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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ESTONIA

FROM 15 TO 19 APRIL 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 Estonia carried out between 15 and 19 April 2013, as part of the FVO audit programme for 2013. The objective was to evaluate the resources and arrangements put in place to implement the European Union requirements for contingency planning, including provisions on the protection of animals during depopulation, in the event of one or more outbreaks of epizootic diseases. This evaluation also included a follow-up of certain actions taken by the competent authorities in response to the relevant recommendations of the previous FVO audit report dealing with contingency planning which has been published as part of the General Audit in Estonia (DG(SANCO)8600/2009). 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.

The competent authorities have the legal powers to carry out all tasks and to call in additional personnel in outbreak of an epizootic disease. Active and passive surveillance systems are in place for the relevant diseases and all these diseases are notifiable, thorough investigations had been carried out on holdings with suspect cases and compulsory biosecurity measures reduce the risk of introduction of diseases into holdings. There are regularly updated and detailed contingency plans in place for all relevant diseases. However, gaps in the contingency planning with regard to the diagnostic preparedness for a number of epizootic diseases, the appointment of expert groups, identification of areas with high animal densities, calculations of vaccine requirements, supply of vaccines and disposal of carcasses, together with the limited supplies of equipment for depopulation, may hamper or delay measures in a crisis and contribute to the spread of a disease.

The lack of alert drills and exercises involving local staff, the lack of designated national laboratories for several diseases, the lack of written agreements with foreign laboratories for important analyses, make the contingency system vulnerable and may lead to mistakes and delays which could contribute to the spread of an epizootic disease in a real crisis situation. In addition, the absence of sufficient rendering capacity means that burning or burial on site will have to be used for disposal of carcasses following depopulation. However, the lack of approved sites for that purpose indicates a potential for environmental damage following disposal of animal carcasses in case of an outbreak as well as a risk that disposal of carcasses may be delayed, which increases the risk for further spread of the disease.

Although several contingency plans have been updated to include the new animal welfare requirements of Article 18 of Regulation (EC) No 1099/2009, detailed instructions for the welfare requirements and reporting thereof are not yet in place, kill rates have not been elaborated and staff instructions and report forms are currently being drafted. However official staff and slaughterhouse personnel have been trained in the new requirements which should ensure that these animal welfare requirements would be met in an outbreak situation.

Whilst actions taken in response to recommendations 7 and 10 in the 2008 FVO report (DG SANCO 2008-7785) could be verified, the actions taken by the competent authorities to address recommendations 2, 4 and 8 in the report had not been sufficient. The non-compliances noted in 2008 with regard to holding registrations, animal movement registrations and hygiene in rendering plants were still present and had not been noted during recent official controls.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AHS	African Horse Sickness
AI	Avian Influenza
ARIB	Agricultural Registration and Information Board
ASF	African Swine Fever
BT	Bluetongue
CSF	Classical Swine Fever
CVC	County Veterinary Centre (of the VFB)
CVO	Chief Veterinary Officer
DG(SANCO)	Health and Consumers Directorate General
EC	European Community
EHD	Epizootic Hemorrhagic Disease of Deer
ELISA	Enzyme-Linked Immuno-Sorbent Assay
EU	European Union
FMD	Foot-and-Mouth Disease
FVO	Food and Veterinary Office
LDCC	Local Disease Control Centre
LSD	Lumpy Skin Disesae
ND	Newcastle Disease
NDCC	National Disease Control Centre
NRL	National Reference Laboratory
PCR	Polymerase Chain Reaction
PPR	Peste de Petits Ruminants
RP	Rinderpest
RVF	Rift Valley Fever
SGP	Sheep and Goat Pox
SOP	Standard Operating Procedure
SVD	Swine Vesicular Disease
VFB	Veterinary and Food Board
VS	Vesicular Stomatitis

1 Introduction

This audit took place in Estonia from 15 to 19 April 2013 and was undertaken as part of the planned audit programme of the Food and Veterinary Office (FVO). The audit team comprised two auditors from the FVO. The team was accompanied throughout the audit by representatives of the Veterinary and Food Board (VFB) which is the central competent authority within the scope of this audit.

2 Objectives

The objective of this audit was to evaluate the resources and arrangements put in place to implement the European Union requirements for contingency planning, including provisions on the protection of animals during depopulation, in the event of one or more outbreaks of the following epizootic diseases: foot-and-mouth disease (FMD), bluetongue (BT), classical swine fever (CSF), African swine fever (ASF), swine vesicular disease (SVD), African horse sickness (AHS), avian influenza (AI), Newcastle disease (ND), rinderpest (RP), peste de petits ruminants (PPR), epizootic haemorrhagic disease of deer (EHD), sheep and goat pox (SGP), vesicular stomatitis (VS) lumpy skin disease (LSD) and Rift Valley fever (RVF).

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 requirements for biosecurity measures on farms.

Whilst an overview of contingency planning for all of these diseases is included within the scope of this audit, the audit concentrated on ASF, and also looked at FMD and AI. ASF was considered to be a risk due to the presence of disease in Russia. FMD is one of the most difficult diseases to contain and affects several livestock species. AI was chosen as an example of a poultry disease where specific requirements for contingency plans are laid down in European legislation. This evaluation also included a follow-up of certain actions taken by the competent authorities in response to the relevant recommendations of the previous FVO audit report dealing with contingency planning which has been published as part of the General Audit in Estonia (DG(SANCO)8600/2009).

As the requirements of Council Regulation (EC) No 1099/2009 have been applicable since 1 January 2013 the audit team also carried out an evaluation of the current state of implementation of the requirements of its Article 18.

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

MEETINGS / VISITS		no.	COMMENTS
Competent authorities	Central	2	Opening and closing meetings with the Veterinary and Food Board
	Regional	2	County Veterinary Centres (regional VFB offices) in Järvamaa and Lääne-Virumaa
	Other	1	Estonian Agricultural Registers and Information Board
Laboratories		1	National reference laboratory for FMD, CSF, ASF, SVD and BT
Holdings		1	One large integrated pig farm

Markets and assembly centres	1	One assembly centre for bovines
Other meetings	2	One visit to a rendering plant, one meeting with a gassing company

3 Legal Basis

The audit was carried out under the general provisions of European Union (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

Given the potential impact of outbreaks of epizootic disease, it is important that Member States can react immediately and effectively in a coordinated manner and in co-operation with neighbouring countries. EU legislation requires Member States to have contingency plans in place to combat such outbreaks so as to reduce their adverse consequences. The swiftness of initial diagnosis and the deployment of the first stages of the contingency plan are of critical importance to the suppression of an outbreak of epizootic disease.

The most recent outbreaks of epizootic diseases in Estonia were ND in 2007, CSF in 1994 and FMD in 1982. There have been no outbreaks of BT, EHD, ASF, SVD, AHS, VS, SGP, LSD, RP, PPR, RVF or highly pathogenic AI in Estonia (source: World Organisation for Animal Health).

The most recent FVO assessment of the contingency planning in Estonia was made in 2008 and described in report DG(SANCO) 2008-7785 (hereafter referred to as the 2008 FVO report). This report was not published separately. Instead it forms part of the report from the 2008/2009 General Audit in Estonia (DG (SANCO) 2009-8600), which has been published on the Commission website. The competent authorities presented an action plan addressing the 11 recommendations in the 2008 FVO report and the FVO noted in August 2009 that all the recommendations had been satisfactorily addressed.

All published FVO reports can be found here: http://ec.europa.eu/food/fvo/ir_search_en.cfm

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 a 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. 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 Estonian competent autorities can be found in the country profile (http://ec.europa.eu/food/fvo/country_profiles_en.cfm). This provides information on the responsibilities of the competent authorities under normal circumstances.

The lead authority for animal health control is The Veterinary and Food Board (VFB) and in particular the VFB Animal Health, Welfare and Feedingstuffs Department. There are 15 VFB County Veterinary Centres (CVC) which are responsible for the practical implementation of, *inter alia,* animal health and welfare programmes and for the supervision of Authorised Veterinarians carrying out official tasks at farm and slaughterhouse levels in the municipalities. As described in the Country Profile, these Authorised Veterinarians have individual contracts with the VBF at county level. In the context of this audit, the Authorised Veterinarians carry out sampling for surveillance programmes. They are also responsible for farm inspections for e.g. animal welfare, holding registration and animal identification. The Authorised Veterinarians would normally be the first to be notified by practising veterinarians of suspected cases of serious infectious diseases.

5.1.2 Legal powers available to the competent authorities

Supervision of animal health is based on Veterinary Organisation Act (16.06.1999; last amended 17.02.2011) which establishes the basis for the organisation of veterinary controls, authorisations of private veterinary practitioners and authorised veterinarians, laboratories and the principle of veterinary control fees.

As described in the 2008 FVO report the main legal instrument is the Infectious Animal Disease Control Act (last amended 05.12.2012) provides the legal framework for disease diagnosis and eradication, including notification of suspected cases, measures to be taken in case of suspicion or confirmation, protection and surveillance zones, eradication, compensation, and sanctions. Under the Infectious Animal Disease Control Act, all licensed veterinarians are obliged to assist the VFB in case of an outbreak of an epizootic disease, when requested to do so.

The VFB has the legal powers to call upon slaughterhouse operators, the police and the Rescue Board to assist them. The legislation covers rules for the reimbursement for such services. Should the outbreak spread nationally, the Law on Crisis Situation can be applied which provides *inter alia* for the use of the army.

The disease-specific EU Directives for epizootic diseases have been transposed into Infectious Animal Health Regulations by the Ministry of Agriculture.

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

The Animal Health, Welfare and Feedingstuffs Department of the VFB is responsible for drafting and revising the contingency plans and their annexes with the assistance of the Veterinary and Food Laboratory regarding sampling, sample submission and analyses. The University for Life Sciences may also be consulted for specific issues. The FVO team noted that:

- there are no procedures for coordination with other competent authorities in the drafting or revising of contingency plans;

- although there is a cooperation agreement with public health services regarding the handling of outbreaks of food-borne diseases, based on rules in the Infectious Animal Diseases Control Act, there are no agreements or rules on how to handle other zoonotic outbreaks, e.g. AI.

Section 5.2.3 below, outlines the responsibilities of the various competent authorities for dealing with an epizootic outbreak, as designated in the contingency plans.

Conclusions on Competent Authorities

The competent authorities have the legal powers to carry out all tasks needed to handle an outbreak of an epizootic disease. The legal provisions for assistance from private veterinarians and other services provide the competent authority with additional staff for implementation of disease eradication measures when needed. However, the lack of consultation with other competent authorities when drafting or revising contingency plans may complicate the close cooperation which, in line with EU legislation, would be necessary in a crisis situation, particularly one where there is a high risk to human health or the environment.

5.2 Contingency Plans

Legal requirements

Requirements for Member States to have contingency plans to control disease outbreaks are stipulated for the following diseases: FMD (Council Directive 2003/85/EC), BT (Council Directive 2000/75/EC), CSF (Council Directive 2001/89/EC), ASF (Council Directive 2002/60/EC), SVD and a number of other diseases (Council Directive 92/119/EEC), AHS (Council Directive 92/35/EEC), AI (Council Directive 2005/94/EC) and ND (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. Requirements for control and verification procedures are laid down in Article 8 of Regulation (EC) No 882/2004.

Findings

5.2.1 Coverage and Approval

There is a general contingency plan which covers a summary of: the legal basis; financial provisions; the chain of command during an outbreak; reimbursement principles, including the valuation of animals; establishment/composition/obligations/rights of the national disease control centre (NDCC) and local disease control centres (LDCC); staff and other resources; the general principles for the different stages of an outbreak; decision-making and procedures for vaccination and staff training.

There are disease specific, detailed contingency plans for all diseases covered by the scope of this audit. The plans for AI, PPR and RP date from May 2008 and are currently in the process of being revised. The contingency plans for EHD and RVF were published in 2009. The plans for CSF, SVD, ASF, VS, LSD and SGP were last updated in January 2011, the plan for BT was last updated in December 2012 and the plans for FMD, ND and AHS were last updated in 2013.

Areas of high animal population densities have not been identified in the contingency plans but the VFB stated that such areas could be rapidly identified using up-to-date information in the national database.

Once drafted or revised, each contingency plan is approved in a Decree by the Director General of the VFB. The FVO team noted that:

- there are now contingency plans in place for EHD and RVF (as well as for viral haemorrhagic septicaemia and infectious salmon anaemia, which are not covered by the scope of this audit). This confirms that the **actions in response to recommendation 10 in the 2008 FVO report have been taken**;

- the general contingency plan available on the VFB website at the beginning of April 2013 did not have a date or a version number;

- the general contingency plan states that a questionnaire for the epidemiological investigation in case of suspicion of an epidemiological disease is provided in an annex to the general contingency plan. However, no such annex is available with the version of the general contingency plan published on the internet:

- those disease-specific contingency plans (FMD, AI, ASF, CSF, BT, AHS) checked by the FVO team included most aspects required under EU legislation (see also point 5.2.10 about vaccination). The plans also include comprehensive practical instructions for staff at local level on how to implement the measures laid down in each plan;

- with the exception of FMD, CSF, ASF, SVD, AI and ND, the contingency plans foresee that samples submitted to the Veterinary and Food Laboratory will be forwarded for analysis to named laboratories in other Member States or in a third country. However, the competent authorities have no agreements or contracts in place to regulate the acceptance and speed of analysis of such samples in the foreign laboratories (see also point 5.4 Laboratories);

- the contingency plans included references to the legal bases for each of the measures covered in the plan;

- neither the general contingency plan nor the plan for FMD include the prior identification of

appropriate sites for the treatment or disposal of animal carcasses and animal waste with a minimum risk to soil, air, plants, animals and surface and groundwater. This is required under Article 72(5) and Annex XVII(13-14) of Council Directive 2003/85/EC. However, several plans (e.g. AI, ASF, CSF, FMD, AHS) include burial or burning as suitable methods of destruction under certain conditions and indicate that sites would be selected when needed, but some of the plans (e.g. ASF, CSF, FMD, AHS) do not state that the views of the (county) environmental board should be taken into account when selecting such sites.

5.2.2 Documentation

All approved contingency plans and their annexes (where applicable) are available on the VFB website. Contingency plans are routinely updated every five years, or more frequently if the VFB so decides e.g. based on new legal requirements, changes to disease patterns or experiences from exercises. All contingency plans / updated plans are sent to each CVC and to the Veterinary and Food Laboratory. Each CVC is responsible for informing the authorised veterinarians in the county. There are no other guidelines or operational manuals.

5.2.3 Competent authority command structure during an epizootic outbreak

The command structure during an outbreak and the role of the Chief Veterinary Officer (CVO) are laid down in the general contingency plan and in the Infectious Animal Diseases Control Act. Briefly, until an outbreak has been confirmed the suspect case is handled by the CVC in close cooperation with the VFB and the Veterinary Food Laboratory. The two latter are responsible for sending samples to foreign laboratories for analysis, where necessary.

Once a disease outbreak has been confirmed, the VFB will establish a LDCC. The LDCC is chaired by the Head of the CVC and is responsible for carrying out the epidemiological investigation(s) and for organising, coordinating and implementing all measures in the protection and surveillance zones. The LDCC reports to the NDCC.

An NDCC will be established at the VFB by the Ministry of Agriculture and will be chaired by the Director-General of the VFB, i.e. the CVO. The NDCC is responsible for the overall coordination of the implementation of control measures at national level, allocation of resources, analysis of the results of investigations, communication and coordination with other countries and international organisations and, when necessary, for making suggestions to the Government of the Republic on how to address the situation.

If there is a risk of rapid and wide spread of an animal disease, the NDCC may advise the Ministry of Agriculture to apply to the Government of the Republic for the application of the national Emergency Act. This Act allows the government to implement national emergency measures including the establishment of a national crisis committee chaired by the Minister of the Interior.

5.2.3.1 National Disease Control Centre

The composition of the NDCC is laid down in the Infectious Animal Diseases Control Act and in the general contingency plan. It comprises a chief specialist from the Veterinary and Food Laboratory, official veterinarians, the Head of a CVC and high level representatives from the border guards/police and the Rescue Board. The Director General of the VFB (i.e. The CVO) is responsible for coordinating the establishment of the NDCC and for chairing it. The FVO team noted that:

- the NDCC has the necessary legal powers to design control measures and ensure their implementation by CVCs, organise emergency vaccination, deploy staff and resources, order private veterinarians to provide assistance, request the use of staff and resources from e.g. the police, the rescue board, slaughterhouses and rendering plants;

- representatives from the competent authority for the environment or from meteorological services are not mentioned as part of an NDCC and there are no systems or procedures in place for how and when liaising with these bodies should take place. The CVO stated that there are established informal contact routes[1];

- staff at the VFB have access to all necessary information technology tools (animal and holding database linked to maps, mapping software, contact lists, journals etc) as well as all modern communication tools as well as several modern meeting rooms which could be used for the NDCC.

5.2.3.2 Local Disease Control Centres

The LDCC comprises representatives from the county and local governments, the head of the CVC, official veterinarians, a chief specialist of the Veterinary and Food Laboratory, an authorised veterinarian and representatives from the local police/border guards and rescue service. It is chaired by the head of the CVC. The FVO team noted that:

- both CVCs visited had contact lists of staff, private veterinarians and other services and organisations which would need to be contacted in an outbreak situation, as required under the contingency plan;

- the CVCs/LDCCs have the same level of access to the animal and holding database and the mapping software as the VFB/NDCC. The officials met all used mobile phones and laptops in their daily work;

- although CVCs are responsible for keeping locations for setting up an LDCC prepared, the location visited by the FVO team in one CVC was not ready for immediate use (e.g. no equipment, only two wall sockets, no land-line phone line) and was unsuitable as an LDCC as it was located in a public area of the administrative building;

- one CVC visited stated that the county government had initiated a project to identify possible sites for burial of carcasses. Although the final approval of these four locations had not been obtained from the environmental authority, there was an informal agreement between all parties concerned that they would be used in an emergency.

5.2.4 Financial provisions

The legal bases for access to emergency funds, budgetary means and financial resources linked to the measures under the contingency plans are: §30(1) of The State Budget Act; Chapter 5 of the Emergency Act; and Regulation No 346 of 16.11.1999 on "Government allocation of reserve funds and procedures for its use".

The general contingency plan lists those measures which are to be funded from the state budget:

1 In their response to the draft report the competent authority stated that the expert group will include representatives of the meteorological services.

sampling; sample analyses; vaccination; mandatory slaughter of animals; killing of animals; processing of carcasses; cleansing and disinfection; recall and destruction of potentially contaminated products; destroyed feed, equipment and inventories; and operational costs for parties involved in the operations.

The application procedure for compensation by animal keepers is regulated in §57(1) of the Infectious Animal Diseases Control Act and described in the general contingency plan. The procedure is to be initiated by an application for compensation from the animal owner to the LDCC, which is responsible for checking that the quantities and sums conform with the rules. The FVO team noted that:

- the undated general contingency plan available on the VFB website at the beginning of April 2013, stated under point 2A that the assessment of the value of animals kept for farming purposes should be made in accordance with the order of the Minister of Agriculture of 01.03.2001.Regulation no.18 (RTL 2001, 39, 536) on the arrangements for calculating the value of animals kept for farming purposes and the conditions and modalities of compensation. The value of breeding animals should be based on the average purchase price which is published quarterly by the Statistical Office for Livestock Quarterly Bulletin;

- some of the more recently updated contingency plans (e.g. ASF, CSF, FMD) made reference to Article 3(3) of the Rural Development and Agricultural Market Regulation Act for evaluation of animals, equipment, feed, packaging, milk and eggs. Other contingency plans refer to "EU legislation" and the Infectious Animal Diseases Control Act for rules for compensation;

- most contingency plans state that animals are to be valued based on the average value of meat per kilo, according to the average meat prices, and weighing of carcasses before destruction. Values of breeding animals should be estimated by experts based on the rules in Ministry of Agriculture Regulation No 6 of 2.2.2010;

- the general contingency plan does not specify at which point during disease eradication the valuation of animals (meat or breeding value) should take place or who is responsible for carrying out such valuations. However, the 2013 contingency plan for FMD states that animals are to be valued before they are destroyed.

5.2.5 Establishment and enforcement of protection and surveillance zones

Protection and surveillance zones are drawn up by the CVC/LDCC in cooperation with the NDCC using mapping software and information from the Agricultural Registration and Information Board (ARIB). Once the zone demarcation lines have been decided using distance markers, information about the location of animal holdings and natural boundaries, the formal decision is issued by the county government.

The general contingency plan describes that the enforcement of movement restrictions in zones are to be supervised and enforced by the police following instructions from the NDCC. Road blocks and re-routing of traffic are to be organised by the Estonian Road Administration. The FVO team noted that:

- the report from an epizootic disease simulation exercise in 2006 stated that the police did not have enough staff available to man check-points and enforce movement restrictions (see also

point 5.3.7.).

5.2.6 Communication procedures during an outbreak

The FVO team noted that:

- communication procedures between the NDCC, LDCC, the Veterinary and Food Laboratory are laid down in the general contingency plan;

- a general procedure for VFB media communication has been issued in a Directive by the VFB. Media communication during an outbreak is included among the tasks allocated to the NDCC in the general contingency plan. The CVO would be responsible for explaining animal welfare implications and the choice of method of killing for depopulation;

- the VFB explained that, at the stage of suspicion, communication with the media would be handled by the CVO/Director General, the deputy Directors General, heads of departments, heads of offices and heads of CVCs;

- communication with stakeholders would be handled by the specialists of heads of CVCs both during a suspicion and once an outbreak has been confirmed;

- internal and external communication had been included in recent contingency exercises and certain problems had been identified, particularly with regard to communication between competent authorities in different Member States.

5.2.7 Availability of epidemiological expertise

Although the obligations and rights of an expert group, in peace-time and during an outbreak as well as the type of expertise required in an expert group, are outlined in the general contingency plan, no general or disease-specific expert groups have been appointed. The VFB stated that the intention would be to appoint one expert group and use its members as an expert panel more than as a permanent group. Furthermore, experts would be available *inter alia* in the Veterinary and Food Laboratory and in the University of Life Sciences. However, most of the experts in Estonia would be directly or indirectly involved in managing the outbreak in case of a major animal disease crisis. The FVO team noted that:

- the requirements to appoint permanently operational expert groups as required under Article 78 of Council Directive 2003/85/EC (FMD), Article 23(5) of Council Directive 2001/89/EC (CSF) and Article 22(5) of Council Directive 2002/60/EC (ASF) have not been met;

- the possibility to arrange a formalised agreement with other Member States on mutual assistance in regard of the expert group as outlined in Article 78(1) of Council Directive 2003/85/EC had not been considered;

- in the contingency plan for AI it is stated that an expert group would be appointed by the VFB once an AI diagnosis has been confirmed or if necessary upon suspicion of AI.

5.2.8 Animal identification and movement control

There are no animal markets in Estonia. Food producing animals are sold directly between holdings

or through registered dealers or assembly centres. The national rules for registration of holdings and for identification of pigs, sheep, goats and bovines are in line with EU requirements. Electronic identification of sheep and goats is only required for animals transported out of Estonia.

All temporary and permanent keepers of animals are obliged to report movements of cattle, sheep and goats within seven days, to the national database which is administered by ARIB. ARIB also manages the register of animal holdings and maintains a central database for horses, which receives its data from the equine passport issuing bodies.

The national database has an in-built flagging system which indicates if an initiated movement from a holding has not been recorded by the intended recipient within two days and a reminder is sent to the receiving animal keeper. If the registration of the movement has not been completed within 30 days a new reminder is sent to the intended recipient. Once per month ARIB provides county-specific lists to all CVCs, where all animals which have been killed are listed as well as any "open" movements of animals off holdings in the county (where the movement out of a holding has been recorded but not the arrival at the next holding).

Based on data from the national database the animal population in Estonia was as follows:

Species	Holdings	Animals	Comment
Bovines	4496	248124	As per 31.12.2012
Pigs	239	367669	Holdings as per 31.12.2012. Animal numbers on 1.5.2012 from owners' reports.
Sheep	1374	77265	As per 31.12.2012
Goats	328	3776	As per 31.12.2012
Sheep and goats	175		As per 31.12.2012
Horses	997	10397	As per 31.12.2012. Animal data as reported from passport issuing bodies/breed organisations
Poultry / all birds	2638		As per 31.12.2012
Poultry / ducks, geese or turkeys only	213		As per 31.12.2012
Laying hens, more than 50 hens	78	700011	As per 31.12.2012. "Animals" are the maximum registered laying hen places.

The FVO team noted that:

- the requirement to register movements of sheep and goats in the national database exceeds the minimum requirements in EU legislation;

- holdings with horses must be registered in the national database. Keepers must keep a record of farm animals belonging to them or in their herd, either electronically or in paper format. Keepers must include the following data in the register: name of the horse, breed, date of birth, date of introduction into the herd and movement from it and the address of origin and destination, with the name and personal ID number or registration code of the keeper;

- the national database is available for all official veterinarians and provides search tools which are user friendly and quick. It was possible during the FVO visit to rapidly list all holdings of a particular category, to view all movements of animals (cattle, sheep and goats) to and from a holding and to trace all movements for individual animals, one-by-one from birth. The official veterinarians can also plot holdings onto a detailed map;

- ARIB can provide additional support to the VFB through specific queries to the database. Such queries are required for identification of all holdings with particular species within a specified number of kilometres from a particular holding. Such queries had successfully been produced for the VFB during the investigations of the BT (vaccine strain, BTV-14) cases in 2012;

- ARIB does not have a contract for 24-hour services to the VFB but experience showed that rapid service had been provided when requested by the VFB;

- when notified, as required under EU legislation, of the death of a horse the passport issuing bodies are obliged under national legislation to report to the national database all horses which have died, been killed or slaughtered. During 2011 and 2012, ARIB had received notifications of 27 such animals, in total;

- there were no instructions or guidelines for CVCs on how to investigate cases of "open" animal movements, included in the monthly reports from ARIB. Such investigations would often require cooperation between the notified CVC and the CVC of the intended recipient holding. In the CVC visited no follow-up checks had been carried out prior to the visit by the FVO team (17 April) for three out of four such cases reported by ARIB six weeks earlier.

With regard to the assembly centre visited the FVO team noted that:

- as noted in the 2008 FVO report, the central database did not reflect the actual number of movements from the assembly centre. A large number of animals (bovines), which were no longer in the assembly centre, had been registered as transported to the assembly centre without any registration of further movement. Many of these animals had arrived at the assembly centre several weeks or even months before the date of the visit by the FVO team;

- the records, of animal movements and transporters/vehicles, kept in the assembly centre only included animals which had remained at least overnight on the premises. The owner and the CVC stated that arrival /re-grouping / re-loading of animals in the centre in one day did not have to be registered in the records kept by the assembly centre. If the animals had been dispatched to other Member States these movements were only recorded in the files for official certificates kept by the CVC;

- the incomplete records had not been noted as a non-compliance by the authorised veterinarian or by the CVC during official controls;

- the owner of the assembly centre and the representatives from the supervising CVC stated that reports to the database must be made by the owners of the animals and not by the temporary keeper, the assembly centre. This is not in line with national or EU legislation;

- database records for three other assembly centres in other counties were checked by the FVO team. These records were up-to-date and re-grouping and re-loading of animals for

slaughter had been duly registered, also when the animals had arrived and left the assembly centre on the same day;

- there were no instructions or guidelines from the VFB to clarify the legal requirements for record keeping in assembly centres and the responsibilities for all temporary and permanent animal keepers to report animal movements to the national database;

- these findings showed that the **actions taken in response to recommendation 4 in the 2008 FVO report had not been sufficient** to address the non-compliances in all assembly centres.

In the pig farm visited the FVO team noted that:

- the animal identification system and record keeping was in line with EU requirements;

- the farm records showed that small groups of pigs (1-5 animals at a time: fattening pigs of 30-40 kg below normal slaughter weight and sows) had been sold approximately twice per month during the past 12 months to one private person without any registration of this person's address or holding number. Such movements had taken place approximately twice per month during the last year. A subsequent check by the audit team in the national database showed that this person was not registered as an animal keeper;

- an investigation by the VFB was initiated immediately and preliminary results showed that the person regularly buying small groups of pigs from the pig farm visited delivered pigs to a slaughterhouse and was involved in a retail business for meat, which could indicate that he might keep pigs for fattening on an unregistered holding. The 2008 FVO report noted that persons who were temporary keepers of pigs had not always been registered in the national database. In response to recommendation 2 in the 2008 FVO report the VFB undertook to ensure that all pig holdings, also those of temporary keepers, would be included in the database. Although the investigation of the current case was still ongoing the preliminary information presented at the closing meeting indicates that the **actions taken in response to recommendation 2 in the 2008 FVO report may not have been sufficient**;

- although clearly recorded in the farm records, the regular pig movements to the unknown location had not been noted during two official controls on animal health and animal welfare carried out by the authorised veterinarian and by the CVC, respectively, during the past twelve months.

5.2.9 Availability of Equipment

The VFB has a procurement official who is responsible for procurement of equipment which would be needed for diagnosis of suspect cases and for measures under the contingency plans. The official is also responsible for at least annual checks on expiry dates, where relevant, to ensure the validity of the equipment. The main part of the equipment is kept at central level in the VFB and can be transported to a CVC within hours when needed.

The general contingency plan includes a list of equipment which should be available in each CVC/LDCC to deal with suspect cases. The quantities should be enough for handling, examining and sampling 250 animals. In addition to office equipment the list includes protective clothing, clinical testing equipment, diagnostic sampling equipment, equipment for sampling dead animals,

equipment for humane killing of animals for diagnostic purposes; disinfectants for different uses, equipment for decontamination and destruction of carcasses, official forms and accessories for labelling, marking, packing and waste collection. The FVO team noted that:

- the minimum quantities of equipment to be kept at central level are decided by the official in charge, based on experience. An inventory list from 1.3.2013 was available;

- new stock can be ordered by the VFB outside the procurement procedure in a crisis situation;

- a decision had been taken to keep the stock of pharmaceuticals for euthanasia and the electric stunning equipment only at central level. According to the supply list of 1.3.2013 there was one set of electrical tongs for large animals, one for smaller animals and one power generator in storage at central level. The quantities of euthanasia solution kept in storage would be sufficient for a total body weight of 1500 Kg if used for cattle (see also point 5.5.3);

- in the CVCs visited:

    - all stock for disease investigations was kept in a locked room;

    - equipment for investigating a suspect case was pre-packed into a case. Protective clothing, including face masks was available;

    - inventories had been made of the stock and routines were in place to check expiry dates of drugs and equipment once per year. New stock would be ordered through the central level.

5.2.10 Vaccination policy and availability of vaccine

The competent authorities do not keep any stock of vaccines for emergency vaccination and there are no contracts with vaccine manufacturers. The FVO team noted that:

- the contingency plans for AHS, FMD, BT, CSF, and AI include criteria for considering vaccination and the basic procedures for emergency vaccination;

- since the ND outbreaks in 2007 vaccination against ND is compulsory in all commercial flocks with more than 50 birds;

- the FMD contingency plan states that, once the VFB has come to a decision to vaccinate, an emergency vaccination programme will be prepared in accordance with the rules in the national Regulation on FMD (Regulation No 4 of 23.01.2007) which transposes Council Directive 2003/85/EC. However, the contingency plan does not contain information about the vaccine requirements considered necessary or the regions containing densely populated livestock areas, which are requirements under Article 72(3) of Council Directive 2003/85/EC;

- the CSF contingency plan states that once the VFB has come to a decision to vaccinate an emergency vaccination programme will be prepared in accordance with procedures in the contingency plan. However, the contingency plan does not contain information about the

vaccine requirements considered necessary or the areas with a high density of pigs, which are requirements under Article 22(1) of Council Directive 2001/89/EC;

- the BT contingency plan outlines ,*inter alia,* the procedures, staff and hygiene measures for carrying out emergency vaccination but does not include the information about the quantity of vaccines deemed necessary in case of emergency vaccination which is required under Annex III(9) to Council Directive 2000/75/EC;

- the AI contingency plan outlines *inter alia* the procedures, staff and hygiene measures for carrying out emergency vaccination but does not include a vaccination plan dealing with a number of scenarios, indicating which bird populations may be vaccinated, an estimate of the amount of vaccine required and its availability, which is a requirement under Annex X(9) of Council Directive 2005/94/EC;

- the AHS contingency plan states that once the VFB has come to a decision to vaccinate an emergency vaccination programme will be prepared in accordance with procedures in the contingency plan. However, the contingency plan does not contain information about the quantity of vaccine estimated to be required for emergency vaccination which is required under Annex IV(9) of Council Directive 92/35/EEC.

Conclusions on Contingency Plans

There are regularly updated and detailed contingency plans in place for all diseases, as required under EU legislation, as well as a general contingency plan which deals with common features for the handling of suspect cases and outbreaks. The identified gaps in the contingency planning with regard to the diagnostic preparedness for a number of epizootic diseases, the appointment of expert groups, identification of areas with high animal densities, calculations of vaccine requirements, supply of vaccines and disposal of carcasses together with the limited supplies of equipment for depopulation may hamper or delay measures in a crisis and contribute to the spread of a disease. In addition, the legal references and procedures for valuation of animals differ between the contingency plans.

Whilst actions taken in response to recommendation 10 in the 2008 FVO report (DG SANCO 2008-7785) could be verified, the actions taken to address recommendations 2 and 4 (holding registration and animal movements) had not been sufficient as the non-compliances noted in 2008 were still present and had not been observed during recent official controls. The lack of documented procedures containing information and instructions for staff performing such official controls is not in line with the requirements of Article 8(1) of Regulation (EC) No 882/2004 and may have contributed to the limited effectiveness of these controls.

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. 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

Formal extensive risk assessments are prepared for the VFB by the University of Life Sciences. Such studies take 6-12 months to complete. The three most recent risk assessments were reported in 2010 (BT) and in 2011 (ASF and CSF). The university is currently working on a risk assessment for ND. The FVO noted that:

- the risk assessment for ASF identified personal luggage and food from a third country as the main risk for Estonia. The VFB had communicated this result, as well as any ASF disease notifications close to the Estonian border, to customs. The VFB stated that there were written procedures for notification and communications between VFB and the customs and the two organisations had been trained together;

- in addition to formal risk assessments, the VFB routinely monitors disease notifications through international notification systems and other information about disease outbreaks in the media. The VFB notifies the CVCs when there is a perceived increased risk. The weekly notifications from the Commission are forwarded to all CVCs and animal health specialists;

- all confirmed animal disease outbreaks of relevance for Estonia are notified to the general public on the VFB website and sometimes through mass media;

- the CVCs are responsible for communicating risks to authorised veterinarians and veterinary practitioners, who in turn inform animal keepers and food business operators. In addition, one CVC visited had telephoned all keepers of large pig herds in the county when there was an increased risk for CSF.

5.3.2 Notification requirements (peacetime)

All diseases covered by the scope of this audit are notifiable under Ministry of Agriculture Regulation No 34 of 25.11.1999. Veterinary practitioners who have reason to suspect an epizootic disease must notify the authorised veterinarian in the municipality or the CVC. Animal keepers are expected to contact their veterinary practitioner if animals show signs of a serious disease but may also contact the authorised veterinarian or CVC.

5.3.3 Monitoring and surveillance systems

Suspect cases: During 2011-2013 (to date) the VFB has investigated suspicions of ASF/CSF in wild boar (1 case), CSF in swine (1), SVD in swine (1), BT in bovines (2), AI/ND in pigeons (4) and AI/ND in waxwing (1). The six suspect cases in wild boar and birds were found through observation of clinical symptoms while the four suspect cases in swine and bovines were detected in the sero-surveillance programmes. All four suspicions of ND in pigeons were confirmed by polymerase-chain reaction (PCR). One BT case was confirmed but, in agreement with the EU reference laboratory, restrictions on the holding were lifted after two months since tests showed that the cattle had been infected with a vaccine virus strain (BTV-14) and no live virus was found in intensified controls in 97 bovine herds within a 20 km zone.

Passive surveillance: Information about clinical symptoms of epizootic diseases is available on the VFB website and is also provided to animal keepers by authorised veterinarians and private veterinary practitioners. Each animal keeper has an obligation to contact a (private, authorised or official) veterinarian if signs of serious disease are observed in the herd. Six of the suspect cases were notified under the passive surveillance system.

Active surveillance: surveillance programmes for AI in domestic birds and in wild birds, BT surveillance in cattle, CSF / ASF/ SVD surveillance in domestic pigs and CSF/ASF surveillance in wild boar are included in the 2013 annual sampling plan for infectious diseases, together with surveillance for other diseases which are not covered by this audit.

The annual sampling plan is broken down per county, based on the animal populations in the counties and the disease situation, and distributed (normally at the beginning of February) to the CVCs together with fact sheets for the relevant diseases. These fact sheets describe *inter alia* the disease symptoms, the procedures for notifying suspicions and make reference to the relevant contingency plans. The Head of each CVC is responsible for the implementation of the plan in the county and for submitting quarterly reports of the progress to the VFB. Sampling is carried out by authorised veterinarians. The FVO team noted that:

- the files for two BT- and two CSF-suspect cases were studied by the FVO team and showed that the competent authorities and the Veterinary and Food Laboratory had carried out the follow-up investigations swiftly and thoroughly;

- the CVCs divided the samples in the county plan between the municipalities, i.e. authorised veterinarians, based on the animal populations. The CVCs also selected the individual farms to be sampled and indicated the expected sample numbers per holding based on data from the national database;

- ten per cent of the bovine herds, distributed over the whole territory, are included in the serological surveillance for BT. This is in line with the requirements in EU legislation. The VFB is responsible for ensuring that the sampling organised by the CVCs really covers 10 % of the herds in the country;

- all poultry holdings (less than 100) with more that 50 laying hens or breeders are included in the serological surveillance for AI. The sampled holdings include one flock of quail but none of the 213 holdings with ducks, geese and/or turkeys or the other approximately 2500 small poultry holdings are sampled because they hold less that 50 birds each;

- the proportions of animals to be sampled for antibodies to AI and BT in each holding are in line with EU requirements;

- the sampling instructions in the BT plans for 2012 and 2013 state that the tests on cows are to be carried out on milk samples taken for the bovine leucosis surveillance programme while serum samples are to be taken from other cattle. However, only serum samples have been taken from all bovines as there is no method for milk tests in the Veterinary and Food Laboratory;

- vector sampling under the BT surveillance programme was carried out 2010-2012 which verified that **recommendation 7 in the 2008 FVO report had been satisfactorily addressed**. Based on the results from this sampling the VFB has defined the vector-free

period and no vector sampling is planned for 2013;

- serological surveillance for CSF/ASF/SVD is carried out in all breeding pig herds with the aim of detecting a 20% prevalence with 95% certainty. All boars used for artificial insemination are tested once per year and serological samples for ASF/CSF are taken from hunted wild boar with the aim of testing 0.1 – 0.5% of the population;

- the 2012 sample numbers for BT, AI in domestic birds, ASF and CSF met the targets in the 2012 plan;

- the 2013 sampling plan includes sampling of wild birds for AI: 100 swabs for detection of virus genome, 70 tissue samples for virus isolation and 70 serum samples for hemagglutination inhibition test. The sampling should target 70% wild waterfowl and 30% other birds. However, in 2012 only half (76) of the expected number (125) of birds were sampled. The VFB stated that there had been problems in persuading the hunters and ornithologists to contribute to the sampling programme;

5.3.4 Public awareness activities in "peacetime"

Information about epizootic diseases and their symptoms are available on the website of the VFB.

As proposed in the report from the 2006 AI contingency exercise a leaflet describing the symptoms of AI (from 2006) is available on the VFB website.

In connection to the outbreaks of ND and the emergence of Schmallenberg virus, the VFB published information on its website and contributed to the publication of awareness-raising newspaper articles in national media.

The FVO team noted that:

- with the exception of general information about diseases and symptoms on the website, the VFB information campaigns have been reactive and triggered by an increased interest from the public and media due to outbreaks.

5.3.5 Bio-security measures in place on animal holdings

Compulsory biosecurity requirements for all keepers of animals are laid down in the Infectious Animal Disease Control Act and checks on biosecurity are part of the standardised check list for on-farm inspections. The requirements include restricted access for persons and vehicles, no access for persons who have been outside Estonia in the past 48 hours, separate facilities for animals which are to be introduced onto the holding, means to separate sick animals from the other animals, regular cleaning and disinfection of areas where feed, bedding material and other potentially contaminated material is handled, regular rodent and insect control, prevention of access for wild animals to areas where domestic animals are kept and any other measures aimed at preventing spread of disease. Keepers of animals (except for own consumption) and persons working with food producing animals must undergo regular health checks and hold medical certificates which need to be provided to food business operators on request. There are no industry-driven biosecurity programmes which have been approved by the VFB.

If an epizootic disease is suspected on a holding the CVC has the legal power under the Infectious

Animal Diseases Control Act to impose specific restrictions on the holding or in the region, depending on the type of disease. The FVO team noted that:

- templates for the placing and lifting of biosecurity measures for suspect holdings are attached to the disease-specific contingency plans.

5.3.6 Staff training

There are meetings twice per year between the VFB and the CVCs where *inter alia* the animal disease situation, official controls and any changes to legislation, such as the new animal welfare rules for killing, would be discussed. Training material from these meetings would be distributed also to staff who were not present. In addition, the University of Life Sciences organises continuing education ("open university") lectures in counties and at central level.

When staff from the VFB and CVCs participate in training courses e.g. on contingency planning and killing methods in the framework of Better Training for Safer Food, course material including slide presentations would be forwarded to the CVCs for use in local training activities. The FVO noted that:

- the CVCs had regularly transmitted information from the VFB in meetings for authorised veterinarians and private veterinarians and would on occasion invite experts from the University of Life Sciences to give lectures in the county;

- evidence was seen that slide shows based on relevant Better Training for Safer Food courses had been translated into Estonian by the VFB and provided to the CVCs;

- in 2010 twenty-five representatives from the CVCs and from the VFB had participated in a training session organised by the French embassy on "organisation of eradication in a holding in case of epizootic disease" (based on experiences from FMD in the UK).

5.3.7 Simulation exercises

The VFB has participated in or arranged the following simulation exercises:

Year	**Disease / type of exercise**	**Number of participants**	**Remarks**
2004	ND/AI / Simulation exercise	48	In Estonia in cooperation with TAIEX
2006	AI / simulation exercise	80	By VFB within the framework of a major crisis exercise cycle "Pandora" organised by the Ministry of the Interior
2008	BT / simulation exercise	25	In the framework of the Nordic-Baltic Bluetongue Simulation exercise
2009	West Nile Fever / simulation exercise	2	In the framework of the Nordic-Baltic West Nile simulation exercise
2011	ASF / simulation exercise	10	In the framework of the Nordic-Baltic African swine fever simulation exercise

The VFB stated that all these exercises had focused on reporting routines, media contacts and paper

work. None had involved actually visiting farms and few had involved staff outside the VFB, CVC and Veterinary and Food Laboratory. The ARIB had been involved in the 2006 AI exercise. The FVO team noted that:

- no real-time alert exercises had been organised on FMD as required by Council Directive 2003/85/EC, neither were there plans or guidelines included in the contingency plan for FMD for the arrangement of real-time alert exercises or for participation in exercises in neighbouring Member States;

- alert exercises for CSF/ASF had not been organised twice per year as required by Annex VII (g)(ii) of Council Directive 2001/89/EC and Annex VI (f)(ii) of Council Directive 2002/60/EC;

- as in 2008 the detailed tracing of animal movements in the national database had to be done animal by animal which showed that the **actions taken in response to recommendation 5 in the 2008 FVO report had not been sufficient** to speed up the traceability of individual animal movements;

- staff from central level and occasionally from certain CVCs had participated in exercises under the Nordic-Baltic cooperation framework. However, since 2006 the VFB had not organised any drills/exercises within Estonia to test the implementation of contingency plans at all levels. The CVO stated that the contingency had been tested and had functioned well during the outbreaks of ND in two farms in 2007;

- one CVC visited had organised and carried out three internal contingency exercises for FMD and AI in 2001, 2006 and 2009 where certain communication problems had been identified. These exercises had been desk based and involved local contacts with rescue workers, the defence league, the police and the environmental agency. Zones had been drawn up using the mapping software and data from the national database and a virtual epidemiological investigation had been carried out;

- the VFB did not keep records of contingency drills/exercises carried out by the CVCs and was not aware of the outcomes of any such exercises.

Evaluation reports of the simulation exercises in 2004, 2006, 2009 and 2011 were provided to the FVO team at the closing meeting. In these reports the FVO noted that:

- the specific implementation of the contingency plan in Estonia was evaluated in the reports from the exercises in 2004 and 2006. The 2004 report (ND/AI) recommended certain revisions of the contingency plan with regard to killing methods, models for communication with media and stakeholders, the need for an information leaflet in AI and improvements with regard to the calculations of compensation. The contingency plans for AI and ND have been revised twice since this exercise;

- in the report from the 2006 exercise on AI (two outbreaks in two different counties), which was the VFB part of a larger exercise cycle organised by the Ministry of the Interior, several serious problems related to the implementation of the contingency plan in these two counties were identified:

    - inexperience in team formation and team leadership at central and county level led to a

chaotic first day of the exercise, delays in setting up the LDCC and not enough staff participating in the exercise. There was also an overlap with LDCC members competing for the same task;

- no written log of events was kept at central level;
- there was poor communication between the NDCC and the LDCC and poor coordination and cooperation, sometimes a conflict, between involved authorities. There was also a failure to convey the necessary messages to the general public via the media;
- as noted in the 2004 ND/AI exercise there were problems with the suitability of the compensation scheme, particularly for laying hens and young chickens;
- not enough police were available to man the zone check-points and the Defence Union was not able to provide personnel on weekdays. The exercise players had to approach the military for assistance;
- insufficient supplies of CO2 gas and protective clothing were available for handling the two simultaneous outbreaks;
- insufficient harmonisation between the Infectious Animal Diseases Control Act and the Emergency Preparedness Act;

- the 2006 exercise report recommends that well-prepared drills/exercises should be conducted regularly and cover all CVCs, staff should be trained, inter-agency cooperation should be tested regularly, personnel from other institutions who may be involved in an outbreak should be trained in personal protection and safety requirements, crisis communication must be improved and well prepared, command structures and operational tasks should be clarified for the NDCC, County and CVC. As the exercise reports were provided to the FVO team at the closing meeting, the team was not in a position to verify that these recommendations had been acted upon by the VFB.

Conclusions on Preparedness and Awareness

Active and passive surveillance systems are in place for the relevant diseases and all these diseases are notifiable. Evidence was seen that recommendation 7 in the 2008 FVO report had been addressed. The VFB has a system in place for notifying stakeholders, official veterinarians, customs and the general public when an increased risk is perceived. Thorough investigations had been carried out on holdings with suspect cases. Compulsory biosecurity measures reduce the risk for introduction of diseases into holdings.

The low number of suspicions and outbreaks means that, although training has been provided, staff in most CVC, are not likely to have experienced working in an outbreak situation. Combined with the deficiencies identified during the 2006 AI exercise and the lack of subsequent alert drills and exercises involving local authorities and field activities, this makes the system vulnerable and may lead to mistakes and delays which could contribute to unnecessary spread of a disease in a real crisis situation.

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

The VFB is responsible for authorising laboratories in the veterinary field. Such laboratories may apply for national reference laboratory status for specified diseases to the Ministry of Agriculture. The Ministry has designated two national reference laboratories (NRL) for the diseases covered by the scope of this audit. The Veterinary and Food Laboratory in Tartu is the NRL for FMD, CSF, ASF, SVD and BT and the Tallinn Veterinary and Food Laboratory is the NRL for AI, ND and equine diseases other than AHS. These laboratories, which are part of the four-laboratory Veterinary and Food Laboratory network, are the only laboratories authorised for carrying out tests for animal diseases and zoonoses in animals. There are no designated Estonian NRLs for the other diseases covered in the scope of this audit. The VFB stated that samples for AHS, EHD, PPR, RP, LSD, SGP and confirmation of FMD would be sent to the NRL in UK, samples for RVF to the NRL in France and samples for VS to a government laboratory outside the EU.

Both NRLs have been accredited to ISO/EN 17025 and use accredited enzyme-linked immune-sorbent assay (ELISA) methods for detection of relevant FMD virus antibodies and antigen, CSF virus antibodies and antigen and for detection of antibodies to SVD, ASF, BT, AI and ND viruses. The following methods are also included in the scopes of accreditation: immunoblotting for antibodies to ASF virus; haemagglutination and haemagglutination-inhibition for detection of AI and ND antigen; virus isolation of AI and ND virus; several PCR methods for detection of AI and ND genes.

The laboratories also use a virus isolation test for CSF, sequencing methods for AI and ND and different polymerase-chain reaction (PCR) methods for FMD, SVD, ASF, BT and differentiation of pestiviruses which have not been included in the scopes of accreditation. The representatives of the laboratory stated that these PCR methods currently could not be included in the scope of accreditation since the laboratory was not in a position to meet the requirements of the accreditation body with regard to assessments of sensitivity.

There is a cooperation agreement between the VFB and the Veterinary and Food Laboratory network which stipulates that routine screening tests shall be carried out and reported within 30 days of arrival in the laboratory. Urgent tests (e.g. for potential dangers to human and animal health) must be started the same day the samples arrive in the laboratory. In an annually updated annex to this plan the parties agree on the level of preparedness in the laboratory, i.e an agreed number of tests by each method for which consumables, reagents and kits must be kept in stock. The annex also specifies the analytical capacity per day per method.

The Quality System in the laboratory comprises disease-specific contingency plans, which include defined timeframes and procedures for analysis and reporting of test results as well as references to national legislation, international standards (e.g. EU diagnostic manuals), the relevant national contingency plans and standard operating procedures (SOP) for the applied methods. These plans listed private contact details for staff approved for carrying out the analyses.

The FVO team visited the Veterinary and Food Laboratory in Tartu and noted that:

- no NRL has been designated for AHS, which is a requirement under Article 14 of Council Directive 92/35/EEC. Although a national laboratory has been designated for SVD, no national laboratory has been designated for the other diseases in Annex I to Council Directive 92/119/EEC, which is a requirement under Article 17 of the Directive;

- should there be need for testing with methods which are not available in Estonia, the Veterinary and Food Laboratory would be responsible for contacts with the foreign laboratory, instructions to samplers and for packing and sending the samples. However, no written contracts or agreements had been drawn up with these foreign laboratories;

- there is a comprehensive quality system in place which includes *inter alia* SOPs for sample acceptance/rejection, validation of methods and procedures for handling non-compliances identified in comparative tests or during audits;

- the SOP for testing of samples for CSF antibodies did not include those measures (inactivation) which had been taken to compensate for poor sample quality in a batch of serum samples submitted within the surveillance programme for CSF;

- there is no plan to extend the scope of analytical methods to cover more epizootic diseases and no plan to add further methods to the scope of accreditation;

- the laboratory had regularly participated in the comparative tests provided by the EU reference laboratories for all of the epizootic diseases for which methods were available in this laboratory (FMD, SVD, CSF, ASF, BT). The comparative test results from 2011 and 2012 had all been satisfactory;

- the contingency plans in the laboratory had been updated in accordance with the updated national contingency plans;

- in an emergency the laboratories can purchase additional consumables, reagents and kits when necessary, in coordination with the National Disease Control Centre, which handles the additional Government funding. There is also an agreement in place with the Labour Inspectorate which allows the employer to reorganise working time and to exceed the total number of working hours in an emergency, such as an outbreak of a particularly dangerous, OIE-listed communicable disease in the country;

- the Veterinary and Food Laboratory has taken part in contingency exercises on reporting routines but has not tested its diagnostic capacity in a simulation or exercise;

- there is limited additional staff available in other parts of the laboratories who can be transferred to the testing laboratories in an emergency. The representatives for the laboratory identified this as a potentially limiting factor should an outbreak require the laboratory to

test samples at its maximum capacity for several weeks;

- comprehensive files were available for the tests carried out on suspect samples. Sample analysis had been initiated on the day of sample arrival and results had been provided within two days in the four cases studied;

- the laboratory occasionally carried out testing for epizootic diseases on private samples for differential diagnosis without notifying the VFB, if it was considered that the suspicion was very mild. The VFB was aware of this practice and stated that it was a way of getting additional information about the health status of farm animals.

Conclusions on Laboratories

The Veterinary and Food Laboratory is capable of producing reliable and relatively timely test results for the seven diseases (FMD, BT, CSF, ASF, SVD, AI and ND) for which methods are available in the Estonian laboratories but the capacity to deal with large numbers of samples for several weeks has never been tested. The lack of written agreements or contracts with foreign laboratories is likely to lead to delays in the investigation of suspect cases of the remaining eight more exotic diseases covered by the contingency plans. In addition, there is no national reference laboratory for AHS, which does not meet the requirements in EU legislation.

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 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 National legislation

Regulation (EC) No 1099/2009 is directly applicable in Estonian law. No changes in legislation are necessary or envisaged for its application. The FVO team noted that:

- the CA has sufficient legal powers in the Infectious Animal Disease Control Act to order the depopulation of farms.

5.5.2 Training

Slaughter and killing on farms would be supervised by CVC staff in cooperation with VFB. The FVO team noted that:

- staff met in both counties had received both theoretical and practical training, which had been given by the Estonian University of Life Sciences during 2013, on the requirements of

Regulation (EC) No 1099/2009 including the permitted methods laid down in Annex 1. Training information had also been sent to CVC staff from VFB and been given in a presentation by staff who had attended a Better Training for Safer Food training course on depopulation;

- training courses approved by the VFB were attended by slaughterhouse staff from throughout the country that had then been granted certificates of competence as required in Article 7 of Regulation (EC) No 1099/2009. Lists of approved slaughtermen who could be called in to assist in the event of an outbreak were kept at CVCs;

- local slaughtermen and authorised veterinarians had been trained in the use of captive bolts and pneumatic rifles respectively (see 5.5.3 below);

5.5.3 Methods of killing and availability of equipment

The VFB is the main repository of equipment and stores which would be needed in case of an outbreak of highly infectious notifiable disease. CVCs should maintain updated inventories with sufficient equipment and stores to deal with a couple of small initial outbreaks. The FVO team noted that:

- the competent authority has not yet reviewed and updated all contingency plans to include the SOPs and the stunning and killing methods required by Article 18(1) of Regulation (EC) No 1099/2009. Nor has the competent authority worked out different kill rates or possible limiting factors for hypothetical disease situations or circumstances where derogations to the requirements of this Regulation may be permitted;

- those contingency plans which have been recently updated (FMD and AHS) do contain relevant methods laid down in the Annex to the Regulation but not yet all the key parameters for each method, such as frequency of equipment calibration for head to body electrical stunning or captive bolt characteristics per species. Neither the old nor the updated plans contain the requirement to report on all the information listed in Article 18(4) of the Regulation, such as killing method used, difficulties encountered and solutions found to alleviate suffering. The competent authority intends to complete the SOPs required to formulate action plans, update methods where appropriate, include the reporting requirements and update the contingency plans accordingly by the end of 2013;

- one new penetrative captive bolt pistol (with cartridges for different weights and sizes of animals) and one new pneumatic rifle were available in each of the CVCs visited. There were no schedules or record keeping requirements for maintenance of captive bolts, and pneumatic guns;

- small quantities of pharmacological agents (some out of date) were also present and general equipment and stores were present as specified in the updated inventories;

- additional equipment (such as electrical tongs) and stores would be sourced from the VFB and other CVCs in the case of a larger outbreak developing. Most of the CVCs and the VFB are only a few hours apart by road.

- as action plans for possible disease scenarios had not yet been discussed or drafted, there were no specific killing methods laid down for particular species or types of premises at

CVC level. Determination of these would be done on a case by case basis in consultation with the VFB. However, the competent authority had used the services of a commercial gas supply company during the outbreak of Newcastle Disease in 2007 to kill caged laying hens. The company had used high concentrations of CO2 supplied to the houses in floor pipelines and the killing of approximately 250,000 birds was stated to have proceeded smoothly;

- there is no written contract with the gas supply company for the supply of services to the competent authority specifying response times, prices etc in the event of an outbreak. The company representative interviewed by the FVO team had no knowledge of the requirements of Regulation (EC) No 1099/2009 and would only be responsible for the supply of gas, the monitoring of its concentration, and the health and safety of its employees. The competent authority would be responsible for the sealing of buildings, the positioning of pipes and methods used to ensure compliance with Regulation (EC) No 1099/2009. The competent authority would issue an order directing the company as required. Staff at one CVC visited mentioned the use of containers with CO2 for depopulation of certain types of birds/premises but the contractor did not mention this as a method for killing and did not have experience with this type of equipment.

Conclusions on depopulation for epizootic disease control

Several contingency plans have been updated to include the new requirements of Regulation (EC) No 1099/2009 but the competent authority has not fully implemented the requirements since detailed instructions for the welfare requirements in relation to killing animals for disease control purposes and reporting thereof are not yet in place and staff instructions and report forms are currently being drafted. However official staff and slaughterhouse personnel have been trained in the new requirements which should ensure that these requirements would be met in an outbreak situation.

5.6 Disposal of carcasses

Legal requirements

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

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

Findings

The VFB has access to one State-owned rendering plant, which is approved for handling Category 1 products, and suitable for collecting and processing animal carcasses from an epizootic outbreak. However the VFB stated that it was not planning to use this facility for outbreak material unless the rendering plant was situated within a restricted zone. The VFB stated that in most cases the preferred method for disposal of carcasses would be burning or burial on site. The FVO team noted

that:

- there is no contract between the VFB and the rendering plant but the company would be obliged to assist the VFB under the Infectious Animal Disease Control Act;

- there are no sites for burning or deep burial identified and agreed with the Environmental authorities. The VFB stated that this would not be done until there was a real need linked to an outbreak. However, there are no agreed procedures between the authorities for how such sites would be identified;

- the rendering plant had a capacity of approximately 34 tonnes per day. The company has a written agreement with a rendering plant in another Member State which provides the basis for re-allocation of approximately 50% of the normal rendering material in an emergency situation. The remaining capacity (approximately 17 tonnes per day) would be insufficient in case of a large outbreak;

- the rendering plant had access to ten leak-proof and securely covered containers approved for collection of Category 1 material and three transport vehicles which could transport 10 tonnes each. However, similar to what was described in the 2008 FVO report, the cleaning and disinfection place for lorries and containers in the rendering plant was inside the room for unloading of container contents. Although the lorries moved from the dirty side of the room to the other side of the room before being cleaned and disinfected, there was no separation between the two sides. These findings showed that **recommendation 8 in the 2008 FVO report had been partially addressed**;

- the rendering plant visited had an own-check plan which included an annex with procedures for cleaning and disinfection in "peace-time". This plan had been approved by the CVC. In a contingency situation the CVC would provide specific information on disinfectants which would be suitable for the disease in question;

- in the rendering plant, the disinfection of transport vehicles, containers and the unloading area was carried out using a disinfectant at another concentration than that indicated on the label and adding another chemical product to the mixture in order to control the smell. Neither the employee responsible for these operations nor the official veterinarian could provide any written instruction for the mixing or use of this disinfectant solution;

- the official veterinarian who was responsible for the official controls in the rendering plant was not aware of what the active substance in the disinfectant was nor had he checked if the disinfecting properties of the used solution were sufficient for its use considering the mode of dilution and mixing of different chemical products.

Conclusions on disposal of carcasses

In the absence of sufficient rendering capacity, burning or burial on site would have to be used for disposal of also moderate quantities of carcasses following depopulation. However, the lack of approved sites for that purpose indicates a potential for environmental damage following disposal of animal carcasses in case of an outbreak, as well as a risk that disposal of carcasses may be delayed, which increases the risk for further spread of the disease. This is neither in compliance with the requirements in Council Directive 2003/85/EC (FMD) nor with the requirements laid down by Article 19(1)(e) of Regulation (EC) No 1069/2009 and Article 15(a) of Regulation (EU) No

142/2011, which concern outbreaks of any epizootic disease. In addition, the cleaning and current disinfection practices in the rendering plant may not be sufficient to to prevent spread of infectious agents and indicate that the actions taken in response to recommendation 8 in the 2008 FVO report have not been effective.

6 Overall Conclusions

The competent authorities have the legal powers to carry out all tasks and to call in additional personnel in outbreak of an epizootic disease. Active and passive surveillance systems are in place for the relevant diseases and all these diseases are notifiable, thorough investigations had been carried out on holdings with suspect cases and compulsory biosecurity measures reduce the risk of introduction of diseases into holdings. There are regularly updated and detailed contingency plans in place for all relevant diseases. However, gaps in the contingency planning with regard to the diagnostic preparedness for a number of epizootic diseases, the appointment of expert groups, identification of areas with high animal densities, calculations of vaccine requirements, supply of vaccines and disposal of carcasses, together with the limited supplies of equipment for depopulation, may hamper or delay measures in a crisis and contribute to the spread of a disease.

The lack of alert drills and exercises involving local staff, the lack of designated national laboratories for several diseases, the lack of written agreements with foreign laboratories for important analyses, make the contingency system vulnerable and may lead to mistakes and delays which could contribute to the spread of an epizootic disease in a real crisis situation. In addition, the absence of sufficient rendering capacity means that burning or burial on site will have to be used for disposal of carcasses following depopulation. However, the lack of approved sites for that purpose indicates a potential for environmental damage following disposal of animal carcasses in case of an outbreak as well as a risk that disposal of carcasses may be delayed, which increases the risk for further spread of the disease.

Although several contingency plans have been updated to include the new animal welfare requirements of Article 18 of Regulation (EC) No 1099/2009, detailed instructions for the welfare requirements and reporting thereof are not yet in place, kill rates have not been elaborated and staff instructions and report forms are currently being drafted. However official staff and slaughterhouse personnel have been trained in the new requirements which should ensure that these animal welfare requirements would be met in an outbreak situation.

Whilst actions taken in response to recommendations 7 and 10 in the 2008 FVO report (DG SANCO 2008-7785) could be verified, the actions taken by the competent authorities to address recommendations 2, 4 and 8 in the report had not been sufficient. The non-compliances noted in 2008 with regard to holding registrations, animal movement registrations and hygiene in rendering plants were still present and had not been noted during recent official controls.

7 Closing Meeting

A closing meeting was held on 19 April with representatives of the central competent authority. At this meeting, the main findings and preliminary conclusions of the audit were presented by the audit team. The representatives of the central competent authority did not indicate any major disagreement with the findings and preliminary conclusions.

8 RECOMMENDATIONS

The competent authorities 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.	The central competent authority should ensure that with regard to vaccination, the contingency plans for FMD, BT, AI, CSF and AHS meet the requirements of Article 72(3) of Council Directive 2003/85/EC, Annex III(9) to Council Directive 2000/75/EC and Annex X(9) of Council Directive 2005/94/EC, Article 22(1) of Council Directive 2001/89/EC and Annex IV(9) to Council Directive 92/35/EEC respectively.
2.	The central competent authority should appoint permanently operational expert groups as required under Article 78 of Council Directive 2003/85/EC (FMD), Article 23(5) of Council Directive 2001/89/EC (CSF) and Article 22(5) of Council Directive 2002/60/EC (ASF).
3.	The central competent authority should organise real-time alert exercises on FMD as required by Article 73 of Council Directive 2003/85/EC and alert exercises for CSF and ASF as required by Annex VII (g)(ii) of Council Directive 2001/89/EC and Annex VI (f)(ii) of Council Directive 2002/60/EC, respectively;
4.	The central competent authority should ensure that control and verification procedures for official controls meet the requirements in Article 8(1) and 8(3) and that these controls and verifications are adequate to ensure that the actions taken in response to recommendations 2, 4 and 8 in FVO report DG(SANCO)2008-7785 (which has been published as part of the General Audit in Estonia, DG(SANCO)8600/2009), have satisfactorily addressed the relevant non-compliances.
5.	The central competent authority should designate a national laboratory for AHS as required under Article 14 of Council Directive 92/35/EEC and for all diseases listed in Annex I to Directive 92/119/EEC, as required under Article 17 of the Directive.
6.	The central competent authority should formalise an agreement with the central competent authority of the United Kingdom in relation to diagnostic work on FMD to be carried out in the EU-RL, as required in Article 68(2) of Council Directive 2003/85/EC.
7.	The central competent authority should, in cooperation with the environmental authorities, identify sites that can be used in case of an outbreak of epizootic disease for deep burial or burning of carcasses as required by Council Directive 2003/85/EC (Article 72(1),(4) and (5) and Annex XVII points 13 and 14) and Article 15(1) of

N°.	Recommendation
	Regulation (EU) No 142/2011.
8.	The central competent authority should ensure that all contingency plans, with the respective operational manuals and guidelines, are updated to include the relevant requirements of Regulation (EC) No 1099/2009 as required by its Art. 18 (1).
9.	The central competent authority should ensure that estimated maximum kill rates for the proposed methods for depopulation are available, so that it can be properly informed to determine when derogations to one or more provisions to Regulation (EC) No 1099/2009 should be granted due to exceptional circumstances, as allowed by its Art. 18 (3).
10.	The central competent authority should ensure that records to be used to register depopulation activities also report the difficulties encountered and solutions found to alleviate or minimise the suffering of the animals as required by Art. 18 (4) of Regulation (EC) No 1099/2009.

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=2013-6781

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)
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**	**SVD Dir. 92/119 Dec. 2000/428**	**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: Art. 1 & 3
Co-operation with other CAs within MS	Art. 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 (1)0
Chain of command	Annex XVII (3)		Art. 23(6) Annex VII (c)	Annex VI (c) Art 22 (6) (for NDCC, LDCC)				
NDCC / LDCC	Art. 74 – 77 Annex XVII (4) & (5)	Annex III (1) & (2)	Art 23	Art. 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)5			Art. 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**	**SVD Dir. 92/119 Dec. 2000/428**	**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	Art. 13(1)		Art. 8	Art. 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)	Art. 22(1) Annex VII (d)	Art 21 (1) Annex VI (d)	Art 20 (1)	Art. 17 Annex IV (5)	Art 62 (2) Annex X (5)	Art 21(1) Annex VII(5)
Diagnostic capabilities and capacity	Art 71 & Annex XVII (8)	Annex III (8)	Art. 17 (d) Annex VII (d)	Annex VI (d)	Annex IV (8)	Annex IV (8)	Annex X (8)	Annex VII (8)
Disease surveillance programme/ early detection		Art. 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)	Art 21 (1)			Annex X (12) Art. 62(2) Annex X (10) Registration of	

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**	**SVD Dir. 92/119 Dec. 2000/428**	**AI Dir 2005/94 Dec. 2006/437 Dec. 2010/367**	**ND Dir 92/66**
			Definition: Art 2(u) 300 pigs/km				commercial poultry holdings	
Vaccination requirements identified	Art 72 (3)(a)	Annex III (9)	Art 22 (1)(a)			Annex IV (9)	Art. 59(1) Art 62 (2)	Art 21 (1) Annex VII (9)
Availability of vaccine identified					Annex IV (9)		Art 62 (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	Art. 23(6) Annex VII (g) (iii)	Annex VI (f)(iii)	Annex IV (4)	Annex IV (4)	Annex X (4)	Annex VII (4) Art 13 (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)	

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**	**SVD Dir. 92/119 Dec. 2000/428**	**AI Dir 2005/94 Dec. 2006/437 Dec. 2010/367**	**ND Dir 92/66**
							Special identification of vaccinated birds	
Diagnostic methods specified	Art 71 & Annex XIII		Diagnostic manual: Decision 2002/106/EC	Diagnostic manual: Decision 2003/422/EC	Diagnostic manual: Decision 2000/428/EC		Diagnostic manual: Decision 2006/437/EC	