

Annex 1

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION
Paris, 12–23 February 2018

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Adopted agenda

1. Meeting with the Director General
2. Adoption of the agenda
3. Cooperation with other Specialist Commissions
4. Texts proposed for adoption in May 2018 General Session
 - 4.1. User's guide
 - 4.2. Glossary Part A
 - 4.3. Import risk analysis (Articles 2.1.1. and 2.1.3.)
 - 4.4. Criteria applied by the OIE for assessing the safety of commodities (Chapter 2.2.)
 - 4.5. Zoning and compartmentalisation (Chapter 4.3.)
 - 4.6. Collection and processing of oocytes and *in vitro* produced embryos from livestock and horses (Chapter 4.8.)
 - 4.7. New chapter on vaccination (Chapter 4.X.)
 - 4.8. The role of the Veterinary Services in food safety systems (Chapter 6.1.)
 - 4.9. Harmonisation of national antimicrobial resistance surveillance and monitoring programmes (Chapter 6.7.) including consideration of the *ad hoc* Group report (January 2018)
 - 4.10. Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals (Articles 6.8.1. and 6.8.1bis.) including consideration of the *ad hoc* Group report (January 2018)
 - 4.11. Prevention and control of *Salmonella* in commercial pig production systems (Articles 6.13.2., 6.13.3. and 6.13.16.)
 - 4.12. New chapter on introduction to recommendations for veterinary public health (Chapter 6.X.)
 - 4.13. Introduction to the recommendations for animal welfare (Article 7.1.1.)
 - 4.14. New article on guiding principles for the use of measures to assess animal welfare (Article 7.1.3.-bis.)
 - 4.15. Animal welfare and pig production systems (Chapter 7.X.) including consideration of the *ad hoc* Group report (January 2018)
 - 4.16. Infection with bluetongue virus (Chapter 8.3.)
 - 4.17. Infection with *Brucella abortus*, *B. melitensis* and *B. suis* (Article 8.4.10.)
 - 4.18. Infection with rinderpest virus (Article 8.16.2.)

Annex 2 (contd)

- 4.19. Infection with lumpy skin disease virus (Articles 11.9.4., 11.9.5., 11.9.6. and 11.9.15.)
- 4.20. Infection with *Burkholderia mallei* (Glanders) (Chapter 12.10.)
- 4.21. Procedures for self-declaration and for official recognition by the OIE (Chapter 1.6.) including questionnaires
- 4.22. Diseases, infections and infestations listed by the OIE (Articles 1.3.1. and 1.3.2.)

5. Texts circulated for Member Countries' comments

- 5.1. Animal health surveillance (Chapter 1.4.)
- 5.2. New chapter on official control of listed and emerging diseases (Chapter 4.Y.)
- 5.3. New introductory chapter in Section 4 on Introduction to recommendations for disease prevention and control (Chapther 4.Z.)
- 5.4. New chapter on killing of reptiles for their skins, meat and other products (Chapter 7.Y.) including consideration of the *ad hoc* Group report (January 2018)
- 5.5. New chapter on animal welfare and laying hen production systems (Chapter 7.X.)
- 5.6. New chapter on infection with *Trypanosoma evansi* (non-equine surra) (Chapter 8.X.) and chapter on infection with Trypanozoon in equids (Chapter 12.3.)
- 5.7. Infection with *Theileria annulata*, *T. orientalis* and *T. parva* (bovidae) (Chapter 11.12.) and new chapter on infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* (small ruminants) (Chapter 14.X.)
- 5.8. Infection with African swine fever virus (Articles 15.1.1.-bis., 15.1.2. and 15.1.3.)
- 5.9. Glossary Part B

6. Amendments or draft new chapters proposed for the *Terrestrial Code*

- 6.1. Procedures for self-declaration and for official recognition by the OIE (Articles 1.6.1. to 1.6.4.)
- 6.2. Welfare of working equids (Articles 7.12.7. and 7.12.12.)
- 6.3. Infection with rabies virus including (Chapter 8.14.) consideration of the *ad hoc* Group report (November 2017)
- 6.4. Infection with avian influenza viruses (Chapter 10.4.) including consideration of the report of the *ad hoc* Group on Avian influenza (December 2017)

7. Other issues

- 7.1. General comments of Member Countries
 - 7.2. Update of the Code Commission's work programme
 - 7.3. Diseases, infections and infestations listed by the OIE (Chapter 1.3.)
 - 7.4. Infection with *Trichinella* spp. (Article 8.17.5.)
 - 7.5. Proposed list of main focus areas and specialties for OIE Collaborating Centres
 - 7.6. Report of the *ad hoc* Group on Veterinary paraprofessionals
 - 7.7. Date of next meetings
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JOINT MEETING BETWEEN THE SCIENTIFIC COMMISSION AND THE CODE COMMISSION

(14 February 2018)

The Scientific Commission for Animal Diseases (the Scientific Commission) and the Terrestrial Animal Health Standards Commission (the Code Commission) convened a joint meeting chaired by the OIE Director General on 14 February 2018.

Dr Monique Eloit, the Director General of the OIE, welcomed and thanked both Commissions for their important work in setting OIE standards. The Director General also thanked all Commission members on behalf of the Member Countries for their full commitment during the three-year period of their mandate.

The Director General noted that the evaluation of the applications for nomination for election to the Specialist Commissions had been completed in December 2017. The report of the Evaluation Committee including the proposed list of suitable candidates will be considered by the Council before the final list is submitted for consideration by the Member Countries in preparation for the elections at the forthcoming General Session in May.

The key issues discussed during the joint meeting are as follows:

1. Update on each Commission's work programme

Dr Etienne Bonbon, the President of the Code Commission, explained that it had recently introduced a new format for its work programme, adding background information such as reasons for new work and current number of rounds for comments. He outlined some of the main issues that needed to be addressed in priority during the coming year, avian influenza (AI), the restructuring of Section 4 of the *Terrestrial Code* on disease prevention and control, including adding new chapters on vaccination and official control of emerging listed diseases and outbreak management, along with the revision of the chapter on animal health surveillance.

Dr Gideon Brückner, the President of the Scientific Commission, introduced some of the priority issues to be discussed in the coming year, namely rabies a tripartite (WHO-OIE-FAO) priority, animal African trypanosomoses, foot and mouth disease (FMD), avian influenza (AI) and bovine spongiform encephalopathy (BSE).

The Director General noted that a very significant proportion of the work programme for Specialist Commissions was ongoing and that OIE resources required to support the Commissions and the increased number of *ad hoc* Groups need to be taken into account. She also noted that the Headquarters would review the current two-year cycle of standard development in response to some Member Country concerns regarding the time constraints to effectively organise national consultation on the large volume of work being undertaken by the Commissions.

2. Proposed revised glossary definitions in the *Terrestrial Code*

The Scientific Commission noted that it had reviewed Member Country comments and found some of them would require careful consideration, such as the definitions of 'disease', 'outbreak', 'containment zone' and 'epidemiological unit'.

The Code Commission noted that some of the comments indeed were valid. However, with respect to the definition of 'disease', it clarified that the word 'disease' would not disappear from the *Terrestrial Code*, instead either the terms 'infection', 'infestation' or 'infection and infestation' would replace 'disease', or the term 'disease' would be retained and italicised when it was used in the generic meaning of the word.

Annex 3 (contd)

3. Proposed revised Chapter 1.6. on Procedures for self-declaration and for official recognition by the OIE

The Code Commission advised that as noted in its September 2017 report, with the assistance of the Headquarters, it had finished its thorough revision of all the questionnaires which had been prepared as separate chapters for each disease and would propose them for adoption in May 2018. The Code Commission noted this would include the slightly revised Chapter 1.6. showing the updated reference to the proposed new chapters and the proposed deletion of the remaining articles.

The Director General commended the Commissions and the secretariat for the progress made regarding the revision of the questionnaires including the presentation as separate chapters. Despite the importance of the revision of the questionnaires for Member Countries, she challenged more generally, reasons for including or maintaining procedural guidance in the *Terrestrial Code*. This position was backed by both Commissions' Presidents.

4. Proposed revised Chapter 4.3. on Zoning and compartmentalisation

Both Commissions discussed the requests and concerns raised by some Member Countries regarding the inclusion of new concepts to address multiple containment zones and 'temporary protection zone'. It was agreed to remove the new paragraphs, for the time being, on the 'temporary protection zone' in order to avoid a delay in the adoption of the revised chapter.

The Commissions agreed on the need to continue to discuss how to provide appropriate guidance, including how to further address the concept of 'temporary protection zone', and respond to the Member Country requests.

5. Antimicrobial resistance

The Headquarters advised that the *ad hoc* Group on Antimicrobial resistance (AMR) met in January 2018 to consider comments from Member Countries on the proposed definitions for 'therapeutic use', 'nontherapeutic use' and 'growth promotion', including proposals to align the OIE definitions with Codex and other international fora.

The Code Commission noted that it had taken into consideration the comments provided by the Scientific Commission and the *ad hoc* Group on AMR and advised that Chapter 6.7. and Articles 6.8.1. and 6.8.1bis. of Chapter 6.8. would be proposed for adoption in May 2018.

6. Chapter 8.11. on Infection with *Mycobacterium tuberculosis* complex

The Headquarters advised that it requested experts from the OIE Reference Laboratories for bovine tuberculosis to evaluate whether the two pathogens (*M. caprae* and *M. tuberculosis*) that are currently not OIE listed diseases, meet the listing criteria of Chapter 1.2. The Headquarters further noted that it would work with the experts to complete the evaluation before the General Session and the Commissions will be informed about the result of the evaluation through electronic communication.

7. Avian influenza (AI) and bovine spongiform encephalopathy (BSE)

Both Commissions commended the OIE Headquarters for its preparatory work and the *ad hoc* Group on AI for the progress made regarding the revision of Chapter 10.4. on AI and expressed their continued support for the new approach of updating the *Terrestrial Code*.

Annex 5 (contd)

The Headquarters noted that two new *ad hoc* Groups on BSE (risk assessment and surveillance) would be convened in 2018 to review Member Country comments and update the chapter accordingly.

8. Information on upcoming *ad hoc* Group meetings

The OIE Headquarters advised that *ad hoc* Groups on AMR, BSE, AI and animal African trypanosomoses would be convened in 2018 to follow up ongoing work and to update the relevant *Terrestrial Code* chapters. It was recalled that following a discussion between the Scientific Commission and the President of the Code Commission, it was agreed that subsequent consideration of the new chapter on infection with *Trypanosoma evansi* (non-equine surra) and the revised chapter on infection with *Trypanozoon* in equids (Chapter 12.3.) would be deferred pending the report of the *ad hoc* Group on animal African trypanosomoses.

9. Other issues

As regards other issues identified for consideration, it was suggested that the review procedure governing the decision on listing or delisting of diseases based on the criteria for listing in Chapter 1.2., be established by the Headquarters to ensure coordination among the Specialist Commissions. It was also proposed that the experts tasked with assessing the diseases against the criteria should not all have expertise directly related to the disease in question and be free from potential bias.

10. Dates of next meeting

The Headquarters proposed the possible dates for the next Specialist Commission meetings in September, noting that the scheduling was proposed in order to facilitate planned orientation sessions for newly elected Members of the Specialist Commissions.

Annex 4

USER'S GUIDE

A. Introduction

- 1) The OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) establishes standards for the improvement of terrestrial animal health and welfare and veterinary public health worldwide. The purpose of this guide is to advise the Veterinary Authorities of OIE Member Countries on how to use the *Terrestrial Code*.
- 2) Veterinary Authorities should use the standards in the *Terrestrial Code* to set up measures providing for early detection, internal reporting, notification, and control or eradication of pathogenic agents, including zoonotic ones, in terrestrial animals (mammals, birds, reptiles and bees) and preventing their spread via international trade in animals and animal products, while avoiding unjustified sanitary barriers to trade.
- 3) The OIE standards are based on the most recent scientific and technical information. Correctly applied, they protect animal health and welfare and veterinary public health during production and trade in animals and animal products, and in the use of animals.
- 4) The absence of chapters, articles or recommendations on particular aetiological agents or commodities does not preclude the application of appropriate sanitary measures by the Veterinary Authorities, provided they are based on risk analyses conducted in accordance with the *Terrestrial Code*.
- 5) The year that a chapter was first adopted and the year of its last revision are noted at the end of each chapter.
- 6) The year that a chapter was first adopted and the year of its last revision are noted at the end of each chapter.

B. *Terrestrial Code* content

- 1) Key terms and expressions used in more than one chapter in the *Terrestrial Code* are defined in the Glossary, in the case where common dictionary definitions are not deemed to be adequate. The reader should be aware of the definitions given in the Glossary when reading and using the *Terrestrial Code*. Defined terms appear in italics. In the on-line version of the *Terrestrial Code*, a hyperlink leads to the relevant definition.
- 2) The term '(under study)' is found in some rare instances, with reference to an article or part of an article. This means that this part of the text has not been adopted by the World Assembly of OIE Delegates and the particular provisions are thus not part of the *Terrestrial Code*.
- 3) The standards in the chapters of Section 1 are designed for the implementation of measures for the diagnosis, surveillance and notification of pathogenic agents. The standards include procedures for notification to the OIE, tests for international trade, and procedures for the assessment of the health status of a country, zone or compartment.
- 4) The standards in Section 2 are designed to guide the importing country in conducting import risk analysis in the absence of OIE recommendations on particular aetiological agents or commodities. The importing country should also use these standards to justify import measures which are more stringent than existing OIE standards.
- 5) The standards in the chapters of Section 3 are designed for the establishment, maintenance and evaluation of Veterinary Services, including veterinary legislation and communication. These standards are intended to assist the Veterinary Services of Member Countries to meet their objectives of improving terrestrial animal health and welfare and veterinary public health, as well as to establish and maintain confidence in their international veterinary certificates.

Annex 4 (contd)

- 6) The standards in the chapters of Section 4 are designed for the implementation of measures for the prevention and control of pathogenic agents. Measures in this section include animal identification, traceability, zoning, compartmentalisation, disposal of dead animals, disinfection, disinsection and general hygiene precautions. Some chapters address the specific sanitary measures to be applied for the collection and processing of semen and embryos of animals.
- 7) The standards in the chapters of Section 5 are designed for the implementation of general sanitary measures for trade. They address veterinary certification and the measures applicable by the exporting, transit and importing countries. A range of model veterinary certificates is provided to facilitate consistent documentation in international trade.
- 8) The standards in the chapters of Section 6 are designed for the implementation of preventive measures in animal production systems. These measures are intended to assist Member Countries in meeting their veterinary public health objectives. They include ante- and post-mortem inspection, control of hazards in feed, biosecurity at the animal production level, and the control of antimicrobial resistance in animals.
- 9) The standards in the chapters of Section 7 are designed for the implementation of animal welfare measures. The standards cover production, transport, and slaughter or killing, as well as the animal welfare aspects of stray dog population control and the use of animals in research and education.
- 10) The standards in each of the chapters of Sections 8 to 15 are designed to prevent the aetiological agents of OIE listed diseases, infections or infestations from being introduced into an importing country. The standards take into account the nature of the traded commodity, the animal health status of the exporting country, zone or compartment, and the risk reduction measures applicable to each commodity.

These standards assume that the agent is either not present in the importing country or is the subject of a control or eradication programme. Sections 8 to 15 each relate to the host species of the pathogenic agent: multiple species or single species of Apidae, Aves, Bovidae, Equidae, Leporidae, Caprinae and Suidae. Some chapters include specific measures to prevent and control the infections of global concern. Although the OIE aims to include a chapter for each OIE listed disease, not all OIE listed diseases have been covered yet by a specific chapter. This is work in progress, depending on available scientific knowledge and the priorities set by the World Assembly.

C. Specific issues

1. Notification

Chapter 1.1. describes Member Countries' obligations under OIE Organic Statutes. Listed and emerging diseases, as prescribed in Chapter 1.1., are compulsorily notifiable. Member Countries are encouraged to also provide information to the OIE on other animal health events of epidemiological significance.

Chapter 1.2. describes the criteria for the inclusion of ~~a disease~~, an infection or infestation in the OIE List and Chapter 1.3. gives the current list. Diseases are divided into nine categories based on the host species of the aetiological agents.

2. Diagnostic tests and vaccines

It is recommended that specified diagnostic tests and vaccines in *Terrestrial Code* chapters be used with a reference to the relevant section in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereafter referred to as the *Terrestrial Manual*). Experts responsible for facilities used for disease diagnosis and vaccine production should be fully conversant with the standards in the *Terrestrial Manual*.

3. Freedom from a disease, infection or infestation

Article 1.4.6. provides general principles for declaring a country or zone free from a disease, infection or infestation. This article applies when there are no specific requirements in the listed disease-specific chapter.

Annex 4 (contd)

4 Prevention and control

Chapters 4.3. and 4.4. describe the measures that should be implemented to establish zones and compartments. Zoning and compartmentalisation should be considered as tools to control diseases and to facilitate safe trade.

Chapters 4.5. to 4.11. describe the measures which should be implemented during collection and processing of semen and embryos of animals, including micromanipulation and cloning, in order to prevent animal health risks, especially when trading these commodities. Although the measures relate principally to OIE listed diseases or infections, general standards apply to all infectious disease risks. Moreover, in Chapter 4.7. diseases that are not listed are marked as such but are included for the information of Member Countries.

Chapter 4.14. addresses the specific issue of the control of bee diseases and some of its trade implications. This chapter should be read in conjunction with the specific bee disease chapters in Section 9.

Chapter 6.4. is designed for the implementation of general biosecurity measures in intensive poultry production. Chapters 6.5., 6.12. and 6.13. is an example of a provide recommendations for some specific on-farm prevention and control plans for the non-unlisted food-borne pathogenic agent Salmonella in poultry as part of the Veterinary Services mission to avoid prevent, eliminate or control food safety hazards in animal production.

Chapter 6.11. deals specifically with the zoonotic risk associated with the movements of non-human primates and gives standards for certification, transportation and import conditions for these animals.

5. Trade requirements

Animal health measures related to international trade should be based on OIE standards. A Member Country may authorise the importation of animals or animal products into its territory under conditions different from those recommended by the *Terrestrial Code*. To scientifically justify more stringent measures, the importing country should conduct a risk analysis in accordance with OIE standards, as described in Chapter 2.1. Members of the WTO should refer to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

Chapters 5.1. to 5.3. describe the obligations and ethical responsibilities of importing and exporting countries in international trade. Veterinary Authorities and all veterinarians directly involved in international trade should be familiar with these chapters. Chapter 5.3. also describes the OIE informal procedure for dispute mediation.

The OIE aims to include an article listing the commodities that are considered safe for trade without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation, regardless of the status of the country or zone of origin for the agent in question, at the beginning of each listed disease-specific chapter in Sections 8 to 15. This is work in progress and some chapters do not yet contain articles listing safe commodities. When a list of safe commodities is present in a chapter, importing countries should not apply trade restrictions to such commodities with respect to the agent in question.

6. International veterinary certificates

An international veterinary certificate is an official document that the Veterinary Authority of an exporting country issues in accordance with Chapters 5.1. and 5.2. It lists animal health requirements and, where appropriate, public health requirements for the exported commodity. The quality of the exporting country's Veterinary Services is essential in providing assurances to trading partners regarding the safety of exported animals and products. This includes the Veterinary Services' ethical approach to the provision of veterinary certificates and their history in meeting their notification obligations.

International veterinary certificates underpin international trade and provide assurances to the importing country regarding the health status of the animals and products imported. The measures prescribed should take into account the health status of both exporting and importing countries, and zones or compartments within them, and be based upon the standards in the *Terrestrial Code*.

Annex 4 (contd)

The following steps should be taken when drafting international veterinary certificates:

- a) identify the diseases, infections or infestations from which the importing country is justified in seeking protection because of its own health status. Importing countries should not impose measures in regards to diseases that occur in their own territory but are not subject to official control programmes;
- b) for commodities capable of transmitting these diseases, infections or infestations through international trade, the importing country should apply the relevant articles in the listed disease-specific chapters. The application of the articles should be adapted to the disease status of the country, zone or compartment of origin. Such status should be established according to Article 1.4.6. except when articles of the relevant listed disease chapter specify otherwise;
- c) when preparing international veterinary certificates, the importing country should endeavour to use terms and expressions in accordance with the definitions given in the Glossary. International veterinary certificates should be kept as simple as possible and should be clearly worded, to avoid misunderstanding of the importing country's requirements;
- d) Chapters 5.10. to 5.13. provide, as further guidance to Member Countries, model certificates that should be used as a baseline.

7. Guidance notes for importers and exporters

It is recommended that Veterinary Authorities prepare 'guidance notes' to assist importers and exporters understand trade requirements. These notes should identify and explain the trade conditions, including the measures to be applied before and after export and during transport and unloading, and the relevant legal obligations and operational procedures. The guidance notes should advise on all details to be included in the health certification accompanying the consignment to its destination. Exporters should also be reminded of the International Air Transport Association rules governing air transport of animals and animal products.

GLOSSARY PART A

ANIMAL WELFARE

means the physical and psychological state of well-being of how an animal is coping with in relation to the conditions in which it lives and dies. An animal is in a good state of welfare if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear and distress. Good animal welfare requires disease prevention and veterinary treatment, appropriate shelter, management, nutrition, humane handling and humane slaughter/killing. Animal welfare refers to the state of the animal; the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

COMPARTMENT

means an animal subpopulation contained in one or more establishments, separated from other populations by under a common biosecurity management system, and with a distinct specific animal health status with respect to a specific one disease or more specific diseases infections or infestations for which required the necessary surveillance, control and biosecurity and control measures have been applied for the purposes of international trade or disease prevention and control in a country or zone international trade.

CONTAINMENT ZONE

means an infected defined zone around and defined within a previously free country or zone which includes including all suspected or confirmed cases that are epidemiologically linked infected establishments, taking into account the epidemiological factors and results of investigations, and where movement control, biosecurity and sanitary measures are applied to prevent the spread of, and to eradicate, the infection infection or infestation are applied.

DISEASE

means the clinical or pathological manifestation of infection or infestation.

FREE ZONE

means a zone in which the absence of a specific the disease, infection or infestation under consideration in an animal population has been demonstrated by in accordance with the relevant requirements specified in of the Terrestrial Code for free status being met. Within the zone and at its borders, appropriate official veterinary control is effectively applied for animals and animal products, and their transportation.

INFECTED ZONE

means a zone either in which an infection or infestation has been confirmed, or one that does not meet the provisions for freedom of is defined as such in the relevant chapters of the Terrestrial Code.

Annex 5 (contd)**PROTECTION ZONE**

means a zone where specific biosecurity and sanitary measures are implemented to prevent the entry of a pathogenic agent into a free country or zone from an adjacent neighbouring country or zone of a different animal health status.

TRANSPARENCY

means the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the risk analysis. Conclusions should be supported by an objective and logical discussion and the document should be fully referenced.

VACCINATION

means the successful immunisation administration of a vaccine, susceptible animals through the administration in accordance with the manufacturer's instructions and the Terrestrial Manual, where when relevant, of a vaccine comprising antigens appropriate to the with the intention of inducing immunity in an animal or group of animals against one or several more pathogenic agents disease to be controlled.

ZONE/REGION

means a clearly defined part of a territory country defined by the Veterinary Authority, containing an animal population or subpopulation with a distinct specific animal health status with respect to an specific disease, infection or infestation for which required surveillance, control and biosecurity measures have been applied for the purposes of international trade or disease prevention or control.

CHAPTER 2.1.

IMPORT RISK ANALYSIS

Article 2.1.1.

Introduction

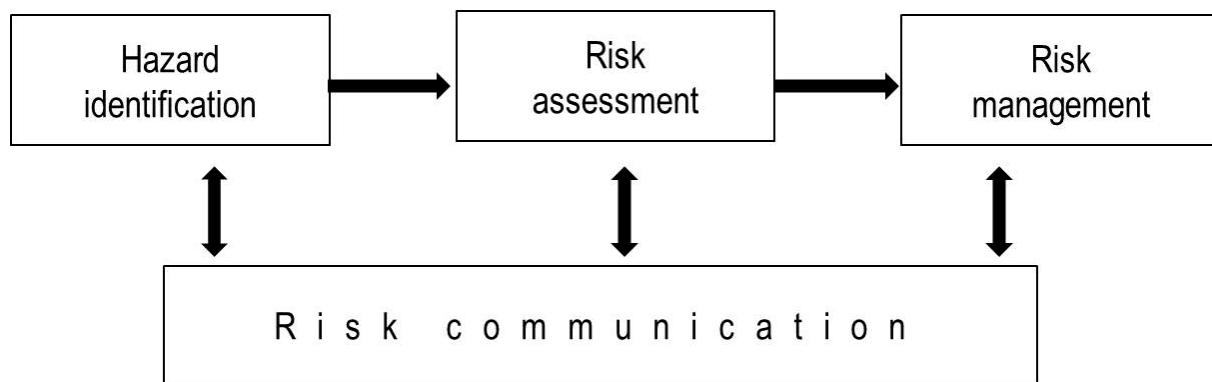
The importation of *animals* and animal products involves a degree of *disease risk* to the *importing country*. This *risk* may be represented by one or several *diseases* or *infections*.

The principal aim of import *risk analysis* is to provide *importing countries* with an objective and defensible method of assessing the *disease risks* associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, biological products and *pathological material*. The analysis should be transparent. Transparency means the comprehensive documentation and communication of all data, information, assumptions, methods, results, discussion and conclusions used in the risk analysis. This is necessary so that the exporting country is and all interested parties are provided with clear reasons for the imposition of import conditions or refusal to import.

Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

This chapter provides recommendations and principles for conducting transparent, objective and defensible *risk analyses* for *international trade*. The components of *risk analysis* are *hazard identification*, *risk assessment*, *risk management* and *risk communication* (Figure 1).

Fig. 1. The four components of risk analysis



The *risk assessment* is the component of the analysis which estimates the *risks* associated with a *hazard*. *Risk assessments* may be qualitative or quantitative. For many *diseases*, particularly for those *diseases* listed in this *Terrestrial Code* where there are well developed internationally agreed standards, there is broad agreement concerning the likely *risks*. In such cases it is more likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making. No single method of import *risk assessment* has proven applicable in all situations, and different methods may be appropriate in different circumstances.

The process of import *risk analysis* usually needs to take into consideration the results of an evaluation of *Veterinary Services*, zoning, compartmentalisation and *surveillance* systems in place for monitoring of animal health in the *exporting country*. These are described in separate chapters in the *Terrestrial Code*.

Annex 6 (contd)

[Article 2.1.2.]

Article 2.1.3.

Principles of risk assessment

- 1) *Risk assessment* should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. *Risk assessment* should be able to accommodate the variety of animal *commodities*, the multiple *hazards* that may be identified with an importation and the specificity of each *disease*, detection and *surveillance* systems, exposure scenarios and types and amounts of data and information.
- 2) Both *qualitative risk assessment* and *quantitative risk assessment* methods are valid.
- 3) The *risk assessment* should be based on the best available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.
- 4) Consistency in *risk assessment* methods should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties. Transparency means the comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the risk analysis.
- 5) *Risk assessments* should document the uncertainties, the assumptions made, and the effect of these on the final *risk estimate*.
- 6) *Risk increases with increasing volume of commodity imported.*
- 7) The *risk assessment* should be amenable to updating when additional information becomes available.

[...]

CHAPTER 2.2.

CRITERIA APPLIED BY THE OIE FOR ASSESSING THE SAFETY OF COMMODITIES

Article 2.2.1.

General provisions

For the purposes of this chapter the word 'safety' is applied only to animal and human health considerations for *listed diseases*.

In many disease-specific chapters, the second article lists *commodities* that can be traded from a country or zone regardless of its status with respect to the specific *listed disease*. The criteria for their inclusion in the list of *safe commodities* are based on the absence of the pathogenic agent in the traded *commodity*, either due to its absence in the tissues from which the *commodity* is derived or to its inactivation by the processing or treatment that the *animal products* have undergone.

The assessment of the safety of the *commodities* using the criteria relating to processing or treatment can only be undertaken when processing or treatments are well defined. It may not be necessary to take into account the entire process or treatment, so long as the steps critical for the inactivation of the pathogenic agent of concern are considered.

For the criteria in Article 2.2.2. to be applied, if it is expected that processing or treatment (i) uses standardised protocols, which include the steps considered critical in the inactivation of the pathogenic agent of concern; (ii) is conducted in accordance with Good Manufacturing Practices; and (iii) that any other steps in the treatment, processing and subsequent handling of the *animal product* do not jeopardise its safety.

Article 2.2.2.

Criteria

For an *animal product* to be considered a *safe commodity* for *international trade*, as described in the User's guide and Article 2.2.1. it should comply with the following criteria:

- 1) There is strong evidence that the pathogenic agent is not present in the tissues from which the *animal product* is derived in an amount able to cause *infection* in a human or *animal* by a natural exposure route. This evidence is based on the known distribution of the pathogenic agent in an infected *animal*, whether or not it shows clinical signs of disease.

OR

- 2) If the pathogenic agent may be present in, or may contaminate, the tissues from which the *animal product* is derived, the standard processing or treatment applied to produce the *commodity* to be traded, while not being specifically directed at this pathogenic agent, inactivates it to the extent that possible *infection* of a human or *animal* is prevented through its action, which is:

Annex 7 (contd)

a) physical (e.g. temperature, drying, irradiation);

or

b) chemical (e.g. iodine, pH, salt, smoke);

or

c) biological (e.g. fermentation);

or

d) a combination of a) to c) above.

CHAPTER 4 . 3 .

ZONING AND COMPARTMENTALISATION

Article 4.3.1.

Introduction

~~For the purposes of the Terrestrial Code, ‘zoning’ and ‘regionalisation’ have the same meaning.~~

~~The purpose of this chapter is to provide recommendations on the principles of zoning and compartmentalisation to Member Countries wishing to establish and maintain different *subpopulations* with specific health status within their territory. These principles should be applied in accordance with the relevant chapters of the Terrestrial Code. This chapter also outlines a process by which trading partners may recognise such *subpopulations*.~~

Establishing and maintaining a disease-free status throughout the country should be the final goal for Member Countries. However, given the difficulty of ~~achieving this goal~~ of establishing and maintaining a disease-free status for an entire territory, especially for diseases the entry of which is difficult to control through measures at national boundaries, there may be benefits to a Member Country in establishing and maintaining a *subpopulation* with a distinct specific health status within its territory ~~for the purposes of international trade or disease prevention or control~~. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate biosecurity management.

~~Zoning and compartmentalisation are procedures implemented by a Member Country under the provisions of this chapter with a view to defining *subpopulations* of distinct health status within its territory for the purpose of disease control and/or international trade.~~

While zoning applies to an animal *subpopulation* defined primarily on a geographical basis (~~using natural, artificial or legal boundaries~~), compartmentalisation applies to an animal *subpopulation* defined primarily by management and husbandry practices related to *biosecurity*. In practice, spatial considerations and ~~good~~ appropriate management, including *biosecurity plans*, play important roles in the application of both concepts.

~~A particular application of the concept of zoning is the establishment of a *containment zone*. In the event of limited outbreaks of a specified disease within an otherwise free country or zone, a single *containment zone*, which includes all cases, can be established for the purpose of minimizing the impact on the entire country or zone.~~

This chapter is to assist Member Countries wishing to establish and maintain different *subpopulations* within their territory using the principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant disease chapter(s). This chapter also outlines a process through which trading partners may recognise such *subpopulations*. This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to outbreaks of disease.

~~Before trade in animals or their products may occur, an *importing country* needs to be satisfied that its animal health status will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its borders and within its territory.~~

~~As well as contributing to the safety of *international trade*, zoning and compartmentalisation may assist disease control or eradication within a Member Country’s territory.~~

Annex 8 (contd)

Zoning may encourage the more efficient use of resources within certain parts of a country, and compartmentalisation may allow the functional separation of a *subpopulation* from other domestic *animals* or *wild animals* through *biosecurity measures*, which *a zone* (through geographical separation) would not *be achieved through geographical separation*. In a country where a disease is endemic, establishment of *free zones* may assist in the progressive control and eradication of the disease. To facilitate disease control and the continuation of trade following a disease *outbreak* in a previously free country or *zone*, zoning may allow a Member Country to limit the extension of the disease to a defined restricted area, while preserving the status of the remaining territory. For the same reasons, the use of compartmentalisation may allow a Member Country to take advantage of epidemiological links among *subpopulations* or common practices relating to *biosecurity*, despite diverse geographical locations, to facilitate disease control and/or the continuation of trade.

A Member Country may thus have more than one *zone* or *compartment* within its territory.

Zoning and compartmentalisation cannot be applied to all diseases but separate requirements will be developed for each disease for which the application of zoning or compartmentalisation is considered appropriate.

To regain free status following a disease *outbreak* in a *zone* or *compartment*, Member Countries should follow the recommendations in the relevant disease chapter in the *Terrestrial Code*.

Article 4.3.2.

General considerations

The Veterinary Services of an *exporting* a Member country *Country* which *that* is establishing a *zone* or *compartment* within its territory for *international trade* purposes should clearly define the *subpopulation* in accordance with the recommendations in the relevant chapters *in* *of* the *Terrestrial Code*, including those on surveillance, *on* *and* the *animal identification* and *animal traceability* *and* *on* *official control programmes* *of* *live animals*. The Veterinary Services of an *exporting* *country* should be able to explain to the Veterinary Services of an *importing* *country* the basis for claiming a distinct *animal health status* for the given *zone* or *compartment* under consideration.

The procedures used to establish and maintain the *distinct specific animal health status* of a *zone* or *compartment* will depend on the epidemiology of the disease, *including* *in particular* the presence and role of *vectors* and *susceptible wildlife species*, and environmental factors, *on the animal production systems* as well as on the application of *biosecurity* and *sanitary measures*, *including movement control*.

Biosecurity and *surveillance* are essential components of zoning and compartmentalisation, and should be developed through active cooperation between industry and Veterinary Services.

The *authority*, *organisation* and *infrastructure* of the Veterinary Services, including *laboratories*, should be clearly documented *established* and *should operate* in accordance with the Chapters 3.1. and 3.2. *on the evaluation of Veterinary Services* *of the Terrestrial Code*, to provide confidence in the integrity of the *zone* or *compartment*. The final authority of *over* the *zone* or *compartment*, for the purposes of domestic and *international trade*, lies with the Veterinary Authority. The Veterinary Authority should conduct an *assessment* of the *resources needed* and *available* to establish and maintain a *zone* or *compartment*. These include the *human and financial resources* and *the technical capability* of the Veterinary Services and of the relevant industry and production system (especially in the case of a *compartment*), including for *surveillance*, *diagnosis* and, when appropriate, *vaccination*, *treatment* and *protection against vectors*.

In the context of maintaining the *animal health status* of a *population* or *subpopulation* of a country, *zone* or *compartment*, references to 'import', 'importation' and 'imported animals/ products' found in the *Terrestrial Code* apply both to importations into a *the* *country as well as* and to the movements of *animals* and their products, *and fomites*, into *the* *zones and/or compartments*. Such movements should be the subject of appropriate *sanitary measures* and *biosecurity* to preserve the *animal health status* of the country, *zone* or *compartment*.

The Veterinary Services should provide movement certification, when necessary, and carry out documented periodic inspections of facilities, *biosecurity*, records and *surveillance* procedures. Veterinary Services should conduct or audit *surveillance*, reporting, *vaccination* and *laboratory diagnostic examinations* and, when relevant, *vaccination*.

Annex 8 (contd)

~~The exporting country should be able to demonstrate, through detailed documentation provided to the importing country, that it has implemented the recommendations in the Terrestrial Code for establishing and maintaining such a zone or compartment.~~

~~An importing country should recognise the existence of this zone or compartment when the appropriate measures recommended in the Terrestrial Code are applied and the Veterinary Authority of the exporting country certifies that this is the case.~~

~~The exporting country should conduct an assessment of the resources needed and available to establish and maintain a zone or compartment for international trade purposes. These include the human and financial resources, and the technical capability of the Veterinary Services (and of the relevant industry and production system, in the case of a compartment) including disease surveillance and diagnosis.~~

~~Biosecurity and surveillance are essential components of zoning and compartmentalisation, and the arrangements should be developed through cooperation of industry and Veterinary Services.~~

~~Industry's responsibilities include the application of biosecurity measures, documenting and recording movements of animals and personnel, quality assurance schemes, monitoring the efficacy of the measures, documenting corrective actions, conducting surveillance, rapid reporting and maintenance of records in a readily accessible form.~~

Industry's The production sector's responsibilities include, in consultation with the Veterinary Services if appropriate, the application of biosecurity, documenting and recording movements of commodities and personnel, managing quality assurance schemes, documenting the implementation of corrective actions, conducting surveillance, rapid reporting and maintenance of records in a readily accessible form.

~~The Veterinary Services should provide movement certification, and carry out documented periodic inspections of facilities, biosecurity measures, records and surveillance procedures. Veterinary Services should conduct or audit surveillance, reporting and laboratory diagnostic examinations.~~

Article 4.3.3.

Principles for defining and establishing a zone or compartment, including protection and containment zones

~~In conjunction with the above considerations, the The following principles should apply when Member Countries define a zone or a compartment.~~

- 1) The extent of a zone and its geographical limits should be established by the Veterinary Authority on the basis of natural, artificial and/or legal boundaries, and made public through official channels.
- 2) A protection zone may be established to preserve the health status of animals in a free country or zone, from adjacent countries or zones of different animal health status. Measures should be implemented based on the epidemiology of the disease under consideration to prevent introduction of the pathogenic agent and to ensure early detection.

~~These measures should include intensified movement control and surveillance and may include:~~

- a) ~~animal identification and animal traceability to ensure that animals in the protection zone are clearly distinguishable from other populations;~~
- b) ~~vaccination of all or at risk susceptible animals;~~
- c) ~~testing and/or vaccination of animals moved;~~
- d) ~~specific procedures for sample handling, sending and testing;~~
- e) ~~enhanced biosecurity including cleansing disinfection procedures for transport means, and possible compulsory routes;~~
- f) ~~specific surveillance of susceptible wildlife species and relevant vectors;~~

Annex 8 (contd)

- g) awareness campaigns to the public or targeted at breeders, traders, hunters, veterinarians.

The application of these measures can be in the entire free zone or in a defined area within and/or outside the free zone.

- 3) In the event of limited outbreaks in a country or zone previously free of a disease, a containment zone may be established for the purposes of trade. Establishment of a containment zone should be based on a rapid response including:

- a) Appropriate standstill of movement of animals and other commodities upon notification of suspicion of the specified disease and the demonstration that the outbreaks are contained within this zone through epidemiological investigation (trace back, trace forward) after confirmation of infection. The primary outbreak has been identified and investigations on the likely source of the outbreak have been carried out and all cases shown to be epidemiologically linked.
- b) A stamping out policy or another effective control strategy aimed at eradicating the disease should be applied and the susceptible animal population within the containment zones should be clearly identifiable as belonging to the containment zone. Increased passive and targeted surveillance in accordance with Chapter 1.4. in the rest of the country or zone should be carried out and has not detected any evidence of infection.
- c) Measures consistent with the disease-specific chapter should be in place to prevent spread of the infection from the containment zone to the rest of the country or zone, including ongoing surveillance in the containment zone.
- d) For the effective establishment of a containment zone, it is necessary to demonstrate that there have been no new cases in the containment zone within a minimum of two incubation periods from the last detected case.
- e) The free status of the areas outside the containment zone would be suspended pending the establishment of the containment zone. The free status of these areas could be reinstated, once the containment zone is clearly established, irrespective of the provisions of the disease-specific chapter.
- f) The containment zone should be managed in such a way that it can be demonstrated that commodities for international trade can be shown to have originated outside the containment zone.
- g) The recovery of the free status of the containment zone should follow the provisions of the disease-specific chapter.

- 24) The factors defining a compartment should be established by the Veterinary Authority on the basis of relevant criteria such as management and husbandry practices related to biosecurity, and made public communicated to the relevant operators through official channels.

- 35) Animals and herds/ or flocks belonging to such subpopulations of zones or compartments need to should be recognisable as such through a clear epidemiological separation from other animals and all things factors presenting a disease risk. For a zone or compartment, the The Veterinary Authority should document in detail The measures taken to ensure the identification of the subpopulation and to the establishment and maintenance of maintain its health status through a biosecurity plan should be documented in detail. These measures used to establish and maintain the distinct specific animal health status of a zone or compartment should be appropriate to the particular circumstances, and will depend on the epidemiology of the disease, environmental factors, the health status of animals in adjacent areas, applicable biosecurity measures (including movement controls, use of natural, and artificial or legal boundaries, the spatial separation of animals, control of fomites, and commercial management and husbandry practices), and surveillance.

- 46) Relevant animals commodities within the zone or compartment should be identified in such a way that their movements are traceable. Depending on the system of production, identification may be done at the herd, or flock lot or individual animal level. Relevant animal movements of commodities into and out of the zone or compartment should be well documented and controlled. The existence of a valid an animal identification system is a prerequisite to assess the integrity of the zone or compartment.

Annex 8 (contd)

- 57) For a compartment, the biosecurity plan should describe the partnership between the relevant industry and the Veterinary Authority, and their respective responsibilities. It should also describe the routine standard operating procedures to provide clear evidence that the surveillance conducted, the live animal identification and traceability system, and the management and husbandry practices are adequate to meet the definition of the compartment. In addition to information on controls of movements of relevant commodities animal movement controls, the plan should include herd or flock production records, feed, water and bedding sources, surveillance results, birth and death records, visitor logbook, morbidity and mortality history and investigations, medications, vaccinations, documentation of training of relevant personnel and any other criteria necessary for evaluation of risk management. The information required may vary in accordance with the species and diseases under consideration. The biosecurity plan should also describe how the measures will be audited to ensure that the risks are being managed and regularly re-assessed reassessed, and the measures adjusted accordingly.

Articles 4.3.4. to 4.3.7. describe different types of zones that can be established by Member Countries. However, other types of zones may be established for the purposes of disease control or trade.

Article 4.3.4.Free zone

A free zone is one in which the absence of a specific infection or infestation in an animal population has been demonstrated in accordance with the relevant requirements of the Terrestrial Code.

In conjunction with Articles 4.3.2. and 4.3.3., and depending on the prevailing epidemiological situation, the attainment or maintenance of free status may require past or ongoing specific surveillance and vector surveillance, as well as appropriate biosecurity and sanitary measures, within the zone and at its borders. The surveillance should be conducted in accordance with Chapter 1.4. and the relevant chapters of the Terrestrial Code.

The free status can apply to one or more susceptible animal species populations, domestic or wild.

So long as an ongoing surveillance demonstrates there is no occurrence of the specific infection or infestation, and principles determined for its definition and establishment are respected, the zone maintains its free status.

Article 4.3.5.Infected zone

An infected zone is one either in which an infection or infestation has been confirmed, or that is defined as such in the relevant chapters of the Terrestrial Code.

An infected zone in which an infection or infestation has been confirmed may be:

- 1) a zone of a country where the infection or infestation is present and has not yet been eradicated, while other zones of the country may be free; or
- 2) a zone of a previously free country or zone, in which the infection or infestation has been introduced or reintroduced, while the rest of the country or zone remains unaffected.

To gain free status in an infected zone, or regain free status following an outbreak in a previously free zone, Member Countries should follow the recommendations in the relevant chapters of the Terrestrial Code.

Article 4.3.6.Protection zone

A protection zone may be established to preserve the animal health status of an animal population in a free country or a free zone by preventing the introduction of a pathogenic agent of a specific infection or infestation from neighbouring countries or zones of different animal health status to that animal population. A protection zone can be established within or outside the free zone or within the free country.

Annex 8 (contd)

Biosecurity and sanitary measures should be implemented in the protection zone based on the animal management systems, the epidemiology of the disease under consideration and the epidemiological situation prevailing in the neighbouring infected countries or zones.

These measures should include intensified movement control and surveillance and specific animal identification and animal traceability to ensure that animals in the protection zone are clearly distinguishable from other populations, and may also include:

- 1) vaccination of all or at risk susceptible animals;
- 2) testing or vaccination of animals moved;
- 3) specific procedures for sample handling, dispatching and testing;
- 4) enhanced biosecurity including disinfection and disinsection procedures for vehicles/vessels and vehicles used for transportation of animal products, feed or fodder, and possible compulsory routes for their movements within, to or from the zone;
- 5) specific surveillance of susceptible wildlife and relevant vectors;
- 6) awareness campaigns aimed at the public or targeted at breeders, traders, hunters or veterinarians.

Anytime the status of the protection zone changes, the status of the country or zone in which it was established should be redetermined in accordance with the relevant listed disease-specific chapters.

In the event of an emergency, such as a sudden increased risk to a free country or zone, a temporary protection zone may be established in a free country or zone. In such a situation, Mmeasures, such as vaccination, implemented in that a protection zone established in a free country or zone will not affect the status of the rest of the free country or zone. However, even if some of such the measures, such as vaccination, may make it necessary to distinguish the status of the protection zone from the rest of the country or zone.

A temporary protection zone should be established for a defined period at the end of which either it is permanently distinguished from the rest of the country or zone or it is disestablished.

In the event of an occurrence, in a temporary protection zone, of a case of an infection or infestation for which it was established, this will not affect the status of the rest of the country or zone, provided that the zone was established at least two incubation periods before the occurrence.

Article 4.3.7.

Containment zone

In the event of outbreaks in a country or zone previously free from a disease, a containment zone, which includes all epidemiologically linked outbreaks may be established to minimise the impact on the rest of the country or zone.

A containment zone is an infected zone that should be managed in such a way that commodities for international trade can be shown to have originated either from inside or outside the containment zone.

Establishment of a containment zone should be based on a rapid response, prepared in a contingency plan, and that includes:

- 1) appropriate control of movement of animals and other commodities upon declaration of suspicion of the specified disease;
- 2) epidemiological investigation (trace-back, trace-forward) after confirmation of infection or infestation, demonstrating that the outbreaks are epidemiologically related and all contained within the defined boundaries of the containment zone;

Annex 8 (contd)

- 3) a stamping-out policy or another effective emergency control strategy aimed at eradicating the disease;
- 4) animal identification of the susceptible population within the containment zone enabling its recognition as belonging to the containment zone;
- 5) increased passive and targeted surveillance in accordance with Chapter 1.4. in the rest of the country or zone demonstrating no occurrence of infection or infestation;
- 6) biosecurity and sanitary measures, including ongoing surveillance and control of the movement of animals and other commodities and fomites within and from the containment zone, consistent with the listed disease-specific chapter, when there is one, to prevent spread of the infection or infestation from the containment zone to the rest of the country or zone.

For the effective establishment of a containment zone, it is necessary to demonstrate that either:

A containment zone is considered as effectively established when the following is demonstrated:

EITHER

- a) there have been no new cases in the containment zone within a minimum of two incubation periods from the disposal of the last detected case.

OR

- b) the containment zone comprises an infected zone where cases may continue to occur and a protection zone, where no outbreaks have occurred for at least two incubation periods after the control measures above are in place, and that separates the infected zone from the rest of the country or zone.

The free status of the areas outside the containment zone is suspended pending the effective establishment of the containment zone. Once the containment zone has been established, the areas outside the containment zone regain free status.

The free status of the containment zone should be regained in accordance with the relevant listed disease-specific chapters or, if there are none, with Article 1.4.6.

In the event of an occurrence of a case of the infection or infestation for which the containment zone was established, either in the containment zone defined in point a) or in the protection zone defined in point b), the rest of the country or zone is considered infected.

Article 4.3.8.

Bilateral recognition of country or zone status by trading countries

While the OIE has procedures for official recognition of status for a number of infections (refer to Chapter 1.6.), for other infections or infestations, countries may recognise each other's status through a bilateral process. Trading partners should exchange information allowing the recognition of different subpopulations within their respective territories. This recognition process is best implemented through establishing parameters and gaining agreement on the necessary measures prior to outbreaks of disease.

The Veterinary Services of an exporting country should be able to explain to the Veterinary Services of an importing country the basis for claiming a specific animal health status for a given zone or compartment under consideration.

Annex 8 (contd)

The *exporting country* should be able to demonstrate, through detailed documentation provided to the *importing country*, that it has implemented the recommendations in the *Terrestrial Code* for establishing and maintaining such a zone or compartment.

In accordance with Chapter 5.3., an *importing country* should recognise the existence of this zone or compartment when the appropriate measures recommended in the *Terrestrial Code* are applied and the Veterinary Authority of the *exporting country* is able to demonstrate that this is the case.

CHAPTER 4.8.

COLLECTION AND PROCESSING OF OOCYTES AND IN VITRO PRODUCED EMBRYOS/OOCYTES FROM LIVESTOCK AND HORSES

Article 4.8.1.

Aims of control

Production of embryos *in vitro* involves the collection of oocytes from the ovaries of donors, *in vitro* maturation and fertilisation of the oocytes, then *in vitro* culture to the morula/ or blastocyst stage. At at this stage, which they are ready for transfer into recipients. The purpose of official sanitary control of *in vitro* produced embryos intended for movement internationally is to ensure that specific pathogenic organisms, which could be associated with such embryos, are controlled and transmission of *infection* to recipient animals and progeny is avoided. The conditions outlined in this chapter are also applicable where the movement of *in vitro* maturing (IVM) oocytes is intended.

Article 4.8.2.

Conditions applicable to the embryo production team

The embryo production team is a group of competent technicians, including at least one *veterinarian*, to perform the collection and processing of ovaries/ and oocytes and the production and storage of *in vitro* produced embryos. The following conditions should apply:

- 1) The team should be approved by the *Competent Authority*.
- 2) The team should be supervised by a team *veterinarian*.
- 3) The team *veterinarian* is responsible for all team operations which include the hygienic collection of ovaries and oocytes and all other procedures involved in the production of embryos intended for international movement.
- 4) Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practised to preclude the introduction of *infection*.
- 5) The production team should have adequate facilities and equipment for:
 - a) collecting ovaries and/or oocytes;
 - b) processing of oocytes and production of embryos at a permanent or mobile laboratory;
 - c) storing oocytes and/or embryos.

These facilities need not necessarily be at the same location.

- 6) The embryo production team should keep a record of its activities, which should be maintained for inspection by the *Veterinary Authority Services* for a period of at least two years after the embryos have been exported.
- 7) The embryo production team should be subjected to regular inspection at least once a year by an *Official Veterinarian* to ensure compliance with procedures for the sanitary collection and processing of oocytes and the production and storage of embryos.

Annex 9 (contd)

Article 4.8.3.

Conditions applicable to the processing laboratories

A processing laboratory used by the embryo production team may be mobile or permanent. It may be contiguous with the oocyte recovery area or at a separate location. It is a facility ~~in which where oocytes which that have been recovered from ovaries are then matured and fertilised, and where the resulting embryos are further cultured in vitro.~~

Embryos may also be subjected to any required treatments such as washing and storage and quarantine in this laboratory.

Additionally:

- 1) The laboratory should be under the direct supervision of the team *veterinarian* and regularly inspected by an *Official Veterinarian*.
- 2) While embryos for export are being produced prior to their storage in ampoules, vials or straws, no oocyte/or embryo of a lesser health status should be recovered or processed in the same laboratory.
- 3) The laboratory should be protected against rodents and insects.
- 4) The processing laboratory should be constructed with materials which permit its effective cleansing and *disinfection*. This should be done frequently and always before and after each occasion when embryos for export are processed.
- 5) The processing laboratory should have and use appropriate facilities to handle and process embryos for export, in accordance with the recommendations in the Manual of the International Embryo Transfer Technology Society (IETS).

Article 4.8.4.

Conditions applicable to donor animals

Oocytes for the *in vitro* production of embryos are obtained from donors basically in two different ways: individual collection or batch collection. The recommended conditions for these differ.

Individual collection usually involves the aspiration of oocytes from the ovaries of individual live animals on the farm where the animal resides, or at the laboratory. Occasionally oocytes may also be recovered from individual live donors by aspiration from surgically excised ovaries. When oocytes are recovered from individual live animals, the conditions for these donors should resemble those set out in Article 4.7.4.

In these cases the cleaning and sterilisation of equipment (e.g. ultrasound guided probes) is especially important and should be carried out between each donor in accordance with the recommendations in the Manual of the International Embryo Transfer Society (IETS)⁴.

Batch collection involves the removal of ovaries from batches of donors slaughtered at a *slaughterhouse/abattoir* (*hereafter ‘abattoir’*); these ovaries are then transported to the processing laboratory where the oocytes are recovered from the ovarian follicles by aspiration or slicing techniques. Batch collection has the disadvantage that it is usually impractical to relate trace the ovaries which are transported to the laboratory back to the donors which were slaughtered at the slaughterhouse/abattoir. Nevertheless, it is critical to ensure that only healthy tissues are obtained and that they are removed from the donors and transported to the laboratory in a hygienic manner.

Annex 9 (contd)

Additionally:

- 1) The *Veterinary Authority Services* should have knowledge of the *herd(s)* or *flock(s)* from which the donor animals ~~have been~~ were sourced.
- 2) The donor animals should not originate from *herds* or *flocks* that are subject to veterinary restrictions for foot and mouth disease, rinderpest and ~~or~~ peste des petits ruminants, and neither should the removal of any tissue or aspiration of oocytes take place in an *infected zone*, or one that is subject to veterinary restrictions for those diseases.
- 3) In the case of oocyte recovery from live donors, post-collection surveillance of the donors and donor *herd(s)* or *flock(s)* should be conducted based on the recognised *incubation periods* of the diseases of concern to determine retrospectively the health status of donors.
- 4) In the case of oocyte recovery from batches of ovaries collected from an *slaughterhouse/abattoir*, the *slaughterhouse/abattoir* ~~it~~ should be officially approved and under the supervision of a *veterinarian* ~~whose responsibility is to ensure responsible for ensuring~~ that ante-mortem and post-mortem inspections of potential donor animals are carried out, and ~~to certify for certifying~~ them ~~to be free from~~ of clinical or pathological signs of the diseases listed in point 2.
- 5) Donor animals slaughtered at an *slaughterhouse/abattoir* should not ~~have been be animals~~ designated for compulsory *slaughter* for a *notifiable disease* and ~~or~~ should not be slaughtered at the same time as such animals ~~donors from which ovaries and other tissues will be removed~~.
- 6) Batches of ovaries and other tissues collected from an *slaughterhouse/abattoir* should not be transported to the processing laboratory before confirmation has been obtained that ante- and post-mortem inspection of donors has been ~~satisfactorily completed~~ carried out with favourable results.
- 7) Equipment for the removal and transport of ovaries and other tissues should be cleaned and sterilised before use and used exclusively used for these purposes.
- 8) Records of the identities and origins of all donors should be maintained for inspection by the *Veterinary Authority Services* for a period of at least two years after the embryos have been exported. While this may be difficult to achieve in the case of batch collection, it is to be expected that the identities of the *herds* or *flocks* from which the donors originated will be maintained.

Article 4.8.5.

Optional Tests and treatments

A supplementary approach for ensuring that *in vitro* produced embryos do not transmit disease is ~~by~~ testing various materials to confirm the absence of pathogenic organisms agents listed in point 2 of Article 4.8.4.

Tests may also be used to assess whether quality control procedures being applied in the processing laboratory are of an acceptable standard.

Tests may be carried out on the following materials:

- 1) non-viable oocytes/ or embryos from any stage of the *in vitro* production line from batches intended for export;
- 2) samples of *in vitro* maturation medium taken prior to mixing the oocytes with semen for the fertilisation process;
- 3) samples of embryo culture medium taken immediately prior to embryo storage;
- 4) a pool of the last three washes from the 10 washes performed on the embryos.

Annex 9 (contd)

These samples should be stored at 4°C and tested within 24 hours. If this is not possible, then the samples should be stored frozen at minus 70°C or lower.

Additionally:

- 1) Semen used to fertilise oocytes *in vitro* should have been collected and processed in accordance with Chapter 4.5, and meet the health requirements and standards set out in Chapter 4.6, as appropriate to the species and in relevant listed disease-specific chapters.

When the donor of the semen used to fertilise the oocytes is dead, and when the health status of the semen donor concerning a particular infectious disease or diseases of concern was not known at the time of semen collection, additional tests on the spare embryos may be required to verify that these infectious diseases were not transmitted.

An alternative may be to test an aliquot of semen from the same collection date.

- 2) Any biological product of animal origin, including co-culture cells and media constituents, used in oocyte recovery, maturation, fertilisation, culture, washing and storage should be free of from living pathogens pathogenic agents. Media should be sterilised prior to use by approved methods in accordance with the IETS Manual⁴ of the IETS and handled appropriately in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the IETS Manual of the IETS⁴.
- 3) All equipment used to recover, handle, culture, wash, freeze and store oocytes/ or embryos should be new or cleaned and sterilised prior to use as recommended in the IETS Manual of the IETS⁴.

Article 4.8.6.

Risk management

With regard to disease transmission, transfer of *in vitro* produced embryos is a low risk method for moving animal genetic material although the *risk* is not quite as low as for *in vivo* derived embryos. It should be noted that categorisation of diseases/ and disease pathogenic agents by the IETS, as described for *in vivo* derived embryos in Article 4.7.14., does not apply in the case of *in vitro* produced embryos. Irrespective of the animal species, there are three phases in the embryo production and transfer process that determine the final level of *risk*. These are as follows:

- 1) the first phase comprises the risk potential for ovary-/oocyte/ or embryo contamination and depends on:
 - a) the disease situation in the *exporting country and/or zone*;
 - b) the health status of the *herds or flocks* and the donors from which the ovaries-/oocytes/ or embryos or semen for fertilisation of oocytes are collected;
 - c) the pathogenic characteristics of the specified disease pathogenic agents listed in point 2 of Article 4.8.4.;
- 2) the second phase covers risk mitigation by the use of internationally accepted procedures for the processing of embryos which are set out in the IETS Manual of the IETS⁴. These include the following:
 - a) oocytes and embryos should be washed between each stage of production;
 - b) after the *in vitro* culture period is finished the embryos should be washed at least ten 10 times with at least 100-fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash;

Annex 9 (contd)

- c8)** only embryos from the same donor (in the case of individual collection) or from the same batch (in the case of batch collection) should be washed together, and no more than ten embryos should be washed at any one time;
- dc)** sometimes, for example when inactivation or removal of certain viruses (e.g. bovine herpesvirus-1, or Aujeszky's disease virus) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual of the IETS⁴;
- ed)** the *zona pellucida* of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free of adherent material;
- 3) the third phase, which is applicable to diseases listed in point 2 of Article 4.8.4. encompasses the *risk* reductions resulting from:
- post-collection surveillance of the donors and donor *herds* or *flocks* based on the recognised incubation periods of the diseases of concern to determine retrospectively the health status of the donors whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the *exporting country*. Post-collection surveillance of donors is not, of course, possible in the case of batch collection from an *slaughterhouse/abattoir*, although surveillance of the *herds* or *flocks* of origin may be possible;
 - testing of oocytes, embryos, co-culture cells, media and other samples (e.g. blood) (as referred to in Article 4.8.5.) in a *laboratory* for presence of disease pathogenic agents.

Article 4.8.7.

Conditions applicable to the storage, and transport and export of oocytes and embryos

Oocytes and *in vitro* produced embryos can be stored and transported fresh, chilled or frozen.

Fresh embryos may undergo culture in portable incubators during transportation and should arrive at the recipient animal within five days, in time for transfer of the mature blastocysts. Chilled embryos should be transferred within 10 days of chilling.

The Veterinary Services should have knowledge of the variety of oocyte and embryo storage systems available and should have procedures in place for the safe and timely inspection and certification of these oocytes and embryos to ensure their viability.

- Only embryos from the same individual donor or from the same batch collection should be stored together in the same ampoule, vial or straw.
- For frozen oocytes and embryos
 - Sterile ampoules, vials or straws should be sealed prior to freezing or after vitrification and should be labelled according to the Manual of the IETS⁴.
 - The frozen oocytes and embryos should if possible, depending on the species, be frozen in fresh liquid nitrogen that has not been used previously or other cryoprotectant and then stored in fresh cryoprotectant liquid phase nitrogen that has not been used previously or in the vapour phase of liquid nitrogen cleaned disinfected containers under strict hygienic conditions at a storage place.
 - Liquid nitrogen containers should be sealed prior to shipment from the exporting country.
- For fresh or chilled oocytes and embryos
 - Sterile Ampoules ampoules, vials or straws should be sealed prior to storing in portable incubators at the time of freezing and should be labelled in accordance with the IETS Manual of the IETS⁴.

Annex 9 (contd)

- b) The fresh or chilled oocytes and embryos should be stored under strict hygienic conditions in portable incubators disinfected in accordance with the IETS Manual of the IETS and manufacturer's instructions.
 - c) Portable incubators should be sealed prior to shipment from the exporting country.
- 4) Liquid nitrogen containers should be sealed prior to shipment from the exporting country.
- 45) Oocytes and embryos—Embryos should not be exported until the appropriate veterinary certificates are completed.

Article 4.8.8.

Procedure for micromanipulation

When micromanipulation of the embryos is to be carried out, this should be done after completion of the treatments described in point 2 of Article 4.8.6. and conducted in accordance with Chapter 4.9.

Annex 10

CHAPTER 4.X.

VACCINATION

Article 4.X.1.

Introduction and objectives

~~In general, Vaccination is intended to prevent and control and prevent the occurrence of a disease and reduce the transmission of the pathogenic agent. For the purpose of disease control Ideally, vaccines should induce immunity that, ideally, prevents infection.~~ However, some vaccines may only prevent clinical signs, or reduce multiplication and shedding of the pathogenic agent.

Vaccination may contribute to improvement of animal and human health, animal welfare, agricultural sustainability and to reduction of the use of antimicrobial agents in animals.

The objective of this chapter is to provide guidance to Veterinary Services Authorities for the successful use of vaccination in support of disease prevention and control programmes. The recommendations in this chapter may be refined by the specific approaches described in the listed disease-specific chapters of the Terrestrial Code. Furthermore, the recommendations in this chapter may also be used for any diseases for which a vaccine exists.

The vaccination strategy applied depends on biological, technical and policy considerations, available resources and the feasibility of implementation. ~~The recommendations in this chapter are intended for all diseases for which a vaccine exists.~~

~~In addition to other disease control measures, vaccination may be a component of a disease control programme. The prerequisites to enable a Member Country to successfully implement vaccination include compliance with:~~

- 1) the recommendations on surveillance in Chapter 1.4.;
- 2) the relevant provisions in Chapters 3.1. and 3.4.;
- 3) the recommendations on vaccination in the listed disease-specific chapters of the Terrestrial Code;
- 4) in vaccine-producing countries, the relevant general and specific recommendations for principles of veterinary vaccine production and quality control in Chapter 1.1.8. of the Terrestrial Manual.

~~The objective of this chapter is to provide guidance to Member Countries for successful implementation of vaccination in support of disease control programmes. The recommendations in this chapter may be refined by the specific approaches described in the disease-specific chapters of the Terrestrial Code.~~

~~Standards for vaccines are described in the Terrestrial Manual.~~

Article 4.X.2.

Definitions

For the purposes of this chapter:

Vaccination programme: means a plan to apply vaccination to an epidemiologically appropriate proportion of the susceptible animal population for the purposes of disease prevention or control.

Emergency vaccination: means a vaccination programme applied in immediate response to an outbreak or increased risk of introduction or emergence of a disease.

Systematic vaccination: means an ongoing routine vaccination programme.

Annex 10 (contd)

Vaccination coverage: means the proportion of the target population to which vaccine was administered during a specified timeframe.

Population immunity: means the proportion of the target population effectively immunised at a specific time.

Article 4.X.3.

Vaccination programmes

The objectives and strategy of a vaccination programme should be defined by the Veterinary Authority before the implementation of the vaccination, taking into account the epidemiology of the disease disease infection, its impact and zoonotic potential, the species affected and their distribution.

If these factors indicate that the programme should be expanded beyond national boundaries, the Veterinary Authority should liaise with the Veterinary Authorities of neighbouring countries. When appropriate, a regional approach to harmonise vaccination programmes is recommended.

Veterinary Authorities should liaise, as relevant, with public health authorities when developing and implementing vaccination programmes against zoonoses.

Vaccination programmes may include systematic vaccination and emergency vaccination.

- 1) Systematic vaccination in infected countries aims to reduce the incidence, prevalence or impact of a disease with the objective of prevention, control and possible eradication. In disease free countries or zones, the objective of systematic vaccination is to prevent the introduction of a pathogenic agent disease from an infected neighbouring country or zone, or to limit the impact in the case of an the introduction of that disease pathogenic agent disease.
- 2) Emergency vaccination provides an adjunct to the application of other essential biosecurity and disease control measures and may be applied to control outbreaks. Emergency vaccination may be used in response to:
 - a) an outbreak in a free country or zone;
 - b) an outbreak in a country or zone that applies systematic vaccination, but when vaccines are revaccination is applied to boost existing immunity;
 - c) an outbreak in a country or zone that applies systematic vaccination, but when the vaccine employed does not provide protection against the strain of the pathogenic agent involved in the outbreak;
 - d) a change in the risk of introduction of a pathogenic agent or emergence of a disease in a free country or zone.

Vaccination programmes should consider other be integrated with other ongoing animal health-related activities involving the target population. This can improve the efficiency of the programme and reduce the cost by sharing optimisation of resources.

Article 4.X.4.

Launching a vaccination programme

When deciding whether to initiate a vaccination programme the Veterinary Authority should consider, among others, the following:

- 1) the epidemiology of the disease disease infection;
- 1bis) the probability that the disease cannot be rapidly contained by means other than vaccination;
- 2) the an increased incidence and prevalence of an existing the disease, if present;

Annex 10 (contd)

- 3) the an increased likelihood of introduction of a pathogenic agent or emergence of a disease;
- 3bis) the zoonotic potential of the disease;
- 4) the density of the exposed susceptible animals population;
- 5) the an insufficient level of population immunity;
- 6) the *risk* of exposure of specific *subpopulations* of susceptible animals;
- 7) the suitability of a vaccination programme as an alternative to or an adjunct to other disease control measures such as a stamp-out policy;
- 7bis) the existence of an animal identification system to differentiate vaccinated from unvaccinated subpopulations;
- 8) the availability of a safe and effective vaccine resources;
- 8bis) the availability of human, financial, and material resources;
- 9) the cost-benefit analysis considerations of the vaccination programme, including the its impact on trade and public health.

Article 4.X.5.

Vaccination strategies

Different vaccination strategies may be applied alone or in combination, taking into account the epidemiological and geographical characteristics of occurrence of the disease. The following strategies may be applied:

- 1) **Blanket vaccination:** *vaccination* of all susceptible animals in an area or an entire country or zone.
- 2) **Ring vaccination:** *vaccination primarily* of all susceptible animals in a delineated area surrounding the location establishments where an *outbreak* has occurred. To prevent outward spread of disease, vaccination should be applied from the outer boundary of the area inwards.
- 3) **Barrier vaccination:** *vaccination* in an area along the border of an infected country or zone to prevent the spread of disease infection into or from a neighbouring country or zone.
- 4) **Targeted vaccination:** *vaccination* of a *subpopulation* of susceptible animals defined by a greater likelihood of exposure or severity of the consequences.

Article 4.X.67.

Choice of vaccine

Depending on the disease, several vaccines may be available. To achieve the objectives of the *vaccination programme*, the choice of a vaccine is a critical element that depends on different several factors including:

1. Availability and cost
 - a) Availability of the vaccine including marketing authorisation relevant regulatory approvals and in adequate quantities at the time required;
 - b) capacity of the providers to supply the vaccine for the duration of the *vaccination campaign* and to respond to increased needs;

Annex 10 (contd)

- c) flexibility in the number of doses per vial to match the structure of the target population;
 - d) a comparison of the costs of vaccines that meet the technical specifications established in the *vaccination* programme.
2. Vaccine characteristics
- a) Physical characteristics
 - Route and ease of administration;
 - volume of dose;
 - type of adjuvant and other components.
 - b) Biological characteristics
 - Immunity against circulating strains;
 - live, inactivated or biotechnology-derived vaccines;
 - number of strains and pathogens included in the vaccine;
 - potency of the vaccine;
 - onset of immunity;
 - shelf-life and expiry date;
 - **thermostability thermotolerance**;
 - duration of the effective immunity;
 - number of doses required to achieve effective immunity;
 - ≡ ability to be monitored for vaccine-induced immunity;
 - **effect on the ability for vaccinated animals to be differentiated from infected from vaccinated animals, at the individual or group level;**
 - suitability of vaccine formulation for species and age of animals in the target population;
 - safety for the users, the consumers and the environment.
 - c) Side effects
 - Adverse reactions;
 - unintentional transmission of live vaccine strains;
 - ≡ reversion of attenuated strains to virulence.

When a single vaccine only is available, the same factors listed above should be considered in deciding whether or not to launch a vaccination programme.

Annex 10 (contd)Article 4.X.76.**Other critical elements of a vaccination programme**

In addition to the choice of vaccine, the *vaccination* programme should include the following other critical elements, and The vaccination programme should be communicated to all stakeholders.

1. Legal basis

There should be a legal basis for the vaccination programme, including for possible compulsory compliance and for possible compensation of animal owners for possible adverse reactions in their animals.

2. Target population

The *vaccination* programme should define the animal population to be vaccinated and the geographical area where the target population is located.

The target population may include the entire susceptible population or an epidemiological relevant *subpopulation* depending on the likelihood of exposure, the consequences of the disease, the role of the different *subpopulations* in the epidemiology of the *disease infection* and the resources available. The target population may include *wildlife*.

Factors to consider in determining the target population may include species, age, health status, maternal immunity, sex, production types, geographical distribution as well as the number of *animals* and *herds*. These factors should be reviewed and updated regularly.

32. Vaccination coverage

In practical terms, it It may be difficult to immunise the entire target population. The *vaccination* programme should define the minimum *vaccination coverage* necessary to achieve for the minimum a sufficient population immunity required to achieve to fulfil the objectives of the programme. The minimum population immunity required will vary according to the epidemiology of the disease, density of susceptible animals, efficacy of the vaccine and geographical factors.

Measuring population immunity during the monitoring of the *vaccination* programme may assist to in identifying subsets of the target *population* that have not been adequately immunised.

43. Stakeholder involvement

Veterinary Services The *vaccination* programme should demonstrate good governance of the *vaccination* programme by the Veterinary Services and by clearly identifying the involvement of different stakeholders including other government agencies governmental organisations, farmers animal owners, farmer organisations, private sector veterinarians, non-governmental organisations, veterinary paraprofessionals, local government authorities and vaccine suppliers. Stakeholder acceptance of *vaccination* is crucial for the success of the *vaccination* programme. Different stakeholders should preferably be involved in the planning and implementation of *vaccination*, the awareness campaigns, the monitoring of *vaccination*, the production and delivery of vaccines and the financing of the *vaccination* programme.

54. Resources

Vaccination programmes may often span several years. To achieve the desired objective, human, financial and material resources should be available throughout the estimated duration of the *vaccination* programme.

65. Actions and timeline

The *vaccination* programme should describe the responsibilities, expected deliverables and timeline for each activity.

Annex 10 (contd)

76. Timing of vaccination campaigns

The *vaccination* programme should describe the periodicity of the any vaccination campaigns. Depending on the disease and type of vaccine, animals may be vaccinated once or several times during their lifetime.

The objective of the a vaccination campaign is should be to achieve the necessary vaccination coverage necessary to attain or maintain and the minimum population immunity in the target *population* within a defined timeframe. The vaccination campaign should be implemented in such a manner as to ensure that the majority of the target *population* is immunised within as short a time as possible. The vaccination programme should include a detailed description of the implementation of the vaccination campaigns, including frequency and starting and ending dates of each campaign.

The frequency, timing and duration of the vaccination campaigns should be determined taking into consideration the following factors:

- a) vaccine characteristics and manufacturer's directions for use;
- abis) vaccine storage facilities and delivery systems;
- b) accessibility of the target population;
- c) animal handling facilities;
- d) animal body condition and physiological state;
- e) geographical factors;
- f) climate conditions;
- fbis) vector activity:
- g) awareness, acceptance and engagement of stakeholders;
- h) types of production systems and animal movement patterns;
- i) timing of agricultural, social or cultural activities;
- j) availability of resources.

87. Auditing of the vaccination campaigns

The vaccination programme should include periodic auditing of all the participants in the any vaccination campaigns. Auditing ensures that all components of the system function and provide verifiable documentation of procedures. Auditing may detect deviations of procedures from those documented in the programme.

Indicators related to auditing of the a vaccination campaign may include:

- a) proportion of the targeted population of animals and herds vaccinated within the defined timeframe;
- b) number of vaccine doses used compared with number of animals vaccinated;
- bbis) number of animals vaccinated compared to census figures for the relevant animal population;
- c) number of reports of breaches of the cold chain;
- d) performance of vaccinator teams in respect of in complying with the standard operating procedures;
- e) timing and length duration of the campaign;

Annex 10 (contd)

- f) overall cost and cost per individual animal vaccinated.

To enable auditing of the *vaccination* programme, a recording system should be in place to measure the indicators above.

Article 4.X.8.

Logistics of vaccination

Vaccination campaigns should be planned in detail and well in advance considering the following elements:

1. Procurement of vaccine

The vaccine selected for use in a *vaccination* programme should ~~have been~~ be subjected to the ~~registration~~ ~~relevant regulatory approval~~ procedure of the country, which is congruent with the recommendation of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medical Medicinal Products (VICH).

For systematic *vaccination* campaigns, the process of procurement of the selected vaccine should be initiated in advance to ensure timely delivery to meet the timeframe of the *vaccination* campaign.

National disease contingency plans should provide for emergency *vaccination*. These provisions may allow for simplified procedures to procure vaccine and grant authorisation for temporary use. If *vaccination* is to be used systematically, definitive relevant regulatory approval ~~registration~~ should be obtained.

Vaccine banks, established in accordance with Chapter 1.1.10. of the *Terrestrial Manual*, facilitate the timely procurement of vaccines.

1bis. Procurement of equipment and consumables

In addition to the vaccine itself, the planning of the vaccination campaigns should include the procurement of all necessary equipment and consumables.

2. Implementation of the vaccination programme

In addition to the vaccine itself, the planning of the vaccination campaigns should include the procurement of all necessary equipment and consumables as well as Standard operating procedures should be established to:

- a) implement the communication plan;
- b) establish, maintain and monitor the fixed and mobile components of the cold chain;
- c) store, transport and administer the vaccine;
- d) clean and disinfect equipment and *vehicles*, including heat sterilisation of reusable equipment;
- e) dispose of waste;
- ebis) determine the disposition of partially used or unused containers of vaccine, (such as ampoules, vials, and bottles, etc.) of vaccine;
- eter) implement biosecurity to ensure vaccination teams do not transmit the pathogenic agent between establishments;
- f) identify vaccinated animals;
- g) ensure the safety and welfare of animals and *vaccination* teams;

Annex 10 (contd)

g) ensure the safety of vaccination teams;

h) record activities of vaccination teams;

i) document vaccinations.

The availability of appropriate animal handling facilities at the vaccination site is essential to ensure effective vaccination as well as safety and welfare of animals and vaccination teams.

3. Human resources

Vaccination should be conducted by appropriately trained and authorised personnel under the supervision of the Veterinary Services Authority. The vaccination programme should provide for periodic training sessions including updated written standard operating procedures for field use.

The number of vaccination teams should be sufficient to implement the vaccination campaign within the defined timeframe. The vaccination teams should be adequately equipped and have means of transport to reach the places where vaccination is carried out sites.

4. Public awareness and communication

The Veterinary Services Authority should develop a communication strategy in accordance with Chapter 3.3., which should be directed at all stakeholders and the public to ensure awareness and acceptability of the vaccination programme, its objectives and potential benefits.

The communication plan may include details on the timing and location of the vaccination, target population and other technical aspects that may be relevant for the public to know.

5. Animal identification

Animal identification allows for the differentiation of vaccinated from non-unvaccinated domestic animals and is required for the monitoring and certification of vaccination.

Identification can range from temporary to permanent identifiers and can be individual or group-based. Animal identification should be carried out implemented in accordance with Chapters 4.1. and 4.2.

6. Record keeping and vaccination certificates

Vaccination programmes under the Veterinary Service's Authority's responsibility should provide for maintenance of detailed records of the vaccinated population.

Whenever needed, the Veterinary Services should consider issuing official certificates of the vaccination status of animals or groups of animals.

7. Additional animal health-related activities

In addition to vaccination against a specific pathogenic agent, vaccination programmes may include other animal health-related activities such as vaccination against other pathogenic agents, treatments, biosecurity, surveillance, animal identification and communication.

Including additional animal health-related activities may enhance the acceptability of the vaccination programme. These activities should not negatively affect the primary objective of the vaccination programme.

Simultaneous vaccination against multiple pathogenic agents may be conducted, provided that compatibility has been demonstrated and the efficacy of the immune response against each of the pathogenic agents is not compromised.

Annex 10 (contd)

Article 4.X.9.

Evaluation and monitoring of a vaccination programme

The A vaccination programme should provide for outcome-based evaluation and monitoring to assess the its achievements of the vaccination programme. Evaluation and monitoring should be carried out periodically during the campaign to enable the timely application of corrective measures and to enhance the sustainability of the vaccination programme.

Based on the objectives and targets of the vaccination programme, the following outcomes should be assessed:

- 1) vaccination coverage stratified by species, age, geographical location and type of production system;
- 2) population immunity measured by testing, stratified by species, geographical location and type of production system;
- 3) frequency and severity of adverse reactions side effects;
- 4) reduction of incidence or prevalence or impact of the disease.

If the objectives and targets of the vaccination programme are not achieved, the reasons for this should be identified and addressed.

Article 4.X.10.

Exit strategy of a vaccination programme

The vaccination programme may provide for an exit strategy to cease vaccination. The cessation of vaccination may apply to the entire target population or to a subset of it, as defined by the risk of exposure and as determined by the Veterinary Authority.

Criteria to cease vaccination may include:

- 1) eradication of the disease in a country or zone has been achieved;
- 2) risk analysis demonstrates sufficient reduction of likelihood of introduction of the pathogenic agent or emergence of the disease;
- 3) reduction of the incidence or prevalence or impact of the disease to a level where alternative measures such as a stamping-out policy may be sufficient more appropriate to achieve disease control;
- 4) inability of the programme to meet the desired objectives;
- 5) adverse public reaction to the vaccination programme;
- 6) a revised cost-benefit analysis leads to decision to cease the vaccination programme.

When the achievement of disease free status requires the cessation of vaccination, the Veterinary Authority should prohibit vaccination and take appropriate measures to control remaining vaccine stocks as well as vaccine importation.

The cessation of vaccination may require the revision of the contingency plan and enhanced biosecurity, sanitary measures and surveillance for early detection of disease.

Annex 10 (contd)

Article 4.X.11.

Impact on disease status and management of vaccinated animals

Vaccination has proved its capacity to help prevent, control and eradicate several diseases in addition to or as alternative to stamping-out policy. However, depending on the disease and type of vaccine used, vaccination may mask underlying infections, affect disease surveillance and have implications for the movement of vaccinated animals and their products.

When appropriate, vaccination programmes should include provisions for the management of vaccinated animals such as 'vaccination to live' or 'suppressive vaccination' policies. Listed Disease-specific chapters of the Terrestrial Code provide additional recommendations on the management and trade of vaccinated animals and their products.

Disease fFree countries or zones applying systematic or emergency vaccination in response to an change in the increased risk of occurrence introduction of a disease should inform trading partners and the OIE of their vaccination programme, as appropriate. Unless otherwise specified in the relevant listed disease-specific chapter, in the absence of cases and unless otherwise specified in the relevant listed disease-specific chapters, vaccination of animals does not affect the disease status of the country or zone, and should not disrupt trade.

CHAPTER 6.1.

THE ROLE OF THE VETERINARY SERVICES IN FOOD SAFETY SYSTEMS

Article 6.1.1.

Introduction

Veterinarians are trained in both animal health (including foodborne zoonoses) and food safety hygiene, which makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of food of animal origin.

Close cooperation and effective communication between all participants in a food safety system, including veterinarians, other relevant professionals and stakeholders, is critical for the effective operation of the system. Food safety systems are now considerably different from those of earlier years and this provides a wider role for the Veterinary Services. The characteristics of these systems are global, Indeed, the global, regional, national and local implications of food safety systems, in reach, especially in relation to the globalisation of the food supply, which requires a greater demands a high level of engagement and collaboration between Competent Authorities responsible for animal health, food safety and public health, in line with the One Health approach. This provides a wider role and greater responsibilities for Veterinary Services. There is a particular emphasis on risk-based food safety systems where implementation is a responsibility shared with a wide range of actors along with assurance of non food safety requirements that are of high importance to consumers.

Food safety activities performed by Veterinary Services should be integrated to the greatest extent possible with the activities of all other responsible agencies throughout the food chain.

The education and training of veterinarians, which includes both animal health (including zoonoses) and food safety components, makes them uniquely equipped to play a central role in ensuring food safety, especially the safety of foods of animal origin. In addition to veterinarians, other professionals are involved in ensuring an integrated food safety system throughout the food chain.

Article 6.1.2.

Purpose and scope

The purpose of this chapter is to provide guidance to Member Countries on the role and responsibilities of the Veterinary Services in food safety systems.

This chapter should be read in conjunction with Chapters 4.1., Chapter 4.2., and relevant chapters of Sections 6 and 7.

The OIE and Codex Alimentarius Commission, through the development and implementation of standards and guidelines, contribute to improving food safety and human health by reducing risks that may arise at the farm and any subsequent stages in the food production continuum.

Therefore, thisThis chapter should also be read in conjunction with the Codex Alimentarius Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013), General Principles of Food Hygiene (CAC/RCP 1-1969), Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009), and other relevant Codex texts on hygienic practices, food import and export certification systems and antimicrobial resistance.

Annex 11 (contd)

Article 6.1.3.

Characteristics of a food safety system**1. Farm to plate approach/Food chain approach**

Food safety is best assured by an integrated, multidisciplinary approach, considering that considers the whole entire food chain. Everyone in the food chain, such as food business operators, the Veterinary Services and consumers, has a responsibility to ensure that food is safe. A modern food safety system should take into account the complexity of food production and the increased globalisation of the food supply, and should be risk-based. The application of traceability systems and sharing of food chain information will enhance the effectiveness of a food safety system. The food safety system It should include consideration of consider hazards and potential risks associated risks at with each component stage of the food chain, namely i.e. primary production, transport, processing, storage and distribution, and integrate risk management responses to such risks at the most appropriate points along these throughout the food chain continuum.

The prevention, detection, and control of foodborne hazards throughout the food chain is generally more effective in reducing or eliminating the risk of unwanted health effects than relying on controls of the final product. The application of traceability systems and sharing food chain information enhance the effectiveness of a food safety system. Everyone involved in the food chain, including food business operators, Veterinary Services and consumers, has a responsibility to ensure that food is safe.

2. Risk-based food safety systems

Risk-based food safety systems include measures based on good practices (such as good agricultural practice Good Agricultural Practice, good hygienic practice Good Hygienic Practice), hazard analysis and critical control points (HACCP) principles and risk analysis assessment. The design and application of a risk-based food safety system depends this risk-based approach depend on the availability of adequate scientific information and effective utilisation of the technical resources of food business operators and Competent Authorities, and technical resources of the Competent Authority. Monitoring and review are essential to evaluate the performance of a risk-based food safety system.

Monitoring food safety outcomes and reviewing control measures are essential to ensure the effective performance of a risk-based food safety system. For example, providing information on the occurrence of infections on the farm prior to dispatch of animals for slaughter may allow more targeted, risk-based inspection at the slaughterhouse/abattoir.

For international trade, a risk-based approach to food safety systems contributes to the determination of equivalence between trading partners.

3. Primary responsibilities of food business operators for food safety

Food business operators, including feed producers, farmers, processors, wholesalers, distributors, importers, exporters and retailers, have primary responsibility for ensuring the safety of their products and should be able to demonstrate that they comply with relevant food safety regulatory requirements. The feed Food business operators have a responsibility to inform the Competent Authority in their country of any non-compliance associated with their product and take action to manage the risk e.g. the withdrawal of the product.

4. Responsibilities of the relevant Competent Authority

Each Member Country should establish its objectives for animal health and public health protection, through consultation with stakeholders (especially livestock producers, processors and consumers) in accordance with the social, economic, cultural, religious and political contexts of the country. Based on these objectives and the analysis of scientific information, the Competent Authorities Authority has are responsible for developing the responsibility to develop national legislation and policies, legislation and regulations relevant to food safety. The Competent Authority They should also take steps to raise awareness of these both communicate these within the their country and to with trading partners.

Annex 11 (contd)

Competent Authorities should collaborate with other responsible agencies to ensure that roles and responsibilities for food safety systems, including responses to foodborne disease outbreaks, are addressed in a coordinated manner.

The Competent Authority should ensure The relevant Competent Authorities should verify that the control systems used by food business operators are appropriate, validated and effective, and operated in such a way that the regulatory requirements standards are met. This should be verified can be achieved through activities such as inspection and audit. In the event of noncompliance, appropriate corrective actions and sanctions should be applied.

When If the Competent Authority delegates some control responsibilities to a third party, it should assess and regularly reassess that third party's competency.

5. Animal and public health roles of the Veterinary Services

At the national level the activities of the Competent Authority serve both public and animal health objectives. In the case of food safety, this duality of roles provides an opportunity for the Veterinary Services to perform complementary activities throughout the food chain in coordination with other relevant agencies. It is important that this duality of functions is recognised, and relevant public health and animal health activities are integrated.

Article 6.1.4.

The role Roles and responsibilities of the Veterinary Services in a food safety system

1. Roles and responsibilities Responsibilities of the Veterinary Services

The Veterinary Authorities Authority or other Competent Authorities Authority should provide an appropriate institutional environment to allow the Veterinary Services to implement the necessary policies and standards, and ensure adequate resources for them to carry out their tasks in a sustainable manner. Within the Veterinary Services there should be have a clear chain of command and well-documented assignment of respective roles and responsibilities should be clearly defined and well documented. and chain of command. In developing policies and national standards for food safety, the Veterinary Authority or other Competent Authority should collaborate with other responsible agencies to ensure that food safety risks are addressed in a coordinated manner.

In order for Veterinary Services to make the best possible contribution to food safety, it is important that the education and training of veterinarians and veterinary para-professionals meet appropriate levels of competence and that there are national programmes for ongoing professional development.

The Veterinary Services should be responsible for, or involved in, be fully involved, in accordance with their mandate and organisational structure at the national level, in the design and implementation of national control programmes of a risk-based food safety system appropriate to their mandate and organisational structure at the national level. Implementation includes verification, audit, assurance and certification. In the implementation of food safety systems for foods of animal origin, the Veterinary Services should retain responsibility for verification and audit and facilitate a flexible approach to operational activities.

Where food safety activities are delegated outside of the Veterinary Services, the Veterinary Services should retain overall responsibility for the delivery and performance of any activities delegated to third party providers competency standards and performance of the delegated activities.

In addition to veterinarians, several other professional groups are involved in ensuring food safety throughout the food chain, including analysts, epidemiologists, food technologists, human and environmental health professionals, microbiologists and toxicologists. Irrespective of the roles assigned to the different professional groups and stakeholders by the administrative system in the country, close cooperation and effective communication between all involved is imperative to achieve the best results from the combined resources.

Annex 11 (contd)

~~In view of the competencies within the Veterinary Services, they Where relevant, the Veterinary Services should contribute to have an active role in other food safety related activities, such as investigations of foodborne disease outbreaks, food defence defense, disaster management, and identifying emerging risks. In addition, Veterinary Services should contribute to have an active role in the development and management of coordinated surveillance and control programmes for foodborne pathogens of public health importance.~~

In order for Veterinary Services to make the best possible contribution to ensuring food safety, the education and training of veterinarians and veterinary paraprofessionals should include appropriate training in food safety systems and ongoing professional development.

2. Activities of Veterinary Services throughout the food chain

The Veterinary Services have a significant role to play throughout the food safety system. Depending on the role and responsibilities of the Competent Authority, the responsibilities of the Veterinary Services may be limited to the first part of the food chain, ~~(from farm to slaughterhouse/abattoir and associated premises for further processing)~~ while in other cases the Veterinary Services may be responsible for the whole food chain.

a) Primary production

Through their presence on farms and appropriate collaboration with farmers, Veterinary Services play a key role in ensuring that animals are healthy and kept under good sanitary and hygienic conditions, and as well as in biosecurity and in the early detection, surveillance and treatment of animal diseases, including conditions of public health significance. The Veterinary Services advise on animal husbandry practices, biosecurity and interventions that limit the transmission of animal diseases, including foodborne zoonoses.

Because of the importance of traceability throughout the food chain, the verification by the Veterinary Services of animal identification is an important function.

~~In regard to food safety, The Veterinary Services assist provide guidance direction to farmers on practices that how to prevent or minimise physical and chemical hazards (e.g. for example, mycotoxins, environmental contaminants drug and pesticide residues, mycotoxins and environmental contaminants) in primary production, including through animal feed.~~

Producers' organisations, particularly those with veterinary advisers, are in a good position to provide awareness and training as they are regularly in contact with farmers and are well placed to understand their priorities. Technical support from the Veterinary Services is important and both private veterinarians and employees of the Veterinary Authority can assist. The Veterinary Services play a central role in ensuring the responsible and prudent use of biological products and veterinary medicinal products drugs, including antimicrobial agents in accordance with Chapter 6.9, in animal husbandry. This helps to minimise the risk likelihood of noncompliant levels of veterinary drug residues developing antimicrobial resistance and unsafe levels of veterinary drug residues in foods of animal origin and the development of antimicrobial resistance.

Veterinary Services also play an important role in ensuring traceability throughout the food chain by verifying animal identification in accordance with Chapters 4.1. and 4.2.

b) Processing-Slaughter, processing and distribution

Activities at the slaughterhouse/abattoir should be designed and implemented according to an integrated, risk-based approach in accordance with Chapter 6.2. The Veterinary Services have an essential role in ensuring that these activities, including meat inspection, minimise processing (including meat inspection) and distribution minimises foodborne risks to public health. This may be provided by supervision and verification of process control and direct involvement in operational activities such as ante-mortem and post-mortem inspection. Slaughterhouse/abattoir inspection of live animals (ante-mortem) and their carcasses (post-mortem) plays a key role both in both the surveillance network for animal diseases and zoonoses, and in ensuring the safety and suitability of meat and by-products for their intended uses. Control or reduction of biological hazards of public health and animal health importance by ante- and post-mortem meat inspection is a core responsibility of the Veterinary Services. and they should have primary responsibility for the development and effective implementation of relevant inspection programmes. Chapter 6.2. provides recommendations for the control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection.

Annex 11 (contd)

~~The Veterinary Services may be responsible for overseeing the control measures during processing and distribution of food of animal origin. They also play an important role in raising the awareness of food producers, processors and distributors regarding other stakeholders of the measures required to assure food safety.~~

~~Veterinarians provide essential inputs in terms of scientific information, risk assessment, validation of control measures, and monitoring and review of public health outcomes, in the design and implementation of a risk-based food safety system.~~

~~Veterinarians have an important role in ensuring food safety in various parts of the food chain, for example through the application of HACCP based controls and other quality assurance systems during food processing and distribution.~~

- c) Assurance schemes and certification of food of animal origin animal products for international trade

~~The Veterinary Services have an important role in providing public health assurance for products of animal origin. When assurance is required for animal products *international trade* assurance may take the form of certification of consignments. In which case, the Veterinary Services ensure that *international veterinary certificates* comply with animal health and food safety standards. Certification of animal products in relation to animal diseases, including foodborne zoonoses, and meat hygiene should be the responsibility of the Veterinary Services. Certification may be provided by other professionals in connection with food processing and hygiene (e.g. pasteurisation of milk products).~~

~~Veterinary Services have an important role in overseeing assurance schemes and an essential role in certifying that food of animal origin complies with animal health and food safety standards.~~

~~Other Competent Authorities may also be involved in providing assurances and certification of food of animal origin (for example, pasteurisation of milk products) for international trade.~~

3. Foodborne disease outbreaks

~~Most reported outbreaks of foodborne disease in humans are due to contamination of foods with zoonotic agents during primary production or processing. The Veterinary Services play a key role in the investigation of, and response to, such foodborne disease outbreaks which may be attributable to or involve animal products, throughout the food chain and in formulating and including the implementation of implementing control measures as appropriate once the source of the outbreak has been identified. This work should be carried out in close collaboration with human and environmental public health professionals, analysts, epidemiologists, food producers, processors and traders and any others involved.~~

~~The Veterinary Services can play a leading role in development and application of new epidemiological and diagnostic tools to better attribute outbreaks of foodborne diseases to specific animal reservoirs.~~

~~In the view Because of the global nature of the food trade, the Veterinary Services should work with other national agencies in reporting to international emergency foodborne disease networks, such as the International Network of Food Safety Authorities (INFOSAN), and in utilising such information for preparedness.~~

4. Animal and public health roles of the Veterinary Services

~~This complementary role of the Veterinary Services is clearly illustrated in relation to inspection and monitoring at the slaughterhouse, for both animal health and public health hazards.~~

~~The Veterinary Services contribute to the development and management of coordinated surveillance and control programmes related to foodborne pathogens of public health importance, such as *Salmonella* and *Trichinella*.~~

CHAPTER 6.7.

HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

Article 6.7.1.

Objective

This chapter provides criteria for the:

- 1) development of national antimicrobial resistance surveillance and monitoring programmes, and the
- 2) harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes,
in food-producing animals and in products of animal origin intended for human consumption.

Article 6.7.2.

Purpose of surveillance and monitoring

Active (~~targeted~~) surveillance and monitoring are core parts of national antimicrobial resistance surveillance programmes. Passive surveillance and monitoring may offer additional information (refer to Chapter 1.4.). The OIE encourages cooperation between among all Member Countries conducting antimicrobial resistance surveillance and monitoring should be encouraged.

Surveillance and monitoring of antimicrobial resistance is necessary to:

- 1) assess and determine the trends and sources of antimicrobial resistance in bacteria;
- 2) detect the emergence of new antimicrobial resistance mechanisms;
- 3) provide the data necessary for conducting *risk analyses* as relevant to animal and human health;
- 4) provide a basis for policy recommendations for animal and human health;
- 5) provide information for evaluating antimicrobial prescribing practices and, for prudent use recommendations;
- 6) assess and determine effects of actions to combat antimicrobial resistance.

Article 6.7.3.

General aspects The development of antimicrobial resistance surveillance and monitoring programmes

1. General aspects

Surveillance of antimicrobial resistance and at targeted intervals or ongoing monitoring of the prevalence of, and trends in, resistance in bacteria from *animals*, food, environment and humans, constitutes a critical part of animal health and food safety strategies aimed at limiting the spread of antimicrobial resistance and optimising the choice of *antimicrobial agents* used in therapy. Animal Feed and the environment should also be considered according to national priorities.

Surveillance or monitoring of bacteria from products of animal origin intended for human consumption collected at different steps of the food chain, including processing, packing and retailing, should also be considered.

Annex 12 (contd)

National antimicrobial resistance monitoring and surveillance programmes should be scientifically based and may include the following components:

- 1a) statistically based surveys;
- 2b) sampling and testing of food-producing animals on the farm, at live animal markets or at *slaughter*;
- 3e) ~~an~~ organised sentinel programme, for example targeted sampling of food-producing animals, *herds, flocks, and vectors* (e.g. birds, rodents);
- 4d) analysis of veterinary practice and diagnostic *laboratory* records;
- 5e) sampling and testing of products of animal origin intended for human consumption;
- 6) sampling and testing of feed ingredients or feed.

Article 6.7.4.Sampling12. Sampling strategies

- a) Sampling should be conducted on a statistical basis. The sampling strategy should ensure:
 - the sample is representative of the population of interest and meets the objectives of the surveillance;
 - the robustness of the sampling method.
- b) The following criteria are to be considered:
 - sample source such as food-producing animal, food, animal feed;
 - animal species;
 - category of *animal* within species such as age group, production type;
 - health status of the *animals* such as healthy, diseased;
 - sample selection method such as targeted, systematic random, non-random;
 - type of sample (e.g. such as faecal, faeces, caeca, carcass, food product);
 - sample size.

23. Sample size

The sample size should be large enough to allow detection or determine prevalence of, or trends in, existing and emerging antimicrobial resistance phenotypes.

The sample should avoid bias and be representative of the animal population, process, product or other unit of interest whilst taking into account the expected prevalence of the bacteria in the sample type, the expected prevalence of the resistance phenotype and the desired level of precision and confidence.

The sample size calculation in Table 1 is should be based on independent samples. However, if there is any clustering at the establishment or animal level, the sample size should be adjusted accordingly. At low levels of expected prevalence, exact methods of sample size calculation should be preferred to approximate methods. Samples from which bacteria were not isolated cannot be used in the calculation of prevalence of the resistance phenotype.

Annex 12 (contd)

~~Sample size estimates for prevalence of antimicrobial resistance in a large population are provided in Table 1 below.~~

Table 1. Sample size estimates for prevalence in a large population

| Expected prevalence | 90% Level of confidence | | | 95% Level of confidence | | |
|---------------------|-------------------------|-----|-------|-------------------------|-----|-------|
| | Desired precision | | | Desired precision | | |
| | 10% | 5% | 1% | 10% | 5% | 1% |
| 10% | 24 | 97 | 2,429 | 35 | 138 | 3,445 |
| 20% | 43 | 173 | 4,310 | 64 | 246 | 6,109 |
| 30% | 57 | 227 | 5,650 | 81 | 323 | 8,003 |
| 40% | 65 | 260 | 6,451 | 92 | 369 | 9,135 |
| 50% | 68 | 270 | 6,718 | 96 | 384 | 9,512 |
| 60% | 65 | 260 | 6,451 | 92 | 369 | 9,135 |
| 70% | 57 | 227 | 5,650 | 81 | 323 | 8,003 |
| 80% | 43 | 173 | 4,310 | 61 | 246 | 6,109 |
| 90% | 24 | 97 | 2,429 | 35 | 138 | 3,445 |

34. Sample sources (Table 2)

Member Countries should examine their livestock production systems on the basis of available information and assess which sources are likely to contribute most to a potential risk to animal and human health.

a) Animal feed

~~Member Countries should consider including animal feed in surveillance and monitoring programmes as they may become contaminated with antimicrobial resistant bacteria, e.g. *Salmonella*.~~

ab) Food-producing animals

Categories of food-producing animals considered for sampling should be relevant to the country's production system. Resource allocation should be guided by criteria such as production volume of the food-producing animal species and the prevalence of resistant bacteria.

bc) Food

Member Countries should consider including products of animal origin intended for human consumption produced locally or imported, in surveillance and monitoring programmes, as foodborne transmission is considered to be an important route for the transfer of antimicrobial resistance.

c) Animal feed

Member Countries should consider including animal feed in surveillance and monitoring programmes as they may become contaminated with antimicrobial resistant bacteria, e.g. *Salmonella*.

d) Environment

Member Countries should consider including the environment (the animal-immediate environment or the wider environment) in surveillance and monitoring programmes as the environment of animals can be an important route for transfer or persistence of antimicrobial resistance.

Annex 12 (contd)45. Type of sample to be collected (Table 2)

Faecal samples should be collected in amounts sufficient for isolation of the resistant bacteria of concern (at least 5 g from bovine and porcine and whole caeca from poultry).

Feed samples representative of the batch should be collected in amounts sufficient for isolation of resistant bacteria of concern (at least 25 g) and should be linked to any pathogen surveillance programmes that may be in place.

Faecal samples should be collected in amounts sufficient for isolation of the resistant bacteria of concern (at least 5 g from bovine and porcine and whole caeca from poultry).

~~Sampling of carcasses at the slaughterhouse/abattoir provides information on slaughter practices, slaughter hygiene and the level of microbiological contamination and cross-contamination of meat. Further sampling of the product at retail sales level may provide additional information on the overall microbiological contamination from slaughter to the consumer.~~

Existing food processing microbiological monitoring, risk-based management and other food safety programmes may provide useful samples for surveillance and monitoring of resistance in the food chain after slaughter.

~~Table 2 provides examples of sampling sources, sample types and monitoring outcomes.~~

Table 2. Examples of sampling sources, sample types and monitoring output

| Source | Type | Output | Additional information required or additional stratification |
|-------------------------|---------------------|---|---|
| Herd or flock of origin | Faeces or bulk milk | Prevalence of resistant bacteria originating from animal populations (of different production types) Relationship between resistance and antimicrobial use | Age categories, production types, etc. Antimicrobial use over time |
| Abattoir | Faeces | Prevalence of resistant bacteria originating from animals at slaughter | |
| | Caeca or intestines | As above | |
| | Carcass | <u>Prevalence of resistant bacteria after carcass dressing, representative of the Hygiene, of the process and the</u> contamination during slaughter | |
| Processing, packing | Food products | <u>Prevalence of resistant bacteria after processing, representative of the Hygiene, of the process and the</u> contamination during processing and handling | |
| Point of sale (Retail) | Food products | Prevalence of resistant bacteria originating from food, exposure data for consumers | |
| Various origins | Animal feed | Prevalence of resistant bacteria originating from animal feed, exposure data for animals | |
| Various origins | Environment | <u>Occurrence of resistant bacteria originating from the animal immediate or the wider environment</u> | |

Annex 12 (contd)Article 6.7.5.**Bacteria subjected to surveillance and monitoring****6. Bacterial isolates**

The following categories of bacteria could may be included in surveillance and monitoring programmes monitored:

1a) Animal bacterial pathogens relevant to the countries' priorities

a) Surveillance and monitoring of antimicrobial resistance in animal bacterial pathogens is important, both to:

i) detect emerging resistance that may pose a concern for animal and human health;

ii) detect changes in susceptibility patterns;

iii) provide information for risk analysis;

iv) provide data guide for veterinarians in to inform their prescribing treatment decisions; and

provide information for epidemiological studies and trend analysis.

b) Information on the occurrence of antimicrobial resistance in animal bacterial pathogens is in general either derived from routine clinical material sent to veterinary diagnostic laboratories or from an active monitoring programme. These samples, often derived from severe or recurrent clinical cases including therapy failure, may provide biased information. Although antimicrobial resistance information provided by diagnostic laboratories is primarily for treatment purposes, it is also useful for identification of novel resistance patterns and can possibly assist in identifying emerging resistance. However, in order to estimate accurately the prevalence of antimicrobial resistance in the bacterial pathogen, in a larger population of animals, an active sampling programme should be implemented.

c) To promote a harmonised global approach to the selection of animal bacterial pathogens for inclusion in national surveillance and monitoring programmes, bacteria should be selected using one or more of the following criteria:

= impact on animal health and welfare;

= implication of antimicrobial resistance in the bacterial pathogen on therapeutic options in veterinary practice;

= impact on food security and on production (economic importance of associated diseases);

= bacterial diseases responsible for the majority of veterinary antimicrobial usage (stratified by usage of different classes or their importance);

= existence of validated susceptibility testing methodologies for the bacterial pathogen;

= existence of quality assurance programmes or other pathogen reduction options that are non-antimicrobial, such as vaccines and Good Agricultural Practices.

The table below, derived using the above criteria, lists suggested animal bacterial pathogens for inclusion in a surveillance or monitoring programme of food-producing animals. This list is not exhaustive and should be adapted according to the situation in the country.

Annex 12 (contd)**Table 3. Examples of target animal species and animal bacterial pathogens that may be included in resistance surveillance and monitoring programmes**

| <u>Target animals</u> | <u>Respiratory pathogens</u> | <u>Enteric pathogens</u> | <u>Udder pathogens</u> | <u>Other pathogens</u> |
|-----------------------|--|--------------------------|------------------------------|---------------------------|
| Cattle | <u>Pasteurella multocida</u> | <u>Escherichia coli</u> | <u>Staphylococcus aureus</u> | |
| | <u>Mannheimia haemolytica</u> | <u>Salmonella spp.</u> | <u>Streptococcus spp.</u> | |
| Pigs | <u>Actinobacillus pleuropneumoniae</u> | <u>Escherichia coli</u> | | <u>Streptococcus suis</u> |
| | | <u>Salmonella spp.</u> | | |
| Poultry | | <u>Salmonella spp.</u> | | <u>Escherichia coli</u> |

2b) Zoonotic bacteria

a) *Salmonella*

Salmonella should be sampled from animal feed, food-producing animals, and animal-derived food products and if relevant, animal feed. For the purposes of consistency and harmonisation, animal samples should be preferably be taken from healthy animals at the slaughterhouse/abattoir from healthy animals and feed samples should preferably be taken at the feed mill.

Surveillance and monitoring programmes may also include sampling of the environment at places where animals are kept or handled or bacterial isolates originating from other sources obtained from designated national laboratories originating from other sources.

Isolation and identification of bacteria and bacterial strains should follow nationally or internationally standardised procedures.

Serovars of public health importance such as *S. Typhimurium* and *S. Enteritidis* should be included in surveillance and monitoring programmes. The inclusion of other relevant serovars will depend on the epidemiological situation in each country.

All *Salmonella* isolates should be characterised by serotyped and, where appropriate, phage-typed according to standard by genotype genotypic methods used at the nationally designated laboratories. For those countries that have the capabilities, *Salmonella* could be genotyped using genetic fingerprinting methods.

bii) *Campylobacter*

Campylobacter jejuni and *C. coli* should be isolated from food-producing animals and/or associated food products (primarily from poultry). Isolation and identification of these bacteria should follow nationally or internationally standardised procedures. *Campylobacter* isolates should be identified to the species level.

ciii) Other bacteria that are pathogenic for humans emerging bacterial pathogens

Other emerging bacterial that are pathogens pathogenic for humans such as methicillin-resistant *Staphylococcus aureus* (MRSA), and Listeria monocytogenes or others which are pathogenic to humans, may be included in resistance surveillance and monitoring programmes.

Annex 12 (contd)3e) Commensal bacteria

E. coli and *enterococci* (*Enterococcus faecium* and *E. faecalis*) may be sampled from animal feed, food-producing animals, their environment and products of animal origin intended for human consumption.

These bacteria are commonly used in surveillance and monitoring programmes as indicators, providing information on the potential reservoir of antimicrobial resistance genes, which may be transferred to pathogenic bacteria. It is considered that For the purposes of consistency and harmonisation, these bacteria should preferably be isolated from healthy animals, preferably at the slaughterhouse/abattoir, for the purpose of consistency and harmonisation and be monitored for antimicrobial resistance.

Article 6.7.6.**7. Storage of bacterial strains**

If possible, isolates should be preserved at least until reporting is completed. Preferably, appropriate isolates should be permanently stored. Bacterial strain collections, established by storage of all isolates from certain years, will provide the possibility of conducting retrospective studies.

Article 6.7.7.**8. Antimicrobial susceptibility testing**

Clinically important antimicrobial agents or classes used in human and veterinary medicine should be included in antimicrobial resistance surveillance programmes. Member Countries should refer to the OIE list of antimicrobials of veterinary importance for surveillance and monitoring purposes. However, recognising that the number of tested antimicrobial agents may have to be limited according to financial resources.

Appropriately validated antimicrobial susceptibility testing methods should be used in accordance with Guideline Chapter 3.1. of the Terrestrial Manual, concerning laboratory methodologies for bacterial antimicrobial susceptibility testing. Antimicrobial susceptibility data should be reported not only qualitatively (susceptible or resistant), but also quantitatively (minimum inhibitory concentrations [MICs] or inhibition zone diameters), rather than qualitatively.

Article 6.7.8.**9. Recording, storage and interpretation of data**

- 1a) Because of the volume and complexity of the information to be stored and the need to keep these data available for an undetermined period of time, careful consideration should be given to database design.
- 2b) The storage of raw (primary, non-interpreted) data is essential to allow the evaluation in response to various kinds of questions, including those arising in the future.
- 3e) Consideration should be given to the technical requirements of computer systems when an exchange of data between different systems (comparability or compatibility of automatic recording of laboratory data and transfer of these data between and within resistance surveillance and monitoring programmes) is envisaged. Results should be collected in a suitable national database. They should be and recorded quantitatively:
 - a*i*) as distributions of MICs in micrograms per millilitre;
 - b*ii*) or inhibition zone diameters in millimetres.

Annex 12 (contd)

- 4d) The information to be recorded should include, where possible, the following aspects:
- a*i*) sampling programme;
 - b*ii*) sampling date;
 - c*iii*) animal species and production type;
 - d*iv*) type of sample;
 - e*v*) purpose of sampling;
 - f*vi*) type of antimicrobial susceptibility testing method used;
 - g*vii*) geographical origin (geographical information system data where available) of *herd, flock or animal*;
 - h*viii*) *animal factors* (e.g. such as age, condition, health status, identification, sex);
 - i) exposure of animals to antimicrobial agents;
 - j) bacterial isolation rate.
- 5e) The reporting of *laboratory* data should include the following information:
- a*i*) identity of *laboratory*,
 - b*ii*) isolation date,
 - c*iii*) reporting date,
 - d*iv*) bacterial species,
- and, where relevant, other typing characteristics, such as:
- e*v*) serotype or serovar,
 - f*vi*) phage type,
 - g*vii*) antimicrobial susceptibility result or resistance phenotype,
 - h*viii*) genotype.
- 6f) ~~The proportion of isolates regarded as resistant should be reported. The number of isolates regarded as resistant should be reported as a proportion of the number of isolates tested.~~ including the defined interpretive criteria used.
- 7g) In the clinical setting, breakpoints are used to categorise bacterial strains as susceptible, intermediate or resistant. These clinical breakpoints may be elaborated on a national basis and may vary between Member Countries.
- 8h) The bacterial isolation methods, antimicrobial susceptibility testing methods, standards and guidelines used should be recorded.
- 9i) For surveillance and monitoring purposes, use of the microbiological breakpoint (also referred to as epidemiological cut-off point), which is based on the distribution of MICs or inhibition zone diameters of the specific bacterial species tested, is preferred. When using microbiological breakpoints, only the bacterial population with acquired resistance that clearly deviates from the distribution of the normal susceptible population will be designated as resistant. Clinical breakpoints, when available, should also be reported.

Annex 12 (contd)

- 10j) Ideally, data should be collected at the individual isolate level. This will allow allowing antimicrobial resistance patterns to be recorded over time to be recorded along with, when available, relevant data on usage of antimicrobial agents and management practices.

Article 6.7.9.**10. Reference laboratory and annual reports**

- 1a) Member Countries should designate a national reference centre that assumes the responsibility to:
- a*i*) coordinate the activities related to the antimicrobial resistance surveillance and monitoring programmes;
 - b*ii*) coordinate and collect information from participating surveillance laboratories within the country;
 - c*iii*) produce an annual report on the antimicrobial resistance situation in the country.
- 2b) The national reference centre should have access to the:
- a*i*) raw data;
 - b*ii*) complete results of quality assurance and inter-laboratory calibration activities;
 - c*iii*) inter-laboratory proficiency testing results;
 - d*iv*) information on the structure of the surveillance or monitoring system;
 - e*v*) information on the chosen laboratory methods.
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CHAPTER 6.8.

MONITORING OF THE QUANTITIES AND USAGE PATTERNS OF ANTIMICROBIAL AGENTS USED IN FOOD-PRODUCING ANIMALS

Article 6.8.1.

Definition and Purpose

~~For the purpose of this chapter, therapeutic use of antimicrobial agents means the administration of antimicrobial agents to animals for treating and controlling infectious diseases.~~

The purpose of these recommendations in this chapter is to describe an approach to the monitoring of the quantities of antimicrobial agents used in food-producing animals.

In order to evaluate antimicrobial exposure in food-producing animals, quantitative information should be collected to monitor usage patterns by animal species, antimicrobial agents or class of antimicrobial agents, route of administration and type of use, (therapeutic (to treat, control or prevent infectious disease) or nontherapeutic (including growth promotion) and route of administration).

Article 6.8.1.-bis.

Definitions

For the purposes of the Terrestrial Code:

Therapeutic use of antimicrobial agents means the administration of an antimicrobial agent to an individual or a group of animals to treat, control or prevent infection or infectious disease:

- = to treat means to administer an antimicrobial agent to an individual or a group of animals showing clinical signs of an infectious disease;
- = to control means to administer an antimicrobial agent to a group of animals containing sick animals and healthy animals (presumed to be infected), to minimise or resolve clinical signs and to prevent further spread of the disease;
- = to prevent means to administer, using an appropriate dose and for a limited, defined duration, an antimicrobial agent to an individual or a group of animals at risk of developing acquiring a specific infection or in a specific situation where infectious disease is likely to occur if the drug is not administered.

Nontherapeutic use of antimicrobial agents means the administration of antimicrobial agents to animals for any purpose other than to treat, control or prevent infection or infectious disease; it includes growth promotion.

Growth promotion means the administration of antimicrobial agents to animals in their feed or water only to increase the rate of weight gain or the efficiency of feed utilisation.

[...]

CHAPTER 6.13.

**PREVENTION AND CONTROL OF SALMONELLA
IN COMMERCIAL PIG PRODUCTION SYSTEMS**

[...]

Article 6.13.2.

Definitions

For the purposes of this chapter:

Commercial pig production systems: means those systems in which the purpose of the operation includes some or all of the following: breeding, rearing and management of pigs for the production and sale of commercially traded pigs or pig meat.

Article 6.13.3.

Purpose and scope

This chapter provides recommendations for the prevention and control of *Salmonella* in commercial pig production systems, including outdoor pig production systems, where practicable, in order to reduce the burden of *infection* in pigs and the *risk* of human illness through foodborne contamination as well as human *infections* resulting from direct or indirect contact with infected pigs.

This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Good Animal Feeding (CAC/RCP 54-2004), and the Guidelines for the Control of Nontyphoidal *Salmonella* spp. in Beef and Pork Meat (CAC/GL 87-2016), and the OIE/FAO Guide to Good Farming Practices for Animal Production Food Safety.

[...]

Article 6.13.16.

Outdoor pig production

For outdoor pigs in commercial production systems, in addition to Where practicable, the prevention and control measures described in Articles 6.13.5. to 6.13.15., should also be applied to outdoor pigs in commercial pig production systems to reduce *Salmonella* infection. In addition, it is recommended that:

- 1) field rotation programmes be used to minimise *Salmonella* contamination and accumulation in soil and surface water and therefore ingestion by pigs;
 - 2) systems used to provide feed, and where possible water, be designed to minimise attraction of, or access by, wildlife birds;
 - 3) the location of other outdoor pig *herds* and the concentration and behaviour of wildlife birds in the area be considered.
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CHAPTER 6.X.

INTRODUCTION TO RECOMMENDATIONS FOR VETERINARY PUBLIC HEALTH

Article 6.X.1.

Veterinary public health is a component of public health that focuses on the application of veterinary science and that includes all actions directly or indirectly linked with animals, their products and by-products, so long as they contribute to the protection and improvement of the physical, mental and social well-being of humans.

Veterinary science has a rich history of contributions to public health, especially with regard to the provision of safe and adequate food, the prevention, control and eradication of zoonoses, the improvement of animal welfare and contributing to biomedical research.

Veterinary Services play a key role in preventing, mitigating and controlling *risks* to public health at the origin or sources of infection. In particular, Veterinary Services contribute to public health in several areas such as food security, food safety (with respect to foodborne diseases as well as residues and pollutants), control of zoonoses and responses to natural disasters and bioterrorism.

Furthermore, a number of anthropogenic factors influence the occurrence of emerging diseases, some of which are zoonotic. These factors include among others, population growth and changing food consumption patterns eating habits and their consequences such as increasing food demand and intensification of production systems; increased movements and trade of *animals* and their products and derived products; the use and misuse of antimicrobial agents generating resistance; the disruption of ecosystems; and climate change, among others.

In this context, Veterinary Services are integrated into the "One Health" approach to the prevention and management of health risks contagious diseases and preservation of the integrity of ecosystems for the benefit of human health, the health of and domestic animals and wildlife, animal health, including domestic animals and wildlife, and biodiversity.

Veterinary training and education should take into account the role of Veterinary Services in public health at national, regional and global level in the development of these veterinary public health capabilities in the local, regional and global context.

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

Article 7.1.1.

Definition-General considerations

Animal welfare means the physical and psychological mental state of how an animal is coping with in relation to the conditions in which it lives and dies.

An animal is in a good state of enjoys experiences good welfare if (as indicated by scientific evidence) if the animal is healthy, comfortable, well nourished, safe, it is not suffering from unpleasant states such as pain, fear and distress, and it is able to express innate behaviours that are important for its physical and psychological mental state. and if it is not suffering from unpleasant states such as pain, fear, and distress.

Good animal welfare requires disease prevention and appropriate veterinary treatment care, shelter, management and nutrition, a stimulating and safe environment, humane handling and humane slaughter or killing. While animal welfare refers to the state of the animal, the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

CHAPTER 7.1.

**INTRODUCTION TO THE
RECOMMENDATIONS FOR ANIMAL WELFARE**

[...]

Article 7.1.3.-bis

Guiding principles for the use of measures to assess animal welfare

- 1) For the OIE animal welfare standards to be applicable globally, they should emphasise favourable outcomes for the animals, although, in some circumstances, it may be necessary to recommend specific conditions of the animals' environment and management. Outcomes are generally measured by assessing the extent to which animals experience enjoyment of the "five freedoms" described in Article 7.1.2.
- 2) For each principle listed in Article 7.1.4., the most relevant criteria (or measurables), ideally comprising animal-based measures, should be included in the standard. Any given animal-based measure may be linked to more than one principle.
- 3) Standards Recommendations should, whenever possible, define explicit targets or thresholds that should be met for animal-based measures. Such target values should be based on relevant science and experience of experts. To guide users, Competent Authorities and other relevant bodies should collect all relevant data that can be used to set relevant target values.
- 4) In addition to animal-based measures, resource-based measures and management-based measures may be used and should be defined on the basis of science and expert experience showing that a welfare outcome is clearly linked to a resource or to a management procedure.
- 5) Users of the standard should select the most appropriate animal-based measures for their farming system or conditions environment, from among those listed in the standard. Outcomes can be measured by an assessment of individuals or animal groups, or a representative sample of those, using data from establishments, transport or slaughterhouses/abattoirs.
- 6) Whatever the basis of the measure, if outcomes are unsatisfactory, users should consider what changes to resources or management are necessary to improve outcomes.

[...]

CHAPTER 7.X.

ANIMAL WELFARE AND PIG PRODUCTION SYSTEMS

Article 7.X.1.

Definitions

'Commercial pig production systems' means those systems in which the purpose of the operation includes some or all of the **following**: breeding, rearing and management of pigs (*Sus scrofa*) for the production **and sale** of **commercially traded pigs or pig meat**.

For the purposes of this chapter, 'management' is defined at the farm management level and at the *animal handler* level. At the level of farm management, human resources management practices, including selection and training of handlers, and animal management practices, such as best practice in housing and husbandry and implementation of welfare protocols and audits, all have an impact on *animal welfare*. At the *animal handler* level this requires a range of well-developed husbandry skills and knowledge of how to care for animals.

For the purposes of this chapter, 'environmental enrichment' means increasing the complexity (e.g. foraging opportunities, social housing) of the animal's environment to foster the expression of normal behaviour, provide cognitive stimulation and reduce the expression of abnormal behaviour. The aim of providing enrichment should be to improve the physical and **psychological mental** state of the animal (Newberry, 1995; Mellor, 2015 and 2016).

For the purposes of this chapter 'stereotypy' is a repetitive behaviour induced by frustration, repeated attempts to cope or central nervous system dysfunction. It is expressed as a sequence of abnormal behaviours which appear to have no obvious purpose or function. Permanent dysfunction of the central nervous system in response to stressful conditions may mean that developed stereotypies may not resolve despite later changes to the environment or other treatments **such as those relating to feeding levels or diet composition**. Some stereotypies commonly observed in pigs include sham chewing, stone chewing, tongue rolling, teeth grinding, bar biting and floor licking (NFACC, 2014; Tuyttens, 2007; Mason, 2008).

For the purposes of this chapter 'apathy' means that the animal ceases to respond to stimuli that would normally elicit a response (Wood-Gush and Vestergaard, 1989). Furthermore, apathetic behaviour has been described as an abnormal or maladaptive behaviour, indicated by reduced activity, lack of interest or concern (i.e. indifference) and lack of feeling or emotion (impassiveness) (Mills and Caplen, 2010).

For the purposes of this chapter 'agonistic behaviour' is a continuum of behaviours expressed in conflict situations, and includes offence, defence and submissive or escape components. The behaviours involved may include contact, such as biting and pushing, or non-contact, such as threats in the form of body postures and gestures. Aggressive behaviour (i.e. fighting) is a component of agonistic behaviour (Petherick and Blackshaw, 1987).

For the purposes of this chapter, 'play behaviour' is characterised by specific neuroendocrinological responses and the appearance of having fun (Spinka *et al.*, 2001; Reimert *et al.*, 2013). It is often prompted by novel or unpredictable stimuli, and is related to exploration. It functions to prepare animals for unexpected situations by increasing the versatility of movements and enhancing their ability to cope with unexpected stressful situations (Spinka *et al.*, 2001). Animals actively seek and create unexpected situations in play, deliberately relaxing their movements or putting themselves into disadvantageous positions.

Article 7.X.2.

Scope

This chapter addresses the welfare aspects of commercial domestic pig production systems. *Captive wild* pigs are not considered.

Annex 18 (contd)

Article 7.X.3.

Commercial pig production systems

Commercial pig production systems include:

1. Indoor systems

These are systems in which pigs are kept indoors, and are fully dependent on humans to provide for basic animal needs such as *feed* and water. The type of housing depends on the environment, climatic conditions and management system. The animals may be kept in groups or individually.

2. Outdoor systems

These are systems in which pigs live outdoors with shelter or shade, have some autonomy over access to shelter or shade, but may be fully dependent on humans to provide for basic animal needs such as *feed* and water. Pigs are typically confined kept in paddocks or pastures according to their production stage. The animals may be kept in groups or individually.

3. Combination systems

These are systems in which pigs are managed in any combination of indoor and outdoor production systems.

Article 7.X.4.

Criteria (or measurables) for the welfare of pigs

The following outcome-based criteria (or measurables), specifically animal-based criteria, can be useful indicators of *animal welfare*. The use of these indicators and their appropriate thresholds should be adapted to the different situations in which pigs are managed such as regional differences, herd health, pig breed or crossbreed, and climate. Consideration should also be given to the resources provided and the design of the systems. These criteria can be considered as tools to monitor the efficiency of design and management, given that both of these they can affect *animal welfare*.

1. Behaviour

Certain behaviours appear to be indicators of good animal welfare and health in pigs such as play and specific vocalisations (Boissy et al., 2007; Reimert et al., 2013).

Certain behaviours could indicate an *animal welfare* and health problem. These include sudden immobility, escape attempts, changes in *feed* and water intake, altered locomotory behaviour or posture, altered lying time, postures and patterns, altered respiratory rate and panting, coughing, shivering and huddling, high-pitched vocalisations and increased call rate, and increased agonistic (including aggression), stereotypic, apathetic or other abnormal behaviours (Weary and Fraser, 1975; Weary et al., 1997; Puppe et al., 2005; Düpjan et al., 2006; Reimert et al., 2013).

Certain behaviours are indicators of good animal welfare. These may include positive social and play behaviour.

Environments that induce stereotypies typically also reduce animal welfare. Although stereotypies are generally held to indicate poor welfare, there are some instances where there is a poor association between stereotypies and stress. For example, frustration-induced stress may be somewhat rectified if the behaviour itself reduces the underlying motivation. Within a group, individuals that perform stereotypies may thus be coping more successfully than those that do not. Nevertheless, stereotypies indicate either a present problem for the animal or a past problem that has resolved. As with other indicators, caution should be used when using stereotypies as a welfare measure in isolation from other indicators (NFACC, 2014; Tuyttens, 2007; Mason, 2006).

Annex 18 (contd)**2. Morbidity rates**

Rates of infectious and metabolic diseases, lameness, peripartum and post-procedural complications, injury and other forms of morbidity, above recognised thresholds, may be direct or indirect indicators of *animal welfare* at the *herd* level. Understanding the aetiology of the disease or syndrome is important for detecting potential *animal welfare* problems. Mastitis and metritis, leg and hoof problems, shoulder ulcers in sows, skin lesions, respiratory and digestive diseases, and reproductive diseases are also particularly important animal health problems for pigs. Scoring systems, such as for body condition ([Coffey et al., 1999](#)), lameness and injuries ([Hodgkiss et al., 1998; de Koning, 1984 and Herskin et al., 2011](#)), and information gathered at the slaughterhouse/abattoir, can provide additional information ([Van Staaveren et al., 2017 and Faucitano, 2001](#)).

Both clinical and *post mortem* pathologic examination should be utilised as indicators of disease, injuries and other problems that may compromise *animal welfare*.

3. Mortality and culling rates

Mortality and culling rates affect the length of productive life and, like morbidity rates, may be direct or indirect indicators of *animal welfare* at the *herd* level. Depending on the production system, estimates of mortality and culling rates can be obtained by analysing the causes of *death* and culling and their temporal and spatial patterns of occurrence. Mortality and culling rates, and their causes, when known, should be recorded regularly, e.g. daily, and used for monitoring e.g. monthly, annually.

Necropsy is useful in establishing the cause of *death*.

4. Changes in body weight and body condition

In growing animals, body weight changes outside the expected growth rate, especially excessive sudden weight loss, are indicators of poor *animal welfare* and health ([Coffey et al., 1999](#)).

Body condition outside an acceptable range or large variation amongst individual animals in the group may be an indicator of compromised *animal welfare* and health, and reproductive efficiency in mature animals.

5. Reproductive efficiency

Reproductive efficiency can be an indicator of *animal welfare* and health status. Poor reproductive efficiency, compared with the targets expected for a particular breed or [hybrid crossbreed](#), can indicate *animal welfare* problems (Hemsworth et al., 1981, 1986, 1989, 1994; Munsterjelm et al., 2006).

Examples may include:

- low conception rates,
- high abortion rates,
- metritis and mastitis,
- small litter size (total born),
- low numbers born alive,
- high numbers of stillborns or mummies.

6. Physical appearance

Physical appearance may be an indicator of *animal welfare* and health. Attributes of physical appearance that may indicate compromised *animal welfare* include:

- body condition outside an acceptable range ([Coffey et al., 1999](#)),
- presence of ectoparasites,
- abnormal texture or hair loss,
- excessive soiling with faeces,
- skin discolouration, [including sunburn](#),
- swellings, injuries or lesions ([Hodgkiss et al., 1998; de Koning, 1984 and Herskin et al., 2011](#)),
- discharges (e.g. from nose or eyes, [including tear staining](#)) ([Telkäranta et al., 2016](#)),
- feet and leg abnormalities ([Seddon et al., 2013](#)),
- abnormal posture (e.g. rounded back, head low),
- emaciation or dehydration.

Annex 18 (contd)**7. Handling response**

Improper handling or lack of human contact can result in fear and distress in pigs. Fear of humans may be an indicator of poor *animal welfare* ([Hemsworth and Coleman, 2011](#)). Indicators may include:

- evidence of poor human-animal relationship, such as marked avoidance of handlers and abnormal or excessive vocalisation when being moved or when *animal handlers* interact with pigs,
- animals slipping or falling during handling,
- injuries sustained during handling, such as bruising, lacerations and fractures ~~sd-legs~~,

8. Lameness

Pigs are susceptible to a variety of infectious and non-infectious musculoskeletal disorders. These disorders may cause lameness and gait abnormalities. Pigs that are lame or have gait abnormalities may have difficulty reaching *feed* and water and may experience pain and distress. Musculoskeletal problems have many causes, including genetic, nutrition, sanitation, floor quality, and other environmental and management factors. There are several gait scoring systems available ([Main et al., 2000; Grégoire et al., 2013; Seddon et al., 2013](#)).

9. Complications from common procedures

Some painful or potentially painful procedures such as surgical castration, tail docking, teeth clipping or grinding, tusk trimming, identification, nose ringing and hoof care are performed ~~in on~~ on pigs to facilitate management, meet market or environmental requirements and improve human safety or safeguard *animal welfare*.

However, if these procedures are not performed properly, *animal welfare* and health can be unnecessarily compromised.

Indicators of problems associated with these procedures could include:

- post-procedure *infection* and swelling,
- post-procedure lameness,
- behaviour indicating pain, fear, distress or suffering (Mellor and Patterson-Kane, 2009),
- increased morbidity, mortality and culling rates,
- reduced *feed* and water intake,
- post procedure body condition and weight loss.

Article 7.X.5.**Recommendations**

Ensuring good welfare of pigs is contingent on several management factors, including system design, environmental management, and animal management practices which include responsible husbandry and provision of appropriate care. Serious problems can arise in any system if one or more of these elements are lacking.

Articles 7.X.6. to 7.X.27. provide recommendations for measures applied to pigs.

Each recommendation in Article 7.X.6. to 7.X.24. includes a list of relevant animal-based criteria (or measurables) derived from Article 7.X.4.

This does not exclude other criteria ([or measurables](#)) being used where or when appropriate.

Annex 18 (contd)

Article 7.X.6.

Training of personnel

Pigs should be cared for by a sufficient number of personnel, who collectively possess the ability, knowledge and competence necessary to maintain the welfare and health of the animals.

All people responsible for pigs should be competent through formal training or practical experience in accordance with their responsibilities. This includes understanding of and skill in animal handling, nutrition, reproductive management techniques, behaviour, *biosecurity*, signs of disease, and indicators of poor *animal welfare* such as stress, pain and discomfort, and their alleviation.

Animal-based criteria (or measurables): handling response, physical appearance, behaviour, changes in body weight, body condition, reproductive efficiency, lameness and morbidity, mortality and culling rates and complications from common procedures.

Article 7.X.7.

Handling and inspection

Animal handlers with positive attitudes to handling and caring for pigs can lead to positive welfare outcomes. This may be shown by the length of time taken for the animals to approach a human, a short flight distance, or a willingness to interact with humans (Coleman and Hemsworth, 2014).

Pigs should be inspected at least once a day when fully dependent on humans to provide for basic needs such as feed and water and to identify welfare and health problems.

Some animals should be inspected more frequently, for example, farrowing sows, new born piglets, newly weaned pigs, newly-mixed gilts and sows, sick or injured pigs and those showing abnormal behaviours such as tail biting.

Pigs identified as sick or injured should be given appropriate treatment *at the first available opportunity as soon as possible* by competent *animal handlers*. If *animal handlers* are unable to provide appropriate treatment, the services of a *veterinarian* should be sought.

Recommendations on the handling of pigs are also found in Chapter 7.3. In particular handling aids that may cause pain and distress (e.g. electric goads) should be used only when other methods fail and provided that the animal can move freely and is able to move away from the handling aid. The use of electric goads should be avoided (see also point 3 of Article 7.3.8.), and should not be repeatedly used on the same animal, and not be used in sensitive areas including the udder, face, eyes, nose, ears or anogenital region. *Animal handlers should be alert for signs of stress in pigs and know when to release handling pressure (by giving pigs more time and space) to reduce the level of threat (National Pork Board, 2014).*

Exposure of pigs to sudden movement, loud noises or changes in visual contrasts should be minimised where possible to prevent stress and fear reactions. Pigs should not be improperly or aggressively handled (e.g. kicked, thrown, dropped, walked on top of, held or pulled by one front leg, ears or tail). Pigs that become distressed during handling should be attended to immediately.

Pigs should be restrained only for as long as necessary and only appropriate, well-maintained restraint devices should be used.

Well designed and maintained handling facilities assists proper handling.

Animal-based criteria (or measurables): physical appearance, behaviour, changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

Annex 18 (contd)**Article 7.X.8.****Painful procedures**

Some procedures such as surgical castration, tail docking, teeth clipping or grinding, tusk trimming, identification, and nose ringing may be performed on in pigs. These procedures should only be performed by trained personnel, when necessary to facilitate management, to meet market or environmental requirements, improve human safety or safeguard *animal welfare*.

These procedures are painful or have the potential to cause pain. They should be performed in such a way as to minimise any pain, distress or suffering to the animal.

Options for enhancing *animal welfare* in relation to these procedures include the internationally recognised ‘three Rs’: replacement (e.g. using entire males or immunocastrated males rather than surgically castrated males), reduction (e.g. tail docking and teeth clipping only when necessary) and refinement (e.g. providing analgesia or anaesthesia under the recommendation or supervision of a *veterinarian*) (Bonastre *et al.*, 2016 and Hansson *et al.*, 2011).

Ovariectomy should not be performed without anaesthesia and prolonged analgesia. An immunological product that reversibly and effectively suppresses ovarian function in pigs is available. Immunological prevention of oestrus should be encouraged to avoid ovariectomy (Dalmau *et al.*, 2015).

Animal-based criteria (or measurables): complications from common procedures, morbidity rates, mortality and culling rates, abnormal behaviour, physical appearance and changes in weight and body condition.

Article 7.X.9.**Feeding and provision of feed and watering of animals**

The amount of feed and nutrients pigs require in any management system is affected by factors such as climate, the nutritional composition and quality of the diet, the age, gender, genetics, size and physiological state of the pigs (e.g. pregnancy, lactation, growth), and their state of health, growth rate, previous feeding levels and level of activity and exercise.

All pigs should receive adequate quantities quantity and quality of feed and nutrients each day to enable each pig to:

- maintain good health;
- meet its physiological requirements and,
- meet its requirements for foraging and feeding behaviour (Bergeron *et al.*, 20082006; Brouns *et al.*, 1994; Ramonet *et al.*, 1999; Robert *et al.*, 1993 and 1997).

Feed and water should be provided in such a way as to prevent excessive or injurious competition.

Pigs should be fed a diet with the intention of minimising the occurrence of gastric ulcers (e.g. increasing dietary fiber or reducing crude protein) (Herskin *et al.*, 2016; Jha and Berrocoso, 2016).

All pigs should have access to an adequate supply of drinkable water that meets their physiological requirements and is free from contaminants hazardous to pig health (Patience, 2013). Water flow rates in drinkers should be set according to the age of the animal, stage of production and environmental conditions (Patience, 2014).

In outdoor systems where pigs have some autonomy over diet selection, stocking density should be matched to the available natural feed supply.

Animal-based criteria (or measurables): changes in body weight and body condition, physical appearance (emaciation, dehydration), behaviour (agonistic behaviour at feeding and watering places and abnormal behaviour such as tail biting), mortality and culling rates, and morbidity rates.

Annex 18 (contd)

Article 7.X.10.

Environmental enrichment

Animals should be provided with an environment that provides complexity, manipulability and cognitive stimulation (e.g. foraging opportunities, social housing) to foster normal behaviour (e.g. rooting, and biting/exploration, foraging such as rooting, biting and/or chewing materials other than feedstuffs, and social interaction), reduce abnormal behaviour (e.g. tail, ear, leg and flank biting, sham chewing, bar biting and apathetic behaviour) and improve their physical and psychological mental state (Bergeron and Gonyou, 1997; Dudnik et al., 2006; Elmore et al., 2011; Newberry, 1995; Spoolder et al., 1995; Van de Weerd et al., 2006; Wittaker et al., 1999).

Pigs should be provided with multiple forms of enrichments that aim to improve their welfare through the enhancement of their physical and social environments, such as:

- sufficient quantity of suitable materials to enable pigs to fulfil their needs to explore and look for feed (edible materials), bite (chewable materials), root (investigable materials) and manipulate materials (Bracke et al., 2006). Novelty is another aspect that is important in maintaining interest in the provided materials (Trickett et al., 2009; Abou-Ismaila and Mendl, 2016; Tarou and Bradshaw 2007);
- social enrichment that involves either keeping pigs in groups or individually with visual, olfactory and auditory contact with other pigs;
- positive human contact (such as regular direct physical contact associated with positive events, which may include feed, pats, rubs, scratching and talking when the opportunity arises) (Hemsworth and Coleman, 2011; Hemsworth and Coleman, 1994).

Animal-based criteria (or measurables): physical appearance (injuries), behaviour (stereotypes, tail biting), changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

Article 7.X.11.

Prevention of abnormal behaviour

In pig production there is a number of abnormal behaviours that can be prevented or minimised with appropriate management procedures.

Many of these problems are multifactorial and minimising their occurrence requires an examination of the whole environment and of several management factors. Management procedures that may reduce the occurrence of some of these behavioural problems include:

- 1) Oral stereotypies (e.g. bar biting, sham chewing, excessive drinking) can may be minimised by providing environmental enrichment and increasing feeding time and satiety by increasing fibre content in the diet or foraging roughage (Robert et al., 1997; Bergeron et al., 2000).
- 2) Tail biting may be reduced by providing an adequate enrichment material and an adequate diet (avoiding deficiencies of minerals (Fraser, 1987) or essential amino acids), and avoiding high stocking densities and competition for resources, such as feed and water (Walker and Bilkei, 2005). Other factors to consider include animal characteristics (breed, genetics, gender) and social environment (herd size, mixing animals) (Schroder-Petersen and Simonsen, 2001; EFSA, 2007; Taylor et al., 2010), general health, thermal comfort and air quality.
- 3) Belly nosing and ear sucking may be reduced by increasing the weaning age, and providing feed to piglets prior to weaning to avoid the abrupt change of feed (Marchant-Forde, 2009; Sybesma, 1981; Worobec, 1999).
- 4) Vulva biting may be reduced by minimising competition for resources, including feed and water, and reducing group size (Bench et al., 2013; Leeb et al., 2001; Rizvi et al., 1998).

Animal-based criteria (or measurables): physical appearance (injuries), behaviour (abnormal behaviour), morbidity rates, mortality and culling rates, reproductive efficiency and changes in body weight and body condition.

Annex 18 (contd)**Article 7.X.12.****Housing (including outdoor production systems)**

When new facilities to accommodate pigs are planned or existing facilities are modified, professional advice on design in regards to welfare and health of animals should be sought.

Housing systems and their components should be designed, constructed and regularly inspected and maintained in a manner that reduces the risk of injury, disease and stress for pigs. Facilities should allow for the safe, efficient and humane management and movement of pigs. In systems where pigs could be exposed to adverse weather conditions they should have access to shelter to avoid thermal stress and sunburn.

There should be a separate pen or area where sick and injured animals or animals that exhibit abnormal behaviour can be isolated, treated and monitored. Certain animals may need to be kept individually. When a separated space is provided, this should accommodate all the needs of the animal e.g. recumbent or lame animals or animals with severe wounds may require additional bedding or an alternative floor surface, and water and feed should be within reach.

Pigs should not be tethered as part of their normal housing systems.

Good outcomes in the welfare and health of animals can be achieved in a range of housing systems. The design and management of the system are critical for achieving these outcomes.

Sows and gilts, like other pigs, are social animals and prefer living in groups (Stolba and Wood-Gush, 1989; Newberry and Wood-Gush, 1988; Gonyou, 2001), therefore pregnant sows and gilts should preferably be housed in groups (Anil *et al.*, 2005; Barnett *et al.*, 2001; Boyle *et al.*, 2002; Broom *et al.*, 1995; Karlen *et al.*, 2007; Marchant and Broom, 1996; McGlone *et al.*, 2004; AVMA, 2015). **Boars may need to be housed in individual pens.**

Animal-based criteria (or measurables): physical appearance (injuries), behaviour, changes in body weight and body condition, handling response, reproductive efficiency, lameness and morbidity, mortality and culling rates.

Article 7.X.13.**Space allowance**

Space allowance should be managed taking into account different areas for lying, standing, feeding and elimination. Stocking density should not adversely affect normal behaviour of pigs and durations of time spent lying.

Insufficient and inadequate space allowance may increase stress, the occurrence of injuries and have an adverse effect on growth rate, feed efficiency, reproduction and behaviour such as locomotion, resting, feeding and drinking, agonistic and abnormal behaviour (Gonyou *et al.*, 2006; Ekkel, 2003; Turner, 2000).

1. Group housing

Floor space may interact with a number of factors such as temperature, humidity, floor type and feeding systems to affect pig welfare (Marchant-Forde, 2009; Verdon, 2015). All pigs should be able to lie down simultaneously and to stand up and move freely. Sufficient space should be provided to enable animals to have access to feed, water, to separate lying and elimination areas and to avoid aggressive animals.

Group housing systems should provide sufficient space and opportunities to avoid or escape from potential aggressors.

If abnormally aggressive behaviour is seen, corrective measures should be taken, such as increasing space allowance and providing barriers where possible or individually housing the aggressive pig.

In outdoor systems where pigs have some autonomy over diet selection, stocking density should be matched to the available feed supply.

Animal-based criteria (or measurables): reduction or variation in body weight and body condition, increasing agonistic and abnormal behaviour such as tail biting, injuries, morbidity, mortality and culling rates, and physical appearance (e.g. excessive presence of faeces on the skin).

Annex 18 (contd)2. Individual pens

Pigs should only be housed in individual pens if necessary. In individual pens, pigs should be provided with sufficient space so that they can stand up, turn around and lie comfortably in a natural position, and that provides separate areas for elimination, lying and eating.

Animal-based criteria (or measurables): increasing abnormal behaviour (stereotypies), morbidity, mortality and culling rates, and physical appearance (e.g. excessive presence of faeces on the skin, injuries).

3. Stalls and crates

Feeding, insemination and gestation stalls and farrowing crates should be sized appropriately to allow pigs to:

- stand up in their natural stance without contact with either side of the stall or crate,
- stand up in their natural stance without contact with the top bars,
- stand without simultaneously touching both ends of the stall or crate,
- lie comfortably on their sides without disturbing neighbouring pigs or being injured by another pig,
except in the case of stalls used only for feeding.

Animal-based criteria (or measurables): physical appearance (e.g. injuries), increasing abnormal behaviour (stereotypies), reproductive efficiency, lameness and morbidity, mortality and culling rates (e.g. piglets).

Article 7.X.14.

Flooring, bedding, resting surfaces

In all production systems, pigs need a well-drained, dry and comfortable place to rest,
except in situations where sprinklers or misters may be used to prevent heat stress.

Floor management in indoor production systems can have a significant impact on pig welfare (Temple *et al.*, 2012; Newton *et al.*, 1980). Flooring, bedding, resting surfaces and outdoor yards should be cleaned as conditions warrant, to ensure good hygiene, comfort and minimise risk of diseases and injuries. Areas with excessive faecal accumulation are not suitable for resting.

Floors should be designed to minimise slipping and falling, promote foot health, and reduce the risk of claw injuries.

If a housing system includes areas of slatted floor, the slat and gap widths should be appropriate to the claw size of the pigs to prevent injuries.

Slopes of the floor should allow water to drain and not pool.

In outdoor systems, pigs should be rotated between paddocks or pastures to ensure good hygiene and minimise risk of diseases.

If bedding or rubber matting is provided it should be maintained to provide pigs with a clean, dry and comfortable place on which to lie.

Animal-based criteria (or measurables): physical appearance (e.g. injuries, presence of faeces on the skin, bursitis), lameness and morbidity rates (e.g. respiratory disorders, reproductive tract infections).

Article 7.X.15.

Air quality

Good air quality and ventilation are important for the welfare and health of pigs and reduce the risk of respiratory discomfort, diseases and abnormal behaviour. Dust, toxins, microorganisms and noxious gases, including ammonia, hydrogen sulphide, and methane caused by decomposing animal waste, can be problematic in indoor systems (Drummond *et al.*, 1980).

Annex 18 (contd)

Air quality is influenced strongly by management and building design in housed systems. Air composition is influenced by stocking density, the size of the pigs, flooring, bedding, waste management, building design and ventilation system (Ni *et al.*, 1999).

Proper ventilation, without draughts (Scheepens *et al.*, 1991a,b), particularly for young pigs, is important for effective heat dissipation in pigs and to prevent the build-up of effluent gases (e.g. ammonia and hydrogen sulphide), including those from manure and dust in the housing unit. The ammonia concentration in enclosed housing should not exceed 25 ppm. A useful indicator is that if air quality at the level of the pigs is unpleasant for humans it is most likely a problem for pigs.

Animal-based criteria (or measurables): morbidity, mortality and culling rates, physical appearance (excessive soiling and tear staining), behaviour (especially respiratory rate, coughing and tail biting), change in body weight and body condition.

Article 7.X.16.

Thermal environment

Although pigs can adapt to a range of thermal environments, particularly if appropriate breeds and housing are used for the anticipated conditions, sudden fluctuations in temperature can cause heat or cold stress.

1. Heat stress

Heat stress is a serious problem in pig production. It can cause significant discomfort, as well as reductions in weight gain and fertility, or sudden death (Werremann and Bazer, 1985).

The risk of heat stress for pigs is influenced by environmental factors including air temperature, solar radiation, relative humidity, wind speed, ventilation rates, stocking density, shade and wallow availability in outdoor systems and animal factors including breed, age and body condition (Heitman and Hughes, 1949; Quiniou and Noblet, 1999).

At a given temperature, the heavier pigs are, the more susceptible they are to heat stress (Renaudeau, 2011).

Animal handlers should be aware of the risk that heat stress poses to pigs and of the thresholds in relation to heat and humidity that may require action. If the risk of heat stress reaches too high levels the *animal handlers* should institute an emergency action plan that gives priority to access to additional water and could include provision of shade and wallows in outdoor systems, fans, reduction of stocking density, water-based cooling systems (dripping or misting), and provision of cooling systems as appropriate for the local conditions.

Animal-based criteria (or measurables): behaviour (feed and water intake, respiratory rate, panting, lying postures and patterns, agonistic behaviour), physical appearance (presence of faeces on the skin, sunburn), morbidity, mortality and culling rates, and reproductive efficiency.

2. Cold stress

Protection from cold should be provided when conditions are likely to compromise the welfare of pigs, particularly in neonates and young pigs and others that are physiologically compromised (e.g. ill animals). Protection can be provided by insulation, extra bedding, heat mats or lamps and natural or man-made shelters in outdoor systems (Blecha and Kelley, 1981).

Animal-based criteria (or measurables): morbidity, mortality and culling rates, physical appearance (long hair, piloerection), behaviour (especially abnormal postures, shivering and huddling) and changes in body weight and body condition.

Article 7.X.17.

Noise

Exposure of pigs to sudden or prolonged loud noises should be avoided to prevent increased aggression, stress and fear. Ventilation fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way that they cause the least possible amount of noise (Algiers and Jensen, 1991; Parker *et al.*, 2010).

Annex 18 (contd)

Animal-based criteria (or measurables): behaviour (e.g. fleeing and abnormal or excessive vocalisation), physical appearance (e.g. injuries), reproductive efficiency, changes in body weight and body condition.

Article 7.X.18.

Lighting

Indoor systems should have light levels sufficient to allow all pigs to see one another, to investigate their surroundings visually and to show other normal behaviour patterns and to be seen clearly by staff to allow adequate inspection of the pigs. The lighting regime should be such as to prevent health and behavioural problems. It should follow a 24-hour rhythm and include sufficient uninterrupted dark and light periods, preferably no less than 6 hours for both.

Artificial light sources should be located so as not to cause discomfort to the pigs.

Animal-based criteria (or measurables): behaviour (locomotive behaviour), morbidity rate, reproductive efficiency, physical appearance (injuries) and changes in body weight and body condition.

Article 7.X.19.

Farrowing and lactation

Sows and gilts need time to adjust to their farrowing accommodation before farrowing. Nesting material should be available to sows and gilts where possible for at least one day prior to farrowing (Yun *et al.*, 2014; Lawrence *et al.*, 1994; Jarvis *et al.*, 1998). Sows and gilts should be observed frequently around their expected farrowing times. As some sows and gilts need assistance during farrowing, there should be sufficient space and competent staff.

Farrowing accommodation should also provide comfort, warmth and protection to the piglets.

Animal-based criteria (or measurables): mortality and culling rates (piglets, **gilts** and sows), morbidity rates (metritis and mastitis), behaviour (restlessness and savaging), reproductive efficiency, physical appearance (injuries).

Article 7.X.20.

Weaning

Weaning is a stressful time for sows and piglets and good management is required. Problems associated with weaning are generally related to the piglets' size and physiological maturity.

Weaned piglets should be moved into clean and disinfected housing separate from where sows are kept, in order to minimise the transmission of diseases to the piglets.

Piglets should be weaned at three weeks or older, unless otherwise recommended by a *veterinarian* for disease control purposes (Hameister *et al.*, 2010; Smith *et al.*, 2010; Gonyou *et al.*, 1998; Worobec *et al.*, 1999). Early weaning systems require good management and nutrition of the piglets.

Delaying weaning to the age of four weeks or more may produce benefits such as improved gut immunity, less diarrhoea and less use of *antimicrobial agents* (EFSA, 2007; Hameister *et al.*, 2010; McLamb *et al.*, 2013; Smith *et al.*, 2010; Gonyou *et al.*, 1998; Bailey *et al.*, 2001).

Regardless of age, low weight piglets require additional care and can benefit from being kept in small groups in specialised pens until they are able to be moved to the common nursery area.

Newly weaned pigs are susceptible to disease challenges, so adherence to high-level hygiene protocols and appropriate diet is important. The area that piglets are weaned into should be clean, dry and warm.

All newly weaned pigs should be monitored **carefully** during the first two weeks after weaning for any signs of ill-health or abnormal stress.

Animal-based criteria (or measurables): mortality and culling rates (piglets), morbidity rates (respiratory disease, diarrhoea), behaviour (belly nosing and ear sucking), physical appearance (injuries) and changes in body weight and body condition.

Annex 18 (contd)**Article 7.X.21.****Mixing**

Mixing of unfamiliar pigs can result in fighting to establish a dominance hierarchy, and therefore mixing should be minimised as much as possible (Moore *et al.*, 1994; Fabrega *et al.*, 2013). When mixing, strategies to reduce aggression should be implemented. Animals should be observed after mixing and interventions applied if the aggression is intense or prolonged, and pigs becoming injured to minimise stress and injury.

Measures to prevent excessive fighting and injuries can include (Arey and Edwards, 1998; Verdon *et al.*, 2015):

- providing additional space and a non-slippery floor,
- feeding before mixing,
- feeding on the floor in the mixing area,
- providing straw or other suitable enrichment materials in the mixing area,
- providing opportunities to escape and to hide from other pigs, such as visual barriers,
- mixing previously familiarised animals whenever possible,
- mixing young animals as soon after weaning as possible,
- avoiding the addition of one or small number of animals to a large established group.

Animal-based criteria (or measurables): mortality, morbidity and culling rates, behaviour (agonistic), physical appearance (injuries), changes in body weight and body condition and reproductive efficiency.

Article 7.X.22.**Genetic selection**

Welfare and health considerations should balance any decisions on productivity and growth rate when choosing a breed or hybrid crossbreed for a particular location or production system.

Selective breeding can improve the welfare of pigs for example by selection to improve maternal behaviour, piglet viability, temperament and resistance to stress and disease and to reduce tail biting and aggressive behaviour (Turner *et al.*, 2006). Including genetic characteristics related to social behaviour effects into breeding programmes may also reduce negative social interactions and increase positive ones and may have major positive effects on group-housed animals (Rodenburg *et al.*, 2010; Rodenburg and Turner, 2012).

Animal-based criteria (or measurables): physical appearance, behaviour (e.g. maternal and agonistic behaviour), changes in body weight and body condition, handling response, reproductive efficiency, lameness, and morbidity, mortality and culling rates.

Article 7.X.23.**Protection from predators and pests**

In outdoor and combination systems pigs should be protected from predators.

Where practicable, pigs should also be protected from pests such as excessive numbers of flies and mosquitoes.

Animal-based criteria (or measurables): morbidity, mortality and culling rates, behaviour, and physical appearance (injuries).

Annex 18 (contd)

Article 7.X.24.

Biosecurity and animal health1. Biosecurity and disease prevention

Biosecurity plans should be designed, implemented and maintained, commensurate with the best possible *herd* health status, available resources and infrastructure, and current disease risk and, for *listed diseases* in accordance with relevant recommendations in the *Terrestrial Code*.

These *biosecurity plans* should address the control of the major sources and pathways for spread of pathogenic agents including:

- introductions to the *herd*, especially from different sources,
- semen,
- other domestic animals, *wildlife* and pests,
- people, including sanitation practices,
- equipment, including *vehicles*, tools and facilities,
- air, water, *feed* and bedding,
- waste, including manure garbage and disposal of dead animals.

Animal -based criteria (or measurables): morbidity, mortality and culling rates, reproductive efficiency, changes in weight and body condition, physical appearance (signs of disease).

a) Animal health management

Animal health management should optimise the welfare and health of pigs in the *herd*. It includes the prevention, treatment and control of diseases and conditions affecting the *herd* (in particular respiratory, reproductive and enteric diseases).

There should be an effective programme for the prevention and treatment of *diseases* and conditions, formulated in consultation with a *veterinarian*. This programme should include *biosecurity* and quarantine protocols, the acclimatisation of replacements, *vaccinations*, and good colostrum management, the recording of production data (e.g. number of sows, piglets per sow per year, *feed* conversion, and body weight at weaning), morbidity, mortality and culling rate and medical treatments. It should be kept up to date by the *animal handler*. Regular monitoring of records aids management and quickly reveals problem areas for intervention.

For parasitic burdens (e.g. endoparasites, ectoparasites and protozoa) and insect and rodents control, a programme should be implemented to monitor, control and treat, as appropriate.

Lameness can be a problem in pigs. *Animal handlers* should monitor the state of feet and legs and take measures to prevent lameness and maintain foot and leg health.

Those responsible for the care of pigs should be aware of early specific signs of *disease*, pain, distress or suffering, such as coughing, abortion, diarrhoea, changes in locomotory behaviour or apathetic behaviour, and non-specific signs such as reduced *feed* and water intake, changes in weight and body condition, changes in behaviour or abnormal physical appearance.

Pigs at higher risk will require more frequent inspection by *animal handlers*. If *animal handlers* suspect the presence of a *disease* or are not able to correct the causes of *disease*, pain, distress or suffering, they should seek advice from those having training and experience, such as *veterinarians* or other qualified advisers, as appropriate.

Annex 18 (contd)

Nonambulatory pigs should not be transported or moved unless absolutely necessary for treatment, recovery, or diagnosis. Such movements should be done carefully using methods that avoid dragging the animal or lifting it in a way that might cause further pain, suffering or exacerbate injuries.

Animal handlers should also be competent in assessing fitness to transport, as described in Chapter 7.3.

In case of disease or injury, when treatment has failed, is not feasible or recovery is unlikely (e.g. pigs that are unable to stand up unaided or refuse to eat or drink), or severe pain that cannot be alleviated the animal should be humanely killed as soon as possible in accordance with Chapter 7.6.

Animal-based criteria (or measurables): morbidity, mortality and culling rates, reproductive efficiency, behaviour (apathetic behaviour), lameness, physical appearance (injuries) and changes in body weight and body condition.

b) Emergency plans for disease outbreaks

Emergency plans should cover the management of the farm in the event of a disease *outbreak*, consistent with national programmes and recommendations of *Veterinary Services* as appropriate.

Article 7.X.25.

Contingency plans

Where the failure of power, water or *feed* supply systems could compromise *animal welfare*, pig producers should have contingency plans in place. These plans may include the provision of fail-safe alarms to detect malfunctions, back-up generators, contact information for key service providers, ability to store water on farm, access to water cartage services, adequate on-farm storage of *feed* and an alternative *feed* supply.

Preventive measures for emergencies should be input-based rather than outcome-based. Contingency plans should be documented and communicated to all responsible parties. Alarms and back-up systems should be checked regularly.

Contingency plans should be documented and communicated to all responsible parties.

Article 7.X.26.

Disaster management

Plans should be in place to minimise and mitigate the effect of disasters (e.g. earthquake, fire, flooding, blizzard and hurricane). Such plans may include evacuation procedures, identifying high ground, maintaining emergency *feed* and water stores, destocking and humane *killing* when necessary.

Procedures for humane *killing* of sick or injured pigs should be part of the disaster management plan and should follow the recommendations of Chapter 7.6. of the *Terrestrial Code*.

Reference to contingency plans can also be found in Article 7.X.25.

Article 7.X.27.

Humane killing

Allowing a sick or injured animal to linger unnecessarily is unacceptable. Therefore, for sick and injured pigs a prompt diagnosis should be made to determine whether the animal should be treated or humanely killed.

The decision to kill an animal humanely and the procedure itself should be undertaken by a competent person.

For a description of acceptable methods for humane *killing* of pigs see Chapter 7.6.

The *establishment* should have documented procedures and the necessary equipment for on-farm humane *killing*. Staff should be trained in humane *killing* procedures appropriate for each class of pig.

Annex 18 (contd)

Reasons for humane *killing* may include:

- severe emaciation, weak pigs that are nonambulatory or at risk of becoming nonambulatory,
 - severely injured or nonambulatory pigs that will not stand up, refuse to eat or drink, or have not responded to treatment,
 - rapid deterioration of a medical condition for which treatment has been unsuccessful,
 - severe pain that cannot be alleviated,
 - multiple joint *infections* with chronic weight loss,
 - piglets that are premature and unlikely to survive, or have a debilitating congenital defect, and
 - as part of disaster management response.
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CHAPTER 8.3.

INFECTION WITH BLUETONGUE VIRUS

Article 8.3.1.

General provisions

For the purposes of the *Terrestrial Code*, bluetongue is defined as an *infection* of ruminants and camelids with bluetongue virus (BTV) that is transmitted by *Culicoides* vectors.

The following defines the occurrence of *infection* with BTV:

- 1) BTV has been isolated from a sample from a ruminant or camelid or a product derived from that ruminant or camelid, or
- 2) antigen or ribonucleic acid specific to BTV has been identified in a samples from a ruminant or camelid showing clinical signs consistent with bluetongue, or epidemiologically linked to a suspected or confirmed case, or
- 3) antigen or ribonucleic acid specific to a BTV live vaccine strain has been identified in a sample from a ruminant or camelid that is unvaccinated, or has been vaccinated with an inactivated vaccine, or with a different live vaccine strain, showing clinical signs consistent with bluetongue, or epidemiologically linked to a suspected or confirmed case, or
- 43) antibodies to structural or nonstructural proteins of BTV that are not a consequence of *vaccination* have been identified in a sample from a ruminant or camelid that either shows clinical signs consistent with bluetongue, or is epidemiologically linked to a suspected or confirmed case.

For the purposes of the *Terrestrial Code*, the *infective period* for bluetongue shall be 60 days.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BTV status of the ruminant and camelid populations of the *exporting country or zone*.

Article 8.3.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any bluetongue-related conditions regardless of the bluetongue status of the *exporting country*:

- 1) *milk and milk products*;
- 2) *meat and meat products*;
- 3) *hides and skins*;
- 4) *wool and fibre*;
- 5) *in vivo* derived bovine embryos collected, processed and stored in accordance with Chapter 4.7.

Annex 19 (contd)

Article 8.3.3.

Country or zone free from bluetongue

- 1) Historical freedom as described in Chapter 1.4. does not apply to bluetongue.
- 2) A country or a zone may be considered free from bluetongue when *infection* with BTV is notifiable in the entire country and either:
 - a) a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17. has demonstrated no evidence of *infection* with BTV in the country or zone during the past two years; or
 - b) an ongoing *surveillance* programme has found no *Culicoides* for at least two years in the country or zone.
- 3) A country or zone free from bluetongue in which ongoing *vector surveillance*, performed in accordance with point 5 of Article 8.3.16., has found no *Culicoides* will not lose its free status through the introduction of vaccinated, seropositive or infective ruminants or camelids, or their semen or embryos from *infected* countries or *infected zones*.
- 4) A country or zone free from bluetongue in which *surveillance* has found evidence that *Culicoides* are present will not lose its free status through the introduction of seropositive or vaccinated ruminants or camelids, or semen or embryos from infected countries or *infected zones*, provided:
 - a) an ongoing *surveillance* programme focused on transmission of BTV and a consideration of the epidemiology of *infection* with BTV, in accordance with Articles 8.3.14. to 8.3.17. and Chapter 4.3., has demonstrated no evidence of transmission of BTV in the country or zone; or
 - b) the ruminants or camelids, their semen and embryos were introduced in accordance with this chapter.
- 5) A country or zone free from bluetongue adjacent to an infected country or *infected zone* should include a zone in which *surveillance* is conducted in accordance with Articles 8.3.14. to 8.3.17.

Article 8.3.4.

Country or zone seasonally free from bluetongue

- 1) A country or zone seasonally free from bluetongue is, respectively, an infected country or a part of an infected country or an infected zone, for which surveillance conducted in accordance with Articles 8.3.14. to 8.3.17. demonstrates no evidence either of transmission of BTV or of adult *Culicoides* for part of a year.
- 2) For the application of Articles 8.3.7., 8.3.9. and 8.3.11., the seasonally free period season is taken to commence the day following the last evidence of transmission of BTV (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides*.
- 3) For the application of Articles 8.3.7., 8.3.9. and 8.3.11., the seasonally free period season is taken to conclude either:
 - a) at least 28 days before the earliest date that historical data show transmission of BTV may recommence; or
 - b) immediately if current climatic data or data from a *surveillance* programme indicate transmission of BTV or an earlier resurgence of activity of adult Culicoides.
- 4) A seasonally free zone in which ongoing *surveillance* has found no evidence that *Culicoides* are present will not lose its free status through the introduction of vaccinated, seropositive or infective ruminants or camelids, or semen or embryos from infected countries or *infected zones*.

Annex 19 (contd)

Article 8.3.5.

Country or zone infected with BTV

For the purposes of this chapter, a country or *zone* infected with BTV is one that does not fulfil the requirements to qualify as either free or seasonally free from bluetongue.

Article 8.3.6.

Recommendations for importation from countries or zones free from bluetongueFor ruminants and camelids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the animals showed no clinical sign of bluetongue on the day of shipment;

AND

- 2) the animals were kept in a country or *zone* free from bluetongue since birth or for at least 60 days prior to shipment; or
- 3) the animals were kept in a country or *zone* free from bluetongue for at least 28 days, then were subjected, with negative results, to a serological test to detect antibodies to the BTV group and remained in the free country or *zone* until shipment; or
- 4) the animals were kept in a ~~free~~ country or *zone* free from bluetongue for at least 14 days, then were subjected, with negative results, to an agent identification test, and remained in the free country or *zone* until shipment; or
- 5) the animals:

- a) ~~were kept in a country or zone free from bluetongue for at least seven days;~~
- ab) were vaccinated, at least 60 days before the introduction into the free country or *zone*, from which they are to be exported, against all serotypes demonstrated to be present in the source population through a surveillance programme as described in Articles 8.3.14. to 8.3.17.;
- bc) were identified as having been vaccinated;
- cd) remained in the free country or *zone* for at least seven days until shipment;

AND

- 6) if the animals were exported from a free *zone* within an infected country, either:
 - a) did not transit through an infected *zone* during transportation to the *place of shipment*; or
 - b) were protected from attacks from *Culicoides* in accordance with point 2 of Article 8.3.13. at all times when transiting through an infected zone; or
 - c) had been vaccinated in accordance with point 5 above.

Annex 19 (contd)

Article 8.3.7.

Recommendations for importation from countries or zones seasonally free from bluetongueFor ruminants and camelids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of bluetongue on the day of shipment;

AND

- 2) were kept during the seasonally free period season in a seasonally free country or zone since birth or for at least 60 days prior to shipment; or
- 3) were kept during the seasonally free period season in a seasonally free country or zone for at least 28 days prior to shipment, and were subjected during that the residence period in the zone to a serological test to detect antibodies to the BTV group, with negative results, carried out at least 28 days after the commencement of the residence period; or
- 4) were kept during the seasonally free period season in a seasonally free country or zone for at least 14 days prior to shipment, and were subjected during that the residence period in the zone to an agent identification test, with negative results, carried out at least 14 days after the commencement of the residence period; or
- 5) were:
 - a) were kept during the seasonally free period in a seasonally free zone and were vaccinated, at least 60 days before the introduction into the free country or zone shipment, against all serotypes demonstrated to be present in the source population through a *surveillance programme* in accordance with Articles 8.3.14. to 8.3.17.; and
 - b) were identified as having been vaccinated; and
 - c) kept during the free season remained in the seasonally free country or zone for at least seven days and until shipment;

AND

- 6) either:
 - a) did not transit through an infected zone during transportation to the *place of shipment*; or
 - b) were protected from attacks from *Culicoides* in accordance with point 2 of Article 8.3.13. at all times when transiting through an *infected zone*; or
 - c) were vaccinated in accordance with point 5 above.

Article 8.3.8.

Recommendations for importation from countries or zones infected with BTVFor ruminants and camelids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

Annex 19 (contd)

- 1) showed no clinical sign of bluetongue on the day of shipment;

AND

- 2) were protected from attacks from *Culicoides* in accordance with Article 8.3.13. in a *vector-protected establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*, or
- 3) were protected from attacks from *Culicoides* in accordance with Article 8.3.13. in a *vector-protected establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test to detect antibodies to the BTV group, with negative results, carried out at least 28 days after introduction into the *vector-protected establishment*, or
- 4) were protected from attacks from *Culicoides* in accordance with Article 8.3.13. in a *vector-protected establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test, with negative results, carried out at least 14 days after introduction into the *vector-protected establishment*, or
- 5) were:
 - a) vaccinated, at least 60 days before shipment, against all serotypes demonstrated to be present in the source population through a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17.;
 - b) identified as having been vaccinated; or
- 6) were demonstrated to have antibodies for at least 60 days prior to dispatch shipment, against all serotypes demonstrated to be present in the source population through a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17.

Article 8.3.9.

Recommendations for importation from countries or zones free or ~~zones~~ seasonally free from bluetongue

For semen of ruminants and camelids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor males:
 - a) showed no clinical sign of bluetongue on the day of collection; and
 - b) were kept in a country or zone free from bluetongue or in a seasonally free country or zone during the seasonally free season period for at least 60 days before commencement of, and during, collection of the semen; or
 - c) comply with point 1 of Article 8.3.10. were subjected to a serological test to detect antibodies to the BTV group, with negative results, between 28 and 60 days after the last collection for this consignment, and, in case of a seasonally free zone, at least every 60 days throughout the collection period; or
 - d) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Annex 19 (contd)

Article 8.3.10.

Recommendations for importation from countries or zones infected with BTVFor semen of ruminants and camelids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor males:
 - a) showed no clinical sign of bluetongue on the day of collection;

AND

 - b) were kept in a *vector-protected establishment* in accordance with point 1 of Article 8.3.13. for at least 60 days before commencement of, and during, collection of the semen; or
 - c) were subjected to a serological test to detect antibodies to the BTV group, with negative results, ~~at least every 60 days throughout the collection period and between 28 and 60 days after the final each~~ collection for this consignment; or
 - d) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 seven days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.3.11.

Recommendations for importation from countries or zones free or ~~zones~~ seasonally free from bluetongueFor *in vivo* derived embryos of ruminants (other than bovine embryos) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females:
 - a) showed no clinical sign of bluetongue on the day of collection; and
 - b) were kept in a country or zone free from bluetongue or in a seasonally free country or zone during the seasonally free period season for at least the 60 days prior to, and at the time of, collection of the embryos; or
 - b) comply with point 1 of Article 8.3.12.;
 - c) ~~were subjected to a serological test to detect antibodies to the BTV group, between 28 and 60 days after collection, with negative results; or~~
 - d) ~~were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;~~
- 2) the embryos were collected, processed and stored in accordance with Chapters 4.7., 4.8. and 4.9., as relevant.
- 3) the semen used to fertilise the oocytes complied with Article 8.3.9. or Article 8.3.10.

Annex 19 (contd)

Article 8.3.12.

Recommendations for importation from countries or zones infected with BTV

For *in vivo* derived embryos of ruminants (other than bovine embryos) and other BTV susceptible animals and for *in vitro* produced bovine embryos

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females:
 - a) showed no clinical sign of bluetongue on the day of collection;

AND

 - b) were kept in a *vector-protected establishment* in accordance with point 1 of Article 8.3.13. for at least 60 days before commencement of, and during, collection of the embryos; or
 - c) were subjected to a serological test to detect antibodies to the BTV group, between 28 and 60 days after collection, with negative results; or
 - d) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;
- 2) the embryos were collected, processed and stored in accordance with Chapters 4.7., 4.8. and 4.9., as relevant;
- 3) the semen used to fertilise the oocytes complied with Article 8.3.9. or Article 8.3.10.

Article 8.3.13.

Protecting animals from *Culicoides* attacks1. Vector-protected establishment or facility

The *establishment* or facility should be approved by the Veterinary Authority and the means of protection should at least comprise the following:

- a) appropriate physical barriers at entry and exit points, such as double-door entry-exit system;
- b) openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide in accordance with manufacturers' instructions;
- c) *vector surveillance* and control within and around the building;
- d) measures to limit or eliminate breeding sites for vectors in the vicinity of the *establishment* or facility;
- e) standard operating procedures, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of animals to the place of *loading*.

2. During transportation

When transporting animals through infected countries or zones, Veterinary Authorities should require strategies to protect animals from attacks from *Culicoides* during transport, taking into account the local ecology of the vector.

Annex 19 (contd)

a) Transport by road

Risk management strategies may include:

- i) treating animals with insect repellents prior to and during transportation;
- ii) *loading*, transporting and *unloading* animals at times of low *vector* activity (i.e. bright sunshine, low temperature);
- iii) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;
- iv) darkening the interior of the *vehicle*, for example by covering the roof or sides of *vehicles* with shade cloth;
- v) *surveillance* for *vectors* at common stopping and *unloading* points to gain information on seasonal variations;
- vi) using historical information or information from appropriately verified and validated bluetongue epidemiological models to identify low risk ports and transport routes.

b) Transport by air

Prior to *loading* the animals, the crates, containers or jet stalls should be sprayed with an insecticide approved in the country of dispatch.

Crates, containers or jet stalls in which animals are being transported and the cargo hold of the aircraft should be sprayed with an approved insecticide when the doors have been closed and prior to take-off. All possible insect harbourage should be treated. The spray containers should be retained for inspection on arrival.

In addition, during any stopover in countries or *zones* not free from bluetongue, prior to the opening of any aircraft door and until all doors are closed, netting of appropriate gauge impregnated with an approved insecticide should be placed over crates, containers or jet stalls.

Article 8.3.14.

Introduction to surveillance

Articles 8.3.14. to 8.3.17. define the principles and provide guidance on *surveillance* for *infection* with BTV, complementary to Chapter 1.4. and for *vectors* complementary to Chapter 1.5.

Bluetongue is a *vector-borne infection* transmitted by various species of *Culicoides* in a range of ecosystems.

The purpose of *surveillance* is the detection of transmission of BTV in a country or *zone* and not determination of the status of an individual animal or *herds*. *Surveillance* deals with the evidence of *infection* with BTV in the presence or absence of clinical signs.

An important component of the epidemiology of bluetongue is the capacity of its *vector*, which provides a measure of disease *risk* that incorporates *vector* competence, abundance, biting rates, survival rates and extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context. Therefore, *surveillance* for bluetongue should focus on transmission of BTV in domestic ruminants and camelids.

The impact and epidemiology of bluetongue widely differ in different regions of the world and therefore it is not appropriate to provide specific recommendations for all situations. Member Countries should provide scientific data that explain the epidemiology of bluetongue in the country or *zone* concerned and adapt the *surveillance* strategies for defining their status to the local conditions. There is considerable latitude available to Member Countries to justify their status at an acceptable level of confidence.

Annex 19 (contd)

Surveillance for bluetongue should be in the form of a continuing programme.

Article 8.3.15.

General conditions and methods for surveillance

- 1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:
 - a) a formal and ongoing system for detecting and investigating *outbreaks* of disease should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspected cases of *infection* with BTV to a *laboratory* for diagnosis;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
- 2) The bluetongue *surveillance* programme should:
 - a) in a free country or *zone* or seasonally free *zone*, have an early warning system which obliges farmers and workers, who have regular contact with domestic ruminants, as well as diagnosticians, to report promptly any suspicion of bluetongue to the *Veterinary Authority*.

An effective *surveillance* system will periodically identify suspected cases that require follow-up and investigation to confirm or exclude whether the cause of the condition is bluetongue. The rate at which such suspected cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected cases of bluetongue should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment be available for those responsible for *surveillance*;

AND

- b) conduct random or targeted serological and virological *surveillance* appropriate to the status of the country or *zone*.

Article 8.3.16.

Surveillance strategies

The target population for *surveillance* aimed at identification of *disease* or *infection* should cover susceptible domestic ruminants and camelids, and other susceptible herbivores of epidemiological significance within the country or *zone*. Active and passive *surveillance* for bluetongue should be ongoing as epidemiologically appropriate. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the status of the country or *zone*.

It may be appropriate to focus *surveillance* in an area adjacent to a border of an infected country or *infected zone* for up to 100 kilometres, taking into account relevant ecological or geographical features likely to interrupt the transmission of BTV or the presence in the bordering infected country or *infected zone* of a bluetongue *surveillance* programme (in accordance with Articles 8.3.14. to 8.3.17.) that supports a lesser distance.

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with BTV in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. sheep).

Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. bovines cattle).

Annex 19 (contd)

In vaccinated populations, serological and virological *surveillance* is necessary to detect the BTV serotypes circulating to ensure that all circulating serotypes are included in the *vaccination* programme.

If a Member Country wishes to declare freedom from bluetongue in a specific zone, the design of the *surveillance* strategy should be aimed at the population within the zone.

For random surveys, the design of the sampling strategy should incorporate epidemiologically appropriate design prevalence. The sample size selected for testing should be large enough to detect evidence of *infection* if it were to occur at a predetermined minimum rate. The sample size and expected prevalence determine the level of confidence in the results of the survey. The Member Country should justify the choice of design *prevalence* and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design *prevalence* in particular should be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination* and *infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following up positive

reactions to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in *surveillance* for disease or *infection* are technically well defined. The design of *surveillance* programmes to prove the absence of *infection* with and transmission of, BTV should be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logically complicated.

1. Clinical surveillance

Clinical *surveillance* aims to detect clinical signs of bluetongue at the *flock* or *herd* level, particularly during a newly introduced *infection*. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

Suspected cases of bluetongue detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

2. Serological surveillance

An active programme of *surveillance* of host populations to detect evidence of transmission of BTV is essential to establish the bluetongue status of a country or zone. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested should reflect the epidemiology of bluetongue. Bovines Cattle are usually the most sensitive indicator species. Management variables that may influence likelihood of *infection*, such as the use of insecticides and animal housing, should be considered.

Samples should be examined for antibodies against BTV. Positive test results can have four possible causes:

- a) natural *infection*,
- b) *vaccination*,
- c) maternal antibodies,
- d) the lack of specificity of the test.

Annex 19 (contd)

It may be possible to use sera collected for other survey purposes for bluetongue *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of *infection* with BTV should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no *infection* with BTV is present in a country or zone. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the animals being sampled.

Serological *surveillance* in a free zone should target those areas that are at highest *risk* of transmission of BTV, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free zone. In view of the epidemiology of bluetongue, either random or targeted sampling is suitable to select herds or animals for testing.

Serological *surveillance* in *infected zones* will identify changes in the boundary of the zone, and can also be used to identify the BTV types circulating. In view of the epidemiology of bluetongue, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of BTV from a proportion of infected animals provides information on serotype and genetic characteristics of the viruses concerned.

Virological *surveillance* can be conducted:

- a) to identify virus transmission in at risk populations,
- b) to confirm clinically suspected cases,
- c) to follow up positive serological results,
- d) to better characterise the genotype of circulating virus in a country or zone.

4. Sentinel animals

Sentinel animals are a form of targeted *surveillance* with a prospective study design. They are the preferred strategy for bluetongue *surveillance*. They comprise groups of unexposed animals that have not been vaccinated and are managed at fixed locations and sampled regularly to detect new *infections* with BTV.

The primary purpose of a sentinel animal programme is to detect *infections* with BTV occurring at a particular place, for instance sentinel groups may be located on the usual boundaries of *infected zones* to detect changes in distribution of BTV. In addition, sentinel animal programmes allow the timing and dynamics of *infections* to be observed.

A sentinel animal programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of bluetongue in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting transmission of BTV at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid bias, sentinel groups should comprise animals selected to be of similar age and susceptibility to *infection* with BTV. Bovines Cattle are the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

Annex 19 (contd)

The frequency of sampling will depend on the reason for choosing the sampling site. In endemic areas, virus isolation will allow monitoring of the serotypes and genotypes of BTV circulating during each time period. The borders between infected and uninfected areas can be defined by serological detection of *infective period*. Monthly sampling intervals are frequently used. Sentinels in declared free zones add to confidence that *infection* with BTV is not occurring unobserved. In such cases, sampling prior to and after the possible period of transmission is sufficient.

Definitive information on the presence of BTV in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required, sentinels should be sampled at sufficiently frequent intervals to ensure that samples are collected during the period of viraemia.

5. **Vector surveillance**

BTV is transmitted between ruminant hosts by species of *Culicoides* which vary around the world. It is therefore important to be able to identify potential *vector* species accurately although many such species are closely related and difficult to differentiate with certainty.

Vector surveillance aims to demonstrate the absence of vectors or to determine areas of different levels of risk and local details of seasonality by determining the various *vector* species present in an area, their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread.

Long term *surveillance* can also be used to assess *vector* abatement measures or to confirm continued absence of vectors.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local *vector* species of *Culicoides* and may include the use of Ondersteopoort-type light

traps or similar, operated from dusk to dawn in locations adjacent to domestic ruminants, or the use of drop traps over ruminants.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and type of traps to be used and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of *vector surveillance* sites at the same locations as sentinel animals is advisable.

The use of a *vector surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low *vector infection* rates mean that such detections can be rare.

Animal-based *surveillance* strategies are preferred to detect virus transmission.

Article 8.3.17.

Documentation of bluetongue free status

1. **Additional surveillance requirements for Member Countries declaring freedom from bluetongue**

In addition to the general requirements described above, a Member Country declaring freedom from bluetongue for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented in accordance with general conditions and methods described in this chapter, to demonstrate absence of *infection* with BTV during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a *laboratory* able to undertake identification of *infection* with BTV through virus detection and antibody tests. This *surveillance* should be targeted to unvaccinated animals. Clinical *surveillance* may be effective in sheep while serological *surveillance* is more appropriate in bovines cattle.

Annex 19 (contd)2. Additional requirements for countries or zones that practise vaccination

Vaccination to prevent the transmission of BTV may be part of a disease control programme. The level of *flock* or *herd* immunity required to prevent transmission will depend on the *flock* or *herd* size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. The vaccine should also comply with the provisions stipulated for BTV vaccines in the *Terrestrial Manual*. Based on the epidemiology of bluetongue in the country or *zone*, it may be decided to vaccinate only certain species or other *subpopulations*.

In countries or *zones* that practise *vaccination*, virological and serological tests should be carried out to ensure the absence of virus transmission. These tests should be performed on unvaccinated *subpopulations* or on sentinels. The tests should be repeated at appropriate intervals in accordance with the purpose of the *surveillance* programme. For example, longer intervals may be adequate to confirm endemicity, while shorter intervals may allow on-going demonstration of absence of transmission.

CHAPTER 8.4.

INFECTION WITH *BRUCELLA ABORTUS*, *B. MELITENSIS* AND *B. SUIS*

[...]

Article 8.4.10.

Herd or flock free from infection with *Brucella* in bovids, sheep and goats, camelids or cervids without vaccination

1) To qualify as free from *infection with Brucella* without vaccination, a *herd* or *flock* of bovids, sheep and goats, camelids or cervids should satisfy the following requirements:

a) the *herd* or *flock* is in a country or zone free from *infection with Brucella* without vaccination in the relevant animal category and is certified free without vaccination by the Veterinary Authority;

OR

b) the *herd* or *flock* is in a country or zone free from *infection with Brucella* with vaccination in the relevant animal category and is certified free without vaccination by the Veterinary Authority; and no animal of the *herd* or *flock* has been vaccinated in the past three years;

OR

c) the *herd* or *flock* met the following conditions:

i) *infection with Brucella* in animals is a *notifiable disease* in the entire country;

ii) no animal of the relevant category of the *herd* or *flock* has been vaccinated in the past three years;

iii) no case has been detected in the *herd* or *flock* for at least the past year;

iv) animals showing clinical signs consistent with *infection with Brucella* such as abortions have been subjected to the necessary diagnostic tests with negative results;

v) for at least the past year, there has been no evidence of *infection with Brucella* in other *herds* or *flocks* of the same *establishment*, or measures have been implemented to prevent any transmission of the *infection with Brucella* from these other *herds* or *flocks*;

vi) two tests have been performed with negative results on all sexually mature animals, *i.e. except castrated males and spayed females*, present in the *herd* at the time of testing, the first test being performed not before 3 *three* months after the *slaughter* of the last case and the second test at an interval of more than 6 *six* and less than 12 months.

Annex 20 (contd)

- 2) To maintain the free status, the following conditions should be met:
- a) the requirements in points 1a) or 1b) or 1c) i) to v) above are met;
 - b) regular tests, at a frequency depending on the prevalence of *herd* or *flock* infection in the country or *zone*, demonstrate the continuing absence of *infection* with *Brucella*;
 - c) animals of the relevant category introduced into the *herd* or *flock* are accompanied by a certificate from an *Official Veterinarian* attesting that they come from:
 - i) a country or *zone* free from *infection* with *Brucella* in the relevant category without *vaccination*;
- OR
- ii) a country or *zone* free from *infection* with *Brucella* with *vaccination* and the animals of the relevant category have not been vaccinated in the past three years;
- OR
- iii) a *herd* or *flock* free from *infection* with *Brucella* with or without *vaccination* and that the animals have not been vaccinated in the past three years and were tested for *infection* with *Brucella* within 30 days prior to shipment with negative results; in the case of post-parturient females, the test is carried out at least 30 days after giving birth. This test is not required for sexually immature animals including castrated males and spayed females.

[...]

Annex 21

CHAPTER 8.16.

INFECTION WITH RINDERPEST VIRUS

[...]

Article 8.16.2.

Definitions and general provisions

For the purposes of the *Terrestrial Code*:

- 1) RPV-containing material as referred to in Article 8.16.9. means field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other clinical pathological material from animals known or suspected to be infected; laboratory-generated diagnostic material containing or encoding live virus, recombinant morbilliviruses (segmented or nonsegmented) containing unique RPV nucleic acid or amino acid sequences, and full length genomic material including virus ribonucleic acid (RNA) and its cDNA copies of virus RNA;
- 2) subgenomic fragments of RPV genome (either as plasmid or incorporated into recombinant viruses) morbillivirus nucleic acid that are not capable of being incorporated into or a replicating morbillivirus or morbillivirus-like virus are not considered as to be RPV-containing material; neither are sera that have been either heat-treated to at least 56°C for at least two hours, or shown to be free from RPV genome sequences by a validated RT-PCR assay;
- 3) a ban on vaccination against rinderpest means a ban on administering any vaccine containing RPV or RPV any components derived from RPV to any animal;
- 4) the *incubation period* for rinderpest shall be 21 days;
- 5) a case is defined as an *animal* infected with RPV whether or not showing clinical signs; and
- 6) for the purposes of this chapter, 'susceptible *animals*' means domestic, *feral* and *wild* artiodactyls.

[...]

CHAPTER 11.9.

INFECTION WITH LUMPY SKIN DISEASE VIRUS

[...]

Article 11.9.4.

Recovery of free status

- 1) When a *case* of LSD occurs in a country or *zone* previously free from LSD, one of the following waiting periods is applicable to regain free status:
 - a) when a *stamp-out policy* has been applied:
 - i) 14 months after the *slaughter* or *killing* of the last *case*, or after the last *vaccination* if emergency *vaccination* has been used, whichever occurred last, and during which period clinical, virological and serological *surveillance* ~~has been~~ conducted in accordance with Article 11.9.15. has demonstrated no occurrence of infection with LSDV;
 - ii) 26 months after the *slaughter* or *killing* of the last *case*, or after the last *vaccination* if emergency *vaccination* has been used, whichever occurred last, and during which period clinical *surveillance* alone ~~has been~~ conducted in accordance with Article 11.9.15. has demonstrated no occurrence of infection with LSDV;
 - b) when a *stamp-out policy* is not applied, Article 11.9.3. applies.
- 2) When preventive *vaccination* is conducted in a country or *zone* free from LSD, in response to a threat but without the occurrence of a *case* of LSD, free status may be regained eight months after the last *vaccination* when clinical, virological and serological *surveillance* ~~has been~~ conducted in accordance with Article 11.9.15. has demonstrated no occurrence of infection with LSDV.

Article 11.9.5.

Recommendations for importation from countries or zones free from LSD

For domestic bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of LSD on the day of shipment;
- 2) come from a country or *zone* free from LSD.

Article 11.9.6.

Recommendations for importation from countries or zones not free from LSD

For domestic bovines and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of LSD on the day of shipment;

Annex 22 (contd)

- 2) were kept since birth, or for the past 60 days prior to shipment, in an *epidemiological unit* where no case of LSD occurred during that period;
- 3) were vaccinated against LSD according to manufacturer's instructions between 60 days and one year prior to shipment;
- 4) were demonstrated to have antibodies at least 30 days after *vaccination*;
- 5) were kept in a *quarantine station* for the 28 days prior to shipment during which time they were subjected to an agent identification test with negative results.

[...]

Article 11.9.15.

Surveillance

1. General principles of surveillance

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with LSDV, even in the absence of clinical signs, given the prevailing epidemiological situation, in accordance with Chapter 1.4. and Chapter 1.5. and under the responsibility of the *Veterinary Authority*.

The *Veterinary Services* should implement programmes to raise awareness among farmers and workers who have day-to-day contact with livestock, as well as *veterinary paraprofessionals*, *veterinarians* and *diagnosticians*, who should report promptly any suspicion of LSD.

In particular Member Countries should have in place:

- a) a formal and ongoing system for detecting and investigating cases;
- b) a procedure for the rapid collection and transport of samples from suspected cases to a *laboratory* for diagnosis;
- c) a system for recording, managing and analysing diagnostic and *surveillance* data.

2. Clinical surveillance

Clinical *surveillance* is essential for detecting cases of infection with LSDV and requires the physical examination of susceptible animals.

Surveillance based on clinical inspection provides a high level of confidence of detection of disease if a sufficient number of clinically susceptible animals is examined regularly at an appropriate frequency and investigations are recorded and quantified. Clinical examination and *laboratory* testing should be pre-planned and applied using appropriate types of samples to clarify the status of suspected cases.

3. Virological and serological surveillance

An active programme of *surveillance* of susceptible populations to detect evidence of *infection* with LSDV is useful to establish the status of a country or zone. Serological and molecular testing of bovines and water buffaloes may be used to detect presence of *infection* with LSDV in naturally infected animals.

The study population used for a serological survey should be representative of the population at risk in the country or zone and should be restricted to susceptible unvaccinated animals. Identification of vaccinated animals may minimise interference with serological *surveillance* and assist with recovery of free status.

Annex 22 (contd)4. Surveillance in high-risk areas

Disease-specific enhanced *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with an infected country or *zone*, based upon geography, climate, history of infection and other relevant factors. The *surveillance* should be carried out over a distance of at least 20 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of LSDV. A country or *zone* free from LSD may be protected from an adjacent infected country or *zone* by a *protection zone*.

CHAPTER 12.10.

INFECTION WITH *BURKHOLDERIA MALLEI* (GLANDERS)

Article 12.10.1.

General provisions

Most glanders-susceptible animals are equids. Equids are the major hosts and reservoirs of glanders although scientific data are not available for on the occurrence of infection in zebras. Camelids, goats and various carnivores including bears, canids and felids can also be infected but play no significant epidemiological role in the epidemiology of the disease. Glanders in humans is a significant and rare but potentially fatal zoonotic disease with fatal outcome if not treated in a timely manner.

For the purposes of the *Terrestrial Code*, glanders is defined as an infection of equids with *Burkholderia mallei* in an equid with or without the presence of clinical signs.

The chapter deals not only with the occurrence of clinical signs caused by *B. mallei*, but also with the presence of infection with *B. mallei* in the absence of clinical signs.

The following defines the occurrence of an infection with *B. mallei*:

- 1) *B. mallei* has been isolated from a sample from an equid; or
- 2) antigen or genetic material specific to *B. mallei* has been identified in a sample from an equid showing clinical or pathological signs consistent with glanders, or epidemiologically linked to a confirmed or suspected outbreak case of glanders infection with *B. mallei*, or giving cause for suspicion of previous contact with *B. mallei*; or
- 3) antibodies specific to *B. mallei* have been identified by a testing regime appropriate to the species in a sample from an equid showing clinical or pathological signs consistent with glanders, or epidemiologically linked to a confirmed or suspected outbreak case of glanders infection with *B. mallei*, or giving cause for suspicion of previous contact with *B. mallei*.

For the purposes of the *Terrestrial Code*, the *infective period* of *B. mallei* in equids is lifelong and the *incubation period* is shall be six months.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 12.10.2.

Country or zone free from infection with *B. mallei*

A country or a zone that does not comply with the point 1 a) of Article 1.4.6. may be considered free from *infection with *B. mallei** when:

- 1) glanders infection with *B. mallei* is has been a notifiable disease in the entire country for at least the past three years;
- 2) either:
 - a) there has been no case outbreak and no evidence of *infection with *B. mallei** in equids during the past three years, following the destruction of the last case; or

Annex 23 (contd)

- 3b) no evidence of infection with *B. mallei* has been found during the past six months following the destruction of the last case; and there is a surveillance programme in place demonstrating the absence of infection in accordance with Article 12.10.8. has demonstrated no evidence of infection with *B. mallei* in the past 12 months;

AND

- 43) imports of equids and their germplasm into the country or zone are carried out in accordance with this chapter.

Article 12.10.3.

Recovery of free status

When a case is detected in a previously free country or zone, freedom from *infection* with *B. mallei* can be regained after the following:

- 1) a standstill of movements of equids and their germplasm from establishments affected or suspected of being affected has been imposed until the destruction of the last case;
- 2) an epidemiological investigation, including (trace-back, and trace-forward), including investigations to determine the likely source of the outbreak, have been carried out;
- 3) a stamping-out policy, which includes at least the destruction of all infected equids and cleansing and the disinfection of the affected establishments, has been applied;
- 4) increased surveillance in accordance with Article 12.10.8. has been carried out and has demonstrated not detected any no evidence of *infection* in the six 12 months after stamping-out disinfection of the last affected establishment and during that period measures have been in place to control the movement of equids.
- 5) measures are in place to control the movement of equids to prevent the spread of *B. mallei*.

When the measures above are not carried out, Article 12.10.2. applies.

Article 12.10.4.

Recommendations for importation of equids from countries or zones free from infection with *B. mallei* infection

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the equid:

- 1) showed no clinical signs of glanders infection with *B. mallei* on the day of shipment;
- 2) either:
 - a) was kept for six months prior to shipment, or since birth, in a the exporting country or zone or countries or zones free from infection with *B. mallei*; or
 - b) if kept at any time in the past six months in a country or zone not free from infection with *B. mallei*, was imported in accordance with Article 12.10.5. into a country or zone free from infection with *B. mallei* kept in an establishment in the exporting country for at least 30 days and was subjected to a prescribed test with negative result on a sample taken during the 10 days prior to shipment.

Annex 23 (contd)

Article 12.10.5.

Recommendations for importation of equids from countries or zones considered infected not free from infection with *B. mallei*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the equid:

- 1) showed no clinical signs of ~~glanders~~ infection with *B. mallei* on the day of shipment;
- 2) was kept for six months prior to shipment, or since birth, in an ~~establishment~~ where no case of ~~glanders~~ infection with *B. mallei* was reported during the ~~six~~12 months prior to shipment;
- 3) was ~~isolated for at least 30 days prior to shipment, and during that time was~~ subjected to ~~two~~ a prescribed test for ~~infection with *B. mallei*~~, with negative results ~~carried out on a two samples taken during the 21 to 30 days apart with the second sample taken within 10 days prior to shipment~~.

Article 12.10.6.

Recommendations for the importation of equine semen

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

- 1) on the day of collection, the donor ~~males~~ animals:
 - a) showed no clinical signs of ~~glanders~~ infection with *B. mallei* ~~on the day of collection; and for the following 21 days;~~
 - b) were examined clinically for signs of orchitis and cutaneous lesions of on the penis or other parts of the body, with negative results; ~~were kept continuously:~~
 - i) either for a period of at least 21 days prior to, and for until at least 21 days after, the collection in a country or a zone free from *infection with *B. mallei**, or
 - ii) for at least six months prior to the collection of the semen and during the collection in an ~~establishment or artificial insemination centre~~ free from *infection with *B. mallei** and were subjected to a prescribed test, with a negative result on a sample taken between 21 and 30 days before the collection, or in the case of frozen semen between 21 and 30 days after the collection;
- 2) the semen was collected, processed and stored in accordance with the relevant recommendations in Chapter 4.5. and in Articles 4.6.5. to 4.6.7.

Article 12.10.7.

Recommendations for the importation of *in vivo* derived equine embryos

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor ~~females~~ animals:
 - a) showed no clinical signs of ~~glanders~~ infection with *B. mallei* on the day of collection ~~and for the following 21 days;~~

Annex 23 (contd)

- b) ~~were kept continuously:~~
- i) either for a period of at least 21 days before, and for until at least 21 days after, the day of collection of the embryos in a country or a zone free from infection with *B. mallei*, or
 - ii) for at least six months prior to the collection and during the collection in an establishment free from infection with *B. mallei* and were subjected to a prescribed test, with a negative result on a sample taken between 21 and 30 days before the collection, or in the case of frozen embryos, between 21 and 30 days after the collection;
- 2) the embryos were collected, processed and stored in accordance with the relevant recommendations in Chapters 4.7. and 4.9., as relevant;
- 3) ~~the semen used for embryo production to fertilise the oocytes~~ complies with the recommendations in Article 12.10.6.

Article 12.10.8.

General principles of surveillance

The purpose of surveillance is to determine the status of a country or a zone with respect to infection with *B. mallei*.

~~Populations of captive wild, feral and wild equids should be included in the surveillance programme, for example through roadkill or population control measures.~~

~~Clinical surveillance aims at detecting signs of glanders by close physical examination of susceptible animals. Clinical inspection is an important component of surveillance contributing to the desired level of confidence of detection of disease, if a sufficiently large number of clinically susceptible animals is examined.~~

~~Systematic pathological surveillance is an effective approach for glanders and should be conducted on dead equids on farm, at slaughterhouses/abattoirs and establishments for the disposal of carcasses of equids. Suspicious pathological findings should be confirmed by agent identification and isolates should be typed.~~

~~When conducting serological surveillance repeated testing of the equine population is necessary to reach an acceptable level of confidence.~~

~~Clinical examination and laboratory testing should be applied to clarify the status of suspects detected by either of these complementary diagnostic approaches. Laboratory testing and necropsy may contribute to confirm clinical suspicion, while clinical examination may contribute to confirmation of positive serology.~~

This article and Article 12.10.9. provide recommendations for surveillance for infection with *B. mallei* and are complementary to Chapter 1.4. The impact and epidemiology of infection with *B. mallei* vary in different regions of the world. The surveillance strategies employed should be adapted to the respective epidemiological situation.

Surveillance should address not only the occurrence of clinical signs caused by *B. mallei*, but also evidence of infection with *B. mallei* in the absence of clinical signs.

The surveillance systems should be designed:

- = to demonstrate that equine populations in a country or zone show no evidence of infection with *B. mallei*; or
- = to detect its introduction into a free population; or
- = if *B. mallei* is known to be present, to allow the estimation of the prevalence and the determination of the distribution of the infection.

Annex 23 (contd)

The surveillance system in accordance with Chapter 1.4. should be under the responsibility of the Veterinary Authority and should have in place:

- a) a system for detecting and investigating outbreaks of disease;
- b) a procedure for the collection and transport of samples from suspected cases to a laboratory with appropriate testing capability for diagnosis of infection with *B. mallei*;
- c) a system for recording, managing and analysing diagnostic, epidemiological and surveillance data;
- d) a procedure for confirmation of inconclusive test results in an OIE Reference Laboratory.

Diagnosticians and those with regular contact with equids, including private veterinarians, veterinary paraprofessionals and animal handlers should report promptly any suspicion of infection with *B. mallei*. The reporting system efficacy should be enhanced by awareness programmes and animal identification of equids.

The Veterinary Services should implement, when relevant and according to taking into account the results of former previous surveillance, regular and frequent clinical inspections of equids and targeted serological surveys of high-risk subpopulations or those neighbouring a country or zone infected with *B. mallei*.

An effective surveillance system is likely to identify suspected cases that require follow-up investigation to confirm or exclude that the cause of the condition is infection with *B. mallei*. All suspected cases should be investigated immediately as soon as possible and samples should be taken and submitted to a laboratory. This requires that sampling kits and other equipment be available to those responsible for the surveillance. Details of the occurrence of suspected cases and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the control measures to which the equids concerned or affected establishments were subjected during the investigation (quarantine, movement control, euthanasia).

Susceptible & Captive wild, feral and wild equine populations should be included in the surveillance.

Surveillance should address not only the occurrence of clinical signs caused by *B. mallei*, but also evidence of infection with *B. mallei* in the absence of clinical signs.

Article 12.10.9.

Surveillance strategies

The strategy employed should be based on the current knowledge of the epidemiological situation, and the expected results of the surveillance, such as the demonstration of a supposed free status. The populations of equids subject to the surveillance can be covered by passive clinical surveillance, active investigation of suspected cases, or randomised or targeted sampling.

Because infection with *B. mallei* usually occurs at a very low prevalence, and randomised samples should be collected in high numbers. If an increased likelihood of infection in particular geographical locations or subpopulations can be identified, targeted sampling is may be more appropriate.

To substantiate freedom from infection in a country or zone, surveillance should be conducted in accordance with the relevant provisions of Article 1.4.6. The relatively high rate of occurrence of false positive reactions to tests for *B. mallei* should be considered and the rate at which these false positives are likely to occur should be calculated in advance. Every positive result should be investigated to determine whether it is indicative of infection or not. This involves supplementary tests, trace-back and trace-forward, and inspection of individual animals and herds for clinical signs.

Clinical or pathological surveillance and laboratory testing are complementary diagnostic approaches that should always be applied in series to clarify the status of suspected cases. Agent identification should be carried out on any equid serologically positive or showing clinical signs consistent with glanders. Any suspected case should be considered infected until contrary evidence is produced.

Annex 23 (contd)1. Clinical surveillance

Clinical surveillance aims at detecting clinical signs by close physical examination of equids. However, systematic clinical surveillance is of limited use only, as asymptomatic carrier animals are the main reservoir of the disease.

2. Pathological surveillance

Systematic pathological surveillance is an effective approach for the detection of infection with *B. mallei* and should be conducted on dead equids on farms, at slaughterhouses/abattoirs and facilities for the disposal of carcasses of equids. Pathological findings indicating possible infection with *B. mallei* should be confirmed by agent identification and any isolates should be characterised.

3. Serological surveillance

Serological surveillance for infection with *B. mallei* is the preferred strategy. Animal identification and repeated testing of the population are necessary to establish its infection status.

4. Malleinisation

Frequently used as a surveillance method, malleinisation demonstrates hypersensitivity to antigens of *B. mallei*. However, this method has shortcomings, such as low sensitivity, interference with other tests and animal welfare concerns.

CHAPTER 1.6.

PROCEDURES FOR SELF-DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

Article 1.6.1.

General principles

Member Countries may wish to make a self-declaration as to the freedom of a country, zone or *compartment* from an OIE *listed disease* or from other animal diseases. The Member Country may inform the OIE of its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim. The OIE does not publish self-declaration for from bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), contagious bovine pleuropneumonia (CBPP), African horse sickness (AHS), peste des petits ruminants (PPR) and classical swine fever (CSF).

Member Countries may request official recognition by the OIE as to:

- 1) the risk status of a country or zone with regard to BSE;
- 2) the freedom of a country or zone from FMD, with or without *vaccination*;
- 3) the freedom of a country or zone from CBPP;
- 4) the freedom of a country or zone from AHS;
- 5) the freedom of a country or zone from PPR;
- 6) the freedom of a country or zone from CSF.

The OIE does not grant official recognition for other *diseases*.

In these cases, Member Countries should present documentation setting out the compliance of their *Veterinary Services* with the applicant country or *zone* with the provisions of Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code* and with the provisions of the relevant *disease* chapters in the *Terrestrial Code* and the *Terrestrial Manual*.

When requesting official recognition of disease status or requesting endorsement by the OIE of an official control programme, the Member Country should submit to the OIE Status Department a dossier providing the information requested in the following Chapters (as appropriate): 1.7., 1.8., 1.9., 1.10., 1.11. or 1.12. in Articles 1.6.5. (for BSE), 1.6.6. (for FMD), 1.6.7. (for CBPP), 1.6.8. (for AHS), 1.6.9. (for PPR) or 1.6.10. (for CSF).

The OIE framework for the official recognition and maintenance of disease status is described in Resolution N° XV (administrative procedures) and Resolution N° XVI (financial obligations) adopted during the 83rd General Session in May 2015.

Article 1.6.2.

Endorsement by the OIE of an official control programme for FMD

Member Countries may wish to request an endorsement by the OIE of their *official control programme* for FMD.

When requesting endorsement by the OIE of an official control programme for FMD, the Member Country should submit to the OIE Status Department a dossier providing the information requested in Article 1.6.11.

Annex 24 (contd)

Article 1.6.3.

Endorsement by the OIE of an official control programme for PPR

Member Countries may wish to request an endorsement by the OIE of their *official control programme for PPR*.

When requesting endorsement by the OIE of an *official control programme* for PPR, the Member Country should submit to the OIE Status Department a dossier providing the information requested in Article 1.6.12.

Article 1.6.4.

Endorsement by the OIE of an official control programme for CBPP

Member Countries may wish to request an endorsement by the OIE of their *official control programme for CBPP*.

When requesting endorsement by the OIE of an *official control programme* for CBPP, the Member Country should submit to the OIE Status Department a dossier providing the information requested in Article 1.6.13.

[...]

CHAPTER 1.7.

ARTICLE 6.8.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF FREE STATUS FOR AFRICAN HORSE SICKNESS

Questionnaires on African horse sickness (AHS)

Article 1.7.1.

Country free from infection with African horse sickness virus

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country free from infection with African horse sickness (AHS) virus in accordance with Chapter 12.1 of the Terrestrial Code.

AHS FREE COUNTRY

Report of a Member Country which applies for recognition of status,
under Chapter 12.1 of the Terrestrial Code,
as an AHS free country

The dossier provided to the OIE should Please address concisely all the following topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these this complies comply with the Terrestrial Code.

Please use The terminology defined in the OIE Terrestrial Code and Terrestrial Manual should be referred to and used in compiling the dossier.

National legislation, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

Any All annexes should be provided in one of the OIE official languages.

[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]

The Delegate of the Member Country applying for recognition of AHS freedom for a country must demonstrate compliance with the Terrestrial Code. That is, the Delegate should submit documentary evidence that the provisions of Article 12.1.2. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- a) there has been no case of infection with AHS virus for at least the past two years;
- b) no routine vaccination against AHS has been carried out during the past year;
- c) and that any equids imported have been done so in accordance with Chapter 12.1.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.

Annex 25 (contd)1. Introduction

- a) Geographical entities features (rivers, mountain ranges, etc.). Provide a general description of the country and, when where relevant, of the region, including physical, geographical and other factors that are relevant to AHS introduction of infection and dissemination spread of AHS virus, taking into account the as well as a short description of countries sharing common borders and other epidemiologic pathways links for the potential introduction of AHS infection.

Provide maps identifying the factors features above.

Specify whether the application includes any noncontiguous territories.

- b) Demographics of domestic equids. What is Describe the composition of the equine population by species (e.g., horses, donkeys, mules, zebras, etc.) within the various sectors.

Equine sectors are defined as equids (including donkeys, mules, hinnies and zebras) used for:

sport and race breeding stock, competition horses, leisure, exhibition, equids working (including transport) donkeys, mules, hinnies, zebras)) and production, and other (donkeys, mules, hinnies, zebras). How are they the equine sectors distributed (e.g., density, etc.) throughout the country?
Provide tables and maps as appropriate.

- c) Equine sectors. Provide a general description of the relative economic importance of the equine sectors in the country. Consider the below-mentioned sector groupings and outline any recent significant changes observed within the sector groupings (if attach relevant documents are if available, please attach):

- i) breeding stock equids:-
- ii) competition Sport and race horses:-
- iii) leisure equids:-
- iv) exhibition equids; Donkeys, mules and hinnies
- v) working, transport and production equids (including donkeys, mules and hinnies).

- d) Wildlife demographics. What captive wild, wild or feral equids are present in the country? Provide estimates of population sizes and geographic distribution.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and Veterinary Authority directives in relation to AHS and a brief description of the relevance of each. This list The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) Veterinary Services. Describe how the Veterinary Services of the country comply with Chapters 1.1., 3.1. and 3.2. of the Terrestrial Code. Describe how the Veterinary Services supervise, and control, enforce and monitor all AHS-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in your the country and follow-up steps within the PVS Pathway and highlight the results relevant to AHS and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmer, including subsistence and small-scale producers, keepers, community animal health workers, veterinary paraprofessionals including community animal health workers, and other relevant groups in AHS surveillance and control. Provide a description of the role and structure of the private veterinary sector, including the number of veterinarians and their distribution, veterinary profession in AHS surveillance and control. Include a description of continuing education and awareness programmes on AHS at all relevant levels.

Annex 25 (contd)

- e) *Animal identification*, registration, traceability and movement control. Are equids identified (individually or at a group level)?

Provide a description of the traceability system, including methods of animal identification and establishment holding or herd registration and traceability for applicable to all equine sectors production systems.

How are movements of equids controlled in the country for all equine sectors production systems? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months two years.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the risk management strategy for uncontrolled movements of susceptible species (e.g., seasonal migration). Describe the actions available under national legislation.

Provide information on illegal movements detected in the past 24 months and the action taken.

Describe the risk management strategy for uncontrolled movements of susceptible species (e.g., seasonal migration). Describe the action available under legislation, and actually taken, when an illegal import is detected.

Provide information on illegal movements detected.

- f) Leisure, exhibition and competition movements of equids. How are movements of competition and leisure these types of equids controlled in the country? Please Provide information on systems including any use of registration. Provide information on any events that include international movements of equids.

- g) Describe the market systems for the sale of, or transfer of ownership of, equids, in particular, if markets require including where the international movement of equids occurs.

3. AHS eradication

- a) History. If the infection has never occurred in the country has never had the disease, or has not occurred had it within the past 25 years, please state explicitly whether or not the country is applying for recognition of historical freedom according to Article 1.4.6. of the Terrestrial Code.

If the country has had the disease infection has occurred in the country within the past 25 years, please describe the following: provide a description of the AHS history in the country, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of outbreaks per year), the susceptible species involved, and the date of the last case or eradication in the country.

- b) Strategy. Describe how AHS was controlled and eradicated (e.g., isolation of cases, *stamping-out policy*, zoning, movement control, protection of equids against vectors). Provide the time frame for eradication.

Describe and justify the corrective actions that have been implemented to prevent future disease outbreaks of AHS in response to any past disease incursions of AHS virus.

Annex 25 (contd)

- c) Vaccines and *vaccination*. Briefly answer the following:
- i) Is there any legislation that prohibits *vaccination*? If so:
 - Provide the date when *vaccination* was formally prohibited;
 - Provide information on cases of detection of illegal vaccination during the reporting period and actions taken in response to the detection.
 - ~~Describe the action available under legislation, and actually taken, when an illegal vaccination is detected;~~
 - ~~Provide information on detected illegal vaccination during the reporting period.~~
 - ii) Was *vaccination* ever used in the country? If so:
 - Provide the date when the last *vaccination* was carried out;
 - What type of vaccine was used?
 - What species were vaccinated?
 - How were vaccinated animals identified?
 - What was the fate of those animals?
 - iii) In addition, if *vaccination* was conducted applied during the past 24 months two years, provide a description and justification of the *vaccination* strategy and programme, including the following: regime.
Briefly answer the following:
 - the vaccine strains;
 - the species vaccinated;
 - identification of vaccinated animals;
 - the way in which the *vaccination* of animals was certified or reported and the records maintained;
 - Provide evidence that the vaccine used complies with Chapter 2.5.1. of the *Terrestrial Manual*.
- d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. AHS diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.5.1. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is AHS *laboratory* diagnosis carried out in the country? If so, provide an overview of the AHS-approved laboratories in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.~~

Annex 25 (contd)

- b) Provide an overview of the AHS approved laboratories in the country. Address the following points:**
- i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for ~~obtaining reporting results~~;
 - ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of disease AHS tests performed in the past 24 months two years in the national *laboratories* as well as abroad and in *laboratories* in other countries, if relevant;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g., Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-laboratory validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent, In particular, describe including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table linking identifying the tests carried out to by each of the laboratories where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If AHS *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.**

5. AHS surveillance

Provide documentary evidence that *surveillance* for AHS in the country complies with Articles 12.1.11. to 12.1.13. of the *Terrestrial Code* and Chapter 2.5.1. of the *Terrestrial Manual*. In particular, The following information should be included: points should be addressed:

- a) What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which equine sectors levels of the equine population system are included in clinical *surveillance*, such as farms establishments, markets, fairs, slaughterhouses/abattoirs, check points, etc.

Provide a summary table indicating, for the past 24 months two years, the number of suspected cases, the number of samples tested for AHS, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude AHS. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Other *surveillance*. Is *surveillance* undertaken as described in Article 12.1.13., specifically:
 - i) Serological *surveillance*.
 - ii) Virological *surveillance* including genome or antigen detection.
 - iii) Sentinel animals.
 - iv) Vector *surveillance*.

If so, provide detailed information on the survey designs including maps target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 12.1.11. and 12.1.13. of the Terrestrial Code. How frequently are they conducted? Which were the equine species are included? Are *wildlife* species included? If not, explain the rationale. Provide a summary table and maps indicating detailed results for at least the past 24 months two years. Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of equids examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance system programme* including indicators.

Annex 25 (contd)

- d) Provide information on risks in the different equine sectors, husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g., targeted serological surveys, active surveillance, participatory epidemiology studies, risk assessments, etc.). and Provide evidence of how that the acquired knowledge acquired through these activities assisted assists in more effective implementation of control measures.
- e) Provide details of the oversight of surveillance programmes by the Veterinary Services including training programmes for personnel involved in clinical, serological, and virological and other surveillance, and the approaches used to increase community involvement in AHS surveillance programmes.

6. AHS prevention

Describe the procedures in place to prevent the introduction of AHS into the country, In particular, provide including include details of:

- a) Coordination with other countries. Describe any relevant factors in about adjacent neighbouring countries that should be taken into account (e.g., size, distance from the border to affected herds or animals, wind currents and possible vector spread)? Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

If the AHS free country borders an infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the pathogenic agent or vectors, taking into consideration the seasonal vector conditions and existing physical, geographical and ecological barriers.

Are protection zones in place? If so, provide details of the measures that are applied (e.g., vaccination, intensified surveillance, density control of susceptible species), and provide a geo-referenced map of the zones.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation-spread of the pathogenic agent within the countryand through trade. Provide evidence that measures to reduce transmission of AHS are in place at markets, such as enhancing awareness of AHS transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good biosecurity practices, hygiene cleaning and disinfection routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

- c) Import control procedures

Provide information on countries, zones or compartments from which the country authorises the import of susceptible animals or their products into the country. Describe the criteria applied to approve such countries, zones or compartments, the controls applied on to entry of such animals and products, and subsequent internal movement. Describe the import conditions measures (e.g., quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health international veterinary certificates are required.

Describe any other procedures used for assessing the risks posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months two years, including temporary import and re-entry, specifying countries, zones or compartments of origin, species and the quantity or volume and eventual destination in the country.

Provide information on whether or not outbreaks have been related to imports or transboundary movements of domestic equids.

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

Annex 25 (contd)

- ii)* Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
- equids;:
 - genetic material (semen, oocytes oocytes and embryos of the equine species);:
 - equine derived (by-)products and biologicals;:
 - AHS vaccines.
 - veterinary medicinal products.

7. Control measures and contingency planning

- a)* List any written guidelines, including contingency plans, available to the Veterinary Services for dealing with suspected or confirmed *outbreaks* of AHS. The contingency plan should be attached as an annex in one of the OIE official languages. and, If not available, provide a brief summary of what is covered should be provided. Provide information on any simulation exercise for AHS that was conducted in the country in the past five years.
- b)* In the event of a suspected or confirmed AHS *outbreak*:
- i)* Is Are quarantine measures imposed on establishments premise with suspicious suspected cases, pending final diagnosis? What other procedures are followed regarding with respect to suspicious suspected cases (e.g., standstills)?
 - ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic causative agent;
 - iii)* Describe the actions that would be taken to control the disease situation in and around the premises establishments where the *outbreak* was is confirmed;
 - iv)* Provide a detailed description of the control or *eradication* procedures (e.g., forward and backward tracing, movement control, *disinfection* of establishments premises, vehicles and equipment, including verification methods, *vaccination*, *Stamping-out policy*, *vector-protected* stabling, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological surveillance programmes, etc.;
 - vi)* Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii)* Describe how control efforts, including *vaccination* and *biosecurity* measures, would target critical risk control points.

8. Compliance with the Terrestrial Code/NB moved to beginning of chapter]

The Delegate of the Member Country applying for AHS freedom must submit documentary evidence that the provisions of Article 12.1.2. have been properly implemented and supervised.

Annex 25 (contd)

~~In addition, the Delegate of the Member Country must submit a declaration indicating that:~~

- ~~a) there has been no case of AHS for at least the past two years;~~
- ~~b) no routine vaccination against AHS has been carried out during the past year;~~
- ~~c) and that equids were imported in accordance with Chapter 12.1.~~

~~In addition, the Delegate of the Member Country applying for historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.~~

89. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 12.1.5. of the *Terrestrial Code* and provide detailed information as specified in Sections 4 a), 4 b), 4 c) and 6, and Sections 1–7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.7.2.Zone free from infection with African horse sickness virus

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a zone free from infection with African horse sickness virus in accordance with Chapter 12.1. of the Terrestrial Code.

AHS FREE ZONE

~~Report of a Member Country which applies for recognition of status,
under Chapter 12.1. of the Terrestrial Code,
as an AHS free zone~~

The dossier provided to the OIE should Please address concisely all the following topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how this these complies comply with the Terrestrial Code.

Please use The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

Any All annexes should be provided in one of the OIE official languages.

[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]

The Delegate of the Member Country applying for recognition of AHS freedom for a zone must demonstrate compliance with the Terrestrial Code. That is, the Delegate should submit documentary evidence that the provisions of Article 12.1.2. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- a) there has been no case of *infection* with AHS virus for at least the past two years in the zone;
- b) no routine vaccination against AHS has been carried out during the past year in the zone;
- c) and that any equids imported into the zone have been done so in accordance with Chapter 12.1.

Annex 25 (contd)

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.

1. Introduction

- a) Geographical entities features (rivers, mountain ranges, etc.). Provide a general description of the country and, where when relevant, of the region, including physical, geographical and other factors that are relevant to AHS introduction of infection and dissemination spread of AHS virus, taking into account as well as a short description of the countries sharing common borders and other epidemiologic pathways links for the potential introduction of AHS infection. The boundaries of the zone must be clearly defined, including a protection zone, if applied.

Provide maps identifying the factors features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone.

- b) Demographics of domestic equids. What is Describe the composition of the equine population by species (e.g., horses, donkeys, mules, zebras, etc.) within the various sectors.

Equine sectors are defined as equids (including donkeys, mules, hinnies and zebras) used for:

sport and race breeding stock, competition horses, leisure, exhibition, equids working (including transport) donkeys, mules, hinnies, zebras)) and production, and other (donkeys, mules, hinnies, zebras). How are they the equine sectors distributed (e.g., density, etc.) throughout the country? Provide tables and maps as appropriate.

- c) Equine sectors. Provide a general description of the relative economic importance of the equine sectors in the country. Consider the below-mentioned sector groupings and outline any recent significant changes observed within the sector groupings (if attach relevant documents are if available please attach):

- i) breeding stock equids;:
- ii) competition Sport and race horses;:
- iii) leisure equids;:
- iv) exhibition equids: Donkeys, mules and hinnies
- v) working, transport and production equids (including donkeys, mules and hinnies).

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and Veterinary Authority directives in relation to AHS and a brief description of the relevance of each. This list The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) Veterinary Services. Describe how the Veterinary Services of the country comply with the provisions of Chapters 1.1., 3.1. and 3.2. of the Terrestrial Code. Describe how the Veterinary Services supervise, and control, enforce and monitor all AHS-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in your the country and follow-up steps within the PVS Pathway and highlight the results relevant to AHS and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, community animal health workers, veterinary paraprofessionals including community animal health workers, and other relevant groups in AHS surveillance and control. Provide a description of the role and structure of the private veterinary sector, including the number of veterinarians and their distribution, and role of the private veterinary profession in AHS surveillance and control. Include a description of continuing education and awareness programmes on AHS at all relevant levels.

Annex 25 (contd)

- e) *Animal identification*, registration, traceability and movement control. Are equids identified (individually or at a group level)?

Provide a description of the traceability system, including methods of animal identification and holding establishment or herd registration and traceability for applicable to all equine sectors production systems.

How are movements of equids controlled in and between zones of the same or different status for all equine sectors production systems? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months two years.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the risk management strategy for uncontrolled movements of susceptible species (e.g., seasonal migration). Describe the actions available under national legislation.

Provide information on illegal movements detected in the past 24 months and the action taken.

Describe the risk management strategy for uncontrolled movements of susceptible species (e.g., seasonal migration). Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on illegal movements detected.

- f) Leisure, exhibition and competition movements of equids. How are movements of these types of competition and leisure equids controlled in the country and the zones? Please Provide information on systems including any use of registration. Provide information on any events that include international movements of equids.
- g) Describe the market systems for the sale of, or transfer of ownership of equids in the country and the zones, in particular, if markets require including where the international movement of equids occurs.

3. AHS eradication

- a) History. If the infection has never occurred in the country, has never had the disease, or has not had it occurred within the past 25 years, please state explicitly whether or not the zone is applying for recognition of historical freedom according to Article 1.4.6. of the Terrestrial Code.

If the zone has had the disease infection has been present occurred in the zone within the past 25 years, please provide a description of the AHS history in the country and zone, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of outbreaks per year), the susceptible species involved, and the date of the last case or eradication in the zone.

- b) Strategy. Describe how AHS was controlled and eradicated in the zone (e.g., isolation of cases, stamping-out policy, zoning, movement control, protection of equids against vectors). Provide the time frame for eradication.

Describe and justify the corrective actions that have been implemented to prevent future disease outbreaks of AHS in response to any past disease incursions of AHS virus.

- c) Vaccines and vaccination. Briefly answer the following:

- i) Is there any legislation that prohibits vaccination? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal vaccination during the reporting period and actions taken in response to the detection.
- Describe the action available under legislation, and actually taken, when an illegal vaccination is detected;
- Provide information on detected illegal vaccination during the reporting period.

Annex 25 (contd)

- ii) Was vaccination ever used in the country? If so:*
- Provide the date when the last vaccination was carried out;
 - What type of vaccine was used in the zone and the rest of the country?
 - What species were vaccinated?
 - How were vaccinated animals identified?
 - What was the fate of those animals?
- iii) In addition, if vaccination was conducted applied during the past 24 months two years, provide a description and justification of the vaccination strategy and programme, including regime. Briefly answer the following:*
- the vaccine strains;
 - the species vaccinated;
 - identification of vaccinated animals;
 - the way in which the vaccination of animals was certified or reported and the records maintained;
 - Provide evidence that the vaccine used complies with Chapter 2.5.1. of the *Terrestrial Manual*.
- d) Provide a description of the legislation, organisation and implementation of the eradication campaign. Outline the legislation applicable to the eradication and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.*

4. AHS diagnosis

Provide documentary evidence that the relevant provisions in of Chapters 1.1.2., 1.1.3. and 2.5.1. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is AHS laboratory diagnosis carried out in the country? If so, provide an overview of the AHS-approved laboratories in the country. If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results. Indicate the laboratories where samples originating from the zone are diagnosed.*
- b) Provide an overview of the AHS approved laboratories in the country. Address the following points:*
- i) How the work is shared between different laboratories, logistics for shipment of samples, the follow-up procedures and the time frame for obtaining reporting results;*
 - ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of AHS tests performed in the past 24 months two years in the national laboratories as well as abroad and in laboratories in other countries, if relevant;*
 - iii) Procedures for quality assurance and for the official accreditation of laboratories. Give details of formal internal quality management systems, e.g., Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system;*
 - iv) Provide details of performance in inter-laboratory validation tests (ring tests), including the most recent results and, if applicable, the corrective measures applied.*

Annex 25 (contd)

- v) Provide details of the handling of live pathogenic agent, In particular, describe including a description of the biosecurity and biosafety measures applied;
- vi) Provide a table identifying linking the tests carried out to by each of the laboratories where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If AHS laboratory diagnosis is not carried out in the country, provide the names of the laboratories in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. AHS surveillance

Provide documentary evidence that *surveillance* for AHS in the zone complies with Articles 12.1.11. to 12.1.13. of the *Terrestrial Code* and Chapter 2.5.1. of the *Terrestrial Manual*. In particular, The following information should be included points should be addressed:

- a) What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which equine sectors levels of the equine population system are included in clinical *surveillance*, such as establishments farms, markets, fairs, slaughterhouses/abattoirs, check points, etc.

Provide a summary table indicating, for the past 24 months two years, the number of suspected cases, the number of samples tested for AHS, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude AHS. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Other *surveillance*. Is *surveillance* undertaken as described in Article 12.1.13., specifically:
 - i) Serological *surveillance*.
 - ii) Virological *surveillance* including genome or antigen detection.
 - iii) Sentinel animals.
 - iv) Vector *surveillance*.

If so, provide detailed information on the survey designs including maps target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 12.1.11. and 12.1.13. of the Terrestrial Code. How frequently are they conducted? Which were the equine species are included? Are *wildlife* species included? If not, explain the rationale. Provide a summary table and maps indicating detailed results for at least the past 24 months two years. Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of equids examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the surveillance system programme including indicators.

- d) Provide information on risks in the different equine sectors husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g., targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). and Provide evidence of how that the acquired knowledge acquired through these activities assisted assists in more effective implementation of control measures.
- e) Provide details of the oversight of surveillance programmes by the Veterinary Services including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in AHS *surveillance* programmes.

Annex 25 (contd)6. AHS prevention

Describe the procedures in place to prevent the introduction of AHS into the country or zone, including details of:

- a) Coordination with other countries. Describe any relevant factors in about adjacent neighbouring countries and zones that should be taken into account (e.g., size, distance from the border to affected herds or animals, wind currents and possible *vector* spread)? Describe coordination, collaboration and information-sharing activities with other countries and zones in the same region or ecosystem.

If the AHS free zone is established in an AHS infected country or borders an infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the pathogenic agent or *vectors*, taking into consideration the seasonal *vector* conditions and existing physical, geographical and ecological barriers.

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed free zones. Provide details of the measures that are applied (e.g., vaccination, intensified surveillance, density control of susceptible species), and provide a geo-referenced map of the zones.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation-spread of the pathogenic agent within the country or zone and through trade. Provide evidence that measures to reduce transmission of AHS are in place at markets, such as enhancing awareness of AHS transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, *practices*, hygiene *cleaning* and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

b) c) Import control procedures

Provide information on countries, zones or compartments from which the country authorises the import of susceptible animals or their products into the country or zone. Describe the criteria applied to approve such countries, zones or compartments, the controls applied on to entry of such animals and products, and subsequent internal movement. Describe the import measures conditions (e.g., quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health international veterinary certificates are required.

Describe any other procedures used for assessing the risks of posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months two years, including temporary import and re-entry, specifying countries, zones or compartments of origin and the quantity or volume and eventual destination in the country or zone.

Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic equids.

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

- ii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the zone or their final destination, concerning the import and follow-up of the following:

- equids;
- genetic material (semen, oocytes and embryos of the equine species);
- equine derived (by-)products and biologicals;
- AHS vaccines;
- = veterinary medical medicinal products.

Annex 25 (contd)7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the official services Veterinary Services for dealing with suspected or confirmed *outbreaks* of AHS. The contingency plan should be attached as an annex in one of the OIE official languages. ~~and, if not available, provide~~ a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for AHS that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed AHS *outbreak*:
 - i) Is Are quarantine measures imposed on establishments premises with suspicious suspected cases, pending final diagnosis? What other procedures are followed regarding with respect to suspicious suspected cases (e.g., standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the causative pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the premises establishments where the *outbreak* ~~was is~~ confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g., forward and backward tracing, movement control, *disinfection* of establishments premises, vehicles and equipment, including verification methods, *vaccination*, *stamp-out policy*, vector-protected stabling, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken;
 - v) In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - vi) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vii) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for *disease* control or *eradication* purposes and the prescribed timetable for payments;
 - viii) Describe how control efforts, including *vaccination* and *biosecurity measures*, would target critical risk control points.

8. Compliance with the *Terrestrial Code* [NB moved to beginning of chapter]

The Delegate of the Member Country applying for AHS freedom must submit documentary evidence that the provisions of Article 12.1.2. of the *Terrestrial Code* have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- a) there has been no case of AHS for at least the past two years in the zone;
- b) no routine vaccination against AHS has been carried out during the past year in the zone;
- c) and that equids were imported into the zone in accordance with Chapter 12.1.

In addition, the Delegate of the Member Country applying for historical freedom must submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

98. Recovery of free status

Member Countries applying for recognition of recovery of free status for a zone should comply with the provisions of Article 12.1.5. of the *Terrestrial Code* and provide detailed information as specified in Sections 4 a), 4 b), 4 c) and 6, and Sections 1–7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

CHAPTER 1.8..Article 1.6.5.**APPLICATION FOR OFFICIAL RECOGNITION BY
THE OIE OF RISK STATUS FOR BOVINE
SPONGIFORM ENCEPHALOPATHY**Article 1.8.1.

The following information should be provided by OIE Member Countries to support applications for official recognition of risk status for bovine spongiform encephalopathy (BSE) in accordance with Chapter 11.4. of the Terrestrial Code.

[Note: The following point has been moved from Article 1.8.2. to improve the logical flow of the document and remove duplication.]

The Delegate of the Member Country submitting documentation regarding of the legislation under which the Veterinary Services is are mandated it should provide a description of the content of any the relevant legal acts described (in one of the three official languages of OIE), as well as the dates of official publication and implementation.

Please The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and the procedures currently applied, in the country explaining how this these complies comply with the Terrestrial Code.

Please use The terminology defined in the OIE Terrestrial Code and Terrestrial Manual should be referred to and used in compiling the dossier.

National legislation, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided where they exist.

Any All annexes should be provided in one of the OIE official languages.

[Note from the TAHSC – The following point has been moved from the end of the questionnaire to improve the logical flow of the document see below.]

The Delegate of the Member Country applying for official recognition of a BSE risk status must submit documentary evidence that the provisions of Article 11.4.2. and Article 11.4.3. or Article 11.4.4. have been properly implemented and supervised.

1. Introduction
Provide a general description of the bovine (*Bos taurus* and *B. indicus*) husbandry and slaughtering practices in the country. Provide figures and tables as appropriate.
2. Veterinary system
 - a) Describe how the Veterinary Services of the country complies with the provisions of Chapters 1.1., 3.1. and 3.2. in of the Terrestrial Code;
 - b) describe how the Veterinary Services supervise, control, enforce and monitor and maintain all BSE-related activities;
 - c) provide maps, figures and tables wherever possible;
 - d) provide information on any OIE PVS evaluation conducted in your the country and follow-up actions steps within the PVS Pathway and highlighting the results relevant to BSE and the susceptible species;

Annex 26 (contd)

- e) provide a description of the structure (including number and distribution) and role of private veterinary sector veterinary profession in BSE surveillance and control.

Article 1.8.2.

BSE risk status requirements: Section 1 – risk assessment (see point 1) of Article 11.4.2.)

Article 11.4.2. of the *Terrestrial Code* Chapter on BSE prescribes the criteria to determine the BSE risk status of the cattle population of a country or zone. This The Delegate of the Member Country applying for recognition of he means whereby a claim for negligible risk status (Article 11.4.3.) or controlled risk status (Article 11.4.4.) must demonstrate compliance with the Terrestrial Code. That is, the Delegate must submit documentary evidence that the provisions of Article 11.4.3. or Article 11.4.4. have been properly implemented and complied with. can be made to the OIE.

[NB the following point has been moved to Article 1.8.1. and modified to avoid duplication.]

The Delegate of the Member Country submitting documentation regarding of the legislation under which the Veterinary Services is are mandated it should provide a description of the content of any the relevant legal acts described (in one of the three official languages of OIE), as well as the dates of official publication and implementation. The dossier submitted to the OIE should follow the format and numbering used in this document.

1. Introduction

The Delegate of the Member Country applying for official recognition by the OIE of BSE risk status of the cattle population of a the country or zone should submit documentary evidence demonstrating that conduct a risk assessment based on Section 2 and 3 and Chapter 4.311.4. of the Terrestrial Code has been carried out.

2. Entry assessment

- a) The potential for the entry of the classical BSE agent through importation of meat-and-bone meal or greaves (including of non-ruminant origin)

Knowledge of the origin of *meat-and-bone meal, greaves or feedstuffs feed ingredients* containing either *meat-and-bone meal* or *greaves*, is necessary to assess the risk of entry of classical BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of undetermined or controlled BSE risk pose a higher likelihood of entry than that from negligible risk countries.

Has meat-and-bone meal, greaves (including of non-ruminant origin) or feedstuffs feed ingredients containing either, been imported within the past eight years? If not se, provide documentary evidence, including supporting legislation, where relevant:

- i) official statistics, to support claims that *meat-and-bone meal* (including of non-ruminant origin), *greaves* or *feedstuffs feed ingredients* containing either *meat-and-bone meal* or *greaves* have not been imported, OR

If meat-and-bone meal, greaves (including of non-ruminant origin) or feedstuffs feed ingredients containing either, has been imported within the past eight years, provide documentary evidence of the following:

- ii) official statistics on annual volume, by country of origin, of *meat-and-bone meal* (including of non-ruminant origin), *greaves* or *feedstuffs feed ingredients* containing them imported during the past eight years;
- iii) the species composition of the *meat-and-bone meal, greaves or feedstuffs feed ingredients*;
- iv) from the Veterinary Service of the country of production that the method used to reduce BSE infectivity complies with Article 11.4.19.

Annex 26 (contd)

- b) The potential for the entry of the classical BSE agent through the importation of potentially infected live cattle

The likelihood of entry is dependent on:

- the BSE status of the country or zone of origin;
- dairy versus meat breeds, where there are differences in exposure in the country or zone of origin because feeding practices result in greater exposure of one category;
- age of animals imported for *slaughter*;
- the effective implementation of the ban on feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants in the country or zone of origin before the birth of the imported animals.

Have live cattle been imported within the past seven years? Provide documentary evidence of the following:

- i) official statistics, to support claims that live cattle have not been imported including supporting legislation OR
 - ii) the country or zone of origin and volume of imports, official statistics, where relevant, in table form, and evidence of compliance with the requirements of Articles 11.4.6. to 11.4.9.
- c) The potential for the entry of the classical BSE agent through the importation of potentially infected products of ruminant origin

The likelihood of entry is dependent on:

- the BSE status of the country or zone of origin and whether these products contain tissues known to contain BSE infectivity (Article 11.4.13.);
- dairy versus meat breeds, where there are differences in exposure in the country or zone of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

What products of ruminant origin have been imported within the past seven years? This includes all products of ruminant origin that are not considered as safe commodities in Article 11.4.1., in particular products listed in points 1 a) v), vi) and vii) of Article 11.4.2. Provide documentary evidence of the following:

- i) the country or zone of origin and volume of imports, in table form, of all products of ruminant origin that are not considered as safe commodities in Article 11.4.1.;
- ii) evidence of compliance with the requirements of Chapter Article 11.4.26.

3. Exposure assessment

- a) The origin of ruminant carcasses, by-products and slaughterhouse/abattoir waste, the parameters of the rendering processes

The overall risk of BSE in the cattle *population* of a country or zone is proportional to the potential for recycling and amplification of the infectivity through rendering practices. For the *risk assessment* to conclude that the cattle *population* of a country or zone is of negligible or controlled BSE risk, it must have demonstrated that appropriate measures have been taken to manage any risks identified. If potentially infected cattle or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity.

Annex 26 (contd)

The Rendering is a process by which inedible animal by-products and slaughter waste, including bones and fallen stock, are transformed into *meat-and-bone meal*.

How have ruminant carcasses, by-products and slaughterhouse/abattoir waste been processed over the past eight years? Provide the following:

- i) A description of the collection and disposal of fallen stock, non-inedible animal by-products, and materials condemned as unfit for human consumption. If your country manages by-products derived from imported cattle are managed differently, describe the process.
- ii) A description of the definition, collection and disposal of material listed in Article 11.4.14.
- iii) A description of the rendering industry and processes and parameters used to produce ruminant meat-and-bone meal and greaves.
- iv) Documentation describing monitoring and enforcement of the above.
- v) Information in a table (see below), on including the audit findings in rendering plants processing material of ruminant origin (including mixed species containing ruminant material) and only material of non-ruminant origin (e.g., fish, poultry, pig, horse), related to the prohibition of the feeding to ruminants of meat-and-bone meal and greaves. The sampling objectives to detect whether material of non-ruminant origin could have been contaminated with ruminant material.

| Year (information should be provided for each of the eight years for which effectiveness is claimed) | Type of renderers | Number of plants | Number of plants in (A) inspected under Competent Authority supervision | Number of inspections in (B) in total | Total number of plants in (B) with infractions | Total number of plants in (B) inspected under Competent Authority supervision with sampling | Total number of plants in (E) with positive test results |
|--|--|------------------|---|---------------------------------------|--|---|--|
| | (A) | (B) | (C) | (D) | (E) | (F) | |
| Year 1 | Material of ruminant origin (or mixed species) | | (e.g.: < or = to A) | (e.g.: > or = to B) | (e.g.: < or = to B) | Not applicable for the purposes of the dossier | Not applicable for the purposes of the dossier |
| | Only material of non-ruminant origin | | (e.g.: < or = to A) | (e.g.: > or = to B) | (e.g.: < or = to B) | (e.g.: < or = to B) | (e.g.: < or = to E) |
| Year 2, etc. | Material of ruminant origin (or mixed species) | | | | | Not applicable for the purposes of the dossier | Not applicable for the purposes of the dossier |
| | Only material of non-ruminant origin | | | | | | |

- vi) Information in a table (see below), on each rendering plant referred to above processing material of ruminant origin (including mixed species containing ruminant material) and only material of non-ruminant origin (e.g., fish, poultry, pig, horse) with infractions, specifying the type of infraction (columns D and F of the table above) and the method of resolution.

Annex 26 (contd)

| Year (information should be provided for each of the eight years for <u>which</u> effectiveness is claimed) | Type of renderers | Plant ID | Nature of infraction | Method of resolution | Follow-up results |
|--|--|----------------------------|-----------------------------|-----------------------------|--------------------------|
| Year 1 | Material of ruminant origin (or mixed species) | ID 1 ID 2 ID 3, etc. | | | |
| | Only material of non-ruminant origin | ID 1 ID 2 ID 3, etc. | | | |
| Year 2, etc. | Material of ruminant origin (or mixed species) | | | | |
| | Only material of non-ruminant origin | | | | |

- b) The potential for the exposure of cattle to the classical and atypical BSE agents through consumption of meat-and-bone meal or greaves of ruminant origin

The overall risk of BSE in the cattle *population* of a country or zone is proportional to the level of known or potential exposure to BSE infectivity. If cattle have not been fed products of ruminant origin (other than *milk* or blood) potentially containing *meat-and-bone meal* or *greaves* of ruminant origin within the past eight years, *meat-and-bone meal* and *greaves* can be dismissed as a risk. Where *meat-and-bone meal* is utilised in the production of any *cattle ruminant feed*, *the a* risk of cross-contamination exists.

Countries applying for negligible risk status will be required to demonstrate that the ruminant *feed ban* has been effective for at least eight years.

Feed mills are processing plants where different *feed ingredients* are mixed and processed together to produce compound feed for animals. This should include on-farm *feed* producers that keep cattle.

Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the past eight years (Articles 11.4.3. and 11.4.4. in the Terrestrial Code)? Describe the following:

- i) the *feed* industry, including repartition between *feed mills* producing *feed* for ruminant only, *feed* for non-ruminant only and *feed* for both;
- ii) methods of animal *feed* production, including details of ingredients used, the extent of use of *meat-and-bone meal* (including of non-ruminant origin) in any livestock *feed*;
- iii) the use of imported *meat-and-bone meal* and *greaves* (including of non-ruminant origin), their country or zone of origin, including the feeding of any animal species;
- iv) the use made of *meat-and-bone meal* and *greaves* produced from ruminants, including the feeding of any animal species;
- v) the measures taken to control cross-contamination of ruminant *feedstuffs feed ingredients* with the *meat-and-bone meal* and *greaves* including the risk of cross-contamination during production, transport, storage and feeding;
- vi) provide details in a table, on the audit findings in *feed mill* processing *feed* for ruminant only, for non-ruminant only and for both, related to the prohibition of the feeding to ruminants of *meat-and-bone meal* and *greaves*. The sampling aims to detect whether material of ruminant origin could have contaminated *feed* intended to ruminant;

Annex 26 (contd)

| Year (information should be provided for each of the eight years for <u>which</u> effectiveness is claimed) | Type of feed mill | Number of feed mills | Number of feed mills in (A) inspected under Competent Authority supervision | Number of inspections in (B) in total | Total number of feed mills in (B) with infractions | Total number of inspected feed mills in (B) with sampling | Total number of feed mills in (E) with positive test results |
|---|-----------------------|-------------------------|--|---|--|--|---|
| | | (A) | (B) | (C) | (D) | (E) | (F) |
| Year 1 | For ruminant only | | | | | | |
| | For non-ruminant only | | | | | Not applicable for the purposes of the dossier | Not applicable for the purposes of the dossier |
| | For both | | | | | | |
| Year 2, etc. | For ruminant only | | | | | | |
| | For non-ruminant only | | | | | Not applicable for the purposes of the dossier | Not applicable for the purposes of the dossier |
| | For both | | | | | | |

- vii) details in a table, on each feed mill processing feed for ruminant only, for non-ruminant only and for both, with infractions, specifying the type of infraction (columns D and F of the table above) and the method of resolution;

| Year (information should be provided for each of the eight years for <u>which</u> effectiveness is claimed) | Type of feed mills | Feed mills ID | Nature of infraction | Method of resolution | Follow-up results |
|---|-----------------------|---------------|----------------------|----------------------|-------------------|
| Year 1 | For ruminant only | ID 1 | | | |
| | | ID 2 | | | |
| | | ID 3, etc. | | | |
| | For non-ruminant only | ID 1 | | | |
| | | ID 2 | | | |
| | | ID 3, etc. | | | |
| | For both | ID 1 | | | |
| | | ID 2 | | | |
| | | ID 3, etc. | | | |
| Year 2, etc. | For ruminant only | | | | |
| | For non-ruminant | | | | |

- viii) why, in light of the findings displayed in the preceding four tables (of Sections 4 and 5), it is considered that there has been no significant exposure of cattle to the BSE agent through consumption of *meat-and-bone meal* or greaves of ruminant origin;
- ix) husbandry practices (multiple species farms) which could lend themselves to cross-contamination of ruminant feed with *meat-and-bone meal* and greaves destined to other species.

Annex 26 (contd)Article 1.8.3.**BSE risk status requirements: Section 2 – other requirements (see points 2) to 4) of Article 11.4.2.)**1. Awareness programme (see point 2) of Article 11.4.2.)

An awareness programme is essential in ensuring detection and reporting of BSE, especially in countries of low prevalence and competing differential diagnoses. Provide documentary evidence of the following:

- a) when the awareness programme was implemented and its continuous application and geographical coverage;
- b) the number and occupation of persons who have participated in the awareness programme (farmers, livestock owners, animal handlers, veterinarians, producers, workers at livestock markets or auctions, workers at slaughterhouses/abattoirs, etc.);
- c) a description of the materials used in the awareness programme (the manual, supportive documents, or other teaching materials) (Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.);
- d) the-contingency plans or preparedness plans to deal with an occurrence of BSE.

2. Compulsory notification and investigation (see point 3) of Article 11.4.2.)

In order to ensure appropriate detection and follow-up of any BSE cases, appropriate legislation to support BSE control and eradication and effective regulatory controls and verification should be in place.

The socioeconomic implications associated with of BSE require that there be incentives and/or obligations to notify and investigate suspected cases.

- a) Describe What the guidance is given to farmers, livestock owners, animal handlers, veterinarians, workers at livestock markets or auctions, workers at slaughterhouses/abattoirs, veterinarians, producers, workers at auctions, slaughterhouses/abattoirs, etc. in terms of the criteria that would initiate the investigation of an animal suspected as being a case of as a BSE suspect? Have these criteria evolved and, if so, how?
- b) What was the date and content of the legal act making notification of suspected cases of BSE suspects compulsory?
- c) Describe the measures in place to stimulate notification, such as compensation payments or penalties for not notifying a suspected case.

3. Examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system described above (see point 4) of Article 11.4.2.)

Provide documentary evidence that the relevant provisions of Chapter 2.4.56. of the Terrestrial Manual are applied, including the following:

- a) if BSE laboratory diagnosis carried out in the country provide an overview of the approved laboratories where samples of cattle tissues from the country or zone are examined for BSE;
- b) if BSE laboratory diagnosis is not carried out in the country, provide the names of the laboratories in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results; information should be provided on the cooperation agreement);
- c) that these diagnostic procedures and methods have been applied through the entire surveillance period.

Annex 26 (contd)Article 1.8.4.**Section 3: BSE surveillance and monitoring systems (see point 1 b) iv) and point 4) of Article 11.4.2.)**

Articles 11.4.20. to 11.4.22. prescribe the number of cattle, by subpopulation, that need to be tested in order to ensure the detection of BSE at or above a minimal threshold prevalence.

- 1) Does the BSE surveillance programme comply with the guidelines in Articles 11.4.20. to 11.4.22. of the Terrestrial Code? Provide documentary evidence of the following:
 - a) that the samples collected are representative of the distribution of the cattle population in the country or zone, including by age and subpopulations as described in Article 11.4.21.;
 - b) the methods applied to assess the ages of animals sampled and the proportions for each method (individual identification, dentition, other methods to be specified);
 - c) the means and procedures whereby samples were assigned to the cattle subpopulations described in Article 11.4.21., including the specific provisions applied to ensure that animals described as clinical met the conditions of point 1) of Article 11.4.21. and that at least three of the four subpopulations have been sampled.
- 2) In a table (see below), provide details of all clinically suspected cases notified complying with the definition in point 1) of Article 11.4.21.

| Laboratory identification number | Age | Description of observed clinical signs | Point of detection (farm, market channels, slaughterhouse) | Final diagnosis |
|----------------------------------|-----|--|--|-----------------|
| | | | | |
| | | | | |

- 3) In a table (see below), provide details of the number of target points applicable to the country or zone and its BSE surveillance requirements (Type A or type B surveillance as a result of the risk assessment of Section 1) are met as described in Articles 11.4.21. and 11.4.22.

| SUMMARY TABLE FOR BSE SURVEILLANCE | | | | | | | | |
|---|-----------------------------|--------|--------------|--------|--------------------|--------|------------------|--------|
| Year: (complete a separate table for each year of surveillance) | | | | | | | | |
| | Surveillance subpopulations | | | | | | | |
| | Routine slaughter | | Fallen stock | | Casualty slaughter | | Clinical suspect | |
| | Samples | Points | Samples | Points | Samples | Points | Samples | Points |
| >1 and <2 years | | | | | | | | |
| >2 and <4 years | | | | | | | | |
| >4 and <7 years | | | | | | | | |
| >7 and <9 years | | | | | | | | |
| >9 years | | | | | | | | |
| Subtotals | | | | | | | | |
| Total points | | | | | | | | |

- 4) Provide the number of adult cattle (over 24 months of age) in the country or zone.

Annex 26 (contd)Article 1.8.5.**Section 4: BSE history of the country or zone (see Articles 11.4.3. and 11.4.4.)**

The categorisation of a country or zone in as either negligible or controlled risk is dependent upon, the outcome of the risk assessment described in Section 1, compliance with the provisions described in Section 2, the results of surveillance described in Section 3, and the history of BSE in the country or zone. Describe the BSE history in the country or zone by providing documentary evidence of the following:

- 1) Whether a case of BSE has ever been diagnosed in the country or zone.
- 2) In the case of positive BSE findings:
 - a) the numbers of BSE cases (classical and atypical), the origin of each BSE case in respect to the country or zone. Indicate the birth date and place of birth;
 - b) the most recent year of birth of the classical BSE cases;
 - c) that the case(s); and
 - d) all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation could not rule out consumption of the same potentially contaminated feed during that period; or
 - e) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE cases; and
 - f) if alive in the country or zone, how they are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Article 1.8.6.**Recovery of BSE risk status**

Member Countries applying for recognition of recovery of BSE risk status for a country or zone should comply with the provisions of Article 11.4.2. and Article 11.4.3. or Article 11.4.4. of the *Terrestrial Code* and provide detailed information as specified in this questionnaire.

CHAPTER 1.9Article 1.6.10.

**APPLICATION FOR OFFICIAL RECOGNITION BY
THE OIE OF FREE STATUS FOR
CLASSICAL SWINE FEVER**

Article 1.9.1**Country or zone free from infection with classical swine fever virus**

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country or zone free from infection with classical swine fever (CSF) virus in accordance with Chapter 15.2. of the Terrestrial Code.

CSF FREE COUNTRY OR ZONE

Report of a Member Country which applies for recognition of status,
under Chapter 15.2. of the Terrestrial Code,
as a CSF free country or zone

Please The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how this these complies comply with the Terrestrial Code.

Please use The terminology defined in the OIE Terrestrial Code and Terrestrial Manual should be referred to and used in compiling the dossier.

National legislation, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

Any All annexes should be provided in one of the OIE official languages.

[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]

8. Compliance with the Terrestrial Code

The Delegate of the Member Country applying for recognition of CSF freedom for a country or zone must demonstrate compliance with the Terrestrial Code. That is, the Delegate should submit documentary evidence that the provisions of Articles 15.2.2. and 15.2.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- a) there has been no outbreak of CSF or evidence of CSFV infection in domestic and captive wild pigs in the country or zone during the past 12 months;
- b) no vaccination against CSF has been carried out in domestic and captive wild pigs in the country or zone during the past 12 months; or, if vaccination is carried out, vaccinated and infected pigs can be distinguished by a means validated according to Chapter 2.8.3. of the Terrestrial Manual;
- c) imported pigs and pig commodities comply with the relevant requirements in Chapter 15.2.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.

Annex 27 (contd)1. Introduction

- a) Geographical ~~entities~~ features (rivers, mountain ~~ranges~~, etc.). Provide a general description of the country and the zone and, where relevant, of the region, including physical, geographical and other factors that are relevant to CSF introduction of infection and dissemination spread of CSF virus, taking into account the as well as a short description of countries or zones sharing common borders and other epidemiologic pathways links for the potential introduction of CSF infection. The boundaries of the country or zone must be clearly defined, including a protection zone, if applied.

Provide maps identifying the ~~factors~~ features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the country or zone.

Specify whether the application includes any noncontiguous territories.

- b) Pig industry. ~~Provide a general description of~~ Describe the composition of the domestic and captive wild pig industry in the country and the zone. In particular, describe:

- i) the types of production systems in the country and the zone;
- ii) the number of herds;
- iii) their geographical distribution;
- iv) herd density;
- v) the degree of integration and role of producer organisations in the different production systems;
- vi) any recent significant changes observed in the production (if attach relevant documents are if available, please attach).

Provide tables and maps.

- c) Wildlife demographics. What captive wild, wild or feral pigs are present in the country and the zone? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and captive wild pigs, and wild and feral pig populations?
- d) Slaughterhouses/abattoirs, markets and events associated with the congregation of susceptible livestock (e.g., fairs, shows, competitions). Where are the major pig marketing or collection centres? What are the patterns of pig movement for marketing within the country or zone, and between zones of the same or different status? How are the pigs sourced, transported and handled during these transactions? What proportions of slaughtered pigs are subjected to meat inspection in different production systems? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and Veterinary Authority directives in relation to CSF and a brief description of the relevance of each. This list The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) Veterinary Services. Describe how the Veterinary Services of the country comply with Chapters 1.1., 3.1. and 3.2. of the Terrestrial Code. Describe how the Veterinary Services supervise, and control, enforce and monitor all CSF-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in your the country and follow-up steps within the PVS Pathway and highlight the results relevant to CSF and pigs.

Annex 27 (contd)

- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, veterinary paraprofessionals including community animal health workers, and other relevant groups in CSF surveillance and control. Provide a description of the role and structure of the private veterinary sector, including number of veterinarians and their distribution, and role of the private veterinarians veterinary profession in CSF surveillance and control. Include a description of continuing education and awareness programmes on CSF at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are pigs identified (individually or at a group level)?

Provide a description of the traceability system, including methods of animal identification and establishment holding or herd registration and traceability for applicable to all susceptible species production systems.

How are pig movements controlled in the country or zone, or between zones of the same or different status for all susceptible species production systems?

Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, origin and destination of the pigs and their products moved within the country in the past two years 24 months.

Describe the *risk management* strategy for uncontrolled movements of pigs. Describe the actions available under national legislation.

~~Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on illegal movements detected in the past 24 months and the action taken.~~

3. CSF eradication

- a) History. If infection has never occurred in the country has never had the disease, or has not had it occurred within the past 25 years, please state explicitly whether or not the country or zone is applying for recognition of historical freedom according to Article 1.4.6. of the *Terrestrial Code*.

If infection has occurred in the country or zone has had the disease within the past 25 years, please provide a description of the CSF history in the country and zone, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the pigs involved, and the date of last case or eradication in the country or zone.

- b) Strategy. Describe how CSF was controlled and eradicated in the country or zone (e.g., *stamp-ing-out policy*, movement control, zoning). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future disease outbreaks of CSF in response to any past disease incursions of CSF virus.

- c) Vaccines and *vaccination*. Briefly answer the following:

- i) Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal vaccination during the reporting period and actions taken in response to the detection.
- ~~Describe the action available under legislation, and actually taken, when an illegal vaccination is detected;~~
- ~~Provide information on detected illegal vaccination during the reporting period.~~

Annex 27 (contd)

- ii) Was vaccination ever used in the country? If so:*
- Provide the date when the last *vaccination* was carried out;
 - What type of vaccine was used? If DIVA vaccine has been used, describe the type of differential tests and results;
 - Which pigs were vaccinated?
 - How were vaccinated pigs identified?
 - What was the fate of those pigs?
- iii) In addition, if vaccination was conducted applied during the past two years 24 months, provide a description and justification of the vaccination strategy and programme, including the following: regime. Briefly answer the following:*
- the vaccine serotypes:
 - the pigs vaccinated;
 - identification of vaccinated pigs;
 - the way in which the *vaccination* of pigs was certified or reported and the records maintained;
 - Provide evidence that the vaccine used complies with Chapter 2.8.3. of the Terrestrial Manual.
- d) Provide a description of the legislation, organisation and implementation of the eradication campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.*

4. CSF diagnosis

Provide documentary evidence that the relevant provisions in Chapters 1.1.2., 1.1.3. and 2.8.3. of the *Terrestrial Manual* are applied. In particular, The following points should be addressed:

- a) Is CSF *laboratory* diagnosis carried out in the country? If so, provide an overview of the CSF-approved laboratories in the country. If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results. Indicate the *laboratories* where samples originating from the zone are diagnosed.*
- b) Provide an overview of the CSF approved laboratories in the country. Address the following points:*
- i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for obtaining reporting results;*
 - ii) Details on of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of CSF tests performed in the past two years 24 months in the national *laboratories* and in *laboratories in other countries, if relevant as well as abroad*;*
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g., Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;*
 - iv) Provide details of performance in inter-laboratory validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;*

Annex 27 (contd)

- v) Provide details of the handling of live pathogenic agent. In particular, describe including a description of the biosecurity and biosafety measures applied;
- vi) Provide a table linking identifying the tests carried out to by each of the laboratories where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If CSF laboratory diagnosis is not carried out in the country, provide the names of the laboratories in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. CSF surveillance

Provide documentary evidence that surveillance for CSF in the country or zone complies with Articles 15.2.26. to 15.2.32. of the *Terrestrial Code* and Chapter 2.8.3. of the *Terrestrial Manual*. In particular, The following information should be included points should be addressed:

- a) What are the criteria for raising a suspicion of CSF? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which levels sectors of the pig production population system are included in clinical *surveillance*, such as establishments farms, markets, fairs, slaughterhouses/abattoirs, check points, etc.

Provide a summary table indicating, for the past two years 24 months, the number of suspected cases, the number of samples tested for CSF, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude CSF. Provide details on follow-up actions taken on all suspicious and positive results.

- c) Serological and or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used) in accordance with Articles 15.2.26. to 15.2.32. of the Terrestrial Code. How frequently are they conducted? Are *wild* and *feral* pigs included in *surveillance*? If not, explain the rationale. For both serological and virological *surveillance* provide a summary table indicating, for the past 12 24 months, the number of samples tested for CSF, type of sample, testing methods and results (including differential diagnosis). Include in the table the number of false-positive results obtained on screening tests. Provide details on of follow-up actions taken on all suspicious and positive results and on how these findings are interpreted and acted upon. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of pigs examined and samples tested in diagnostic *laboratories*. Provide details of on the methods selected and applied for monitoring the performance of the *surveillance* system including indicators.
- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g., targeted serological surveys, active *surveillance*, participatory epidemiology studies, risk assessments, etc.). Provide evidence of how and that the acquired knowledge acquired through these activities assisted assists in more effective implementation of control measures.
- e) Provide details on of the oversight of surveillance programmes by the Veterinary Services including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in CSF *surveillance* programmes.

6. CSF prevention

Describe the procedures in place to prevent the introduction of CSF into the country, including In particular, provide details of on:

Annex 27 (contd)

- a) Coordination with other countries. Describe any relevant factors about adjacent in neighbouring countries or zones that should be taken into account (e.g., size, distance from the border to affected herds or animals). Describe coordination, collaboration and information-sharing activities with other countries and zones in the same region or ecosystem.

If the CSF free zone is ~~situated established~~ in a CSF infected country or borders an infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration existing physical or geographical barriers.

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed free country or zones. Provide details ~~on of~~ the measures that are applied (e.g., vaccination, intensified surveillance, density control of pigs), and provide a geo-referenced map of the zones.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation spread of the pathogenic agent within the country or zone and through trade. Provide evidence that measures to reduce transmission of CSF are in place at markets, such as enhancing awareness of CSF transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity practices*, hygiene, cleaning and disinfection routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

- c) What measures are taken to limit access of susceptible domestic, *captive wild*, *feral* and *wild* pigs to waste products of animal origin? Is the feeding of swill ~~containing animal products~~ to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

- d) Import control procedures

Provide information on countries, zones or compartments from which the country authorises the import of pigs or their products into the country or zone. Describe the criteria applied to approve such countries, zones or compartments, the controls applied ~~on to~~ entry of such pigs and products and subsequent internal movement. Describe the import measures conditions (e.g., quarantine) and test procedures required. Advise whether imported pigs are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health international veterinary certificates are required.

Describe any other procedures used for assessing the risks posed by import of pigs or their products. Provide summary statistics on imports of pigs and their products for at least the past ~~two years 24 months~~, including temporary import and re-entry, specifying countries, zones or compartments of origin, species and the quantity or volume and eventual destination in the country or zone.

Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts;
- ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past ~~two years 24 months~~, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?
- iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or zone or their final destination, concerning the import and follow-up of the following:
 - pigs;
 - genetic material (semen, oocytes and embryos);
 - *fresh meat*, pig products and by-products;
 - *veterinary medicinal products* (i.e. *biologics, vaccines*);
 - other materials at risk of being contaminated with CSF virus.

Annex 27 (contd)7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the Veterinary Services for dealing with suspected or confirmed *outbreaks* of CSF. The contingency plan should be attached as an annex in one of the OIE official languages. ~~and, If not available, provide a brief summary of what is covered should be provided.~~ Provide information on any simulation exercise for CSF that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed CSF *outbreak*:
 - i) ~~Is Are quarantine measures imposed on establishments premises with suspicious suspected cases, pending final diagnosis? What other procedures are followed regarding suspicious with respect to suspected cases (e.g., standstills)?~~
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the causative pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the establishments premises where the *outbreak was is* confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g., forward and backward tracing, movement control, *disinfection* of establishments premises, vehicles and equipment, including verification methods, policies on emergency vaccination, *stamping-out policy*, partial *slaughter*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency vaccination, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological surveillance programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when pigs are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments.
 - vii) Describe how control efforts, including vaccination and biosecurity, would target critical risk control points.
- c) If DIVA vaccine is used as part of risk mitigation, provide details of the vaccine and the differential tests.

8. Compliance with the Terrestrial Code

~~The Delegate of the Member Country applying for CSF freedom must submit documentary evidence that the provisions of Articles 15.2.2. and 15.2.3. have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating:~~

- a) ~~there has been no outbreak of CSF or evidence of CSFV infection in domestic and captive wild pigs in the country or zone during the past 12 months;~~
- b) ~~no vaccination against CSF has been carried out in domestic and captive wild pigs in the country or zone during the past 12 months; or, if vaccination is carried out, vaccinated and infected pigs can be distinguished by a means validated according to Chapter 2.8.3. of the Terrestrial Manual;~~
- c) ~~imported pigs and pig commodities comply with the relevant requirements in Chapter 15.2.~~

~~The Delegate of the Member Country applying for historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.~~

Annex 27 (contd)89. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country or zone should comply with Article 15.2.6. of the *Terrestrial Code* and provide detailed information as specified in Sections 3 a), 3 b), 3 c), 5 b) and 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

CHAPTER 1.10.

Article 1.6.7.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF FREE STATUS FOR CONTAGIOUS BOVINE PLEUROPNEUMONIA

CBPP FREE COUNTRY

~~Report of a Member Country which applies for recognition of status,
under Chapter 11.75. of the Terrestrial Code,
as a CBPP free country~~

Article 1.10.1.

Country free from infection with *Mycoplasma mycoides* subsp. *mycoides* SC (contagious bovine pleuropneumonia)

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country free from infection with *Mycoplasma mycoides* subsp. *mycoides* SC (MMmsSC) in accordance with Chapter 11.75. of the Terrestrial Code.

The dossier provided to the OIE should Please address concisely all the following topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these this complies comply with the Terrestrial Code.

Please use The terminology defined in the OIE Terrestrial Code and Terrestrial Manual should be referred to and used in compiling the dossier.

National legislation, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

Any All annexes should be provided in one of the OIE official languages.

[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]

The Delegate of the Member Country applying for recognition of CBPP freedom for a country must demonstrate compliance with the Terrestrial Code. That is, the Delegate should submit documentary evidence that the provisions of Article 11.57.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- a) there has been no outbreak case of infection with *Mycoplasma mycoides* subsp. *mycoides* SC MMmsSC during the past 24 months;
- b) no evidence of CBPP infection with *Mycoplasma mycoides* subsp. *mycoides* SC MMmsSC has been found during the past 24 months;
- c) no vaccination against CBPP has been carried out during the past 24 months.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.

Annex 28 (contd)1. Introduction

- a) Geographical entities features (rivers, mountain ranges, etc.). Provide a general description of the country and, when where relevant, of the region, including physical, geographical and other factors that are relevant to CBPP introduction of infection and dissemination spread of MMmsSC, taking into account the as well as a short description of countries sharing common borders and other epidemiologic pathways links for the potential introduction of infection CBPP.

Provide maps identifying the factors features above.

Specify whether the application includes any noncontiguous territories.

- b) Livestock demographics. Provide a general description of Describe the composition of the livestock industry in the country. In particular, describe:

- i) the susceptible animal *population* by species and types of production systems;
- ii) the number of *herds*, etc. of each susceptible species;
- iii) their geographical distribution;
- iv) *herd density*;
- v) the degree of integration and role of producer organisations in the different production systems;
- vi) any recent significant changes observed in the production (if attach relevant documents are if available), please attach.

Provide tables and maps.

- c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g., fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movements of domestic susceptible species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and *Veterinary Authority* directives in relation to CBPP and a brief description of the relevance of each. This list The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) Veterinary Services. Describe how the Veterinary Services of the country comply with the provisions of Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the Veterinary Services supervise, and control, enforce and monitor all CBPP-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in your the country and follow-up steps within the PVS Pathway and highlight the results relevant to CBPP and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers including subsistence and small-scale producers and keepers, veterinary paraprofessionals including community animal health workers, and other relevant groups in CBPP surveillance and control. Provide a description of the structure and role and structure of the private veterinary sector, including number of veterinarians and their distribution, in CBPP surveillance and control. Include a description of continuing education and awareness programmes on CBPP at all relevant levels.

Annex 28 (contd)

- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of animal identification and establishment holding or herd registration and traceability for applicable to all susceptible species production systems.

How are animal movements controlled in the country for all susceptible species production systems?

Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past two years 24 months.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g., seasonal migration). Describe the actions available under national legislation.

~~, and actually taken, when an illegal import is detected.~~ Provide information on illegal movements detected in the past 24 months and the action taken.

3. CBPP eradication

- a) History. If infection has never occurred in the country ~~has never had the disease~~, or has not occurred had it within the past 25 years, please state explicitly whether or not the country is applying for recognition of historical freedom according to Article 1.4.6. of the Terrestrial Code.

If ~~the country has had the disease~~ infection has occurred in the country within the past 25 years, provide a description of the CBPP history in the country, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of last case or *eradication* in the country.

- b) Strategy. Describe how CBPP was controlled and eradicated (e.g., slaughter policy, *zoning*, *vaccination*, movement control). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~disease outbreaks of CBPP~~ in response to any past ~~disease~~ incursions of MMmsSC.

- c) Vaccines and *vaccination*. Briefly answer the following:

- i) Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal vaccination during the reporting period and actions taken in response to the detection.

~~Describe the action available under legislation, and actually taken, when an illegal vaccination is detected;~~

- ii) Was *vaccination* ever used in the country? If so:

- Provide the date when the last *vaccination* was carried out;
- What type of vaccine was used?
- What species were vaccinated?
- How were vaccinated animals identified?
- What was the fate of those animals?

Annex 28 (contd)

- iii) In addition, if vaccination was conducted applied during the past two years 24 months, provide a description and justification of the vaccination strategy and programme, including the following: regime. Briefly answer the following:*
- = the vaccine strains:
 - the species vaccinated;
 - identification of vaccinated animals;
 - the way in which the vaccination of animals was certified or reported and the records maintained;
 - Provide evidence that the vaccine used complies with Chapter 2.4.8. of the *Terrestrial Manual*.
- d) Provide a description of the legislation, organisation and implementation of the eradication campaign. Outline the legislation applicable to the eradication and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.*
4. CBPP diagnosis
- Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.4.8. of the *Terrestrial Manual* are applied. In particular, The following points should be addressed:
- a) Is CBPP laboratory diagnosis carried out in the country? If so, provide an overview of the CBPP-approved laboratories in the country, including the following: If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.*
- b) Provide an overview of the CBPP approved laboratories in the country. Address the following points:*
- i) How the work is shared between different laboratories, logistics for shipment of samples, the follow-up procedures and the time frame for obtaining reporting results;*
 - ii) Details of test capability, and the types of tests undertaken, including procedures to isolate and identify *M. mycoides* subsp. *mycoides* (*Mmm*), and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of CBPP tests performed in the past two years 24 months in the national laboratories and in laboratories in other countries, if relevant as well as abroad;*
 - iii) Procedures for quality assurance and for the official accreditation of laboratories. Give details of formal internal quality management systems, e.g., Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system;*
 - iv) Provide details of performance in inter-laboratory validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;*
 - v) Provide details of the handling of live pathogenic agent, In particular, describe including a description of the biosecurity and biosafety measures applied;*
 - vi) Provide a table linking identifying the tests carried out to by each of the laboratories where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.*
- b) If CBPP laboratory diagnosis is not carried out in the country, provide the names of the laboratories in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.*

Annex 28 (contd)5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the country complies with Articles 11.75.13. to 11.75.175. of the *Terrestrial Code* and Chapter 2.4.8. of the *Terrestrial Manual*. ~~In particular, The following information should be included~~ ~~points should be addressed:~~

- a) What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which ~~levels of the sectors of the~~ livestock production system are included in clinical *surveillance*, such as ~~establishments~~ farms, markets, fairs, slaughterhouses/abattoirs, check points, etc.

Provide a summary table indicating, for the past ~~two years~~ 24 months, the number of suspected cases, the number of samples tested for CBPP, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude CBPP. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Serological *surveillance*. Explain whether serological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the ~~survey design~~ (*target population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used) in accordance with Articles 11.75.13. ~~and to~~ 11.75.4517. of the *Terrestrial Code*.
- d) Slaughterhouses/abattoirs and slaughter slabs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past ~~two years~~ 24 months, the number of suspected cases, the number of samples tested for CBPP agent, species, type of sample, testing methods and results (including differential diagnosis).
- e) For countries where a significant proportion of animals are not slaughtered in controlled slaughterhouses/abattoirs, what are the alternative *surveillance* measures applied to detect CBPP (e.g., active clinical *surveillance* programmes, laboratory follow-up).
- f) Provide a description of the means employed during the ~~two years~~ 24 months preceding this application to rule out the presence of CBPP in the susceptible *population*. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of animals examined and samples tested. Provide details of the methods selected and applied for monitoring the performance of the *surveillance programme system* including indicators.
- g) Provide details of the oversight of surveillance programmes by the Veterinary Services including training programmes for personnel involved in clinical and *slaughterhouse/abattoir surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.

6. CBPP prevention

Describe the procedures in place to prevent the introduction of CBPP into the country, ~~In particular, provide including~~ details of:

- a) Coordination with other countries. Describe any relevant factors ~~about adjacent in neighbouring~~ countries that should be taken into account (e.g., size, distance from the border to affected herds or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

Are protection zones in place? If so, provide details of the measures that are applied (e.g., vaccination, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the zones.

Annex 28 (contd)

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread propagation of the pathogenic agent within the country ~~and through trade~~. Provide evidence that measures to reduce transmission of CBPP are in place at markets, such as enhancing awareness of CBPP transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good biosecurity practices, hygiene cleaning and disinfection routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

c) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied ~~on to~~ entry of such animals and products and subsequent internal movement. Describe the import measures conditions (e.g., quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and ~~health~~ international veterinary certificates are required.

Describe any other procedures used for assessing the *risks posed by* of import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past ~~two years~~ 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country.

Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map showing the number and location of all ports, airports and land ~~border~~ crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border inspection posts*, and between *border inspection posts*.
- ii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - *Mmm* strains including vaccines;
 - veterinary medicinal products;
 - other materials at risk of being contaminated with *Mmm*.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of CBPP. The contingency plan should be attached as an annex in one of the OIE official languages. ~~and, If not available, provide~~ a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for CBPP that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed CBPP *outbreak*:
 - i) ~~Is Are~~ quarantine measures imposed on establishments premises with suspicious suspected cases, pending final diagnosis? What other procedures are followed ~~regarding~~ suspicious with respect to suspected cases (e.g., livestock standstills)?

Annex 28 (contd)

- ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the causative pathogenic agent;*
- iii) Describe the actions that would be taken to control the disease situation in and around the premises establishments where the outbreak was confirmed;*
- iv) Provide a detailed description of the control or eradication procedures (e.g., forward and backward tracing, disinfection of premises establishments premises, vehicles and equipment, including verification methods, vaccination, stamp-out policy, slaughter policy, movement control, pastured livestock and livestock as pets, control of offal, especially lungs, and carcasses, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken.*
- v) In the case of emergency vaccination, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;*
- vi) Describe the criteria and procedures that would be used to confirm that an outbreak has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological surveillance programmes, etc.;*
- vii) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or eradication purposes and the prescribed timetable for payments;*
- viii) Describe how control efforts, including vaccination and biosecurity measures, would target critical risk control points.*

8. Compliance with the Terrestrial Code/NB moved to beginning of chapter]

The Delegate of the Member Country applying for CBPP freedom must submit documentary evidence that the provisions of Article 11.57.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- a) there has been no outbreak of CBPP during the past 24 months;*
- b) no evidence of CBPP infection has been found during the past 24 months;*
- c) no vaccination against CBPP has been carried out during the past 24 months.*

The Delegate of the Member Country applying for historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.

89. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 11.57.4. of the Terrestrial Code and provide detailed information as specified in Sections 3 a), 3 b), 3 c), 5 a), 5 b), 5 c) and 5 d) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Annex 28 (contd)Article 1.10.2.**Zone free from infection with *Mycoplasma mycoides* subsp. *mycoides* SC (contagious bovine pleuropneumonia)**

The information should be provided by OIE Member Countries to support applications for official recognition of status as a zone free from infection with *Mycoplasma mycoides* subsp. *mycoides* SC (MMmsSC) in accordance with Chapter 11.7. of the *Terrestrial Code*.

CBPP FREE ZONE

~~Report of a Member Country which applies for recognition of status, under Chapter 11.7. of the Terrestrial Code,~~

~~as a CBPP infection free zone~~

~~The dossier provided to the OIE should Please address concisely all the following topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how these this complies comply with the Terrestrial Code.~~

Please use The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

Any All annexes should be provided in one of the OIE official languages.

[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]

The Delegate of the Member Country applying for recognition of CBPP freedom for a zone must demonstrate compliance with the Terrestrial Code. That is, the Delegate should submit documentary evidence that the provisions of Article 11.57.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- a) there has been no outbreak case of infection with MMmsSC during the past 24 months;
- b) no evidence of CBPP infection with MMmsSC has been found during the past 24 months;
- c) no vaccination against CBPP has been carried out during the past 24 months.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.

1. Introduction

- a) Geographical entities features (rivers, mountain ranges, etc.). Provide a general description of the country and the zone and, when relevant, of the region, including physical, geographical and other factors that are relevant to CBPP introduction of infection and spread of MMmsSC and dissemination, taking into account the as well as a short description of countries or zones sharing common borders and other epidemiologic pathways links for the potential introduction of infection CBPP. The boundaries of the zone must be clearly defined, including a protection zone, if applied.

Provide maps identifying the features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone.

Annex 28 (contd)

- b) Livestock demographics. ~~Provide a general description~~ Describe the composition of the livestock industry in the country and the zone. In particular, describe:
- i) the susceptible animal *population* by species and types of production systems in the country and the zone;
 - ii) the number of *herds*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (*if attach relevant documents are if available, please attach*).

Provide tables and maps.

- c) *Wildlife* demographics. What susceptible *captive wild, wild or feral* species are present in the country and the zone? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g., fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movements of domestic susceptible species for marketing within the country or zone, and between zones of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and *Veterinary Authority* directives in relation to CBPP and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with ~~the provisions of Chapters 1.1., 3.1. and 3.2. of the Terrestrial Code~~. Describe how the *Veterinary Services* supervise, ~~and control, enforce and monitor~~ all CBPP-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in ~~your~~ the country and follow-up steps within the PVS Pathway and highlight the results relevant to CBPP and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers including subsistence and small-scale producers and keepers, veterinary paraprofessionals including community animal health workers, and other relevant groups in CBPP surveillance and control. Provide a description of the role and structure of the private veterinary sector, including number of veterinarians and their distribution, in CBPP surveillance and control. Include a description of continuing education and awareness programmes on CBPP at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of the traceability system, animal identification and establishment holding or herd registration and traceability applicable to for all susceptible species production systems.

Annex 28 (contd)

How are animal movements controlled in and between zones of the same or different status for all susceptible species production systems?

Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past two years 24 months.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g., seasonal migration). Describe the actions available under national legislation. and actually taken, when an illegal import is detected.

Provide information on illegal movements detected in the past 24 months and the action taken.

3. CBPP eradication

- a) History. If infection has never occurred in the zone has never had the disease, or has not occurred had it within the past 25 years, please state explicitly whether or not the zone is applying for recognition of historical freedom in the zone according to Article 1.4.6. of the *Terrestrial Code*.

If infection has occurred in the zone has had the disease within the past 25 years, provide a description of the CBPP history in the country and zone, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of last case or *eradication* in the zone.

- b) Strategy. Describe how CBPP was controlled and eradicated in the zone (e.g., slaughter policy, *zoning*, *vaccination*, movement control, etc.). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future disease outbreaks of CBPP in response to any past disease incursions of MMmsSC.

- c) Vaccines and *vaccination*. Briefly answer the following:

- i) Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal vaccination during the reporting period and actions taken in response to the detection.
- Describe the action available under legislation, and actually taken, when an illegal vaccination is detected;
- Provide information on detected illegal vaccination during the reporting period.

- ii) Was *vaccination* ever used in the country? If so:

- Provide the date when the last *vaccination* was carried out;
- What type of vaccine was used in the zone and the rest of the country?
- What species were vaccinated?
- How were vaccinated animals identified?
- What was the fate of those animals?

Annex 28 (contd)

- iii) In addition, if vaccination was conducted applied during the past two years 24 months, provide a description and justification of the vaccination strategy and programme, including the following regime. Briefly answer the following:*
- the vaccine strains;
 - the species vaccinated;
 - identification of vaccinated animals;
 - the way in which the vaccination of animals was certified or reported and the records maintained;
 - Provide evidence that the vaccine used complies with Chapter 2.4.8. of the *Terrestrial Manual*.
- d) Provide a description of the legislation, organisation and implementation of the eradication campaign. Outline the legislation applicable to the eradication and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.*
4. CBPP diagnosis
- Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.4.8. of the *Terrestrial Manual* are applied. In particular, The following points should be addressed:
- a) Is CBPP *laboratory* diagnosis carried out in the country? If so, provide an overview of the CBPP-approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.~~ Indicate the *laboratories* where samples originating from the zone are diagnosed.
- b) Provide an overview of the CBPP approved laboratories in the country. Address the following points:*
- i) How the work is shared between different laboratories, logistics for shipment of samples, the follow-up procedures and the time frame for obtaining reporting results;*
 - ii) Details of ~~on~~ test capability, and the types of tests undertaken, including procedures to isolate and identify *M. mycoides* subsp. *mycoides* (*Mmm*), and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of CBPP tests performed in the past two years 24 months in the national laboratories and in laboratories in other countries, if relevant as well as abroad;*
 - iii) Procedures for quality assurance and for the official accreditation of laboratories. Give details of formal internal quality management systems, e.g., Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system;*
 - iv) Provide details of performance in inter-laboratory validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;*
 - v) Provide details of the handling of live pathogenic agent, In particular, describe including a description of the biosecurity and biosafety measures applied;*
 - vi) Provide a table linking identifying the tests carried out to by each of the laboratories where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.*
- b) If CBPP laboratory diagnosis is not carried out in the country, provide the names of the laboratories in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.*

Annex 28 (contd)5. CBPP surveillance

Provide documentary evidence that *surveillance* for CBPP in the *zone* complies with Articles 11.75.13. to 11.75.175. of the *Terrestrial Code*, and Chapter 2.4.8. of the *Terrestrial Manual*. In particular, The following information should be included points should be addressed:

- a) What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which sectors levels of the livestock production system are included in clinical *surveillance*, such as establishments farms, markets, fairs, slaughterhouses/abattoirs, check points, etc.

Provide a summary table indicating, for the past two years 24 months, the number of suspected cases, the number of samples tested for CBPP, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude CBPP. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Serological *surveillance*. Explain whether serological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used) in accordance with Articles 11.75.13. and to 11.75.1517. of the *Terrestrial Code*.
- d) Slaughterhouses/abattoirs and slaughter slabs. What are the criteria for raising a suspicion of CBPP lesion? What is the procedure to notify (by whom and to whom)? Provide a summary table indicating, for the past two years 24 months, the number of suspected cases, the number of samples tested for CBPP agent, species, type of sample, testing methods and results (including differential diagnosis).
- e) For countries where a significant proportion of animals in the *zone* are not slaughtered in controlled slaughterhouses/abattoirs, what are the alternative *surveillance* measures applied to detect CBPP (e.g., active clinical *surveillance* programmes, laboratory follow-up).
- f) Provide a description of the means employed during the two years 24 months preceding this application to rule out the presence of CBPP in the susceptible *population* of the *zone*. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the surveillance programme system including indicators.
- g) Provide details of the oversight of surveillance programmes by the Veterinary Services including training programmes for personnel involved in clinical and *slaughterhouse/abattoir surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.

6. CBPP prevention

Describe the procedures in place to prevent the introduction of CBPP into the country or *zone*, In particular, provide including details of:

- a) Coordination with other countries. Describe any relevant factors about adjacent in neighbouring countries and zones that should be taken into account (e.g., size, distance from the border to affected herds or animals). Describe coordination, collaboration and information-sharing activities with other countries and zones in the same region or ecosystem.

If the CBPP free *zone* is situated established in a CBPP infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration existing physical or geographical barriers.

Annex 28 (contd)

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed free zones. Provide details of the measures that are applied (e.g., vaccination, intensified surveillance, density control of susceptible species), and provide a geo-referenced map of the zones.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation spread of the pathogenic agent within the country or zone and through trade. Provide evidence that measures to reduce transmission of CBPP are in place at markets, such as enhancing awareness of CBPP transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity practices*, hygiene-, cleaning and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).
- c) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country or zone? Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied ~~or to~~ entry of such animals and products and subsequent internal movement. Describe the import measures conditions (e.g., quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health international veterinary certificates are required.

Describe any other procedures used for assessing the *risks posed by* of import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past ~~two years~~ 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country.

Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - *Mmm* strains including vaccines;
 - *veterinary medicinal products*;
 - other materials at risk of being contaminated with *Mmm*.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of CBPP. The contingency plan should be attached as an annex in one of the OIE official languages. ~~and, If not available, provide~~ a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for CBPP that was conducted in the country in the past five years.

Annex 28 (contd)

- b) In the event of a suspected or confirmed CBPP outbreak:
- i) Is Are quarantine measures imposed on establishments premises with suspicious suspected cases, pending final diagnosis? What other procedures are followed regarding suspicious with respect to suspected cases (e.g., livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the causative pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the establishments premises where the outbreak was is confirmed;
 - iv) Provide a detailed description of the control or eradication procedures (e.g., forward and backward tracing, disinfection of establishments premises, vehicles and equipment, including verification methods, vaccination, stampin-out policy, slaughter policy, movement control, pastured livestock and livestock as pets, control of offal, especially lungs, and carcasses, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken;
 - v) In the case of emergency vaccination, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - vi) Describe the criteria and procedures that would be used to confirm that an outbreak has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological surveillance programmes, etc.;
 - vii) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or eradication purposes and the prescribed timetable for payment;
 - viii) Describe how control efforts, including vaccination and biosecurity measures, would target critical risk control points.

8.- Compliance with the Terrestrial Code

The Delegate of the Member Country applying for CBPP freedom must submit documentary evidence that the provisions of Article 11.57.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that in the zone:

- a) there has been no outbreak of CBPP during the past 24 months;
- b) no evidence of CBPP infection has been found during the past 24 months;
- c) no vaccination against CBPP has been carried out during the past 24 months,

The Delegate of the Member Country applying for historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.

89. Recovery of free status

Member Countries applying for recognition of recovery of free status for a zone should comply with the provisions of Article 11.57.4. of the Terrestrial Code and provide detailed information as specified in Sections 3 a), 3 b), 3 c), 5 a), 5 b), 5 c) and 5 d) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Annex 28 (contd)Article 1.10.3.1.6.13.Application for endorsement by the OIE of an official control programme for contagious bovine pleuropneumoniaQuestionnaire on endorsement of official control programme for contagious bovine pleuropneumonia (CBPP)**COUNTRY WITH AN OIE ENDORSED OFFICIAL CONTROL PROGRAMME FOR CBPP**

Report of a Member Country which applies for the OIE endorsement
of its official control programme for CBPP
under Chapter 11.75. of the *Terrestrial Code*

The following information should be provided by OIE Member Countries to support applications for endorsement by the OIE of an official control programme for contagious bovine pleuropneumonia (CBPP) in accordance with Chapter 11.75. of the *Terrestrial Code*.

The dossier provided to the OIE should ~~In sections 1 to 3.5. please address concisely all the following topics under the headings~~ provided in Sections 1 to 4.3 e) 5 to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

In Sections 3 f) to 3 i) 3.6. to 3.9. please address describe concisely the work plan and timelines of the control programme for the next five years.

Please use The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

Any All annexes should be provided in one of the OIE official languages.

NB the paragraph below has been moved from the end of the chapter

5. Compliance with the *Terrestrial Code*

The Delegate of the Member Country applying for endorsement of the official control programme should submit documentary evidence that the provisions of Article 11.57.18. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for CBPP.

1. Introduction

- a) Geographical entities features (rivers, mountains ranges, etc.). Provide a general description of the country and zones and, when where relevant, of the region, including physical, geographical and other factors that are relevant to CBPP introduction of infection and dissemination spread of CBBP, taking into account the as well as a short description of countries sharing common borders and other epidemiologic pathways links for the potential introduction of infection CBPP.

Provide maps identifying the factors features above.

Specify whether the application includes any noncontiguous territories.

Annex 28 (contd)

- b) If the endorsed plan is gradually implemented in stages in to specific parts of the country, the boundaries of the zones should be clearly defined, including the *protection zones*, if applied. Provide a digitalised, geo-referenced map with a description of the geographical boundaries of the zones.
 - c) Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country or any zones. In particular, describe:
 - i) the susceptible animal *population* by species and types of production systems;
 - ii) the number of *herds* of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* density, etc. Provide tables and maps as appropriate;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (*if attach relevant documents if are available, please attach*).
- Provide tables and maps.
- d) *Wildlife* demographics. What susceptible captive wild, wild or feral susceptible species are present in the country and any zones? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible wildlife susceptible species?
 - e) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g., fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic susceptible species movement for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and *Veterinary Authority* directives in relation to the CBPP control programme and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) Veterinary Services. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, and control, enforce and monitor all CBPP-related activities. Provide maps, figures and tables wherever possible
- c) Provide information on any OIE PVS evaluation conducted in your the country and follow-up steps within the PVS Pathway and highlight the results relevant to CBPP and the susceptible species.
- d) Provide a description or of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, veterinary paraprofessionals including community animal health workers, and other relevant groups in CBPP surveillance and control. Provide a description of the role and structure of the private veterinary sector, (including number of veterinarians and their distribution), and the role of the private veterinarians veterinary profession in CBPP surveillance and control.

Include a description of continuing education and awareness programmes on CBPP at all relevant levels of the susceptible species value.

- e) Animal identification, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of animal identification and establishment holding, or herd registration and traceability for applicable to all susceptible species production systems. How are animal movements controlled in the country for all susceptible species production systems? Provide evidence or of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months two years.

Annex 28 (contd)

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g., seasonal migration). Describe the actions available under national legislation. ~~and actually taken, when an illegal import is detected.~~

Provide information on illegal movements detected in the past 24 months and the action taken.

3. Official control programme for CBPP submitted for OIE endorsement

Submit a concise plan ~~on~~ of the measures for the control and eventual *eradication* of CBPP in the country, including:

a) Epidemiology

- i) ~~Provide a description of~~ Describe the CBPP history in the country, with emphasis on recent years. Provide tables and maps showing the date of first detection, the number and location of *outbreaks* per year, the sources and routes of introduction of *infection*, the types and subtypes of *Mmm* present and the date of implementation of the control programme in the country.
- ii) Describe the epidemiological situation of CBPP in the country and the surrounding countries or zones highlighting the current knowledge and gaps. Provide maps ~~on~~ of:
 - the geography of the country with the relevant information concerning CBPP situation;
 - livestock density and movements and estimated CBPP prevalence.

b) CBPP surveillance

Provide documentary evidence ~~on whether~~ that surveillance for CBPP in the country complies with Articles 11.57.143. ~~to~~and 11.57.15. of the *Terrestrial Code* and Chapter 2.4.8. of the *Terrestrial Manual*. ~~In particular, The following information should be included points should be addressed:~~

- i) What are the criteria for raising a suspicion of CBPP? What is the procedure to notify (by whom and to whom), and what incentives are there for reporting and what penalties are involved for failure to report?
- ii) Describe how clinical *surveillance* is conducted, including which ~~levels of~~ sectors of the livestock production system are included in clinical *surveillance*, such as ~~establishments~~ farms, markets, fairs, *slaughterhouses/abattoirs*, check points, etc. Provide details of follow-up actions taken on clinical suspicions.
- iii) Serological *surveillance*. Explain whether serological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the ~~survey~~ design (target *population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used) in accordance with Articles 11.57.13. and 11.5.147.45 of the *Terrestrial Code*.
- iv) *Surveillance at slaughterhouses/abattoirs*, slaughter slabs. Explain whether *slaughterhouses/abattoirs* surveys are conducted and, if so, how frequently and for what purpose. What are the criteria for suspecting a lesion is CBPP? What is the procedure for notify (by whom and to whom)?

Annex 28 (contd)

- v) Provide a summary table indicating, for at least the past ~~24 months two years~~, the number of suspected cases, the number of samples tested for CBPP species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details of follow-up actions taken on suspicious and positive results and on how these findings are interpreted and acted upon.

Provide criteria for selection of *populations* for targeted *surveillance* and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods applied for monitoring the performance of the *surveillance* system including indicators.

- vi) In countries where a significant proportion of animals in the country or zone are not slaughtered in controlled *slaughterhouses/abattoirs*, what are the alternative *surveillance* measures applied to detect CBPP (e.g., active clinical *surveillance* programme, *laboratory* follow-up).
- vii) Provide information on the level of risk in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g., targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.) and that the acquired knowledge assists in more effective implementation of control measures.
- viii) Provide details ~~on~~ of the oversight of surveillance programmes by the Veterinary Services including training programmes for personnel involved in clinical and *slaughterhouse/abattoir surveillance*, and the approaches used to increase community involvement in CBPP *surveillance* programmes.
- ix) Provide evidence that surveys are carried out to assess *vaccination coverage* and *population immunity* of the target *populations*, show analysis of *surveillance* data to assess the change in CBPP prevalence over time in the target *populations*, assess the control measures (cost effectiveness, degree of implementation, impact). Provide information on outcomes of *outbreak investigations* including *outbreaks* that have occurred despite control measures, documented inspections showing compliance with biosecurity and hygiene requirements.

c) CBPP *laboratory* diagnosis

Provide documentary evidence that the relevant provisions ~~in~~ of Chapters 1.1.1., 1.1.3. and 2.4.8. of the *Terrestrial Manual* are applied. ~~In particular,~~ The following points should be addressed:

- i) Is CBPP *laboratory* diagnosis carried out in the country? If so, provide an overview of the CBPP-approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.~~
- ~~b) Provide an overview of the CBPP approved laboratories in the country. Address the following points:~~
- How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for obtaining reporting results;
 - Details of test capability and the types of tests undertaken including procedures to isolate and identify *M. mycoides* subsp. *mycoides* (*Mmm*) and their performance for their applied use (specificity and sensitivity per type of test). Provide details ~~on~~ of the number of CBPP tests performed in the ~~past~~ 24 months two years in the national *laboratories* and in laboratories in other countries, if relevant as well as abroad;
 - Procedures for quality assurance and, if available, for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g., Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;

Annex 28 (contd)

- Provide details ~~on~~ of the handling of live pathogenic agent, ~~in particular, describe including a description of the~~ biosecurity and biosafety measures applied;
 - Provide a table identifying linking the tests carried out ~~to by each of the laboratories~~ where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- ii) If CBPP laboratory diagnosis is not carried out in the country, provide the names of the laboratories in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.*
- d) Strategies
- i) Provide a description of the legislation, organisation and implementation of the current CBPP control programme. Outline the legislation applicable to the control programme and how its implementation is organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.
 - ii) Describe CBPP control strategies in the country or any zones, including in terms of animal movement control, fate of infected and in-contact animals, *vaccination* and possible use of antibiotics. Strategies should be based on the assessment of the CBPP situation in the zones, country and region.
 - iii) Provide information on what types of vaccines are used and which species are vaccinated. Provide evidence that the vaccine used complies with Chapter 1.1.8. of the *Terrestrial Manual*. Provide information on the licensing process for the vaccines used. Describe the *vaccination* programme in the country and in any zones, including records kept, and provide evidence to show its effectiveness, such as *vaccination coverage*, *population immunity*, etc. Provide details ~~on~~ of the studies carried out to determine the *vaccination coverage* and the *population immunity*, including the study designs and the results.
 - iv) Provide a description of the policy on antibiotic treatment within the strategy. If it is banned how is the ban implemented?
 - v) Describe how the *stamp-out policy* is implemented in the country or any zones and under which circumstances.
 - f) ~~Describe how the stamping-out policy is implemented in the country or any zones and under which circumstances.~~
 - vi) In the event of outbreaks, ~~In the event of outbreaks,~~ provide evidence of the impact of the control measures already implemented ~~in the event of outbreaks~~ on their reduction in number of outbreaks and their distribution. If possible, provide information on primary and secondary outbreaks.
- e) CBPP prevention

Describe the procedures in place to prevent the introduction of CBPP into the country, including ~~in particular~~ provide details of:

- i) Coordination with other countries. Describe any relevant factors ~~about adjacent in neighbouring~~ countries and zones that should be taken into account (e.g., size, distance from the border to affected herds or animals). Describe coordination, collaboration and information-sharing activities with other countries and zones in the same region or ecosystem.

Are *protection zones* in place? If so, provide details ~~on~~ of the measures that are applied (e.g., *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the zones.

Annex 28 (contd)

ii) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation spread of the pathogenic agent within the country or zone and through trade. Provide evidence that measures to reduce transmission of CBPP are in place at markets, to reduce transmission of CBPP such as enhancing awareness of CBPP transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good biosecurity practices, hygiene, cleaning and disinfection routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

iii) Import control procedures

Provide information on countries, zones or compartments from which the country authorises the import of susceptible animals or their products into the country or into any zones. Describe the criteria applied to approve such countries, zones or compartments, the controls applied on to entry of such animals and products and subsequent internal movement. Describe the import measures conditions (e.g., quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health international veterinary certificates are required.

Describe any other procedures used for assessing the risks of posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months two years, including temporary import and re-entry, specifying countries, zones or compartments of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not outbreaks have been related to imports or transboundary movements of domestic animals.

- Provide a map with showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - *Mmm* strains including vaccines;
 - veterinary medicinal products;
 - other materials at risk of being contaminated with *Mmm*.

iviii) Describe the actions available under legislation, and actually taken, when an illegal import is detected.

Provide information on detected illegal imports detected and the action taken.

- f) Work plan and timelines of the control programme for the next five years, including cessation of vaccination. Describe the progressive objectives including expected status to be achieved for in the next five years: for zones (if applicable) and for the whole country.

Annex 28 (contd)

- g) Performance indicators and timeline. The performance indicators should relate to the most important areas and steps where improvements in the programme are needed. These may include, but are not restricted to, strengthening Veterinary Services, legislation, clinical and slaughterhouse/abattoir reporting, availability and quality of vaccines, animal identification systems, vaccination coverage, population immunity, movement control, disease awareness, CBPP seroprevalence reduction, cattle owners' participatory perception on the effectiveness of the programme, etc. The progressive reduction of outbreak incidence towards elimination of CBPP transmission of Mmm in all susceptible livestock in at least one zone of the country should also be measured and monitored.
- h) Assessment of the evolution of the official control programme since the first date of implementation. This should include documented evidence demonstrating that the control programme has been implemented and that the first results are favourable. Measurable evidence of success such as the performance indicators should include, but not be limited to, vaccination data, decreased prevalence, successfully implemented import measures, control of animal movements and finally decrease or elimination of CBPP outbreaks in the whole country or selected zones as described in the programme.

This should include documented evidence of the good effective implementation of Sections 3 d) 3.4. and 3 e) 3.5. above.

- i) Description of Describe the funding for the control programme and annual budgets for its duration.

4. Control measures and emergency response

- a) List any written guidelines, including emergency response contingency plans, available to the Veterinary Services for dealing with suspected or confirmed outbreaks of CBPP. The contingency plan should be attached as an annex and if not available in one of the OIE official languages. If not available, provide a brief summary of what is covered should be provided. Provide information on any simulation exercise for CBPP that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed CBPP outbreak:
 - i) Is Are quarantine measures imposed on establishments premises with suspected suspicious cases, pending final diagnosis? What other procedures are followed regarding suspected suspicious cases (e.g., livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the causative pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the establishments premises where the outbreak was is confirmed;
 - iv) Describe in detail provide a detailed description of the control or eradication procedures (e.g., forward and backward tracing, disinfection of establishments premises, vehicles and equipment, including verification methods, vaccination, stamping-out policy, slaughter, movement control, pastured livestock and livestock as pets, control of offal, especially lungs, and carcasses, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency vaccination, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an outbreak has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological surveillance programmes, etc.;

Annex 28 (contd)

- vi) give Provide details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or eradication purposes and the prescribed timetable for payments;
- vii) Describe how control efforts, including *vaccination* and biosecurity measures, would target critical risk control points.

5. Compliance with the Terrestrial Code

~~The Delegate of the Member Country must submit documentary evidence that the provisions of Article 11, 57.18. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for CBPP.~~

CHAPTER 1.1.1.

Article 1.6.6.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF FREE STATUS FOR FOOT AND MOUTH DISEASE

Questionnaires on foot and mouth disease (FMD)

FMD FREE COUNTRY WHERE VACCINATION IS NOT PRACTISED

Report of a Member Country which applies for recognition of status,
under Chapter 8.8. of the *Terrestrial Code*,
as a FMD free country not practising vaccination

Article 1.11.1.

Country free from foot and mouth disease where vaccination is not practised

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country where vaccination is not practised, that is free from infection with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*,

Please The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how these comply with the *Terrestrial Code*.

Please use The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

Any All annexes should be provided in one of the OIE official languages.

[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]

8. Compliance with the Terrestrial Code

The Delegate of the Member Country applying for recognition of FMD freedom for a country where vaccination is not practised must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.2. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- a) there has been no case of FMD during the past 12 months;
- b) no vaccination against FMD has been carried out during the past 12 months.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

Annex 29 (contd)1. Introduction

- a) Geographical entities features (rivers, mountain ranges, etc.). Provide a general description of the country and, when where relevant, of the region, including physical, geographical and other factors that are relevant to FMD introduction of infection and dissemination spread of FMD virus, taking into account the as well as a short description of countries or zones sharing common borders and other epidemiologic pathways links for the potential introduction of the infection FMD.

Provide maps identifying the factors features above.

Specify whether the application includes any noncontiguous territories.

- b) Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country. In particular, describe:
- i) the susceptible animal *population* by species and types of production systems;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (*if attach relevant documents are if available, please attach*).

Provide tables and maps.

- c) *Wildlife* demographics. What susceptible *captive wild, wild or feral* species are present in the country? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible wildlife susceptible species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g., fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic susceptible species movement for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) Veterinary Services. Describe how the Veterinary Services of the country comply with ~~the provisions of~~ Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the Veterinary Services supervise, ~~and control, enforce and monitor~~ all FMD-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the your country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.
- d) Provide a description of ~~on~~ the involvement and the participation of industry, producers, farmers including subsistence and small-scale producers and keepers, veterinary paraprofessionals including community animal health workers, and other relevant groups in FMD surveillance and control. Provide a description of the role and structure of the private veterinary sector, including number of veterinarians and their distribution, ~~and role of the private veterinary profession~~ in FMD surveillance and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.

Annex 29 (contd)

- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of animal identification, holding, and establishment or herd or flock registration and traceability for applicable to all susceptible species production systems.

How are animal movements of all susceptible species controlled in the country for all susceptible species production systems?

Provide evidence on of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months two years.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g., seasonal migration). Describe the actions available under national legislation.

Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

- a) History. If infection has never occurred in the country has never had the disease, or has not had it occurred within the past 25 years, please state explicitly whether or not the country is applying for recognition of historical freedom according to point 1 of Article 1.4.6. of the *Terrestrial Code*.

If infection has occurred in the country has had the disease within the past 25 years, provide a description of the FMD history in the country, with emphasis on recent years. If applicable, provide tables and maps to showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last case or *eradication*, and the types and strains in the country.

- b) Strategy. Describe how FMD was controlled and eradicated (e.g., *stamp-out policy*, zoning, *vaccination*, movement control). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future disease outbreaks of FMD in response to any past disease incursions of FMD virus.

- c) Vaccines and *vaccination*. Briefly answer the following:

- i) Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal vaccination during the reporting period and actions taken in response to the detection.
- Describe the action available under legislation, and actually taken, when an illegal vaccination is detected;
- Provide information on detected illegal vaccination during the reporting period.

- ii) Was *vaccination* ever used in the country? If so:

- Provide the date when the last *vaccination* was carried out;
- What type of vaccine was used?
- What species were vaccinated?
- How were vaccinated animals identified?
- What was the fate of those animals?

Annex 29 (contd)

- iii) In addition, if vaccination was conducted applied during the past 24 months two years, provide a description and justification of the vaccination strategy and programme, including the following: regime. Briefly answer the following:*
- the vaccine strains;
 - potency and formulation, purity, details of any vaccine matching performed;
 - the species vaccinated;
 - identification of vaccinated animals;
 - the way in which the vaccination of animals was certified or reported and the records maintained;
 - Provide evidence that the vaccine used complies with Chapter 2.1.8. of the *Terrestrial Manual*.
- d) Provide a description of the legislation, organisation and implementation of the eradication campaign. Outline the legislation applicable to the eradication and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.*

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. In particular, The following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide an overview of the FMD-approved laboratories in the country, including the following: If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.*
- b) Provide an overview of the PPR approved laboratories in the country. Address the following points:*
- i) How the work is shared between different laboratories, logistics for shipment of samples, the follow-up procedures and the time frame for reporting obtaining results;*
 - ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months two years in the national laboratories and in laboratories in other countries, if relevant as well as abroad;*
 - iii) Procedures for quality assurance and for the official accreditation of laboratories. Give details of formal internal quality management systems, e.g., Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system;*
 - iv) Provide details of performance in inter-laboratory validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;*
 - v) Provide details of the handling of live pathogenic agent, including a description of the In particular, describe biosecurity and biosafety measures applied;*
 - vi) Provide a table identifying linking the tests carried out by each of the laboratories where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.*
- b) If FMD laboratory diagnosis is not carried out in the country, provide the names of the laboratories in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.*

Annex 29 (contd)5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code* and Chapter 2.1.8. of the *Terrestrial Manual*. ~~In particular, The following information should be included~~ ~~points should be addressed:~~

- a) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which ~~levels~~ ~~sectors~~ of the livestock production system are included in clinical *surveillance*, such as ~~establishments~~ ~~farms~~, markets, fairs, slaughterhouses/abattoirs, check points, etc.

Provide a summary table indicating, for the past ~~24 months~~ ~~two years~~, the number of suspected cases, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Serological ~~and~~ or virological *surveillance*. ~~Have~~ Are serological ~~and~~ or virological surveys ~~been~~ conducted ~~to demonstrate freedom from infection?~~ If so, provide detailed information on the *survey design* (*target population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used) in accordance with Articles 8.8.40. to 8.8.42. of the Terrestrial Code. How frequently are ~~they~~ surveys conducted? Are susceptible *wildlife* species included in serological ~~and~~ or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past ~~24 months~~ ~~two years~~, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and on how these findings are interpreted and acted upon. Provide criteria for selection of *populations* for targeted *surveillance* based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods applied for monitoring the performance of the *surveillance* system including indicators.

- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g., targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). ~~Provide evidence of how the and that the acquired knowledge acquired through these activities assisted assists~~ in more effective implementation of control measures.
- e) Provide details of the oversight of surveillance programmes by the Veterinary Services including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, ~~In particular provide including~~ details of:

- a) Coordination with other countries. Describe any relevant factors ~~about adjacent in neighbouring~~ countries that should be taken into account (e.g., size, distance from the border to affected *herds*, *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

Are protection zones in place? If so, provide details of the measures that are applied (e.g., vaccination, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the zones.

Annex 29 (contd)

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation-spread of the pathogenic agent within the country or zone and through trade. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good biosecurity practices, hygiene, cleaning and disinfection routines at critical points all along the production and marketing networks (typically where animals are being moved; and marketed through the country or region).
- c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill containing animal products to pigs regulated? If so, provide information on the extent of the practice, and describe controls and surveillance measures.
- d) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied on to entry of such animals and products and subsequent internal movement. Describe the import measures conditions (e.g., quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health international veterinary certificates are required.

Describe any other procedures used for assessing the *risks of posed by* import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months two years, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts and between border inspection posts.
- ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months two years, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?
- iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - *veterinary medicinal products (i.e. biologics)*;
 - other materials at risk of being contaminated with FMD virus, including bedding, litter and feed.

Annex 29 (contd)7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the Veterinary Services for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex and if not available in one of the OIE official languages. If not available, provide a brief summary of what is covered should be provided. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed FMD *outbreak*:
 - i) Is Are quarantine measures imposed on establishments premises with suspicious suspected cases, pending final diagnosis? What other procedures are followed regarding suspicious with respect to suspected cases (e.g., livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the causative pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the premises establishments where the outbreak was is confirmed;
 - iv) Provide a detailed description of the control or eradication procedures (e.g., forward and backward tracing, movement control, disinfection of establishments premises, vehicles and equipment, including verification methods, vaccination including vaccination vaccine delivery and cold chain, stamping-out policy, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency vaccination, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an outbreak has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological surveillance programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or eradication purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including vaccination and biosecurity measures, would target critical risk control points.

8. Compliance with the Terrestrial Code

~~The Delegate of the Member Country applying for FMD freedom must submit documentary evidence that the provisions of Article 8.8.2 have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating that:~~

- a) ~~there has been no case of FMD during the past 12 months;~~
- b) ~~no vaccination against FMD has been carried out during the past 12 months.~~

~~In addition, the Delegate of the Member Country applying for historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.~~

98. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 8.8.7. and points 1, 3 and 4 of Article 8.8.2. of the *Terrestrial Code* and provide detailed information as specified in Sections 1–7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Annex 29 (contd)Article 1.11.2.**FMD FREE COUNTRY WHERE VACCINATION IS PRACTISED**

~~Report of a Member Country which applies for recognition of status,
under Chapter 8.8. of the Terrestrial Code,
as a FMD free country practising vaccination~~

Country where vaccination is practised

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country where vaccination is practised, that is free from infection with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the Terrestrial Code.

Please ~~The dossier provided to the OIE should~~ address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how ~~this~~ these ~~complies~~ comply with the *Terrestrial Code*.

Please use ~~The terminology defined in the OIE Terrestrial Code and Terrestrial Manual should be referred to and used in compiling the dossier.~~

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

Any All annexes should be provided in one of the OIE official languages.

[Note from the TAHSC – Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]

8. Compliance with the Terrestrial Code

The Delegate of the Member Country applying for recognition of FMD freedom for a country where vaccination is practised must demonstrate compliance with the Terrestrial Code. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- a) there has been no case of FMD for the past 24 months ~~two years~~;
- b) no evidence of FMDV transmission for the past 12 months;
- c) surveillance for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;
- d) routine vaccination is carried out for the purposes of the prevention of FMD;
- e) the vaccine used complies with the standards described in the Terrestrial Manual.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.

1. Introduction

- a) Geographical entities features (rivers, mountain ranges, etc.). Provide a general description of the country and, when where relevant, of the region, including physical, geographical and other factors that are relevant to FMD introduction of infection and dissemination spread of FMD virus, taking into account the as well as a short description of countries or zones sharing common borders and other epidemiologic pathways links for the potential introduction of the infection FMD.

Provide maps identifying the factors features above.

Specify whether the application includes any noncontiguous territories.

Annex 29 (contd)

- b) Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country. In particular, describe:
- i) the susceptible animal *population* by species and types of production systems;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (*if attach relevant documents are if available, please attach*).

Provide tables and maps.

- c) *Wildlife* demographics. What susceptible captive wild, wild or feral susceptible species are present in the country? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible wildlife susceptible species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g., fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic susceptible species movement for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. This list The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with the provisions of Chapters 1.1., 3.1. and 3.2. of the Terrestrial Code. Describe how the *Veterinary Services* supervise, and control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers including subsistence and small-scale producers and keepers, veterinary paraprofessionals including community animal health workers, and other relevant groups in FMD surveillance and control. Provide a description of the role and structure of the private veterinary sector, including number of veterinarians and their distribution, and role of the private veterinary profession in FMD surveillance and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of *animal identification, holding, and establishment or herd or flock registration and traceability for applicable to all susceptible species production systems*.

How are *animal movements of all susceptible species* controlled in the country for all production systems?

Annex 29 (contd)

Provide evidence of ~~on~~ the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the ~~last past 24 months~~ two years.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g., seasonal migration). Describe the actions available under national legislation.

~~Describe the action available under legislation, and actually taken, when an illegal import is detected.~~
Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

a) History. Provide a description of the FMD history in the country, with emphasis on recent years. If applicable, provide tables and maps ~~to~~ showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last case or *eradication*, and the types and strains in the country.

b) Strategy. Describe how FMD was controlled and eradicated (e.g., *stampin-out policy*, modified stamping-out policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~disease outbreaks of FMD~~ in response to any past ~~disease~~ incursions of FMD virus.

c) Vaccines and *vaccination*. Describe any legislation regulating *vaccination*. Provide a description and justification of the *vaccination* strategy and programme, including the following: regime. Briefly answer the following:

- i) the vaccine strains;
- ii) potency and formulation, purity, details of any vaccine matching performed;
- iii) the species vaccinated;
- iv) identification of vaccinated animals;
- v) the way in which the *vaccination* of animals was certified or reported and the records maintained;
- vi) the date on which the last *vaccination* was performed;
- vii) Provide evidence that the vaccine used complies with Chapter 2.1.8. of the *Terrestrial Manual*.

d) Provide detailed evidence of *vaccination* coverage and *population immunity* as follows:

Describe how the number of animals intended for *vaccination* and the number of vaccinated animals are estimated.

For serological surveys to estimate *population immunity*, provide detailed information on the sampling frame (target population, age, species and *vaccination* status) and survey design (expected prevalence, acceptable error, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How long after *vaccination* are samples collected? Describe how the threshold for protective immunity has been established.

Provide the results of the *vaccination* coverage and *population immunity* by year, serotype, species, as relevant.

Provide details of any additional methods applied for monitoring the performance of *vaccination*.

Annex 29 (contd)

- e) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions in Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. In particular, The following points should be addressed:

- a) Is FMD *laboratory diagnosis* carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following: If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.
- b) Provide an overview of the PPR approved laboratories in the country. Address the following points:
- i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting obtaining results;
 - ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months two years in the national *laboratories* and in *laboratories* in other countries, if relevant as well as abroad;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g., Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent, including a description of the In particular, describe biosecurity and biosafety measures applied;
 - vi) Provide a table identifying linking the tests carried out by each of to the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If FMD *laboratory diagnosis* is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code* and Chapter 2.1.8. of the *Terrestrial Manual*. In particular, The following information should be includedpoints should be addressed:

- a) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which levels sectors of the livestock production system are included in clinical *surveillance*, such as establishments farms, markets, fairs, slaughterhouses/abattoirs, check points, etc.

Provide a summary table indicating, for the past 24 months two years, the number of suspected cases, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

Annex 29 (contd)

- c) Serological and or virological surveillance. Are serological and or virological surveys conducted to demonstrate freedom from infection with FMDV in unvaccinated animals and of FMDV transmission in vaccinated animals, in particular applying the provisions of Article 8.8.42? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used) in accordance with Articles 8.8.40 to 8.8.42 of the Terrestrial Code. How frequently are they surveys conducted? Are susceptible wildlife species included in serological and or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months two years, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and how these findings are interpreted and acted upon. Provide criteria for selection of populations for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic laboratories. Provide details of the methods applied for monitoring the performance of the surveillance system including indicators.

- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g., targeted serological surveys, active surveillance, participatory epidemiology studies, risk assessments, etc.). Provide evidence of how the and that the acquired knowledge acquired through these activities assisted assists in more effective implementation of control measures.
- e) Provide details of the oversight of surveillance programmes by the Veterinary Services including training programmes for personnel involved in clinical, serological and virological surveillance, and the approaches used to increase community involvement in FMD surveillance programmes.
- f) Provide evidence that surveys are carried out to assess vaccination coverage and population immunity of the target populations, show laboratory evidence that the vaccine strains used is appropriate.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country. In particular, provide details of:

- a) Coordination with other countries. Describe any relevant factors about adjacent in neighbouring countries that should be taken into account (e.g., size, distance from the border to affected herds, flocks or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

Are protection zones in place? If so, provide details of the measures that are applied (e.g., vaccination, intensified surveillance, density control of susceptible species) and provide a geo-referenced map of the zones.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation spread of the pathogenic agent within the country or zone and through trade. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good biosecurity practices, hygiene, cleaning and disinfection routines at critical points all along the production and marketing networks (typically where animals are being moved, and marketed through the country or region).
- c) What measures are taken to limit access of susceptible domestic, feral and wild animals to waste products of animal origin? Is the feeding of swill containing animal products to pigs regulated? If so, provide information on the extent of the practice, and describe controls and surveillance measures.

Annex 29 (contd)

d) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied ~~on to~~ entry of such animals and products and subsequent internal movement. Describe the import measures conditions (e.g., quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health-international veterinary certificates are required.

Describe any other procedures used for assessing the *risks of posed by* import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months two years, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts and between border inspection posts.
- ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months two years, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?
- iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the point of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - *veterinary medicinal products (i.e. biologics)*;
 - other materials at risk of being contaminated with FMD virus, including bedding, litter and feed.

7. Control measures and contingency

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex and if not available in one of the OIE official languages. If not available, provide a brief summary of what is covered should be provided. Provide information on any simulation exercise for FMD that was conducted in the country in the last five years.
- b) In the event of a suspected or confirmed FMD *outbreak*:
 - i) Is Are quarantine measures imposed on establishments premises with suspected suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious with respect to suspected cases (e.g., livestock standstills)?

Annex 29 (contd)

- ii)* Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the ~~causative~~ pathogenic agent;
- iii)* Describe the actions that would be taken to control the disease situation in and around the ~~premises~~ establishments where the *outbreak was* is confirmed;
- iv)* Provide a detailed description of the control or *eradication* procedures (e.g., forward and backward tracing, movement control, *disinfection* of establishments premises, vehicles and equipment, including verification methods, *vaccination* including vaccination vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
- v)* Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
- vi)* Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
- vii)* Describe how control efforts, including *vaccination* and *biosecurity measures*, would target critical risk control points.

8. Compliance with the Terrestrial Code

~~The Delegate of the Member Country must submit documentary evidence that the provisions of Article 8.8.3. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit a declaration indicating that:~~

- a)* ~~there has been no case of FMD for the past two years;~~
- b)* ~~no evidence of FMDV transmission for the past 12 months;~~
- c)* ~~surveillance for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;~~
- d)* ~~routine vaccination is carried out for the purpose of the prevention of FMD;~~
- e)* ~~the vaccine used complies with the standards described in the Terrestrial Manual.~~

89. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 8.8.7. and points 1, 3 and 4 of Article 8.8.3. of the *Terrestrial Code* and provide detailed information as specified in Sections 1–7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Annex 29 (contd)Article 1.11.3.**FMD FREE ZONE WHERE VACCINATION IS NOT PRACTISED**

~~Report of a Member Country which applies for recognition of status,
under Chapter 8.8. of the Terrestrial Code,
as a FMD free zone not practising vaccination~~

Zone free from foot and mouth disease where vaccination is not practised

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a zone where vaccination is not practised that is free from infection with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the Terrestrial Code.

Please The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how this these complies comply with the *Terrestrial Code*.

Please use The terminology defined in the OIE Terrestrial Code and Terrestrial Manual should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

Any All annexes should be provided in one of the OIE official languages.

[Note from the TAHSC – Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below:]

8. Compliance with the Terrestrial Code

The Delegate of the Member Country applying for recognition of FMD zonal freedom must demonstrate compliance with the Terrestrial Code. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.2. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- a) there has been no case of FMD during the past 12 months;
- b) no vaccination against FMD has been carried out during the past 12 months.

In addition, the Delegate of the Member Country applying for recognition of historical zonal freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.

1. Introduction

- a) Geographical entities features (rivers, mountain ranges, etc.). Provide a general description of the country and the zone and, when where relevant, of the region, including physical, geographical and other factors that are relevant to FMD introduction of infection and dissemination spread of FMD virus, taking into account the as well as a short description of countries or zones sharing common borders and other epidemiologic pathways links for the potential introduction of the infection FMD.

The boundaries of the zone must be clearly defined, including a *protection zone*, if applied.

Provide maps identifying the factors features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone.

Annex 29 (contd)

- b) Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country and the zone. In particular, describe:
- i) the susceptible animal *population* by species and types of production systems in the country and the zone;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (*if attach relevant documents are if available, please attach*).

Provide tables and maps.

- c) *Wildlife* demographics. What susceptible captive wild, wild or feral susceptible species are present in the country and the zone? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible wildlife susceptible species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g., fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic susceptible species movement for marketing within the country or zone, and between zones of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. This list The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with the provisions of Chapters 1.1., 3.1. and 3.2. of the Terrestrial Code. Describe how the *Veterinary Services* supervise, and control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers including subsistence and small-scale producers and keepers, veterinary paraprofessionals including community animal health workers, and other relevant groups in FMD surveillance and control. Provide a description of the role and structure of the private veterinary sector, including number of veterinarians and their distribution, and role of the private veterinary profession in FMD surveillance and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of animal identification, and holding, establishment or herd or flock registration and traceability applicable to for all susceptible species production systems.

Annex 29 (contd)

How are animal movements of all susceptible species controlled in and between zones of the same or different status for all production systems?

Provide evidence of ~~on~~ the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the ~~last past 24 months two years~~.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g., seasonal migration). Describe the actions available under national legislation.

~~Describe the action available under legislation, and actually taken, when an illegal import is detected.~~
Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

- a) History. If infection has never occurred in the country ~~has never had the disease~~, or has not ~~had it occurred~~ within the last 25 years, please state explicitly whether or not the zone is applying for recognition of historical freedom according to point 1 of Article 1.4.6. of the *Terrestrial Code*.

If infection has occurred in the zone ~~has had the disease~~ within the past 25 years, provide a description of the FMD history in the country and zone, with emphasis on recent years. If applicable, provide tables and maps ~~to~~ showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last case or *eradication* and the types and strains in the country.

- b) Strategy. Describe how FMD was controlled and eradicated in the zone (e.g., *stamp-ing-out policy*, modified stamping-out policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~disease outbreaks of FMD~~ in response to any past ~~disease~~ incursions of FMD virus.

- c) Vaccines and *vaccination*. Briefly answer the following:

- i) Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal vaccination during the reporting period and actions take in response to the detection. Describe the action available under legislation, and actually taken, when an illegal vaccination is detected;
- Provide information on detected illegal vaccination during the reporting period.

- ii) Was *vaccination* ever used in the zone? If so:

- Provide the date when the last *vaccination* was carried out;
- What type of vaccine was used?
- What species were vaccinated?
- How were vaccinated animals identified?
- What was the fate of those animals?

Annex 29 (contd)

- iii) In addition, if *vaccination* was conducted ~~applied~~ during the past ~~24 months~~~~two years~~, provide a description and justification of the *vaccination* strategy and *programme*, including the following *regime*. *Briefly answer the following:*
 - the vaccine strains;
 - potency and formulation, purity, details of any vaccine matching performed;
 - the species vaccinated;
 - identification of vaccinated animals;
 - the way in which the *vaccination* of animals was certified or reported and the records maintained;
 - *Provide* evidence that the vaccine used complies with Chapter 2.1.8. of the *Terrestrial Manual*.
- iv) If *vaccination* continues to be used in the rest of the country, give details of the species vaccinated and on the post-vaccination monitoring programme.
- d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of ~~in~~ Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. In particular, The following points should be addressed:

- a) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results. Indicate the laboratories where samples originating from the zone are diagnosed.~~
- b) Provide an overview of the FMD approved laboratories in the country. Address the following points:
 - i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting ~~obtaining~~ results;
 - ii) Details of test capability and the type of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the past ~~24 months~~~~two years~~ in national *laboratories* and in laboratories in other countries, if relevant as well as abroad;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g., Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent, In particular, describe including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table linking identifying the tests carried out to~~by~~ each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

Annex 29 (contd)

- b) If FMD laboratory diagnosis is not carried out in the country, provide the names of the laboratories in other countries providing the service as well as arrangements in place, including logistics for shipment of samples and the time frame for reporting results.**

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the zone complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code* and Chapter 2.1.8. of the *Terrestrial Manual*. In particular, The following information should be included points should be addressed:

- a) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which levels sectors of the livestock production system are included in clinical *surveillance*, such as establishments farms, markets, fairs, slaughterhouses/abattoirs, check points, etc.

Provide a summary table indicating, for the past 24 months two years, the number of suspected cases, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Serological and or virological *surveillance*. Have Are serological and or virological surveys been conducted to demonstrate freedom from infection? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used) in accordance with Articles 8.8.40. to 8.8.42. of the Terrestrial Code. How frequently are they surveys conducted? Are susceptible *wildlife* species included in serological and or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months two years, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and of how these findings are interpreted and acted upon. Provide criteria for selection of *populations* for targeted *surveillance* based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods applied for monitoring the performance of the *surveillance* system including indicators.

- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g., targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how and that the acquired knowledge acquired through these activities assisted assists in more effective implementation of control measures.
- e) Provide details of the oversight of surveillance programmes by the Veterinary Services including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, In particular, provide including details of:

- a) Coordination with other countries. Describe any relevant factors about adjacent in neighbouring countries and zones that should be taken into account (e.g., size, distance from the border to affected *herds*, *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and zones in the same region or ecosystem.

If the FMD free zone without *vaccination* is situated in a FMD infected country or borders an infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers.

Annex 29 (contd)

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed FMD free zones, provide details of the measures that are applied (e.g., *vaccination*, intensified *surveillance*, density control of susceptible species) and provide a geo-referenced map of the zones.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation spread of the pathogenic agent within the country or zone and through trade. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity practices*, hygiene, cleaning and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved; and marketed through the country or region).
- c) What measures are taken to limit access of susceptible domestic, feral and wild animals to waste products of animal origin? Is the feeding of swill ~~containing animal products~~ to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.
- d) Import control procedures

Provide information on countries, zones or compartments from which the country authorises the import of susceptible animals or their products into the zone. Describe the criteria applied to approve such countries, zones or compartments, the controls applied ~~on to~~ entry of such animals and products and subsequent internal movement. Describe the import measures conditions (e.g., quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and ~~health~~ international veterinary certificates are required.

Describe any other procedures used for assessing the *risks* of posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months two years, including temporary import and re-entry, specifying countries, zones or compartments of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts and between border inspection posts.
- ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months two years, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?
- iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the zone or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - *veterinary medicinal products (i.e. biologics)*;
 - other materials at risk of being contaminated with FMD virus, including bedding, litter and feed.

Annex 29 (contd)7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the Veterinary Services for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex and if not available in one of the OIE official languages. If not available, provide a brief summary of what is covered should be provided. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed FMD *outbreak*:
 - i) Is Are quarantine measures imposed on establishments premises with suspicious suspected cases, pending final diagnosis? What other procedures are followed regarding suspicious with respect to suspected cases (e.g., livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the causative pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the premises establishments where the outbreak was is confirmed;
 - iv) Provide a detailed description of the control or eradication procedures (e.g., forward and backward tracing, movement control, disinfection of establishments premises, vehicles and equipment, including verification methods, vaccination including vaccination vaccine delivery and cold chain, stamping-out policy, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency vaccination, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an outbreak has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological surveillance programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or eradication purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including vaccination and biosecurity measures, would target critical risk control points.

8. Compliance with the Terrestrial Code

~~The Delegate of the Member Country must submit documentary evidence that the provisions of Article 8.8.2. have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating that:~~

- ~~a) there has been no case of FMD during the past 12 months;~~
- ~~b) no vaccination against FMD has been carried out during the past 12 months;~~

~~In addition, the Delegate of the Member Country applying for historical zonal freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.~~

89. Recovery of free status

Member Countries applying for recognition of recovery of free status for a zone where vaccination is not practised should comply with the provisions of Article 8.8.7. and points 1, 3 and 4 of Article 8.8.2. of the Terrestrial Code and provide detailed information as specified in Sections 1–7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Annex 29 (contd)Article 1.11.4.**FMD FREE ZONE WHERE VACCINATION IS PRACTISED**

~~Report of a Member Country which applies for recognition of status,
under Chapter 8.8. of the Terrestrial Code,
as a FMD free zone practising vaccination~~

Zone where vaccination is practised

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a zone where vaccination is practised, that is free from infection with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the Terrestrial Code.

Please ~~The dossier provided to the OIE should~~ address concisely all the following topics under the headings provided to describe the actual situation in the country and procedures currently applied, explaining how this complies with the *Terrestrial Code*.

Please use ~~The terminology defined in the OIE Terrestrial Code and Terrestrial Manual should be referred to and used in compiling the dossier.~~

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

Any All annexes should be provided in one of the OIE official languages.

[Note from the TAHSC – Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below:]

8. Compliance with the Terrestrial Code

The Delegate of the Member Country applying for recognition of FMD zonal freedom must demonstrate compliance with the Terrestrial Code. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- a) there has been no case of FMD for the past 24 months two years;
- b) no evidence of FMDV transmission for the past 12 months;
- c) surveillance for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;
- d) routine vaccination is carried out for the purposes of the prevention of FMD;
- e) the vaccine used complies with the standards described in the Terrestrial Manual.

In addition, the Delegate of the Member Country applying for recognition of historical zonal freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.

1. Introduction

- a) Geographical entities features (rivers, mountain ranges, etc.). Provide a general description of the country and the zone and, when where relevant, of the region, including physical, geographical and other factors that are relevant to FMD introduction of infection and spread of FMD virus, dissemination, taking into account the as well as a short description of countries or zones sharing common borders and other epidemiologic pathways links for the potential introduction of the infection FMD.

Annex 29 (contd)

The boundaries of the zone must be clearly defined, including a *protection zone*, if applied.

Provide maps identifying the ~~factors~~ features above, including a digitalised, geo-referenced map with a description of the geographical boundaries of the zone.

b) Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country and the zone. In particular, describe:

- i) the susceptible animal *population* by species and types of production systems in the country and the zone;
- ii) the number of *herds* or *flocks*, etc. of each susceptible species;
- iii) their geographical distribution;
- iv) *herd* or *flock* density;
- v) the degree of integration and role of producer organisations in the different production systems;
- vi) any recent significant changes observed in the production (~~if attach relevant documents if are available, please attach~~).

Provide tables and maps.

c) *Wildlife* demographics. What susceptible *captive wild, wild or feral* susceptible species are present in the country and the zone? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?

d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g., fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic susceptible species movement for marketing within the country or zone, and between zones of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. ~~This list~~ This table should include, but not be limited to, the legislation on disease control measures and compensation systems.

b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with ~~the provisions of~~ Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, ~~and control, enforce and monitor~~ all FMD-related activities. Provide maps, figures and tables wherever possible.

c) Provide information on any OIE PVS evaluation conducted in ~~your~~ the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.

d) Provide a description of the involvement and the participation of industry, producers, farmers including subsistence and small-scale producers and keepers, veterinary paraprofessionals ~~including~~ community animal health workers, and other relevant groups in FMD surveillance and control. Provide a description of the role and structure of the private veterinary sector, ~~including number of veterinarians and their distribution, and role of the private veterinary profession~~ in FMD surveillance and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.

e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Annex 29 (contd)

Provide a description of the traceability system, including methods of animal identification, and establishment or holding, herd or flock registration and traceability for applicable to all susceptible species all production systems.

How are animal movements of all susceptible species controlled in and between zones of the same or different status for all production systems?

Provide evidence of on the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the last past 24 months ~~two years~~. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g., seasonal migration). Describe the actions available under national legislation.

~~Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on illegal movements detected in the past 24 months and the action taken.~~

3. FMD eradication

a) History. Provide a description of the FMD history in the country and zone, with emphasis on recent years. If applicable, provide tables and maps ~~to showing~~ the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of outbreaks per year), the susceptible species involved, the date of last case or *eradication* and the types and strains in the country.

b) Strategy. Describe how FMD was controlled and eradicated in the zone (e.g., *stamp-out policy*, zoning, *vaccination*, movement control). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~disease outbreaks of FMD~~ in response to any past ~~disease~~ incursions of FMD virus.

c) Vaccines and *vaccination*. Describe any legislation regulating *vaccination*. Provide a description and justification of the *vaccination* strategy and programme, including the following: regime. Briefly answer the following:

- i) the vaccine strains;
- ii) potency and formulation, purity, details of any vaccine matching performed;
- iii) the species vaccinated;
- iv) identification of vaccinated animals;
- v) the way in which the *vaccination* of animals was certified or reported and the records maintained;
- vi) the date on which the last *vaccination* was performed;
- vii) evidence that the vaccine used complies with Chapter 2.1.8. of the *Terrestrial Manual*.

d) Provide detailed evidence of *vaccination* coverage and *population immunity* as follows:

Describe how the number of animals intended for *vaccination* and the number of vaccinated animals are estimated.

For serological surveys to estimate *population immunity*, provide detailed information on the sampling frame (target population, age, species and *vaccination* status) and survey design (expected prevalence, acceptable error, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How long after *vaccination* are samples collected? Describe how the threshold for protective immunity has been established.

Annex 29 (contd)

Provide the results of the *vaccination coverage* and *population immunity* by year, serotype, species, as relevant.

Provide details of any additional methods applied for monitoring the performance of *vaccination*.

- e) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. In particular, The following points should be addressed:

- a) Is FMD *laboratory diagnosis* carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following: If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results. Indicate the laboratories where samples originating from the zone are diagnosed.
- b) Provide an overview of the FMD approved laboratories in the country. Address the following points:
- i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for obtaining reporting results;
 - ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months two years in the national *laboratories* and in *laboratories* in other countries, if relevant as well as abroad;
 - iii) Procedures for quality assurance and for the official accreditation of laboratories. Give details of formal internal quality management systems, e.g., Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system;
 - iv) Provide details of performance in inter-laboratory validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent. In particular, describe including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table linking identifying the tests carried out to by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If FMD *laboratory diagnosis* is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the zone complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code* and Chapter 2.1.8. of the *Terrestrial Manual*. In particular, The following information should be included: points should be addressed:

- a) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which sectors levels of the livestock production system are included in clinical *surveillance*, such as establishments farms, markets, fairs, slaughterhouses/abattoirs, check points, etc.

Annex 29 (contd)

Provide a summary table indicating, for the past 24 months two years, the number of suspected cases, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude FMD. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Serological and or virological surveillance. Are serological and or virological surveys conducted to demonstrate freedom from infection with FMDV in unvaccinated animals and of FMDV transmission in vaccinated animals, in particular applying the provisions of Article 8.8.42? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used) in accordance with Articles 8.8.40. to 8.8.42. of the Terrestrial Code. How frequently are they surveys conducted? Are susceptible wildlife species included in serological and or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months two years, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis).

Provide details of follow-up actions taken on all suspicious and positive results and how these findings are interpreted and acted upon. Provide criteria for selection of populations for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic laboratories. Provide details of the methods applied for monitoring the performance of the surveillance system including indicators.

- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g., targeted serological surveys, active surveillance, participatory epidemiology studies, risk assessments, etc.) Provide evidence of how the and that the acquired knowledge acquired through these activities assisted assists in more effective implementation of control measures.
- e) Provide details of the oversight of surveillance programmes by the Veterinary Services including training programmes for personnel involved in clinical, serological and virological surveillance and the approaches used to increase community involvement in FMD surveillance programmes.
- f) Provide evidence that surveys are carried out to assess vaccination coverage and population immunity of the target populations, show laboratory evidence that the vaccine strains used are appropriate.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country. In particular, provide including details of:

- a) Coordination with other countries. Describe any relevant factors about adjacent in neighbouring countries and zones that should be taken into account (e.g., size, distance from the border to affected herds, flocks or animals). Describe coordination, collaboration and information-sharing activities with other countries and zones in the same region or ecosystem.

If the FMD free zone with vaccination is situated in a FMD infected country or borders an infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

Are protection zones in place? If so, indicate whether or not the protection zones are included in the proposed FMD free zones, provide details of the measures that are applied (e.g., vaccination, intensified surveillance, density control of susceptible species) and provide a geo-referenced map of the zones.

Annex 29 (contd)

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation spread of the pathogenic agent within the country or zone and through trade. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good biosecurity practices, hygiene, cleaning and disinfection routines at critical points all along the production and marketing networks (typically where animals are being moved; and marketed through the country or region).
- c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill containing animal products to pigs regulated? If so, provide information on the extent of the practice, and describe controls and surveillance measures.
- d) Import control procedures

Provide information on countries, zones or compartments from which the country authorises the import of susceptible animals or their products into the country or zone. Describe the criteria applied to approve such countries, zones or compartments, the controls applied on to entry of such animals and products and subsequent internal movement. Describe the import measures conditions (e.g., quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and if so, the duration and location of quarantine. Advise whether import permits and international veterinary certificates are required.

Describe any other procedures used for assessing the risks of posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months two years, including temporary import and re-entry, specifying countries, zones or compartments of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not outbreaks have been related to imports or transboundary movements of domestic animals.

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts and between border inspection posts.
- ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months two years, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?
- iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the zone or their final destination, concerning the import and follow-up of the following:
- animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - veterinary medicinal products (i.e. biologics);
 - other materials at risk of being contaminated with FMD virus, including bedding, litter and feed.

Annex 29 (contd)7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the Veterinary Services for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex ~~and if not available~~ in one of the OIE official languages. ~~If not available, provide~~ a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for FMD that was conducted in the country in the last five years.
- b) In the event of a suspected or confirmed FMD *outbreak*:
 - i) ~~Is~~ ~~Are~~ quarantine measures imposed on premises establishments with ~~suspicious~~ suspected cases, pending final diagnosis? What other procedures are followed ~~regarding~~ ~~suspicious~~ with respect to suspected cases (e.g., livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the causative pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the premises establishments where the *outbreak* was confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g., forward and backward tracing, movement control, *disinfection* of establishments premises, vehicles and equipment, including verification methods, *vaccination* including vaccination vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological surveillance programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;(17)
 - vii) Describe how control efforts, including *vaccination* and *biosecurity measures*, would target critical risk control points.

8. Compliance with the Terrestrial Code

~~The Delegate of the Member Country must submit documentary evidence that the provisions of Article 8.8.3. are have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating that:~~

- a) ~~there has been no case of FMD for the past two years;~~
- b) ~~no evidence of FMDV transmission for the past 12 months;~~
- c) ~~surveillance for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;~~
- d) ~~routine vaccination is carried out for the purpose of the prevention of FMD;~~
- e) ~~the vaccine used complies with the standards described in the Terrestrial Manual.~~

89. Recovery of status

Member Countries applying for recognition of recovery of free status for a zone where vaccination is practised should comply with the provisions of Article 8.8.7 and points 1, 3 and 4 of Article 8.8.3. of the *Terrestrial Code* and provide detailed information as specified in Sections 1–7 (inclusive) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Annex 29 (contd)Article 1.6.11.**Questionnaire on endorsement of official control programme for foot and mouth disease (FMD)****COUNTRY WITH AN OIE ENDORSED OFFICIAL CONTROL PROGRAMME FOR FMD**

Report of a Member Country which applies for the OIE endorsement
of its official control programme for FMD
under Chapter 8.8. of the *Terrestrial Code*

Article 1.11.5.**Application for endorsement by the OIE of an official control programme for foot and mouth disease**

The following information should be provided by OIE Member Countries to support applications for endorsement by the OIE of an official control programme for foot and mouth disease (FMD) in accordance with Chapter 8.8. of the *Terrestrial Code*.

The dossier provided to the OIE should ~~In sections 1 to 3.5.~~ please address concisely all the following topics under the headings provided ~~in Sections 1 to 3.e)~~ 4 to describe the actual situation in the country and procedures currently applied, explaining how these comply with the *Terrestrial Code*.

In Sections ~~3 f) to 3 i)~~ ~~3.6. to 3.9.~~ please address describe concisely the work plan and timelines of the control programme for the next five years.

Please use The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

Any All annexes should be provided in one of the OIE official languages.

NB the paragraph below has been moved from the end of the chapter

5. Compliance with the *Terrestrial Code*

The Delegate of the Member Country applying for endorsement of the official control programme should submit documentary evidence that the provisions of Article 8.8.39. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for FMD.

1. Introduction

- a) Geographical entities features (rivers, mountains ranges, etc.). Provide a general description of the country, zones and, ~~when where~~ relevant, of the region, including physical, geographical and other factors that are relevant to FMD introduction ~~of infection~~ and ~~dissemination spread of FMD, taking into account the as well as a short description of countries or zones sharing common borders and other epidemiologic pathways~~ links for the potential introduction of infection FMD.

Provide maps identifying the factors features above.

Specify whether the application includes any noncontiguous territories.

- b) If the endorsed plan is gradually implemented in stages to ~~in~~ specific parts of the country, the boundaries of the zones should be clearly defined, including the *protection zones*, if applied. Provide a digitalised, geo-referenced map with a description of the geographical boundaries of the zones.

Annex 29 (contd)

- c) Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country and any zones. In particular, describe:
- i) the susceptible animal *population* by species and types of production systems;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (*if attach relevant documents are if available, please attach*).

Provide tables and maps.

- d) *Wildlife* demographics. What susceptible captive wild, wild or feral susceptible species are present in the country and any zones? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible wildlife susceptible species?
- e) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g., fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic susceptible species movement for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and *Veterinary Authority* directives in relation to the FMD control programme and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) Veterinary Services. Describe how the *Veterinary Services* of the country comply with ~~the provisions of~~ Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, ~~and control, enforce and monitor~~ all FMD-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in *your* the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.
- d) Provide a description of ~~on~~ the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, veterinary paraprofessionals including community animal health workers, and other relevant groups in FMD surveillance and control. Provide a description of the role and structure of the private veterinary sector, ~~(including number of veterinarians and their distribution)~~, ~~and role of the private veterinary profession in FMD surveillance and control~~.

Include a description of continuing education and awareness programmes on FMD at all relevant levels.

- e) *Animal identification, registration, traceability and movement control*. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of animal identification and holding, establishment or herd or flock registration and traceability applicable to all susceptible species production systems. How are animal movements controlled in the country for all susceptible species production systems? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months last two years.

Annex 29 (contd)

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g., seasonal migration). Describe the actions available under national legislation., ~~and actually taken, when an illegal import is detected.~~

Provide information on illegal movements detected in the past 24 months and the action taken.

3. Official control programme for FMD submitted for OIE endorsement

Submit a concise plan ~~on~~ of the measures for the control and eventual *eradication* of FMD in the country, including:

3.1.a) Epidemiology

- a)ii) ~~Provide a description of~~ Describe the FMD history in the country, with emphasis on recent years. Provide tables and maps showing the date of first detection, the number and location of *outbreaks* per year, the sources and routes of introduction of *infection*, the types and strains present, the susceptible species involved and the date of implementation of the control programme in the country.
- b)ii) Describe the epidemiological situation of FMD in the country and the surrounding countries or zones highlighting the current knowledge and gaps. Provide maps ~~on~~ of:
 - i) the geography of the country with the relevant information concerning FMD situation;
 - ii) livestock density and movements and estimated FMD prevalence.

3.2.b) FMD surveillance

Provide documentary evidence ~~on whether that~~ surveillance for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code* and Chapter 2.1.8. of the *Terrestrial Manual*. In particular, The following information should be included points should be addressed:

- a)i) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b)ii) Describe how clinical *surveillance* is conducted, including which ~~levels~~ sectors of the livestock production system are included in clinical *surveillance*, such as ~~establishments~~ farms, markets, fairs, *slaughterhouses/abattoirs*, check points, etc. Provide details of ~~on~~ follow-up actions taken on clinical suspicions.
- c)iii) Serological and or virological *surveillance*. Explain whether or not serological and or virological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the ~~survey design~~ (*target population*, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used) in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. Are susceptible *wildlife* species included in serological and or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for at least the past 24 months two years, the number of suspected cases, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details of follow-up actions taken on suspicious and positive results and on how these findings are interpreted and acted upon.

Provide criteria for selection of *populations* for targeted *surveillance* and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of ~~on~~ the methods applied for monitoring the performance of the *surveillance* system including indicators.

Annex 29 (contd)

- aiv) Provide information on circulating strains and the level of risk in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g., targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.) and that the acquired knowledge assists in more effective implementation of control measures.
- ev) Provide details ~~on of the oversight of surveillance programmes by the Veterinary Services including~~ training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.
- fvj) Provide evidence that surveys are carried out to assess *vaccination coverage* and *population immunity* of the target *populations*, show laboratory evidence that the vaccine used is appropriate for circulating strains of virus, show analysis of *surveillance* data to assess the change in FMD prevalence over time in the target *populations*, assess the control measures (cost effectiveness, degree of implementation, impact). Provide information on outcomes of *outbreak* investigations including *outbreaks* that have occurred despite control measures, documented inspections showing compliance with biosecurity and hygiene requirements.

3.3-c) FMD laboratory diagnosis

Provide documentary evidence that the relevant provisions ~~on of~~ Chapters 1.1.2., 1.1.3. and 2.1.8. of the *Terrestrial Manual* are applied. In particular, The following points should be addressed:

- a) Is FMD *laboratory diagnosis* carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following: ~~If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.~~
- b) ~~Provide an overview of the FMD approved laboratories in the country. Address the following points:~~
 - i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for obtaining reporting results;
 - ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details ~~on of~~ the number of FMD tests performed in the past 24 months last two years in the national *laboratories* and in laboratories in other countries, if relevant as well as abroad;
 - iii) Procedures for quality assurance and, if available, the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g., Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory system*;
 - iv) Provide details of performance in inter-*laboratory validation* tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details ~~on of~~ the handling of live pathogenic agent. In particular, including a description of the describe biosecurity and biosafety measures applied;
 - vi) Provide a table linking identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
 - ii) If FMD laboratory diagnosis is not carried out in the country, provide the names of the laboratories in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

Annex 29 (contd)3.4-d) Strategies

- a(i)* Provide a description of the legislation, organisation and implementation of the current FMD control programme. Outline the legislation applicable to the control programme and how its implementation is organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- b(ii)* Describe FMD control strategies in the country or any zones, including in terms of animal movement control, fate of infected and in-contact animals and *vaccination*. Strategies should be based on the assessment of the FMD situation in the zones, country and region.
- c(iii)* Provide information on what types of vaccines are used and which species are vaccinated. Provide information on the licensing process ~~of~~ for the vaccines used. Describe the *vaccination* programme in the country and any zones, including records kept, and provide evidence to show its effectiveness, such as *vaccination coverage*, *population immunity*, etc. Provide details of the studies carried out to determine the *vaccination coverage* and the *population immunity*, including the study designs and the results.
- d(iv)* Describe how the *stamping-out policy* is implemented in the country or any zones and under which circumstances.
- e(v)* In the event of outbreaks, provide evidence of the impact of the control measures already implemented ~~in the event of outbreaks~~ on the reduction in number of outbreaks and their distribution. If possible, provide information on primary and secondary *outbreaks*.

3.5-e) FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, ~~- In particular provide including details of~~ or:

- a(i)* Coordination with other countries. Describe any relevant factors in neighbouring about adjacent countries and zones that should be taken into account (e.g., size, distance from the border to affected *herds*, *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and zones in the same region or ecosystem.
- Are *protection zones* in place? If so, provide details of the measures that are applied (e.g., *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the zones.
- b(ii)* Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation spread of the pathogenic agent within the country or zone ~~and through trade~~. Provide evidence that measures to reduce transmission of FMD are in place at markets, ~~to reduce transmission of FMD~~ such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity practices*, hygiene *cleaning* and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).
- c(iii)* What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill ~~containing animal products~~ to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

d(iv) Import control procedures

Provide information on countries, zones or compartments from which the country authorises the import of susceptible animals or their products into the country or any zones. Describe the criteria applied to approve such countries, zones or compartments, the controls applied ~~on to~~ entry of such animals and products and subsequent internal movement. Describe the import measures conditions (e.g., quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and international veterinary certificates are required.

Annex 29 (contd)

Describe any other procedures used for assessing the *risks of posed by* import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past ~~24 months two years~~, including temporary import and re-entry, specifying countries, zones or compartments of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not outbreaks have been related to imports or transboundary movements of domestic animals.

- #) Provide a map showing with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- #) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past ~~24 months two years~~, of the quantity disposed of and the disposal locations. What are the biosecurity measures is in place at waste disposal sites?
- ##) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - veterinary medicinal products; i.e. biologics, vaccines,
 - other materials at risk of being contaminated with FMD virus, including bedding, litter and feed.

- v) Describe the actions available under legislation when an illegal import is detected.

Provide information on illegal imports detected and the action taken.

f)3.6. Work plan Workplan and timelines of the control programme for the next five years, including cessation of vaccination. Describe the progressive objectives including expected status to be achieved for in the next five years: for zones (if applicable) and for the whole country.

g)3.7. Performance indicators and timeline. The performance indicators should relate to the most important areas and steps where improvements in the programme are needed. These may include, but are not restricted to, strengthening Veterinary Services, legislation, reporting, availability and quality of vaccines, animal identification systems, vaccination coverage, population immunity, movement control, disease awareness, livestock owners' participatory perception on the effectiveness of the programme, etc. The progressive reduction of outbreak incidence towards elimination of FMD virus transmission in all susceptible livestock in at least one zone of the country should also be measured and monitored.

h)3.8. Assessment of the evolution of the official control programme since the first date of implementation. This should include documented evidence demonstrating that the control programme has been implemented and that the first results are favourable. Measurable evidence of success such as the performance indicators should include, but not be limited to, vaccination data, decreased prevalence, successfully implemented import measures, control of animal movements and finally decrease or elimination of FMD outbreaks in the whole country or selected zones as described in the programme. Where relevant, the transition to the use of vaccines, which are fully compliant with the Terrestrial Manual in order to enable demonstration of no evidence of FMD virus transmission, should be included in the timeline.

This should include documented evidence of the effective good implementation of Sections 3 d) and 3 e) 3.4. and 3.5. above.

i)3.9. Description of Describe the funding for the control programme and annual budgets for its duration.

Annex 29 (contd)4. Control measures and emergency response

- a) List any written guidelines, including contingency plans, available to the Veterinary Services for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex ~~and if not available~~ in one of the OIE official languages. If not available, provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for FMD that was conducted in the country in the last five years.
- b) In the event of a suspected or confirmed FMD *outbreak*:
 - i) ~~is Are~~ quarantine measures imposed on establishments premises with suspected suspicious cases, pending final diagnosis? What other procedures are followed regarding suspected suspicious cases (e.g., livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the causative pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the premises establishments where the *outbreak* ~~was is~~ confirmed;
 - iv) ~~provide a detailed description of~~ Describe in detail the control or eradication procedures (e.g., forward and backward tracing, disinfection of premises establishments, vehicles and equipment, including verification methods, vaccination including vaccination delivery and cold chain, stamping-out policy, movement control, control of wildlife, pastured livestock and livestock as pets, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency vaccination, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological surveillance programmes, etc.;
 - vi) ~~give~~ Provide details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or eradication purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including vaccination and biosecurity measures, would target critical risk control points.

5. Compliance with the Terrestrial Code

~~The Delegate of the Member Country must submit documentary evidence that the provisions of Article 8.8.39. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for FMD.~~

CHAPTER 1.12.

Article 1.6.9.

APPLICATION FOR OFFICIAL RECOGNITION BY THE OIE OF FREE STATUS FOR PESTE DES PETITS RUMINANTS

Questionnaires on peste des petits ruminants (PPR)

PPR FREE COUNTRY

Report of a Member Country which applies for recognition of status, under Chapter 14.7. of the *Terrestrial Code*, as a PPR free country
Article 1.12.1.

Country free from infection with peste des petits ruminants virus

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a country free from infection with peste des petits ruminants (PPR) virus in accordance with Chapter 14.7. of the *Terrestrial Code*.

Please The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how this these complies comply with the *Terrestrial Code*.

Please use The terminology defined in the OIE Terrestrial Code and Terrestrial Manual should be referred to and used in compiling the dossier.

National legislation, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

Any All annexes should be provided in one of the OIE official languages.

[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]

8. Compliance with the Terrestrial Code

The Delegate of the Member Country applying for recognition of PPR freedom for a country must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 14.7.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- a) there has been no outbreak of PPR during the past 24 months;
- b) no evidence of PPRV infection with PPR virus has been found during the past 24 months;
- c) no vaccination against PPR has been carried out during the past 24 months;
- d) importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with Articles 14.7.8. to 14.7.26.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.

Annex 30 (contd)1. Introduction

- a) Geographical entities features (rivers, mountain ranges, etc.). Provide a general description of the country and, when where relevant, of the region, including physical, geographical and other factors that are relevant to PPR introduction of infection and dissemination spread of PPR virus, taking into account the as well as a short description of countries sharing common borders and other epidemiologic pathways links for the potential introduction of infection.

Provide maps identifying the factors features above.

Specify whether the application includes any noncontiguous territories.

- b) Livestock demographics. Provide a general description of Describe the composition of the livestock industry in the country. In particular, describe:
- i) the susceptible animal population by species and types of production systems;
 - ii) the number of herds or flocks, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) herd or flock density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (# attach relevant documents are if available), please attach.

Provide tables and maps.

- c) Wildlife demographics. What susceptible captive wild, wild or feral susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible wildlife susceptible species?
- d) Slaughterhouses/abattoirs, markets and events associated with the congregation of susceptible livestock (e.g., fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of domestic susceptible domestic species movement for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and Veterinary Authority directives in relation to PPR and a brief description of the relevance of each. This list The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) Veterinary Services. Describe how the Veterinary Services of the country comply with the provisions of Chapters 1.1., 3.1. and 3.2. of the Terrestrial Code. Describe how the Veterinary Services supervise, and control, enforce and monitor all PPR-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in your the country and follow-up steps within the PVS Pathway and highlight the results relevant to PPR and the susceptible species.

Annex 30 (contd)

- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, veterinary paraprofessionals including community animal health workers, and other relevant groups in PPR surveillance and control. Provide a description of the structure and role of the private veterinary sector, including number of veterinarians and their distribution, ~~and role of the private veterinarians~~ veterinary profession in PPR surveillance and control. Include a description of continuing education and awareness programmes on PPR at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of *animal identification* and ~~holding, establishment or herd or flock registration and traceability applicable to for all susceptible species production systems~~.

How are animal movements controlled in the country for all susceptible species production systems?

Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past two years ~~24 months~~.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g., seasonal migration for pastures and water). Describe the actions available under national legislation.

~~Describe the action available under legislation, and actually taken, when an illegal import is detected.~~ Provide information on illegal movements detected in the past 24 months and the action taken.

3. PPR eradication

- a) History. If infection has never occurred in the country ~~has never had the disease~~, or has not had it occurred within the past 25 years, ~~please~~ state explicitly whether or not the country or zone is applying for recognition of historical freedom according to Article 1.4.6. of the *Terrestrial Code*.

If the infection has occurred in the country ~~has had the disease~~ within the past 25 years, provide a description of the PPR history in the country, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of last case or *eradication* in the country.

- b) Strategy. Describe how PPR was controlled and eradicated (e.g., *stamp-ing-out policy*, modified stamping-out policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*.

Describe and justify the corrective actions that have been implemented to prevent future ~~disease outbreaks of PPR~~ in response to any past ~~disease~~ incursions of PPR virus.

- c) Vaccines and *vaccination*. Briefly answer the following:

- i) Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal vaccination during the reporting period and actions taken in response to the detection.
- ~~Describe the action available under legislation, and actually taken, when an illegal vaccination is detected;~~
- ~~Provide information on detected illegal vaccination during the reporting period.~~

Annex 30 (contd)

- ii) Was vaccination ever used in the country? If so:*
- Provide the date when the last vaccination was carried out;
 - What type of vaccine was used?
 - What species were vaccinated?
 - How were vaccinated animals identified?
 - What was the fate of those animals?
- iii) In addition, if vaccination was conducted applied during the past two years-24 months, provide a description and justification of the vaccination strategy and programme, including the following: regime. Briefly answer the following:*
- the vaccine strains;
 - the species vaccinated;
 - identification of vaccinated animals;
 - the way in which the vaccination of animals was certified or reported and the records maintained;
 - Provide evidence that the vaccine used complies with Chapter 2.7.10. of the *Terrestrial Manual*.
- d) Provide a description of the legislation, organisation and implementation of the eradication campaign. Outline the legislation applicable to the eradication and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.*

4. PPR diagnosis

Provide documentary evidence that the relevant provisions in Chapters 1.1.2., 1.1.3. and 2.7.10. of the *Terrestrial Manual* are applied. In particular, The following points should be addressed:

- a) Is PPR laboratory diagnosis carried out in the country? If so, provide an overview of the PPR-approved laboratories in the country, including the following: If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.*
- b) Provide an overview of the PPR approved laboratories in the country. Address the following points:*
- i) How the work is shared between different laboratories, logistics for shipment of samples, the follow-up procedures and the time frame for reporting obtaining results;*
 - ii) Details on of test capability, and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details on of the number of PPR tests performed in the past two years-24 months in the national laboratories and in laboratories in other countries, if relevant as well as abroad;*
 - iii) Procedures for quality assurance and for the official accreditation of laboratories. Give details of formal internal quality management systems, e.g., Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system;*
 - iv) Provide details of performance in inter-laboratory validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;*

Annex 30 (contd)

- v) Provide details of the handling of live pathogenic agent, In particular, describe including a description of the biosecurity and biosafety measures applied;
- vi) Provide a table linking identifying the tests carried out to by each of the laboratories where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If PPR laboratory diagnosis is not carried out in the country, provide the names of the laboratories in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. PPR surveillance

Provide documentary evidence that *surveillance* for PPR in the country complies with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code* and Chapter 2.7.10. of the *Terrestrial Manual*. In particular, The following information should be included points should be addressed:

- a) What are the criteria for raising a suspicion of PPR? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which levels-sectors of the livestock production system are included in clinical *surveillance*, such as establishments farms, markets, fairs, slaughterhouses/abattoirs, check points, etc.

Provide a summary table indicating, for the past two years-24 months, the number of suspected cases, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude PPR. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Serological *surveillance*. Are serological surveys conducted? If so, provide detailed information on the survey design target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code*. Are susceptible *wildlife* species included in serological surveys? If not, explain the rationale. Provide a summary table indicating, for the past 24 months-two years, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and on how these findings are interpreted and acted upon. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* system including indicators.
- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g., targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the and that the acquired knowledge acquired through these activities assisted assists in more effective implementation of control measures.
- e) Provide details of the oversight of surveillance programmes by the Veterinary Services including training programmes for personnel involved in clinical and serological *surveillance*, and the approaches used to increase community involvement in PPR *surveillance* programmes.

6. PPR prevention

Describe the procedures in place to prevent the introduction of PPR into the country, In particular including provide details on of:

Annex 30 (contd)

- a) Coordination with other countries. Describe any relevant factors ~~about adjacent in neighbouring~~ countries that should be taken into account (e.g., size, distance from the border to affected herds or flocks or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (e.g., vaccination, intensified surveillance, density control of susceptible species), and provide a geo-referenced map of the zones.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation spread of the pathogenic agent within the country ~~and through trade~~. Provide evidence that measures ~~to reduce transmission of PPR~~ are in place at markets ~~to reduce transmission of PPR~~, such as enhancing awareness of PPR transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity practices*, hygiene, cleaning-and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

- c) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied ~~on to~~ entry of such animals and products and subsequent internal movement. Describe the import measures ~~conditions~~ (e.g., quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health international veterinary certificates are required.

Describe any other procedures used for assessing the risks posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past ~~two years~~ 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country.

- i) Provide a map ~~with showing~~ the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
- animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - *veterinary medicinal products* (i.e. *biologics, vaccines*);
 - other materials at risk of being contaminated with PPR virus.

Annex 30 (contd)7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the Veterinary Services official services for dealing with suspected or confirmed outbreaks of PPR. The contingency plan should be attached as an annex in one of the OIE official languages. ~~and, If not available, provide~~ a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for PPR that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed PPR outbreak:
 - i) ~~Are~~ ~~is~~-quarantine measures imposed on establishments premises with suspicious suspected cases, pending final diagnosis? What other procedures are followed ~~regarding~~ ~~suspicious~~ with respect to suspected cases (e.g., livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the causative pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the premises establishments where the outbreak ~~was~~ is confirmed;
 - iv) Provide a detailed description of the control or eradication procedures (e.g., forward and backward tracing, disinfection of establishments premises, vehicles and equipment, including verification methods, vaccination, stamp-out policy, movement control, control of wildlife, pastured sheep and goats, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers, etc.) that would be taken. In the case of emergency vaccination, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an outbreak has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological surveillance programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or eradication purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including vaccination and biosecurity measures, would target critical risk control points.

8. Compliance with the Terrestrial Code

~~The Delegate of the Member Country applying for PPR freedom must submit documentary evidence that the provisions of Article 14.7.3. have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating that:~~

- a) ~~there has been no outbreak of PPR during the past 24 months;~~
- b) ~~no evidence of PPRV infection has been found during the past 24 months;~~
- c) ~~no vaccination against PPR has been carried out during the past 24 months;~~
- d) ~~importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with Articles 14.7.8. to 14.7.26.~~

~~The Delegate of the Member Country applying for historical freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.~~

Annex 30 (contd)98. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 14.7.7. of the *Terrestrial Code* and provide detailed information as specified in Sections 1 to 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.12.2.**Zone free from infection with peste des petits ruminants virus**

The following information should be provided by OIE Member Countries to support applications for official recognition of status as a zone free from infection with peste des petits ruminants (PPR) virus in accordance with Chapter 14.7. of the Terrestrial Code.

PPR FREE ZONE

~~Report of a Member Country which applies for recognition of status, under Chapter 14.7. of the Terrestrial Code, as a PPR free zone~~

Please The dossier provided to the OIE should address concisely all the following topics under the headings provided to describe the actual situation in the country and the procedures currently applied, explaining how this these complies comply with the *Terrestrial Code*.

Please use the The terminology defined in the OIE Terrestrial Code and Terrestrial Manual should be referred to and used in compiling the dossier.

National legislation, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

AnyAll annexes should be provided in one of the OIE official languages.

[Note from the TAHSC - Point 8 has been moved from the end of the questionnaire to improve the logical flow of the document see below.]

8. Compliance with the Terrestrial Code]

The Delegate of the Member Country applying for recognition of PPR freedom for a zone must demonstrate compliance with the Terrestrial Code. That is, the Delegate should submit documentary evidence that the provisions of Article 14.7.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that:

- a) there has been no outbreak of PPR during the past 24 months;
- b) no evidence of PPRV infection with PPR virus has been found during the past 24 months;
- c) no vaccination against PPR has been carried out during the past 24 months;
- d) importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with Articles 14.7.8. to 14.7.26.

In addition, the Delegate of the Member Country applying for recognition of historical freedom must also submit documentary evidence that the provisions of point 1 a) of Article 1.4.6. of the Terrestrial Code have been properly implemented and supervised.

1. Introduction

- a) Geographical entities features (rivers, mountain ranges, etc.). Provide a general description of the country and the zone and, when where relevant, of the region, including physical, geographical and other factors that are relevant to PPR introduction of infection and dissemination spread of PPR virus, taking into account the as well as a short description of countries or zones sharing common borders and other epidemiologic pathways links for the potential introduction of PPR infection. The boundaries of the zone must be clearly defined, including a protection zone, if applied.

Annex 30 (contd)

Provide maps identifying the ~~factors~~ features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the zone.

- b) Livestock demographics. ~~Provide a general description of~~ Describe the composition of the livestock industry in the country and the zone. In particular, describe:
 - i) the susceptible animal *population* by species and types of production systems in the country and the zone;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (*if attach relevant documents are if available, please attach*).

Provide tables and maps.

- c) *Wildlife* demographics. What susceptible captive wild, wild or feral susceptible species are present in the country and the zone? Provide estimates of *population* sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g., fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species movement for marketing within the country or zone, and between zones of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and *Veterinary Authority* directives in relation to PPR and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) Veterinary Services. Describe how the Veterinary Services of the country comply with ~~the provisions of~~ Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code*. Describe how the Veterinary Services supervise, and control, enforce and monitor all PPR-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in ~~your~~ the country and follow-up steps within the PVS Pathway and highlight the results relevant to PPR and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, veterinary paraprofessionals including community animal health workers, and other relevant groups in PPR surveillance and control. Provide a description of the role and structure of the private veterinary sector, (including number of veterinarians and their distribution,) and role of the private veterinary profession, in PPR surveillance and control. Include a description of continuing education and awareness programmes on PPR at all relevant levels.

Annex 30 (contd)

- e) Animal identification, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of *animal identification* and holding, establishment or herd or flock registration and traceability applicable to for all susceptible species production systems.

How are animal movements controlled in and between zones of the same or different status for all susceptible species production systems?

Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past two years 24 months.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g., seasonal migration for pastures and water). Describe the actions available under national legislation.

Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on illegal movements detected in the past 24 months and the action taken.

3. PPR eradication

- a) History. If infection has never occurred in the zone has never had the disease, or has not had it occurred within the past 25 years, please state explicitly whether or not the zone is applying for recognition of historical freedom according to Article 1.4.6. of the Terrestrial Code.

If infection has occurred in the zone has had the disease within the past 25 years, provide a description of the PPR history in the country and zone, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, and the date of last case or eradication in the zone.

- b) Strategy. Describe how PPR was controlled and eradicated in the zone (e.g., *stamping-out policy*, modified stamping-out policy, zoning, *vaccination*, movement control). Provide the time frame for eradication.

Describe and justify the corrective actions that have been implemented to prevent future disease outbreaks of PPR in response to any past disease incursions of PPR virus.

- c) Vaccines and *vaccination*. Briefly answer the following:

- i) Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal vaccination during the reporting period and actions taken in response to the detection.
- Describe the action available under legislation, and actually taken, when an illegal vaccination is detected;
- Provide information on detected illegal vaccination during the reporting period.

- ii) Was *vaccination* ever used in the country? If so:

- Provide the date when the last *vaccination* was carried out;
- What type of vaccine was used in the zone and the rest of the country?
- What species were vaccinated?
- How were vaccinated animals identified?
- What was the fate of those animals?

Annex 30 (contd)

- iii) In addition, if vaccination was applied conducted during the past two years 24 months, provide a description and justification of the vaccination strategy and programme, including the following regime. Briefly answer the following:*
- the vaccine strains;
 - the species vaccinated;
 - identification of vaccinated animals;
 - the way in which the vaccination of animals was certified or reported and the records maintained;
 - provide evidence that the vaccine used complies with Chapter 2.7.10. of the *Terrestrial Manual*.
- d) Provide a description of the legislation, organisation and implementation of the eradication campaign. Outline the legislation applicable to the eradication and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.*
4. PPR diagnosis
- Provide documentary evidence that the relevant provisions in Chapters 1.1.2., 1.1.3. and 2.7.10. of the *Terrestrial Manual* are applied. In particular, The following points should be addressed:
- a) Is PPR *laboratory* diagnosis carried out in the country? If so, provide an overview of the PPR-approved laboratories in the country, including the following: If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results. Indicate the laboratories where samples originating from the zone are diagnosed.
- b) Provide an overview of the PPR approved laboratories in the country. Address the following points:
- i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for obtaining reporting results;
 - ii) Details on of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of PPR tests performed in the past two years 24 months in the national *laboratories* and in laboratories in other countries, if relevant as well as abroad;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g., Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-laboratory validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent. In particular, describe, including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table linking identifying the tests carried out to by each of the laboratories where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If PPR *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

Annex 30 (contd)5. PPR surveillance

Provide documentary evidence that *surveillance* for PPR in the zone complies with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code* and Chapter 2.7.10. of the *Terrestrial Manual*. ~~In particular, the following information should be included~~points should be addressed:

- a) What are the criteria for raising a suspicion of PPR? What is the procedure to notify (by whom and to whom), what incentives are there for reporting and what penalties are involved for failure to report?
- b) Describe how clinical *surveillance* is conducted, including which ~~levels~~ sectors of the livestock production system are included in clinical *surveillance*, such as ~~establishments~~ farms, markets, fairs, slaughterhouses/abattoirs, check points, etc.

Provide a summary table indicating, for the past ~~two years~~ 24 months, the number of suspected cases, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide an indication of the timelines of the response including completion of testing to confirm or exclude PPR. Provide details of follow-up actions taken on all suspicious and positive results.

- c) Serological *surveillance*. Are serological surveys conducted? If so, provide detailed information on the ~~survey design~~ target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code*. Are susceptible *wildlife* species included in serological surveys? If not, explain the rationale. Provide a summary table indicating, for the past ~~24 months~~ two years, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and on how these findings are interpreted and acted upon. Provide criteria for selection of *populations* for targeted *surveillance* and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* system including indicators.
- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g., targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). ~~Provide evidence of how and that the acquired knowledge acquired through these activities assisted~~ assists in more effective implementation of control measures.
- e) Provide details of the oversight of surveillance programmes by the Veterinary Services including training programmes for personnel involved in clinical and serological *surveillance*, and the approaches used to increase community involvement in PPR *surveillance* programmes.

6. PPR prevention

Describe the procedures in place to prevent the introduction of PPR into the country or zone, ~~In particular, provide including~~ details of:

- a) Coordination with other countries. Describe any relevant factors ~~in about adjacent neighbouring~~ countries and zones that should be taken into account (e.g., size, distance from the border to affected herds or flocks or animals). Describe coordination, collaboration and information-sharing activities with other countries and zones in the same region or ecosystem.

If the PPR free zone is ~~situated~~ established in a PPR infected country or borders an infected country or zone, describe the animal health measures implemented to effectively prevent the introduction of the *pathogenic agent*, taking into consideration existing physical or geographical barriers.

Are *protection zones* in place? If so, indicate whether or not the *protection zones* are included in the proposed free zones. Provide details of the measures that are applied (e.g., *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the zones.

Annex 30 (contd)

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation spread of the pathogenic agent within the country or zone ~~and through trade~~. Provide evidence that measures to reduce transmission of PPR are in place at markets ~~to reduce transmission of PPR~~, such as enhancing awareness of PPR transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good biosecurity practices, hygiene, cleaning and disinfection routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

c) Import control procedures

Provide information on countries, zones or compartments from which the country authorises the import of susceptible animals or their products into the country or zone. Describe the criteria applied to approve such countries, zones or compartments, the controls applied ~~on~~ to entry of such animals and products and subsequent internal movement. Describe the import measures conditions (e.g., quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health international veterinary certificates are required.

Describe any other procedures used for assessing the risks posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past ~~two years~~ 24 months, including temporary import and re-entry, specifying countries, zones or compartments of origin, species and the quantity or volume and eventual destination in the country or zone.

- i) Provide a map ~~with~~ showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central Veterinary Services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the zone or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - veterinary medicinal products (i.e. biologics, vaccines);
 - other materials at risk of being contaminated with PPR virus.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the Veterinary Services official services for dealing with suspected or confirmed outbreaks of PPR. The contingency plan should be attached as an annex in one of the OIE official languages. ~~and, If not available, provide~~ a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for PPR that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed PPR outbreak:
 - i) Is Are quarantine measures imposed on establishments premises with suspicious suspected cases, pending final diagnosis? What other procedures are followed ~~regarding~~ suspicious with respect to suspected cases (e.g., livestock standstills)?

Annex 30 (contd)

- ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the causative pathogenic agent;*
- iii) Describe the actions that would be taken to control the disease situation in and around the establishments premises where the *outbreak was is* confirmed;*
- iv) Provide a detailed description of the control or *eradication* procedures (e.g., forward and backward tracing, *disinfection of establishments* premises, vehicles and equipment, including verification methods, *vaccination*, *stamping-out policy*, movement control, control of *wildlife*, pastured sheep and goats, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers, etc.) that would be taken; in the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;*
- v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological surveillance programmes, etc.;*
- v) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;*
- vii) Describe how control efforts, including *vaccination* and *biosecurity measures*, would target critical risk control points.*

8. Compliance with the Terrestrial Code

~~The Delegate of the Member Country applying for PPR freedom must submit documentary evidence that the provisions of Article 14.7.3. have been properly implemented and supervised.~~

~~In addition, the Delegate of the Member Country must submit a declaration indicating that:~~

- ~~a) there has been no outbreak of PPR during the past 24 months;~~
- ~~b) no evidence of PPRV infection has been found during the past 24 months;~~
- ~~c) no vaccination against PPR has been carried out during the past 24 months;~~
- ~~d) importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with Articles 14.7.8. to 14.7.26.~~

~~The Delegate of the Member Country applying for historical zonal freedom must also submit documentary evidence that the provisions of point 1 of Article 1.4.6. of the *Terrestrial Code* have been properly implemented and supervised.~~

Annex 30 (contd)89. Recovery of free status

Member Countries applying for recognition of recovery of free status for a zone should comply with the provisions of Article 14.7.7. of the *Terrestrial Code* and provide detailed information as specified in Sections 1 to 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

Article 1.6.12.**Questionnaire on endorsement of official control programme for peste des petits ruminants (PPR)****COUNTRY WITH AN OIE ENDORSED OFFICIAL CONTROL PROGRAMME FOR PPR**

Report of a Member Country which applies for the OIE endorsement
of its official control programme for PPR
under Chapter 14.7. of the *Terrestrial Code*

Article 1.12.3.**Application for endorsement by the OIE of an official control programme for peste des petits ruminants**

The following information should be provided by OIE Member Countries to support applications for endorsement by the OIE of an official control programme for peste des petits ruminants (PPR) in accordance with Chapter 14.7. of the *Terrestrial Code*.

The dossier provided to the OIE should ~~In sections 1 to 3.5. please~~ address concisely all the following topics under the headings ~~please~~ provided in Sections 1 to 4.3.e). to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

In Sections 3 f) to 3 i) 3.6. to 3.9. please address describe concisely the work plan and timelines of the control programme for the next five years.

Please use The terminology defined in the OIE *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and Veterinary Authority directives may be referred to and annexed as appropriate in one of the OIE official languages. Weblinks to supporting documents in one of the official languages of the OIE may also be provided, where they exist.

Any All annexes should be provided in one of the OIE official languages.

NB the paragraph below has been moved from the end of the chapter**5. Compliance with the *Terrestrial Code***

The Delegate of the Member Country applying for endorsement of the official control programme should submit documentary evidence that the provisions of Article 14.7.34. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for PPR.

1. Introduction

- a) Geographical entities features (rivers, mountains ranges, etc.). Provide a general description of the country, zones and, when where relevant, of the region, including physical, geographical and other factors that are relevant to PPR introduction of infection and spread of PPR dissemination, taking into account the as well as a short description of countries or zones sharing common borders and other epidemiologic pathways links for the potential introduction of infection-PPR.

Provide maps identifying the factors features above.

Specify whether the application includes any noncontiguous territories.

Annex 30 (contd)

- b) If the endorsed plan is gradually implemented in stages to in specific parts of the country, the boundaries of the zones should be clearly defined, including the protection zones, if applied. Provide a digitalised, geo-referenced map with a description of the geographical boundaries of the zones.
- c) Livestock demographics. ~~Provide a general description of~~Describe the composition of the livestock industry in the country and any zones. In particular, describe:
 - i) the susceptible animal population by species and types of production systems;
 - ii) the number of herds or flocks, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) herd or flock density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (~~if attach relevant documents if are available, please attach~~).

Provide tables and maps.

- d) Wildlife demographics. What susceptible captive wild, wild or feral susceptible species are present in the country and any zones? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and susceptible wildlife susceptible species?
- e) Slaughterhouses/abattoirs, markets and events associated with the congregation of susceptible livestock (e.g., fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic susceptible species movement for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislations, regulations and Veterinary Authority directives in relation to the PPR control programme and a brief description of the relevance of each. ~~This list~~ The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) Veterinary Services. Describe how the Veterinary Services of the country comply with ~~the provisions of~~ Chapters 1.1., 3.1. and 3.2. of the Terrestrial Code. Describe how the Veterinary Services supervise, and control, enforce and monitor all PPR-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any OIE PVS evaluation conducted in ~~your~~ the country and follow-up steps within the PVS Pathway and highlight the results relevant to PPR and the susceptible species.
- d) Provide a description of ~~on~~ the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, veterinary paraprofessionals including community animal health workers, and other relevant groups in PPR surveillance and control. Provide a description of the role and structure of the private veterinary sector, ~~(including number of~~ veterinarians and their distribution) ~~and role of the private veterinary profession~~, in PPR surveillance and control.

Include a description of continuing education and awareness programmes on PPR at all relevant levels.

Annex 30 (contd)

- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)?

Provide a description of the traceability system, including methods of animal identification and holding, establishment or herd or flock registration and traceability applicable to all susceptible species production systems. How are animal movements controlled in the country for all susceptible species production systems? Provide evidence on of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 monthslast two years.

Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g., seasonal migration for pastures and water). Describe the actionsavailable under national legislation, and actually taken, when an illegal import is detected.

Provide information on illegal movements detected in the past 24 months and the action taken.

3. Official control programme for PPR submitted for OIE endorsement

Submit a concise plan on of the measures for the control and eventual *eradication* of PPR in the country, including:

a) Epidemiology

- i) ~~Provide a description of~~Describe the PPR history in the country, with emphasis on recent years. Provide tables and maps showing the date of first detection, the number and location of *outbreaks* per year, the sources and routes of introduction of *infection*, the types and lineages present, the susceptible species involved and the date of implementation of the control programme in the country.
- ii) Describe the epidemiological situation of PPR in the country and the surrounding countries or zones highlighting the current knowledge and gaps. Provide maps on of:
 - the geography of the country with the relevant information concerning PPR situation;
 - small ruminant density and movements and estimated PPR prevalence.

b) PPR surveillance

Provide documentary evidence on whether that surveillance for PPR in the country complies with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code* and Chapter 2.7.10. of the *Terrestrial Manual*. In particular, The following information should be includedpoints should be addressed:

- i) What are the criteria for raising a suspicion of PPR? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- ii) Describe how clinical *surveillance* is conducted, including which levels sectors of the livestock production system are included in clinical *surveillance*, such as establishments farms, markets, fairs, slaughterhouses/abattoirs, check points, etc. Provide details of follow-up actions taken on clinical suspicions.
- iii) Serological and or virological *surveillance*. Explain whether or not serological and or virological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the survey design—(target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used)—in accordance with Articles 14.7.27. to 14.7.33. of the *Terrestrial Code*. Are susceptible *wildlife* species included in serological and or virological surveys? If not, explain the rationale.

Annex 30 (contd)

Provide a summary table indicating, for at least the past ~~24 months two years~~, the number of suspected cases, the number of samples tested for PPR, species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details ~~on of~~ follow-up actions taken on suspicious and positive results and on how these findings are interpreted and acted upon.

Provide criteria for selection of *populations* for targeted *surveillance* and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods applied for monitoring the performance of the *surveillance* system including indicators.

- iv) Provide information on the level of risk in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g., targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.) and that the acquired knowledge assists in more effective implementation of control measures.
- v) Provide details ~~on of~~ of the oversight of surveillance programmes by the Veterinary Services including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in PPR *surveillance* programmes.
- vi) Provide evidence that surveys are carried out to assess *vaccination coverage* and *population immunity* of the target *populations*, show analysis of *surveillance* data to assess the change in PPR prevalence over time in the target *populations*, assess the control measures (cost effectiveness, degree of implementation, impact). Provide information on outcomes of *outbreak* investigations including *outbreaks* that have occurred despite control measures, documented inspections showing compliance with biosecurity and hygiene requirements.

c) PPR *laboratory* diagnosis

Provide documentary evidence that the relevant provisions of in Chapters 1.1.2., 1.1.3. and 2.7.10. of the *Terrestrial Manual* are applied. In particular, The following points should be addressed:

- i) Is PPR *laboratory* diagnosis carried out in the country? If so, provide an overview of the PPR-approved *laboratories* in the country, including the following: If not, provide the names of the laboratories from other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for obtaining results.
- b) Provide an overview of the PPR approved *laboratories* in the country. Address the following points:
 - How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for obtaining reporting results;
 - Details ~~on of~~ test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of ~~on~~ the number of PPR tests performed in the past ~~24 months two years~~ in the national *laboratories* and in *laboratories* in other countries, if relevant as well as abroad;
 - Procedures for quality assurance and, if available, the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g., Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - Provide details ~~on of~~ the handling of live pathogenic agent. In particular, describe, including a description of the biosecurity and biosafety measures applied;
 - Provide a table identifying linking the tests carried out to by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

Annex 30 (contd)

- ii) If PPR laboratory diagnosis is not carried out in the country, provide the names of the laboratories in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.*

d) Strategies

- i) Provide a description of the legislation, organisation and implementation of the current PPR control programme. Outline the legislation applicable to the control programme and how its implementation is organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- ii) Describe PPR control strategies in the country or any zones, including in terms of animal movement control, fate of infected and in-contact animals and vaccination. Strategies should be based on the assessment of the PPR situation in the zones, country and region.
- iii) Provide information on what types of vaccines are used and which species are vaccinated. Provide evidence that the vaccine used complies with Chapter 1.1.8. of the *Terrestrial Manual*. Provide information on the licensing process ~~of~~ for the vaccines used. Describe the vaccination programme in the country and any zones, including records kept, and provide evidence to show its effectiveness, such as vaccination coverage, population immunity, etc. Provide details ~~on~~ of the studies carried out to determine the vaccination coverage and the population immunity, including the study designs and the results.
- iv) Describe how the *stamping-out policy* is implemented in the country or any zones and under which circumstances.
- v) ~~In the event of outbreaks, p~~Provide evidence of the impact of the control measures already implemented ~~in the event of outbreaks~~ on their reduction in number ~~of outbreaks~~ and ~~their~~ distribution. If possible, provide information on primary and secondary outbreaks.

e) PPR prevention

Describe the procedures in place to prevent the introduction of PPR into the country, ~~In particular provide~~ including details of:

- i) Coordination with other countries. Describe any relevant factors ~~about adjacent in neighbouring~~ countries and zones that should be taken into account (e.g., size, distance from the border to affected herds, flocks or animals). Describe coordination, collaboration and information-sharing activities with other countries and zones in the same region or ecosystem.

Are protection zones in place? If so, provide details ~~of~~ on the measures that are applied (e.g., vaccination, intensified surveillance, density control of susceptible species), and provide a geo-referenced map of the zones.

- ii) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the ~~spread propagation of the pathogenic~~ agent within the country or zone ~~and through trade~~. Provide evidence that measures to reduce transmission of PPR are in place at markets, ~~to reduce transmission of PPR~~ such as enhancing awareness of PPR transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good ~~biosecurity practices~~, hygiene ~~cleaning~~ and ~~disinfection~~ routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

Annex 30 (contd)*iii) Import control procedures*

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country or any *zones*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to an entry of such animals and products and subsequent internal movement. Describe the import measures conditions (e.g., quarantine) and test procedures required. Advise whether imported animals of susceptible-species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health international veterinary certificates are required.

Describe any other procedures used for assessing the risks posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months two years, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- Provide a map with showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts and between border inspection posts.
- Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, ova, oocytes and embryos);
 - animal products;
 - *veterinary medicinal products*; i.e. biologics, vaccines;
 - other materials at risk of being contaminated with PPR virus.

iv) Describe the actions available under legislation when an illegal import is detected.

Provide information on illegal imports detected and the action taken.

- f) Work plan and timelines of the control programme for the next five years, including cessation of *vaccination*. Describe the progressive objectives including expected status to be achieved for in the next five years: for *zones* (if applicable) and for the whole country.
- g) Performance indicators and timeline. The performance indicators should relate to the most important areas and steps where improvements in the programme are needed. These may include, but are not restricted to, strengthening *Veterinary Services*, legislation, reporting, availability and quality of vaccines, *animal identification* systems, *vaccination coverage*, *population immunity*, movement control, disease awareness, livestock owners' participatory perception on the effectiveness of the programme, etc. The progressive reduction of *outbreak* incidence towards elimination of PPR virus transmission in all susceptible livestock in at least one *zone* of the country should also be measured and monitored.
- h) Assessment of the evolution of the official control programme since the first date of implementation. This should include documented evidence demonstrating that the control programme has been implemented and that the first results are favourable. Measurable evidence of success such as the performance indicators should include, but not be limited to, *vaccination* data, decreased prevalence, successfully implemented import measures, control of animal movements and finally decrease or elimination of PPR *outbreaks* in the whole country or selected *zones* as described in the programme.

Annex 30 (contd)

This should include documented evidence of the ~~good effective~~ implementation of Sections ~~3 d) to 3 e)~~ ~~3.4. and 3.5.~~ above.

- i) ~~Describe~~ Describe the funding for the control programme and annual budgets for its duration.
4. Control measures and emergency response
- a) List any written guidelines, including contingency plans, available to the Veterinary Services for dealing with suspected or confirmed *outbreaks* of PPR. The contingency plan should be attached as an annex ~~and if not available~~ in one of the OIE official languages. ~~If not available,~~ provide a brief summary of what is covered ~~should be provided~~. Provide information on any simulation exercise for PPR that was conducted in the country in the past five years.
 - b) In the event of a suspected or confirmed PPR *outbreak*:
- i) ~~Are~~ is quarantine measures imposed on establishments premises with suspected suspicious cases, pending final diagnosis? What other procedures are followed regarding suspected suspicious cases (e.g., livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the causative pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the establishments premises where the *outbreak* ~~was~~ is confirmed;
 - iv) ~~provide a detailed description of~~ Describe in detail the control or eradication procedures (e.g., forward and backward tracing, *disinfection* of establishments premises, vehicles and equipment, including verification methods, vaccination, *stamp-out* policy, movement control, control of *wildlife*, pastured sheep and goats, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological surveillance programmes, etc.;
 - vi) ~~give~~ Provide details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity measures*, would target critical risk control points.

5. Compliance with the Terrestrial Code

~~The Delegate of the Member Country must submit documentary evidence that the provisions of Article 14.7.34. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for PPR.~~

CHAPTER 1.3

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY THE OIE

[...]

Article 1.3.1.

The following are included within the category of multiple species *diseases, infections and infestations*:

- Anthrax
- Bluetongue
- Crimean Congo hemorrhagic fever
- Epizootic haemorrhagic disease
- Equine encephalomyelitis (Eastern)
- Heartwater
- Infection with Aujeszky's disease virus
- ≡ Infection with bluetongue virus
- Infection with *Brucella abortus*, *Brucella melitensis*, *Brucella suis*
- Infection with *Echinococcus granulosus*
- Infection with *Echinococcus multilocularis*
- ≡ Infection with epizootic hemorrhagic disease virus
- Infection with foot and mouth disease virus
- ≡ Infection with *Mycobacterium tuberculosis* complex
- Infection with rabies virus
- Infection with Rift Valley fever virus
- Infection with rinderpest virus
- Infection with *Trichinella* spp.
- Japanese encephalitis
- New World screwworm (*Cochliomyia hominivorax*)
- Old World screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Surra (*Trypanosoma evansi*)
- Tularemia
- West Nile fever.

Annex 31 (contd)

Article 1.3.2.

The following are included within the category of cattle *diseases and infections*:

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- ~~Bovine tuberculosis~~
- Bovine viral diarrhoea
- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- ≡ Infection with lumpy skin disease virus
- Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- ~~Lumpy skin disease~~
- Theileriosis
- Trichomonosis
- Trypanosomosis (tsetse-transmitted).

[...]

Article 1.3.5.

The following are included within the category of swine *diseases and infections*:

- Infection with African swine fever virus
- Infection with classical swine fever virus
- ≡ Infection with porcine reproductive and respiratory syndrome
- Infection with *Taenia solium* (Porcine cysticercosis)
- Nipah virus encephalitis
- ~~Porcine reproductive and respiratory syndrome~~
- Transmissible gastroenteritis.

[...]

CHAPTER 7.12.

WELFARE OF WORKING EQUIDS

[...]

Article 7.12.7.

Shelter

Effective shelter should be provided for working equids both in the resting and working environments. Shelter should provide protection against adverse weather conditions and against predators and injury as well as good ventilation and the ability to rest comfortably. Resting space should be dry, clean and large enough for the equid to lie down, get up and turn around easily.

1. Heat stress

Heat stress is a common condition in working equids in hot, humid environments and *animal handlers* should be aware of the risk that heat stress poses. Equid owners and handlers should be aware of how to prevent it through provision of appropriate shade or shelter along with sufficient drinking water and avoiding work at extreme high temperatures. Owners may also be trained in effective treatment of hyperthermia as timely veterinary assistance may not be available.

Behaviours which indicate heat stress include increased respiratory rate and effort; flared nostrils; increased head movement and lack of response to the environment; excessive sweating.

Outcome-based measurables: behaviour, morbidity, mortality, body condition and physical appearance and fitness to work.

2. [...]

3. [...]

[...]
