir. 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. 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

ANNEX 2 - SUMMARY OF LEGAL REQUIREMENTS

RELATED TO CONTINGENCY PLANNING FOR EPIZOOTIC DISEASE

Criteria	Disease & applicable legislation							
	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 Dir. 92/119 Dec. 2000/428	AHS Dir. 92/35	AI Dir 2005/94 Dec. 2006/437 Dec. 2010/367	ND Dir 92/66
Requirement for approval by Commission	Art 72 (6) – (9)	Art 18 (2)	Art 22 (3)	Art 21 (3)	Art 20 (3) & (4)	Art 17(2)	Art 62 (4)	Art 21 (3) & (4)
Requirement to update on 5 yearly basis	Art 72 (10)		Art 22 (3)	Art 21 (3)			Art 62 (5)	
Disease notifiable within MS	Art 3 (1)(a)	Art 3	Art 3 (1)	Art 3 (1)	Art 3	Art 3	Art 5 (1)	Art 3
Disease notifiable to Commission /other MS	Art 3 (2)	Dir. 82/894: Art 1 & 3	Art 3 (2)	Art 3 (2)	Dir. 82/894: Art 1 & 3	Dir. 82/894: Art 1 & 3	Art 5 (2) Annex II (details notification requirements)	Dir. 82/894: Article 1 & 3
Co-operation with other CAs within MS	Article 74(3) (d),(g) & (i) Annex XVII (6)						Art 62 (3)	
Co-ordination with neighbouring MS & TC	Art 72(2) Art 17 provides for co-ordination by Commission/ ScoFCAH					Art 8 (2)(c) (where PZ, SZ includes territory of other MS)		
Sufficient legal powers to control outbreaks	Annex XVII (1)	Annex III (10)	Annex VII (a)	Annex VI (a)	Annex IV (10)	Annex IV (10)	Annex X (13)	Art 26(1) (requiring transposition) Annex VII (10)
Chain of command	Annex XVII (3)		Article 23(6) Annex VII (c)	Annex VI (c) Art 22 (6) (for NDCC, LDCC)				
NDCC / LDCC	Article 74 – 77 Annex XVII (4) & (5)	Annex III (1) & (2)	Art 23	Article 22(2), (3) & (4)	Annex IV (1) & (2)	Annex IV (1) & (2)	Art 62 (6) Annex X (1) & (2)	Annex VII (1) & (2)
Permanent expert group	Art 78 Annex XVII (7)		Art 23 (5)	Art 22 (5)			Article 62(6)	

Criteria	Disease & applicable legislation							
	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 Dir. 92/119 Dec. 2000/428	AHS Dir. 92/35	AI Dir 2005/94 Dec. 2006/437 Dec. 2010/367	ND Dir 92/66
Information on personnel, qualifications, responsibilities		Annex III (3)			Annex IV (3)	Annex IV (3)	Annex X (3)	Annex VII (3)
Operational manual	Annex XVII (9)		Annex VII (e)	Annex VI (e)				
Instructions available to staff		Annex III (6)	Annex VII (e)	Annex VI (e)	Annex IV (6)	Annex IV (6)	Annex X (6)	Annex VII (6)
Questionnaire for epidemiological enquiry	Article 13(1)		Article 8	Article 8			Art 6 (1) Annex X (3)	
Staff training	Annex XVII (11.1) & (11.3)	Annex III (7)	Annex VII (g) (i)	Annex VI (f)(i) & (f) (iii)	Annex IV (7)	Annex IV (7)	Annex X (7)	Annex VII (7)
Access to sufficient financial resources	Annex XVII (2)		Art 22 (1) Annex VII (b)	Annex VI (b)				
Availability of equipment and materials	Art 72 (2) Annex XVII (2) & (8)	Art 18 (1) & Annex III (5)	Article 22(1) Annex VII (d)	Art 21 (1) Annex VI (d)	Art 20 (1)	Article 17 Annex IV (5)	Art 62 (2) Annex X (5)	Art 21(1) Annex VII(5)
Diagnostic capabilities and capacity	Art 71 & Annex XVII (8)	Annex III (8)	Article 17 (d) Annex VII (d)	Annex VI (d)	Annex IV (8)	Annex IV (8)	Annex X (8)	Annex VII (8)
Disease surveillance programme/ early detection		Article 4 and Annex I & V to Reg 1266/2007					Art 1 (1) Art 4 (1) & (2) & Dec. 2010/367	
Definition of worst case scenario	Annex XVII (12)							
Areas of high population density identified	Art 72 (3)(b) Regions of densely populated areas Def: Annex X, (3)		Art 22 (1)(b) Regions with high density of pigs (higher level of awareness/preparedness) Definition: Art	Art 21 (1)			Annex X (12) Article 62(2) Annex X (10) Registration of commercial poultry holdings	

Criteria	Disease & applicable legislation							
	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 Dir. 92/119 Dec. 2000/428	AHS Dir. 92/35	AI Dir 2005/94 Dec. 2006/437 Dec. 2010/367	ND Dir 92/66
			2(u) 300 pigs/km					
Vaccination requirements identified	Art 72 (3)(a)	Annex III (9)	Art 22 (1)(a)			Annex IV (9)	Article 59(1) Art 62 (2)	Art 21 (1) Annex VII (9)
Availability of vaccine identified					Annex IV (9)		Annex X (9)	
Plans & procedures for emergency vaccination	Conditions and criteria specified in Art 49 – 58 & Annex X	Conditions and criteria specified in Art 5 & 6 (as amended by Dir. 2012/5)	Annex VII (f) Annex VI (criteria for deployment of emergency vaccination)				Annex X (9)	
Means of destroying carcasses		Annex III (6)			Annex IV (6)	Annex IV (6)	Annex X (6)	
Environmentally sound means of disposal of carcasses, etc.	Art 72 (1), (4),(5) Annex XVII (13) & (14)							
Real time alert exercises	Art 73 & Annex XVII (11.2)						Art 62 (6) (COM may make further rules)	
Alarm drills	Annex XVII (11.2.4)		Annex VII (g) (ii)	Annex VI (f)(ii)				
Co-operation with neighbouring MS in exercises	Art 73 (2) & Annex XVII (11.2)							
Communications strategy	Annex XVII (15) & (11.3)	Art 14	Article 23(6) Annex VII (g) (iii)	Annex VI (f)(iii)	Annex IV (4)	Annex IV (4)	Annex X (4)	Annex VII (4) Art 13 (information to PZ, SZ)
Disease awareness and preparedness	Art 72(1) Annex XVII (11.3)		Art 22(1)(b) – regions with high density pig population					
Preventive vaccination							Dec. 2007/598 - in approved bodies, zoos (list) Special identification of vaccinated birds	

Criteria	Disease & applicable legislation							
	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 Dir. 92/119 Dec. 2000/428	AHS Dir. 92/35	AI Dir 2005/94 Dec. 2006/437 Dec. 2010/367	ND Dir 92/66
Diagnostic methods specified	Art 71 & Annex XIII		Diagnostic manual: Decision 2002/106/EC	Diagnostic manual: Decision 2003/422/ EC	Diagnostic manual: Decision 2000/428/E C		Diagnostic manual: Decision 2006/437/EC	