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Activities of the Specialist Commissions

TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

**Proposed amendments to the
Terrestrial Animal Health Code**

(90 SG/10SC1)

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1. OVERVIEW OF TECHNICAL ACTIVITIES

1.1. INTRODUCTION

Since the 89th General Session in May 2022, the Terrestrial Animal Health Standards Commission (the Code Commission) met twice, from 13 to 22 September 2022 and from 7 to 17 February 2023. Among its activities, the Commission progressed work on the development of new and revised texts of the *Terrestrial Animal Health Code* (the *Terrestrial Code*), in accordance with its work programme. Details of the Code Commission's activities, including the texts circulated for comment, were published in the Commission's September 2022 and February 2023 meeting reports and are available on the Delegate's only website as well as the [WOAH Website](#).

This document provides some background information for each of the new and revised texts of the *Terrestrial Code* that will be presented for adoption at the 90th General Session. Details of the Commission's considerations of comments received on draft texts circulated for comment were provided in the Commission's [September 2022](#) and [February 2023](#) reports. The Commission encourages Members to refer to these reports as well as [other previous Commission reports](#), as relevant, for more details about the amended texts being proposed for adoption.

The annexes in this document present the proposed amendments to the *Terrestrial Code* that will be presented to the World Assembly of Delegates for adoption at the 90th General Session. The annex numbers used in this document align with the annex numbers provided in the Code Commission's February 2023 report.

In the process of drafting and reviewing these amendments, the Code Commission considered comments submitted by Members and by International Organisations that have a Cooperation Agreement with WOA. The Code Commission also worked in close cooperation with the [Scientific Commission for Animal Diseases](#) (the Scientific Commission), the [Biological Standards Commission](#), [WOAH Working Groups](#) and several *ad hoc* Groups.

2. TERRESTRIAL CODE TEXTS THAT WILL BE PROPOSED FOR ADOPTION

2.1. USER'S GUIDE (ANNEX 4)

Amendments have been proposed to the User's Guide to address specific points derived from several horizontal revisions undertaken to harmonise terminology throughout the *Terrestrial Code* to ensure consistent use of the defined terms 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services', and to improve consistency between the species categories in Chapter 1.3. and the section names in Volume II of the *Terrestrial Code*, and to address the addition of a new Section 16. Camelidae.

The proposed amendments have been circulated in recent Commission's reports, in accordance with the progress of related texts.

The revised User's Guide, **Annex 4**, is to be presented for adoption at the 90th General Session in May 2023.

2.2. GLOSSARY (ANNEX 5)

The following amendments have been proposed to the Glossary: the addition of a new definition for 'protein meal' together with the deletion of the definition for 'meat-and-bone meal', derived from the work undertaken to review Chapter 11.4.; and the movement into the Glossary of the definitions for 'distress' and 'pain' currently included in Chapter 7.8. (proposal derived from the revision of Chapter 7.5. Slaughter of animals).

The proposed amendments have been circulated in recent Commission's reports, in accordance with the progress of related texts.

The revised Glossary, **Annex 5**, is to be presented for adoption at the 90th General Session in May 2023.

2.3. DEFINITIONS IN CHAPTER 7.8. (ANNEX 6)

As noted in Item 2.2. the definitions for 'distress' and 'pain' will be added to the Glossary as these terms are used in more than one chapter. Consequently, they will be removed from Article 7.8.1. of Chapter 7.8. Use of animals in research and education. It is also proposed to delete the definition for 'suffering' from Article 7.8.1. as the Commission considered there was no need for a specific definition for the *Terrestrial Code*.

The proposed amendments have been circulated in recent Commission's reports, in accordance with the progress of related texts.

The revised Article 7.8.1., **Annex 6**, is to be presented for adoption at the 90th General Session in May 2023.

2.4. CHAPTER 1.3. DISEASES, INFECTIONS AND INFESTATIONS LISTED BY WOAHP (ANNEX 7)

Amendments have been proposed to Articles 1.3.1., 1.3.2., 1.3.3., 1.3.7. and 1.3.9. of Chapter 1.3. The amendments derived from proposals related to other texts, and comprise: the addition of 'Infection with *Theileria lestoquardi*, *Theileria luwenshuni* and *Theileria uilenbergi*' in Article 1.3.3. (sheep and goat diseases); the placement of 'Infection with *Leishmania* spp. (Leishmaniosis)' under Article 1.3.1. (multiple species diseases); and the naming of some of the species categories.

The proposed amendments have been circulated in recent Commission's reports, in accordance with the progress of related texts.

The revised Chapter 1.3. Diseases, infections and infestations listed by WOAHP, **Annex 7**, is to be presented for adoption at the 90th General Session in May 2023.

2.5. CHAPTER 8.8. INFECTION WITH FOOT AND MOUTH DISEASE VIRUS (ANNEX 8)

Chapter 8.8. has undergone a comprehensive revision.

The *ad hoc* Group on Foot and mouth disease contributed to the development of the revised chapter (refer to June 2016 and June 2020 reports for details). The revised chapter has been reviewed by the Code Commission and by the Scientific Commission throughout this process, and inputs have also been sought from the Biological Standards Commission.

The revised text has been circulated five times, the first time in the September 2015 Commission report.

The revised Chapter 8.8. Infection with foot and mouth disease virus, **Annex 8**, is to be presented for adoption at the 90th General Session in May 2023.

2.6. ARTICLE 8.14.6BIS., ARTICLE 8.14.7. AND ARTICLE 8.14.11BIS. OF CHAPTER 8.14. INFECTION WITH RABIES VIRUS (ANNEX 9)

Chapter 8.14. has been partially revised to amend the provisions for the importation of vaccinated dogs from infected countries or zones, including a new Article 8.14.6bis. and the revision of Article 8.14.7., and a new Article 8.14.11bis to address the implementation of a rabies vaccination programme for dogs.

The *ad hoc* Group on rabies (October 2019 report) and the *ad hoc* Group on dog population management (April 2020 report) contributed to the development of the revised chapter. The revised chapter has been reviewed by the Code Commission and by the Scientific Commission throughout this process, and inputs have also been provided by the WOAHP Rabies Reference Laboratory network.

The revised text has been circulated four times, the first time in the September 2020 Commission report.

The new Article 8.14.6bis., the revised Article 8.14.7. and the new Article 8.14.11bis., **Annex 9**, are to be presented for adoption at the 90th General Session in May 2023.

2.7. CHAPTER 8.15. INFECTION WITH RIFT VALLEY FEVER VIRUS (ANNEX 10)

Chapter 8.15. has undergone a comprehensive revision.

The *ad hoc* Group on Rift Valley fever ([June 2021 report](#)) contributed to the development of the revised chapter. The revised chapter has been reviewed by the Code Commission and by the Scientific Commission throughout this process.

The revised text has been circulated six times, the first time in the February 2019 Commission report.

The revised Chapter 8.15. Infection with Rift Valley fever virus, **Annex 10**, is to be presented for adoption at the 90th General Session in May 2023.

2.8. ARTICLE 10.9.1. OF CHAPTER 10.9. INFECTION WITH NEWCASTLE DISEASE VIRUS (ANNEX 11)

Chapter 10.9. has undergone a partial revision to address Article 10.9.1. to delete the definition for 'poultry' as this is a defined term in the Glossary of the *Terrestrial Code*.

The revised text has been circulated three times, the first time in the February 2022 Commission report.

The revised Article 10.9.1., **Annex 11**, is to be presented for adoption at the 90th General Session in May 2023.

2.9. CHAPTER 11.4. BOVINE SPONGIFORM ENCEPHALOPATHY (ANNEX 12)

Chapter 11.4. has undergone a comprehensive revision.

The *ad hoc* Group on bovine spongiform encephalopathy contributed to the development of the revised chapter, including reviewing Member comments and assessing potential impacts on official status recognition ([seven reports 2018 to 2022](#)). The revised chapter has been reviewed by the Code Commission and by the Scientific Commission throughout this process, and inputs have also been sought from the Biological Standards Commission, when relevant.

The revised text has been circulated seven times, the first time in the September 2019 Commission report.

The revised Chapter 11.4. Bovine spongiform encephalopathy, **Annex 12**, is to be presented for adoption at the 90th General Session in May 2023.

2.10. CHAPTER 1.8. APPLICATION FOR OFFICIAL RECOGNITION BY WOAHP OF RISK STATUS FOR BOVINE SPONGIFORM ENCEPHALOPATHY (ANNEX 13)

Chapter 1.8. has undergone a comprehensive revision to ensure alignment with amendments proposed for the revision of Chapter 11.4. Bovine spongiform encephalopathy. The revised text has been developed and circulated as part of the process to review that chapter (see Item 2.9.).

The revised Chapter 1.8. Application for official recognition by WOAHP of risk status for bovine spongiform encephalopathy, **Annex 13**, is to be presented for adoption at the 90th General Session in May 2023.

2.11. CHAPTER 12.2. CONTAGIOUS EQUINE METRITIS (ANNEX 14)

Chapter 12.2. has undergone a comprehensive revision.

The WOAHP expert Group on contagious equine metritis contributed to the development of the revised chapter, including reviewing Member comments ([2019](#) and [2021](#) reports). The revised chapter has been reviewed by the Code Commission and by the Scientific Commission throughout this process, and inputs have also been sought from the Biological Standards Commission, when relevant.

The revised text has been circulated four times, the first time in the September 2020 Commission report.

The revised Chapter 12.2. Contagious equine metritis, **Annex 14**, is to be presented for adoption at the 90th General Session in May 2023.

2.12. CHAPTER 12.6. INFECTION WITH EQUINE INFLUENZA VIRUS (ANNEX 15)

Chapter 12.6. has undergone a comprehensive revision.

The revised chapter has been reviewed by the Code Commission and by the Scientific Commission throughout this process, and inputs have also been sought from the Biological Standards Commission and WOAHP Reference Laboratory experts, when relevant.

The revised text has been circulated six times, the first time in the February 2019 Commission report.

The revised Chapter 12.6. Infection with equine influenza virus, **Annex 15**, is to be presented for adoption at the 90th General Session in May 2023.

2.13. CHAPTER 12.7. EQUINE PIROPLASMOSIS (ANNEX 16)

Chapter 12.7. has undergone a comprehensive revision.

The WOAHP expert Group on equine piroplasmosis contributed to the development of the revised chapter, including reviewing Member comments ([2019](#) and [2021](#) reports). The revised chapter has been reviewed by the Code Commission and by the Scientific Commission throughout this process, and inputs have also been sought from the Biological Standards Commission, as relevant.

The revised text has been circulated four times, the first time in the September 2020 Commission report.

The revised Chapter 12.7. Equine piroplasmosis, **Annex 16**, is to be presented for adoption at the 90th General Session in May 2023.

2.14. CHAPTER 14.X. INFECTION WITH *THEILERIA LESTOQUARDI*, *T. LUWENSHUNI* AND *T. UILENBERGI* (ANNEX 17)

A new Chapter 14.X. has been developed, following the proposed addition of the disease to the WOAHP List (Chapter 1.3.) and the development of a corresponding new chapter in the *Terrestrial Manual*.

The *ad hoc* Group on Theileriosis (February [2017](#) report) contributed to the development of the new chapter. The new chapter has been reviewed by the Code Commission and by the Scientific Commission throughout this process, and inputs have also been sought from the Biological Standards Commission, when relevant.

The revised text has been circulated four times, the first time in the September 2017 Commission report.

The new Chapter 14.X. Infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi*,

Annex 17, is to be presented for adoption at the 90th General Session in May 2023.

2.15. CHAPTER 16.1. INFECTION WITH MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS (ANNEX 18)

A new Chapter 16.1. has been developed following the proposed addition of this disease to the WOAHL List (Chapter 1.3.) and the development of a corresponding new chapter in the *Terrestrial Manual*. The new chapter consists of a single article for general provisions, aimed at providing Members with precise definitions to fulfil their notification obligations.

The development of the new draft chapter by the Code Commission was based on a case definition drafted by disease experts, that was endorsed by the Scientific Commission.

The revised text has been circulated three times, the first time in the February 2022 Commission report.

The new Chapter 16.1. Infection with Middle East respiratory syndrome coronavirus, **Annex 18**, is to be presented for adoption at the 90th General Session in May 2023.

2.16. CHAPTER 8.Y. INFECTION WITH *LEISHMANIA* SPP. (LEISHMANIOSIS) (ANNEX 19)

A new Chapter 8.Y. has been developed as no chapter existed for this disease in the *Terrestrial Code*. The new chapter consists of a single article for general provisions, aimed at providing Members with precise definitions to fulfil their notification obligations.

The development of the new draft chapter by the Code Commission was based on a case definition drafted by disease experts, that was endorsed by the Scientific Commission.

The revised text has been circulated three times, the first time in the February 2022 Commission report.

The new Chapter 8.Y. Infection with *Leishmania* spp. (Leishmaniosis), **Annex 19**, is to be presented for adoption at the 90th General Session in May 2023.

2.17. TERMINOLOGY: USE OF TERMS 'FETAL', 'FOETAL', 'FETUS' AND 'FOETUS' (ANNEX 20)

With the aim of harmonizing terminology throughout the *Terrestrial Code*, the Commission proposed to replace 'foetal/foetus' with 'fetal/fetus' throughout the *Terrestrial Code* (except for the pathogen name, i.e. *Trichomonas foetus*). This resulted in an amendment to Article 4.10.3. of Chapter 4.10., in the English version only.

The revised text has been circulated twice, the first time in the September 2022 Commission report.

The revised Article 4.10.3. of Chapter 4.10. Collection and processing of micromanipulated oocytes for embryos from livestock and horses, **Annex 20**, is to be presented for adoption at the 90th General Session in May 2023.

2.18. TERMINOLOGY: ANIMAL CATEGORIES (SECTION TITLES) (ANNEX 21)

Amendments have been proposed for the titles of Sections 9 (from APIDAE to APINAE) and 11 (from BOVIDAE to BOVINAE), together with the addition of a new Section 16. Camelidae.

These amendments are derived from revisions undertaken to harmonise terminology throughout the *Terrestrial Code* to consistently address the use of the terms 'bovid', 'bovidae', 'bovine' and 'cattle' and to improve consistency between the species categories in Chapter 1.3. and the section names in Volume II of the *Terrestrial Code*. The addition of the new Section 16 is due to the development of the first chapter for a disease of camelids (Chapter 16.1.).

The proposed amendments have been circulated in recent Commission's reports, in accordance with the progress of related texts.

The revised titles of Sections 9 and 11 and the new title for Section 16, **Annex 21**, are to be presented for adoption at the 90th General Session in May 2023.

2.19. TERMINOLOGY: USE OF TERMS ‘ENZOOTIC’, ‘ENDEMIC’, ‘EPIZOOTIC’ AND ‘EPIDEMIC’ (ANNEX 22)

With the aim of harmonizing terminology throughout the *Terrestrial Code*, the Commission proposed to replace the terms ‘enzootic/epizootic’ with the terms ‘endemic/epidemic’ throughout the *Terrestrial Code* (except where part of a disease name). This resulted in amendments to Article 4.19.1. of Chapter 4.19. and Article 9.3.1. of Chapter 9.3.

The revised text has been circulated twice, the first time in the September 2022 Commission report.

The revised Articles 4.19.1. and 9.3.1., **Annex 22**, are to be presented for adoption at the 90th General Session in May 2023.

3. ANNEXES

USER'S GUIDE

[...]

B. Terrestrial Code content

[...]

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 and Veterinary Authority 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.

[...]

10. The standards in each of the chapters of Sections 8 to 15-16 are designed to prevent the pathogenic 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 15-16 each relate to the host species of the pathogenic agent: multiple species or single species of Apidae Apinae, Aves, Bovidae Bovinae, Equidae, Leporidae, Caprinae, and Suidae and Camelidae. Some chapters include specific measures to prevent and control the infections of global concern. Although WOAHA aims to include a chapter for each listed disease, not all 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

[...]

5. Trade requirements

[...]

WOAH 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 15-16. 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. Chapter 2.2. describes the criteria used to assess the safety of commodities.

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' Veterinary Authority's ethical approach to the provision of veterinary certificates and their history in meeting their notification obligations.

[...]

GLOSSARY

[...]

DISTRESS

means the state of an animal, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

[...]

MEAT AND BONE MEAL

means the solid protein products obtained when animal tissues are rendered, and includes any intermediate protein product other than peptides of a molecular weight less than 10,000 daltons and amino-acids.

[...]

PAIN

means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

[...]

PROTEIN MEAL

means any final or intermediate solid protein-containing product, obtained when animal tissues are rendered, excluding : ~~blood and blood products,~~ peptides of a molecular ~~weight~~ **mass** less than 10,000 daltons and amino-acids.

[...]

CHAPTER 7.8.

USE OF ANIMALS IN RESEARCH AND EDUCATION

[...]

Article 7.8.1.

Definitions

For the purposes of this chapter the following definitions apply:

Biocontainment means the system and procedures designed to prevent the accidental release of biological material including allergens.

Bioexclusion means the prevention of the unintentional transfer of adventitious organisms with subsequent infection of animals, resulting in adverse effects on their health or suitability for research.

Biosecurity means a continuous process of risk assessment and risk management designed to minimise or eliminate microbiological infection with adventitious organisms that can cause clinical disease in the infected animals or humans, or make animals unsuitable for biomedical research.

Cloned animal means a genetic copy of another living or dead animal produced by somatic cell nuclear transfer or other reproductive technology.

Distress means the state of an animal, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

Endangered species means a population of organisms which is at risk of becoming extinct because it is either few in numbers, or threatened by changing environmental or predation parameters.

Environmental enrichment means increasing the complexity (e.g. with toys, cage furniture, foraging opportunities, social housing, etc.) in a captive animal's environment to foster the expression of non-injurious species-typical behaviours and reduce the expression of maladaptive behaviours, as provide cognitive stimulation.

Ethical review means consideration of the validity and justification for using animals including: an assessment and weighing of the potential harms for animals and likely benefits of the use and how these balance (see harm-benefit analysis below); and consideration of experimental design; implementation of the Three Rs; animal husbandry and care and other related issues such as personnel training. Ethical judgements are influenced by prevailing societal attitudes.

Harm-benefit analysis means the process of weighing the likely adverse effects (harms) to the animals against the benefits likely to accrue as a result of the proposed project.

Humane endpoint means the point in time at which an experimental animal's pain and/or distress is avoided, terminated, minimised or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure, removing the animal from the study, or humanely killing the animal.

Laboratory animal means an animal that is intended for use in research. In most cases, such animals are purpose-bred to have a defined physiological, metabolic, genetic or pathogen free status.

Operant conditioning means the association that an animal makes between a particular response (such as pressing a bar) and a particular reinforcement that may be positive (for example, a food reward) or negative (e.g. a mild electric shock). As a result of this

association, the occurrence of a specific behaviour of the animal can be modified (e.g. increased or decreased in frequency or intensity).

Pain means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species specific traits of behaviour, including social behaviour.

Project proposal (sometimes called protocol) means a written description of a study or experiment, programme of work, or other activities that includes the goals of the work, characterises the use of the animals, and includes ethical considerations.

Suffering means an unpleasant, undesired state of being that is the outcome of the impact on an animal of a variety of noxious stimuli and/or the absence of important positive stimuli. It is the opposite of good welfare.

[...]

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY WOAHP

Preamble

The diseases, *infections* and *infestations* in this chapter have been assessed in accordance with Chapter 1.2. and constitute the WOAHP list of terrestrial animal diseases.

In case of modifications of this list adopted by the World Assembly of Delegates, the new list comes into force on 1 January of the following year.

Article 1.3.1.

The following are included within the category of multiple species diseases, *infections* and *infestations*:

- Anthrax
- Crimean Congo hemorrhagic fever
- Equine encephalomyelitis (Eastern)
- Heartwater
- Infection with *Trypanosoma brucei*, *Trypanosoma congolense*, *Trypanosoma simiae* and *Trypanosoma vivax*
- Infection with Aujeszky's disease virus
- Infection with bluetongue virus
- Infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*
- Infection with *Echinococcus granulosus*
- Infection with *Echinococcus multilocularis*
- Infection with epizootic hemorrhagic disease virus
- Infection with *Leishmania* spp. (Leishmaniasis)
- 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.

Article 1.3.2.

The following are included within the category of ~~cattle~~ cattle-ovine diseases and *infections*:

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- 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
- Infection with *Theileria annulata*, *Theileria orientalis* and *Theileria parva*
- Trichomonosis.

Article 1.3.3.

The following are included within the category of sheep and goat diseases and *infections*:

- Caprine arthritis/encephalitis
- Contagious agalactia
- Contagious caprine pleuropneumonia
- Infection with *Chlamydia abortus* (Enzootic abortion of ewes, ovine chlamydiosis)

- Infection with peste des petits ruminants virus
- Infection with *Theileria lestoquardi*, *Theileria luwenshuni* and *Theileria uilenbergi*
- Maedi–visna
- Nairobi sheep disease
- Ovine epididymitis (*Brucella ovis*)
- Salmonellosis (*S. abortusovis*)
- Scrapie
- Sheep pox and goat pox.

Article 1.3.4.

The following are included within the category of equine diseases and *infections*:

- Contagious equine metritis
- Dourine
- Equine encephalomyelitis (Western)
- Equine infectious anaemia
- Equine piroplasmosis
- Infection with *Burkholderia mallei* (Glanders)
- Infection with African horse sickness virus
- Infection with equid herpesvirus-1 (Equine rhinopneumonitis)
- Infection with equine arteritis virus
- Infection with equine influenza virus
- Venezuelan equine encephalomyelitis.

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 virus
- Infection with *Taenia solium* (Porcine cysticercosis)
- Nipah virus encephalitis

- Transmissible gastroenteritis.

Article 1.3.6.

The following are included within the category of avian diseases and *infections*:

- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Duck virus hepatitis
- Fowl typhoid
- Infection with high pathogenicity avian influenza viruses
- Infection of birds other than *poultry*, including *wild* birds, with influenza A viruses of high pathogenicity
- Infection of domestic and *captive wild* birds with low pathogenicity avian influenza viruses having proven natural transmission to humans associated with severe consequences
- Infection with *Mycoplasma gallisepticum* (Avian mycoplasmosis)
- Infection with *Mycoplasma synoviae* (Avian mycoplasmosis)
- Infection with Newcastle disease virus
- Infectious bursal disease (Gumboro disease)
- Pullorum disease
- Turkey rhinotracheitis.

Article 1.3.7.

The following are included within the category of lagomorph-leporids diseases and *infections*:

- Myxomatosis
- Rabbit haemorrhagic disease.

Article 1.3.8.

The following are included within the category of bee diseases, *infections* and *infestations*:

- Infection of honey bees with *Melissococcus plutonius* (European foulbrood)
- Infection of honey bees with *Paenibacillus larvae* (American foulbrood)
- Infestation of honey bees with *Acarapis woodi*
- Infestation of honey bees with *Tropilaelaps* spp.
- Infestation of honey bees with *Varroa* spp. (Varroosis)

- Infestation with *Aethina tumida* (Small hive beetle).

Article 1.3.9.

The following are included within the category of other camelids diseases and *infections*:

- Camelpox
 - Infection of dromedary camels with Middle East respiratory syndrome coronavirus
 - ~~Leishmaniasis.~~
-

CHAPTER 8.8.

INFECTION WITH
FOOT AND MOUTH DISEASE VIRUS

Article 8.8.1.

General provisions

- 1) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with foot and mouth disease virus (FMDV). Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contacts between them. Amongst *Camelidae*, only Bactrian camels (*Camelus bactrianus*) are sufficiently susceptible to have potential for epidemiological significance. Dromedaries (*Camelus dromedarius*) are not susceptible to *infection* with FMDV while South American camelids are not considered to be of epidemiological significance.
 - 2) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the ~~suborder ruminantia~~ and of the families *Suidae* and the subfamilies *bovinæ*, *caprinæ* and *cervidæ* *Cervidae*, the subfamilies *bovinæ*, and *caprinæ* and *antilopinae* of the family *Bovidae*, order *Artiodactyla*, and *Camelus bactrianus* with FMDV (hereafter 'susceptible animals').
- 2bis) For the purposes of this chapter, 'cattle' a 'bovine' means an animals of the species *Bos taurus* or *Bos indicus*.
- 3) The following defines the occurrence of *infection* with FMDV:
 - a) FMDV has been isolated and identified as such from a sample from an animal listed in point 2; or
 - b) ~~viral~~ antigen or ~~viral ribonucleic nucleic~~ acid specific to FMDV has been ~~identified~~ detected in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a ~~suspected or~~ confirmed or suspected outbreak case of FMD, or giving cause for suspicion of previous association or contact with FMDV; or
 - c) antibodies to structural proteins (SP) or non-structural proteins (NSP) of FMDV, that are not a consequence of *vaccination*, have been ~~identified~~ detected in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a ~~suspected or~~ confirmed or suspected outbreak case of FMD, or giving cause for suspicion of previous association or contact with FMDV.
 - 4) Transmission of FMDV in a vaccinated *population* is demonstrated by change in virological or serological evidence indicative of recent *infection*, even in the absence of clinical signs or any cause for suspicion of previous association or contact with FMDV. Transmission of FMDV shall be notified to WOAHA as occurrence of infection.
 - 5) For the purposes of the *Terrestrial Code*, the *incubation period* of FMD shall be 14 days.
 - 6) *Infection* with FMDV can give rise to disease of variable severity and to ~~FMDV~~ transmission of FMDV. FMDV may persist in the pharynx and associated lymph nodes of ruminants for a variable but limited period of time beyond 28 days after infection. Such animals have been termed carriers. ~~However, The only persistently infected species from for~~ which transmission of FMDV has been proven from persistently infected individuals is the African buffalo (*Syncerus caffer*). However, transmission from this species African buffalo to domestic livestock is rare.
 - 7) ~~This chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of infection with FMDV and transmission of FMDV in the absence of clinical signs.~~

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

Article 8.8.1bis.

Safe commodities

When authorising the importation or transit of the following commodities, Veterinary Authorities should not require any type of FMD-related conditions, regardless of the FMD-animal health status of the exporting country or zone:

- 1) UHT milk and derivatives thereof;
- 2) heat-treated meat products in hermetically sealed container with a F₀ value of 3 or above;
- 3) meat and bone meal and blood protein meal;
- 4) gelatine;
- 5) in vivo derived bovine embryos collected, processed and stored in accordance with Chapter 4.8.;
- 6) limed hides, pickled pelts, and semi-processed leather;
- 7) extruded dry pet food.

Other commodities of susceptible species animals can be traded safely if in accordance with the relevant articles in this chapter.

Article 8.8.2.

~~FMD-free~~ Country or zone free from FMD where vaccination is not practised

~~In defining a zone where vaccination is not practised the principles of Chapter 4.34. should be followed.~~

~~Susceptible animals in the FMD free country or zone free from FMD, where vaccination is not practised should be protected by the application of biosecurity measures that prevents the entry of FMDV into the free country or zone.~~

~~Taking into consideration physical or geographical barriers with any neighbouring infected country or zone, these measures may include a protection zone.~~

A country or zone may be considered free from FMD where vaccination is not practised when the relevant provisions in point 2 of Article 1.4.6. have been complied with, and when within the proposed free country or zone for at least the past 12 months:

~~To qualify for inclusion in the list of FMD free countries or zones free from FMD, where vaccination is not practised, a Member Country should:~~

- ~~1) have a record of regular and prompt animal disease reporting;~~
- ~~2) send a declaration to the OIE stating that during the past 12 months, within the proposed FMD free country or zone:~~
 - ~~1) a) there has been no case of infection with FMDV;~~
 - ~~2) the Veterinary Authority has current knowledge of, and authority over, all herds of domestic and captive wild susceptible animals in the country or zone;~~
 - ~~3) the Veterinary Authority has current knowledge of the distribution, and habitat and indication of disease occurrence through passive surveillance of wild and feral susceptible animals in the country or zone;~~
 - ~~4) appropriate surveillance has been implemented in accordance with:~~

- a) Article 1.4.6. where historical freedom can be demonstrated; or
- b) no vaccination against FMD has been carried out;
- 3) supply documented evidence that for the past 12 months:
- a) surveillance in accordance with Articles 8.8.40. to 8.8.42. where historical freedom cannot be demonstrated which includes the has been implemented to detection of clinical signs of FMD and demonstrate no evidence of;
- i) no infection with FMDV in unvaccinated animals;
- ii) no FMDV transmission of FMDV in previously vaccinated animals when the FMD free country or zone where vaccination is practised is seeking to become one where vaccination is not practised;
- 5) measures to prevent the introduction of the infection have been in place: in particular, the importations or movements of commodities into the country or zone have been carried out in accordance with this chapter and other relevant chapters of the Terrestrial Code. Introduction of vaccinated animals have only been carried out either:
- a) from countries or zones free from FMD where vaccination is practised in accordance with Articles 8.8.11. or 8.8.11bis, or the control of the movement of susceptible animals, their meat and other products, and fomites into the proposed FMD free country or zone, in particular the measures described in Articles 8.8.8., 8.8.9. and to 8.8.12. has been effectively implemented and supervised;
- measures to prevent the introduction of no vaccinated animals has been introduced, except in accordance with Articles 8.8.8. and 8.8.9., 8.8.9bis, 8.8.11. and 8.8.11bis. have been effectively implemented and supervised. Any vaccinated animals introduced
- b) for direct slaughter in accordance with Articles 8.8.8. and 8.8.9.bis and 8.8.11bis, were should be subjected to ante- and post-mortem inspections in accordance with Chapter 6.32. with favourable results; . For ruminants, the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.31.;
- 6) vaccination against FMD is prohibited and the prohibition has been effectively implemented and supervised.

The country Member Country or the proposed free or zone will be included in the list of FMD free countries or zones free from FMD, where vaccination is not practised in accordance with Chapter 1.6 only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Retention on the list requires annual reconfirmation of compliance with all points above and relevant provisions under point 4 of Article 1.4.6. Documented evidence should be resubmitted that the information in points 2, 3 and 4 above be re-submitted annually for all points above. And Any changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported notified to WOA in accordance with the requirements in Chapter 1.1.

A country or zone free from FMD may maintain its free status despite an incursion of potentially infected African buffaloes provided that the surveillance programme substantiates the absence of transmission of FMDV.

Provided the conditions of points 1 to 4 3 4 are is are fulfilled, the status of a country or *zone* will not be affected by applying official emergency vaccination to FMD susceptible animals in zoological collections in the face of a FMD threat identified by the *Veterinary Authorities*, provided that the following conditions are met:

- the zoological collection has the primary purpose of exhibiting animals or preserving rare species, has been identified, including the boundaries of the facility, and is included in the country's contingency plan for FMD;
- appropriate *biosecurity* measures are in place, including effective separation from other susceptible domestic *populations* or *wildlife*;
- the animals are identified as belonging to the collection and any movements can be traced;

- the vaccine used complies with the standards described in the *Terrestrial Manual*;
- *vaccination* is conducted under the supervision of the *Veterinary Authority*;
- the zoological collection is placed under *surveillance* for at least 12 months after *vaccination*.

~~In the event of the application for the status of a new FMD free zone where *vaccination* is not practised to be assigned to a new zone being adjacent to another FMD free zone of the same status where *vaccination* is not practised, it should be stated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of animals between the *zones* of the same status in accordance with Chapter 4.3.~~

~~In the case of an incursion of stray African buffalo, a *protection zone* according to Article 4.4.6. should be established to manage the threat and maintain the free status of the rest of the country.~~

~~If Aa *protection zone* used is established, to preserve the status of a free country or zone from a newly identified likelihood of introduction of FMDV it should comply with Article 4.43.6. If *vaccination* is implemented in the *protection zone*, this will not affect the freedom of the rest of the country or zone the animal health status of the rest of the country or zone is not affected.~~

A country or zone free from FMD where *vaccination* is not practised may maintain its free status despite an incursion of African buffalo from a neighbouring infected country or zone provided that it is demonstrated that the relevant conditions are provisions in this article continue to be met and documented evidence has been submitted to and accepted by WOA.

Article 8.8.3.

FMD-free Country or zone free from FMD where vaccination is practised

~~In defining a *zone* where *vaccination* is practised the principles of Chapter 4.3. should be followed.~~

~~Susceptible animals in the FMD free country or zone free from FMD where *vaccination* is practised should be protected by the application of *biosecurity* measures that prevent the entry of FMDV into the free country or zone. Taking into consideration physical or geographical barriers with any neighbouring infected country or zone, these measures may include a *protection zone*.~~

~~Based on the epidemiology of FMD in the country, it may be decided to vaccinate only a defined *subpopulation* comprised of certain species or other subsets of the total susceptible *population*.~~

A country or zone may be considered free from FMD where *vaccination* is practised when the relevant provisions in point 2 of Article 1.4.6. have been complied with, and when within the proposed free country or zone To qualify for inclusion in the list of FMD free countries or zones free from FMD where *vaccination* is practised, a Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting; for at least the past 12 months;
- 2) send a declaration to the OIE stating that, based on the *surveillance* described in point 3, within the proposed FMD free country or zone:
 - a) there has been no case of FMD during the past two years;
 - b) there has been no evidence of FMDV transmission of FMDV during the past 12 months;
 - c) there has been no *infection* of FMDV in the unvaccinated subpopulations case with clinical sign of FMD during the past 12 months;
 - d) the *Veterinary Authority* has current knowledge of, and authority over, all *herds* of domestic and *captive wild* susceptible animals in the country or zone;

- d) the Veterinary Authority has current knowledge of the distribution, and habitat and indication of disease occurrence through passive surveillance of wild and feral susceptible animals in the country or zone;
- e) compulsory systematic vaccination in the target population has been carried out to achieve adequate vaccination coverage and population immunity; based on the epidemiology of FMD in the country or zone, it may be decided to vaccinate only a defined subpopulation comprised of certain species or other subsets of the total susceptible population.
- f) vaccination has been carried out following appropriate vaccine strain selection;
- g) measures to prevent the introduction of infection have been in place; in particular, the importations or movements of commodities into the country or zone have been carried out in accordance with this chapter and other relevant chapters of the Terrestrial Code;

23) for the past 24 months supply documented evidence that:

a) appropriate surveillance to detect clinical signs of FMD has been implemented in accordance with Articles 8.8.40. to 8.8.42. has been implemented to detect clinical signs of FMD for the past two years and demonstrates points 1 a) and 1 b) above. No evidence of that there has been no:

- i) infection with FMDV in unvaccinated animals for the past two years 12 months;
- ii) FMDV transmission of FMDV in vaccinated animals for the past 12 months;

b) regulatory measures for the prevention and early detection of FMD have been implemented for the past 12 months two years;

c) compulsory systematic vaccination in the target population has been carried out to achieve adequate vaccination coverage and population immunity for the past 12 months two years;

d) vaccination has been carried out following appropriate vaccine strain selection for the past 12 months two years;

4) describe in detail and supply provide documented evidence that for the past 12 months the following have been properly implemented and supervised:

a) in case of FMD free zone, the boundaries of the proposed FMD free zone have been established and effectively supervised;

b) the boundaries and biosecurity measures of any protection zone, if applicable have been established and effectively supervised;

c) the system for preventing the entry of FMDV into the proposed FMD free country or zone, in particular the measures described in Articles 8.8.8., 8.8.9. and 8.8.12. has been established and effectively supervised;

d) the control of the movement of susceptible animals and their products into the proposed FMD free country or zone has been effectively implemented and supervised.

The country Member Country or the proposed free zone will be included in the list of FMD-free countries or zones free from FMD where vaccination is practised in accordance with Chapter 1.6. only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Retention on the list requires annual reconfirmation of compliance with all points above and relevant provisions under point 4 of Article 1.4.6. Documented evidence should be resubmitted that the information in points 2, 3 and 4 above be re-submitted annually for all points above. And Any changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported notified to WOA in accordance with the requirements in Chapter 1.1.

Article 8.8.3bis.

Transition of vaccination status in a country or zone free from FMD

As recommended in Article 4.18.10., vaccination programmes may include an exit strategy.

If a Member Country that meets the requirements of a ~~FMD-free~~ country or zone free from FMD where vaccination is practised and is recognised by WOAH as such, wishes to change its status to ~~FMD-free~~ country or zone free from FMD where vaccination is not practised, it should notify WOA'H in advance of the intended date of cessation of vaccination and apply for the new status within 24 months of the cessation. The status of this country or zone remains unchanged until compliance with Article 8.8.2. is approved by WOA'H. If the ~~dossier application~~ for the new status is not provided within 24 months of the cessation or the compliance is not approved by WOA'H, then the status of the country or zone as being free with vaccination from FMD where vaccination is practised will be suspended. If the country or zone does not comply with requirements of Article 8.8.2., evidence should be provided ~~within three months~~ that it complies with Article 8.8.3. Otherwise the status will be withdrawn suspended.

If a Member Country that meets the requirements of a country or zone free from FMD where vaccination is not practised and is recognised by WOA'H as such, wishes to change its status to country or zone free from FMD where vaccination is practised, it should provide WOA'H with an application and a plan following the structure of the Questionnaire of Article 1.6.6., indicating the intended date of beginning of vaccination. The status as country or zone free from FMD where vaccination is not practised of this country or zone remains unchanged until the application and plan are approved by WOA'H. As soon as it is recognised free from FMD where with vaccination is practiced, the country or zone will begin the vaccination. The Member Country should provide evidence within six months that it complies with Article 8.8.3. for this time period. Otherwise the status will be withdrawn suspended.

If a country needs to define a protection zone in accordance with Article 4.34.6. in response to an increased risk, including by the application of vaccination, once a the protection zone has been approved by the OIE, the freedom of the rest of the country or zone remains unchanged.

In the event of the application for the status of a new FMD free free zone where vaccination is practised to be assigned to a new zone being adjacent to another FMD free zone of the same status where vaccination is practised, it should be stated if the new zone is being merged with the adjacent zone to become one enlarged zone. If the two zones remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate zones and particularly on the identification and the control of the movement of animals between the zones of the same status in accordance with Chapter 4.3.

Article 8.8.4.

FMD-free Compartment free from FMD where vaccination is not practised

A ~~FMD-free~~ compartment free from FMD where vaccination is not practised can be established in either a ~~FMD-free any~~ country or zone or in an infected country or zone. In defining such a compartment the principles of Chapters 4.34. and 4.45. should be followed. Susceptible animals in the ~~FMD~~ free compartment should be separated from any other susceptible animals by the effective application of an ~~effective~~ biosecurity plan management system.

A Member Country wishing to establish a ~~FMD-free~~ compartment free from FMD where vaccination is not practised should:

- 1) have a record of regular and prompt animal *disease* reporting and, if not ~~FMD~~ free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or zone;
- 2) declare for the ~~FMD~~ free compartment that:
 - a) ~~there has been no case of FMD during the past 12 months;~~
 - a) no ~~evidence of infection~~ with FMDV has ~~been found~~ detected occurred during the past 12 months;
 - e) vaccination against FMD is prohibited;
 - d) no animal vaccinated against FMD within the past 12 months is in the compartment;

- ed) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;
- fe) documented evidence shows that *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation;
- gf) an *animal identification* and *traceability* system in accordance with Chapters 4.~~21.~~ and 4.~~32.~~ is in place;

3) describe in detail:

- a) the animal *subpopulation* in the *compartment*;
- b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out in accordance with point 1.

The *compartment* should be approved by the *Veterinary Authority*. The ~~first~~ approval should only be granted when no *infection case* or *transmission* of FMDV has occurred within a 10~~ten~~-kilometre radius of the *compartment* during the ~~past~~ three months prior to the effective establishment of the *biosecurity plan*.

Article 8.8.4bis.

Compartment free from FMD where vaccination is practised

A *compartment* free from FMD where *vaccination* is practised can be established in either a free country or *zone* where *vaccination* is practised or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.~~34.~~ and 4.~~45.~~ should be followed. Susceptible animals in the free *compartment* should be separated from any other susceptible animals by the application of an effective *biosecurity plan*.

A Member Country wishing to establish a *compartment* free from FMD where *vaccination* is practised should:

- 1) have a record of regular and prompt animal disease reporting and, if not free, have an *official control programme* and a *surveillance* system for FMD in place in accordance with Articles 8.8.40. to 8.8.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;
- 2) declare for the free *compartment* where *vaccination* is practised that:
 - a) ~~there has been no case of FMD during the past 12 months;~~
 - ab) ~~no evidence of infection with~~ infection or transmission of FMDV has ~~been found~~ occurred during the past 12 months;
 - be) compulsory systematic *vaccination* is carried out using a vaccine that complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection. The *vaccination* coverage and population immunity are closely monitored;
 - cd) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;
 - de) documented evidence shows that regular clinical, serological and virological *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation, so as to detect *infection* at an early stage with a high level of confidence;
 - ef) an *animal identification* and *traceability* system in accordance with Chapters 4.~~12.~~ and 4.~~23.~~ is in place;
- 3) describe in detail:
 - a) the animal *subpopulation* in the *compartment*;
 - b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out according to point 1 and the *vaccination plan*;

c) implementation of points 2 ~~be~~, 2 ~~de~~ and 2 ~~ef~~.

The *compartment* should be approved by the *Veterinary Authority*. The approval should only be granted when no *infection case* or transmission of FMDV has occurred within a 10-kilometre radius of the *compartment* during the three months prior to the effective establishment of the *biosecurity plan*.

Article 8.8.5.

~~FMD-infected~~ Country or zone infected with FMDV

~~For the purposes of this chapter, a FMD-infected country or zone shall be considered as infected with FMDV is one that does not fulfil when the requirements for acceptance to qualify as a country or zone free from FMD either FMD free where vaccination is not practised or FMD free where vaccination is practised are not fulfilled.~~

Article 8.8.5bis.

Establishment of a protection zone within a country or zone free from FMD

Susceptible animals in ~~the~~ a country or zone free from FMD should be protected by the application of *biosecurity* that prevents the entry of FMDV into the free country or zone. Taking into consideration physical or geographical barriers with any neighbouring infected country or zone, these measures may include a *protection zone*.

A *protection zone* may be established, in response to an increased risk of FMD, in accordance with Article 4.4.6. The *Veterinary Authority* should submit as soon as possible to WOA, in addition to the requirements of Article 4.4.6, in support of the application, documented evidence that, in addition to the requirements of Article 4.4.6.:

- 1) the susceptible animal populations within the *protection zone* are clearly identified as belonging to the *protection zone*;
- 2) strict movement control of susceptible animals and their products is in place in line with the relevant provisions of this chapter;
- 3) enhanced *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in place in the *protection zone* and in the rest of the country or zone;
- 4) intensified *biosecurity* in the ~~rest of the country~~ *protection zone* is in place;
- 5) awareness campaigns aimed at the general public, breeders, traders, *veterinarians* and other relevant stakeholders are implemented;
- 6) a *biosecurity plan* including the implementation of emergency *vaccination* is in place, in particular when the *protection zone* is established in a country or zone free from FMD where *vaccination* is not practised.

The *protection zone* is considered as effectively established when the conditions described in this article and in Article 4.4.6. have been applied and documented evidence is submitted to and has been accepted by WOA.

If *vaccination* is implemented in the *protection zone* established within a country or zone free from FMD where *vaccination* is not practised, the free status of the *protection zone* is suspended while and the free status of the rest of the country or zone is not affected. The status of the *protection zone* can be recovered following point 1 of Article 8.8.7. Alternatively, should the Member Country wish to maintain *vaccination* in the *protection zone*, Article 8.8.3bis applies.

In the event of an *outbreak* within a previously free *protection zone*, the free status of the *protection zone* is suspended and the status of the *protection zone* can be recovered following Article 8.8.7., while the free status of the rest of the country or zone is not affected. For the establishment of Alternatively, if the *Veterinary Authority* establishes a *containment zone* after an *outbreak* in the *protection zone*, an application in accordance with Articles 4.4.7. and 8.8.6 should be submitted as soon as possible. In particular, when applying for a *containment zone*, it should be stated whether the boundaries would be the same as the boundaries of the *protection zone* or within the boundaries of the *protection zone*.

A protection zone, in which the free status has remained unchanged, should be limited to less than 24 months from the date of its approval by WOA. The Member Country should either apply for the removal of the protection zone or official recognition of the protection zone as a separate zone within 24 months from the date of its approval by WOA.

Article 8.8.6.

Establishment of a containment zone within a FMD-free country or zone previously free from FMD

In the event of limited outbreaks within a FMD-free country or zone previously free from FMD where vaccination is either practised or not, including within a protection zone, with or without vaccination, a single containment zone, which includes all epidemiologically linked outbreaks, may be established, in accordance with Article 4.4.7., for the purpose of minimising to minimise the impact on the entire rest of the country or zone in accordance with Article 4.4.7.

For this to be achieved and for the Member Country to take full advantage of this process, the Veterinary Authority should submit as soon as possible to WOA, in addition to the requirements of Article 4.4.7. in support of the application, documented evidence that:

- 1) on suspicion, a strict standstill has been imposed on the suspected establishments and in the country or zone animal movement control has been imposed and effective controls on the movement of animals and other commodities mentioned in this chapter are in place in the country or zone;
- 2) on confirmation, an additional the standstill and movement controls described in point 1 have been reinforced of susceptible animals has been imposed in the entire containment zone and the movement controls described in point 1 have been reinforced;
- 3) the definitive boundaries of the containment zone have been established after an epidemiological investigation (trace back, trace forward) has demonstrated that the outbreaks are epidemiologically related and limited in number and geographic distribution;
- 34) epidemiological investigations into the likely source of the outbreaks have been carried out;
- 5 a stamping-out policy, with or without the use of emergency vaccination, has been applied;
- 6) no new cases have been found in the containment zone within a minimum of two incubation periods as defined in Article 8.8.1. after the application of a stamping-out policy to the last detected case;
- 7) the susceptible domestic and captive wild animal populations within the containment zone are clearly identified as belonging to the containment zone;
- 48) surveillance in accordance with Articles 8.8.40. to 8.8.42. is in place in the containment zone and in the rest of the country or zone;
- 59) measures that prevent the spread of FMDV to the rest of the country or zone, taking into consideration physical and geographical barriers, are in place.

The free status of the areas outside the containment zone is suspended while the containment zone is being established. The free status of the areas outside the containment zone is suspended while the containment zone is being established. The free status of the these these areas outside the containment zone may be reinstated irrespective of the provisions of Article 8.8.7., once the containment zone has been approved by WOA as complying with points 1 to 59 above. Commodities from susceptible animals for international trade should be identified as to their origin, either from inside or outside the containment zone.

In the event of recurrence of infection with FMDV in unvaccinated animals or FMDV transmission of FMDV in vaccinated animals in the containment zone, established in accordance with point 4 a) of Article 4.4.7., the approval of the containment zone is withdrawn and the FMD-free status of the whole country or zone is suspended until the relevant requirements of Article 8.8.7. are fulfilled.

In the event of occurrence of infection with FMDV in unvaccinated animals or transmission of FMDV in vaccinated animals in the outer zone of a containment zone established in accordance with point 4 ab) of Article 4.4.7., the approval of the containment zone

is withdrawn and the free status of the whole country or zone is suspended until the relevant requirements of Article 8.8.7. are fulfilled.

The recovery of the FMD free status of the *containment zone* should be achieved within ~~12-18-24~~ months of its approval and follow the provisions of Article 8.8.7.

Article 8.8.7.

Recovery of free status ~~(see Figures 1 and 2)~~

- 1) When a infection with FMDV case occurs in a FMD-free country or zone previously free from FMD where *vaccination* is not practised, one of the following waiting periods is required to regain this free status:
 - a) three months after the disposal of the last animal killed where a *stamping-out policy*, without emergency *vaccination*, and *surveillance* are applied in accordance with Articles 8.8.40. to 8.8.42.; or
 - b) three months after the disposal of the last animal killed or the *slaughter* of all vaccinated animals, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied; or
 - c) six months after the disposal of the last animal killed or the last *vaccination*, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated animals, and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied. However, this requires a serological survey based on the detection of antibodies to ~~non-structural proteins~~ NSP of FMDV to demonstrate no ~~evidence of infection~~ transmission of FMDV in the remaining vaccinated population. This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of infection in the non-vaccinated population, and absence of transmission in the emergency vaccinated population based on the provisions of point 7 of Article 8.8.40. effectiveness of vaccination is demonstrated by a serological survey and serological surveillance for antibodies to nonstructural proteins is carried out in all vaccinated herds by sampling all vaccinated ruminants and their unvaccinated offspring, and a representative number of FMD-susceptible animals of other species.

The country or zone will regain ~~the its free status of FMD free country or zone where vaccination is not practised~~ only after the submitted evidence, based on the provisions of Article Chapter 1.116.6., has been accepted by WOAHP.

The time periods in points 1 a) to 1 c) are not affected if official emergency *vaccination* of zoological collections has been carried out following the relevant provisions of Article 8.8.2.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.8.2. applies.

- 2) When a ~~FMD case of infection with FMDV~~ occurs in a FMD-free country or zone previously free from FMD where *vaccination* is not practised, the following waiting period is required to gain the status of FMD-free country or zone free from FMD where *vaccination* is practised: six months after the disposal of the last animal killed where a *stamping-out policy* has been applied and a continued *vaccination* policy has been adopted, provided that *surveillance* is applied in accordance with Articles 8.8.40. to 8.8.42., and a serological survey based on the detection of antibodies to ~~nonstructural proteins~~ NSP of FMDV demonstrates no ~~evidence of FMDV transmission of FMDV~~.

The country or zone can gain the status of FMD free country or zone from FMD where *vaccination* is practised only after the submitted evidence, based on the provisions of Article Chapter 1.116.6. has been accepted by WOAHP.

Where a *stamping-out policy* is not practised, the above waiting periods does not apply, and Article 8.8.3. applies.

- 3) When a ~~case of infection with FMDV or transmission of FMDV~~ occurs in a FMD-free country or zone previously free from FMD where *vaccination* is practised, one of the following waiting periods is required to regain this free status:
 - a) six months after the disposal of the last animal killed where a *stamping-out policy*, with emergency *vaccination*, and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological *surveillance* based on the detection of antibodies to ~~nonstructural proteins~~ NSP of FMDV demonstrates no ~~evidence of virus transmission of FMDV~~.

This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of infection in the non-vaccinated population and absence of transmission of FMDV in the vaccinated population based on the provisions of points 7 and 8 of Articles 8.8.40. as appropriate; or

- b) 12 months after the detection of the last case where a *stamping-out policy* is not applied, but where emergency vaccination and surveillance in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological surveillance based on the detection of antibodies to ~~nonstructural proteins~~ NSP of FMDV demonstrates no evidence of ~~virus~~ transmission of FMDV.

The country or zone will regain its free status only after the submitted evidence, based on the provisions of Article 1.6.6 Chapter 1.11., has been accepted by WOA.

When emergency vaccination is not applied, the above waiting periods do not apply, and Article 8.8.3. applies.

~~The country or zone will regain the status of FMD free country or zone where vaccination is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.~~

- 4) When a ~~FMD case of infection with FMDV~~ occurs in a ~~FMD free compartment free from FMD~~, Article 8.8.4. ~~or Article 8.8.4bis~~ applies.
- 5) Member Countries applying for the recovery of status should do so only when the respective requirements for the recovery of status are met. When a *containment zone* has been established, the restrictions within the *containment zone* should be lifted ~~in accordance with the requirements of this article~~ only when the ~~disease FMD~~ has been successfully eradicated within the *containment zone* and status has been regained following the provisions in this article.

For Member Countries not applying for recovery within 24 months after suspension of status, the provisions of Article 8.8.2., Article 8.8.3. ~~or~~ Article 8.8.4. ~~or Article 8.8.4bis~~ apply.

Article 8.8.8.

Direct transfer within a country of FMD susceptible animals from an infected zone, including containment zone, for slaughter in a free zone (whether vaccination is practised or not)

In order not to jeopardise the status of a free zone, FMD susceptible animals should only leave the infected zone if transported directly ~~to~~ for slaughter in the nearest designated *slaughterhouse/abattoir* under the following conditions:

- 1) no FMD susceptible animal has been introduced into the *establishment* of origin and no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;
- 2) the animals were kept in the *establishment* of origin for at least three months prior to movement;
- 3) FMD has not occurred within a 10-kilometre radius of the *establishment* of origin for at least four weeks prior to movement;
- 4) the animals ~~should be~~ are transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;
- 5) such a the *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the infected zone;
- 6) *vehicles* and the *slaughterhouse/abattoir* ~~should be~~ are subjected to thorough cleansing and *disinfection* immediately after use.

The animals should have been subjected to ante- and post-mortem inspection within 24 hours before and after *slaughter* with no evidence of FMD, and the *meat* derived from them treated in accordance with point 2 of Article 8.8.22. or Article 8.8.23. Other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.8.31. to 8.8.38. in order to destroy any FMDV potentially present.

~~Article 8.8.9.~~

~~Direct transfer of FMD-susceptible animals from a containment zone for slaughter in a free zone (whether vaccination is practised or not)~~

~~In order not to jeopardise the status of a free zone, FMD-susceptible animals should only leave the containment zone if transported directly to for slaughter in the nearest designated slaughterhouse/abattoir under the following conditions:~~

- ~~1) the containment zone has been officially established in accordance with the requirements in Article 8.8.6.;~~
- ~~2) the animals should be are transported under the supervision of the Veterinary Authority in a vehicle, which was cleansed and disinfected before loading, directly from the establishment of origin to the slaughterhouse/abattoir without coming into contact with other susceptible animals;~~
- ~~3) such an slaughterhouse/abattoir is not approved for the export of fresh meat during the time it is handling the meat of animals from the containment zone;~~
- ~~4) vehicles and the slaughterhouse/abattoir should be are subjected to thorough cleansing and disinfection immediately after use.~~

~~The animals should have been subjected to ante- and post-mortem inspection within 24 hours before and after slaughter with no evidence of FMD and the meat derived from them treated in accordance with point 2 of Article 8.8.22. or Article 8.8.23. Other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.8.31. to 8.8.38. in order to destroy any FMDV potentially present.~~

Article 8.8.9bis.

Direct transfer within a country of FMD vaccinated animals from a free zone free from FMD where vaccination is practised or not for slaughter in a free zone where vaccination is not practised

In order not to jeopardise the status of a free zone where vaccination is not practised, FMD vaccinated animals should only leave the free zone if transported directly for slaughter in ~~the a~~ nearest designated slaughterhouse/abattoir under the following conditions:

- 1) no animal in the establishment of origin has shown clinical signs of FMD for at least 30 days prior to movement;
- 2) the animals were kept in the country or zone of origin for at least three months prior to movement;
- 3) the animals are transported under the supervision of the Veterinary Authority in a vehicle, directly from the establishment of origin to the slaughterhouse/abattoir;
- 4) if transiting an infected zone, the animals were not exposed to any source of FMDV during transportation to the place of shipment.

Article 8.8.10.

Recommendations for importation of susceptible animals from FMD-free countries, or zones or compartments free from FMD where vaccination is not practised ~~or FMD-free compartments free from FMD~~

For FMD-susceptible animals

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

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept since birth or for at least the past three months in a FMD-free country, or zone or compartment free from FMD where vaccination is not practised ~~or a FMD-free compartment free from FMD~~;
- 3) if transiting an infected zone, were not exposed to any source of FMDV during transportation to the place of shipment;

- 4) if previously vaccinated, comply with point 4 of Article 8.8.11.

Article 8.8.11.

Recommendations for importation of domestic ruminants and pigs from FMD-free countries, or zones or compartments free from FMD where vaccination is practised

For domestic ruminants and pigs

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

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept since birth or for at least the past three months in a FMD-free country, or zone or compartment free from FMD where vaccination is practised;
- 3) if not vaccinated were subjected to a virological and serological tests for FMD with negative results on samples collected not earlier than 14 days before the shipment;
- 4) if vaccinated were subjected to virological and NSP serological tests for FMD with negative results on samples collected not earlier than 14 days before the shipment;
- 5) if transiting an infected zone, were not exposed to any source of FMDV during transportation to the *place of shipment*;
- 6) if transiting a free zone where vaccination is not practised, were not in contact with any FMD-susceptible animal during transportation to the place of shipment.

Article 8.8.11bis.

Recommendations for the importation of vaccinated animals destined for slaughter from a free country, zone or compartment free from FMD where vaccination is practised

For vaccinated animals destined for slaughter

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

- 1) no animal in the establishment of origin has shown clinical signs of FMD for at least 30 days prior to shipment;
- 2) the animals were kept in the country, zone or compartment of origin since birth or for at least three months prior to shipment;
- 3) the animals were transported under the supervision of the Veterinary Authority directly from the establishment of origin in sealed vehicles/vessels;
- 4) if transiting an infected zone, the animals were not exposed to any source of FMDV during transportation to the place of shipment.

Article 8.8.12.

Recommendations for importation of domestic ruminants and pigs from FMD-infected countries or zones infected with FMDV, where an official control programme exists

For domestic ruminants and pigs

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

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

- ~~2) pigs have not been fed swill not complying with Article 8.8.31bis.;~~
- ~~32) prior to isolation, the animals were kept in the establishment of origin:~~
- ~~a) for 30 days, or since birth if younger than 30 days, if a stamping-out policy is applied to control FMD in the exporting country or zone, or~~
 - ~~b) for three months, or since birth if younger than three months if a stamping-out policy is not applied to control FMD in the exporting country or zone;~~
- ~~43) the establishment of origin is covered by the official control programme and FMD has not occurred within it the establishment of origin for the relevant period as defined in points 23 a) and 23 b) above;~~
- ~~54a) the animals were isolated for the 30 days prior to shipment:~~
- ~~a) in an establishment or a quarantine station for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period, and or~~
 - ~~b) if the animals were isolated in an establishment that is not a quarantine station, that FMD did not occur within a 10-kilometre radius of the establishment during that period, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period, or the establishment is a quarantine station;~~
- ~~65) the animals were not exposed to any source of FMDV during their transportation from the establishment to the place of shipment.~~

~~Article 8.8.13.~~

~~Recommendations for importation from FMD free countries, or zones free from FMD where vaccination is not practised or FMD free compartments free from FMD~~

~~For fresh semen of domestic ruminants and pigs~~

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

- ~~1) the donor males:~~
 - ~~a) showed no clinical sign of FMD on the day of collection of the semen;~~
 - ~~b) were kept for at least three months prior to collection in a FMD free country, or zone free from FMD where vaccination is not practised or FMD free compartments free from FMD;~~
 - ~~c) were kept in an artificial insemination centre where none of the animals had a history of infection with FMDV;~~
- ~~2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.~~

Article 8.8.14.

Recommendations for importation of fresh and frozen semen of domestic ruminants and pigs from FMD free countries, or zones or compartments free from FMD where vaccination is not practised or FMD free compartments free from FMD

For fresh and frozen semen of domestic ruminants and pigs

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

- 1) the donor males:

- a) showed no clinical sign of FMD on the day of collection of the semen ~~and for the following 30 days;~~
 - b) were kept for at least three months prior to collection in a ~~FMD-free country, or zone or compartment free from FMD~~ where *vaccination* is not practised ~~or FMD-free compartments free from FMD;~~
 - c) were kept in an artificial insemination centre;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.56. and 4.67.

Article 8.8.15.

Recommendations for importation of frozen semen of domestic ruminants and pigs from ~~FMD-free~~ countries ~~or zones or compartments free from FMD~~ where vaccination is practised

For frozen semen of domestic ruminants and pigs

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least three months prior to collection in a ~~FMD-free country, or zone or compartment free from FMD~~ where *vaccination* is practised;
 - c) either
 - i) have been vaccinated at least twice; with the last *vaccination* not ~~less more~~ than ~~one six~~ months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;
 - or
 - ii) have not been vaccinated and were subjected, not less than 21 days and not more than 60 days after collection of the semen, to tests for antibodies against FMDV, with negative results;
- 2) the semen:
 - a) was collected, processed and stored in accordance with Chapters 4.56. and 4.67.;
 - b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor ~~animals~~ males were kept showed any clinical sign of FMD.

Article 8.8.16.

Recommendations for importation of frozen semen of domestic ruminants and pigs from ~~FMD-infected~~ countries or zones infected with FMDV

For frozen semen of domestic ruminants and pigs

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

- b) were kept in an *artificial insemination centre* ~~where to which~~ no animal had been added in the 30 days before collection, and within a 10-kilometre radius of which, that FMD has not occurred ~~within a 10 kilometre radius of the artificial insemination centre for in~~ the 30 days before and after collection;
 - c) either
 - i) have been vaccinated at least twice, with the last *vaccination* not ~~less more~~ than one six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;
 - or
 - ii) have not been vaccinated and were subjected, not less than 21 days and not more than 60 days after collection of the semen, to tests for antibodies against FMDV, with negative results;
- 2) the semen:
- a) was collected, processed and stored in accordance with Chapters 4.56. and 4.67.;
 - b) was subjected, with negative results, to a test for evidence of FMDV if the donor male has been vaccinated within the 12 months prior to collection;
 - c) was stored in the country of origin for a period of at least one month following collection, and that during this period no animal on the *establishment* where the donor males were kept showed any sign of FMD.

~~Article 8.8.17.~~

~~Recommendations for the importation of *in vivo* derived embryos of bovines cattle~~

~~Irrespective of the FMD status of the *exporting country, zone or compartment*, *Veterinary Authorities* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of bovines cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in accordance with the relevant provisions of Chapters 4.7. and 4.9., as relevant.~~

Article 8.8.18.

Recommendations for importation of *in vitro* produced bovine embryos from FMD free countries or zones or compartments free from FMD where vaccination is not practised ~~or FMD free compartments free from FMD~~

For *in vitro* produced embryos of bovines cattle

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

- 1) the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the oocytes;
 - b) were kept for at least three months prior to collection in a FMD free country, or zone or compartment free from FMD where *vaccination* is not practised ~~or FMD free compartments free from FMD~~;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles ~~8.8.13.,~~ 8.8.14., 8.8.15. or 8.8.16., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in accordance with Chapters 4.8., ~~and 4.9.~~ and 4.10. as relevant.

Article 8.8.19.

Recommendations for importation for *in vitro* produced bovine embryos from ~~FMD-free countries or~~ zones or compartments free from FMD where vaccination is practised

For *in vitro* produced embryos of bovines cattle

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

- 1) the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the oocytes;
 - b) were kept for at least three months prior to collection in a ~~FMD-free country~~ or zone or compartment free from FMD where *vaccination* is practised;
 - c) either
 - i) have been vaccinated at least twice, with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;
 - or
 - ii) were subjected, not less than 21 days and not more than 60 days after collection, to tests for antibodies against FMDV, with negative results;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles ~~8.8.13,~~ 8.8.14., 8.8.15. or 8.8.16., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in accordance with Chapters 4.8., ~~and 4.9.,~~ and 4.10. as relevant.

Article 8.8.20.

Recommendations for importation of fresh meat or meat products of susceptible animals from ~~FMD-free countries or~~ zones or compartments free from FMD where vaccination is not practised ~~or FMD-free compartments free from FMD~~

For fresh meat or meat products of FMD-susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from animals which:

- 1) have been kept in a ~~FMD-free country or~~ zone or compartment free from FMD where *vaccination* is not practised ~~or FMD-free compartment free from FMD~~, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 8.8.21.

Recommendations for importation of fresh meat and meat products of ruminants and pigs from ~~FMD-free countries or~~ zones or compartments free from FMD where vaccination is practised

For fresh meat and meat products of ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from animals which:

- 1) ruminants or pigs that have been kept in the FMD-free country or zone or compartment free from FMD where *vaccination* is practised, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.;
- 2) ruminants or pigs that have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections ~~for FMD~~ with favourable results;
- 3) ~~for~~ ruminants from which the head, including the pharynx, tongue and associated lymph nodes, has been excluded from the shipment.

Article 8.8.22.

Recommendations for importation of fresh meat of bovines and water buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera) from ~~FMD-infected~~ countries or zones infected with FMDV, where an official control programme exists

~~For fresh meat of bovines cattle and water buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)~~

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

- 1) comes from animals which:
 - a) have remained, for at least three months prior to *slaughter*, in a *zone* of the *exporting country* where ~~bovines cattle~~bovines and water buffaloes are regularly vaccinated against FMD and where an *official control programme* is in operation;
 - b) have been vaccinated at least twice with the last *vaccination* not more than six months, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to *slaughter*;
 - c) were kept for the past 30 days in:
 - = a quarantine station; or in
 - = an establishment, within a ten 10-kilometre radius of which and that FMD has not occurred within a 10 kilometre radius of the establishment during that period, or the establishment is a quarantine station;
 - d) have been transported, in a *vehicle* which was cleansed and disinfected before the ~~bovines cattle~~bovines and water buffaloes were loaded, directly from the *establishment* of origin or *quarantine station* to the approved *slaughterhouse/abattoir* without coming into contact with other FMD susceptible animals which do not fulfil the required conditions for export;
 - e) have been slaughtered in an approved *slaughterhouse/abattoir*:
 - i) which is officially designated for export;
 - ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;
 - f) were subjected to ante- and post-mortem inspections in accordance with Chapter 6.23., with favourable results ~~have been subjected, with favourable results, to ante mortem inspection within 24 hours of slaughter and to post-mortem inspections within 24 hours before and after slaughter with no evidence of FMD;~~
- 2) comes from deboned carcasses:
 - a) from which the major lymphatic nodes have been removed;

- b) which, prior to deboning, have been submitted to maturation at a temperature greater than + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was less than 6.0 when tested in the middle of both the longissimus dorsi muscle.

Article 8.8.22bis.

Recommendations for importation of fresh meat of domestic pigs from countries or zones infected with FMDV, where an official control programme exists

For fresh meat of domestic pigs

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

- 1) the meat comes from animals complying with ~~points 1 to 6 of Article 8.8.12.~~
- 2) the animals were transported, in a vehicle which was cleaned and disinfected before the pigs were loaded, directly from the establishment of origin or quarantine station to the approved slaughterhouse/abattoir without coming into contact with other FMD susceptible animals that do not fulfil the conditions required for export, either during transport or at the slaughterhouse/abattoir;
- 3) the animals were slaughtered in an approved slaughterhouse/abattoir:
 - a) which is officially designated for export;
 - b) in which no FMD has been detected during the period between the last disinfection carried out before slaughter and the shipment for export has been dispatched;
- 4) the animals were subjected to ante- and post-mortem inspections in accordance with Chapter 6.23., with favourable results;
- 5) the carcasses were not released earlier than 24 hours after slaughter and not before Veterinary Authorities have confirmed that FMD has not occurred in the establishment of origin.

Article 8.8.22ter.

Recommendations for importation of fresh meat of domestic ~~sheep and goats small ruminants~~ (excluding feet, head and viscera) from FMD infected countries or zones where an official control programme exists

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the meat comes from:

- 1) animals that were transported, in a vehicle which was cleaned and disinfected before the domestic sheep and goats were loaded, directly from the establishment of origin or quarantine station to the approved slaughterhouse/abattoir without coming into contact with other FMD susceptible animals that do not fulfil the conditions required for export, either during transport or at the slaughterhouse/abattoir;
- 2) animals that were slaughtered in an approved slaughterhouse/abattoir:
 - a) which is officially designated for export;
 - b) in which no FMD has been detected during the period between the last disinfection carried out before slaughter and the shipment for export has been dispatched;
- 3) animals that were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable results; and

EITHER,

- 4) animals that comply with Article 8.8.12.; and the carcasses were not released earlier than 24 hours after *slaughter* and not before *Veterinary Authorities* have confirmed that FMD has not occurred in the *establishment* of origin;

OR

- 5) animals that:

- a) have remained, for at least three months prior to *slaughter*, in a *zone* of the *exporting country* where bovines and water buffaloes are regularly vaccinated against FMD and where an *official control programme* is in operation;
- b) were kept for the past 30 days in:
 - a *quarantine station*; or
 - an *establishment*, within a ten-kilometre radius of which FMD has not occurred during that period, and no susceptible animals were introduced into the *establishment* during that period;
- c) had their carcasses deboned:
 - i) from which the major lymphatic nodes have been removed;
 - ii) which, prior to deboning, have been submitted to maturation at a temperature greater than + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was less than 6.0 when tested in the middle of both the *longissimus dorsi* muscle.

Article 8.8.23.

Recommendations for importation of meat products of susceptible animals from ~~FMD infected~~ countries or zones infected with FMDV

For meat products of FMD susceptible animals

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

- 1) the entire consignment of *meat products* come from animals which have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections ~~for FMD~~ with favourable results;
- 2) the *meat products* have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.31.;
- 3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMDV.

Article 8.8.24.

Recommendations for importation of milk and milk products of animal origin (other than those covered by other articles listed in Article 8.8.1bis.) intended for human consumption and for products of animal origin (from susceptible animals) intended for use in animal feeding or for agricultural or industrial use from FMD free countries or, zones or compartments free from FMD where whether vaccination either is practised or is not practised or FMD free compartments free from FMD

For milk and milk products (other than those defined in Article 8.8.1bis.) intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a ~~FMD free~~ country, zone or compartment free from FMD, or which have been imported in accordance with Article 8.8.10., Article 8.8.11. or Article 8.8.12.

Article 8.8.25.

Recommendations for importation of milk and milk products (other than those listed in Article 8.8.1bis.) from FMD-infected countries or zones infected with FMDV, where an official control programme exists

For milk and milk products (other than those defined in Article 8.8.1bis.)

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

- 1) these products:
 - a) originate from *establishments* which at the time of milk collection were not infected or suspected of being infected with FMD at the time of milk collection;
 - b) have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.8.35. and in Article 8.8.36;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Article 8.8.26.

Recommendations for importation from FMD-infected countries or zones infected with FMDV

For blood-meal and meat-meals from FMD-susceptible animals

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

- 1) the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Article 8.8.27.

Recommendations for importation of wool, hair, bristles, raw hides and skins from domestic susceptible animals from FMD-infected countries or zones infected with FMDV

For wool, hair, bristles, raw hides and skins from FMD-susceptible animals

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

- 1) these products have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Articles 8.8.32., 8.8.33. and 8.8.34.;
- 2) the necessary precautions were taken after collection or-and processing to avoid contact of the products with any potential source of FMDV.

~~*Veterinary Authorities* should authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather such as wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.~~

Article 8.8.28.

Recommendations for importation of straw and forage from FMD-infected countries or zones infected with FMDV

For straw and forage

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

- 1) are free of grossly identified contamination with material of animal origin;
- 2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:
 - a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ~~ten~~ 10 minutes,
 - b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35-40% in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;

OR

- 3) have been kept in bond for at least four months before being released for export.

Article 8.8.29.

Recommendations for importation of skins and trophies derived from susceptible wildlife animals (other than those listed in Article 8.8.1bis.) from FMD-free countries or zones or compartments free from FMD, where whether vaccination either is practised or is not practised

For skins and trophies derived from FMD-susceptible wildlife

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been killed in ~~such~~ a country or zone free from FMD or which have been imported from a country, zone or compartment free from FMD.

Article 8.8.30.

Recommendations for importation of skins and trophies derived from susceptible wildlife animals (other than those listed in Article 8.8.1bis.) from FMD-infected countries or zones infected with FMDV

For skins and trophies derived from FMD-susceptible wildlife

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of FMDV in accordance with the procedures in Article 8.8.37.

Article 8.8.31.

Procedures for the inactivation of FMDV in meat and meat products

For the inactivation of FMDV present in *meat* and *meat products*, one of the following procedures should be used:

1. Canning

Meat and *meat products* are subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate FMDV.

2. Thorough cooking

Meat, previously deboned and defatted, and *meat products* are subjected to a heat treatment that results in a core temperature of at least 70°C for a minimum of 30 minutes.

After cooking, they should be packed and handled in such a way they are not exposed to a source of FMDV.

3. Drying after salting

When *rigor mortis* is complete, the *meat* is deboned, treated with salt (NaCl) and 'completely dried'. It should not deteriorate at ambient temperature.

'Completely dried' is defined as a moisture protein ratio that is not greater than 2.25:1 or a water activity (Aw) that is not greater than 0.85.

Article 8.8.31bis.

Procedures for the inactivation of FMDV in swill

For the inactivation of FMDV in swill, one of the following procedures should be used:

- 1) the swill is maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or
- 2) the swill is maintained at a temperature of at least 121°C for at least ten minutes at an absolute pressure of 3 bar; or
- 3) the swill is subjected to an equivalent treatment that has been demonstrated to inactivate FMDV.

Article 8.8.32.

Procedures for the inactivation of FMDV in wool and hair

For the inactivation of FMDV present in wool and hair ~~for industrial use~~, one of the following procedures should be used:

- 1) for wool, industrial washing, which consists of the immersion ~~of the wool~~ in a series of baths of water, soap and sodium hydroxide (~~soda~~ NaOH) or potassium hydroxide (~~potash~~ KOH);
- 2) chemical depilation by means of slaked lime or sodium sulphide;
- 3) fumigation with formaldehyde in a hermetically sealed chamber for at least 24 hours;
- 4) for wool, industrial scouring which consists of the immersion ~~of wool~~ in a water-soluble detergent held at 60-70°C;
- 5) for wool, storage ~~of wool~~ at 4°C for four months, 18°C for four weeks or 37°C for eight days.

Article 8.8.33.

Procedures for the inactivation of FMDV in bristles

For the inactivation of FMDV present in bristles ~~for industrial use~~, one of the following procedures should be used:

- 1) boiling for at least one hour; or
- 2) immersion for at least 24 hours in a 1% aqueous solution of formaldehyde.

Article 8.8.34.

Procedures for the inactivation of FMDV in raw hides and skins

For the inactivation of FMDV present in raw hides and skins ~~for industrial use~~, the following procedure should be used: treatment for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na₂CO₃).

Article 8.8.35.

Procedures for the inactivation of FMDV in milk ~~and milk products~~ and cream for human consumption

For the inactivation of FMDV present in ~~milk and cream for human consumption~~, one of the following procedures should be used:

- ~~1) a process applying a minimum temperature of 132°C for at least one second (ultra high temperature [UHT]); or~~
- ~~21) if the milk has a pH less than 7.0, a process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]); or~~
- ~~32) if the milk has a pH of 7.0 or greater, the HTST process applied twice; or~~
- 3) any equivalent treatment that has been demonstrated to inactivate FMDV.**

~~Article 8.8.36.~~

Procedures for the inactivation of FMDV in milk for animal consumption

For the inactivation of FMDV present in ~~milk~~ for animal consumption, one of the following procedures should be used:

- ~~1) the HTST process applied twice; or~~
- ~~2) HTST combined with another physical treatment, e.g., maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with desiccation; or~~
- ~~3) UHT combined with another physical treatment referred to in point 2 above.~~

Article 8.8.37.

Procedures for the inactivation of FMDV in skins and trophies from susceptible wildlife animals ~~susceptible to the disease~~

For the inactivation of FMDV present in skins and trophies from susceptible wildlife animals ~~wild animals susceptible to FMD~~, one of the following procedures should be used prior to complete taxidermal treatment

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed; or
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher); or
- 3) soaking, with agitation, in a 4% (weight/volume) solution of sodium carbonate (Na_2CO_3) maintained at pH 11.5 or greater for at least 48 hours; or
- 4) soaking, with agitation, in a formic acid solution (100 kg salt $[\text{NaCl}]$ and 12 kg formic acid per 1,000 litres water) maintained at pH less than 3.0 for at least 48 hours; wetting and dressing agents may be added; or
- 5) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na_2CO_3).

Article 8.8.38.

Procedures for the inactivation of FMDV in casings of ruminants and pigs

For the inactivation of FMDV present in casings of ruminants and pigs, the following procedures should be used: treating for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl , $a_w < 0.80$), or with phosphate supplemented salt containing 86.5% NaCl , 10.7% Na_2HPO_4 and 2.8% Na_3PO_4 (weight/weight), either dry or as a saturated brine ($a_w < 0.80$), and kept at a temperature of greater than 12°C during this entire period.

Article 8.8.39.

WOAH endorsed official control programme for FMD

~~The overall objective of an OIE endorsed official control programme for FMD is for countries to progressively improve the situation and eventually attain FMD free status. The official control programme should be applicable to the entire country even if certain measures are directed towards defined subpopulations only.~~

A Member Country may, on a voluntary basis, apply for endorsement of ~~their~~ its official control programme for FMD in accordance with Chapter 1.6., when ~~they have~~ it has implemented measures in accordance with this article.

For a Member Country's official control programme for FMD to be endorsed by WOA, the Member Country should provide a description of an official control programme for the control and eventual eradication of FMD in the country or zone. This document should address and provide documented evidence on the following:

1) epidemiology:

- a) the detailed epidemiological situation of FMD in the country, highlighting the current knowledge and gaps;
- b) the main production systems and movement patterns of susceptible animals and their products within and into the country and, where applicable, the specific zone;

2) surveillance and diagnostic capabilities:

- a) FMD surveillance in place, in accordance with Chapter 1.4. and Articles 8.8.40. to 8.8.42.;
- b) diagnostic capability and procedures, including regular submission of samples to a laboratory that performs diagnostic testing and further characterisation of strains;
- c) serosurveillance conducted in susceptible species, including wildlife, to serve as sentinels for FMDV circulation in the country;

3) vaccination:

- a) vaccination is compulsory in the target population and is practised in accordance with Chapter 4.18.;
- b) detailed information on vaccination campaigns, in particular:
 - i) the strategy that is adopted for the vaccination campaign;
 - ii) target populations for vaccination;
 - iii) target geographical area for vaccination;
 - iv) monitoring of vaccination coverage, including serological monitoring of population immunity;
 - v) the strategy to identify vaccinated animals;
 - vi) technical specification of the vaccines used including matching with the circulating FMDV strains and description of the vaccine licensing procedures in place;
 - vii) if relevant, proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the Terrestrial Manual;
 - viii) the proposed strategy and work plan including the timeline for transition to the cessation of vaccination;

4) the measures implemented to prevent the introduction of the pathogenic agent and to ensure the rapid detection of all FMD outbreaks;

- 5) an emergency preparedness plan and an emergency response plan to be implemented in case of FMD outbreaks;
- 6) work plan and timelines of the official control programme;
- 7) performance indicators for assessing the effectiveness of the control measures to be implemented;
- 8) monitoring, evaluation and review of the official control programme to demonstrate the effectiveness of the strategies.
- 1) have a record of regular and prompt animal *disease* reporting in accordance with the requirements in Chapter 1.1.;
- 2) submit documented evidence of the capacity of the *Veterinary Services* to control FMD; one way of providing this evidence is through the OIE PVS Pathway;
- 3) submit a detailed plan of the programme to control and eventually eradicate FMD in the country or zone including:
 - a) the timeline;
 - b) the performance indicators for assessing the efficacy of the control measures to be implemented;
 - c) documentation indicating that the *official control programme* for FMD is applicable to the entire country;
- 4) submit a dossier on the epidemiology of FMD in the country describing the following:
 - a) the general epidemiology in the country highlighting the current knowledge and gaps and the progress that has been made in controlling FMD;
 - b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all FMD outbreaks in order to reduce the incidence of FMD outbreaks and to eliminate FMDV transmission of FMDV in at least one zone in the country;
 - c) the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;
- 5) submit evidence that FMD *surveillance* is in place:
 - a) FMD surveillance is in place, taking into account provisions in accordance with Chapter 1.4. and the provisions on *surveillance* of this chapter;
 - b) ~~it has~~ have diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains;
- 6) where *vaccination* is practised as a part of the *official control programme* for FMD, provide:
 - a) evidence (such as copies of legislation) that *vaccination* of selected *populations* is compulsory;
 - b) detailed information on *vaccination* campaigns, in particular on:
 - i) target populations for *vaccination*;
 - ii) monitoring of *vaccination* coverage, including serological monitoring of population immunity;
 - iii) technical specification of the vaccines used, including matching with the circulating FMDV strains, and description of the licensing procedures in place;
 - iv) the proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;

- 7) ~~provide an emergency preparedness and response plan to be implemented in case of outbreaks.~~

~~The Member Country's official control programme for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence, based on the provisions of Article 1.6.11., has been accepted by the OIE.~~

The country will be included in the list of countries having a WOAHO endorsed official control programme for FMD in accordance with Chapter 1.6.

~~Retention on the list requires an annual update on the progress of the official control programme and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.~~

~~The OIE may withdraw the endorsement of the official control programme if there is evidence of:~~

- ~~– non-compliance with the timelines or performance indicators of the programme; or~~
- ~~– significant problems with the performance of the Veterinary Services; or~~
- ~~– an increase in the incidence or an extension of the distribution of FMD that cannot be addressed by the programme.~~

Article 8.8.40.

General principles of surveillance

Articles 8.8.40. to 8.8.42. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Member Countries seeking establishment, maintenance or recovery of freedom from FMD at the country, *zone* or *compartment* level or seeking endorsement by WOAHO of their *official control programme* for FMD, in accordance with Article 8.8.39. *Surveillance* aimed at identifying disease and ~~FMDV infection with~~, or transmission ~~of, FMDV~~ should cover domestic and, where appropriate, *wildlife* species as indicated in point 2 of Article 8.8.1.

1. Early detection

A *surveillance* system in accordance with Chapter 1.4. should be the responsibility of the *Veterinary Authority* and should provide an *early warning system* to report suspected *cases* throughout the entire production, marketing and processing chain. A procedure should be in place for the rapid collection and transport of samples to a *laboratory* for FMD diagnosis. This requires that sampling kits and other equipment be available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to seek assistance from a team with expertise in FMD diagnosis and control.

2. Demonstration of freedom

The impact and epidemiology of FMD widely differ in different regions of the world and therefore it is inappropriate to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from FMD in the country, *zone* or *compartment* at an acceptable level of confidence should be adapted to the local situation. For example, the approach to demonstrating freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMDV should differ significantly from an approach designed to demonstrate freedom from FMD in a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*.

Surveillance for FMD should be in the form of a continuing programme. Programmes to demonstrate no evidence of *infection* with ~~FMDV~~ and transmission ~~of, FMDV~~ should be carefully designed and implemented to avoid producing results that are insufficient to be accepted by WOAHO or trading partners, or being excessively costly and logistically complicated.

The strategy and design of the *surveillance* programme will depend on the historical epidemiological circumstances including whether ~~or not~~ *vaccination* has been ~~used~~ practised or not.

A Member Country wishing to substantiate FMD freedom where *vaccination* is not practised should demonstrate no evidence of *infection* with FMDV in unvaccinated animals. Previously or newly introduced vaccinated animals should be considered in the strategy and design of the surveillance programme.

A Member Country wishing to substantiate FMD freedom where *vaccination* is practised should demonstrate that FMDV has not been transmitted in any susceptible *populations*. Within vaccinated *populations*, serological surveys to demonstrate no evidence of ~~FMDV~~ transmission of FMDV should target animals that are less likely to show vaccine-derived antibodies to ~~non-structural proteins NSP~~, such as young animals vaccinated a limited number of times, or unvaccinated animals. In any unvaccinated *subpopulation*, *surveillance* should demonstrate no evidence of *infection* with FMDV.

Surveillance strategies employed for establishing and maintaining a *compartment* should identify the prevalence, distribution and characteristics of FMD outside the *compartment*.

3. WOAH endorsed official control programme

Surveillance strategies employed in support of a WOAHE endorsed *official control programme* should demonstrate evidence of the effectiveness of any *vaccination* used and of the ability to rapidly detect all FMD *outbreaks*.

Therefore, considerable latitude is available to Member Countries to design and implement *surveillance* to establish that the whole territory or part of it is free from ~~FMDV infection with~~, and transmission of, FMDV and to understand the epidemiology of FMD as part of the *official control programme*.

The Member Country should submit a dossier to WOAHE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors, including the role of *wildlife*, if appropriate, are identified and managed. This should include provision of scientifically based supporting data.

4. Surveillance strategies

The strategy employed to establish the prevalence of *infection* with FMDV or to substantiate freedom from ~~FMDV infection with~~, or transmission of, FMDV may be based on randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence, as described in Articles 1.4.4. and 1.4.5. If an increased likelihood of *infection* in particular localities or species can be identified, targeted sampling may be appropriate. Clinical inspection may be targeted at particular species likely to exhibit clear clinical signs (e.g., ~~bovines cattle~~cattle ~~cattle~~bovines and pigs). The Member Country should justify the *surveillance* strategy chosen and the frequency of sampling as adequate to detect ~~the presence of FMDV infection with~~, or transmission of, FMDV in accordance with Chapter 1.4. and the epidemiological situation.

The design of the sampling strategy should incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing should be adequate to detect *infection* or transmission if it were to occur at a predetermined minimum rate. The sample size and expected disease 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 prevailing or historical epidemiological situation, in accordance with Chapter 1.4.

5. Follow-up of suspected cases and interpretation of results

An effective *surveillance* system will identify suspected *cases* that require immediate follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Samples should be taken and submitted for diagnostic testing, unless the suspected *case* can be confirmed or ruled out by epidemiological and clinical investigation. 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 animals concerned were subjected during the investigation.

The sensitivity and specificity of the diagnostic tests employed, including the performance of confirmatory tests, are key factors in the design, sample size determination and interpretation of the results obtained. Selection of diagnostic tests and interpretation of results should take into account ~~The sensitivity and specificity of the tests used should be validated for the vaccination or infection history and production class of animals in the target population.~~

The *surveillance* 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 positives ~~results~~ to determine with a high level of confidence, whether or not they are indicative of *infection* or transmission. This should involve supplementary tests and follow-up investigation to collect diagnostic material from the original *epidemiological unit* and *herds* which may be epidemiologically linked to it.

Laboratory results should be examined in the context of the epidemiological situation. ~~Corollary ii~~ Information needed to complement the serological survey and assess the possibility of viral transmission includes but is not limited to:

- characterisation of the existing production systems;
- results of clinical *surveillance* of the suspects and their cohorts;
- description of number of, and protocol for, *vaccinations* performed in the area under assessment;
- *biosecurity* and history of the *establishments* with reactors;
- identification and traceability of animals and control of their movements;
- other parameters of regional significance in historic ~~FMDV~~ transmission of FMDV.

6. Demonstration of population immunity

Following routine *vaccination*, evidence should be provided to demonstrate the effectiveness of the *vaccination* programme such as adequate *vaccination* coverage and population immunity. This can support the interpretation of help to reduce reliance ~~on~~ post-*vaccination* surveys for residual *infection* and transmission.

In designing serological surveys to estimate population immunity, blood sample collection should be stratified by age to take account of the number of *vaccinations* the animals have received. The interval between last *vaccination* and sampling depends upon the intended purpose. Sampling at one or two months after *vaccination* provides information on the efficiency of the *vaccination* programme, while sampling before or at the time of revaccination provides information on the duration of immunity. When multivalent vaccines are used, tests should be carried out to determine the antibody level at least for each serotype, if not for each antigen blended into the vaccine. The test cut-off for an acceptable level of antibody should be selected with reference to protective levels demonstrated by vaccine-challenge test results for the antigen concerned. Where the threat from circulating virus has been characterised as resulting from a field virus with significantly different antigenic properties from the vaccine virus, this should be taken into account when interpreting the protective effect of population immunity. Figures for population immunity should be quoted with reference to the total of susceptible animals in a given *subpopulation* and in relation to the subset of vaccinated animals.

7. Additional measures for early recovery of free status free from FMD where ~~without~~ vaccination is not practised or early recovery of free status free from FMD where ~~with~~ vaccination is practised in the area(s) where emergency vaccination has been applied but not followed by the slaughtering of all vaccinated animals

In addition to the general conditions described in this chapter, a Member Country seeking either recovery of status of a country or zone previously free from FMD where *vaccination* is not practised, including a *containment zone*, or recovery of status of a country or zone previously free from FMD where *vaccination* is practised, earlier than the six months as specified respectively under point 1 c) of Article 8.8.7. or under point 3 a) of Article 8.8.7. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved when answering the relevant questionnaire in Chapter 1.11. by demonstrating compliance with either a) or b) and c) below, in the area(s) where emergency *vaccination* has been applied. It is advisable that the *Veterinary Authority* ~~countries should~~ consider the different options for the recovery of a free status when control measures are first implemented at the onset of the *outbreak* in order to plan for the applicable requirements to be met.

a) The following serological surveys have been conducted in the area where emergency *vaccination* has been applied and have demonstrated the absence of *infection* in unvaccinated *animals* and the absence of transmission in emergency vaccinated *animals*:

- i) for vaccinated ruminants, serological surveys using ~~nonstructural protein~~ NSP tests to detect antibodies in all vaccinated ruminants and their non-vaccinated offspring in all *epidemiological units* (census serosurveillance);
- ii) for vaccinated pigs and their non-vaccinated offspring, serological surveys using ~~nonstructural protein~~ NSP tests to detect antibodies in all vaccinated *epidemiological units* with maximum 5% within *herd* design prevalence (95% confidence level);

- iii) for non-vaccinated susceptible species that do not show reliable clinical signs or husbandry systems that do not allow sufficient observation, serological surveys with maximum design prevalence of 1% at herd level and 5% within herds (95% confidence level).
 - b) The following surveillance components have been implemented in the area where emergency vaccination has been applied and have demonstrated the absence of infection in unvaccinated animals and the absence of transmission in vaccinated animals:
 - i) risk-based serological surveillance in vaccinated herds with stratification according to relevant factors such as proximity to known infected herds, region/establishment with numerous movement of animals, epidemiological links to infected herds, species, production management systems and herd size;
 - ii) random serological surveillance in vaccinated herds with maximum design prevalence of 1% at herd level and 5% within herds (95% confidence level) in each emergency vaccination area;
 - iii) intensified clinical and slaughterhouse/abattoir surveillance;
 - iv) for non-vaccinated susceptible species that do not show reliable clinical signs or husbandry systems that do not allow sufficient observation, serological surveys with maximum design prevalence of 1% at herd level and 5% within herds (95% confidence level);
 - v) virological surveillance to investigate the status of vaccinated herds may also be conducted to contribute to additional confidence in demonstrating freedom.
 - c) Vaccine efficacy and vaccination effectiveness of the emergency vaccination deployed have been demonstrated by documenting the following:
 - i) Vaccine efficacy
 - = vaccine that provides high potency of at least 6PD50 or equivalent probability of protection which may be achieved by a vaccine with high potency of at least 6PD50 or equivalent and evidence of a good match between the vaccine strain and the field virus; or
 - = evidence that the vaccine used can protect against the field strain that has caused the outbreak, demonstrated through the results of a heterologous challenge test or indirect serological assay (i.e., sera from vaccinated animals tested against the field virus). This should also establish the cut-off titre for protection to be used in the test for population immunity studies.
 - ii) Vaccination effectiveness
 - = objective and strategy of the emergency vaccination deployed;
 - = evidence of the timeliness of the emergency vaccination (start and completion dates);
 - = evidence of vaccination delivery including preservation of vaccine (e.g., cold chain) and at least 95% vaccination coverage achieved in the targeted and eligible population;
 - = evidence of high population immunity at herd and individual level through serological surveillance.

8. Additional measures for early recovery of free status free from FMD where with vaccination is practised in the area outside of the area(s) where emergency vaccination has been applied.

In addition to the general conditions described in this chapter, a Member Country seeking recovery of status of a country or zone previously free from FMD where vaccination is practised in the area outside of the area(s) where emergency vaccination has been applied, earlier than six months as specified under point 3 a) of Article 8.8.7. should justify the circumstances and measures that demonstrate sufficient confidence to substantiate a claim for freedom. This may be achieved either by meeting

the requirements listed in a) below or by demonstrating compliance with the requirements listed in b) and c) below, when answering the questionnaire in Article 1.11.2. or Article 1.11.4.

With regard to the surveillance requirements listed in b), it should be noted that clinical signs may not be apparent in the routinely vaccinated population. The expression of clinical signs would depend on the relationship between the virus strain used in the routine vaccination to the virus that caused the outbreak. For example, following an incursion of a new serotype it would be expected that the routinely vaccinated animals would show clinical signs if infected. In contrast, following an incursion of a serotype or strain covered by the vaccine it would be expected that most of the routinely vaccinated animals would be protected and therefore less likely to be infected and to show clinical signs if infected. Other factors such as vaccination coverage and timing of vaccination could influence the likelihood of infection and expression of clinical signs.

It is advisable that countries should the Veterinary Authority consider the different options for the recovery of a free status when control measures are first implemented at the onset of the outbreak in order to plan for the applicable requirements to be met.

a) Establishment of a containment zone

A containment zone that includes all emergency vaccination area(s) has been established based on the provisions of Article 8.8.6. to provide assurance that FMD has not occurred in the area outside the emergency vaccination area(s).

b) The following surveillance components have been implemented in the area outside of the area(s) where emergency vaccination has been applied and have demonstrated the absence of infection in unvaccinated animals and the absence of transmission in vaccinated animals:

- i) risk-based serological surveillance in vaccinated herds with stratification according to relevant factors such as proximity to the emergency vaccination area, region/establishment with numerous movement of animals, epidemiological links to infected herds, species and age, production management systems, herd size;
- ii) random serological surveillance in vaccinated herds with maximum design prevalence of 1% at herd level and 5% within herds (95% confidence level);
- iii) intensified clinical and slaughterhouse/abattoir surveillance;
- iv) serological survey in non-vaccinated susceptible species that do not show reliable clinical signs or husbandry systems that do not allow sufficient observation with risk-based stratification according to factors such as proximity to the emergency vaccination area, region/establishment with numerous movement of animals, epidemiological links to infected herds, species, production management systems, herd size;
- v) virological surveillance to investigate the status of vaccinated herds may also be conducted to contribute to additional confidence in demonstrating freedom.

The efficacy of the routine vaccine against the virus that caused the outbreak(s) has been documented.

The entire investigative process should be documented within the surveillance programme.

All the epidemiological information should be substantiated, and the results should be collated in the final report.

Article 8.8.41.

Methods of surveillance

1. Clinical surveillance

Farmers and workers who have day-to-day contact with livestock, as well as *veterinary para-professionals, veterinarians* and diagnosticians, should report promptly any suspicion of FMD. The *Veterinary Services Authority* should implement programmes to raise awareness among them.

Clinical *surveillance* requires the physical examination of susceptible *animals*. Although significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection may provide a high level of confidence of detection of disease if a sufficient number of clinically susceptible *animals* is examined at an appropriate frequency and investigations are recorded and quantified.

Clinical examination and diagnostic testing should be applied to clarify the status of suspected *cases*. Diagnostic testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive laboratory test results. Clinical *surveillance* may be insufficient in *wildlife and domestic* species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such situations, serological *surveillance* should be used. However, recognising the difficulty in sampling wildlife, surveillance of domestic species in close contact with susceptible wildlife can provide supportive evidence of the animal health status of these wildlife populations. Hunting, capture and non-invasive sampling and observation methods can also be used to obtain information and diagnostic samples from *wildlife* species.

2. Virological surveillance

Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is mostly dependent upon clinical *surveillance* to provide samples. FMDV isolates should be sent regularly to a WOA Reference Laboratory.

Virological *surveillance* aims to:

- a) confirm clinically suspected *cases*;
- b) follow up positive serological results;
- c) characterise isolates for epidemiological studies and vaccine matching;
- d) monitor *populations* at risk for the presence and transmission of the virus.

3. Serological surveillance

Serological *surveillance* aims to detect antibodies resulting from *infection* or *vaccination* using ~~nonstructural protein NSP~~ tests or ~~structural protein SP~~ tests.

Serological *surveillance* may be used to:

- a) estimate the prevalence or substantiate freedom from ~~FMDV infection~~ with, or transmission of, FMDV;
- b) monitor population immunity.

Serum collected for other purposes can be used for FMD *surveillance*, provided the principles of survey design described in this chapter are met.

The results of random or targeted serological surveys are important in providing reliable evidence of the FMD situation in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Article 8.8.42.

The use and interpretation of serological tests ~~(see Figure 3)~~

The selection and interpretation of serological tests should be considered in the context of the epidemiological situation. Test protocols, reagents, performance characteristics and validation of all tests used should be known. Where combinations of tests are used, the overall test system performance characteristics should also be known.

Animals infected with FMDV produce antibodies to both the ~~structural proteins SP~~ and the ~~nonstructural proteins NSP~~ of the virus. Vaccinated *animals* produce antibodies mainly or entirely to the ~~structural proteins SP~~ of the virus depending upon vaccine purity. ~~The structural protein SP tests are serotype specific and for optimal sensitivity one should select an antigen or virus closely related~~

~~to the field strain expected.~~ In unvaccinated *populations*, ~~structural protein SP~~ tests may be used to screen sera for evidence of ~~FMDV infection with, or transmission of, FMDV~~ or to detect the introduction of vaccinated *animals*. In vaccinated *populations*, ~~structural protein SP~~ tests may be used to monitor the serological response to the *vaccination*. The SP tests are serotype specific, and for optimal sensitivity one should select an antigen or virus closely related to the field strain expected should be selected.

~~Nonstructural protein NSP~~ tests may be used to screen sera for evidence of *infection* or transmission of all serotypes of FMDV regardless of the *vaccination* status of the *animals* provided the vaccines comply with the standards of the *Terrestrial Manual* with respect to purity. However, although *animals* vaccinated and subsequently infected with FMDV develop antibodies to ~~nonstructural proteins NSP~~, the levels may be lower than those found in infected *animals* that have not been vaccinated. To ensure that all *animals* that had contact with FMDV have seroconverted, it is recommended that for each *vaccination* area samples for ~~nonstructural protein NSP~~ antibody testing are taken not earlier than 30 days after the last *case* and in any case not earlier than 30 days after the last *vaccination*.

Positive FMDV antibody test results can have four possible causes:

- *infection* with FMDV;
- *vaccination* against FMD;
- maternal antibodies (maternal antibodies in ~~bovines cattle~~cattle ~~bovines~~ are usually found only up to six months of age but in some individuals and in some other species, maternal antibodies can be detected for longer periods);
- non-specific reactivity of the serum in the tests used.

1. Procedure in case of positive test results

The proportion and strength of seropositive reactors should be taken into account when deciding if they are *laboratory* confirmed reactors or further investigation and testing are required.

When false positive results are suspected, seropositive reactors should be retested in the *laboratory* using repeat and confirmatory tests. Tests used for confirmation should be of high diagnostic specificity to minimise false positive test results. The diagnostic sensitivity of the confirmatory test should approach that of the screening test.

All *herds* with at least one ~~laboratory confirmed~~ reactor that has been confirmed in a laboratory should be investigated. The investigation should examine all evidence, which may include the results of ~~virological tests and~~ of any further serological tests ~~that might used to~~ confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to ~~FMDV transmission of FMDV, as well as of virological tests~~. This investigation should document the status for each positive *herd*. Epidemiological investigation should be continued concurrently.

Clustering of seropositive results within *herds* or within a region should be investigated as it may reflect any of a series of factors or events, including the demographics of the *population* sampled, vaccinal exposure or the presence of *infection* or transmission. As clustering may signal *infection* or transmission, the investigation of all instances should be incorporated in the survey design.

Paired serology can be used to identify ~~FMDV transmission of FMDV~~ by demonstrating an increase in the number of seropositive *animals* or an increase in antibody titre at the second sampling.

The investigation should include the reactor *animals*, susceptible *animals* of the same *epidemiological unit* and susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animals*. The *animals* sampled should be identified as such and remain in the *establishment* pending test results, should be ~~clearly identified,~~ accessible and should not be vaccinated during the investigations, so that they can be retested after an appropriate period of time. Following clinical examination, a second sample should be taken, after an appropriate time has elapsed, from the *animals* tested in the initial survey with emphasis on *animals* in direct contact with the reactors. If the *animals* are not individually identified, a new serological survey should be carried out in the *establishments* after an appropriate time, repeating the application of the primary survey design. If FMDV is not circulating, the magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample.

In some circumstances, unvaccinated sentinel *animals* may also be used. These can be young *animals* from unvaccinated dams or *animals* in which maternally conferred immunity has lapsed and preferably of the same species as in the positive sampling units. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the *animals* of the *epidemiological unit* under investigation for at

least two *incubation periods*, and if there is no transmission of FMDV, they should will remain serologically negative ~~if FMDV is not circulating~~.

2. Follow-up of field and laboratory findings

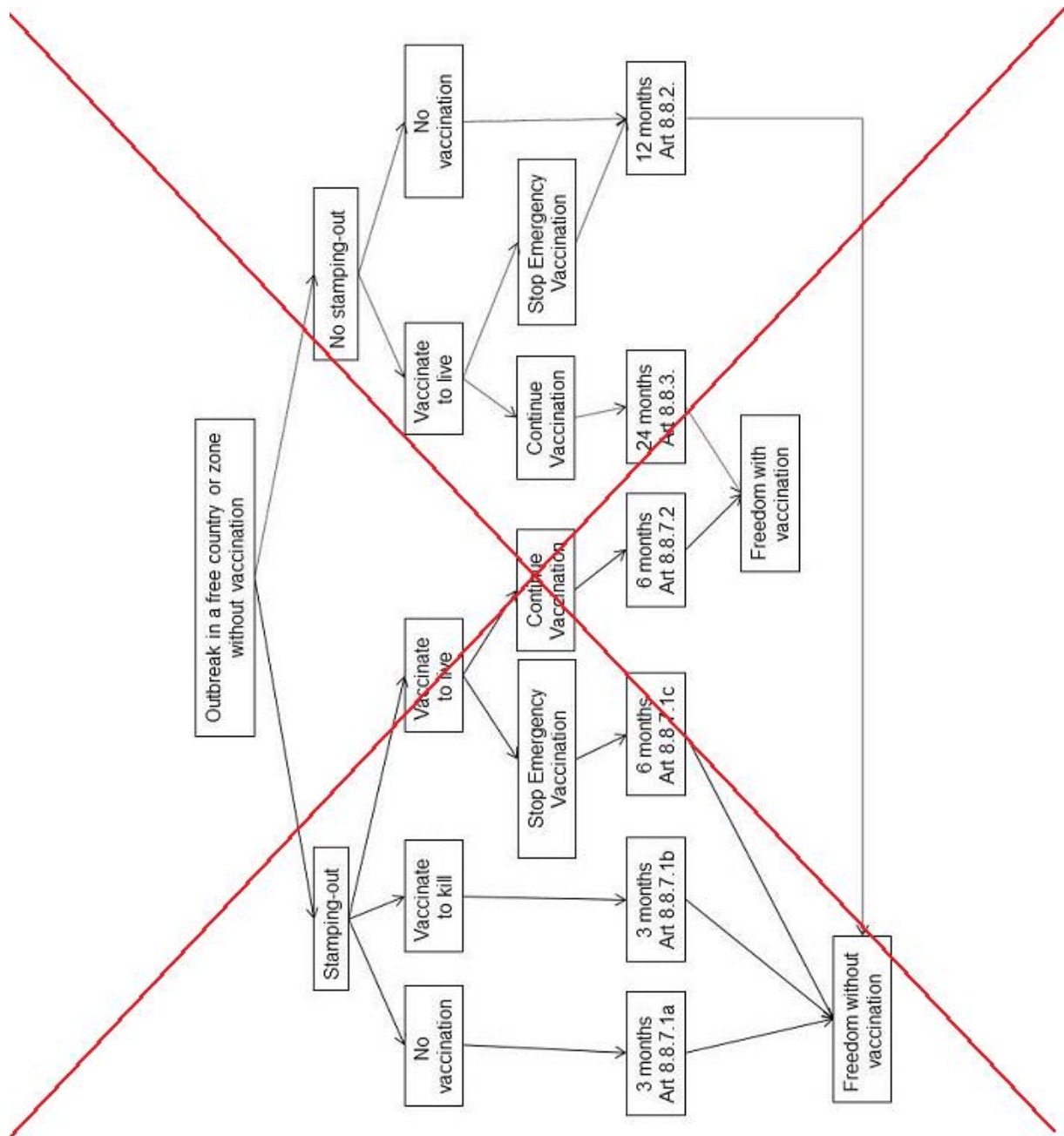
If transmission is demonstrated, an *outbreak* is declared.

~~It is difficult to determine~~ The significance of small numbers of seropositive *animals* in the absence of current FMDV transmission ~~is difficult to determine~~. Such findings may be an indication of past *infection* followed by recovery or by the development of a carrier state, in ruminants, or due to non-specific serological reactions. Antibodies to ~~nonstructural proteins~~ NSP may be induced by repeated *vaccination* with vaccines that do not comply with the requirements for purity. However, the use of such vaccines is not permissible in countries or *zones* applying for an official status. In the absence of evidence of ~~FMDV~~ *infection with*, and transmission of, FMDV, such findings do not warrant the declaration of a new *outbreak* and the follow-up investigations may be considered complete.

However, if the number of seropositive *animals* is greater than the number of false positive results expected from the specificity of the diagnostic tests used, susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animals* should be investigated further.

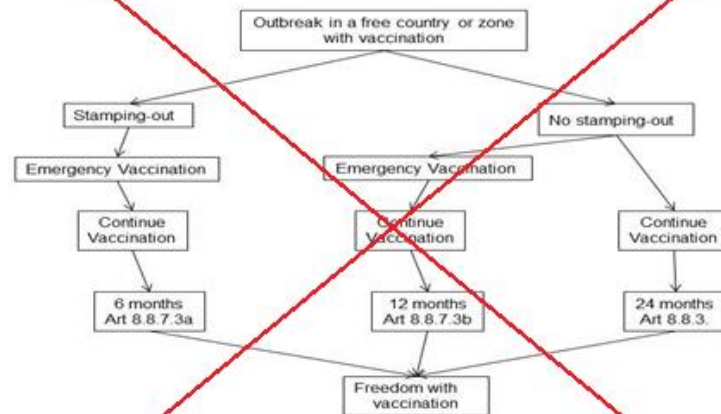
Abbreviations and acronyms:	
ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Nonstructural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP-antibody test
SP	Structural protein of foot and mouth disease virus

Fig. 1. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak of FMD in a previously free country or zone where vaccination is not practised



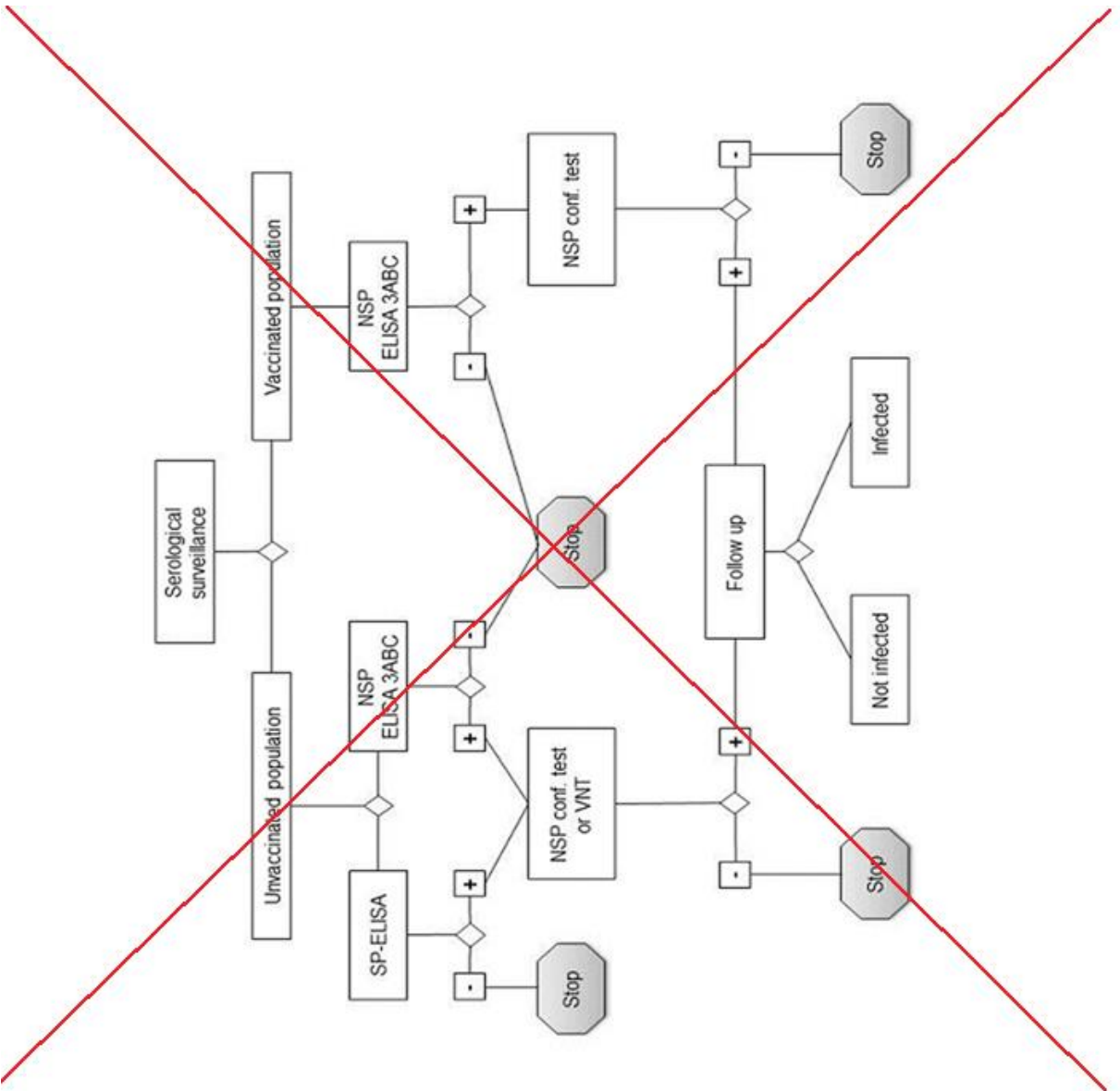
Waiting periods are minima depending upon outcome of surveillance specified in respective articles. If there are multiple waiting periods because of different control measures, the longest applies.

Fig. 2. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak of FMD in a previously free country or zone where vaccination is practised



Waiting periods are minima depending upon outcome of surveillance specified in respective articles. If there are multiple waiting periods because of different control measures, the longest applies.

Fig. 3. Schematic representation of laboratory tests for determining evidence of infection with FMDV by means of serological surveys



CHAPTER 8.14.

INFECTION WITH RABIES VIRUS

[...]

Article 8.14.6bis.

Recommendations for importation of dogs from countries or zones infected with rabies virus

Veterinary Authorities should require the presentation of an *international veterinary certificate* complying with the model of Chapter 5.11. attesting that the dogs:

- 1) showed no clinical signs of rabies the day prior to or on the day of shipment;
- 2) were permanently identified and their identification ~~number~~code stated in the certificate;
- 3) and either:
 - a) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the *Terrestrial Manual* and were subjected, not less than 30 days and not more than 12 months prior to shipment, to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5 IU/ml;

or

- b) were kept in a *quarantine station* for six months prior to shipment.

Article 8.14.7.

Recommendations for importation of ~~dogs~~, cats and ferrets from countries or zones infected with rabies virus

Veterinary Authorities should require the presentation of an *international veterinary certificate* complying with the model of Chapter 5.11. attesting that the animals:

- 1) showed no clinical signs of rabies the day prior to or on the day of shipment;
- 2) were permanently identified and their identification ~~number~~code stated in the certificate;
- 3) and either:
 - a) were vaccinated or revaccinated in accordance with the recommendations of the manufacturer, with a vaccine that was produced in accordance with the *Terrestrial Manual* and were subjected not less than 3 months and not more than 12 months prior to shipment to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5 IU/ml;

or

- b) were kept in a *quarantine station* for six months prior to shipment.

Article 8.14.11bis.

Recommendations for dog-mediated rabies vaccination programmes

When developing and implementing vaccination programmes for dog-mediated rabies, in addition to provisions in Chapter 4.18., Member Countries should:

1. Prepare for the vaccination programme:

- a) consult with all relevant stakeholders, including target communities to define the most appropriate time to increase community participation and reduce the time required to complete vaccination;
- b) ensure safety of vaccination teams including training in humane dog capture and handling, and a strategy to manage exposure to suspect rabid animals.

2. Choose a vaccine and the vaccination strategy:

- a) Priority should be given to vaccinating free-roaming dogs, including puppies, to immediately quickly interrupt the rabies virus transmission cycle.
- b) Vaccination campaigns should be conducted recurrently (usually annually). More regular frequent vaccination campaigns may be considered in especially high-risk areas, or to quickly interrupt the cycle of virus transmission.
- c) The vaccination strategy should take into account simultaneous dog population management programmes as described in Chapter 7.7.

3. Monitor the vaccination programme:

- a) To monitor the vaccination coverage, vaccinated dogs should be identified and registered in a database an animal identification system.
 - b) Vaccination certificates which state identification of the dog, date of vaccination and product should be provided to dog owners as proof of vaccination.
 - c) Vaccination coverage should be monitored at the smallest administrative level possible.
-

CHAPTER 8.15.

INFECTION WITH RIFT VALLEY FEVER VIRUS

Article 8.15.1.

General provisions

- 1) The aim of this chapter is to mitigate the animal and public health risks posed by Rift Valley fever (RVF) and to prevent its international spread.
- 2) For the purposes of this chapter:
 - a) 'epizooticepidemic area' means a part of a country or zone in which an epizooticepidemic of RVF is occurring, and which does not correspond to the definition of zone;
 - b) 'epizooticepidemic of RVF' means a sudden and unexpected change in the distribution or increase in incidence of, or morbidity or mortality of RVF;
 - c) 'inter-epizooticepidemic period' means a period with low levels of vector activity and low rates of RVF virus (RVFV) transmission between two epidemics;
 - d) 'susceptible animals' means ruminants and dromedary camels.
- 32) Humans and many animal species are susceptible to infection can be affected by RVF. For the purposes of the Terrestrial Code, RVF is defined as an infection of ruminants 'susceptible animals' with Rift Valley fever virus (RVFV).
- 43) The following defines the occurrence of infection with RVFV:
 - a) RVFV, excluding vaccine strains, has been isolated and identified as such from a sample from a ruminant susceptible animal; or
 - b) antigen or ribonucleic acid specific to RVFV, excluding vaccine strains, has been identified detected in a sample from a ruminant susceptible animal showing clinical signs or pathological lesions consistent with RVF, or epidemiologically linked with epidemiological links either to a confirmed or suspected case of RVF, including in or to a human infected with RVFV, or giving cause for suspicion of association or contact with RVFV; or
 - c) antibodies specific to RVFV antigens which that are not the consequence of vaccination, have been identified detected in a sample from a ruminant susceptible animal showing clinical signs or pathological lesions consistent with RVF, or with either epidemiological links either to a confirmed or suspected case of RVF, including in or to a human infected with RVFV, or giving cause for suspicion of association or contact with RVFV.
- 54) For the purposes of the Terrestrial Code, the infective period for RVF shall be 14 days and the incubation period shall be 7 days.
- 6) For the purposes of the Terrestrial Code, the incubation period for RVF shall be 7 days.
- 765) In areas where RVFV is present, epizooticepidemics of RVF may occur following favourable climatic, and other environmental conditions and availability of susceptible host animal and competent vector populations. Epizooticepidemics are separated by inter-epizooticepidemic periods. The transition from an inter-epizooticepidemic period to an epizooticepidemic complies with point 1)(d) of Article 1.1.3. in terms of notification.

- 6) For the purposes of this chapter:
- a) 'area' means a part of a country that experiences epizootics and inter-epizootic periods, but which does not correspond to the definition of zone;
 - b) 'epizootic of RVF' means the occurrence of outbreaks at an incidence substantially exceeding that during an inter-epizootic period or the occurrence of indigenous human cases;
 - c) 'inter-epizootic period' means the period of variable duration, often long, with intermittent low level of vector activity and low rate of virus transmission, which is often not detected;
 - d) ruminants include dromedary camels.
- 7) The historical distribution of RVF has been parts of the African continent, Madagascar, some other Indian Ocean Islands and the south-western Arabian Peninsula. However, vectors, environmental and climatic factors, land use dynamics, and animal movements may modify the temporal and spatial distribution of the infection.
- 78) When authorising importation or transit of the commodities covered in the chapter, with the exception of those listed in Article 8.15.2., Veterinary Authorities should require the conditions prescribed in this chapter relevant to the RVF status of the ruminant susceptible animal population of the exporting country.
- 89) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.15.2.

Safe commodities

When authorising the importation or transit of the following commodities and any products made from them, Veterinary Authorities should not require any RVF-related conditions, regardless of the RVF animal health status of the ruminant susceptible animal population of the exporting country or zone:

- 1) hides and skins;
- 2) wool and fibre;
- 3) extruded dry pet food;
- 4) heat-treated meat products in a hermetically sealed container with an F0 value of 3 or above.

Article 8.15.3.

Country or zone free from RVF

A country or a zone may be considered free from RVF when infection with RVFV is notifiable in the entire country and either:

- 1) it meets the requirements for historical freedom in ~~point 1 a)~~ of Article 1.4.6.; or
- 2) it meets the following conditions:
 - a) an on-going pathogen-specific surveillance programme in accordance with Chapter 1.4. has demonstrated no evidence of infection with RVFV in ruminants susceptible animals in the country or zone for a minimum of ten years; and
 - b) during that period no indigenous human cases infections in humans have occurred ~~has~~ have been reported by the public health authorities in the country or zone.

A country or zone free from RVF will not lose its free status through the importation of ruminants susceptible animals that are seropositive, so long as they are either permanently identified as such or destined for immediate slaughter.

Article 8.15.4.

Country or zone infected with RVFV ~~during the inter-epizootic period~~

A country or *zone* infected with RVFV, ~~during the inter-epizootic period~~, is one that does not comply with meet the requirements of Article 8.15.3. in which virus activity is present at a low level but the factors predisposing to an epizootic are absent.

~~Article 8.15.5.~~

~~Country or zone infected with RVFV during an epizootic~~

~~A country or zone infected with RVFV, during an epizootic, is one in which outbreaks of RVF are occurring at an incidence substantially exceeding that of the inter-epizootic period; or one in which indigenous human cases of RVF are occurring even in the absence of detection of animal cases.~~

Article 8.15.65.

Strategies to protect from vector attacks during transport

Strategies to protect **susceptible** animals from *vector* attacks during transport should take into account the local ecology and potential insecticide resistance of the vectors, and potential **Risk management-Protection** measures include:

- 1) treating animals and vehicles/vessels with insect repellents and insecticides prior to and during transportation;
- 2) *loading*, transporting and *unloading* animals at times of low *vector* activity;
- 3) ensuring *vehicles/vessels* do not stop en route ~~during dawn or dusk, or overnight~~, unless the animals are ~~held behind insect-proof netting protected from vector attacks~~;
- 4) using historical and current information to identify lower risk ports and transport routes.

Article 8.15.76.

Recommendations for importation of susceptible animals from countries or zones free from RVF

For ruminants susceptible animals

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

- 1) were kept in a country or *zone* free from RVF since birth or for at least 14 days prior to shipment;

AND

- 2) either:
 - a) were vaccinated at least 14 days prior to leaving the free country or *zone*; or
 - b) did not transit through an epizooticepidemic area ~~experiencing an epizootic during transportation to the place of shipment; or~~
 - c) ~~were protected from vector attacks when transiting through an epizootic area experiencing an epizootic.~~

Article 8.15.87.

Recommendations for importation of susceptible animals from countries or zones infected with RVFV ~~during the inter-epizootic period~~

For ruminants susceptible animals

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

- 1) showed no clinical signs of RVF on the day of shipment;
- 2) met one of the following conditions:
 - a) were vaccinated against RVF at least 14 days prior to shipment ~~with a modified live virus vaccine~~; or
 - b) were held for at least 14 days prior to shipment in a *vector-protected quarantine station*, which is located in an area of demonstrated low *vector* activity. During this period the animals showed no clinical sign of RVF;

AND

- 3) either:
 - a) did not originate in or transit through an area experiencing an epizootic/epidemic area during transportation to the *place of shipment*; or
 - b) ~~were protected from vector attacks when transiting through an area experiencing an epizootic area.~~

Article 8.15.98.

Recommendations for importation of susceptible animals from countries or zones infected with RVFV during an epizootic

For ruminants susceptible animals

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

~~1~~

- ~~1) showed no clinical signs of RVF on the day of shipment;~~
- ~~2) did not originate from an in the epizootic area of the epizootic;~~
- ~~3) were vaccinated against RVF at least 14 days prior to shipment;~~
- ~~4) were held for at least 14 days prior to shipment in a *vector-protected quarantine station*, which is located in an area of demonstrated low *vector* activity outside the of an epizootic area of the epizootic. During this period the animals showed no clinical signs of RVF;~~

AND

- 5) either:
 - a) ~~did not transit through an epizootic area experiencing an epizootic during transportation to the *place of shipment*; or~~
 - b) ~~were protected from vector attacks when transiting through an epizootic area experiencing an epizootic.~~

Article 8.15.1098.

Recommendations for importation of semen and *in vivo* derived embryos of susceptible animals from countries or zones ~~not free from infected with~~ RVFV

For semen and *in vivo* derived embryos of ruminants susceptible animals

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

- 1) showed no clinical signs of RVF within the period from 14 days prior to and 14 days following collection of the semen or embryos;
- AND
- 2) either:
 - a) were vaccinated against RVF at least 14 days prior to collection; or
 - b) were subjected to a serological test demonstrated to be seropositive on the day of collection, with positive result; or
 - c) were subjected to a serological test on two occasions with negative results on the day of collection and at least 14 days after collection ~~testing of paired samples has demonstrated that seroconversion did not occur within 14 days of between semen or embryo collection and 14 days after.~~

Article 8.15.11109.

Recommendations for importation of fresh meat and meat products ~~and meat products~~ from ruminants-susceptible animals from countries or zones ~~not free from infected with RVFV~~

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

- 1) the entire consignment of meat or meat products comes from:
 - 1a) ~~ruminants which~~ susceptible animals that showed no clinical signs of RVF within 24 hours before *slaughter*;
 - 2b) ~~ruminants which~~ susceptible animals that were slaughtered in an approved *slaughterhouse/abattoir* and were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3. with favourable results;
 - 3c) ~~carcasses which that~~ were submitted to maturation at a temperature above 2°C for a minimum period of 24 hours following *slaughter*;
- 2) the necessary precautions were taken to avoid contact of the products meat or meat products with any potential source of RVFV.

Article 8.15.10bis.

Recommendations for importation of meat products from susceptible animals from countries or zones infected with RVFV

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of meat products comes from meat that complies with Article 8.15.10.

Article 8.15.121110.

Recommendations for importation of milk and milk products ~~of from~~ susceptible animals from countries or zones ~~not free from infected with RVFV~~

For milk and milk products

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

- 1) was subjected to pasteurisation; or

- 2) was subjected to a combination of control measures-treatments with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Article 8.15.131211.

Surveillance

Surveillance for RVF should be carried out in accordance with Chapter 1.4.

Surveillance for arthropod vectors should be carried out in accordance with Chapter 1.5., especially to determine areas of low *vector activity*.

Detection of RVFV in vectors has low sensitivity and therefore is not a recommended surveillance method.

An epidemic should be suspected in countries or zones infected with RVFV, or countries or zones adjacent to a country or zone in which epidemics have been reported notified, when ecological conditions favour the breeding of large numbers of mosquitoes and other vectors with concurrent or consequent occurrence of an increased number of abortions, and mortality particularly in new-born susceptible animals showing clinical signs or pathological lesions consistent with RVE, or reports of indigenous infection in humans.

Ecological conditions can be assessed through the sharing and analysis of meteorological data, and data on precipitation and water levels data, as well as the monitoring of vector activity. Clinical surveillance targeted at abortions and the use of sentinel herds can support detection of epidemics. Serological surveillance can also be used to assess the increase of in the number of seroconversions.

- 1) During an epizootic epidemic, surveillance should be conducted to define the extent of the affected area epidemic area for the purpose of disease prevention and control as well as the extent of movements and trade of susceptible animals.
- 2) During the inter-epizootic epidemic periods, surveillance and monitoring of climatic factors predisposing to an epizootic should be carried out in countries or zones infected with RVFV.
 - 1) the level of virus transmission should be assessed and determined by surveillance in sentinel herds of susceptible animals;
 - 2) monitoring of ecological and meteorological factors should be carried out.
- 3) Countries or zones adjacent to a country or zone in which epizootic epidemics have been reported-notified should determine their RVF status through an on-going specific surveillance programme.

To determine areas of low vector activity (see Articles 8.15.87. and 8.15.98.) surveillance for arthropod vectors should be carried out in accordance with Chapter 1.5.

Examination of vectors for the presence of RVFV is an insensitive surveillance method and is therefore not recommended.

The Veterinary Authority should coordinate in a timely manner with public health and other relevant authorities and share information to support the surveillance outcomes, the use of public health messages to prevent human exposure and the decision-making process for the prevention and control of RVE.

CHAPTER 10.9.

INFECTION WITH NEWCASTLE DISEASE VIRUS

Article 10.9.1.

General provisions!

- 1) For the purposes of the *Terrestrial Code*, Newcastle disease (ND) is defined as an *infection of poultry* caused by Newcastle disease virus (NDV), which is an avian paramyxovirus serotype 1 (APMV-1) that meets one of the following criteria for virulence:
 - a) the virus has an intracerebral pathogenicity index (ICPI) in day-old chicks (*Gallus gallus*) of 0.7 or greater; or
 - b) multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term 'multiple basic amino acids' refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test.

In this definition, amino acid residues are numbered from the N-terminus of the amino acid sequence deduced from the nucleotide sequence of the F0 gene, 113–116 corresponds to residues –4 to –1 from the cleavage site.'

- 2) ~~Poultry is defined as 'all domesticated birds, including backyard poultry, used for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.~~

~~Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions, or for breeding or selling these categories of birds as well as pet birds, are not considered to be poultry.~~

- ~~3)~~ For the purposes of the *Terrestrial Code*, the *incubation period* for ND shall be 21 days.
- ~~43)~~ This chapter deals with NDV *infection of poultry as defined in point 2 above* in the presence or absence of clinical signs.
- ~~54)~~ The occurrence of *infection* with NDV is defined as the isolation and identification of NDV as such or the detection of viral ribonucleic acid specific for NDV.
- ~~65)~~ A Member Country should not impose bans on the trade in *poultry commodities* in response to information on the presence of any APMV-1 in birds other than *poultry*, including *wild* birds.
- ~~76)~~ Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. When the use of ND vaccines is appropriate, those vaccines should comply with the standards described in the *Terrestrial Manual*.

[...]

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.4.1.

General provisions

- 1) Bovine spongiform encephalopathy (BSE) is an invariably fatal neurological prion disease of bovines caused by a misfolded form of the prion protein (PrP^{Sc}), which includes both classical (C-type (classical BSE) and atypical strains (H- and L-type (atypical BSE) agents. The recommendations in this chapter are intended to mitigate the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agents in cattle only. BSE manifests in two main forms: classical BSE and atypical BSE. Oral exposure to contaminated feed is the main route of transmission of classical BSE. Atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle bovine population. Oral exposure to contaminated feed is the main route of transmission of classical BSE. Given that cattle A bovine has been experimentally infected by the oral route with a low molecular weight type of atypical BSE (L-type BSE₇), therefore and the potential for recycling of atypical BSE cannot be ruled out, is also potentially considered capable of being recycled in a cattle population if cattle are orally exposed to contaminated feed but although there is no evidence that it plays a significant role in the epidemiology of BSE.
- 2) BSE primarily affects cattle bovines. Other animal species may be naturally and experimentally susceptible to BSE, but they are not regarded as being epidemiologically significant, particularly when feeding ruminants with ruminant-derived protein meal/protein meal is not practiced/practised. The recommendations in this chapter are intended to mitigate the human and animal health risks associated with BSE in bovines only.
- 3) For the purposes of the *Terrestrial Code*,:
 - 1a) BSE is an invariably fatal neurological prion disease of cattle caused by a misfolded form of the prion protein (PrP^{BSE}PrP^{Sc}), including which includes both classical (C type BSE) and atypical strains (H- and L-type BSE), for respectively having, respectively, a protease resistant PrP^{BSE}PrP^{Sc} fragment of higher and lower molecular mass than classical BSE). The term 'BSE' includes both classical and atypical forms, unless otherwise specified.
 - 2b) The occurrence of a BSE case of BSE is defined by the immunohistochemical (IHC) or immunochemical detection of the C-type/classical BSE-PrP^{BSE}PrP^{Sc} agent in brain tissue of a bovid bovine of the species *Bos taurus* or *Bos indicus*, with discrimination between atypical and classical BSE strains is based on the Western immunoblot banding pattern, as described in the *Terrestrial Manual*.
- 4) For the purposes of this chapter:
 - 3a) —, 'Cattlebovine' means a bovids an animal of the species *Bos taurus* or *Bos indicus*.
 - 4b) 'Protein meal' means any final or intermediate solid protein-containing product, obtained when animal tissues are rendered, excluding blood and blood products, peptides of a molecular weight less than 10,000 daltons and amino acids.
- 5) When *commodities* are imported in accordance with this chapter, the BSE risk of the *importing country* or *zone* of destination is not affected by the BSE risk of the *exporting country, zone* or *compartment* of origin.
- 6) Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 11.4.1bis.

Safe commodities

When authorising the importation or transit of the following commodities derived from cattle bovines, *Veterinary Authorities* should not require any conditions related to BSE, regardless of the BSE risk posed by the cattle bovine population of the *exporting country, zone or compartment*:

- 1) *milk and milk products*;
- 2) *semen and in vivo derived cattle bovine embryos collected and handled in accordance with the relevant chapters of the Terrestrial Code*;
- 3) *hides and skins*;
- 4) *gelatine and collagen*;
- 5) *tallow with maximum level of insoluble impurities of 0.15% in weight and derivatives made from this tallow*;
- 6) ~~tallow derivatives~~;
- 7) ~~dicalcium phosphate (with no trace of protein or fat)~~;
- 7) ~~fetal-fetal blood~~.

Other *commodities of cattle bovines* can be traded safely if in accordance with the relevant articles of this chapter.

Article 11.4.2.

~~The General criteria for the determination of the BSE risk of the cattle population~~ of a country, zone or compartment

~~The Due~~ Owing to its specific etiological and epidemiological features, the BSE risk of the cattle population of a country, zone or compartment is determined on the basis of the following criteria:

- 1) ~~a~~ A BSE risk assessment, in accordance with the provisions of Chapter 1.8. the “Application for official recognition by WOA of risk status for bovine spongiform encephalopathy” that evaluates the likelihood risk of the classical BSE agents being recycled within the cattle bovine population by identifying all potential factors associated with the occurrence of BSE and their historic perspective. Member Countries should review the risk assessment annually to determine whether the situation has changed.

~~A~~ The risk assessment for the purpose of BSE, based on the framework provided by Article 2.1.4., consists of:

a) Entry assessment

~~A~~ The entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country, zone or compartment via imported through the importation of the following commodities in the preceding eight years:

- i) Cattle bovines;
- ii) Ruminant-derived protein meal protein meal;
- iii) Feed (except packaged and labelled pet food not intended for pets) that contains ruminant-derived protein meal protein meal;
- iv) Fertilizers that contain ruminant-derived protein meal protein meal;
- v) Any other commodity that either is or could be contaminated by commodities listed in Article 11.4.14.

b) Exposure assessment

~~A~~The exposure assessment evaluates the likelihood of ~~cattle-bovines~~ being exposed to ~~the classical~~ BSE agents during the preceding eight years, either through imported *commodities* or as a result of the presence of ~~the classical~~ BSE agents ~~in within~~ the indigenous ~~cattle-bovine~~ population of the country, *zone* or *compartment*.

The first step in the exposure assessment involves an evaluation of livestock industry practices through a consideration of the impact of:

i) Livestock industry practices ~~on preventing cattle-bovines from being fed ruminant-derived protein meal~~protein meal, taking account of:

- = demographics of the ~~cattle-bovine~~ population and production and farming systems;
- = feeding practices, including the use of fertilisers containing ruminant proteins on land for grazing or harvesting forage;
- = slaughtering and waste management practices;
- = rendering practices;
- = feed production, labelling, distribution and storage.

Depending on the outcome from this step, an evaluation of risk mitigation measures specifically targeting BSE may also need to be included through a consideration of the impact of:

ii) Specific risk mitigation measures ~~on preventing cattle-bovines from being fed ruminant-derived protein meal~~protein meal, taking account of:

- = the nature and scope of a feed ban on feeding ruminants with ~~protein meal~~protein meal derived from ruminants;
- = the fate of commodities with the greatest BSE infectivity (~~those commodities~~ as listed in point 1 of Article 11.4.14.);
- = parameters of the rendering process;
- = prevention of cross-contamination during rendering, feed production, transport, storage and feeding;
- = an awareness programme under the scope of the feed ban;
- = monitoring and enforcement of the feed ban.

Depending on the outcome of the exposure assessment, a consequence assessment (in point c) below) may not be required.

c) Consequence assessment

~~A~~The consequence assessment evaluates the likelihood of ~~cattle-bovines~~ becoming infected with following exposure to ~~the classical~~ BSE agents together with the likely extent and duration of any subsequent recycling and amplification ~~within the cattle-bovine population during the preceding eight years~~. The factors to be considered in the consequence assessment are:

- i) age at exposure;
- ii) production type;
- iii) the impact of ~~cattle-bovine~~ industry practices or the implementation of ~~BSE~~-BSE-specific mitigation measures under a feed ban.

d) Risk estimation

The risk estimation combines the results and conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk that of the classical BSE agents have been being recycled in within the cattle bovine population through the feeding of ruminant derived protein meal, with indigenous cases arising as a consequence, and to determine the date from which the risk of BSE agents being recycled within the cattle bovine population has been negligible.

- 2) ~~the~~The ongoing implementation of a *surveillance* programme for classical BSE in the cattle bovine population in accordance with Article 11.4.18.
- 3) ~~the~~The history of occurrence and management of ~~BSE cases~~ of BSE and bovines affected by atypical BSE.

Determination of the date from which the risk of BSE agents being recycled within the bovine population has been negligible is based on the points 1 to 3 above.

Article 11.4.3.

Negligible BSE risk

The BSE risk of ~~the cattle population of a country, or zone or compartment~~ can be considered to be negligible if all the following conditions for the cattle bovine population are met for ~~at least~~ at least the preceding eight years:

- 1) A *risk assessment* as described in point 1 of Article 11.4.2. ~~that has identified all potential risk factors associated with the occurrence of classical BSE, including feeding ruminants with ruminant derived protein meal,~~ has been conducted, and the Member Country has demonstrated through documented evidence that any identified risk factors have been adequately managed and that the likelihood risk of the classical BSE agents being recycled in within the cattle bovine population has been negligible as a result of ~~as the result of.~~

EITHER:

- a) ~~livestock industry practices ensuring that protein meal derived from ruminants has not been fed to ruminants;~~

OR

- b) ~~effective and continuous mitigation of each identified risk ensuring that protein meal derived from ruminants has not been fed to ruminants.~~

EITHER:

- a) livestock industry practices ensuring that *protein meal* derived from ruminants has not been fed to ruminants;

OR

- b) effective and continuous mitigation of each identified risk ensuring that *protein meal* derived from ruminants has not been fed to ruminants.

- 2) The *surveillance* provisions as described in Article 11.4.2018. have been implemented.

- 3) EITHER:

- a) there has been no *case* of BSE or, if there has been a *case*, ~~every each case~~ of BSE has been demonstrated to have been imported ~~or has been diagnosed as atypical BSE as defined in this chapter;~~

OR

- b) if there has been an indigenous *case* of ~~classical~~ BSE;

~~EITHER~~ either:

- i) ~~all cases were born at least eight years ago before the date from which the risk of BSE agents being recycled within the cattle-bovine population has been negligible;~~

~~OR~~ or

- ii) ~~where a case was born within the preceding eight years after that date, subsequent investigations have confirmed that any identified source of infection has been mitigated and the likelihood risk of BSE agents being recycled within the cattle-bovine population has continued to be negligible.~~

- 4) Any cases of BSE or any bovines affected by atypical BSE that have been detected have been completely destroyed or disposed of to ensure that they do not enter the animal feed chain.

The country or the *zone* will be included in the list of countries or *zones* posing a negligible risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1 to 4 above. Documented evidence should be resubmitted annually for points 1 to 4 above.

Any changes in the epidemiological situation or other significant events should be notified to WOA in accordance with Chapter 1.1.

~~Article 11.4.3bis.~~

Recovery of negligible BSE risk status

~~When Should an indigenous case of classical BSE is reported in an animal born within the preceding eight years occur in a country or zone recognised as having posing a negligible BSE risk for BSE, the status, of the negligible BSE risk status country or zone is suspended and the recommendations for controlled BSE risk status apply, pending. The status may be recovered when the outcome of subsequent investigations confirming confirms that any identified source of infection has been mitigated and the likelihood risk of BSE agents being recycled within the cattle population continues to be negligible. The In the interim, the provisions for a country or zone will regain with a controlled BSE risk status apply.~~

The negligible BSE risk status of the country or zone will be reinstated only after the submitted evidence has been accepted by the OIE.

Article 11.4.4.

Controlled BSE risk

The BSE risk ~~of the cattle population~~ of a country or, *zone* ~~or compartment~~ can be considered to be controlled provided all of the conditions of Article 11.4.3. are met, but ~~at least~~ one or more of these conditions has not been met for ~~at least the preceding~~ eight years.

The country or the *zone* will be included in the list of countries or *zones* posing a controlled risk for BSE in accordance with Chapter 1.6. Retention on the list requires annual confirmation of the conditions in points 1 to 4 of Article 11.4.3. Documented evidence should be resubmitted annually for points 1 to 4 of Article 11.4.3.

Any changes in the epidemiological situation or other significant events should be notified to WOA in accordance with Chapter 1.1.

Article 11.4.4bis.

Compartment with negligible or controlled BSE risk

The establishment and bilateral recognition of a *compartment* posing negligible or controlled BSE risk should follow the relevant requirements of this chapter and the principles laid down in Chapters 4.4. and 4.5.

Article 11.4.5.

Undetermined BSE risk

The BSE risk ~~of the cattle population~~ of a country ~~or, zone or compartment~~ is considered to be undetermined if it cannot be demonstrated that it meets the requirements for negligible or controlled BSE risk.

Article 11.4.5bis.

Maintenance of BSE risk status

The BSE risk status of a country or zone is not affected by imported cases of BSE or cases of BSE born before the date from which the risk of BSE agents being recycled within the bovine population has been negligible, or by any bovine affected by atypical BSE, as long as managed in accordance with Articles 11.4.3. or 11.4.4.

Should an indigenous case of classical BSE in an animal bovine born after the date from which the risk of BSE agents being recycled within the cattle bovine population has been negligible occur in a country or zone recognised as posing a negligible or controlled risk for BSE, the status of the country or zone is maintained, provided that documented evidence regarding the outcome of subsequent investigations is submitted to WOAHP within 90 days demonstrating that any identified source of infection has been controlled and the risk of BSE agents being recycled within the cattle bovine population has continued to be negligible.

If no documented evidence is provided or if it is not accepted by WOAHP, the provisions of Article 11.4.3. or Article 11.4.4. apply.

~~Article 11.4.6.~~

~~Recommendations for importation of cattle from a country, zone or compartment posing a negligible BSE risk~~

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that cattle selected for export came from a country, zone or compartment posing a negligible BSE risk.~~

Article 11.4.7.

Recommendations for importation of cattle bovines from a country, zone or compartment posing a negligible or controlled BSE risk

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

- 1) the cattle bovines selected for export:
- 1) came from a country, zone or compartment posing a negligible or controlled BSE risk and are identified through an animal identification system enabling each animal them to be traced throughout its lifetime;

AND EITHER:

- 2) the cattle bovines selected for export were born and kept in the a country, zone or compartment posing a negligible or controlled BSE risk after the date from which during the period when the likelihood risk of the BSE agents being recycled in within the cattle bovine population has been demonstrated to be negligible;

OR

- 3)
 - a) ~~are identified by a permanent individual identification system from birth enabling each animal to be traced throughout its lifetime; and~~
 - b) ~~are it is demonstrated as having that the cattle bovines selected for export have~~ **not never** ~~been fed protein meal/protein meal derived from ruminants.~~

Article 11.4.8.

Recommendations for importation of cattle-~~bovines~~ from a country or, zone or ~~compartment~~ posing an undetermined BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that ~~cattle selected for export~~:

- 1) ~~the~~The cattle-~~bovines~~ selected for export are identified by a permanent individual through an animal identification system from birth-enabling each animal them to be traced throughout ~~its~~their lifetime;₂
- 2) ~~are it~~It is demonstrated as having that the cattle-~~bovines~~ selected for export have not never been fed ~~protein meal~~protein meal derived from ruminants.

Article 11.4.9.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the cattle from which the ~~fresh meat and meat products~~ were derived:

- 1) ~~came from a country, zone or compartment~~ posing a negligible BSE risk;
- 2) ~~have been subjected to an ante-mortem inspection with favourable results.~~

Article 11.4.10.

Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible or controlled BSE risk

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

- 1) the cattle-~~bovine~~ from which the *fresh meat* and *meat products* were derived ~~came from a country, zone or compartment posing a controlled BSE risk~~negligible or controlled BSE risk and are identified through an animal identification system;
- 2) they have been subjected to an ante-mortem inspection with favourable results;

~~AND EITHER:~~

- 3) they were born and kept in the
 - a) a country, zone or compartment posing a negligible BSE risk; or
 - b) a country, zone or compartment posing a controlled BSE risk after the date from which the risk of the BSE agents being recycled within the bovine population has been demonstrated to be negligible; or or controlled BSE risk after the date from which during the period when the likelihood risk of the BSE agents being recycled in within the cattle population has been demonstrated to be negligible;
 - c) a country, zone or compartment posing a controlled BSE risk before the date from which the risk of the BSE agents being recycled within the bovine population has been demonstrated to be negligible, and the *fresh meat* and *meat products*:
 - i) derived from bovines not subjected to a *stunning* process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to *slaughter*; and

- ii) were produced and handled in a manner which ensures that such products do not contain and are not contaminated with the commodities listed in point 1 of Article 11.4.14. or mechanically separated meat from the skull or from the vertebral column of bovines over 30 months of age.

OR

4) ~~the fresh meat and meat products:~~

- a) ~~derived from cattle not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to slaughter; and~~
- b) ~~were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:~~
 - i) ~~the commodities listed in points 1) a) and 1) b) of Article 11.4.14.;~~
 - ii) ~~mechanically separated meat from the skull and/or or from the vertebral column from of cattle over 30 months of age.~~

Article 11.4.11.

Recommendations for importation of fresh meat and meat products from a country, or zone ~~or compartment~~ posing an undetermined BSE risk

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

- 1) ~~the cattle-bovines~~ from which the *fresh meat and meat products* were derived:
 - a) ~~are identified through an animal identification system;~~
- 2) ~~it is demonstrated as having that the cattle-bovines from which the fresh meat and meat products were derived have not never been fed protein meal/protein meal derived from ruminants;~~
- 3) ~~the cattle-bovines from which the fresh meat and meat products were derived:~~
 - a) ~~were subjected to an ante-mortem inspection with favourable results;~~
 - b) ~~were not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate blood with nervous tissue, prior to slaughter;~~
- 24) *the fresh meat and meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
 - a) ~~the commodities listed in points 1) a) and 1) b) of Article 11.4.14.;~~
 - b) ~~mechanically separated meat from the skull and/or or from the vertebral column from of cattle-bovines over 30 months of age.~~

Article 11.4.12.

Recommendations for importation of bovine ~~cattle~~-derived protein meal from a country, zone or compartment posing a negligible BSE risk

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the ~~cattle-bovines~~ from which the ~~protein meal/protein meal~~ was derived ~~came from a country, zone or compartment posing a negligible BSE risk. 1) came from a country, zone or compartment posing a negligible BSE risk;~~

2) were identified through an animal identification system and were born and kept in a country, zone or compartment posing a negligible BSE risk, and

EITHER

1) they were born after the date from which during the period when the risk of the BSE agents being recycled in within the cattle bovine population has been demonstrated to be negligible

OR

2) the protein meal was processed in accordance with Article 11.4.17.

Article 11.4.13.

Recommendations for importation of blood and blood products derived from bovine cattle (except foetal-fetal blood)

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

EITHER:

1) the blood and blood products came from a country, zone or compartment posing a negligible or controlled BSE risk; and

OR

12) the blood and blood products came from a country, zone or compartment posing a controlled BSE risk and the cattle bovines from which the blood and blood products were derived from bovines that were identified through an animal identification system and were born and kept in a country, zone or compartment posing a negligible risk, or a country, zone or compartment posing a controlled BSE risk after the date from which the risk of BSE agents being recycled within the bovine population has been demonstrated to be negligible after the date from which during the period when the likelihood risk of the BSE agents being recycled in within the cattle population has been demonstrated to be negligible;

OR

23) the blood and blood products were:

- a) collected from cattle bovines not subjected to a stunning process, or to any other procedure that can contaminate the blood with nervous tissue, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate the blood with nervous tissue, prior to slaughter; and
- b) collected and processed in a manner that ensures they are not contaminated with nervous tissue.

Article 11.4.14.

Recommendations in relation to the trade of the commodities with the greatest BSE infectivity

1) Unless covered by other articles in this chapter, the following commodities originating from a country, zone or compartment posing a controlled or undetermined BSE risk, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices:

a1) distal-Distal ileum from cattle bovines of any age; b) skull, brain, eyes, vertebral column and spinal cord from cattle bovines that were at the time of slaughter over 30 months of age; or any commodity contaminated by them, for the preparation of protein products, food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices, which originate from a country, zone or compartment posing:

- a) an undetermined BSE risk;

- b) a controlled BSE risk or a negligible BSE risk if the commodities they are derived from cattle-bovines born before the period when date from which the risk of the BSE agents being recycled in within the cattle-bovine population has been demonstrated to be negligible.
- 2) Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices or any other product containing proteins prepared using commodities listed in points 1) a) or 1) b) above of this article, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk, should not be traded.
- 3) CattleBovine-derived protein mealprotein meal, or any commodities containing such products, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk, should not be traded.

These points do not apply to cattle in a country or zone with a controlled BSE risk when they are born during the period when the likelihood of the BSE agents being recycled in the cattle population has been demonstrated to be negligible.

Article 11.4.15.

Recommendations for importation of tallow (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

- 1) the tallow came from a country, zone or compartment posing a negligible BSE risk; or
- 2) the tallow is derived from cattle-bovines which have been subjected to an ante-mortem inspection with favourable results, and has not been prepared using the *commodities* listed in points point 1) a) and 1) b) of Article 11.4.14.

Article 11.4.15bis.

Recommendations for importation of tallow derivatives (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

- 1) originate from a country, zone or compartment posing a negligible BSE risk; or
- 2) are derived from tallow that meets the conditions referred to in Article 11.4.15.; or
- 3) have been produced by hydrolysis, saponification, or transesterification that uses high temperature and pressure.

Article 11.4.16.

Recommendations for importation of dicalcium phosphate (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

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

- 1) the dicalcium phosphate came from a country, zone or compartment posing a negligible BSE risk; or
- 2) the dicalcium phosphate is a co-product of bone gelatine.

Article 11.4.16bis.

Recommendations for importation of tallow derivatives (other than as defined in Article 11.4.1bis.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the tallow derivatives either:

- 1) originate from a country, zone or compartment posing that poses a negligible BSE risk; or
- 2) are derived from tallow that meets the conditions referred to in Article 11.4.15.; or
- 3) have been produced by hydrolysis, saponification or transesterification that uses high temperature and pressure.

Article 11.4.17.

Procedures for reduction of BSE infectivity in bovine protein meal

The following procedure should be used to reduce the infectivity of any ~~transmissible spongiform encephalopathy~~BSE agents ~~which~~that may be present during the production of ~~protein meal~~protein meal containing ~~ruminant~~bovine proteins:-

- 1) ~~The~~ raw material should be reduced to a maximum particle size of 50 mm before heating;
- 2) ~~The~~ and ~~the~~ raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar; or
- 2) an alternative procedure that has been demonstrated to achieve at least an equivalent level of reduction in BSE infectivity.

Article 11.4.18.

Surveillance

The objective of BSE surveillance is to detect occurrence of BSE within the ~~cattle~~ bovine population.

- 1) Surveillance for BSE consists of the regular reporting of animals with clinical signs suggestive of BSE to the Veterinary Authority for subsequent investigation and diagnosis. The credibility of the surveillance programme is supported by:
 - a) ~~compulsory notification of BSE throughout the whole territory by all those stakeholders involved in the rearing and production of livestock including farmers, herdsmen, veterinarians, transporters and slaughterhouse/abattoir workers;~~
 - b) ~~an ongoing awareness programme to ensure that all stakeholders are familiar with the clinical signs suggestive of BSE as well as the reporting requirements;~~
 - c) ~~appropriate laboratory investigations in accordance with the Terrestrial Manual and follow up field investigation as necessary of all clinical suspects.~~
- 2) BSE is a progressive, fatal disease of the nervous system of ~~cattle~~ bovines that usually has an insidious onset and that is refractory to treatment. A range of clinical signs that vary in severity and between animals have been described for classical BSE:
 - a) progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch and/or sound (hyperaesthesia), tremors, excessive ~~vocalization~~ vocalisation, panic-stricken response and excessive alertness;
 - b) postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head, ~~{head shyness},~~ difficulty avoiding obstacles, inability to stand and recumbency;
 - c) ~~generalized~~ generalised non-specific signs such as reduced *milk* yield, loss of body condition, weight loss, bradycardia and other disturbances of cardiac rhythm.

Some of these signs are also likely to be relevant for atypical BSE, particularly those associated with difficulty in rising and recumbency. A nervous form of atypical BSE resembling classical BSE may be observed with over-reactivity to external stimuli, unexpected startle responses and ataxia. In contrast, a dull form of atypical BSE may be observed, with dullness combined with a low head carriage and compulsive behaviour (licking, chewing, pacing in circles).

The clinical signs of BSE usually progress on a spectrum over a few weeks to several months, but ~~in on~~ rare occasions cases can develop acutely and progress rapidly. ~~In the continuum of the disease spectrum, the~~ The final stages of the disease are characterised by recumbency, coma and death.

~~Cattle displaying some of the above mentioned progressive neurological signs without signs of infectious illness, and that are refractory to treatment, are candidates for examination.~~

Since these signs are not pathognomonic for either classical or atypical BSE, all Member Countries with cattle-bovine populations may be likely to observe individual animals displaying clinical signs suggestive of BSE. ~~The rate at which they are likely to occur~~ General statements about the likely frequency of occurrence of such animals cannot be reliably predicted made as they will vary depending on the epidemiological situation in a particular country. ~~In addition, in~~

- 2) Surveillance for BSE consists of the reporting of includes all animals-bovines that lie on the continuum of the show symptoms signs of the clinical spectrum of BSE ~~spectrum to the Veterinary Authority~~ Veterinary Services for subsequent investigation and follow up.

~~In those countries where cattle are intensively reared and~~ production and farming systems that allow cattle-bovines to be subjected to regular observation, it is likely that such animals that display clinical signs suggestive of BSE will be more readily seen. Behavioural changes, ~~that which~~ may be very subtle in the early clinical phase, are best identified by those who handle animals on a daily basis and who can monitor them closely for a progression of the signs. In ~~more extensive~~ production and farming systems, ~~however,~~ where cattle-bovines are not monitored as closely, situations may inevitably arise where an animal might be considered as a clinical suspect, yet if it ~~was has~~ not been observed for a period of time, it may only be initially seen as a downer (non-ambulatory) or found dead (fallen stock). ~~Under such circumstances, if there is an appropriate supporting clinical history, these animals that lie on the continuum of a progressive disease from clinical suspect to downer to fallen stock may still be suitable candidates for surveillance.~~

The investigation of potential surveillance programme candidates should take into account that the vast majority of BSE-cases of BSE arise as single, isolated events. ~~The concurrent occurrence~~ concurrence of multiple animals with behavioural or neurological signs, or non-ambulatory or fallen stock is most likely associated with other causes.

The following animals that lie on the continuum of the disease-clinical spectrum of BSE should be targeted for BSE surveillance and the following animals should be reported and followed up with appropriate laboratory testing in accordance with the Terrestrial Manual to accurately confirm or rule out the presence of BSE agents, including discrimination between atypical and classical BSE strains:

- a) those displaying some of the progressive clinical signs suggestive of BSE mentioned in point 1 of Article 11.4.18, suggestive of BSE that are refractory to treatment, and where the presentation cannot be attributed to other common causes of behavioural or neurological signs (e.g. infectious, metabolic, traumatic, neoplastic or toxic causes) have been ruled out;
- b) those showing behavioural or neurological signs at that have been subjected to an ante-mortem inspection with unfavourable results at slaughterhouses/abattoirs;
- c) those presented as downers (non-ambulatory), with an appropriate supporting clinical history (i.e. the presentation cannot be attributed to other common causes of recumbency has have been ruled out);
- d) those found dead (fallen stock), with an appropriate supporting clinical history (i.e. the presentation cannot be attributed to other common causes of death has have been ruled out).

All these animals should be followed up with appropriate laboratory testing in accordance with the Terrestrial Manual to accurately confirm or rule out the presence of BSE agents.

3) The credibility of the *surveillance* programme is supported by:

- a) ongoing awareness and training programmes to ensure that all those stakeholders involved in the rearing and production of livestock, including ~~farmers, herdsman, cattle~~ bovine breeders, owners and keepers, *veterinarians*, transporters and *slaughterhouse/abattoir* workers are familiar with the clinical signs suggestive of BSE as well as the statutory reporting requirements;
 - b) the fact that BSE is a ~~compulsory~~ *notifiable disease* throughout the whole territory;
 - c) appropriate *laboratory* testing in accordance with the *Terrestrial Manual*;
 - d) robust, documented, evaluation procedures and protocols for:
 - = the definition of the target population for BSE *surveillance*;
 - = the identification and the reporting of potential candidates ~~animals~~ *bovines* described in points 2 a) to 2 d) targeted for BSE *surveillance*;
 - = ~~for~~ the determination of animals to be subjected to laboratory testing;
 - = ~~for~~ the collection and submission of samples for laboratory testing;
 - = ~~and for~~ the follow-up epidemiological investigations for BSE positive findings.
-

DRAFT CHAPTER 1.8.

APPLICATION FOR OFFICIAL RECOGNITION BY WOAH OF RISK STATUS FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 1.8.1.

GuidelinesGeneral principles

In accordance with Article 11.4.2., the bovine spongiform encephalopathy (BSE) risk of ~~the cattle (*Bos indicus* and *Bos taurus*)~~ ~~population of a country or zone~~ is determined on the basis of a *risk assessment* that evaluates the risk of the classical BSE agents ~~(classical and atypical)~~ being recycled within the ~~cattle-bovine (*Bos indicus* and *Bos taurus*)~~ population by identifying all potential factors associated with the occurrence of BSE, the ongoing implementation of a *surveillance* programme, and the history of occurrence and management of BSE ~~cases~~.

In this chapter, “BSE” refers to both classical and atypical forms, unless specified otherwise.

For the purposes of this chapter, ‘A case of BSE case’ means the occurrence of classical BSE, as is defined in point 3 of Article 11.4.1.

The information specified in Articles 1.8.2. to 1.8.6. should be provided by WOA Member Countries in support of their application for official recognition of BSE risk status in accordance with Chapter 11.4. of the *Terrestrial Code*. The structure of the dossier should follow guidelines provided in the “Standard Operating Procedure for official recognition of disease status and for the endorsement of national official control programmes of Member Countries” (available on the WOA website).

Each element of the core document of the dossier provided to WOA, should be clearly and concisely addressed, with an explanation, where relevant, of how each one complies with the provisions of the *Terrestrial Code* for the BSE risk status for which the Member is applying. The rationale leading to the conclusions reached for each section needs to be clearly explained and, as appropriate, figures, tables and maps should be provided. The core document of the dossier should include the following sections:

- ~~– The history of occurrence and management of BSE cases in the country or zone (Article 1.8.2.)~~
- ~~– Legislation (Article 1.8.3.)~~
- ~~– Veterinary system (Article 1.8.4.)~~
- ~~– BSE risk assessment (Article 1.8.5.)~~
- ~~– BSE surveillance (Article 1.8.6.)~~
- the history of occurrence and management of BSE in the country or zone.

The dossier should indicate the date from which it can be considered that the risk of BSE agents being recycled within the bovine population has been negligible.

The terminology defined in the *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in the dossier. The dossier and all of its annexes should be provided in one of the WOA official languages.

Article 1.8.2.

History of occurrence and management of BSE cases in the country or zone

Describe the history of occurrence and management of BSE cases by providing the following documentary evidence:

- 1) If a case of BSE ~~case~~ has ever been diagnosed in the country or zone, indicate the total number of BSE cases, and:
 - a) Provide a table of aggregated data on all cases of BSE ~~cases~~ encountered in the country or zone, by type (classical or atypical), origin (indigenous or, if imported, the country of origin), and the year of birth;
 - b) For the past eight years, provide a table to indicate, for each case, the year of occurrence, the origin (indigenous or, if imported, the country of origin), the type (classical or atypical), and the year of birth of each indigenous ~~case of classical BSE~~.
- 2) If there have been cases of BSE ~~cases~~ or bovines affected by atypical BSE, confirm that they were excluded from the feed chain and describe how this was achieved. In the table under Article 1.8.3. provide details of the national legislation, regulations and Veterinary Authority directives that describe these procedures.

Article 1.8.3.

Legislation

Provide a table listing all relevant legislation, regulations, Veterinary Authority directives, legal instruments, rules, orders, acts, decrees, etc., related to BSE. For each, provide the date of promulgation and implementation as well as a brief description of the relevance to mitigating against the risks associated with BSE. The table should include the legislation, regulations and directives referred to in the core document of the dossier. These instruments may be provided as annexes or as weblinks to supporting documents.

Article 1.8.4.

Veterinary system

The quality of the Veterinary Services of a Member is important to the establishment and maintenance of confidence in its international veterinary certificates by the Veterinary Services of other Members (Article 3.2.1.). It also supports an evaluation of the BSE risk status of the cattle population of a country or zone.

- 1) Describe how the Veterinary Services of the country comply with the provisions of Chapters 1.1., 3.2. and 3.3.
- 2) The applicant Member may provide information on any recent (not older than five years) WOAHPVS evaluation conducted in the country and follow-up steps within the PVS Pathway, and highlight the results relevant to BSE.
- 3) Describe how the Veterinary Services supervise, control, enforce and monitor all BSE-related activities.
- 4) Provide a description of the involvement and the participation of industry; ~~producers, farmers, herdsmen, cattle-bovine breeders, owners and keepers;~~ private veterinarians; veterinary paraprofessionals; transporters; workers at livestock markets, auctions and slaughterhouses/abattoirs; and other relevant non-governmental stakeholders in the control of BSE.
- 5) Describe the official cattle-bovine identification, registration, *traceability* and movement control system. Provide evidence of its effectiveness. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic. Indicate ~~if whether~~ there are any industry associations or organisations involved in cattle-bovine identification, registration, *traceability* and movement control systems that provide guidance, set standards or provide third party audits; include a description of their role, membership and interaction with the Veterinary Services or ~~other relevant~~ Competent Authorities.

Article 1.8.5.

BSE risk assessment (point 1 of Article 11.4.3.)

1.) Entry assessment (point 1 a) of Article 11.4.2.)

As described in Article 11.4.2., an entry assessment evaluates the likelihood that the classical BSE agent has been introduced into the country or *zone* through the importation of *commodities*.

For the purposes of undertaking an entry assessment, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.).

The *commodities* to be considered in the entry assessment are:

- ~~Cattle~~bovines;
- ~~Ruminant-derived protein meal~~protein meal;
- ~~Feed (not intended for pets)~~except packaged and labelled pet food that contains ruminant-derived ~~protein meal~~protein meal;
- ~~Fertilizers~~ that contain ruminant-derived ~~protein meal~~protein meal;
- ~~Any other commodity that either is or could be contaminated by commodities listed in Article 11.4.14., e.g. over 30 months old cattle carcass or half carcass from which the spinal cord and vertebral column were not removed, originating from a country, zone or compartment posing a controlled or undetermined BSE risk.~~

- a) For each commodity listed above indicate if whether they were imported in the preceding eight years, and, if so, from which countries.

For each *commodity* listed above describe the import requirements applied by the applicant country or *zone* and how they are related to the BSE risk status of the *exporting country or zone* and whether or not they are consistent with, or provide an equivalent level of assurance ~~with to~~, the recommendations laid out in Chapter 11.4. for the importation of such a *commodity*. Where the import requirements are not consistent with the recommendations in Chapter 11.4. but are considered to provide an equivalent level of assurance, provide an explanation outlining the rationale and supporting evidence. In situations where an import requirement does not provide an equivalent level of assurance to the relevant measure in Chapter 11.4., provide an explanation of how this is likely to impact the entry assessment.

Describe the importation process for these *commodities* and how are they controlled, regulated and monitored by the *Competent Authority* with references as appropriate to the relevant legislation in the table under Article 1.8.3. Provide supporting evidence of the importation process including, where relevant, import permits or their equivalent, and examples of *international veterinary certificates* issued by *exporting countries*.

Describe the intended end use of the imported *commodities*, for example: ~~cattle~~bovines may be imported for breeding or immediate *slaughter*; rendered products may be imported for incorporation into *feed* for non-ruminant species such as pigs or *poultry*. Provide information on any systems in place ~~and their results~~ to monitor or track imported *commodities* and their results to ensure they are used as intended.

Describe the actions available under national legislation to prevent illegal introduction of the *commodities* considered above and provide information on any illegal introductions detected and the actions taken.

- b) Conclusions for the entry assessment.

Given the sanitary measures applied (if any), what was the likelihood that, during the preceding eight years, any of the *commodities*, in the form that they were imported, harboured or were contaminated by the classical BSE agent?

Clearly and concisely describe the rationale leading to the conclusions reached.

2.) Exposure assessment (point 1 b) of Article 11.4.2.)

As emphasised in Article 11.4.1., atypical BSE is a condition that occurs at a very low rate and is assumed to occur spontaneously in any cattle population. Although uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated *feed*, this is the main route of transmission of classical BSE. Considering that atypical BSE may potentially be capable of being recycled in a cattle population if cattle were to be exposed to contaminated *feed*, it is necessary to undertake an exposure assessment regardless of the outcome of the entry assessment.

As described in Article 11.4.2., an exposure assessment evaluates the likelihood of cattle-*bovines* being exposed to the classical BSE agents either through imported *commodities* (classical BSE) or as a result of the presence of classical BSE agents (classical or atypical BSE) in within the indigenous cattle-*bovine* population of the country or zone.

For the purposes of undertaking an exposure assessment for the evaluation of BSE status, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.). At its discretion, the applicant Member may provide the information requested for a different period (i.e. longer than eight years for those applying for a negligible risk status, or for the time period for which they have the information if applying for a controlled risk status) to establish the period when indicate the date from which the likelihood-risk of the BSE agents being recycled in within the cattle-*bovine* population has been demonstrated to be negligible (i.e. to determine the period of time date to be attested in point 2 of accordance with Articles 11.4.6., 11.4.7., 11.4.910, 11.4.12, and 11.4.13. and 11.4.14.).

As indicated in point 1.b) of Article 11.4.2., the first step in the exposure assessment involves an evaluation of the impact of livestock industry practices on preventing cattle-*bovines* from being fed ruminant-derived protein-meal~~protein meal~~ and, depending on the outcome of this step, an evaluation of the impact of specific mitigation measures on preventing cattle-*bovines* from being fed ruminant-derived protein-meal~~protein meal~~.

a) Livestock industry practices (point 1 b) i) of Article 11.4.2.)

Because oral exposure to contaminated *feed* is the principal route of transmission of ~~the BSE agents~~, the exposure assessment begins with a detailed description of the cattle-*bovine* population and associated industry practices, with a particular emphasis on: feeding practices; disposal of dead ~~stock animals~~ and waste from slaughtered animals; rendering; and production, labelling, distribution and storage of *feed* that may lead to cattle-*bovines* being exposed to potentially contaminated *feed*.

The intent of this section is not to describe the implementation and enforcement of measures specifically targeting the exposure of the cattle-*bovine* population to BSE agents (such as a legislated *feed* ban) as they will be considered where relevant in ~~Section point b) An evaluation of BSE specific mitigation measures~~. The intention here is to evaluate the likelihood and extent of exposure of the cattle-*bovine* population to the classical BSE agents, given the ongoing livestock industry practices in a country or zone.

i) Demographics of the cattle-*bovine* population and production and farming systems-

Describe the composition of the cattle-*bovine* population and how the cattle-*bovine* industry is structured in the country or zone, considering the types of production, ~~systems, including all that apply,~~ such as dairy, beef rearing, feedlot, fattening and beef finishing, and the farming systems, such as intensive, extensive, ~~semi~~-semi-intensive, transhumant, pastoral, agropastoral, and mixed-species farming. The description should include the number and size of herds farms in each type of production and farming system.

ii) Feeding practices-

For each type of production system, describe the rearing and production practices related to feeding ruminants of various ages, including the types of *feed* and *feed ingredients* (animal or plant based). Where animal-based ingredients are used, describe whether or not they are derived from rendered products of ruminant or non-ruminant origin as well as the respective proportions used.

Provide an indication of the proportion of the national *feed* production prepared commercially (including local mills) or mixed on farm using either imported or domestically produced ingredients.

Describe whether or not fertilizers containing ruminant-derived ~~protein meal~~ protein meal, composted materials derived from fallen stock (i.e. ~~cattle-bovines~~ of any age which were found dead or were killed on a farm, during transportation, ~~at livestock markets or auctions~~, or at a *slaughterhouse/abattoir*), *slaughterhouse/abattoir* waste or animals condemned at ~~ante-ante-mortem~~ inspections or any other materials derived from or that incorporate ruminant proteins are applied to land where ~~cattle-bovines~~ graze or where forage is harvested for feeding to ~~cattle-bovines~~. Where such fertilizers ~~or composted materials~~ are used, provide information on the extent and frequency of use and any risk mitigation measures to prevent accidental ingestion.

Describe, for mixed-species farms that include ruminants, the number and size of such farms and whether or not there are any practices in place to ensure that ruminants are not likely to be fed with *feed* meant for non-ruminant species or that ruminant *feed* is not likely to be cross-contaminated with *feed* intended for non-ruminants that may contain rendered products of ruminant origin.

iii) Slaughtering and waste management practices-

Describe the practices for fallen stock, including cattle-bovines euthanised as part of a BSE surveillance programme under Article 11.4.18 that occur on farm, during transport, at livestock markets or auctions or prior to slaughter, with particular reference to their transportation, disposal or destruction, including composting, burial, rendering or incineration. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Describe the places where ~~cattle-bovines~~ are slaughtered (for example, on farm, at a *slaughterhouse/abattoir* or *market*) together with the respective proportions and associated ages.

Describe whether or not places where animals are slaughtered are required to be registered or approved by the *Veterinary Services* or ~~other-relevant~~ Competent Authority and if they are subject to official veterinary supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Describe how animals condemned at ~~ante-ante-mortem~~ inspection and waste declared as unfit for human consumption from slaughtered animals are processed, disposed of or destroyed, including composting, burial, rendering, incineration or other industrial uses such as salvaging and crushing bones for use in animal *feed*. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

iv) Rendering practices-

Rendering is a process by which animal material is transformed into products such as ~~protein meal~~ protein meal that may be used in animal *feed*. It provides ~~the a~~ pathway for the introduction of ~~the classical~~ BSE agents (classical or atypical) into the animal feed chain.

Describe whether or not there are any rendering facilities in the country or *zone*, if they are required to be registered or approved by the *Veterinary Services* or ~~other-relevant~~ Competent Authority and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

Using tables as appropriate, for each of the preceding eight years, provide a breakdown of the number of rendering facilities operating, indicating for each facility:

- the source and types of raw materials handled;
- whether or not they receive and process material from a particular species or process mixed materials including those derived from ruminants;
- whether or not ruminant waste is segregated from non-ruminant waste and if so how segregation is maintained to avoid potential cross-contamination of non-ruminant rendered materials during processing, storage and transport of rendered products, for example through dedicated lines, storage bins or silos, transport vehicles or establishments;
- the parameters of the rendering process (time, temperature, pressure, etc.);

- the type and intended end use of the rendered products ~~produced~~. If available, provide the amount of rendered products produced annually by type and intended end use;
- if materials derived from imported cattle-bovines are managed differently, describe the process.

Indicate if there are any industry associations or organisations involved in the rendering industry that provide guidance, set standards or provide third party audits in relation to Hazard Analysis and Critical Control Points (HACCP) programmes, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the *Veterinary Services* or other-relevant Competent Authorities.

v) Feed production, labelling, distribution and storage-

Where rendered products are used as ingredients in the production of animal *feed* the exposure of cattle-bovines to the classical BSE agents (classical or atypical) may arise as a result of the use of rendered products containing materials of ruminant origin as ingredients in cattle-bovine feed or as a result of cattle-bovine feed being cross-contaminated when such products are used in the production of *feed* for other species.

Describe whether ~~or not~~ facilities producing *feed* for ruminant or non-ruminant livestock as well as for pets are required to be registered or approved by the *Veterinary Services* or other-relevant Competent Authority and if they are subject to official veterinary control or supervision. In the table under Article 1.8.3., provide any legislation, regulation or directives relevant to this topic.

For each of the preceding eight years, provide a breakdown using tables as appropriate of the number and types of facilities producing *feed*, indicating for each facility:

- ~~excluding those listed in Article 11.4.1bis.,~~ whether or not rendered ruminant products, excluding those listed in Article 11.4.1bis., were used as ingredients in *feed* for ruminants, non-ruminants and pets;
- whether or not each facility was dedicated to manufacturing *feed* for a particular species or manufactured *feed* for multiple species including ruminants.

Where facilities manufactured *feed* for multiple species including ruminants, indicate whether or not there were any practices in place to avoid ruminant *feeds* from being contaminated with rendered ruminant products during *feed* manufacture, storage and transport.

Indicate if there are any industry associations or organisations involved in *feed* production, distribution and storage that provide guidance, set standards or provide third party audits in relation to HACCP programmes, *good manufacturing practices*, etc. Include a description of their role, membership and interaction with the *Veterinary Services* or other-relevant Competent Authorities.

vi) Conclusions for livestock industry practices-

- Given the livestock industry practices described above, is the likelihood that the cattle-bovine population has been exposed to ~~either the~~ classical or atypical BSE agents during the preceding eight years negligible or non-negligible?
- Clearly and concisely describe the rationale leading to the conclusion reached.
- Where the likelihood estimate is negligible, proceed to *Section 4) Risk estimation*.
- Where the likelihood estimate is non-negligible, proceed to *Section b) An evaluation of BSE specific mitigation measures*.

b) An evaluation of BSE BSE-specific risk mitigation measures. (point 1 b) ii) of Article 11.4.2.)

For those countries that have reported classical cases of BSE cases in indigenous cattle-bovines, it is apparent that their historic livestock industry practices did not prevent the recycling of the classical BSE agent ~~in within~~ their cattle-bovine

populations. These countries, together with others whose livestock industry practices would have been conducive to recycling, may have implemented specific measures, ~~such as~~ notably through a legislated *feed* ban, to ensure that the likelihood of recycling would be negligible. To qualify for official recognition of a BSE risk status, these countries need to demonstrate that ~~the~~ these measures specifically targeting BSE have been and continue to be effectively implemented and enforced.

i) The nature and scope of a feed ban-

Indicate ~~if~~ whether there is a ban on feeding ruminants with ~~protein meal~~ protein meal derived from ruminants.

Where a *feed* ban has been implemented, clearly and concisely describe the date it was introduced, its nature and scope and how it has evolved over time.

In addition, if the *feed* ban has been implemented through national legislation, provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

ii) Commodities with the greatest BSE infectivity-

Indicate whether ~~or not~~ any of those *commodities* listed in point 1 of Article 11.4.14. are removed from the carcass at the time of *slaughter* or subsequent fabrication or processing.

If so, also:

- Describe how they are disposed of or destroyed through burial, composting, rendering, alkaline hydrolysis, thermal hydrolysis, gasification, incineration, etc.
- Describe any measures in place that ensure *slaughter* waste declared as unfit for human consumption that is rendered is not ~~cross~~-contaminated with these *commodities*.
- Describe whether these *commodities* from fallen stock and animals condemned at ~~ante~~ ante-mortem inspection are excluded from rendering and how this is done.
- Where these *commodities* are not ~~excluded~~ removed from fallen stock, animals condemned at ante-mortem inspection, or slaughter waste declared as unfit for human consumption, describe their final disposal ~~of this waste~~, and how it is handled and processed.
- Describe whether or not all these processes and methods are subject to approval and oversight by the *Veterinary Services* or ~~other~~ relevant *Competent Authority*.

In addition, if there is specific national legislation concerning the definition, identification, removal and disposal or destruction of those *commodities* listed in point 1 of Article 11.4.14., provide pertinent information in the table under Article 1.8.3. and a summary of any relevant legislation with references as appropriate.

iii) Parameters of the rendering process-

Describe whether or not the parameters of the rendering process are prescribed in legislation and if they are consistent with, or provide an equivalent level of assurance to, the procedures for the reduction of BSE infectivity in ruminant ~~bovine~~-derived ~~protein meal~~ protein meal as described in Article 11.4.17. Provide details of the legislation, if applicable, in the table under Article 1.8.3.

iv) Cross-contamination-

Describe the measures in place to prevent cross-contamination during rendering, *feed* production, transport, storage and feeding such as dedicated facilities, lines and equipment, as well as measures to prevent misfeeding, such as the use of warning labels. Provide information as to whether any of these measures are prescribed in legislation and if facilities involved in rendering and *feed* production are required to be registered or approved under the *feed* ban by the *Veterinary Services* or ~~other~~ relevant *Competent Authority*.

v) Awareness programme under the scope of the feed ban-

Provide information on the existence of any ongoing awareness programmes or other forms of guidance given to all those stakeholders involved in rendering, *feed* production, transport, storage, distribution, sale and feeding under the scope of the *feed* ban. Provide examples of communication materials including publications, brochures and pamphlets.

vi) Monitoring and enforcement of the feed ban-

Describe how the *feed* ban, if implemented, has been and continues to be monitored and enforced. Provide information on:

- official oversight from the *Veterinary Authority*, other *Competent Authority* or an approved third party;
- training and accreditation programmes for inspectors;
- the planned frequency of inspections, and the procedures involved including manuals and inspection forms;
- sampling programmes and *laboratory* testing methods used to check the level of compliance with the *feed* ban and cross-contamination;
- options available to deal with infractions (non-compliances) such as recalls, destruction and monetary penalties.

Provide information on the ongoing results of the official inspection programme for each of the preceding eight years, using tables as appropriate:

- planned *versus* actual delivery inspections at rendering facilities, *feed* mills, farms, etc., with an explanation of any significant ~~variance~~ variation and how ~~they~~ it may have impacted the programme;
- number and type of samples taken during inspections to verify that ruminant *feed* does not contain or is not ~~cross~~ cross-contaminated with rendered products containing ruminant material (excluding those listed in Article 11.4.1bis.). Provide information by year, by source (rendering facility, *feed* mill or farm), indicating the *laboratory* test(s) used and the results obtained;
- the types of infractions (non-compliance) that occurred and corrective actions undertaken;
- any infractions (non-compliances) that were likely to have led to ~~cattle~~ cattle-bovines being exposed to *feed* contaminated with ruminant material (excluding those listed in Article 11.4.1bis) and how they were resolved.

vii) Conclusions for the evaluation of ~~BSE~~ BSE-specific risk mitigation measures-

- In evaluating the effectiveness of a *feed* ban, if implemented, for each of the preceding eight years, consideration needs to be given to:
 - the management of *commodities* listed in point 1 of Article 11.4.14., and the associated likelihood that these materials, or other materials ~~cross~~ cross-contaminated by them, may have entered the animal feed chain;
 - the rendering industry and the associated likelihood that rendered products containing ruminant material may retain BSE infectivity;
 - the *feed* industry and the associated likelihood that *feed* for ~~cattle~~ cattle-bovines may contain or has been cross-contaminated with ruminant-derived ~~protein meal~~ protein meal.

- Given the evaluation of ~~BSE-BSE~~-specific risk mitigation measures and their enforcement as described above, is the likelihood that, during the preceding eight years, the cattle-ovine population has been exposed to either the classical or atypical BSE agent negligible or non-negligible?
- Clearly and concisely describe the rationale leading to the conclusion reached.
- Where the likelihood estimate is negligible, proceed to *Section 4) Risk estimation*.
- Where the likelihood estimate is non-negligible, proceed to *Section 3) Consequence assessment*.

3.) **Consequence assessment (point 1 c) of Article 11.4.2.)**

~~While uncertainty remains regarding the potential transmissibility of atypical BSE through oral exposure to contaminated feed, it is reasonable to assume for the purposes of a consequence assessment, that the likelihood of cattle becoming infected would be similar to that for classical BSE.~~

As described in Article 11.4.2., a consequence assessment evaluates the likelihood of cattle-ovines becoming infected following exposure to the classical BSE agents (~~classical or atypical~~) together with the likely extent and duration of any subsequent recycling and amplification.

For the purposes of undertaking a consequence assessment for the evaluation of BSE risk status, the period of interest is the preceding eight years.

Considering that, for all practical purposes, oral exposure to contaminated *feed* is the principal, if not the only, route of transmission of ~~the~~ the classical BSE agents, to initiate a cycle of BSE infectivity within a cattle-ovine population the following series of events would need to unfold:

- *commodities* listed in point 1 of Article 11.4.14. from an infected animal are included in raw materials that are rendered into ruminant-derived ~~protein meal~~ protein meal;
- the rendering process does not destroy BSE infectivity of the BSE agent(s);
- the ruminant-derived ~~protein meal~~ protein meal is incorporated as an ingredient in cattle-ovine feed, or cattle-ovine feed is cross-contaminated during *feed* production, distribution and storage, or cattle-ovines are incorrectly fed with *feed* intended for non-ruminant species that includes the ruminant-derived ~~protein meal~~ protein meal as an ingredient;
- one or more animals that ingest contaminated *feed* become infected;
- the infected animal survives long enough to reach the later stages of a protracted incubation period when the levels of the classical BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically;
- *commodities* listed in point 1 of Article 11.4.14. are then included in raw materials that are rendered into ruminant-derived ~~protein meal~~ protein meal, completing one cycle.

Recycling arises when this cycle is repeated one or more times. Any level of recycling within a given period is sufficient to conclude that the consequences of exposure to contaminated *feed* for that period within the cattle-ovine population are non-negligible.

a) Factors to consider when evaluating the likely extent of recycling of the classical BSE agents within a cattle-ovine population:

i) Age at exposure-

Animals less than 12 months of age are considered to be much more susceptible to *infection* than older animals, which are likely to be increasingly refractory to *infection* as they mature.

ii) Production type-

- Calves reared as replacement animals for the breeding herd-

Cattle-Bovines exposed to the classical BSE agents at less than 12 months of age and destined to enter the breeding *herd* are much more likely to become infected and survive long enough to reach the later stages of a protracted incubation period when the levels of the classical BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically. If these materials were rendered and subsequently contaminated cattle-bovine feed, it is highly likely that some level of recycling would occur.

- Feedlot ~~cattle-bovines~~-

Even if ~~cattle-bovines~~ reared in a feedlot that were destined to be slaughtered within the next two to six months were to become infected after consuming contaminated *feed*, the likelihood that they would have reached the later stages of a protracted incubation period (when the levels of the classical BSE agent in those *commodities* listed in point 1 of Article 11.4.14. would begin to rise dramatically) would essentially be negligible.

Considering that mature ~~cattle-bovines~~ are likely to be much more refractory to *infection* than animals within their first year of life, even if they were to consume contaminated *feed*, it is highly unlikely that those *commodities* listed in point 1 of Article 11.4.14. would pose a threat if they were rendered and subsequently contaminated cattle-bovine feed.

iii) The impact of livestock industry practices or the implementation of measures under a *feed* ban-

When evaluating the potential for the recycling of the classical BSE agents ~~in-within~~ the ~~cattle-bovine~~ population where an infraction (non-compliance) has occurred that may have led to *feed* being ~~cross~~-contaminated, it is important to consider the impact of both the livestock industry practices and the ongoing measures under a *feed* ban. Even if an infraction that arose several years ago led to susceptible young animals becoming infected, in evaluating the likelihood of recycling in future years, consideration would need to be given to the effectiveness of the *feed* ban in subsequent years or whether or not any changes to livestock industry practices may have influenced the exposure risk.

b) Conclusions for the consequence assessment-

Where the outcome of the evaluation of livestock industry practices or the evaluation of ~~BSE-BSE~~-specific mitigation measures, that include the nature and scope of the *feed* ban and its enforcement, has concluded that there was a non-negligible likelihood that the ~~cattle-bovine~~ population has been exposed to the classical BSE agents, what is the likelihood that they have been recycled within the ~~cattle-bovine~~ population during the preceding eight years?

Clearly describe the rationale leading to the conclusions reached.

4.) Risk estimation (point 1 d) of Article 11.4.2.)

As described in Article 11.4.2., risk estimation combines the results and the conclusions arising from the entry, exposure and consequence assessments to provide an overall measure of the risk ~~that of the classical BSE agents have been being recycled in within the cattle bovine population through the feeding of ruminant derived protein meal.~~

- a) Provide a summary of the entry and exposure assessments and the conclusions reached.
- b) If applicable, provide a summary of the consequence assessment, and the conclusions reached.

~~c) When the condition of point 1 of Article 11.4.3. has not been met, that is, it cannot be demonstrated that for at least eight years the risk that the BSE agents have been recycled in the cattle population has been negligible, provide an explanation for the period of time within the preceding eight years for which it can be considered that the risk has been negligible. Clearly indicate the period of time for date from which it can be considered that the risk of classical BSE agents being recycled in within the cattle bovine population has been negligible. Provide explanations and clearly describe the rationale leading to the conclusions reached.~~

Article 1.8.6.

BSE surveillance (point 2 of Article 11.4.3.)

Article 11.4.18. describes the criteria that underpin a credible *surveillance* programme, together with an overview of the range and progression of clinical signs that ~~cattle bovines~~ affected by BSE are likely to exhibit.

Requirements under point 2 of Article 11.4.18. are focused on subsets of the ~~cattle bovine~~ population where ~~disease BSE~~ is more likely to be detected, ~~if it is actually present.~~

The Member applying for recognition of a negligible or a controlled BSE risk status should submit documentary evidence that the provisions of point 3 of Article 11.4.18. have been effectively implemented.

For the purposes of *surveillance*, the period of interest is the preceding eight years (Articles 11.4.3. and 11.4.4.).

~~Animals that lie on the continuum show symptoms signs of the clinical disease spectrum of BSE (i.e. from clinically ill to non-ambulatory to fallen stock) should be targeted for BSE surveillance and should include those animals described in points 2(a) to 2(d) of Article 11.4.18.~~

1.) Awareness and training programmes (point 3 a) of Article 11.4.18.)

Ongoing awareness and training programmes are essential to ensure that all stakeholders are familiar with clinical signs suggestive of BSE (those described in point 1 of Article 11.4.8.) as well as their statutory reporting requirements.

- a) Describe the stakeholder groups targeted for BSE awareness and training programmes. Describe the methods used to identify stakeholder groups within the jurisdiction and methods used to identify how, for example, the size and characteristics of the stakeholder group changes over time.
- b) Describe the type(s) of awareness and training programmes implemented for specific stakeholder groups. Describe how these programmes are adapted to meet the specific obligations and activities of each stakeholder group ~~by those involved in caring for livestock, as well as the protocols for sample collection and submission by veterinarians and animal health technicians~~.
- c) Provide information on the number of awareness and training activities, the stakeholder groups targeted, the number of individuals reached per activity (if available), and the geographical coverage ~~for~~ of these activities.
- d) Provide a description including examples of materials used in the awareness programme ~~including such as~~ training manuals, supporting documents such as publications in local newspapers and farming magazines, pamphlets and videos (weblinks to supporting documents in one of the WOA official languages may also be provided, where they exist).
- e) Provide details on how the effectiveness of the awareness and training programmes is evaluated.
- f) Provide details of any contingency or preparedness plan for BSE.

2.) Compulsory notification-BSE reporting system (point 3 b) of Article 11.4.18.)

~~To ensure the reporting and further investigations of any animals that lie on the continuum show symptoms signs of the clinical BSE spectrum of BSE, appropriate legislation, policies and incentives to support compulsory notification, investigation and verification should be in place.~~

- a) ~~Indicate whether~~ Describe the BSE reporting system, including the date of implementation of any supporting legislation and associated policies making BSE a notifiable disease ~~notification of BSE compulsory~~. Indicate if a definition for a "suspicion of BSE suspect" exists. If appropriate, outline relevant legislation in the table under Article 1.8.3.
- b) Describe the supportive measures in place for ~~notification of targeting~~ animals that ~~lie on the continuum~~ show symptoms signs of the clinical BSE spectrum of BSE and for reporting of animals described in points 2 a) to 2 d) of Article 11.4.18., such as incentives, compensations or penalties.
- c) Describe the guidance given to all stakeholders involved in the rearing and production of livestock including ~~farmers, herdsmen, cattle-bovine breeders, owners and keepers, veterinarians,~~ transporters, and workers at livestock markets, auctions and slaughterhouses/abattoirs in terms of the criteria for reporting ~~animals that lie on the continuum~~ show symptoms signs of the clinical BSE spectrum of BSE. What mechanisms are in place to ensure that these guidelines reach those stakeholders?
- d) Describe the evaluation of the reporting system ~~framework for animals that lie on the continuum~~ show symptoms signs of the clinical BSE spectrum of BSE for evaluation. Has this framework reporting system evolved over time and, if so, how?

3.) Laboratory testing (point 3 c) of Article 11.4.18.)

Provide documentary evidence that the relevant provisions of Chapter 3.4.5. of the *Terrestrial Manual* are applied, including the following:

- a) If BSE samples are submitted to ~~a laboratory~~ laboratories in the country ~~or zone~~ for testing, provide an overview of ~~how many are involved in testing BSE samples,~~ how they are approved or certified, their number, location and diagnostic procedures and the time frame for reporting results.
- b) If the BSE samples are not submitted to ~~a laboratory~~ ies in the country ~~or zone~~ for testing, or if suspicious or positive samples are referred to ~~a laboratory~~ laboratories outside 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.
- c) Describe the diagnostic protocol and tests used for processing samples for ~~classical and atypical~~ BSE and how they may have evolved over time, indicating: ~~what is the primary test used?~~; ~~what would be the series of secondary tests performed, if any, depending on the results of the primary test (i.e. negative, positive and inconclusive)?~~; ~~and what test would be undertaken if discordant results arise between primary and secondary tests arise (e.g. primary positive result followed by a secondary negative result)?~~; and tests undertaken to discriminate classical BSE from atypical BSE.

4-) Evaluation procedures and protocols to identify and report potential candidates animals targeted for BSE surveillance, to determine animals to be subjected to laboratory testing, to collect and submit samples for laboratory testing, and to follow up BSE positive findings with epidemiological investigation BSE positive findings (point 3 d) of Article 11.4.18.)

~~Because Given that the incidence of BSE is likely to be very low in Member Countries it is important that surveillance efforts focus on subsets of the cattle bovine population where disease is more likely to be detected, if it is actually present. Hence, those animals described in points 2(a) to 2(d) of Article 11.4.18. must be targeted for BSE surveillance.~~

Considering that BSE is a progressive disease and that animals to be included in the *surveillance* programme may arise at the farm, the *slaughterhouse/abattoir*, or during transportation, procedures and protocols should be in place covering all points in the livestock production chain for: (1) the identification ~~and reporting of animals potentially lying on the continuum showing symptoms signs of the clinical BSE spectrum of BSE (e.g. by the farmer breeder, owner or keeper, animal handler, veterinarian, etc.);~~; (2) the criteria to determine which of these ~~reported animals need to be reported and tested for BSE (e.g. the criteria used by the veterinarian that allows the discrimination of reported animals subject to laboratory testing);~~; (3) the collection and submission of samples for testing in a laboratory; and (4) a follow-up epidemiological investigation for BSE positive findings.

It is important that appropriate procedures and protocols are in place to ensure that BSE can be definitively ruled out on the list of differential diagnoses.

- a) List the common ~~cattle bovine~~ disorders with clinical signs compatible with BSE in the country or *zone*. If available, provide the incidence/prevalence of these disorders, ideally by production system (e.g. dairy, beef) and by age group.
- b) Describe the procedures and protocols in place for reporting animals ~~potentially lying on the continuum showing symptoms signs of the clinical BSE spectrum of BSE (those described in points 2 a) to 2 d) of Article 11.4.18.) to the Competent Authority.~~ For example, these procedures and protocols may include the steps that a ~~farmer breeder, owner or keeper~~ may follow once an animal with clinical signs suggestive of BSE is identified. These procedures and protocols should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock.
- c) Describe the procedures and protocols in place for the investigation of reported animals ~~potentially lying on the continuum showing symptoms signs of the clinical BSE spectrum of BSE (those described in points 2(a) to 2(d) of Article 11.4.18.) that allow the discrimination of reported animals to be subjected to laboratory testing.~~ For example, these procedures and protocols may include the range of clinical signs to be considered, and how the age, the clinical history of the animal and epidemiological data of the *herd* are taken into account. An evaluation procedure may, for example, be in the form of a protocol, a checklist or a decision tree, and should cover the clinical continuum of the disease spectrum ranging from clinical suspects to non-ambulatory to fallen stock.
- d) Describe the methods applied to assess the age of animals investigated, such as individual identification or dentition.

- e) Describe the procedures and protocols for the transport of live or dead animals for sampling, and transfer of samples to laboratories for testing, including details of the ~~cattle-ovine~~ identification system, the maintenance of the chain of custody of the carcass and the samples, and the reconciliation of samples with the animals they were collected from.
- f) Provide the procedures and protocols for a follow-up epidemiological investigation of BSE positive results.
- g) Provide a summary table for each of the preceding eight years (Table 1) of the number of animals reported and the number of animals subjected to BSE testing for each clinical presentation (those in points 2 a) to 2 d) of Article 11.4.18.).

Table 1.		
Year: _____		
Table 1 - Summary of all animals that were reported and evaluated for testing by the Veterinary Authority		
Clinical presentation (see point 2 of Article 11.4.18.)	Number of reported animals	Number of animals subjected to BSE testing
(A) Cattle-Bovines displaying progressive behavioural or neurological signs suggestive of BSE that are refractory to treatment		
(B) Cattle-Bovines showing behavioural or neurological signs that did not pass the ante-mortem inspection at slaughterhouses/abattoirs		
(C) Cattle-Bovines presented as downers (non-ambulatory) with an appropriate supporting clinical history		
(D) Cattle-Bovines found dead (fallen stock) with an appropriate supporting clinical history		

5.) **Animals subjected to laboratory testing**

- a) Provide in Table 2, for each of the preceding eight years, details of all animals counted in Table 1 that were subjected to laboratory testing (see point 2 of Article 11.4.18.).

Table 2. Details of the animals that were subjected to laboratory testing-							
Year notified	Laboratory identification number or individual identification number	Age (in months) at <u>the time of reporting first detection</u>	Type of production system (dairy, beef, mixed, etc.)	Description of observed clinical signs	Clinical presentation (A, B, C or D)	Final diagnosis (if BSE, specify <u>the strain if C, L or H type</u>)	For a <u>case of</u> BSE case , indicate the origin (indigenous or imported; if imported, indicate the country of birth)

Article 1.8.6bis.

History of occurrence and management of BSE in the country or zone (points 3 and 4 of Article 11.4.3.)

Describe the history of occurrence and management of BSE by providing the following documentary evidence:

- 1) If a case of BSE has ever been diagnosed in the country or zone, indicate the total number of cases of BSE, and:
 - a) Provide a table of aggregated data on all cases of BSE encountered in the country or zone, origin (indigenous or, if imported, the country of origin), and the year of birth;
 - b) For the past eight years, provide a table to indicate, for each case, the year of occurrence, the origin (indigenous or, if imported, the country of origin), and the year of birth of each indigenous case.
- 2) If there have been cases of BSE or bovines affected by atypical BSE, confirm that they were completely destroyed or disposed of to ensure they are excluded from the feed chain and describe how this was achieved. In the table under Article 1.8.2. provide details of the national legislation, regulations and Veterinary Authority directives that describe these procedures.

Article 1.8.7.

Recovery-Maintenance of BSE risk status

Following the occurrence of an indigenous case of classical BSE in an animal bovine born ~~within the preceding eight years after the date from which the risk of BSE agents being recycled within the cattle-bovine population has been negligible occur in a country or zone with a negligible or controlled BSE risk status of a country or zone,~~ the outcome of the investigation together with any additional measures implemented that confirm or ensure that the risk of BSE agents being recycled within the cattle-bovine population continues to be negligible should be provided with reference to the provisions in Article 1.8.5. as appropriate. Information in relation to other sections need to only be supplied if relevant.

CHAPTER 12.2.

INFECTION WITH *TAYLORELLA EQUIGENITALIS* (CONTAGIOUS EQUINE METRITIS)

Article 12.2.1.

General provisions

This chapter addresses the occurrence of clinical or asymptomatic *infection* of a mare caused by *Taylorella equigenitalis* as well as the presence of *T. equigenitalis* on the genital mucous membrane surface in the male horse.

For the purposes of the *Terrestrial Code*, the following defines *infection* with *T. equigenitalis*:

- 1) *T. equigenitalis* has been isolated and identified as such from a genital swab sample from a horse; or
- 2) nucleic acid specific to *T. equigenitalis* has been identified detected in a sample from a horse; or
- 3) antigen or genetic material antigen specific to *T. equigenitalis* has been identified detected in a sample from a mare-horse showing clinical or pathological signs consistent with *infection* with *T. equigenitalis*, or epidemiologically linked to a confirmed or suspected case of *infection* with *T. equigenitalis*;
- 3) genetic material specific to *T. equigenitalis* has been identified in a sample from a male horse.

For the purposes of the *Terrestrial Code*:

- due to long-term persistence of *T. equigenitalis* in horses, in the absence of effective treatment, the *infective period* shall be lifelong;
- the *incubation period* in mares shall be 14 days.

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

For the purposes of this chapter, a temporary importation refers to the introduction of horses into a country or zone, ~~for competition or cultural events excluding breeding~~, for a defined period of time, not exceeding 90 days, during which the *risk* of transmission of the *infection* is mitigated through specific measures under the supervision of the *Veterinary Authority*. Temporary imported horses are re-exported at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or zone, should be defined in advance.

When authorising the importation or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 12.2.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *T. equigenitalis* status of the exporting country, zone or ~~establishment~~ herd.

Article 12.2.2.

Safe commodities

When authorising importation or transit of the following *commodities*, *Veterinary Authorities* should not require any *T. equigenitalis*-related conditions, regardless of the ~~*T. equigenitalis* infection~~ animal health status of the animal population of the exporting country, zone or ~~establishment~~ herd:

- 1) geldings;
- 2) milk and milk products;
- 3) meat and meat products;
- 4) hides and skins;
- 5) hooves;
- 6) gelatine and collagen.

Article 12.2.3.

Establishment free from infection with *T. equigenitalis*

1) Prerequisite

Infection with T. equigenitalis has been a *notifiable disease* in the entire country for at least the past two years.

2) Qualification

To qualify as free from *infection* with *T. equigenitalis*, an establishment herd should satisfy the following conditions:

- a) it is under the control of the *Veterinary Authority*;
- b) no case has occurred for at least two years;
- c) all horses from the establishment herd have been subjected to *T. equigenitalis* tests, with negative results, on samples collected ~~These tests should have been carried out~~ on three occasions, within a 12-day period, with an interval of no less than three days ~~apart between each test~~ sample collections. Horses must have not been treated with antibiotics for at least 7 days prior to the first sampling, nor subjected to antiseptic washing of genital mucous membrane for at least 21 days ~~before prior to~~ the first sampling;
- d) any stored semen was subjected to a test for detection of genetic material/nucleic acid ~~of to detect~~ *T. equigenitalis* with negative results, carried out on an aliquot of the stored semen.

3) Maintenance of freedom

- a) the requirements in points 1 and 2(a) and 2(b) of Article 12.2.3. are met;
- b) appropriate *surveillance*, capable of detecting *infection* with *T. equigenitalis* even in the absence of clinical signs, is in place; this may be achieved through a *surveillance* programme in accordance with Chapter 1.4. and this chapter;
- c) the introduction of horses and their germplasm germinal products into the establishment herd is carried out in accordance with the importation conditions for these *commodities* listed in this chapter.

4. Recovery of freedom

When a case is detected in a previously free establishment herd the free status ~~of the establishment~~ should be suspended until the following conditions are met ~~in the affected establishment~~:

- a) the *disinfection* of the *establishment* has been applied;
- b) not before 21 days after the last removal or the last treatment of an infected horse, all horses have been subjected to a *T. equigenitalis* test for the detection of the agent, with negative results, on samples collected on three occasions, within a 12-day period with an interval of no less than three days ~~apart between each test~~ sample collections;

- c) any fresh semen from all infected horses in the herd has been destroyed; aliquots of each collection of stored semen from all infected horses in the herd was were subjected to a test to detect for detection of genetic material nucleic acid of *T. equigenitalis* with negative results in accordance with Article 12.2.8, carried out on an aliquot of the stored semen; and all positive stored semen has been destroyed;
- d) the introduction of horses and their germplasm germinal products into the establishmentherd is carried out in accordance with the importation conditions for these *commodities* listed in this chapter.

Article 12.2.4.

Recommendations for importation of stallions or mares

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

- 1) mares showed no clinical sign of *infection* with *T. equigenitalis* on the day of shipment;

AND

- 2) horses have been kept in an *establishment*:
 - a) kept since birth or for at least two years prior to shipment in an establishmentherd that has been free from *infection* with *T. equigenitalis* since birth or for at least two years prior to shipment;

OR

- b)
 - i) kept for at least the last 60 days in an establishmentherd in which no *case* has been reported during that period the 60 days prior to shipment;

AND

- ii) were subjected to tests for the detection of the agent *T. equigenitalis* tests, with negative results, carried out on samples collected on three occasions, within a 12-day period, with an interval of no less than three days apart between each testssample collections, being the last testone being carried out within the 30 days prior to shipment. Horses must not have not been treated with antibiotics for at least 21 7 days nor subjected to antiseptic washing of genital mucous membranes for at least 21 days prior to the first sample collection,ing and have not been mated or inseminated after the first sampling.

Article 12.2.5.

Recommendations for temporary importation of stallions and maresorses

When importing on a temporary basis stallions or mares horses that do not comply with recommendations in Article 12.2.4. for purposes different other than breeding and rearing, *Veterinary Authorities* should:

- 1) require:
 - a) the animals horses to be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status *subpopulation* as defined in Chapter 4.17.;
 - b) the presentation of an *international veterinary certificate* attesting that the mares showed no clinical sign of *infection* with *T. equigenitalis* on the day of shipment;

- c) the duration of the temporary importation period ~~and~~, the destination after this period, and the conditions required to leave the country or zone to be defined;
- 2) ensure that during their stay in the country or zone, the ~~animals~~ horses:
- a) are not used for breeding (including artificial insemination, semen collection, used as teasers ~~stallions~~) and do not have any sexual contact with other horses;
 - b) ~~do not undergo any genital examinations~~ are not subjected to any practice that may represent a risk of transmission of infection with *T. equigenitalis*;
 - c) are kept and transported individually in stalls and *vehicles/vessels* which are subsequently cleaned and disinfected before re-use.

Article 12.2.6.

Recommendations for importation of semen ~~of from~~ horses/stallions

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

- 1) semen was collected in an *approved* centre and collection, processing and storing was were done in accordance with Chapter 4.6; and

EITHER

- 2) the donor stallion was kept in an ~~establishment~~ herd free from infection with *T. equigenitalis*;

OR

- 3)
 - a) the donor stallion was kept for at least 60 days prior to semen collection in an ~~establishment~~ herd in which no case has been reported during that period ~~the 60 days prior to semen collection~~; and
 - b) the donor stallion was subjected to tests for the detection of the agent *T. equigenitalis* tests, with negative results, carried out on samples collected on three occasions, within a 12-day period with an interval of no less than three days ~~apart~~ between each ~~test~~ sample collections, being the last ~~test~~ one being carried out within the 30 days prior to shipment. ~~The donor stallion must not have been treated with antibiotics for at least 21 days prior to sampling. Horses have not been treated with antibiotics for at least 21-7 days nor subjected to antiseptic washing of genital mucous membranes for at least 21 days prior to the first sample collection, ing~~ and have not been mated or inseminated after the first sampling;

OR

- 4) aliquots of fresh semen were subjected to culture and a test for detection of genetic material/nucleic acid ~~for of~~ *T. equigenitalis* with negative results, carried out immediately prior to processing and on an aliquot of semen collected within 15 ~~to~~ = 30 days after the first collection of the semen to be exported;

OR

- 5) aliquots of frozen stored semen corresponding to the ~~earliest-oldest~~ and the most recent collection were subjected to culture and a test for detection of genetic material/nucleic acid for *T. equigenitalis* with negative results.

Article 12.2.7.

Recommendations for importation of oocytes or embryos of horses

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

- 1) the oocytes and embryos were collected, processed and stored in approved centres following the general provisions in accordance with Chapters 4.8, 4.9. and 4.10.;
- 2) the donor mare showed no clinical signs of infection with *T. equigenitalis* on the day of collection;

AND

- 2) for the importation of embryos:
- 3) the semen used for embryo production complied with Article 12.2.6. and Chapters 4.6. and 4.7.

Article 12.2.8.

Surveillance

1) General principles of surveillance

*Surveillance for infection with *T. equigenitalis* is relevant for establishments seeking to achieve and demonstrate freedom from infection, as well as being part of an official control programme in countries where the disease is endemic.*

*The surveillance strategy chosen should be adequate to detect ~~the~~ infection with *T. equigenitalis* even in the absence of clinical signs.*

*The Veterinary Services should implement programmes to raise awareness among ~~farmers~~ owners, breeders and workers who have day-to-day contact with horses, as well as *veterinarians, veterinary paraprofessionals* and diagnosticians, who should report promptly any suspicion of infection with *T. equigenitalis* to the Veterinary Authority.*

Under the responsibility of the Veterinary Authority, Member Countries should have in place an early warning system in accordance with Article 1.4.5. and:-

- 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;~~
- e) a system for recording, managing and analysing diagnostic and surveillance data.

2) Clinical surveillance

*Clinical surveillance aims at detecting clinical signs by close physical examination of horses and based on ~~reproduction~~ reproductive performance. However, clinical surveillance should be complemented by culture for *T. equigenitalis* ~~bacteriological~~ and molecular teststesting, as asymptomatic carriers play an important role in the maintenance and transmission of the infection.*

3) Agent surveillance

*An active programme of surveillance of horses to detect cases should be implemented to establish the status of a country, zone or ~~establishment~~ herd. Culture for *T. equigenitalis* and molecular testing are the most effective methods of detection of ~~the~~ a case.*

Stored semen should be included in surveillance programmes. It represents a valuable source of material and may be very helpful in contributing to retrospective studies, including providing support for claims of freedom from infection and may allow certain studies to be conducted more quickly and at lower cost than other approaches. Samples can be gathered through representative sampling or following a risk-based approach.

4) Serological surveillance

Serological *surveillance* is not the preferred strategy for detecting *T. equigenitalis*. If used, serology should be ~~used~~ done in conjunction with ~~agent identification~~ culture in assessing the status of a mare that may have been infected with *T. equigenitalis*. The usefulness of serological tests is further described in the *Terrestrial Manual*.

CHAPTER 12.6.

INFECTION WITH EQUINE INFLUENZA VIRUS

Article 12.6.1.

General provisions

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an *infection* of domestic and *captive wild* equids with equine influenza virus (EIV), i.e. subtypes H3N8 and H7N7 of influenza A viruses (~~H7N7 and H3N8~~).

This chapter deals not only with the occurrence of clinical signs caused by *infection with equine influenza virus (EIV)*, but also with the presence of *infection* with EIV in the absence of clinical signs.

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

- 1) EIV, excluding modified-live virus vaccine strains following recent *vaccination*, has been isolated and identified as such from in a sample from a domestic or *captive wild* equid; or
- 2) antigen or ribonucleic acid or antigen specific to EIV has been detected in a sample from a domestic or *captive wild* equid showing clinical signs or pathological lesions suggestive of consistent with equine influenza, or epidemiologically linked to a confirmed or suspected or confirmed case of equine influenza; or
- 3) seroconversion due to recent exposure to EIV virus, demonstrated by a significant increase in antibody titres which are which is not the consequence of *vaccination*, have has been detected in paired samples from a domestic or *captive wild* equid showing clinical signs or pathological lesions consistent with suggestive of consistent with equine influenza, or epidemiologically linked to a confirmed or suspected or confirmed case of *infection* with EIV.

~~For the purposes of this chapter, isolation is defined as ‘the separation of domestic equids from domestic equids of a different EI health status, utilising appropriate *biosecurity* measures, with the purposes of preventing the transmission of *infection*’.~~

For the purposes of the *Terrestrial Code*, the *infective period* for EI shall be ~~21~~ 10 14 days.

For the purposes of this chapter, a temporary importation refers to the introduction of horses into a country or *zone*, for a defined period of time, not exceeding 90 days, during which the *risk* of transmission of the *infection* is mitigated through specific measures under the supervision of the *Veterinary Authority*. Temporarily imported horses are re-exported at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or *zone*, should be defined in advance.

When authorising the importation or transit of the *commodities* listed in this chapter, with the exception of those listed in Article 12.6.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the EI status of the equine population of the *exporting country, zone or compartment*.

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

Article 12.6.2.

Safe commodities

When authorising the importation or transit of the following *commodities*, *Veterinary Authorities* should not require any EIV-related conditions, regardless of the EI animal health status of the equine animal population of the *exporting country, zone or compartment*:

- 1) equine semen;
- 2) *in vivo* derived equine embryos collected, processed and stored in accordance with Chapters 4.8. and 4.10., as relevant; ~~(under study)~~;
- 3) meat and meat products from equids that have been slaughtered in a slaughterhouse/abattoir and have been subjected to ante- and post-mortem inspections with favourable results.

Article 12.6.3.

Determination of the EI status of a country, a zone or a compartment

The EI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

- 1) the outcome of a *risk assessment* identifying all risk factors and their historic relevance;
- 2) whether EI is notifiable in the whole country, an ongoing EI awareness programme is in place, and all notified suspect occurrences of EI are subjected to field and, where applicable, *laboratory* investigations;
- 3) appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in domestic and captive wild equids.

Article 12.6.4.

~~EI-free~~ Country, zone or compartment free from EI

A country, *zone* or *compartment* may be considered free from EI provided ~~the disease that~~ infection with EIV is notifiable in the whole country and it shows evidence, through an effective *surveillance* programme, planned and implemented in accordance with the general principles in Chapter 1.4., that no case of ~~EI~~ infection with EIV occurred in the past two years. The *surveillance* may need to be adapted to parts of the country, *zone* or *compartment* depending on historical or geographical factors, industry structure, population data, movements of equids within and into the country, *zone* or *compartment*, *wild* equine populations or proximity to recent *outbreaks*.

A country, *zone* or *compartment* seeking freedom from EI, in which *vaccination* is practised, should also demonstrate that EIV has not been circulating in the population of domestic, captive wild, feral, and wild equids during the past 12 months, through *surveillance*, in accordance with Chapter 1.4.

In a country in which *vaccination* is not practised, *surveillance* may be conducted using serological testing alone. In countries where *vaccination* is practised, the *surveillance* should include agent identification methods described in the *Terrestrial Manual* for evidence of *infection*.

A country, *zone* or *compartment* seeking freedom from EI should apply appropriate movement controls to minimise the risk of introduction of EIV in accordance with this chapter and should be in accordance with relevant requirements and principles described in Chapter 4.4. and Chapter 4.5.

~~If an outbreak of clinical EI occurs in a previously free country, zone or compartment, free status can be regained 12 months after the last clinical case, providing that surveillance for evidence of infection has been carried out during that twelve month period in accordance with Chapter 1.4.~~

Article 12.6.4bis.

Recovery of free status

If a case of infection with EIV occurs in a previously free country, zone or compartment, free status can be regained 12 months after the last case, provided that outbreaks were managed in accordance with Chapter 4.19. and that surveillance, in accordance with Chapter 1.4. Article 12.6.4., has been carried out during that 12-month period, with negative results.

Article 12.6.5.

Recommendations for the importation of domestic and captive wild equids for immediate slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the domestic and or captive wild equids showed no clinical sign of EI on the day of shipment.

Article 12.6.6.

Recommendations for the importation of domestic and captive wild equids ~~for unrestricted movement~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the domestic or captive wild equids :

- 1) came from an EI free country, *zone or compartment* in which they had been resident for at least 21 10-14 days; in the case of vaccinated ~~domestic~~ equids, information on their *vaccination* status should be included in the veterinary certificate;

OR

- 2) ~~a) came from a country, zone or compartment not known to be free from EI,~~ were subjected to pre-export isolation for 21 10-14 days and showed no clinical sign of EI during isolation nor on the day of shipment; and

AND

- ~~3b) were immunised/vaccinated in accordance with the recommendations of the manufacturer with a vaccine complying with the standards described in the *Terrestrial Manual* and considered effective against the epidemiologically relevant virus strains, between 21 and 90 days before shipment either with a primary course or a booster; information on their *vaccination* status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12. in accordance with one of the following procedures:~~

~~ai) between 14 and 90 days before shipment either with either a primary course or a booster; or~~

~~bii) between 14 and 180 days before shipment, if they are older than four years of age, previously having received up to the date of this pre-shipment *vaccination*, at least four doses of the same vaccine at intervals not greater than 180 days.~~

Information on the *vaccination* status should be included in the *international veterinary certificate* or the passport in accordance with Chapter 5.12. as relevant.

~~For additional security, c) Countries that are free of from EI or undertaking an eradication programme may also request that the equids were tested negative for EIV by subjected to an agent identification test for EI described in the *Terrestrial Manual* with negative results, conducted on samples collected on two occasions, at 7 to 14 days four to six days after commencement of pre-export isolation and less than 5 prior to within four days before of prior to shipment.~~

Article 12.6.7.

Recommendations for the temporary importation of ~~domestic equid which will be kept in isolation (see Article 12.6.1.)~~ horses

If the importation of horses on a temporary basis does not comply with the recommendations in Article 12.6.6., *Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the domestic equids:

- 1) require that:

a) that the horses be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status *subpopulation* as defined in Chapter 4.17.;

b) the presentation of an *international veterinary certificate* attesting that the horses:

- 1i) came from an ~~EI free country, zone or compartment free from EI~~, in which they had been resident for at least ~~21~~ 14 days; in the case of a vaccinated ~~domestic equid horses~~, information on ~~its~~ their *vaccination* status should be included in the veterinary certificate;

OR

- 2ii) showed no clinical sign of EI in any premises in which the ~~domestic equids~~ horses had been resident for the ~~21~~ 14 days prior to shipment nor on the day of shipment; and

- 3iii) were ~~immunised in accordance~~ vaccinated with ~~the recommendations of the manufacturer with~~ a vaccine complying with the standards described in the *Terrestrial Manual*; information on their *vaccination* status should be included in the veterinary certificate or the passport in accordance with Chapter 5.12.;

- 2) ensure that during their stay in the country or zone domestic equids horses are kept separated from domestic and captive wild equids of a different EI health status through appropriate biosecurity.

Article 12.6.8.

~~Recommendations for the importation of fresh meat of equids~~

~~Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the fresh meat came from equids which had been subjected to ante- and post-mortem inspections as described in Chapter 6.3.~~

CHAPTER 12.7.

EQUINE PIROPLASMOSIS INFECTION WITH *THEILERIA EQUI* AND *BABESIA CABALLI* (EQUINE PIROPLASMOSIS)

Article 12.7.1.

General provisions

The infection with use of the term equine piroplasmosis indicates clinical diseases caused by the transmission of *Theileria equi* (*T. equi*) or *Babesia caballi* (*B. caballi*) established after transmission of these pathogenic agents through competent ticks or iatrogenic practices may be asymptomatic or may cause a clinical disease known as equine piroplasmosis. Vertical transmission from mares to foals has also been reported. This chapter deals not only with the occurrence of clinical disease signs caused by infection with *T. equi* or *B. caballi*, but also with asymptomatic infections the presence of infection with *T. equi* or *B. caballi* in the absence of clinical signs.

Susceptible a Animals for susceptible to infection with *T. equi* or *B. caballi* are primarily domestic and wild equids. Although old-world camelids are susceptible to infection and are potential reservoirs, they are not found to play a significant role in the epidemiology of the disease.

Equids infected with *T. equi* or *B. caballi* may remain carriers of these blood parasites for long periods, sometimes lifelong and act as sources of infection for competent tick vectors, including species of the genera *Dermacentor*, *Rhipicephalus*, *Hyalomma* and *Amblyomma*.

For the purposes of the *Terrestrial Code*, the following defines infection with *T. equi* or *B. caballi*:

- 1) *T. equi* or *B. caballi* has been observed and identified as such identification of the parasite by microscopic examination of in a sample from an equid which may be showing clinical or pathological signs consistent with infection with *T. equi* or *B. caballi* or epidemiologically linked to a confirmed or suspected case of infection with *T. equi* or *B. caballi*; or
- 2) antigen or genetic material nucleic acid specific for to *T. equi* or *B. caballi* has been identified detected in a sample from an equid which may be showing clinical or pathological signs consistent with infection with *T. equi* or *B. caballi*, or epidemiologically linked to a confirmed or suspected case of infection with *T. equi* or *B. caballi*; or
- 3) antibodies specific to *T. equi* or *B. caballi* have been identified detected in a sample from an equid which may be showing clinical or pathological signs consistent with infection with *T. equi* or *B. caballi*, or epidemiologically linked to a confirmed or suspected case of infection with *T. equi* or *B. caballi*.

For the purposes of the *Terrestrial Code*, the incubation period of infection with *T. equi* or *B. caballi* in equids shall be 30 days and the infective period shall be lifelong.

For the purposes of this chapter, a temporary importation refers to the introduction of equidshorses into a country or zone, for a defined period of time, not exceeding 90 days, during which the risk of transmission of the infection is mitigated through specific measures under the supervision of the Veterinary Authority. Temporarily imported horses are re-exported or slaughtered at the end of this period. The duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or zone, should be defined in advance.

When authorising the importation or transit of the commodities listed in this chapter, with the exception of those listed in Article 12.7.2., Veterinary Authorities should require the conditions prescribed in this chapter relevant to the status of infection with *T. equi* and *B. caballi* of the exporting country or zone.

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

Article 12.7.2.

Safe commodities

When authorising importation or transit of the following commodities, Veterinary Authorities should not require any conditions related to conditions related with infection with *T. equi* or *B. caballi*-related conditions, regardless of the infection animal health status of the animal population of the exporting country or zone:

- 1) milk and milk products;
- 2) meat and meat products;
- 3) hides and skins;
- 4) hooves;
- 5) gelatine and collagen;
- 6) semen collected in accordance with the relevant chapters of the *Terrestrial Code*;
- 7) sterile filtered horse serum;
- 8) embryos collected, processed and stored in accordance with Chapters 4.8., 4.9. and 4.10.

Article 12.7.3.

Country or zone free from infection with *T. equi* and *B. caballi*

- 1) Historical freedom as described in Chapter 1.4. does not apply to infection with *T. equi* and *B. caballi*.
- 2) A country or a zone may be considered free from infection with *T. equi* and *B. caballi* when:
 - a) infection with *T. equi* and infection with *B. caballi* have been notifiable diseases in the entire country for at least the past 10 years and, in the country or zone:

EITHER:

 - i) there has been no case of infection with *T. equi* and no case of infection with *B. caballi* during the past six years; and
 - ii) a surveillance programme performed in accordance with Article 12.7.9. has demonstrated no evidence of infection with *T. equi* and no evidence of infection with *B. caballi* infor the past six years and has considered the presence or absence of competent vectors in the epidemiological situation;

OR

 - iii) an ongoing surveillance programme performed in accordance with Article 12.7.9. has found no competent tick vectors for at least six years;
- b) importations of equids into the country or zone are-is carried out in accordance with this chapter. A country or zone free from infection with *T. equi* and *B. caballi* in which an epidemiological investigation has been conducted with favourable results ongoing vector surveillance, performed in accordance with Article 12.7.9., has found no competent tick vector will not lose its free status through the introduction of seropositive or infective equidshorses were imported temporarily in accordance with Article 12.7.6. will not lose its free status provided an epidemiological investigation demonstrates that there has been no transmission of infection;

- c) a country or zone free from infection with *T. equi* and *B. caballi* adjacent to an infected country or zone should include a high-risk area in which continuous serological, agent and vector surveillance is conducted in accordance with Article 12.7.9.

Article 12.7.4.

Recovery of a free status

When infection with *T. equi* or *B. caballi* is detected in a previously free country or zone, Article 12.7.3. applies.

Article 12.7.25.

Recommendations for the importation of equines equids

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

- 1) the animals showed no clinical signs ~~equine piroplasmosis~~ of infection with *T. equi* or *B. caballi* on the day of shipment, and
- 2) EITHER:
 - a) the animals were kept in a country or zone free from infection with *T. equi* and *B. caballi* since birth;

OR

 - 2) were subjected to diagnostic tests for equine piroplasmosis (*Theileria equi* and *Babesia caballi*) with negative results during the 30 days prior to shipment;
 - b) i) were subjected to a serological or agent identification tests with molecular techniques for the detection of *T. equi* and *B. caballi* with negative results carried out on a blood sample taken within the 14 days prior to shipment; and
- 3) were maintained free from ticks, by preventive treatment when necessary, during the 30 days prior to shipment.
 - ii) were maintained free from competent ticks in accordance with Article 12.7.7. and not subjected to any practice that may present a risk of iatrogenic transmission of infection with *T. equi* or *B. caballi* during the 30 days prior to sampling and after sampling until shipment and throughout the transport to the destination country or zone; and
 - iii) have not been treated with antiparasitic drugs capable of masking an infection with *T. equi* and *B. caballi*, for at least six months prior to sampling.

Article 12.7.36.

Recommendations for the temporary importation of equids horses of competition horses on a temporary basis

Veterinary Authorities of importing countries should consider the possibility of importing competition horses on a temporary basis and which are positive to the testing procedure referred to in point 2) of Article 12.7.2. under the following safeguards:

If the importation of equids horses on a temporary basis does not comply with the recommendations in Article 12.7.5., Veterinary Authorities of importing countries should:

1-1) require that:

- a) the horses are that the animals horses be accompanied by a passport in accordance with the model contained in Chapter 5.12. or be individually identified as belonging to a high health status subpopulation as defined in Chapter 4.17.;

2-b) ~~the Veterinary Authorities of importing countries require the presentation of an international veterinary certificate attesting that the animals~~horses:

a-i) showed no clinical sign of equine piroplasmosis infection with *T. equi* or *B. caballi* on the day of shipment;

b) ~~were treated against ticks within the seven days prior to shipment;~~

ii) were maintained free from ticks in accordance with Article 12.7.7. during the 30 days prior to shipment and during transport;

c) that the duration of the temporary importation period and the destination after this period, as well as the conditions required to leave the country or zone, be defined;

3) ~~the horses are kept in an area where necessary precautions are taken to control ticks and that is under the direct supervision of the Veterinary Authority;~~

4) ~~the horses are regularly examined for the presence of ticks under the direct supervision of the Veterinary Authority.~~

2) ensure that during their stay in the country or zone:

a) the animalshorses are protected from ticks in accordance with Article 12.7.7.;

b) equidshorses are examined daily for the presence of ticks ~~of the genera *Dermacentor*, *Rhipicephalus*, *Hyalomma* and *Amblyomma*~~ with particular attention to the ears, false nostrils, inter-mandibular space, mane, lower body areas, including the axillae, and inguinal region, and the perineum and tail, with negative results;

c) the animalshorses are not subjected to any practice that may represent a risk of iatrogenic transmission of infection with *T. equi* or *B. caballi*.

Article 12.7.7.

Protecting equids from ticks

1) Under the direct supervision of the Veterinary Authority:

a1) equids are kept in tick-protected facilities and transported in protected vehicles-vehicles/vessels according to Article 12.7.8.point 3;

b2) equids have been preventively treated according to received preventive treatment in accordance with the manufacturer's recommendations with an acaricide effective against the competent ticks.

Article 12.7.8.

Protecting facilities and transports from ticks

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

a1) measures to limit or eliminate habitats for competent tick vectors should be implemented for an appropriate time and over an appropriate distance in the vicinity of the area where equids are kept;

b2) the facility and immediate surroundings of the stables and exercise or competition areas should be treated with an effective acaricide before the arrival of equids.

3) When transporting animals equids through infected countries or zones:

a) the vehicle/vessel should be treated with an effective acaricide before transporting the animals;

- b) preventive treatment of the equids with an acaricide with an extended residual effect that lasts at least for the duration of any stopover during the trip should be conducted.

Article 12.7.9.

Surveillance strategies

1. General principles of surveillance

A Member Country should justify the surveillance strategy chosen as being adequate to detect the presence of infection with *T. equi* and the presence of infection with *B. caballi*, 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.

An active programme of surveillance of equids to detect evidence of infection with *T. equi* and evidence of infection with *B. caballi* by serological or agent identification molecular testing is required to establish the status of a country or zone, considering that asymptomatic carriers play an important role in the maintenance and transmission of the infection.

The Veterinary Services should implement programmes to raise awareness among veterinarians, horse breeders, owners, keepers, and riders and workers who have day-to-day contact with equids, as well as veterinary paraprofessionals and diagnosticians, who should report promptly any suspicion of infection with *T. equi* and any suspicion of infection with *B. caballi* to the Veterinary Authority.

Under the responsibility of the Veterinary Authority, Member Countries should have in place an early warning system in accordance with Article 1.4.5. and:

- a formal and ongoing system for detecting and investigating cases;
- a procedure for the rapid collection and transport of samples from suspected cases of infection with *T. equi* or *B. caballi* to a laboratory for diagnosis;
- a system for recording, managing and analysing diagnostic and surveillance data.

2. Clinical surveillance

Clinical surveillance aims at detecting clinical signs by close physical examination of equids.

3. Serological and agent surveillance

- 3) An active programme of surveillance of equids to detect evidence of infection with *T. equi* and evidence of infection with *B. caballi* by serological or agent identification testing with molecular techniques is required to establish the status of a country or zone considering that asymptomatic carriers play an important role in the maintenance and transmission of the infection.
- 4) The study population used for a serological survey should be representative of the population at risk in the country or zone.

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 particularly over the border with that country or zone unless there are relevant ecological or geographical features likely to limit the spatial distribution and thereby prevent the infestation of equids from competent ticks and interrupt the transmission of infection with *T. equi* or *B. caballi*.

5. Vector surveillance

Infection with *T. equi* or *B. caballi* is transmitted between equine hosts by species of competent ixodid-ticks including species of the genera *Dermacentor*, *Rhipicephalus*, *Hyalomma*, and *Amblyomma*.

Vector surveillance is aimed at demonstrating the absence of tick vectors or defining high, medium and low-risk areas and local details of seasonality by determining the various 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 the continued absence of vectors.

Vector surveillance sampling should be scientifically based. The choice of the number and types of traps collection methods to be used in vector surveillance and the frequency of their use should consider the size and ecological characteristics of the area to be surveyed as well as the biology and behavioural characteristics of the local vector species of competent ixodid ticks.

The use of a vector surveillance system to detect the presence of circulating *T. equi* or *B. caballi* is not recommended as a routine procedure. Rather, Animal-based surveillance strategies are preferred to detect *T. equi* or *B. caballi* transmission than entomological surveillance.

CHAPTER 14.X.

INFECTION WITH *THEILERIA LESTOQUARDI*,
T. LUWENSHUNI AND *T. UILENBERGI*

Article 14.X.1.

General provisions

~~Animals susceptible to infection with *Theileria* are~~ Theileriosis is a disease of bovines (*Bos indicus*, *B. taurus*, and *B. grunniens*), water buffaloes (*Bubalus bubalis*), and African buffaloes (*Syncerus caffer*), sheep (*Ovis aries*), goats (*Capra hircus*), camels (*Camellus dromedarius* and *C. bactrianus*) and some wild ruminants.

~~Infection with *Theileria*~~ Theileriosis can give rise to disease of variable severity and ~~to *Theileria* transmission. *Theileria* the pathogenic agent~~ may persist in ruminants for their lifetime. Such animals are considered carriers.

Only sheep and goats play a significant epidemiological role in the infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi*.

For the purposes of the *Terrestrial Code*, infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi* are defined as a tickborne infection of sheep and goats with *T. lestoquardi*, *T. luwenshuni* and *T. uilenbergi*.

For the purposes of this chapter, *Theileria* means *T. lestoquardi*, *T. luwenshuni* and *T. uilenbergi*.

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

- 1) ~~*Theileria* has been identified~~ observed and identified as such in a sample from a sheep or goat; or
- 2) ~~antigen or~~ nucleic acid specific to *Theileria* has been identified ~~detected~~ in a sample from a sheep or goat showing clinical signs consistent with infection with *Theileria*, or epidemiologically linked to a confirmed or suspected ~~or confirmed~~ case, or giving cause for suspicion of previous association with *Theileria*; or
- 3) antibodies specific to *Theileria* have been detected in a sample from a sheep or goat ~~that either shows~~ showing clinical signs consistent with *Theileria*, or ~~is~~ epidemiologically linked to a confirmed or suspected ~~or confirmed~~ case, or giving cause for suspicion of previous association with *Theileria*.

For the purposes of the *Terrestrial Code*, the incubation period for infection with *Theileria* shall be 35 days.

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

Article 14.X.2.

Safe commodities

When authorising the importation or transit of the following commodities, Veterinary Authorities should not require any *Theileria*-related conditions regardless of the ~~*Theileria* infection~~ animal health status of the animal population of the exporting country or zone:

- 1) meat and meat products;
- 2) casings;
- 3) milk and milk products;

- 4) gelatine and collagen;
- 5) tallow;
- 6) semen and embryos collected in accordance with the relevant chapters of the *Terrestrial Code*;
- 7) hooves and horns;
- 8) bones.

Article 14.X.3.

Country or zone free from infection with *Theileria* in sheep and goats

- 1) A country or a *zone* may be considered free from *infection* with *Theileria* when the disease is notifiable in the entire country, importation of sheep and goats and their *commodities* is carried out in accordance with this chapter, and:
 - a) the country or *zone* is historically free as described in Article 1.4.6.; or
 - b) a *surveillance* programme in accordance with Chapter 1.4. has demonstrated no evidence of *infection* with *Theileria* in the country or *zone* for at least two years; or
 - c) an ongoing *surveillance* programme in accordance with Chapter 1.5. has found no competent tick *vectors* for at least two years in the country or *zone*.
- ~~2) A country or zone free from infection with *Theileria* in which ongoing vector surveillance, performed in accordance with Chapter 1.5., has found no competent tick vectors will not lose its free status through the introduction of vaccinated, test positive or infected sheep and goats from infected countries or zones.~~
- ~~3) A country or zone free from infection with *Theileria* will not lose its status as a result of introduction of seropositive or vaccinated sheep and goats or their commodities, provided they were introduced in accordance with this chapter.~~

Article 14.X.4.

Recommendations for importation of sheep and goats from countries or zones free from infection with *Theileria*

For sheep and goats

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

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

Article 14.X.5.

Recommendations for importation of sheep and goats from countries or zones not free from infection with *Theileria*

For sheep and goats

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

- 1) showed no clinical sign of *infection* with *Theileria* and no *infestation* with tick *vectors* on the day of shipment;
- 2) were kept isolated for at least 35 days prior to shipment in an *establishment* where no *case of infection* with *Theileria* has occurred during the preceding two years;

- 3) were treated with a registered acaricide, the efficacy of which has been confirmed in relation to the area of origin of the animals, at the time of entry into the isolation establishment and then at regular intervals, according to manufacturer's instructions, allowing continuous protection against ticks until their shipment 48 hours prior to entry to the establishment, no more than two days after entering the establishment and three days prior to shipment;
- 4) were subjected to ~~serological and~~ agent detection tests with negative results on samples taken immediately prior to entry and at least 25 days after entry into the isolation establishment and five days before shipment.

Article 14.X.6.

Recommendations for importation of hides and skins from countries or zones not free from infection with *Theileria*

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

- 1) dry-salted or wet-salted for a period of at least 14 days prior to dispatch; or
- 2) treated for a period of at least seven days in salt (NaCl) with the addition of 2% sodium carbonate (Na₂CO₃); or
- 3) dried for a period of at least 42 days at a temperature of at least 20°C; or
- 4) frozen to at least -20°C for at least 48 hours.

Article 14.X.7.

Recommendations for importation of wool and fibre of sheep and goats from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products were subjected to:

- 1) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide or potassium hydroxide; or
- 2) industrial scouring, which consists of the immersion of wool in a water-soluble detergent held at 60–70°C.

Article 14.X.8.

Recommendations for importation of trophies derived from susceptible ~~wild~~ ruminants from countries or zones not free from infection with *Theileria*

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the products have been processed to ensure the destruction of tick *vectors*.

CHAPTER ~~X.16.~~ ~~X.1.~~INFECTION WITH MIDDLE EAST RESPIRATORY
SYNDROME CORONAVIRUSArticle ~~X.X16.1.~~1.

General provisions

Middle East respiratory syndrome (MERS) is a viral respiratory infection of humans and dromedary camels (*Camelus dromedarius*) which is caused by a coronavirus called Middle East Respiratory Syndrome Coronavirus (MERS-CoV).

Dromedary camels (*Camelus dromedarius*) have been confirmed by several studies to be are the natural host and zoonotic source of the MERS-CoV infection in humans. Other species may be susceptible to *infection* with MERS-CoV. However, their epidemiological significance has not been demonstrated.

MERS-CoV has been associated with mild upper respiratory signs in some dromedary camels. While the impact of MERS-CoV on animal health is very low, human infections have a significant public health impact it can causes severe and sometimes fatal disease in humans.

For the purposes of the *Terrestrial Code*, MERS is defined as an *infection* of dromedary camels with MERS-CoV.

The following defines the occurrence of *infection* with MERS-CoV:

- 1) MERS-CoV has been isolated and identified as such in a sample from a dromedary camel; ~~or~~
- 2) ribonucleic acid specific to MERS-CoV has been identified ~~detected~~ in a samples from a dromedary camel showing clinical signs or pathological lesions suggestive of consistent with MERS-CoV, or epidemiologically linked with epidemiological links either to a suspected or confirmed or suspected case of MERS-CoV or to a human infected with MERS-CoV, or from a dromedary camel giving cause for suspicion of previous association or contact with MERS-CoV.

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

CHAPTER ~~X~~8.Y.INFECTION WITH *LEISHMANIA* SPP. (LEISHMANIOSIS)Article ~~X~~8.Y.1.

General provisions

For the purposes of the *Terrestrial Code*, ~~infection with *Leishmania* spp. – leishmaniosis~~ is defined as an *infection* of dogs and cats (hereafter ‘susceptible animal’) by protozoan parasites of the genus *Leishmania*, family *Trypanosomatidae*, order *Kinetoplastida*.

The *infection* is usually transmitted by the bite of an infected ~~*Phlebotomus* sandfly~~ phlebotomine sand fly belonging to the genera *Phlebotomus* (Old World) or *Lutzomyia* (New World).

The following defines the occurrence of *infection* with *Leishmania* spp.:

- 1) *Leishmania* spp. amastigotes have been observed and identified as such in a samples from a ~~dog or a cat~~ susceptible animal; or
- 2) nucleic acid specific to *Leishmania* spp. has been detected in a sample from a ~~dog or a cat~~ susceptible animal showing clinical signs or pathological lesions consistent with infection with *Leishmania* spp., or epidemiologically linked to a confirmed or suspected case, or giving cause for suspicion of previous association or contact with *Leishmania* spp.; or
- 3) antibodies specific to *Leishmania* spp. that are not the consequence of vaccination have been detected in a sample from a ~~dog or a cat~~ susceptible animal showing clinical signs or pathological lesions consistent with infection with *Leishmania* spp., or epidemiologically linked to a confirmed or suspected case, or giving cause for suspicion of previous association or contact with *Leishmania* spp.

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

TERMINOLOGY: USE OF THE TERMS 'FETAL', 'FOETAL', 'FETUS' AND 'FOETUS'

Article 4.10.3.

Procedures for micromanipulation

The term “micromanipulated” covers several different procedures and a variety of specialised microsurgical instruments and other equipment may be used. However, from the standpoint of animal health, any cutting, penetrating or breaching of the integrity of the zona pellucida is an action that can alter the health status of an embryo. To maintain health status during and after micromanipulation, the following conditions should apply:

1. Media

Any product of animal origin, including co-culture cells and media constituents, used in the collection or production of oocytes, embryos or other cells, and in their micromanipulation, culture, washing and storage should be free from pathogenic agents (including transmissible spongiform encephalopathy agents, sometimes called prions). All media and solutions should be sterilised by approved methods in accordance with the Manual of the IETS and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to all fluids and media as recommended in the Manual of the IETS.

2. Equipment

Equipment (e.g. microsurgical instruments which have direct contact with embryos) should either be of the single-use type (disposed of after each oocytes or embryos batch) or should be effectively sterilised between oocytes or embryos batch in accordance with recommendations in the Manual of the IETS.

3. Nuclei for transplantation (“nuclear transfer”)

- a) Where it is intended to transplant nuclei derived from pre-hatching stage (i.e. zona pellucida intact) embryos, the parent embryos from which those nuclei are derived should fulfil the conditions of this chapter. Where nuclei derived from other types of donor cell (e.g. post-hatching stage embryos, embryonic, ~~foetal~~ fetal and adult cells, including spermatozoa or spermatids for ICSI) are to be transplanted, the parent embryo, ~~foetus~~ fetus or animal from which those donor cells originate, and the methods whereby they are derived, including cell culture, should comply with the relevant animal health standards recommended elsewhere in this *Terrestrial Code* and in the *Terrestrial Manual*.
- b) Where it is intended to transplant a nucleus into an intact oocyte (e.g. for ICSI), or into an enucleated oocyte (for nuclear transfer), those oocytes should be collected, cultured and manipulated in accordance with the recommendations in this chapter.

TERMINOLOGY

[...]

SECTION 9. APIDAE APINAE

SECTION 11. BOVIDAE BOVINAE

SECTION 16. CAMELIDAE

Chapter 16.1. Infection with Middle East respiratory syndrome coronavirus

TERMINOLOGY: USE OF THE TERMS 'ENZOOTIC', 'ENDEMIC', 'EPIZOOTIC' AND 'EPIDEMIC'

Article 4.19.1.

Introduction

The purpose of this chapter is to provide recommendations for the preparation, development and implementation of *official control programmes* for *listed* and *emerging diseases*. It is not aimed at providing ready-made fit-for-all solutions, but rather at outlining principles to follow when combating transmissible animal diseases, including zoonoses. Although this chapter focuses primarily on *listed* and *emerging diseases*, the recommendations may also be used by the *Veterinary Authorities* for any *notifiable diseases* or diseases against which they have established *official control programmes*.

The *Veterinary Authority* should determine the diseases against which *official control programmes* are to be prepared, developed and implemented, according to an evaluation of the actual or likely impact of the disease. *Official control programmes* should be prepared by the *Veterinary Authority* and *Veterinary Services* in close collaboration with the relevant stakeholders and other authorities, as appropriate.

When a *listed disease* or *emerging disease* occurs in a Member Country, the *Veterinary Authority* should implement control measures proportionate to the likely impact of the disease in order to minimise its spread and consequences and, if possible, eradicate it. These measures can vary from a rapid response (e.g. to the first occurrence of a disease) to long-term control (e.g. of an endemic disease).

Official control programmes should be justified by rationales developed on the basis of *risk analyses* and taking into account animal health, public health, socio-economic, *animal welfare* and environmental aspects. They should preferably be supported by relevant cost-benefit analysis and should include the necessary regulatory, technical and financial tools.

Official control programmes should be developed with the aim of achieving defined measurable objectives, in response to a situation in which private action is not sufficient. Depending on the prevailing epidemiological, environmental and socio-economic situations, the goal may vary from the reduction of impact to the *eradication* of a given *infection* or *infestation*.

The general components of an *official control programme* should include:

- 1) a plan of the programme to control or eradicate the relevant *infection* or *infestation* in the country or zone;
- 2) appropriate *veterinary legislation*;
- 3) emergency preparedness plans and emergency response plans;
- 4) *surveillance* of the relevant *infection* or *infestation* in accordance with Chapter 1.4.;
- 5) regular and prompt animal disease reporting;
- 6) detection and management of *cases* of the relevant *infection* or *infestation*, to reduce the *incidence* and the *prevalence* by minimising transmission;
- 7) measures implemented to prevent introduction or spread of the relevant *infection* or *infestation*, including *biosecurity* and *sanitary measures* such as movement control;

- 8) a *vaccination* programme, if appropriate;
- 9) measures to protect public health, if appropriate;
- 10) communication and collaboration among all relevant *Competent Authorities*;
- 11) awareness programme for relevant stakeholders including the general public if appropriate.

The critical components of *official control programmes* for diseases that are not present in the country or *zone* are measures to prevent their introduction, an *early warning system*, and a plan for rapid response and effective action, possibly followed by long-term measures. Such programmes should include options for revising or ending them.

Official control programmes and the application of their components should be regularly evaluated. Learning from past *outbreaks*, from both ~~epizootic epidemic~~ or ~~enzootic endemic~~ situations, reviewing the response sequence and revising the methods are critical for adaptation to evolving circumstances and for better future performance. Experiences of the *Veterinary Services* of other Member Countries may also provide useful lessons. Plans should be tested regularly to ensure that they are fit-for-purpose, practical, feasible and well understood, and that staff are proficient and other stakeholders are fully aware of their respective roles and responsibilities.

Article 9.3.1.

General provisions

For the purposes of the *Terrestrial Code*, European foulbrood is a disease of the larval and pupal stages of honey bees (species of the genus *Apis*), caused by *Melissococcus plutonius* (*M.plutonius*), a non-sporulating bacterium, which is widely distributed. Subclinical *infections* are common and require *laboratory* diagnosis. *Infection* remains ~~enzootic endemic~~ because of mechanical contamination of the honeycombs. Recurrences of disease can therefore be expected in subsequent years.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the European foulbrood status of the honey bee population of the *exporting country or zone*.

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