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FINAL REPORT OF AN AUDIT

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GERMANY

FROM 28 JANUARY TO 08 FEBRUARY 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 Germany carried out between 28 January and 8 February 2013, as part of the FVO audit programme. The objective was to evaluate the resources and arrangements put in place to implement the European Union (EU) requirements for contingency planning in the event of one or more outbreaks of epizootic diseases.*

*As an overall conclusion, the combination of an excellent early warning system and excellent emergency preparedness measures and arrangements make the systems in place in the German Federal States visited (hereafter, the Bundesländer) very robust and capable to manage the situation in the event of an epizootic disease outbreak, in particular thanks to:*

- a satisfactory level of animal health surveillance that should detect any unusual disease event in domestic and wild animal populations;*
- the availability of largely adequate legal powers and well conceived financial provisions to cope with the unexpected and marginal costs of a disease outbreak;*
- the availability of comprehensive and updated operation manuals providing adequate instructions and guidance for staff involved in managing a disease outbreak;*
- good levels of training and preparation amongst staff of all the competent authorities (CAs) involved;*
- the availability of adequate technical and epidemiological expertise and of effective data analysis and information management tools that have in recent years proved to be effective in limiting the spread of diseases and speeding up their eradication;*
- adequate provision of equipment and resources as necessary to cope with a major disease outbreak, and*
- the largely satisfactory preparation in case animal depopulation is necessary, so that compliance is ensured with EU animal welfare requirements and with EU provisions on disposal of dead animals.*

*Nevertheless, there are still some deficiencies with regard to some components of the emergency preparedness system, such as:*

- decision-making procedures to activate emergency vaccination in case of outbreaks of epizootic diseases such as foot-and-mouth disease (FMD) and classical swine fever (CSF) are not yet well established and operational to ensure the effective application of vaccination for these diseases, and*
- effective mechanisms are not yet in place to ensure that good practices found to alleviate or minimise the suffering of animals killed in the context of depopulation activities are shared nation and EU wide.*

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

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**ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT**

<b>Abbreviation</b>	<b>Explanation</b>
ABP	Animal by-products not intended for human consumption, as defined in Regulation (EC) No 1069/2009
AHS	African Horse Sickness
AI	Avian Influenza
ASF	African Swine Fever
BMELV	Federal Ministry of Food, Agriculture and Consumer Protection ( <i>Bundesministerium für Ernährung, Bundeslandwirts und Verbraucherschutz</i> )
BT	Bluetongue
Bundesland (länder)	German Federal State(s)
BVL	Federal Office of Consumer Protection and Food Safety ( <i>Bundesamt für Verbraucherschutz und Lebensmittelsicherheit</i> )
BY	Federal State of Bavaria ( <i>Bayern</i> )
CA(s)	Competent Authority(ies)
CCA	Central Competent Authority
CP	Contingency Plan
CSF	Classical Swine Fever
CVO	Chief Veterinary Officer
DG(SANCO)	Health and Consumers Directorate General
EAG	Epidemiological Advisory Group
EU	European Union
FMD	Foot-and-Mouth Disease
FLI	Friedrich-Loeffler-Institute, Federal Research Institute for Animal Health ( <i>Bundesforschungsinstitut für Tiergesundheit</i> )
FVO	Food and Veterinary Office
HI-Tier	Identification and Information System for Animals ( <i>Herkunftssicherungs- und Informationssystem für Tiere</i> )
HPAI	Highly pathogenic AI
IVD	Institute of Diagnostic Virology of the FLI ( <i>Institut für Virusdiagnostik</i> )
IfE	Institute of Epidemiology of the FLI ( <i>Institut für Epidemiologie</i> )
LALLF	State Office for Agriculture, Food Safety and Fisheries of MV ( <i>Bundeslandesamt für Bundeslandwirtschaft, Lebensmittelsicherheit und Fischerei Mecklenburg-Vorpommern</i> )
LANUV	State Office for Nature Conservation, Protection of the Environment and Consumer Protection of NW ( <i>Bundeslandesamt für Natur-, Umwelt- und Verbraucherschutz</i> )

LAVES	State Office for Consumer Protection and Food Safety of NI ( <i>Bundeslandesamt für Verbraucherschutz und Lebensmittelsicherheit</i> )
LDCC	Local Disease Control Centre
LGL	State Office for Public Health and Food Safety of BY ( <i>Bundeslandesamt für Gesundheit und Lebensmittelsicherheit</i> )
LIMS	Laboratory Information Management System
Local CA	CA responsible for rural districts ( <i>Bundeslandkreise</i> ) and district-free cities ( <i>Kreisfreie Städte</i> )
LPAI	Low pathogenic AI
LU	Ministry for Agriculture, the Environment and Consumer Protection of MV ( <i>Ministerium für Bundeslandwirtschaft, Umwelt und Verbraucherschutz Mecklenburg-Vorpommern</i> )
MBZ	Mobile Disease Crisis Control Centre ( <i>Mobiles Bekämpfungszentrum Tierseuchen</i> )
MKULNV	Ministry for Climate Protection, the Environment, Agriculture, Nature Conservation and Consumer Protection of NW ( <i>Ministerium für Klimaschutz, Umwelt, Bundeslandwirtschaft, Natur- und Verbraucherschutz</i> )
ML	Ministry for Food, Agriculture and Consumer Protection of NI ( <i>Ministerium für Ernährung, Landwirtschaft und Verbraucherschutz</i> )
MS	Member States (of the EU)
MV	Federal State of Mecklenburg-Western Pomerania ( <i>Mecklenburg-Vorpommern</i> )
ND	Newcastle Disease
NDCC	National Disease Control Centre
NI	Federal State of Lower Saxony ( <i>Niedersachsen</i> )
NRL	National Reference Laboratory
NW	Federal State of North Rhine-Westphalia ( <i>Nordrhein-Westfalen</i> )
OV	Official Veterinarian
PCR	Polymerase Chain Reaction
QMS	Quality Management System
StMUG	Ministry for the Environment and Public Health of BY ( <i>Staatsministerium für Umwelt und Gesundheit</i> )
SVD	Swine Vesicular Disease
TF-TSB	Animal Disease Control Task Force ( <i>Bund-Länder Task Force Tierseuchenbekämpfung</i> )
THW	Federal Agency for Technical Relief ( <i>Bundesanstalt Technisches Hilfswerk</i> )
TSBH	Manual on Animal Disease Control ( <i>Tierseuchenbekämpfungshandbuch</i> )
TSK	Animal Health Fund ( <i>Tierseuchenkasse</i> )
TSN	Animal Disease Reporting System ( <i>Tierseuchennachrichten</i> )

## 1 INTRODUCTION

This audit took place in Germany from 28 January to 8 February 2013 and was undertaken as part of the FVO (Food and Veterinary Office) planned audit programme. The audit team comprised three auditors from the FVO. The team was accompanied throughout the audit by representatives of the Federal Office of Consumer Protection and Food Safety (*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* – BVL), which is the coordinating department for FVO audits taking place in Germany. In addition:

- representatives of the Federal Ministry of Food, Agriculture and Consumer Protection (*Bundesministerium für Ernährung, Bundeslandwirts und Verbraucherschutz* – BMELV), which is the Central Competent Authority (CCA) within the scope of this audit, were present during part of the audit, and
- representatives of the CAs of the Bundesländer visited accompanied the audit team during their time in their respective territories (see 5.1.1 for further details).

## 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 & Mouth Disease (FMD), Bluetongue (BT), Classical Swine Fever (CSF), African Swine Fever (ASF), Swine Vesicular Disease (SVD), African Horse Sickness (AHS), Avian Influenza (AI), Newcastle Disease (ND) and a number of other exotic diseases.

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

Whilst contingency planning for all of these diseases is included within the scope of this audit, the audit in Germany concentrated, in particular, on the evaluation of emergency preparedness in the event of an outbreak of ASF, CSF, FMD or AI:

- ASF is considered to be a serious emerging risk due to the presence of the disease in Russia and recent incursions in Ukraine;
- CSF constitutes a permanent risk for the pig industry in MS, in particular in the central and eastern regions of the EU;
- 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 (CPs) are laid down in EU legislation.

In addition, attention has also been paid to the state of readiness as regards early detection and crisis management in case of other emerging and re-emerging infectious animal diseases.

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

In pursuit of these objectives, the audit team visited four Bundesländer: North Rhine-Westphalia (*Nordrhein-Westfalen* – NW), Mecklenburg-Western Pomerania (*Mecklenburg-Vorpommern* - MV), Bavaria (*Bayern* – BY) and Lower Saxony (*Niedersachsen* – NI), where the following sites were

visited:

MEETINGS / VISITS		no.	COMMENTS
Competent Authorities	Central	2	Opening and closing (debriefing) meetings
	Regional	4	Meetings with the CAs of the four Bundesländer visited
	Local	4	Meetings with district CAs in the the four Bundesländer visited. Private veterinary practitioners were also met.
Laboratories		3	NRL for epizootic diseases within the scope of this audit (FLI) and two laboratories responsible for diagnosis of some epizootic diseases in NI and BY
Holdings		2	One pig holding and one poultry holding
Markets, dealers & Assembly centres		3	One assembly centre for cattle, one livestock market and one dealer for cattle and pigs
Slaughterhouses		2	One slaughterhouse for poultry and one for pigs
ABP processing plants		1	One category 1 ABP processing plant
Other establishments/operators		3	Mobile Disease Crisis Centre and two stores of district owned emergency equipment

### 3 LEGAL BASIS

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

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Full legal references to EU legal acts quoted in this report are provided in Annex 1 and refer, where applicable, to the last amended version.

### 4 BACKGROUND

Germany has a significant share of the livestock industry in the EU, being the largest pork producer and the second-largest beef producer in Europe, behind France. According to data from the BMELV for 2011, Germany has 27 million pigs (about one sixth of the EU total), 12.7 million cattle (with approximately 25% slaughtered per year), and 72 million hens.

With regard to the Bundesländer visited, BY and NI are amongst the main producers of beef, and approximately half of the country's pigs are raised in Northwest Germany near the Dutch border (NI and NW) and nearly half of poultry meat and one third of eggs are produced in NI.

Given the potential impact of outbreaks of epizootic disease, it is important that Member States can react immediately and effectively in a co-ordinated manner and in co-operation with neighbouring countries. EU legislation requires MS to have CPs in place to combat such outbreaks so as to reduce their adverse consequences.

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

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

- FMD has not occurred since January 1988, and SVD has not been reported since 1985;

- CSF has not been confirmed in domestic pigs since November 2006, and the last case in wild boars occurred in July 2009;
- The most recent case of Highly pathogenic AI (HPAI) occurred in October 2008, and sporadic cases of low pathogenic AI (LPAI), of both H7 and H5 serotypes, have been confirmed in several Bundesländer in recent years; for instance, in MV in November 2010, in NW in May 2011 (affecting several Bundesländer, including NI and BY), and in December 2012 in Schleswig-Holstein. All those cases were found in domestic poultry and were detected during the AI routine monitoring programme in place.
- The latest cases of ND in poultry and wild birds were detected in 2010.
- The last occurrence of BT was in November 2011, and
- AHS and ASF, as well as other exotic diseases such as Peste des petits ruminants, Rift-Valley fever or vesicular stomatitis, have never been reported from Germany.

The latest audit carried out in Germany on the same topic took place in 2003 (ref.: DG(SANCO)/9087/2003 – MR Final). The report of that audit is published on the FVO website at:

[http://ec.europa.eu/food/fvo/index\\_en.cfm](http://ec.europa.eu/food/fvo/index_en.cfm)

The outcome of the previous audit was largely satisfactory with just some weaknesses highlighted in relation to the planning and implementation of simulation and real-time alert exercises for epizootic diseases. An updated situation concerning that subject is described in section 5.3.7 of this report.

## **5 FINDINGS AND CONCLUSIONS**

### **5.1 COMPETENT AUTHORITIES**

#### **Legal requirements:**

Regulation (EC) No 882/2004 lays down rules for the performance of official controls; in particular Article 4 requires the designation of competent authorities; co-ordination and co-operation between and within competent authorities and that sufficient legal powers are available to the competent authorities. The availability of sufficient legal powers for the implementation of CP is specified in most of the relevant Directives (see Annex 2). In addition Council Directive 2003/85/EC (Article 74 (3)(d), (g) & (i) and Annex XVII (6) requires close cooperation with environmental authorities and enforcement bodies in relation to FMD control and Council Directive 2005/94/EC on the control of avian influenza (Article 62 (3)) requires close cooperation between the competent authorities responsible for the different sectors, particularly those in charge of animal health, public health, environmental matters and health and safety of workers.

#### **Findings:**

##### *5.1.1 Competent Authority structure*

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

[http://ec.europa.eu/food/fvo/controlsystems\\_en.cfm?co\\_id=DE](http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=DE)

This provides information on the responsibilities of the CAs under normal circumstances and, in particular, describes the particularities of the German federal state and the relationships between the BMLEV and the CAs in the Bundesländer, as well as the level of responsibility allocated further



down to the CAs responsible for rural districts (*Bundeslandkreise*) and district-free cities (*Kreisfreie Städte*). These are hereafter in this report referred to as local CAs.

The CCA for animal health control is the BMLEV, which is responsible *inter alia* for overall coordination of the drawing up of CPs which are required under EU animal health legislation, and for policy making regarding animal disease outbreaks at federal level. A specific Unit within the BMLEV constitutes the national disease control centre for animal diseases (NDCC), whose responsibilities in this regard, both in relation to the early warning system for epizootic diseases and to the overall coordination of the emergency preparedness system, are described in brief in the country profile mentioned above and further explained in the chapters here below.

The CCA, and also other CAs in Germany involved in animal health controls, are advised by the Friedrich-Loeffler-Institute, which is the Federal Research Institute for Animal Health (*Bundesforschungsinstitut für Tiergesundheit – FLI*). It includes several research Institutes in its structure, some of which are directly involved in emergency preparedness and management of outbreaks of epizootic diseases, such as:

- The Institute of Diagnostic Virology (*Institut für Virusdiagnostik – IVD*), which includes all the national reference laboratories relevant for diagnosis of epizootic diseases (NRLs), and
- The Institute of Epidemiology (*Institut für Epidemiologie – IfE*), which has developed a number of tools that significantly contribute to facilitate the operation of CAs that must confront a disease outbreak and it is also available to provide epidemiological advice in those situations.

In the four Bundesländer visited, the different CAs share responsibilities in the context of the objectives of this audit. In MV, BY and NI, the respective Ministries have overall responsibility in the decision-making process in relation to animal disease emergencies, while the State Offices just have implementing responsibilities.

These CAs are:

- In NW, the State Office for Nature Conservation, Protection of the Environment and Consumer Protection (*Bundeslandesamt für Natur-, Umwelt- und Verbraucherschutz – LANUV*) of the Ministry for Climate Protection, the Environment, Agriculture, Nature Conservation and Consumer Protection (Ministerium für Klimaschutz, Umwelt, Bundeslandwirtschaft, Natur- und Verbraucherschutz – MKULNV);
- In MV, the State Office for Agriculture, Food Safety and Fisheries (*Bundeslandesamt für Bundeslandwirtschaft, Lebensmittelsicherheit und Fischerei Mecklenburg-Vorpommern – LALLF*) of the Ministry for Agriculture, the Environment and Consumer Protection (*Ministerium für Bundeslandwirtschaft, Umwelt und Verbraucherschutz Mecklenburg-Vorpommern – LU*);
- In BY, the State Office for Public Health and Food Safety (*Bundeslandesamt für Gesundheit und Lebensmittelsicherheit – LGL*) of the Ministry for the Environment and Public Health (*Staatsministerium für Umwelt und Gesundheit – StMUG*), and
- In NI, the State Office for Consumer Protection and Food Safety (*Bundeslandesamt für Verbraucherschutz und Lebensmittelsicherheit – LAVES*) of the Ministry for Food, Agriculture and Consumer Protection (*Ministerium für Ernährung, Landwirtschaft, und Verbraucherschutz – ML*).

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

The audit team found that:

- All CAs in the Bundesländer visited had set up quality management systems within their organisations. These systems include in all cases provisions for verification, including audits, of the level of preparedness on and proper implementation of the rules on animal disease contingency planning by both the Bundesländer CAs and, mainly, the local disease control centres (LDCCs) to be set up by the local CAs (see 5.2.3.2). These initiatives are in some cases carried out by all CAs (Bundesländer and local), as it is the case for instance in NW and NI; a dual system is in place whereby, with different frequency, both the Bundesländer and the local CAs implement verification and audit activities, as it is the case in MV; or it is only the responsibility of a specific department of the local CAs, as it is the case in BY.
- Examples seen of the application of those verification initiatives showed that they are well aimed at contributing to keep a high level of preparedness amongst the local CAs. Areas verified include availability of both the basic arrangements to react quickly and effectively to any suspicion or confirmation of an epizootic disease (e.g. presence of a clear chain of command at local level, including other CAs and stakeholders, availability of proper documentation, adequate distribution of tasks and responsibilities, sufficient level of training to obtain and manage epidemiological information, etc.) and of all necessary equipment for these emergency situations (e.g. clothing, material for sampling and killing of animals, temporary road signs, etc.).

#### *5.1.2 Legal powers available to the CAs*

A number of federal legal provisions give the necessary power to the CAs to implement the measures necessary for controlling epizootic disease outbreaks. This includes mainly the Animal Diseases Act (*Tierseuchengesetz*), which sets out obligations in respect of the notification of suspicion of animal diseases, and the Ordinance on notifiable animal diseases (*Verordnung über anzeigepflichtige Tierseuchen*), which lists those notifiable diseases. In addition, a number of derived specific legal provisions aimed at implementing specific EU legal requirements, set out specific measures to control and eradicate various epizootic diseases, such as FMD, CSF, ASF, AI or BT.

In addition, the Bundesländer have introduced additional legislation that adds to the extensive powers conferred to the CAs by provisions of federal law and, in general, makes special emphasis on the application of animal health controls as a fundamental pillar of the early warning system for detection of epizootic diseases.

The combination of federal and state legislation ensures that CAs at all levels have sufficient powers to: enter into all premises possibly involved in a disease outbreak, impose restrictions on animal movements, require application of the necessary cleaning and disinfection measures, impose protection zones and surveillance zones according to the epidemiological evaluation of the situation, order the killing of animals etc.

#### *5.1.3 Cooperation between and within CAs in development of CPs*

Rules of procedure for the NDCC have been in place since 1994 in order to ensure a coordinated course of action between the federal government and the Bundesländer and to ensure consistency in the action taken by the Bundesländer for purposes of animal disease control. The rules of procedure already envisaged coordination at federal level for the preparation of CPs. After analysis of what happened with disease outbreaks that occurred in the nineties in Germany and in the wake of the

FMD outbreak that occurred in several MS in 2001, the CAs decided to change the federal approach to manage animal health crises. An Animal Disease Control Task Force (*Bund-Länder-Task Force Tierseuchenbekämpfung* – TF-TSB) was set up in 2004 to bring together the federal government and the Bundesländer with a view to increasing cooperation between and within all CAs in relation to preparation of contingency planning for highly contagious animal diseases and to coordinate the application of emergency measures in the event of an outbreak.

In this regard, the audit team found that:

- The TF-TSB operates on the basis of an agreement between all CAs that sets out the basic principles of collaboration between the federal government and the Bundesländer in the crisis management of animal diseases. This agreement is legally binding on all participants since October 2010, but the rules of procedure had already been in place since July 2007. Operations of the TF-TSB are ensured by a standing working group constituted of staff dedicated full time to this activity and whose salaries and expenses are covered by funds provided by the Bundesländer.
- Other bilateral or multilateral agreements have been concluded between several Bundesländer on the basis of the TS-TSB higher agreement. In this regard, it is worth highlighting the bilateral agreement between NW and NI that, preceded the one setting up the TS-TSB, and contributed very significantly to the development of current arrangements on contingency planning at federal level (see 5.2).
- The main purposes of the TF-TSB are:
  - in general, to give advice, provide technical and administrative support and strengthen networking with the objective of ensuring a coordinated approach in protecting and controlling animal diseases;
  - in particular, to ensure that preparation and updating of CPs is done in a consistent manner throughout Germany (see 5.2);
  - to provide the necessary technical preparation of meetings held by the NDCC convening either the higher political representatives of the CCA and the Bundesländer, and/or the Bundesländer CAs in charge of animal disease control. Meetings with participation of the former are usually not necessary unless there is a widespread outbreak affecting several Bundesländer or when its economical impact is envisaged to become very high for the agricultural sector or the wider federal or Bundesland's economy.
- In the context of the TF-TSB, the CAs have reached several important agreements with other stakeholders to ensure that an effective early response can be set up in the event of a disease outbreak; these include:
  - In January 2006, an agreement was signed on the establishment of a Mobile Disease Crisis Control Centre (*Mobile Bekämpfungszentrum Tierseuchen* – MBZ), that should be operational at federal level, whenever and wherever is needed in the event of a disease outbreak. The MBZ has been based in NI since 2006.
  - Other agreements related to the establishment of the MBZ followed; one with the Federal Agency for Technical Relief (*Bundesanstalt Technisches Hilfswerk* – THW), to ensure the logistics and necessary help for the assembly and disassembly of the MBZ, one with the cooperative of German veterinarians, in relation to the provision of equipment in case of animal health emergencies, and another one that ensures that adequate information technology will be always available to the MBZ irrespective of the Bundesländer where it has to be installed.

- Agreements, that include contracts with the supplying companies, have been signed by all Bundesländer in order to set up FMD vaccine and diagnostic banks at federal level. Likewise, similar agreements are in place with companies that will supply CO<sub>2</sub> in order to depopulate herds or flocks in the event of an outbreak (see 5.5.2).
  - Specific agreements have been reached between the Bundesländer for the creation of an expert list in the context of emergency preparedness for animal health crisis (see 5.2.7);
  - Finally, another agreement sets out common rules for the inter-State collaboration with regard to destruction of animal by-products not intended for human consumption (ABP) in the event of an animal health crisis (see 5.6).
- Within the framework of the German Association of District Councils, the majority of the local CAs concluded a master agreement in 2012 for the provision of mutual support in human and material resources for the protection of consumer health, particularly in the event of an outbreak of an epizootic animal disease. Examples of cooperation in that respect could be seen in some of the local CAs visited.
  - In addition, both at federal level and in the Bundesländer visited, evidence was provided of the arrangements in place to ensure that all other necessary authorities (e.g. police forces, environmental authorities, meteorological services, hunting associations, food business operators associations, etc.) have been incorporated, as appropriate, in the emergency preparedness routines and their roles, and their possible necessary inputs have been identified in the context of an early response to a disease outbreak. Similar initiatives were seen in the Bundesländer visited with regard to cooperation with numerous stakeholders, mainly with associations of animal producers and food business operators.

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

### **Conclusions on Competent Authorities:**

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

- the formal agreements in place between the different levels of the CAs, at federal and Bundesländer level, channelled effectively through the establishment and operation of the TF-TSB, and
- the additional efforts made to involve many other CAs, that can provide the necessary technical and logistical support, and to ensure the cooperation and availability of numerous stakeholders, whose contribution is vital in complementing the activities of the animal health services in the event of an outbreak of an epizootic disease.

## **5.2 CONTINGENCY PLANS**

### **Legal requirements:**

Requirements for Member States to have CPs to control disease outbreaks are required for the following diseases: Foot & Mouth Disease (Council Directive 2003/85/EC), Bluetongue (Council Directive 2000/75/EC), Classical Swine Fever (Council Directive 2001/89/EC), African Swine Fever (Council Directive 2002/60/EC), Swine Vesicular Disease and a number of other diseases (Council Directive 92/119/EEC), African Horse Sickness (Council Directive 92/35/EEC), Avian

Influenza (Council Directive 2005/94/EC) and Newcastle Disease (Council Directive 92/66/EEC). A summary of some specific requirements of each is provided in Annex 2.

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

## **Findings:**

### *5.2.1 Coverage & Approval*

There is a Federal Catalogue of Measures Pertaining to Animal Diseases, which contains the general measures approved by the Commission in relation to FMD, originally in 1993, CSF (in 1999) and AI and ND (in 2007) and that forms the basis for the CPs for FMD, CSF, ASF, AI and ND. Later on, simultaneously to the agreement on the introduction of the TF-TSB, a decision was taken to further develop on the previous experience of NI and NW, and prepare a comprehensive internet-based federal guidance for all CAs in respect of CPs for epizootic diseases. As a result of that, further information to control most major animal diseases is included in an online platform set up by the government and the Bundesländer known as the Manual on Animal Disease Control (*Tierseuchenbekämpfungshandbuch – TSBH*):

- This platform has been recently extended and comprehensively developed to incorporate the CP for CSF, as notified to the Commission in September 2011. Following a favourable opinion by the Commission during 2012 on the fitness for purpose of that CP, the CAs were in the process of adding into it additional tailor-made modules and initiatives to cater for the specificities of other diseases.
- Nevertheless, at the time of the audit, formally speaking, on top of the recently evaluated and updated CP for CSF, the latest updates of other CPs in the process of being added to the TSBH, included those for FMD and HPAI (version March 2009), ASF (version January 2012), SVD (version January 2004) and AHS (version March 2004). The two last ones had not been reviewed because SVD has not been detected for many years (since 1985) and AHS has never been detected in Germany. With regard to BT, it is dealt with as rather an endemic disease due to the vast experience gained with this disease since 2006; at that time, a CP was not in place and, afterwards, it was no longer considered as an exotic disease worth developing a CP to use in case it was detected again. Nevertheless, since 2012, a working group of the TF-TSB is in the process of developing specific modules for the TSBH in respect of this disease.
- The process of development and approval of new CPs or their updates and modifications is spearheaded by an standing working group of the TF-TSB convening representatives of the BMLEV, the Bundesländer and permanent staff of the task force.

### *5.2.2 Documentation*

The audit team found that:

- In all Bundesländer visited, specific arrangements had been incorporated to the state-wide CPs and local CAs operational manuals (OMs), available also online to all staff, in order to cover a broad range of diseases, including, for instance, the particular epidemiological features of vector-borne diseases. Both the CPs and the OMs have been developed mostly for diseases such as FMD, CSF and ASF, or AI. Representatives of both the Bundesländer

and the local CAs met acknowledged that even though the general TSBH enables them to cope with outbreaks of any emerging animal disease:

- They were ready to resort to (or they had already in a few cases) the available technical expertise of the FLI and other well-known experts in the country in order to better adapt their early response and management of such a situation (see 5.2.7).
- The local CAs had adapted their OMs to their particular circumstances following general rules laid down in the TSBH, as according to them this is the only way to make them really operational for staff of all CAs involved in the situation.
- Several examples of very comprehensive OMs were checked during the visits to the local CAs, including examples of how they had been used, for instance, during recent cases of LPAI. All of them contained very detailed instructions, including clearly defined command and control structures for dealing with epizootic outbreaks, as well as specific details on cooperation arrangements with other CAs (police, civil protection, environmental authorities, etc.) and communication protocols with stakeholders and the general public.
- Both the Bundesländer adaptations of the TSBH and the local OMs are constantly updated with new features, pieces of information, operational documentation, legal requirements, or epidemiological updates. They are accessible online to a restricted user group, staff of the CAs with responsibilities in this area, and they are password protected and not available to the general public.
- According to representatives of the BMLEV and other CAs met, there is no need to keep control of the available versions of the CPs, as it used to happen with previous paper-based ones. All operational documentation on the TSBH online platform is always the most-updated, for instance after modifications made as a result of simulation exercises or introduction of new legislation, and the only one operational for staff with access to it in case of an outbreak.

### 5.2.3 CA command structure during an epizootic outbreak – NDCCs and LDCCs

In general, the local CA of the area where the disease is confirmed is held responsible for the early response and management of an epizootic outbreak, and also the setting up of the LDCC. Sometimes, depending on the circumstances (e.g. immediate perception of a widespread transmission of the disease) and the size and outreach of the outbreak; for instance, when it affects other districts or Bundesländer; other CAs at state or federal level would intervene and take over the overall command of the situation:

- The Chief Veterinary Officers (CVOs) of the Bundesländer CAs would take over the management of outbreaks going beyond the borders of one particular district and affecting several areas in a Bundesländer. In any case, in all the Bundesländer visited, the CAs had set up specific animal health task forces that are responsible for overseeing the operation of any early response to an epizootic disease.
- In the extreme situation of an outbreak affecting several Bundesländer, the level of responsibility and the chain of command at the NDCC would escalate up to the German CVO at the BMLEV, and even to a central crisis unit headed by a State Secretary of the BMLEV in case of a significant crisis.
- In any case, as described in section 5.1.3, the TF-TSN always oversees the situation and convenes representatives of all Bundesländer, along with the relevant necessary experts, in order to agree on the best approach to take depending on the risks and the epidemiological

situation of the disease.

On top of the availability of well trained staff and sufficient equipment (see sections below), the activities of the LDCC and, as appropriate, the NDCC, are modulated by the availability of a number of interlinked information management systems and databases, that are aimed at easing up the CAs decision-making process in the event of a disease outbreak; it is worth being highlighted that:

- Since 1995, the Animal Disease Reporting System (*Tierseuchennachrichten* – TSN) developed by the IfE, has been used by the CAs as the standard electronic system for registration of all notifiable animal diseases and since 1997 also for reportable animal diseases. Since then, the TSN has evolved considerably and it has been gradually optimized with regard to data quality, functional range and user-friendliness. At the time of this audit, the third generation of TSN in use offers to some 500 local users (mostly local CAs) diverse farm management and georeferenced data functions concerning animal disease outbreak control, response, and crisis management. This latest version allows the CAs to plan and document all legal measures in case of an outbreak, to plan all visits to and sampling activities in holdings within the protection and surveillance zones, as appropriate, to overlook the situation as a whole, and thus it has become an essential operational and verification tool for all CAs in Germany.
- The Identification and Information System for Animals (*Herkunftssicherungs- und Informationssystem für Tiere* – HI-Tier), is the computerised, Internet-based herd and animal identification and registration system that was initially established in Germany in 1999 in line with EU legislation on cattle and beef traceability, to be further expanded later on to also include, first, pigs, and later on sheep and goats (see 5.2.8).
- The software system used by the CAs to monitor the veterinary and food sectors (BALVI system). The programme integrates the areas defined by law for veterinary and food surveillance in the form of individual programme modules which all work with the same standardised data. The BALVI system offers a variety of interfaces to related information and technology platforms, such as TSN and HI-Tier, making available to them, mainly at the level of local CAs, relevant information on farms and food business operators that can be used in the event of an outbreak of an epizootic disease.
- The laboratory information management system database (LIMS) that enables the CAs to retrieve all necessary information on the diagnostic procedures and results of tests carried out on samples taken in the context of confirmation, eradication and surveillance of epizootic diseases.

As indicated in section 5.1.3, the MBZ based in NI can be made available to any Bundesländer for use by the LDCC as an additional logistics centre:

- The permanent maintenance cost of the MBZ is around €120 000, which is entirely financed by contributions from all Bundesländer.
- According to representatives of some of the CAs met in NW and BY, at the moment, deployment of the MBZ as a LDCC for just one Bundesländer is not financially viable as it is extremely costly. They, and representatives of other CAs, added that discussions were taken place in the context of the TF-TSB in order to reorganise the process of deployment and installation so that it could become more operational for all Bundesländer<sup>1</sup>.

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<sup>1</sup> In their comments to the draft report, the CA indicated that the transfer of the MBZ in the context of an animal disease exercise in NI in September 2013 showed that, in technical terms, the MBZ is still fully operational. They added that the existing TF-TSB working group on the further development of the MBZ will continue its work.

In addition, the audit team found that:

- During the meetings with the local CAs visited it could be verified that all CPs and OMs available to their staff; i.e. the instructions and guidelines on the operation of the LDCCs; contained very specific details clearly underlining the chain of command in case of an animal health emergency situation.
- Some examples of the real operation of LDCCs could be seen with regards to the most recent outbreaks of LPAI; in all cases, and also in those where no disease event had occurred recently, the arrangements in place included:
  - easy and operational access to all information management systems; staff were very familiar with the use of TSN, including its geographical information facilities, and the added value in case of an outbreak of its interaction with other sources of information, such as HI-Tier, the BALVI system and the LIMS;
  - managerial staff of the local CAs were well aware of the options and rules for their interaction with the CAs of the Bundesländer and with disease experts from the IfE and the NRL. Examples of collaboration with and advised received from the latter could be seen in some cases;
  - the TSN provides very comprehensive details of all the activities carried out by the LDCC, giving data on all sorts of daily activities in chronological order, from maps on the evolution of the protection and surveillance zones, through to personalised information of what was done, and where, by each member of the staff each and every day during the outbreak. For instance, it was easy to verify what samples had been taken, when, where and by whom, and to find the results in the LIMS and follow the evolution of the holding in the TSN, up until restrictions had been lifted. The TSN even includes details on valuation and compensation of animals that died or were killed as a result of a disease outbreak;
  - provision for suitable means of communication including telephones, fax and, in some cases, facilities for communication with the media, and
  - updated information on other necessary resources, such as agreements with other CAs and stakeholders that are needed in these situations (companies involve in depopulation, cleaning and disinfection, ABP processing plants, etc.).

#### 5.2.4 *Financial provisions*

In Germany, the main institutional system that compensates livestock holders for animal losses caused by epidemic diseases are the animal disease funds (*Tierseuchenkassen* – TSKs):

- In accordance with the regional implementing laws for the Animal Diseases Act, the TSKs are facilities set up as public bodies or special assets of the Bundesland. They are normally financed through mandatory levies on livestock operators. In the event of an animal disease in a species subject to a compulsory levy, compensation is initially paid by the TSK and the Bundesland (50% each) and is subsequently reduced in proportion to the payment of EU refunds.
- The legal foundation for the TSKs is the Animal Diseases Act, but additional legislation in the Bundesländer are also applicable. Fifteen of Germany's sixteen Bundesländer have their own TSK, each with its own administration and decision-making body (e.g. a Governing Board or a Bundesland Committee). Members are representatives of agricultural and veterinary authorities and agricultural associations.



- Provided farmers cooperate with the CAs and comply with general agricultural requirements, and with requirements on notification of suspicions of epizootic diseases; compensation amounts for animal losses are based on prevailing market values and capped by federal law. Compensation for costs incurred for killing of animals is refunded in addition. Moreover, costs for rendering and disposing of carcasses and other ABP are part of the required refunding for some TSKs in some Bundesländer. In addition, in NI, financial aid is granted to support cleaning and disinfection services. In case EU co-financing is requested, compensation is to be made within 90 days of slaughtering of livestock.
- According to representatives of the CAs met, the responsibilities of specific livestock sectors and Bundesländer (even regions within them) are kept separate, which acts as an incentive for farmers to invest in prevention and monitor each other in case of an outbreak (see 5.3.5).
- In principle, in the event of an animal disease in a species subject to a compulsory levy, compensation costs are borne by the TSK and the Bundesland (50% each). EU refunds in the context of co-financing are shared proportionally between the Bundesland and the TSK and their financial participation is reduced accordingly.
- In addition to compensation provided by the TSKs, private insurance is available for farmers to cover interruptions in livestock production. This private insurance covers consequential losses and some direct losses, as well as the value of animals that exceeds the maximum amount paid by the TSKs. According to representatives of the CAs met, more than half of farmers in Germany have insurance policies that cover consequential losses; about half of all cows and 30% of all sows are insured in this manner. However, significant variation exists between Bundesländer, as much lower percentages are found in the South; e.g. in BY, where only some 10% of the farmers have insurance.

In the context of the extensive funds ensured by the TSKs available in all visited Bundesländer, examples were presented of recent modifications incorporated to the operation of the system, which are aimed mainly at ensuring quick availability of additional funds to speed up the control of an outbreak and the eradication of the relevant disease, including, in some Bundesländer:

- provisions for a fast depopulation in the areas immediately surrounding a confirmed case (see 5.5);
- administrative arrangements to ensure prompt payment of compensation to affected farmers, in compliance at least with the 90 days deadline;
- provisions for additional purchase of any necessary materials, such as disinfectants or clothing, including special contracts with private companies that must be readily available at any time to provide those materials, if not in store, and carry out those tasks if necessary;
- administrative arrangements to compensate costs for additional staff who could be hired in case of a large outbreak (e.g. officials on temporary contracts, private practitioners, personnel for on-farm killing of animals), or for other private operators such as those involved in transport of carcasses and bedding, or in collection and destruction of milk or other products of animal origin, and
- emergency funds for payment to processing plants for the quick disposal of carcasses.

#### *5.2.5 Establishment and enforcement of protection and surveillance zones*

The audit team found that:

- The TSBH contains all necessary instructions and guidance for establishment and

enforcement of protection and surveillance zones in accordance with relevant EU legislation, as appropriate for the type of disease involved and the preliminary, and evolving, epidemiological picture of the situation; e.g. different provisions are in place for vector borne diseases, such as BT or AHS. The zones are adapted to the production area thanks to the geographical accuracy of the information retrieved from and assessed with the TSN. The latter, along with other inter-linked databases, can provide immediately up-to-date details on all farms and other relevant stakeholders, including geographical coordinates and specific data on the activities of all those operators.

- Additional provisions are in place to ensure that when more than one local CA or more than one Bundesländer are affected, delimitation of the zones does also prioritise compliance with the minimum rules and is adapted to better cope with the disease in the environment where it occurs. This has to be coordinated by the TF-TSB. Examples of cooperation in this regard could be seen by the audit team at local level between several local CAs. In any case, enforcement of restrictions is always the responsibility of the local CA in charge of the particular territory and no administrative or operational problem was observed or declared in that respect. According to representatives of the local CAs met, the fact that the TSBH lays down common standards for everybody, and that application and verification of measures within the zones is done by each local CA on the basis of details contained in their own module of the TSN, being it the same tool for all local CAs throughout Germany; makes it easier to coordinate the emergency and eradication measures.
- As soon as a reasonable suspicion of an epizootic disease is notified to the CAs (sometimes, only upon confirmation), while the epidemiological situation is analysed, interim emergency measures are immediately applied to order an animal movement standstill. The duration of the standstill will depend on the certainty about the possible geographical extension of the disease and it can reach the whole country; usually, on the basis of the advise provided by the epidemiological advisory group (EAG) of the IfE. These legal provisions have been established in cooperation with the industry and have shown in recent years to be very effective at stopping the spread of epizootic diseases, as demonstrated, for instance, by a six days geographically extended standstill during the outbreak of LPAI that occurred in May 2011.
- In the local CAs visited, there were a varied range of posting signs aimed at marking on roads entering the protection and surveillance zones; in addition, all of them had different arrangements in place with other CAs and private stakeholders to set up road control measures, in order to reinforce application of movement restriction measures, and cleaning and disinfection facilities for vehicles entering or leaving the zones, as appropriate.
- Representatives of the BMLEV advised the audit team that derogations with respect to permitting movement to slaughter for animal welfare purposes; e.g. overstocking on farms in the protection or surveillance zone during an outbreak, are always considered, as appropriate; in addition:
  - The overall priority is always to eradicate the disease as a matter of urgency and to prevent it from spreading further afield. They added that studies had been carried out in that respect in several Bundesländer, as the level of sensitivity with regard to animal welfare issues had grown considerably over recent years, and that this possibility had been considered in detail as part of the TSBH;
  - The TSBH includes general instructions to follow in those cases, in particular on the need for a comprehensive evaluation of all the animals of susceptible species present on the relevant holdings and of the epidemiological circumstances prevailing in the area, so that the presence of infected or contaminated animals on the holding is

unequivocally excluded.

- Finally, they added that even if CSF had not been a problem in domestic pigs since 2006, and no outbreak of FMD had occurred for many years; the approach incorporated in the TSBH derives from the lessons learnt from the experience of past outbreaks in Germany and the large outbreaks of CSF in the Netherlands in the late nineties and of FMD in the United Kingdom in 2001.

#### 5.2.6 *Communication procedures during an outbreak*

The audit team could verify that communication arrangements were in place to facilitate exchange at all times of information between the local CAs where a LDCC would be set up and the relevant superior CA, be it at Bundesländer level, or with the BMLEV:

- In all Bundesländer visited, very modern facilities and procedures had been set up in order to ensure that relevant information, as appropriate for the receiver, could be delivered in a timeless manner both internally and to all concerned stakeholders and the general public.
- In many cases, such as in BY at central level or in some local CAs in NI and NW, expert teams on communication operating within the structure of the local or Bundesländer governments, had been trained specifically for the particular task of the external communication in case of an outbreak of an epizootic disease, including in particular preparations for the rapid establishment of comprehensive and sufficiently manned helplines. According to representatives of the CAs met, this move had been triggered by the increasing understanding and preoccupation amongst the general public and, in particular, the animal production sector, about the far reaching consequences, both for public and animal health and for the economy in general, that possible outbreaks of diseases such as AI or FMD may bear in those respects.
- As part of the OMs discussed in all areas visited, and in general as standard documentation contained in all local versions of the TSBH, arrangements were in place to ensure the effective communication of restrictions to farmers in protection and surveillance zones. Once they are identified thanks to the TSN and other inter-linked databases, that standard documentation is easily prepared and dispatched immediately by the local CAs. According to some of the CAs met, in particular those that had been involved in outbreaks of diseases more recently, additional efforts are made to convey the relevant information by liaising with national and regional media, as appropriate. Examples in that respect were seen in cases of outbreaks of AI, informing the public in general, or when BT or the infection with Schmallerberg virus caused major problems amongst the farming community.

#### 5.2.7 *Availability of Epidemiological expertise*

The audit team found that epidemiological expertise was available amongst staff of the local CAs in all areas visited and that they have been trained in particular in relation to how to tackle any suspicion or confirmation of an epizootic disease. Most of the local CAs met had had to avail of that expertise on several occasions over recent years, mostly in relation to the detection of HPAI or LPAI, but many had been involved for many years in tackling other diseases such as CSF. In addition, the animal health departments of the CAs of all the Bundesländer visited have also a number of staff trained in the same areas. Moreover, sources of additional expertise that can be used in the event of a disease outbreak in Germany are:

- The Animal Diseases Act lays down specific provisions on the epidemiological

investigations to be carried out by the FLI (IfE - EAG) in the event of animal disease outbreaks. These are carried out by the EAG, which at the time of this audit was formed by five scientists of the IfE, who thanks to their extensive experience in coping with outbreaks of epizootic diseases, and in cooperation with the expert virologists of the NRL, are in a position to perform a comprehensive epidemiological investigation of any disease outbreak. They, in particular, provide quick evaluations of the spatial and temporal dimensions of the disease spread, and thereby can advise the local or Bundesländer CAs on the most effective measures to prevent further spreading and eradication of the disease.

- When requested, this is accompanied by an on-the-spot evaluation by the EAG of the situation in the field in order to better investigate the events surrounding a suspicion. Examples were provided of a number of field investigations carried out during 2012, which involved investigations on suspicions of diseases such as equine infectious anaemia, infection with Schmallenberg virus or Anthrax.
- The audit team could verify the involvement of the EAG in many activities related to prevention and control of epizootic diseases, such as frequent provision of training to staff of numerous CAs, participation in simulation exercises, risk assessment of introduction of some epizootic diseases in Germany (e.g. ASF or HPAI), evaluation of outbreaks of AI, evaluation of risks related to wild animals (e.g. CSF and ASF, AI), development of epidemiological tools that facilitate a quick evaluation of data and speed up identification and traceability of animal movements and contacts, and of disease outbreak information management tools that ease up the activities of the NDCC and of the LDCCs.
- In the context of the TF-TSB, the Bundesländer have agreed on a series of specifications for the creation of a list of experts on animal disease emergency preparedness, covering as many Bundesländer as possible, and who are available both at local level in their own Bundesland and for the CAs of the other Bundesländer if necessary. The agreement includes provisions and procedures for the selection and use of the experts, and the approximately 50 already available cover a very broad range of expertise to be used in the event of a disease outbreak, from the epidemiological evaluation of the situation, to the logistics or arrangements for depopulation of animals and destruction of carcasses.

#### *5.2.8 Animal identification and movement control*

The audit team found that:

- Registration of holdings is done according to the pertinent EU legislation for the identification of bovine animals, sheep and goats as well as pigs. According to representatives of the CAs met, a holding generally constitutes an epidemiological unit; this may also apply to cattle holdings that keep animals in several locations, provided they are operated by the same personnel. In this case, any movement of animals between these locations do not have to be notified. The local CA decides whether a holding that comprises several locations constitutes one or several epidemiological units. Representatives of the IfE advised the audit team that, on occasion, but mostly exceptionally, they had encountered problems with this policy, as in some cases they had missed some animal movements of relevant importance for the traceability of possible animal contacts and early detection of possibly infected animals or animals that could have been exposed to vector borne diseases, such as in the case of BT or infection with the Schmallenberg virus.
- Upon checking by the audit team during some of the visits carried out, the following could be verified:

- Operation of the HI-Tier and the movement recording systems seen on-the-spot are fit for purpose and can effectively contribute to facilitate the activities of the CAs in dealing with outbreaks of epizootic diseases, in particular during the early stages of a suspicion in order to perform reliable epidemiological investigations. This is significantly enhanced by the interoperability with the BALVI system and in the TSN, which ease up the activity of keeping up-to-date herd/flock registers available therein and the fast preparation of forward and backward movement traceability reports.
- Activities checked during the visits to assembly centres, dealers and slaughterhouses showed that animal movements through these stakeholders are immediately available in the system as the application operates on-line under strict deadlines for these operators.

### 5.2.9 Availability of Equipment

In the context of the numerous agreements described in section 5.1.3, be it on the TF-TSB, the MBZ, agreements with associations of veterinary practitioners or agreements between local CAs and with other CAs than those responsible directly for coping with disease outbreaks; one common feature was the emphasis put on provisions to ensure that there will sufficient availability of equipment to handle emergency situations.

The audit team found that:

- In the four Bundesländer visited, there were adequate logistic arrangements to ensure that all equipment and resources necessary in the event of an outbreak were readily available to the local CAs involved. In some cases, in particular at the MBZ, storage of emergency equipment was impressive and included all sorts of materials, such as thousands of protection clothing sets, pairs of boots, masks, goggles, disinfectants, sampling and vaccination sets, etc. All local CAs had an storehouse with a broad variety of emergency equipment, at least sufficient to address initially any emergency situation; in most cases, special contracts had been signed with suppliers to ensure that additional equipment could be provided at short notice.
- All Bundesländer had organised service contracts with at least one of the two companies available in Germany that provide equipment, mainly for depopulation purposes for the poultry and pig sector (see 5.5.1), but also in the context of other activities that are needed in these cases, such as construction of vehicle control points, cleaning and disinfection and transport of killed animals to processing plants. The companies were originally set up in NI, and were mainly funded by associations of producers; even though nowadays their activities are basically sustained by the contracts with the Bundesländer CAs and/or the TSKs, in the context of emergency preparedness related to epizootic disease outbreaks<sup>2</sup>.

### 5.2.10 Vaccination policy and availability of vaccine

According to representatives of the BMLEV, several studies have been carried out to explore the possibility of vaccinating animals against CSF, AI and FMD in the event of an outbreak; however, they are considered preliminary options and, despite the variety of scenarios considered, they will

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<sup>2</sup> In their comments to the draft report, the CA indicated that in MV the contract with the service provider was concluded through the TSK. In NI, the Bundesland has not concluded any contracts with the service providers; only farmers have a contractual relationship with the companies, while the TSK pays subsidies to the companies on behalf of farmers.

need to be adapted to the particular circumstances of the particular outbreak, before submission for approval at national and EU level:

- As mentioned in section 5.1.3, a vaccine bank has been set up for FMD. It includes vaccines for eight strains of the disease (10 up until 2012, which are still kept – 0.1 million doses – in a vaccine bank by Hesse Bundesland), and initial availability of a minimum of 1,75 million doses for each strain is ensured with the contractor.
- The FLI is carrying out studies aimed at identifying the best options for the use of vaccination in the event of an FMD outbreak by considering several scenarios. These studies include worst-case scenarios where several high densely populated areas could be affected, and weigh up the possible effectiveness of combinations of vaccine and diagnostic approaches along with epidemic models of the disease and possible market and trade effects of these scenarios. According to representatives of the BMLEV, these studies should be concluded by the end of 2015.
- With regard to CSF, several studies on the possible use of vaccination have been carried out, and policy documents have been prepared both at federal level and by the Bundesländer with the higher populations of pigs, such as NI and NW. According to representatives of the BMLEV and the NRL, policies are leaning more and more towards avoiding large scale stamping-out options on animal welfare grounds; whereas the main technical limitation remains the lack of a safe and effective vaccine that could be used in combination with a diagnostic system to differentiate vaccinated and non-vaccinated animals. They added that this scenario could change very soon, with the availability of those tools, and that they were still considering the policy options in this respect. Finally, the BMLEV advised the audit team that Germany keeps an open discussion in this respect with the neighbouring MS, mainly with the Netherlands, as they have followed a similar vaccination approach; i.e. conditional on the availability of the above mentioned new vaccines.
- In all the above mentioned studies, some consideration have been given to the logistics involved in the implementation of vaccination, and rough estimates for the amount of vaccines and of staff needed, and options for how to do that, had been discussed at different levels in the TF-TSB and some Bundesländer (e.g. with associations of veterinary practitioners).

### **Conclusions on Contingency Plans:**

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

- The development by a national coordinating task force of a far-reaching, comprehensive Web-based CP, which is further elaborated and regularly updated with specific technical and operational areas for each epizootic disease.
- Availability to the relevant CAs of comprehensive and updated OMs, that have been adapted to the local circumstances and include the necessary generic instructions, guidance and clearly defined command and control structures, for them to deal effectively with epizootic disease outbreaks.
- Access by all CAs to adequate information management tools that:
  - speed up the evaluation of the crisis situation, providing all the necessary data and facilitating a spatial and temporal assessment that allows them to quickly define protection and surveillance zones in accordance with EU requirements, and

- enable the CAs in command to manage all necessary activities in real-time and processes and compiles all details and information on the daily progress with the eradication of the disease.
- Adequate logistic arrangements to ensure that all necessary equipment and resources necessary in the event of an outbreak are readily available to all CAs involved.
- Availability of satisfactory technical expertise in all areas involved in managing epizootic disease outbreaks.
- The animal health fund in place in all Bundesländer that adequately contributes to cope with compensation of affected animal keepers in case of disease outbreaks and also provides additional resources for animal health prevention and disease surveillance activities.

Significant efforts have been made in order to study possible scenarios for the application of emergency vaccination in case of outbreaks of epizootic diseases such as FMD and CSF; however, considerable uncertainty still remains in relation to the functioning of the decision-making process that should make this disease protection measures fully operational so that they will be effectively applied in accordance with Article 50 of Directive 2003/85/EC and Articles 19 and 20 of Directive 2001/89/EC.

### 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. All these diseases except epizootic haemorrhagic disease, must be notified by the competent authority to the Commission. 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 CP. Specific preparedness and awareness criteria are specified for FMD; for most other relevant diseases, a communications strategy and appropriate communications training are required.

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

Annex 2 to this report summarises relevant legislative requirements.

#### Findings:

##### 5.3.1 *Epizootic disease risk analysis and alert levels*

The audit team found that:

- Several risk assessment exercises have been carried out in recent years to prioritise animal health prevention and surveillance activities, in particular in relation to AI, FMD, BT, CSF and ASF. As a direct consequence of these assessments, several initiatives have been organised over the recent years to raise awareness amongst all stakeholders of the importance of early detection and notification of these diseases.
- Even though, import controls at border inspection posts are not necessarily risk targeted on the basis of the above mentioned risk assessments; i.e. beyond standard requirements laid down in EU legislation in this area; several initiatives were in place to, for instance:

- enhance the application of controls on risks of introduction of ASF related to the frequent transport from Germany of live pigs to high risk areas in Russia, Ukraine or neighbouring countries, and
- increase the alert levels of the CAs, in particular those working in border inspection posts, in case of confirmation of an epizootic disease in non-EU countries, as it had been recently the case with FMD in Egypt.

### 5.3.2 Notification requirements (peacetime)

As indicated in section 5.1.2, the Animal Diseases Act and the Ordinance on notifiable animal diseases, lay down obligations for all stakeholders in Germany in respect of the notification of suspicion of animal diseases, including all those epizootic diseases covered by the scope of this audit. See the next section for additional information on notification of suspect cases of epizootic diseases.

The FVO audit team noted that:

- farmers, food business operators and veterinary practitioners met during the on-the-spot visits were fully aware of their obligations to report suspicions of epizootic diseases;
- the TSN contains a specific module where comprehensive details can be retrieved of all investigations carried out on suspicions and confirmed cases of notifiable diseases.

### 5.3.3 Monitoring and surveillance systems

Both at national level and in the Bundesländer visited, the audit team could verify the extensive animal health surveillance programmes in place, including examples of a satisfactory level of passive surveillance, in particular:

- The CAs had taken advantage of the risk assessments mentioned in section 5.3.1 and many other sources of information at local level in order to put in place tailor-made risk targeted surveillance systems for AI, CSF and ASF, or BT, in wild and domestic animals:
  - Examples concerning AI demonstrated their effectiveness at detecting several cases of LPAI in recent years (e.g. in NW) and monitoring of the situation in wild birds, very targeted to areas with significant migrating populations, including areas in the four Bundesländer visited, was seen to be done in accordance with guidelines laid down in EU legislation and with the AI surveillance revised plan that had been submitted to the Commission on August 2012.
  - Areas with some of the highest densities of pig farms in the EU, such as regions of NW and NI, have developed intensive monitoring and surveillance systems based both on on-farm comprehensive inspections (see 5.3.5), targeted sampling of domestic pigs related to the intensity of animal movements, the presence of wild boars, or done in high-throughput slaughterhouses and rendering plants. In addition, specific monitoring activities are implemented throughout the year on found dead and hunted wild boars.
  - Targeted surveillance of BT is based mainly in sampling carried out in the context of the intensive flow of trade of cattle towards other MS and non-EU countries. Several of the Bundesländer CAs met stressed the dimension of this surveillance component as many of the holdings regularly involved in this activity played a significant role as sentinels for the detection of the disease due to the frequency and density of



movements happening through them. The BT surveillance plan for 2013 was originally submitted to the Commission on March 2012 and a revised one later on during September.

- According to representatives of the CAs in the Bundesländer visited, the long-standing good level of cooperation with stakeholders works out very well in the poultry and the pig sectors, where the sensitivity of the system has repeatedly proved that farmers and practitioners are quick at reporting suspicions of unexpected events amongst their animals. Examples could be seen of situations where sudden changes in productive indicators (e.g. drop in egg production) or health events (e.g. increased mortality, increased abortion rates, slight respiratory problems, etc.) had triggered further investigations that:
  - had cleared up situations whose cause could not be easily ascertained, by performing a differential diagnosis that usually includes ruling out the presence of epizootic diseases such as AI, CSF and, since early 2012, ASF, and
  - had significantly facilitated the setting up of effective responses to the most recent disease events, such as LPAI, including for instance very effective pre-emptive depopulations and quick traceability exercises to prevent further spreading of the disease and detection of all other possibly affected regions in Germany.
- The above mentioned practice of performing a differential diagnosis that excludes the presence of a notifiable disease, without necessarily involving an official suspicion, has been introduced in recent years and, according to representatives of all CAs met, it facilitates notification and investigation of cases where the presence of an epizootic disease, such as FMD, CSF, AI or ND, cannot be unequivocally excluded. According to representatives of the BMLEV, this approach, identified as 'exclusion diagnosis', increases the sensitivity of the surveillance system and can significantly contribute to the early detection of the incursion of an exotic or emerging disease. They added that this policy has since its advent demonstrated its effectiveness as a reinforcement of the early warning system, as there has been a significant increase in the number of cases notified and investigated in the context of this initiative, including investigations to exclude the presence of CSF, ASF or FMD.

#### *5.3.4 Public awareness activities in “peacetime”*

The audit team found that:

- There is a high level of disease awareness amongst veterinary practitioners, farmers and other stakeholders, such as staff responsible for ABP processing plants or animal markets. This is regularly enhanced by all CAs through targeted campaigns and continuous training of veterinary practitioners and official staff, as well as by maintaining well updated Web-pages where extensive information and adequate guidance can be found in relation to all these diseases and to the actions to be taken in case of any suspicion.

#### *5.3.5 Bio-security measures in place on animal holdings*

The audit team found that:

- There are specific legal requirements at national level, which are further developed by the Bundesländer, that require poultry and pig farmers to comply with strict bio-security provisions in order to prevent the appearance of transmissible and contagious diseases. Moreover, these provisions incorporate the need for the CAs to intensify animal health

controls to ensure that those requirements are complied with by the producers. In addition, for instance in MV there is an official guidance document that recommends similar measures to be applied by cattle farmers; although representatives of the LU acknowledged that the guidance document for the cattle sector cannot be applied in the same way by the CAs in the same way as legally binding provisions in the pig and poultry sectors.

- Some Bundesländer have provisions in the context of the TSKs that link herd health management practices aimed at preventing some enzootic or sporadic contagious diseases with the levies farmers have to pay. The higher the herd health status with regard to some diseases, the lower the levy paid will be; which indirectly contributes to increase the overall level of disease prevention and vigilance and encourages animal keepers to notify quickly any abnormal animal health event.
- In the state of MV, levies for pig farmers are 50% lower for farms participating in a programme with special hygiene standards that are checked twice a year by the local CAs. Nonetheless, representatives of other Bundesländer, such as NI, underlined that graduated levies for pigs based on hygiene status were scrapped after the required hygiene measures were prescribed by law and ceased to be voluntary on the part of holdings. NI at present has graduated levies paid to the TSK by cattle holdings depending on the disease status achieved by the holding (e.g. in relation to infectious bovine rhinotracheitis).

#### *5.3.6 Staff training*

As it has been mentioned in several sections of this report, the audit team found that, in general, a lot of attention has been paid to ensure that staff of all CAs at all levels have received adequate training to be prepared to act in the event of an epizootic disease outbreak according to their responsibilities. During the meetings held with staff of the local CAs, they demonstrated a high level of awareness, for instance in relation to:

- evaluation of symptomatology conducive to suspicion and early detection of epizootic diseases, including on how to perform preliminary epidemiological investigations before the disease is confirmed or ruled out by laboratory diagnosis. This included adequate and safe methods for collection and delivery of samples to the laboratory;
- use of the available information management systems and databases in order to further investigate the epidemiological situation and set up an early response to speed up the detection of possible transmission routes of the disease beyond the suspected holding;
- structure and content of both the TF-TSB and their OMs. Some members of the staff had been specifically trained in areas such as valuation related to compensation payments, communication with the media, organisation of depopulation activities or liaison with and supervision of the activities of ABP processing plants in case of larger disease outbreaks.

#### *5.3.7 Simulation exercises*

The audit team found that:

- Simulation and real-time exercises in dealing with epizootic disease outbreaks take place regularly in the four Bundesländer visited and many of them involve co-operation between several Bundesländer, for instance NW and NI, and with other MS, such as the Netherlands (one on CSF and FMD foreseen in 2013), Belgium and Luxemburg (some carried out over recent years, for instance on FMD in 2011), or Poland (on FMD in 2010);
- All CAs made available to the audit team detailed reports and summaries of the exercises

they had carried out in recent years, which covered a broad range of epizootic diseases, such as AI, FMD, CSF or ASF. These covered exercises at local, Bundesländer, inter-Bundesländer and national level, and they included standard operational arrangements at district level, including intervention of all necessary CAs and related stakeholders (e.g. farmers, staff responsible for depopulation, the police and the establishment of movement restrictions, animal and carcasses transporters, etc.), or larger initiatives going beyond the boundaries of one Bundesländer, trying to carry out large scale traceability exercises for animals and their products (AI, FMD, ASF), or evaluating laboratory capacities in the event of a large outbreak of AI or FMD.

- In all cases, the CAs could show evidence that they had processed the lessons learnt from the outcome and discussed possible improvements to correct the weaknesses identified during the exercises; the audit team could verify that CPs and OMs had been updated or modified as a result of that, or they were in the process of being studied, such as in the cases of emergency vaccination or traceability and processing of products of animal origin.

### **Conclusions on Preparedness and Awareness:**

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

- Availability to federal and Bundesländer CAs of regularly updated disease risk analyses that are used to:
  - prioritise allocation of resources to animal health prevention and risk targeting of disease surveillance systems, in particular in relation to AI, FMD, CSF, ASF and BT;
  - plan well-focussed training courses for veterinary staff and raise awareness amongst all stakeholders of the importance of early detection and notification of these diseases;
  - determine how laboratory diagnostic capabilities need to be strengthened, and
  - planning disease response strategies, including comparative evaluation of different disease-control options.
- The very satisfactory collaboration between the industry, including animal keepers and private veterinary practitioners, and official laboratories and staff of the local CAs. This system facilitates prompt investigations in case of disease situations whose cause can not be easily ascertained and thereby allow the CAs to exclude the presence of epizootic diseases.
- Organisation of simulation and real-time exercises in dealing with epizootic disease outbreaks that take place regularly in the four Bundesländer visited, often involving co-operation between several of them and with other MS, and that effectively contribute to:
  - train personnel designated to be involved in an emergency situation related to the control of potentially rapid spreading animal diseases, and
  - testing, reviewing and up-dating CPs, disease eradication strategies and capabilities at local, regional and national level.

## **5.4 LABORATORIES**

### **Legal requirements:**

Articles 11 & 12 of Regulation (EC) No 882/2004 set out requirements in relation to sampling, analysis and official laboratories, including that laboratories must be accredited to and operate in accordance with ISO 17025.

Specific requirements relating to laboratories are laid down in the various Directives on epizootic disease control including the designation and functions of National Reference Laboratories, the tests and criteria to be applied, and the provision of adequate diagnostic capabilities and capacity. Diagnostic manuals are provided for FMD, CSF, ASF, SVD and AI (see Annex 2).

### **Findings:**

As indicated in section 5.1.1, the IVD includes all the NRLs relevant for diagnosis of epizootic diseases. In addition, in their respective area of jurisdiction, the 16 Bundesländer have designated laboratories for official veterinary examinations, including preliminary investigation and diagnosis of some epizootic diseases, such as AI, CSF and BT. In addition, some of them have developed the potential to cooperate with the preliminary diagnosis (serology) of other diseases such as FMD and ASF, in order to increase the diagnostic capacity of the NRL in the event of a large outbreak. In any case, all official confirmatory testing must be carried out by the relevant NRL.

The audit team noted that:

- The NRLs at the FLI and the two Bundesländer laboratories visited operate to very high levels of expertise and can deliver technically valid results thanks to the QMS in place in all of them:
  - The IVD, with the support of other Institutes of the FLI, has the capability to diagnose any of the epizootic diseases covered by the scope of this audit; in addition, staff of the IVD has demonstrated their enormous potential to cope with diagnostic uncertainties involved in the appearance of unknown emerging diseases, as it has been recently proved by their successful investigations on the infection with Schmallengerg virus.
  - Standard protocols for the diagnosis of the relevant diseases are usually validated according to international standards, the operation of the laboratories has been accredited, even if for some particular diagnostic techniques in the Bundesländer laboratories this had not been finalised yet, and they follow the provisions laid down on EU diagnostic manuals, when available, or in other relevant international standards, as appropriate.
  - The NRLs dedicate considerable resources to research on the epidemiology, pathobiology and diagnosis of many of the epizootic diseases covered by the scope of this audit.
- All NRLs participate regularly with satisfactory results in inter-laboratory comparison tests organised by the network of EU reference laboratories for all relevant infectious diseases.
- For the standard diagnostic techniques used by in Bundesländer laboratories for testing to detect the diseases mentioned in the first paragraph, the relevant NRL organises regularly, at least annually, inter-laboratory comparison tests to verify their operation. In all cases evaluated, these tests had been organised in a satisfactory manner and their results showed the good performance of the involved laboratories.
- The NRLs have made significant efforts in relation to emergency preparedness in order to contribute to the faster detection and control of outbreaks of exotic diseases:

- As mentioned above, one example is the knowledge transfer from the NRLs for FMD, CSF and ASF, and AI to Bundesländer laboratories, in order to increase their diagnostic capacity if an outbreak escalated out of control. Specific evaluations have been carried out to ascertain the potential diagnostic capacity of the overall system in the event of a serious outbreak and, in particular, CPs had been drafted by the NRLs to set out procedures to cope with the upscaling of their activities. For instance, as mentioned in section 5.1.3, special arrangements are in place to ensure availability of sufficient reagents to carry out laboratory diagnosis for all laboratories that would be involved in a large FMD outbreak.
- In addition, in the context of the early warning system, the NRLs have contributed to the introduction of diagnostic protocols fit for purpose in the context of the new policy described in section 5.3.3 on exclusion diagnosis of epizootic diseases.
- The NRLs have a very active involvement in training activities aimed at raising the awareness of staff of the CAs and other stakeholders about the importance of the early detection of exotic diseases.

### **Conclusions on Laboratories:**

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

## **5.5 DEPOPULATION FOR EPIZOOTIC DISEASE CONTROL**

### **Legal requirements:**

Council Regulation (EC) No 1099/2009 lays down rules for the killing of animals, including when this is performed for the purpose of depopulation. In particular, Article 18 of the Regulation requires that the stunning and killing methods planned and the corresponding standard operating procedures for ensuring compliance with the rules laid down in the Regulation shall be included in the CPs 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 Methods of killing and availability of equipment*

The audit team found that:

- Guidance on appropriate methods of killing, with criteria based on species and categories of animals, is provided in the TSBH. This guidance has been further developed by some Bundesländer, such as NI and NW, and even included in the QMS of all the Bundesländer visited to take account of their differing administrative arrangements.
- The size and location of any depopulation operation is taken into account by the CAs through the use of spreadsheets or by the use of QMS forms. Input of data into such spreadsheets allows the required personnel, equipment and materials to be estimated. Filling

in QMS forms during the initial on farm investigation allowed decisions to be made regarding the most appropriate methods of killing, plus the personnel and time required to carry this out.

- The necessary equipment to apply the methods of killing is available either directly at the CA offices, through contracted companies (see 5.2.9), or in relation to lethal injections, through arrangements with private veterinary practices in some Bundesländer. In NI pay and insurance for personnel outside of the CA who would be working in depopulation operations had already been defined and agreed.
- Contracted companies also have operational procedures for carrying out depopulation taking account of the animal welfare requirements. There are also contracts between poultry keepers and private companies who would carry out the killing, and these have allowed, in some Bundesländer, that specific plans be developed for each site in advance of such an operation being necessary. The local CAs would supervise any such depopulation operation.
- German legislation does not allow the method of killing poultry by progressive exposure to CO<sub>2</sub>, which is laid down in Chapter I (table 3 (2)) of Annex I to Regulation (EC) No 1099/2009, and which is used in whole house gassing. There is a procedure whereby the local CAs can derogate from national requirements and apply methods such as whole house gassing, if it is the only suitable method which can be used in the individual circumstance.
- There are templates provided for reporting on a depopulation operation. However these provide a free format for recording the conclusions. The templates currently available do not directly require the recording of the difficulties encountered and solutions found, contrary to Article 18 (4) (d) of Regulation (EC) No 1099/2009.
- An inter-Bundesländer working group is reviewing the technical issues related to killing animals in a depopulation operation; in addition, the FLI has been nominated on 5 February 2013 as the contact point in the sense of Article 20 of Regulation (EC) No 1099/2009 for all the scientific tasks covered within the scope of the said Regulation.

### **Conclusions on depopulation for epizootic disease control:**

The CAs have highly developed strategies for dealing with depopulation operations, which take into account legal requirements such as the size and location of outbreaks. There are many examples of good practice in this area, including the drawing up of contracts, including defined arrangements for pay and insurance, for the personnel involved from outside the CAs.

Methods of killing are in compliance with Regulation (EC) No 1099/2009 and are more restrictive in relation to certain procedures such as whole house gassing. The CAs can grant derogations from national legislation in which case they limit such derogations to methods prescribed in the said Regulation.

The CAs have already put in place a system for recording and reporting depopulation operations; however, this does not take full account of the requirement to record the difficulties encountered and solutions found, as required by Article 18 (4) of Regulation (EC) No 1099/2009, which may provide valuable information for further refining methods and procedures.

## **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 in principle, and provided Category 1 material is not present, as Category 2 animal by-products and therefore subject to the disposal methods specified in the Regulation. Ruminants from which specified risk material has not been removed must be disposed of as Category 1.

In relation to FMD controls, Directive 2003/85/EC (Article 72 (1), (4) & (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 CP.

### **Findings:**

As part of the agreements reached under the auspices of the far-reaching cooperation arrangements in place in the context of the TF-TSB, a system has been set out to facilitate the availability of sufficient rendering capacity to all Bundesländer, in particular in case of large outbreaks when the transporting and processing capacity in any of them could not be sufficient to cope with the situation. In this regard:

- in all Bundesländer visited, ABP processing plants had CPs that had been discussed with the relevant CAs and legal, financial and operational arrangements were in place to facilitate their immediate intervention if and when necessary;
- in all cases the processing plants had overcapacity in reserve that would make relatively easy the processing of material resulting from an average outbreak of an epizootic disease;
- nonetheless, special provisions were in place to anticipate the possible occurrence of a larger outbreak, so that, during the outbreak processing plants in neighbouring Bundesländer would take over the responsibility of handling the ABP that are collected and processed routinely by the local plants, whereas these would dedicate their capacity to the higher risk material resulting from the emergency situation;
- as a consequence of the above mentioned arrangements, it is extremely unlikely that disposal capacities of the network of available processing plants in Germany were exceeded in the event of an outbreak of an epizootic disease and, therefore, that the CAs would have to resort to the derogations on burning and burial of carcasses contemplated in Article 19 (e) of Regulation (EC) No 1069/2009.
- In the context of works ongoing in the context of the working groups operating within the TF-TSB, and in some Bundesländer in particular, such as MV and BY; the CAs were in the process of evaluating new methods to make processing and destruction of large quantities of milk easier, as they acknowledged that this was more complicated than it is for carcasses and that it had been found as a major issue in the context of their evaluation of worst-case scenarios in the event of an outbreak of FMD.

### **Conclusions on disposal of carcasses:**

Satisfactory arrangements in line with the requirements of Regulation (EC) No 1069/2009 were seen in the four Bundesländer visited concerning disposal of dead animals and other ABP in the event of an outbreak, including specific measures that should ensure an effective cooperation between Bundesländer if necessary. Processing and destruction capacities have been thoroughly evaluated in the context of emergency preparedness and should be sufficient to deal with epizootic outbreaks; therefore, it is unlikely that other disposal methods would be needed and used in such cases.

## **6 OVERALL CONCLUSIONS**

The combination of an excellent early warning system and excellent emergency preparedness measures and arrangements make the systems in place in the German Bundesländer visited very robust and capable to manage the situation in the event of an epizootic disease outbreak, in particular thanks to:

- a satisfactory level of animal health surveillance that should detect any unusual disease event in domestic and wild animal populations;
- the availability of largely adequate legal powers and well conceived financial provisions to cope with the unexpected and marginal costs of a disease outbreak;
- the availability of comprehensive and updated operation manuals providing adequate instructions and guidance for staff involved in managing a disease outbreak;
- good levels of training and preparation amongst staff of all the CAs involved;
- the availability of adequate technical and epidemiological expertise and of effective data analysis and information management tools that have in recent years proved to be effective in limiting the spread of diseases and speeding up their eradication;
- adequate provision of equipment and resources as necessary to cope with a major disease outbreak, and
- the largely satisfactory preparation in case animal depopulation is necessary, so that compliance is ensured with EU animal welfare requirements and with EU provisions on disposal of dead animals.

Nevertheless, there are still some deficiencies with regard to some components of the emergency preparedness system, such as:

- decision-making procedures to activate emergency vaccination in case of outbreaks of epizootic diseases such as FMD and CSF are not yet well established and operational to ensure the effective application of vaccination for these diseases, and
- effective mechanisms are not yet in place to ensure that good practices found to alleviate or minimise the suffering of animals killed in the context of depopulation activities are shared nation and EU wide.

## **7 CLOSING MEETING**

A closing meeting was held on 8 February 2013 with representatives of the CCA and the CAs of the Bundesländer visited. At this meeting, the main findings and conclusions of the audit were presented by the audit team. The representatives of the CAs did not indicate any major disagreement with the preliminary findings and conclusions and provided additional clarification on a number of issues.

## **8 RECOMMENDATIONS**

The 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.	To ensure that procedures in place to activate emergency vaccination in case of outbreaks of epizootic diseases such as FMD and CSF ensure the effective application of this disease protection measures in accordance with Article 50 of Directive 2003/85/EC and Articles 19 and 20 of Directive 2001/89/EC.
2.	To ensure that a report is made of each depopulation operation so that difficulties encountered and solutions found are recorded, as required by Article 18 (4) (d) 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=2013-6778](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6778)

## 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

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
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)

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
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)

## 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 (10)
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)			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 X (9)	
Plans & procedures for emergency vaccination	Conditions and criteria specified in Art 49 – 58 & Annex X	Conditions and criteria specified in Art 5 & 6 (as amended by Dir. 2012/5)	Annex VII (f) Annex VI (criteria for deployment of emergency vaccination)				Annex X (9)	
Means of destroying carcasses		Annex III (6)			Annex IV (6)	Annex IV (6)	Annex X (6)	
Environmentally sound means of disposal of carcasses, etc.	Art 72 (1), (4),(5) Annex XVII (13) & (14)							
Real time alert exercises	Art 73 & Annex XVII (11.2)						Art 62 (6) (COM may make further rules)	
Alarm drills	Annex XVII (11.2.4)		Annex VII (g) (ii)	Annex VI (f)(ii)				
Co-operation with neighbouring MS in exercises	Art 73 (2) & Annex XVII (11.2)							
Communications strategy	Annex XVII (15) & (11.3)	Art 14	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) Special	

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
							identificatio n of vaccinated birds	
Diagnostic methods specified	Art 71 & Annex XIII		Diagnostic manual: Decision 2002/106/EC	Diagnostic manual: Decision 2003/422/E C	Diagnostic manual: Decision 2000/428/E C		Diagnostic manual: Decision 2006/437/E C	