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Activities of the Specialist Commissions

TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Proposed amendments to the *Terrestrial Animal Health Code*

[Technical Working Document]



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I. Overview of technical activities

1. Since the 90th General Session in May 2023, the Terrestrial Animal Health Standards Commission (the Code Commission) met twice, from 5 to 14 September 2023 and from 6 to 16 February 2024. 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 meetings are available on the Delegate's website and the [WOAH website](#).
2. This document provides some background information for each of the new and revised texts of the *Terrestrial Code* that will be proposed for adoption at the 91st General Session in May 2024. When revising these texts, the Code Commission considered comments submitted by Members and by International Organisations that have a Cooperation Agreement with WOA, recommendations from several *ad hoc* Group reports, as well as subject-matter experts. The Code Commission also worked in close cooperation with the Scientific Commission for Animal Diseases (the Scientific Commission), the Biological Standards Commission, the Aquatic Animal Health Standards Commission and WOA Working Groups.
3. Details of the Code Commission's considerations of comments received on draft texts circulated for comment were provided in the Commission's [September 2023](#) and [February 2024](#) reports. **The Commission encourages Members to refer to these reports for more details on the amended texts to be proposed for adoption.**
4. The amendments to the *Terrestrial Code* presented in Annexes 4 to 21 will be proposed for adoption at the 91st General Session. The annex numbers used in this document align with the annex numbers provided in the Code Commission's February 2024 report.

1. *Terrestrial Code* texts to be proposed for adoption

1.1 Chapter 4.6. 'General hygiene in semen collection and processing centres' (Annex 7)

5. Chapter 4.6. has undergone a comprehensive revision. An *ad hoc* Group was convened to revise Chapter 4.6. 'General hygiene in semen collection and processing centres' and Chapter 4.7. 'Collection and processing of bovine, small ruminant and porcine semen' ([meeting reports](#)).
6. The revised text has been circulated four times, the first time in the September 2022 Code Commission report.
7. The revised Chapter 4.6. 'General hygiene in semen collection and processing centres' is presented in Annex 7 and will be proposed for adoption at the 91st General Session in May 2024.

1.2 Chapter 4.7. 'Collection and processing of bovine, small ruminant and porcine semen' (Annex 8)

8. Noting that the revised Chapter 4.6. will be proposed for adoption at the 91st General Session, the Code Commission agreed to propose the deletion of Articles 4.7.5., 4.7.6. and 4.7.7. of Chapter 4.7. 'Collection and processing of bovine, small ruminant and porcine semen' to remove any inconsistencies between Chapters 4.6 and 4.7 if the revised Chapter 4.6. is adopted.
9. The revised text has been circulated two times, the first time in the September 2023 Code Commission report.

10. The revised Chapter 4.7. 'Collection and processing of bovine, small ruminant and porcine semen' is presented in Annex 8 and will be proposed for adoption at the 91st General Session in May 2024.

1.3 Chapter 6.10. 'Responsible and prudent use of antimicrobial agents in veterinary medicine' (Annex 9)

11. Chapter 6.10. has undergone a comprehensive revision in response to Member comments. The Commission agreed not to commence the revision until the Codex Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005) had been adopted to avoid potential inconsistencies between the respective texts.
12. The revised chapter was drafted by the WOAHA Working Group on Antimicrobial Resistance (Working Group) and the Working Group has been consulted to address some comments received.
13. The revised text has been circulated three times, the first time in the September 2022 Code Commission report.
14. The Code Commission also requested the Biological Standards Commission to provide its opinion on specific comments, which were considered, and will be addressed by the revision of the corresponding *Terrestrial Manual* chapter ([February 2023 report](#)).
15. The revised Chapter 6.10. 'Responsible and prudent use of antimicrobial agents in veterinary medicine' is presented in Annex 9 and will be proposed for adoption at the 91st General Session in May 2024.

1.4 Chapter 7.5. 'Slaughter of animals' (Annexes 10 and 11)

16. Chapter 7.5. has undergone a comprehensive revision. An *ad hoc* Group was convened to undertake this work as well as the revision of associated Glossary definitions ([meeting reports](#)).
17. The revised text has been circulated five times, the first time in the February 2021 Code Commission report.
18. The revised Chapter 7.5. 'Slaughter of animals' is presented in Annex 10 (in track change) and Annex 11 (clean text) and will be proposed for adoption at the 91st General Session in May 2024

1.5 Chapter 8.8. 'Infection with foot and mouth disease virus' (Annex 12)

19. 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 ([June 2016](#) and [June 2020](#) 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.
20. The revised chapter was proposed for adoption at the 90th General Session in May 2023 but due to diverging views expressed by Members on the proposed text and some inconsistencies in the proposed text, the President of the Code Commission decided to withdraw the proposed chapter so that the Commission could consider the comments raised and further revise the text to address the different points of view. Since then, the Code Commission further reviewed the text considering comments received, together with the inputs from the Biological Standards Commission, the Scientific Commission and experts.
21. The revised text has been circulated eight times, the first time in the September 2015 Code Commission report.

22. The revised Chapter 8.8. 'Infection with foot and mouth disease virus' is presented in Annex 12 and will be proposed for adoption at the 91st General Session in May 2024.

1.6 Chapter 1.11. 'Application for official recognition by WOA of free status for foot and mouth disease' (Annex 13)

23. Chapter 1.11. has been revised to ensure alignment with amendments proposed for the revised Chapter 8.8. 'Infection with foot and mouth disease virus'.
24. The revised chapter was drafted by the Code Commission in collaboration with the Scientific Commission.
25. The revised text has been circulated twice, the first time in the September 2023 Code Commission report.
26. The revised Chapter 1.11. 'Application for official recognition by WOA of free status for foot and mouth disease' is presented in Annex 13 and will be proposed for adoption at the 91st General Session in May 2024.

1.7 Article 8.16.8. of Chapter 8.16. 'Infection with Rift Valley fever virus' (Annex 14)

27. Article 8.16.8. of Chapter 8.16. has been revised to address the recommendations of the Biological Standards Commission to align this article with the revised Chapter 3.1.19. 'Rift Valley fever (Infection with Rift Valley fever virus)' of the *Terrestrial Manual*, which was adopted at the 90th General Session in May 2023.
28. The revised text has been circulated twice, the first time in the September 2023 Code Commission report.
29. The revised Article 8.16.8. of Chapter 8.16. 'Infection with Rift Valley fever virus' is presented in Annex 14 and will be proposed for adoption at the 91st General Session in May 2024.

1.8 Article 8.18.1. of Chapter 8.18. 'Infection with *Trichinella* spp.' (Annex 15)

30. Article 8.18.1. of Chapter 8.18. has been revised to address the recommendations of the Biological Standards Commission to align this article with the revised Chapter 3.1.22. 'Trichinellosis (Infection with *Trichinella* spp.)' of the *Terrestrial Manual*, which was adopted at the 90th General Session in May 2023.
31. The revised text has been circulated twice, the first time in the September 2023 Code Commission report.
32. The revised Article 8.18.1. of Chapter 8.18. 'Infection with *Trichinella* spp.' is presented in Annex 15 and will be proposed for adoption at the 91st General Session in May 2024.

1.9 Chapter 8.X. 'Infection with *Coxiella burnetii* (Q Fever)' (Annex 16)

33. A new Chapter 8.X. has been developed to include a single article for general provisions, including a definition of its occurrence, to provide Members with precise definitions to fulfil their notification obligations.
34. The new chapter was developed by the Code Commission based on a case definition drafted by experts and reviewed by the Scientific Commission.
35. The revised text has been circulated four times, the first time in the September 2022 Code Commission report.

36. The new Chapter 8.X. 'Infection with *Coxiella burnetii* (Q Fever)' is presented in Annex 16 and will be proposed for adoption at the 91st General Session in May 2024.

1.10 Chapter 8.Z. 'Infection with *Trypanosoma evansi* (Surra)' (Annex 17)

37. A new Chapter 8.Z. has been developed to address surra of multiple species, including equids. This work is also part of the work that led to the adoption, in May 2021, of the new Chapter 8.18. 'Infection with *Trypanosoma brucei*, *T. congolense*, *T. simiae* and *T. vivax*'.
38. An *ad hoc* Group was convened to draft the new chapter and address comments received. The text has been reviewed by the Code Commission with the input of the Scientific Commission along this process.
39. The revised text has been circulated three times, the first time in the February 2023 Code Commission report.
40. The new Chapter 8.Z. 'Infection with *Trypanosoma evansi* (Surra)' is presented in Annex 17 and will be proposed for adoption at the 91st General Session in May 2024.

1.11 Articles 13.2.1. and 13.2.2. of Chapter 13.2. 'Rabbit haemorrhagic disease' (Annex 18)

41. Articles 13.2.1. and 13.2.2. of Chapter 13.2. have been revised to include a new definition of its occurrence to provide Members with precise definitions to fulfil their notification obligations.
42. These articles were revised by the Code Commission based on a case definition drafted by experts and reviewed by the Scientific Commission.
43. The revised text has been circulated three times, the first time in the February 2023 Code Commission report.
44. The revised Articles 13.2.1. and 13.2.2. of Chapter 13.2. 'Rabbit haemorrhagic disease' is presented in Annex 18 and will be proposed for adoption at the 91st General Session in May 2024.

1.12 Article 15.1.2. of Chapter 15.1. 'Infection with African swine fever virus' (Annex 19)

45. Article 15.1.2. of Chapter 15.1. has been revised to amend the list of safe commodities following Members' comments.
46. The revised text has been circulated twice, the first time in the September 2023 Code Commission report.
47. The revised Article 15.1.2. of Chapter 15.1. 'Infection with African swine fever virus' is presented in Annex 19 and will be proposed for adoption at the 91st General Session in May 2024.

1.13 Chapter 16.Z. 'Infection with *Camelpox virus*' (Annex 20)

48. A new Chapter 16.Z. has been developed to include a single article for the general provisions, including a definition of its occurrence, to provide Members with precise definitions to fulfil their notification obligations.
49. The new chapter was developed by the Code Commission based on a case definition drafted by experts and reviewed by the Scientific Commission.

50. The proposed new text has been circulated four times, the first time in the September 2022 Code Commission report.

51. The new Chapter 16.Z. 'Infection with Camel pox virus' is presented in Annex 20 and will be proposed for adoption at the 91st General Session in May 2024.

1.14 *Glossary: 'animal product', 'biological product', 'commodity', 'death', 'euthanasia', 'germinal products', 'greaves', 'semen collection centre', 'slaughter' and 'stunning' (Annex 4)*

'Animal product', 'germinal products' and 'commodity'

52. The Code Commission revised the Glossary definition for 'commodity' and developed new definitions for 'animal product' and 'germinal products' to clarify the use of these terms in the Terrestrial Code.

53. The new and revised definitions have been circulated three times, the first time in the February 2023 Code Commission report.

'Biological product'

54. As part of the work noted in the point above, the Code Commission, in consultation with the Biological Standards Commission, developed a new Glossary definition for 'biological product'.

55. This new definition has been circulated twice, the first time in the September 2023 Code Commission report.

'Artificial insemination centre' and 'semen collection centre'

56. As part of the work to revise Chapter 4.6. 'General hygiene in semen collection and processing centres', the Code Commission agreed to replace the Glossary definition for 'artificial insemination centre' with 'semen collection centre'.

57. The revised text has been circulated twice, the first time in the September 2023 Code Commission report.

'Greaves'

58. The Code Commission agreed to delete the Glossary definition for 'greaves', as it considered it was redundant given the new Glossary definition for 'protein meal' adopted at the 90th General Session in May 2023.

59. The revised text has been circulated twice, the first time in the September 2023 Code Commission report.

'Death', 'euthanasia', 'slaughter' and 'stunning'

60. As part of the work to revise Chapter 7.5. 'Animal welfare during slaughter', the Code Commission agreed to revise the Glossary definitions for 'euthanasia', 'slaughter' and 'stunning', and to delete the definition for 'death'.

61. The amendments were circulated at the same time as the revised Chapter 7.5.

62. The revised Glossary definitions for 'commodity', 'euthanasia', 'slaughter' and 'stunning'; the replacement of the Glossary definition for 'artificial insemination centre' with 'semen collection centre'; the deletion of definitions for 'greaves' and 'death'; and the new Glossary definitions for 'animal product', 'germinal products', and 'biological product' are presented in Annex 4 and will be proposed for adoption at the 91st General Session in May 2024.

1.15 Chapter 1.3. 'Diseases, infections and infestations listed by WOAH' (Annexes 5 and 6)

63. Chapter 1.3. has been revised to address several issues noted during recent work on the development of new or revised disease-specific chapters. Amendments include:
- reorder the articles to align with the order used in Sections of Volume II;
 - align the animal categories noted in the first paragraph of each article with the titles of relevant Sections of Volume II, i.e., scientific names of animal categories, using 'nouns', not 'adjectives' (e.g. replace 'The following are included within the category of equine diseases and infections' with 'The following are included within the category of diseases and infections of equidae.');
 - reorder the diseases in each article so they are in alphabetical order; and
 - amend disease names to align with the title of the corresponding disease-specific chapter, as relevant.
64. The Code Commission also proposed the following revisions to names of the following listed diseases to align with proposed amendments to relevant disease-specific chapters:
- in Article 1.3.1., replace 'Q fever' with 'Infection with *Coxiella burnetii* (Q fever)';
 - in Article 1.3.1., replace 'Surra (*Trypanosoma evansi*)' with 'Infection with *Trypanosoma evansi* (Surra)';
 - in the current Article 1.3.2., replace 'Bovine viral diarrhoea' with 'Infection with bovine pestiviruses (Bovine viral diarrhoea)';
 - in the current Article 1.3.4., replace 'Contagious equine metritis' with 'Infection with *Taylorella equigenitalis* (Contagious equine metritis)';
 - in the current Article 1.3.4., replace 'Equine piroplasmiasis' with 'Infection with *Theileria equi* and *Babesia caballi* (Equine piroplasmiasis)';
 - in the current Article 1.3.7., replace 'Rabbit haemorrhagic disease' with 'Infection with pathogenic rabbit lagoviruses (Rabbit haemorrhagic disease)';
 - in Article 1.3.9. to replace 'Camelpox' with 'Infection with camelpox virus'.

65. The revised Chapter 1.3. 'Diseases, infections and infestations listed by WOAH' is presented in Annex 5 (in track change) and Annex 6 (clean text) and will be presented for adoption at the 91st General Session in May 2024.

1.16 Use of terms 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' (Annex 21)

66. The amendments proposed are to ensure consistent usage of the revised Glossary definitions, adopted in 2022, for 'Competent Authority', 'Veterinary Authority' and 'Veterinary Services' used throughout relevant sections of the *Terrestrial Code*.
67. These amendments have been developed in coordination with the Aquatic Animals Commission, who has proposed amendments for the usage of 'Aquatic Animal Health Services', 'Competent Authority' and 'Veterinary Authority' throughout the *Aquatic Code*.
68. The revised texts have been circulated three times, the first time in the February 2023 Code Commission report.
69. The revised texts are presented in Annex 21 and will be proposed for adoption at the 91st General Session in May 2024.

2. Annexes

Annex 4

GLOSSARY

ANIMAL PRODUCTS

means any parts of an animal, and or a raw or manufactured products containing any material derived from animals, excluding germinal products, biological products and pathological material.

BIOLOGICAL PRODUCTS

means a products of animal or microorganism origin, used as reagents in the diagnosis of diseases, for treatment, control and prevention of diseases, and or in the collection and processing of germinal products.

COMMODITY

means a live animals, an animal products of animal origin, animal genetic material, germinal products, a biological products and or pathological material.

DEATH

means the irreversible permanent loss of all vital functions brain activity demonstrable by the loss of brain stem reflexes. This may be confirmed through a combination of criteria such as dilated pupil and absence of corneal reflex, cardiac activity and breathing.

EUTHANASIA

means the killing of an animal act of inducing death for welfare purposes using a method that causes a rapid and irreversible loss of consciousness with minimum pain and distress to animal.

GERMINAL PRODUCTS

means animal semen, oocytes, embryos and or hatching eggs.

GREAVES

means the protein-containing residue obtained after the partial separation of fat and water during the process of rendering.

ARTIFICIAL INSEMINATION CENTRE/SEMEN COLLECTION CENTRE

means an approved facility approved by the Veterinary Authority and which that meets the conditions set out in the *Terrestrial Code* for the collection, processing and/or storage of semen.

SLAUGHTER

means the any killing procedure that causes the death of an animal by bleeding of an animals primarily intended for human consumption.

STUNNING

means any mechanical, electrical, chemical or other procedure that causes rapid immediate loss of consciousness for the purpose of killing without minimal avoidable distress, fear and pain and other types of and suffering for the purpose of killing; when used before slaughter, the loss of consciousness lasts until death from the slaughter process; in the absence of slaughter, the procedure would allow the animal to recover consciousness.

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY
WOAH

Preamble

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

In case of modifications of this list adopted by the World Assembly of WOA H 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* of multiple species:

- Anthrax
- Crimean Congo hemorrhagic fever
- Equine encephalomyelitis (Eastern)
- Heartwater
- Infection with Aujeszky's disease virus
- Infection with bluetongue virus
- Infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*
- Infection with *Coxiella burnetii* (Q fever)
- Infection with *Echinococcus granulosus*
- Infection with *Echinococcus multilocularis*
- Infection with epizootic hemorrhagic disease virus
- Infection with foot and mouth disease virus
- Infection with *Leishmania* spp. (Leishmaniosis)
- Infection with *Mycobacterium tuberculosis* complex
- Infection with rabies virus
- Infection with Rift Valley fever virus
- Infection with rinderpest virus
- Infection with *Trichinella* spp.
- Infection with *Trypanosoma brucei*, *Trypanosoma congolense*, *Trypanosoma simiae* and *Trypanosoma vivax*

- Infection with *Trypanosoma evansi* (Surra)
- Japanese encephalitis
- New World screwworm (*Cochliomyia hominivorax*)
- Old World screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Surra (*Trypanosoma evansi*)
- Tularemia
- West Nile fever.

Article 1.3.24.

The following are included within the category of ~~bovine~~ diseases and infections of bovinæ:

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- ~~Bovine viral diarrhoea~~
- Enzootic bovine leukosis
- Haemorrhagic septicaemia (*Pasteurella multocida* serotypes 6:b and 6:e)
- Infection with bovine pestiviruses (Bovine viral diarrhoea)
- Infection with lumpy skin disease virus
- Infection with *Mycoplasma mycoides* subsp. *mycoides* (Contagious bovine pleuropneumonia)
- Infection with *Theileria annulata*, *Theileria orientalis* and *Theileria parva*
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Trichomonosis.

Article 1.3.37.

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

- 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 1.3.45.

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

- ~~— Contagious equine metritis~~
- Dourine
- Equine encephalomyelitis (Western)
- Equine infectious anaemia
- ~~— Equine piroplasmosis~~
- Infection with African horse sickness virus
- Infection with *Burkholderia mallei* (Glanders)
- Infection with equid herpesvirus-1 (Equine rhinopneumonitis)
- Infection with equine arteritis virus
- Infection with equine influenza virus
- Infection with *Taylorella equigenitalis* (Contagious equine metritis)
- Infection with *Theileria equi* and *Babesia caballi* (Equine piroplasmosis)
- Venezuelan equine encephalomyelitis.

Article 1.3.58.

The following are included within the category of ~~swine~~ diseases and infections of suidae:

- 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 1.3.63.

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

- 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 1.3.76.

The following are included within the category of ~~leporids~~ diseases and infections of leporidae:

- Infection with pathogenic rabbit lagoviruses (Rabbit haemorrhagic disease)
- Myxomatosis₂
- ~~Rabbit haemorrhagic disease.~~

Article 1.3.82.

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

- 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 ~~camelids~~ diseases and *infections of camelidae*:

- Infection with Camelpox virus
 - Infection of with Middle East respiratory syndrome coronavirus.
-

CHAPTER 1.3.

DISEASES, INFECTIONS AND INFESTATIONS LISTED BY
WOAH

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 WOAHP 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 diseases, *infections* and *infestations* of multiple species:

- Anthrax
- Crimean Congo hemorrhagic fever
- Equine encephalomyelitis (Eastern)
- Heartwater
- Infection with Aujeszky's disease virus
- Infection with bluetongue virus
- Infection with *Brucella abortus*, *Brucella melitensis* and *Brucella suis*
- Infection with *Coxiella burnetii* (Q fever)
- Infection with *Echinococcus granulosus*
- Infection with *Echinococcus multilocularis*
- Infection with epizootic hemorrhagic disease virus
- Infection with foot and mouth disease virus
- Infection with *Leishmania* spp. (Leishmaniosis)
- Infection with *Mycobacterium tuberculosis* complex
- Infection with rabies virus
- Infection with Rift Valley fever virus
- Infection with rinderpest virus
- Infection with *Trichinella* spp.
- Infection with *Trypanosoma brucei*, *Trypanosoma congolense*, *Trypanosoma simiae* and *Trypanosoma vivax*

- Infection with *Trypanosoma evansi* (Surra)
- Japanese encephalitis
- New World screwworm (*Cochliomyia hominivorax*)
- Old World screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Tularemia
- West Nile fever.

Article 1.3.2.

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

- 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 1.3.3.

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

- 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 1.3.4.

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

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- Enzootic bovine leukosis
- Haemorrhagic septicaemia (*Pasteurella multocida* serotypes 6:b and 6:e)
- Infection with bovine pestiviruses (Bovine viral diarrhoea)
- Infection with lumpy skin disease virus
- Infection with *Mycoplasma mycoides* subsp. *mycoides* (Contagious bovine pleuropneumonia)
- Infection with *Theileria annulata*, *Theileria orientalis* and *Theileria parva*
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Trichomonosis.

Article 1.3.5.

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

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

Article 1.3.6.

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

- Infection with pathogenic rabbit lagoviruses (Rabbit haemorrhagic disease)
- Myxomatosis.

Article 1.3.7.

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

- 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 1.3.8.

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

- 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 1.3.9.

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

- Infection with camelpox virus
- Infection of with Middle East respiratory syndrome coronavirus.

CHAPTER 4.6.

~~GENERAL HYGIENE IN SEMEN COLLECTION, PROCESSING AND STORAGE~~

Article 4.6.1.

General provisions

The objective of this chapter is to provide recommendations that ~~will aim at~~ reducing the likelihood of introduction and spread of *listed diseases* and contamination of fresh, chilled, or frozen semen ~~of from~~ various species of donor animals with ~~potentially~~ pathogenic agents in a *semen collection centre*.

1) This chapter provides recommendations on:

- 1a) procedures for the collection, processing, and storage of semen ~~of from~~ bovine, ovine, caprine, porcine, equine, and cervid donor animals;
- 2b) ~~biosecurity measures for the operation of semen collection centres;~~
- 3c) conditions applicable to the management and housing of semen donor animals and teasers.

~~This chapter provides a comprehensive framework for processes that can be applied to reduce the likelihood of transmission of listed diseases in through semen.~~ *Veterinary Services* play a key role in identifying, assessing, and managing disease risk posed by the collection, processing, and storage of semen from various species of donor animals in a *semen collection centre* and establishing appropriate measures to minimize this risk. The *Veterinary Authority* should provide the regulatory standards and ~~for~~ oversight to ensure that the recommendations in this chapter, as appropriate, are complied with.

~~Although this chapter is focused on reducing the probability of transmitting listed diseases through international trade of semen, t~~The recommendations in this chapter ~~may also be appropriately applied when to~~ semen is collected, processed, and stored for international trade or for domestic distribution.

Recommendations on *animal welfare* in accordance with the principles in Chapter 7.1. of the Terrestrial Code ~~are applicable should be applied~~ to the animals kept within the *semen collection centre*, ~~in accordance with relevant articles in Chapter 7.1. of the Terrestrial Code.~~

Recommendations regarding specific animal health requirements for donor animals to provide assurance of the absence of selected *listed diseases*, *infections* and *infestations* are found in Chapter 4.7. and ~~other~~ relevant disease-specific chapters.

2) For the purposes of the *Terrestrial Code*, the *semen collection centre* ~~is comprised of~~:

- 1a) animal accommodation facilities;
- 2b) semen collection facilities;
- 3c) semen processing facilities, including mobile ~~laboratories~~ processing units;
- 4d) semen storage facilities;
- 5e) administration offices.

The listed facilities may be ~~on in~~ one location or consist of single or multiple ~~facility~~ entity ~~on in~~ several locations.

3) For the purposes of this chapter, 2:

- 1a) 'biosecure' refers to the state of a place or facility, in which *biosecurity* is ~~effectively~~ implemented effectively;
- 2b) 'resident facility' means a biosecure animal accommodation facility where donor and teaser animals are kept for the purpose of semen collection;
- 3c) 'pre-entry isolation facility' means a biosecure animal accommodation facility where donor and teaser animals are subjected to testing prior to entering the resident facility;
- 4d) '~~germplasm cryogenic storage tank~~' means a sealable ~~canister~~ tank for storage and transport of frozen semen, embryos or oocytes.

Article 4.6.2.

General conditions applicable to semen collection centres

~~For the approval of the semen collection centre should be approved by the Veterinary Authority.~~

~~For that purpose, the Veterinary Services should conduct regular audits of *biosecurity plans*, protocols, procedures and records on the health of the animals in the *semen collection centre* and on the hygienic production, storage and dispatch of semen, at least annually, and request and verify appropriate corrective actions, if needed.~~

Each facility in the *semen collection centre* should be under the direct supervision of a *veterinarian* who is responsible for ensuring that, in the facilities under its their supervision, the health, and welfare of animals are monitored, ~~and the *biosecurity plan* in the facilities under his/her supervision are is implemented~~, and all documentation including records of procedures is kept current and accessible. The supervising veterinarian should communicate directly with the Veterinary Services in the event of a disease incursion or serious adverse hygiene event.

Animal identification, animal traceability, and movement *registration* should be in accordance with Chapter 4.2. and Chapter 4.3.

The *semen collection centre* should implement and document processes that ensure identification and traceability of semen from collection to processing ~~and~~ storage and final dispatch from the semen storage facility. Fresh, chilled, or frozen semen products ~~stored and/or~~ dispatched from the semen storage facility should be identified ~~in accordance with the national regulation~~ to allow accurate and transparent identification of the donor animal, where the semen was collected ~~and/or~~ processed, and when it was collected.

Donor and teaser animals should be ~~maintained~~ kept in animal accommodation facilities separately from animals not associated with the *semen collection centre* ~~or maintained in separate animal accommodation facilities that may have a different animal health status~~.

Biosecurity plans should be developed for the *semen collection centre* in accordance with a *risk analysis* and should, at a minimum, address the following ~~for each facility~~:

- 1) Personnel ~~on at~~ the *semen collection centre* should be technically competent and apply ~~high standards of personal hygiene~~, to prevent the introduction of pathogenic agents. Personnel should receive regular training and demonstrate competency ~~of in~~ skills applicable to the *semen collection centre* and covering ~~his/her~~ their specific responsibilities at the centre, which are documented.
- 2) In general, only donor and teaser animals of the same species should be permitted ~~to at~~ the *semen collection centre*. All donor and teaser animals should meet the ~~animal health status~~ health requirements as determined by the *semen collection centre* and comply with the regulations set out by the *Veterinary Authority*. If other animals are needed ~~on at~~ the *semen collection centre*, such as dogs for herding purposes, these should be kept ~~on at~~ the *semen collection centre* and not transferred from one establishment to another, and measures to prevent their contacts with *wildlife* should be implemented. ~~If other species are needed may be resident on at the semen collection centre, provided that appropriate pre-entry tests should have been conducted and biosecurity is should be in place to ensure they meet the animal health status health requirements as determined by the semen collection centre prior to entry. These animals should be kept in separate biosecure animal accommodation facilities that are physically separate from animals associated with semen production.~~

3) Isolation facilities should be washed and disinfected prior to the admittance of each new group of animals. Animals exhibiting any signs of illness upon arrival or during the isolation period should be removed to a separate area.

4) Natural mating should be avoided for at least ~~four weeks~~ 30 days prior to entry into the pre-entry isolation facility and ~~avoided~~ should not occur after entry into the animal accommodation facility or semen collection facility.

- 54) Measures should be in place to prevent the entry of ~~wildlife-wild or feral animals-animals~~ (including rodents, and arthropods) or other domestic animals susceptible to pathogenic agents transmissible to the animals in the *semen collection centre*.
- 65) In accordance with a *biosecurity plan*:
- ia) ~~The~~ entry of visitors to any part of the *semen collection centre* where *biosecurity* is required should only be allowed if authorised and controlled;
 - ib) Appropriate protective clothing and footwear only for use within the *semen collection centre* facilities should be provided;
 - ic) Footbaths should be provided, where necessary, and regularly cleaned and the disinfectant renewed based on the manufacturer's recommendations;
 - id) any additional measures such as complete change of clothing or shower may be required depending on the risks; and
 - ie) Records should be kept of the daily movements of all staff and visitors that enter the *semen collection centre*.
- 76) Appropriate *disinfection* of work areas and equipment should be implemented and documented regularly by trained and competent staff.
- 7) ~~Control measures should be in place to minimise the entry of insects and rodents.~~
- 88) Vehicles for the transport of animals, *feed*, and waste and manure removal should be used in a manner which minimises health risks to animals in the *semen collection centre*.
- 98) Up-to-date and accessible records should be kept of all movements of animals and *germinal products* associated with the *semen collection centre* to ensure *traceability*.

For the approval of the *semen collection centre* by the *Veterinary Authority*, the *Veterinary Services* should conduct regular audits of *biosecurity plans, protocols, procedures and records on the health of the animals in the semen collection centre and on the hygienic production, storage and dispatch of semen, at least annually, and request and verify appropriate corrective actions, if needed.*

Article 4.6.3.

Recommendations applicable to animal accommodation facilities

Animal accommodation facilities should be designed so that cleaning and *disinfection* measures ~~are easy and efficient to can be implemented efficiently.~~ Individual and group housing pens should be kept clean ~~and the bedding renewed as often as necessary to ensure it is dry and clean.~~

The animal accommodation facilities should include dedicated areas for *feed* storage, ~~for~~ manure storage, bedding storage, and for the isolation of any sick animals. Animal accommodation facilities should be species-specific, where relevant.

There should be a separate pre-entry isolation facility that is managed as a separate biosecure facility for holding animals that are required to complete testing and isolation prior to entry to the resident facility. Procedures for animal identification, blood sampling and vaccination of animals within the *semen collection centre* should be conducted in accordance with relevant recommendations in the *Terrestrial Code*. In the instance where the *Veterinary Authority* has determined that a pre-entry isolation facility is not required, such as for the collection of equine semen, pre-entry conditions ~~to for~~ entering the resident facility or semen collection facility should be included in the *biosecurity plan* of the *semen collection centre*.

The decision to house animals indoors or outdoors will be determined by the *semen collection centre* in accordance with the *biosecurity plan*. Donor animals and teasers that are housed outdoors, or allowed access outdoors, should be accommodated to minimise *vector* attacks and adequately protected from adverse weather conditions. ~~Donor animals and teasers that are housed indoors, should be accommodated to allow for adequate ventilation and proper footing and bedding.~~

All donor and teaser animal accommodations should be adapted to the needs of the species of donor ~~being collected~~. Watering and feeding systems should be constructed so that ~~it~~ they provides minimum contact between donor animals and can be easily cleaned.

Bedding should be clean and dry, soft, and easy to spread and remove. Bedding should be removed regularly and replaced, following thorough cleaning and *disinfection* of relevant surfaces.

Feed and bedding material should be kept in a dry place ~~and~~ stored in a manner to prevent access by *wildlife* or pests, and stored in conditions that are well monitored.

Manure, litter, and bedding material should be disposed of in such a way as to prevent the transmission of diseases ~~and be in compliance with all relevant health and environmental legislation~~.

Article 4.6.4.

Recommendations applicable to semen collection and semen collection facilities

The semen collection facility can be co-located with the resident facility and share *biosecurity* to accommodate the same designated *animal health status* ~~of as~~ the resident facility. If the semen collection facility is co-located with a resident facility, the semen collection facility should not be used to collect from other donor animals not housed in the resident facility. If the semen collection facility is a separate facility, *biosecurity* should be in place to allow only animals ~~of that meet~~ the same *animal health status* health requirements to be permitted entry into that facility.

Donors and teaser animals should be kept and prepared in such a way as to facilitate the hygienic collection of semen. Donor animals should be dry and clean when arriving in the semen collection area.

~~Donor animals~~ Semen should be collected from donor animals in the semen collection facility and not ~~collected~~ in the resident facility. Any exception should be justified and adequately managed by the *biosecurity plan*.

In addition to point 5 of Article 4.6.2., Personnel and visitors ~~should~~ may be provided with specific protective clothing and footwear for use only at the semen collection facilities and worn at all times, and waiting periods before re-entering the centre can be required.

Equipment used for the animals should be dedicated to the semen collection facility and ~~or, if not new,~~ disinfected before being introduced to the *semen collection* centre. All other equipment and tools brought ~~on~~ to the ~~premises~~ *semen collection facility* should be examined and *disinfected*, if necessary, to minimise the introduction of pathogenic agents.

The semen collection facility and associated equipment should be designed in such a way as to allow for effective cleaning and *disinfection*, where applicable.

The floor of the mounting area should be clean and provide safe footing. When rubber mats are used, they should be cleaned after each collection.

Preputial orifices of donor animals should be clean and free of excessive hair or wool to avoid contamination of the semen. Hair or wool at the preputial orifice should be regularly trimmed as needed but not completely removed to avoid excessive irritation of the preputial mucosa while urinating.

Hair or wool on the hindquarters of teaser animals should be kept short to avoid contamination during the collection process. A teaser animal should have its hindquarters thoroughly cleaned before each collection session. A plastic apron can be used to cover the hindquarters of the teaser animal, but the apron should be replaced with a clean apron or thoroughly cleaned and *disinfected* between donor animals.

A dummy mount, if used, should be made of a material that is easy to clean and disinfect and should be thoroughly cleaned after each collection. Disposable plastic covers may be used.

When used, ~~the an~~ artificial vagina should be cleaned completely after each collection. It should be dismantled, washed, rinsed, dried, and protected from dust. The inside of the body of the device and the cone should be *disinfected* before re-assembly using *disinfection* procedures approved by the *Veterinary Authority*.

Lubricant used in the artificial vagina should be new and the equipment used to spread the lubricant should be clean and free of dust.

The artificial vagina should be handled in a manner to prevent dirt and debris from entering.

When successive ejaculates are being collected from the same donor, a new artificial vagina should be used for each collection to prevent any contamination. The artificial vagina should also be changed when the animal has inserted its penis without ejaculating.

All semen should be collected into a labelled sterile receptacle, either disposable or sterilised by autoclaving or heating and kept clean prior to use.

After semen collection, the receptacle should be left attached to the cone within its sleeve or sheath until it has been removed from the *semen* collection area ~~facility~~ to the laboratory *semen processing facility*.

During collection, the technician should wear disposable gloves and change them between donor animals.

Article 4.6.5.

General principles applicable to semen processing and semen processing facilities

The semen processing facility should be physically separated from ~~the other~~ semen collection facilities and may include separate areas for the preparation and cleaning of artificial vaginas, semen evaluation and processing, semen pre-storage and storage.

The semen processing facility should be constructed with materials that permit effective cleaning and *disinfection*, in accordance with Chapter 4.14.

Entry to the facility should be restricted to authorised personnel only.

Protective clothing for use only in the semen processing facility should be provided and worn at all times.

The facility and its equipment should be regularly cleaned and well maintained. Work surfaces for semen evaluation and processing should be regularly cleaned and disinfected.

Only semen from the same species and from donors ~~that meet with~~ the same ~~health requirements~~ *animal health status* should be processed at the same time. Semen from donors ~~that do not meet with a different~~ ~~the same health requirements~~ *animal health status* or from different species may be processed consecutively if appropriate hygienic measures in accordance with the *biosecurity plan* have been implemented.

Semen should be collected ~~and processed~~ in a manner that ensures accurate identification and traceability of collecting tubes from the time of semen collection until storage.

All containers and instruments used for the collection, processing, preservation or freezing of semen should be single-use or be cleaned and disinfected or sterilised before use, depending on the manufacturer's instructions.

~~If not immediately processed,~~ The receptacle containing freshly collected semen should be ~~stoppered or covered in a way~~ to prevent contamination as soon as possible after collection, until processing. During processing, containers containing the semen should be ~~stoppered or covered~~ during times when diluent or other components are not being added.

Equipment used for gender-sorting of sperm should be clean and disinfected between ejaculates in accordance with the recommendations of the manufacturer. Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from animals ~~of that meet~~ the same ~~health requirements~~ *animal health status*.

Recommendations regarding the use of diluents for processing semen:

- 1) Buffer solutions used in diluents prepared on the premises should be sterilised ~~by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes)~~ or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additives, or antibiotics.
- 2) In the case of ready-to-use commercial extenders, the manufacturer's recommendations should be followed.
- 3) If the constituents of a diluent are supplied in commercially available powder form, the water used ~~for preparing the semen diluent~~ should have been distilled or demineralised, sterilised ~~(121°C for 30 minutes or equivalent)~~, stored correctly and allowed to cool before use.
- 4) Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product should be free from pathogenic agents or sterilised; ~~milk heat treated at 92°C for 3–5 minutes, eggs from SPF flocks when available.~~ When ~~an~~ egg yolk ~~only~~ is used ~~as the extender~~, it should be separated from the egg white using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption ~~may be used,~~ or egg yolk treated ~~by, for example, pasteurisation or irradiation~~ to reduce bacterial contamination. Commercial ~~UHT-ultra-high temperature (UHT) milk or powdered skimmed~~ milk for human consumption may be used. Other additives should be sterilised before use.
- 5) Diluent should be stored according to ~~the~~ manufacturer's instructions. Storage vessels should be ~~stoppered~~ closed.

- 6) Antibiotics may be added to the diluent to minimise the growth of bacterial contaminants or control specific venereal pathogens that may be present in semen. The names of the antibiotics and their concentration should be recorded.

Article 4.6.6.

General principles applicable to semen storage and storage facilities

Semen storage facilities and ~~cryogenic germplasm storage~~ tanks should allow for easy cleaning and *disinfection*.

Cryogenic tanks, if not new, should be disinfected before being introduced to the semen collection centre.

The manufacturer's instructions for the safe *disinfection* of ~~cryogenic germplasm storage~~ tanks should be complied with.

Movement of ~~cryogenic germplasm storage~~ tanks from one semen storage facility to another should be completed under controlled conditions subject to the *biosecurity plan* of the *semen collection centre*.

Measures should be in place to ensure that ~~Access to the semen storage facility should be~~ is restricted to authorised personnel ~~and the storage room should be locked when not in use.~~

Accurate records should be maintained that identify semen being transferred into, stored, and transferred out of the semen storage facility. Semen straws should be clearly and permanently identified.

Only semen from the same species and from donors that meet the same health requirements should be stored in the same liquid nitrogen.

Only new liquid nitrogen should be used to fill or top up ~~cryogenic germplasm storage~~ tanks.

CHAPTER 4.7.

COLLECTION AND PROCESSING OF BOVINE, SMALL RUMINANT AND PORCINE SEMEN

Article 4.7.1.

General considerations

The purposes of official sanitary control of semen production are to:

- 1) maintain the health of animals on ~~an artificial insemination centre~~ a semen collection centre at a level which permits the international distribution of semen with a negligible risk of infecting other animals or humans with pathogenic agents transmissible by semen;
- 2) ensure that semen is hygienically collected, processed and stored.

~~Artificial insemination centres~~ Semen collection centres should comply with recommendations in Chapter 4.6.

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

Article 4.7.2.

Conditions applicable to testing of bulls and teaser animals

Bulls and teaser animals should enter ~~an artificial insemination centre~~ a semen collection centre only when they fulfil the following requirements.

1. Prior to entering pre-entry isolation facility

The animals should comply with the following requirements prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the diseases in question.

- a) Brucellosis – Chapter 8.4.
- b) Bovine tuberculosis – ~~Point 3 or 4 of Article 8.124.75.~~
- c) Bovine viral diarrhoea (BVD)

The animals should be subjected to:

- i) a virus isolation test or a test for virus antigen, with negative results; and
 - ii) a serological test to determine the serological status of every animal.
- d) Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

If the ~~artificial insemination centre~~ semen collection centre is to be considered as infectious bovine rhinotracheitis/infectious pustular vulvovaginitis free (IBR/IPV), the animals should either:

- i) come from an IBR/IPV free *herd* as defined in Article 11.8.3.; or
 - ii) be subjected, with negative results, to a serological test for IBR/IPV on a blood sample.
- e) Bluetongue

The animals should comply with Articles 8.3.7. or 8.3.8., depending on the bluetongue status of the country or zone of origin of the animals.

2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the ~~artificial insemination centre~~ semen collection centre, bulls and teaser animals should be kept in a pre-entry isolation facility for at least 28 days. The animals should be tested as described below a minimum of 21 days after entering the pre-entry isolation facility, except for *Campylobacter fetus* subsp. *venerealis* and *Tritrichomonas foetus*, for which testing may commence after 7 days in pre-entry isolation. All the results should be negative except in the case of BVD antibody serological testing (see point 2 b) i) below).

A) Brucellosis

The animals should be subjected to a serological test with negative results.

b) BVD

- i) The animals should be subjected to a virus isolation test or a test for virus antigen, with negative results. Only when all the animals in pre-entry isolation have had negative results, may the animals enter the semen collection facilities.
- ii) All animals should be subjected to a serological test to determine the presence or absence of BVD antibodies.
- iii) Only if no seroconversion occurs in the animals which tested seronegative before entry into the pre-entry isolation facility, may any animal (seronegative or seropositive) be allowed entry into the semen collection facilities.
- iv) If seroconversion occurs, all the animals that remain seronegative should be kept in pre-entry isolation until there is no more seroconversion in the group for a period of three weeks. Serologically positive animals may be allowed entry into the semen collection facilities.

c) *Campylobacter fetus* subsp. *venerealis*

- i) Animals less than six months old or kept since that age only in a single sex group prior to pre-entry isolation should be tested once on a preputial specimen, with a negative result.
- ii) Animals aged six months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

d) *Tritrichomonas foetus*

- i) Animals less than six months old or kept since that age only in a single sex group prior to pre-entry isolation, should be tested once on a preputial specimen, with a negative result.
- ii) Animals aged six months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

e) IBR/IPV

If the ~~artificial insemination centre~~ semen collection centre is to be considered as IBR/IPV free, the animals should be subjected, with negative results, to a diagnostic test for IBR/IPV on a blood sample. If any animal tests positive, the animal should be removed immediately from the pre-entry isolation facility and the other animals of the same group should remain in pre-entry isolation and be retested, with negative results, not less than 21 days after removal of the positive animal.

f) Bluetongue

The animals should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* where the pre-entry isolation facility is located.

3. Testing programme for bulls and teasers resident in the semen collection facilities

All bulls and teasers resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country or *zone* where the semen collection facilities are located is not free:

- a) Brucellosis
- b) Bovine tuberculosis
- c) BVD

Animals negative to previous serological tests should be retested to confirm absence of antibodies.

Should an animal become serologically positive, every ejaculate of that animal collected since the last negative test should be either discarded or tested for virus with negative results.

- d) *Campylobacter fetus* subsp. *venerealis*
 - i) A preputial specimen should be tested.
 - ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay-off of more than six months should be tested not more than 30 days prior to resuming production.
- e) Bluetongue

The animals should comply with the provisions referred to in Article 8.3.9. or Article 8.3.10.

- f) *Trichostrongylus axei*
 - i) A preputial specimen should be cultured.
 - ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay-off of more than six months should be tested not more than 30 days prior to resuming production.
- g) IBR/IPV

If the ~~artificial insemination centre~~ semen collection centre is to be considered as IBR/IPV free, the animals should comply with the provisions in point 2 c) of Article 11.8.3.

4. Testing for BVD prior to the initial dispatch of semen from each serologically positive bull

Prior to the initial dispatch of semen from BVD serologically positive bulls, a semen sample from each animal should be subjected to a virus isolation or virus antigen test for BVD. In the event of a positive result, the bull should be removed from the centre and all of its semen destroyed.

5. Testing of frozen semen for IBR/IPV in ~~artificial insemination centres~~ semen collection centres not considered as IBR/IPV free

Each aliquot of frozen semen should be tested as per Article 11.8.7.

Article 4.7.3.

Conditions applicable to testing of rams/bucks and teaser animals

Rams/bucks and teaser animals should only enter ~~an artificial insemination centre~~ a semen collection centre if they fulfil the following requirements.

1. Prior to entering pre-entry isolation facility

The animals should comply with the following requirements prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the diseases in question.

- a) Brucellosis – Chapter 8.4.
- b) Ovine epididymitis – Article 14.6.3.
- c) Contagious agalactia – Points 1 and 2 of Article 14.2.1.
- d) Peste des petits ruminants – Points 1, 2 a) or 3 of Article 14.7.10.
- e) Contagious caprine pleuropneumonia – Article 14.3.7., depending on the CCPP status of the country or *zone* of origin of the animals.
- f) Paratuberculosis – Free from clinical signs for the past two years.
- g) Scrapie – Comply with Article 14.8.8. if the animals do not originate from a scrapie free country or *zone* as defined in Article 14.8.3.
- h) Maedi-visna – Article 14.5.2.
- i) Caprine arthritis/encephalitis – Article 14.1.2. in the case of goats.
- j) Bluetongue

The animals should comply with Articles 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* of origin of the animals.

- k) Tuberculosis – In the case of goats, a single or comparative tuberculin test, with negative results.

2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the ~~artificial insemination centre~~ semen collection centre, rams/bucks and teasers should be kept in a pre-entry isolation facility for at least 28 days. The animals should be tested as described below a minimum of 21 days after entering the pre-entry isolation facility, with negative results.

- a) Brucellosis – Chapter 8.4.
- b) Ovine epididymitis – Point 1 d) of Article 14.6.4.
- c) Maedi-visna and caprine arthritis/encephalitis – Test on animals.
- d) Bluetongue

The animals should comply with the provisions referred to in Articles 8.3.6., 8.3.7. or 8.3.8., depending on the bluetongue status of the country or *zone* where the pre-entry isolation facility is located.

3. Testing programme for rams/bucks and teasers resident in the semen collection facilities

All rams/bucks and teasers resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country or *zone* where the semen collection facilities are located is not free:

- a) Brucellosis;
- b) ovine epididymitis;

- c) Maedi-visna and caprine arthritis/encephalitis;
- d) tuberculosis (for goats only);
- e) bluetongue.

The animals should comply with the provisions referred to in Article 8.3.9. or Article 8.3.10.

Article 4.7.4.

Conditions applicable to testing of boars

Boars should only enter an ~~artificial insemination centre~~ semen collection centre if they fulfil the following requirements.

1. Prior to entering pre-entry isolation facility

The animals should be clinically healthy, physiologically normal and comply with the following requirements within 30 days prior to entry into isolation at the pre-entry isolation facility where the country or *zone* of origin is not free from the diseases in question.

- a) Brucellosis – Chapter 8.4.
- b) Foot and mouth disease – Articles 8.8.10., 8.8.11. or 8.8.12.
- c) Aujeszky's disease – Article 8.2.9. or Article 8.2.10.
- d) Transmissible gastroenteritis – Article 15.5.2.
- e) African swine fever – Article 15.1.6. or Article 15.1.7.
- f) Classical swine fever – Article 15.2.9. or Article 15.2.10.
- g) Porcine reproductive and respiratory syndrome – Test complying with the standards in the *Terrestrial Manual*.

2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities

Prior to entering the semen collection facilities of the ~~artificial insemination centre~~ semen collection centre, boars should be kept in a pre-entry isolation facility for at least 28 days. The animals should be subjected to diagnostic tests as described below a minimum of 21 days after entering the pre-entry isolation facility, with negative results.

- a) Brucellosis – Chapter 8.4.
- b) Foot and mouth disease – Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16.
- c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.
- d) Transmissible gastroenteritis – Article 15.5.4.
- e) African swine fever – Article 15.1.9. or Article 15.1.10.
- f) Classical swine fever – Article 15.2.11. or Article 15.2.12.
- g) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

3. Testing programme for boars resident in the semen collection facilities

All boars resident in the semen collection facilities should be tested at least annually for the following diseases, with negative results, where the country or *zone* where the semen collection facilities are located is not free:

- a) Brucellosis – Chapter 8.4.

- b) Foot and mouth disease – Articles 8.8.13., 8.8.14., 8.8.15. or 8.8.16.
- c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.
- d) Transmissible gastroenteritis – Article 15.5.4.
- e) African swine fever – Article 15.1.9. or Article 15.1.10.
- f) Classical swine fever – Article 15.2.11. or Article 15.2.12.
- g) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

Article 4.7.5.

General considerations for hygienic collection and handling of semen

Observation of the recommendations described in the articles below will very significantly reduce the likelihood of the semen being contaminated with common bacteria which are potentially pathogenic.

Article 4.7.6.

Conditions applicable to the collection of semen

- 1) — The floor of the mounting area should be clean and provide safe footing. A dusty floor should be avoided.
- 2) — The hindquarters of the teaser, whether a dummy or a live teaser animal, should be kept clean. A dummy should be cleaned completely after each period of collection. A teaser animal should have its hindquarters cleaned carefully before each collecting session. The dummy or hindquarters of the teaser animals should be sanitized after the collection of each ejaculate. Disposable plastic covers may be used.
- 3) — The hand of the person collecting the semen should not come into contact with the animal's penis. Disposable gloves should be worn by the collector and changed for each collection.
- 4) — The artificial vagina should be cleaned completely after each collection where relevant. It should be dismantled, its various parts washed, rinsed and dried, and kept protected from dust. The inside of the body of the device and the cone should be disinfected before re-assembly using approved *disinfection* techniques such as those involving the use of alcohol, ethylene oxide or steam. Once re-assembled, it should be kept in a cupboard which is regularly cleaned and disinfected.
- 5) — The lubricant used should be clean. The rod used to spread the lubricant should be clean and should not be exposed to dust between successive collections.
- 6) — The artificial vagina should not be shaken after ejaculation, otherwise lubricant and debris may pass down the cone to join the contents of the collecting tube.
- 7) — When successive ejaculates are being collected, a new artificial vagina should be used for each mounting. The vagina should also be changed when the animal has inserted its penis without ejaculating.
- 8) — The collecting tubes should be sterile, and either disposable or sterilised by autoclaving or heating in an oven at 180°C for at least 30 minutes. They should be kept sealed to prevent exposure to the environment while awaiting use.
- 9) — After semen collection, the tube should be left attached to the cone and within its sleeve until it has been removed from the collection room for transfer to the laboratory.

Article 4.7.7.

Conditions applicable to the handling of semen and preparation of semen samples in the laboratory

1. — Diluents

- a) All receptacles used should have been sterilised.
- b) Buffer solutions employed in diluents prepared on the premises should be sterilised by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.
- c) If the constituents of a diluent are supplied in commercially available powder form, the water used should have been distilled or demineralised, sterilised (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.
- d) Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product should be free from pathogenic agents or sterilised; milk heat treated at 92°C for 3–5 minutes, eggs from SPF flocks when available. When egg yolk is used, it should be separated from eggs using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination, may be used. Other additives should also be sterilised before use.
- e) Diluent should not be stored for more than 72 hours at +5°C before use. A longer storage period is permissible for storage at –20°C. Storage vessels should be stoppered.
- f) A mixture of antibiotics should be included with a bactericidal activity at least equivalent to that of the following mixtures in each ml of frozen semen: gentamicin (250 µg), tylosin (50 µg), lincomycin-spectinomycin (150/300 µg); penicillin (500 IU), streptomycin (500 µg), lincomycin-spectinomycin (150/300 µg); or amikacin (75 µg), divekacin (25 µg).

The names of the antibiotics added and their concentration should be stated in the *international veterinary certificate*.

2. Procedure for dilution and packing

- a) The tube containing freshly collected semen should be sealed as soon as possible after collection, and kept sealed until processed.
- b) After dilution and during refrigeration, the semen should also be kept in a stoppered container.
- c) During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be disinfected with alcohol, ethylene oxide, steam or other approved *disinfection* techniques.
- d) If sealing powder is used, care should be taken to avoid its being contaminated.

3. Conditions applicable to the storage and identification of frozen semen

Semen for export should be stored in straws separately from other genetic material not meeting the requirements of this chapter with fresh liquid nitrogen in sterilised/sanitised flasks before being exported.

Semen straws should be sealed and code marked in line with the international standards of the International Committee for Animal Recording (ICAR).

Prior to export, semen straws should clearly and permanently be identified and placed into new liquid nitrogen in a new or sterilised flask or container under the supervision of an *Official Veterinarian*. The contents of the container or flask should be verified by the *Official Veterinarian* prior to sealing with an official numbered seal before export and accompanied by an *international veterinary certificate* listing the contents and the number of the official seal.

4. Sperm sorting

Equipment used for sex-sorting sperm should be clean and disinfected between animals in accordance with the recommendations of the licencer of the system. Where seminal plasma, or components thereof, is added to sorted semen prior to cryopreservation and storage, it should be derived from animals of same or better health status.

Semen straws containing sex-sorted sperm should be permanently identified as such.

CHAPTER 6.10.

RESPONSIBLE AND PRUDENT USE OF
ANTIMICROBIAL AGENTS
IN VETERINARY MEDICINE

Article 6.10.1.

Purpose and scope

This document provides guidance for the responsible and prudent use of *antimicrobial agents* in veterinary medicine for treatment, control and prevention of diseases in food- and non-food-producing animals, with the aim of protecting both *animal* and human health as well as minimising and containing antimicrobial resistance risks in the relevant animal the environment, as part of a One Health approach.

It defines the respective responsibilities of the *Competent Authorities* and stakeholders such as the veterinary pharmaceutical industry, *veterinarians*, animal feed manufacturers, distributors, and food-animal producers-breeders, owners and keepers, who are involved in any or all of the following activities: the authorization regulatory approval, production, control, importation, exportation, sales, advertising, distribution, prescription and use of *veterinary medicinal products (VMPs)* containing *antimicrobial agents*.

Responsible and prudent use is determined by taking into account the importance of the antimicrobial agent to veterinary and human medicine, the risk of development of antimicrobial resistance, the specifications detailed in the relevant regulatory approval and the indications for use, including off-label use, marketing authorization and their implementation when antimicrobial agents are administered to animals, and it is part of good veterinary and good agricultural good animal husbandry practices. All measures to keep *animals* healthy, such as preventing infectious *animal* diseases through vaccination, biosecurity, good agricultural practices and animal husbandry practices and adequate nutrition contribute to a decreased need of using *antimicrobial agents* in *animals*, thus reducing the risk for development and spread of antimicrobial resistance.

Activities associated with the responsible and prudent use of *antimicrobial agents* should involve all relevant stakeholders.

Coordination of these activities at the national or regional level is recommended and may support the implementation of targeted actions by the stakeholders involved and enable clear and transparent communications.

Article 6.10.2.

Objectives of responsible and prudent use

~~Responsible and prudent veterinary medical use of antimicrobial agents includes implementing practical measures and recommendations intended to improve animal health and animal welfare while preventing or reducing the selection, emergence and spread of antimicrobial-resistant bacteria and resistance determinants in animals, humans and the relevant animal environment; in animals and humans. Such measures include: The objectives of responsible and prudent veterinary medical use of antimicrobial agents are to:~~

- 1) ~~ensuring the responsible and prudent rational use of antimicrobial agents in animals with the purpose of optimising preserve~~ the both their effectiveness of antimicrobial agents used in veterinary and human medicine efficacy and their safety in animals;
- 2) ~~complying~~ with the ethical obligation and economic need to keep *animals* in good health;
- 3) ~~preventing or reducing the transfer of resistant micro-organisms or resistance determinants within animal populations, between animals, humans, and the relevant animal environment the environment and between animals and humans;~~

4) ~~contributing to the maintenance~~ maintaining of the effectiveness, efficacy and usefulness of antimicrobial agents used in animal, veterinary and human medicine;

5) protecting ~~consumer~~ human health by ensuring the safety of food of *animal* origin with respect to residues of *antimicrobial agents*.

In order to achieve the objectives of responsible and prudent veterinary medical use of antimicrobial agents, a range of measures intended to improve animal health and animal welfare while preventing or reducing the selection, emergence and spread of antimicrobial resistant microorganisms and resistance determinants in animals, humans and the relevant animal environment should be implemented. These measures include promotion of good animal husbandry practices, hygiene procedures, biosecurity, and vaccination strategies, access to laboratory testing, and alternatives to the use of antimicrobials, which can help to minimise the need for antimicrobial use in animals.

Article 6.10.3.

Responsibilities of the Competent Authorities

1. National Action Plan for Antimicrobial Resistance

The Competent Authorities should design and oversee the implementation of the relevant part of their National Action Plan considering the findings of the situational analysis of the country, the objectives of the WOAHA, WHO, FAO and UNEP Global Action Plan (GAP) for Antimicrobial Resistance and existing guidance for developing National Action Plans for antimicrobial resistance. The Competent Authorities in cooperation with animal health, plant health, environment and public health professionals, and other relevant stakeholders should adopt a One Health approach to promote the responsible and prudent use of antimicrobial agents as an element of a national strategy to minimise and contain antimicrobial resistance. Furthermore, the Competent Authorities should allocate budgetary resources for the design and implementation of the relevant part of their National Action Plan including communication strategies and professional training programmes. The Competent Authorities should also conduct regular monitoring and evaluation of the National Action Plan.

National Action Plans should incorporate, and educate/inform on, best management practices, including disease prevention and control measures, implementation of biosecurity policies and development of animal health programmes to reduce the burden of animal disease thereby reducing the need for antimicrobial use. As part of National Action Plans for antimicrobial resistance, the Competent Authorities should ensure that surveillance for antimicrobial use and antimicrobial resistance in the animal health sector are in place and should work closely together with human, plant and environmental sectors on the harmonisation, analysis and integration of surveillance across sectors. The Competent Authorities should implement a programme in accordance with Chapters 1.4. and 6.8.

National Action Plans should include recommendations to relevant professional organisations as appropriate to develop evidence-based, species or sector-specific antimicrobial use guidelines.

12. Regulatory approval/Marketing authorisation

~~All Member Countries should combat the unauthorised manufacture, compounding, importation, advertisement, trade, distribution, storage and use of unlicensed, adulterated and counterfeit products, including bulk active ingredients, through appropriate regulatory controls and other measures.~~

The Competent Authority is responsible for granting relevant regulatory approval/marketing authorisation which should be done in accordance with the provisions of the Terrestrial Code. The Competent Authority has a significant role in specifying the terms of this authorisation/approval and in providing the appropriate information to veterinarians and all other relevant stakeholders.

The Competent Authority should establish and implement efficient statutory registration procedures that evaluate the quality, safety and efficacy and proposed post-marketing surveillance programmes for VMP/veterinary medicinal products containing antimicrobial agents. According to Article 3.2.2., the Competent Authority should be free from any commercial, financial, hierarchical, political or other pressures which might influence/affect its judgement or decisions.

Member Countries lacking the necessary resources to implement an efficient registration procedure for VMP/veterinary medicinal products containing antimicrobial agents, and which are importing them, should undertake the following measures:

a) evaluate the effectiveness/efficacy of administrative controls on the import of these VMP/veterinary medicinal

products;

- b) evaluate the validity of the registration procedures of the exporting ~~and or~~ manufacturing country as appropriate;
- c) develop the necessary technical co-operation with an experienced relevant authorities Competent Authority to check the quality of imported ~~VMP~~ veterinary medicinal products as well as the validity of the recommended conditions of use.

The Competent Authorities of importing countries should request the veterinary pharmaceutical industry to provide quality certificates of quality prepared by the Competent Authority of the exporting ~~or~~ and manufacturing country as appropriate.

Regulatory approval Marketing authorisation is granted for treatment, control and prevention of diseases and veterinary medical use, which excludes growth promotion, on the basis of the data submitted by a the pharmaceutical company industry or other applicant and only if the criteria of quality, safety, quality and efficacy are met.

Member countries The Competent Authority are is encouraged to consult and apply, as appropriate, or require the use of the existing guidelines based on the technical requirements for veterinary product registration established by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

An evaluation of the ~~potential~~ risks and benefits to both animals and humans resulting from the use of antimicrobial agents in with particular focus on use in food-producing animals, should be carried out. The evaluation may should focus on each individual antimicrobial agent; and the findings from one agent should not be generalised to the antimicrobial class to which the particular active ingredient belongs. Guidance on use usage should be provided for all target species, route of administration, dosage regimens, (dose, dosing interval and duration of the treatment administration), and withdrawal period as relevant and different durations of treatment that are proposed.

The Competent Authority should expedite implement timely the regulatory approval processes for new antimicrobial agents or treatment other options, including alternatives to the use of antimicrobials, in order to address a specific needs for the treatment of animal diseases and should take into account recommendations included in the WOAH List of Antimicrobials of Veterinary Importance.

23. Quality control of antimicrobial agents and ~~VMP~~ veterinary medicinal products containing antimicrobial agents

The Competent Authority should make sure that the quality of the veterinary medicinal products was determined by the applicant in accordance with national and international guidance to ensure that:

Quality controls should be performed:

- a) the specifications of antimicrobial agents in compliance with the provisions of good manufacturing practices;
- b) to ensure that analysis specifications of antimicrobial agents used as active ingredients comply with the provisions of registration documentations (such as monographs) approved by the relevant Competent Authority;
- cb) to ensure that the quality of antimicrobial agents in the marketed dosage forms is maintained until the expiry date, established under the recommended storage conditions;
- dc) to ensure the stability and compatibility of antimicrobial agents are stable and compatible when mixed with feed or drinking water;
- ed) to ensure that all antimicrobial agents and the VMP veterinary medicinal products containing them are manufactured to the appropriate quality and in compliance with the provisions of good manufacturing practices purity in order to guarantee their safety and efficacy.

34. Assessment of therapeutic efficacy

The Competent Authority should conduct an assessment of the therapeutic efficacy based on data provided in the relevant regulatory approval application submitted by the applicant to enable marketing:

a) Preclinical trials

i) Preclinical trials should:

- establish the spectrum of activity of *antimicrobial agents* against relevant pathogenic agents and non-pathogenic agents (commensals);
- assess the capacity of the *antimicrobial agents* to select for resistance *in vitro* and *in vivo*, taking into consideration intrinsically resistant ~~and pre-existing resistant strains~~ and strains with acquired resistance;
- establish an appropriate dosage regimen (~~dose, dosing interval and duration of the treatment~~) and route of administration necessary to ensure the therapeutic efficacy of the *antimicrobial agents* and limit the selection of antimicrobial resistance. Pharmacokinetic and pharmacodynamic data and models can assist in this appraisal. Such data together with clinical data could be used by independent experts to establish clinical breakpoints per animal species, antimicrobial agent and pathogen combination.

ii) The activity of *antimicrobial agents* towards the targeted microorganism should be established by pharmacodynamics investigations. The following characteristics-criteria should be taken into account, as appropriate:

- spectrum of activity and mode of action;
- minimum inhibitory concentration (MIC) and minimum bactericidal concentrations (MBC) against recent isolates;
- time-kill kinetics when appropriate;
- time-dependent or concentration-dependent activity, or co-dependency;
- activity and concentration at the site of *infection*.

iii) The dosage regimens allowing maintenance of effective antimicrobial concentrations levels should be established-informed by pharmacokinetics and pharmacodynamics investigations. The following criteria and should be taken into account:

- bio-availability in accordance with the route of administration;
- any potential routes of administration proposed by the applicant;
- absorption, distribution, metabolism and elimination, and of the antimicrobial agents in the treated animal and concentration at the site of infection, metabolism and elimination;
- metabolism;
- excretion routes;
- any potential routes of administration proposed by the applicant.

Further dose determination studies may be conducted to examine the microbiological and clinical response to several dose levels or dosing intervals.

Any proposed use of combinations of *antimicrobial agents* should be scientifically supported.

b) Clinical trials

Clinical trials in the target animal species should be performed to confirm the validity of the claimed therapeutic indications and dosage regimens established during the preclinical phase. The following criteria should be taken into account:

- diversity of the clinical cases encountered when performing multi-centre trials;
- compliance of protocols with good clinical practice;
- eligibility of studied clinical cases, based on appropriate criteria of clinical and bacteriological diagnoses;
- parameters for qualitatively and quantitatively assessing the efficacy of the treatment.

45. Assessment of the potential of antimicrobial agents to select for resistance

Other studies may be requested in support of the assessment of the potential of *antimicrobial agents* to select for resistance. The applicant for regulatory approval ~~The party applying for market authorisation~~ should, where possible, supply data derived in target animal species under the intended conditions of use.

For this assessment the following may be considered:

- a) the concentration of ~~either active antimicrobial agents or and, where appropriate, active metabolites~~ in the gut of the *animal* (where the majority of ~~potential food-borne pathogenic and commensal bacteria agents~~ reside) at the defined dosage level;
- b) the antimicrobial activity of the antimicrobial agents and metabolites in the intestinal environment;
- ~~bc)~~ the pathway for the human exposure to antimicrobial resistant microorganisms, antimicrobial resistance determinants and antimicrobial residues in the relevant animal environment;
- ~~ed)~~ the presence of and potential degree for co-selection, co-resistance and cross-resistance;
- ~~de)~~ the intrinsic and pre-existing, baseline level of resistance, including intrinsic and acquired resistance, in the pathogenic agents, commensal and food-borne bacteria of human health relevance concern in both animals and humans.

6. Assessment of the impact on the relevant animal environment

The Competent Authority should consider the results of an antimicrobial resistance environmental risk assessment in accordance with Chapter 6.11. For both food and non-food producing animals the following risk factors should be taken into consideration as appropriate: reuse of wastewater for irrigation, use of manure, other waste-based fertilisers for soil fertilisation, transfer of antimicrobial resistant microorganisms and determinants in veterinary practice. When a significant antimicrobial resistance risk is determined the need for monitoring and proportionate risk management measures should be discussed.

~~6. Establishment of clinical breakpoints~~

~~In order to interpret the result of a susceptibility test, there is a need for clinical breakpoints for each bacteria-antimicrobial animal species combination. Those clinical breakpoints should be established by independent experts.~~

57. Establishment of acceptable daily intake (ADI), maximum residue limit (MRL) and withdrawal periods in food-producing animals

- a) The establishment of an ADI for each antimicrobial agent, and an MRL for each animal-derived food, should be undertaken before a veterinary medicinal product containing it is granted regulatory approval.
- ~~ab)~~ When setting the ADI and MRL for an antimicrobial agent, the safety evaluation should also include the potential microbiological biological effects on the intestinal flora microbiome microbiota of humans to derive ADI.
- ~~b)~~ The establishment of an ADI for each antimicrobial agent, and an MRL for each animal-derived food, should be undertaken before a VMP veterinary medicinal product containing it is granted marketing authorization regulatory approval.
- c) For all VMP veterinary medicinal products containing antimicrobial agents for use in food-producing animals, withdrawal periods should be established for each animal species in order to ensure compliance with the MRLs, taking into account:

- the MRLs established for the *antimicrobial agent* in the target animal edible tissues;
 - the composition of the product and the pharmaceutical form;
 - the dosage regimen;
 - the route of administration.
- d) ~~The applicant should describe~~ Methods used for regulatory testing of residues in food should be described and based on the established marker residues.

~~68. Assessment Protection of the impact on the relevant animal environment~~

~~An assessment of the impact of the proposed antimicrobial use on risks to the relevant environment should be conducted in accordance with national or international guidelines.~~

~~The Competent Authority should consider the results of an antimicrobial resistance environmental risk assessment. For both food and non-food producing animals the following risk factors should be taken into consideration as appropriate: reuse of wastewater for irrigation, use of manure, other waste-based fertilizers for soil fertilization, transfer of antimicrobial resistant genes or bacteria in veterinary practice. When a significant antimicrobial resistance risk is determined the need for monitoring and proportionate risk management measures should be discussed.~~

~~798. Establishment of a summary of product characteristics or equivalent for each VMP veterinary medicinal product containing antimicrobial agents~~

~~The summary of product characteristics contains~~ The Competent Authority should ensure that the Summary of Product Characteristics (SPC) or equivalent, the package insert, and labelling includes the information necessary for the appropriate use of VMP veterinary medicinal products containing antimicrobial agents and constitutes the official reference for their labelling and package insert. ~~This~~ The SPC or equivalent summary should contain the following items as appropriate:

- a) name of the veterinary medicinal product;
- ~~a~~b) active ingredient and class;
- c) pharmaceutical form;
- d) quantitative composition;
- ~~b~~e) pharmacological properties;
- e) any potential adverse effects;
- ~~d~~g) target animal species and, as appropriate, age or production category;
- ~~e~~h) therapeutic indications;
- f) target micro-organisms;
- ~~e~~j) dosage regimen (i.e. dose, frequency of dosing, and route and duration of administration) and route of administration;
- ~~k~~k) withdrawal periods;
- i) incompatibilities and interactions;
- ~~j~~m) storage conditions and shelf-life;
- ~~k~~n) operator safety;
- ~~l~~o) particular precautions before use;

- p) precautions for the protection of the environment;
- q) use during pregnancy, lactation or lay;
- ~~mr)~~ particular precautions for the proper disposal of unused ~~un-used~~ or expired products;
- ns) information on conditions of use relevant to responsible and prudent use of antimicrobials and minimising the development the potential for selection of resistance;
- ~~et)~~ Contraindications;
- u) known signs of overdose and information about its treatment.

8109. Post-marketing antimicrobial resistance surveillance

The Competent Authority should assess ~~the~~ information collected through existing pharmacovigilance and surveillance programmes, including reporting of lack of response efficacy, and any other relevant scientific data. These information sources should form part of the comprehensive strategy to detect and minimise antimicrobial resistance.

In addition, ~~to this, the following~~ specific surveillance should be considered:

- a) ~~General epidemiological surveillance~~

The surveillance of animal microorganisms resistant to antimicrobial agents is essential. The Competent Authority relevant authorities should implement a programme in accordance with Chapter 1.4.

- b) ~~Specific surveillance~~

~~Specific surveillance~~ to assess the impact of the use of a specific antimicrobial agent veterinary medicinal product, where scientific evidence indicates a specific risk and may be implemented after the granting of the relevant regulatory approval marketing authorisation. The surveillance programme should evaluate not only resistance in target animal pathogens pathogenic agents, but also in foodborne and other relevant zoonotic pathogens pathogenic agents, and commensals if relevant and possible. This will also contribute to general epidemiological surveillance of antimicrobial resistance.

9110. Distribution Supply and administration of the antimicrobial agents or VMP veterinary medicinal products containing antimicrobial agents

~~The relevant authorities~~ The Competent Authority should ensure that all the antimicrobial agents and veterinary medicinal products containing antimicrobial agents used in animals including through feed and water are:

- a) ~~prescribed by a veterinarian or other suitably trained person authorised to prescribe VMP containing antimicrobial agents in accordance with the national legislation and under the supervision of a veterinarian;~~
- ~~ba)~~ supplied only through licensed or authorised distribution systems;
- b) not illegal, substandard, falsified medicines or unapproved formulations and that these are prevented from entering distribution systems;
- c) prescribed by a veterinarian or other suitably trained person authorised to prescribe veterinary medicinal products containing antimicrobial agents in accordance with the national legislation;
- ~~ed)~~ administered to animals by a veterinarian or under the supervision or by direction of a veterinarian, ~~or by other authorised suitably trained persons, animal breeders, owners or keepers as appropriate.~~

The Competent Authority should encourage the availability of authorised products on the market and in collaboration with the veterinary pharmaceutical industry follow-up any potential drug shortages.

The relevant authorities The Competent Authority – Veterinary Services should develop and implement effective procedures for the safe collection and disposal or destruction of unused or expired ~~VMPs~~ veterinary medicinal products containing *antimicrobial agents*. Their labels should have appropriate instructions for disposal and destruction.

101211. Control of advertising

All advertising of *antimicrobial agents* should be compatible with the principles of responsible and prudent use and should be controlled by codes of advertising standards. The Competent Authority relevant authorities must should ensure that:

- a) the advertising of these products complies with the regulatory approval marketing authorisation granted, in particular regarding the content of the summary of product characteristics or equivalent;
- b) it advertising is restricted to a *veterinarian* or other suitably trained person authorised to prescribe ~~VMP~~ veterinary medicinal products containing antimicrobial agents, or to persons permitted to supply veterinary medicinal products in accordance with the national legislation and under the supervision of a veterinarian; and
- c) their promotion is done in a manner consistent with specific regulatory recommendations for the product.

12. Establishment of clinical breakpoints

The Competent Authority should encourage and support the development of clinical breakpoints for each bacteria-antimicrobial-animal species combination to interpret the results of susceptibility tests. Those clinical breakpoints should be established in accordance with the Terrestrial Manual.

113. Training related to the use-on the usage of antimicrobial agents and antimicrobial resistance

The Competent Authority should take a key role in promoting targeted training for responsible and prudent use of antimicrobials and on antimicrobial resistance. The target audiences for tThe training on the usage use of antimicrobial agents should include all the relevant stakeholders and organisations, such as the Competent Authority, veterinary pharmaceutical industry, veterinary schools and paraprofessional education establishments, research institutes, veterinary professional and paraprofessional organisations and other approved users such as breeders, owners and keepers of food-producing animals owners and manufacturers of medicated animal feed. This training may should focus on preserving the effectiveness of antimicrobial agents and include:

- a) information on disease prevention, management and mitigation strategies;
- ba) the ability of antimicrobial agents to select for resistant microorganisms in animals and the relative importance of that resistance to public and animal health and the relevant animal environment;
- eb) the need to observe responsible and prudent use principles recommendations for the use of antimicrobial agents in animal husbandry in agreement with the provisions of the marketing authorisations regulatory approval, national and international guidelines and recommendations from the WOAHA List of Antimicrobial Agents of Veterinary Importance
- ec) information on the appropriate storage conditions before and during use and proper disposal of unused or expired VMP veterinary medicinal products;
- e) record-keeping;
- d) training in existing and new methodologies for target pathogen identification, susceptibility testing, molecular detection of resistance and risk assessment models, understanding methods and results of antimicrobial susceptibility testing and molecular analysis and their use in risk assessment;
- e) interpretation of relevant risk assessment outputs of antimicrobial resistance derived from the use of veterinary medicinal products containing antimicrobial agents in animals and how to use these outputs to inform the development of risk communication-management and risk communication management strategies;
- f) the collection and reporting of antimicrobial resistance and antimicrobial use data to the Competent Authority to complement existing national and international surveillance programmes;

- g) information on disease prevention, management and mitigation strategies that can contribute to reducing the need to use antimicrobial agents in animals.

14. Monitoring of antimicrobial use

In accordance with Chapter 6.9., The Competent Authority should collate data on antimicrobial use in a harmonised manner to improve the understanding of the extent and trends of antimicrobial use and antimicrobial resistance in animal populations at national level and identify areas for further research. The data collected on antimicrobial use at country level should:

- a) give an indication of the trends in the use of antimicrobial agents in animals over time and potential associations with antimicrobial resistance in animals;
- b) help in the interpretation of antimicrobial resistance surveillance data and assist in responding to problems of antimicrobial resistance in a precise and targeted way;
- c) assist in risk management to evaluate the effectiveness of efforts and mitigation strategies;
- d) inform risk communication strategies;
- e) foster improved antimicrobial stewardship, ensuring continued availability of safe and effective antimicrobial agents for both animal and human health.

The Competent Authority should provide the antimicrobial use data to the 'Animal Antimicrobial Use Global database of the World Organisation for Animal Health' on a yearly basis.

15. Knowledge gaps and Research

The Competent Authority ~~relevant authorities~~ should encourage coordination of public- and industry/private-funded research, including in the following areas but not limited to: for example on methods to identify and mitigate the public health risks associated with specific antimicrobial agent uses, or on the ecology of antimicrobial resistance.

- a) improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of antimicrobial agents to optimize the dosage regimens for veterinary medical use and their effectiveness;
- b) improve the knowledge about the mechanisms of ~~transmission~~, selection, co-selection, emergence and dissemination-transmission of resistance determinants and resistant microorganisms in animal populations, and between animals, humans and the relevant animal environment, and including along the food chain;
- c) develop practical models for applying the concept of risk analysis to assess the animal and public health concerns linked to the development of antimicrobial resistance in animals and animal-derived foods;
- d) further develop protocols to predict, during the ~~authorization~~ regulatory approval process, the impact of the proposed use of the antimicrobial agents in animals on the rate and extent of antimicrobial resistance development and spread to animals, humans, plants and the relevant animal environment, following a One Health approach;
- e) assess the primary drivers leading to use of antimicrobial agents in animals, and the effectiveness of different interventions to change behaviour and reduce the need to use antimicrobial agents in animals;
- f) develop safe and effective alternatives to antimicrobial agents, new antimicrobial agents, rapid diagnostics, and vaccines for infectious diseases to reduce the need for antimicrobial use in animals;
- g) improve knowledge on the role of the environment on the persistence of antimicrobial agents, and the emergence, transfer and persistence of antimicrobial resistance determinants and resistant microorganisms resulting from antimicrobial use in the relevant animals environment.

16. Competent Authorities should implement appropriate regulatory measures to control the unauthorised manufacture, compounding, importation, advertisement, trade, distribution, storage and use of unlicensed, adulterated and counterfeit veterinary medicinal products containing antimicrobial agents, including bulk active ingredients.

Article 6.10.4.

Responsibilities of the veterinary pharmaceutical industry with regards to ~~VMP-veterinary medicinal products~~ containing antimicrobial agents

1. Regulatory approval~~Marketing authorisation~~

The veterinary pharmaceutical industry has responsibilities to:

- a) ~~Supply~~ provide all the information requested by the national *Competent Authority* as specified in Article 6.10.3;
- b) guarantee the quality of this information in compliance with the provisions of good manufacturing, laboratory and clinical practices;
- c) implement, and regularly ~~timely~~ report in a timely manner on a pharmacovigilance programme, and on request, specific surveillance for bacterial susceptibility and resistance data~~;~~. For the latter, the veterinary pharmaceutical industry should
- ~~d) isolate and identify bacteria, and collect relevant data and submit them to the Competent Authority. The~~ These data will ~~may~~ enable independent experts to establish clinical breakpoints for use in the laboratory to guide antimicrobial therapy.

2. Marketing and export

For the marketing and export of ~~VMP-veterinary medicinal products~~ containing antimicrobial agents:

- a) only licensed and officially approved ~~VMP-veterinary medicinal products~~ containing antimicrobial agents should be sold and supplied, and then only through ~~licensed/~~ authorised distribution systems;
- b) the veterinary pharmaceutical industry should provide ~~quality~~ certificates of quality prepared by the *Competent Authority* of the exporting or ~~and~~ manufacturing countries to the *importing country*;
- c) the veterinary pharmaceutical industry should endeavour to guarantee ensure the availability of authorised products and cooperate with the Competent Authority to forecast and avoid any drug shortage;
- ~~ed)~~ the veterinary pharmaceutical industry should provide the Competent Authority ~~national regulatory authority~~ should be provided with the information necessary to evaluate the amount of antimicrobial agents marketed.

3. Advertising

The veterinary pharmaceutical industry should respect principles of responsible and prudent use and should comply with established codes of advertising practices ~~standards~~, including to:

- a) distribute information in compliance with the provisions of the granted ~~authorization~~ approval;
- b) not advertise ~~VMP-veterinary medicinal products~~ containing antimicrobial agents directly to the food animal ~~producer~~ breeder, owner and keeper or to the general public.

4. Training

The veterinary pharmaceutical industry should participate in training programmes as defined in point ~~131~~ of Article 6.10.3.

5. Research

The veterinary pharmaceutical industry should contribute to research as defined in point ~~125~~ of Article 6.10.3.

Article 6.10.5.

Responsibilities of wholesale and retail distributors

- 1) ~~Distributors of VMP containing antimicrobial agents should only distribute antimicrobial agents do so in accordance with the national legislation on the prescription of as prescribed by a veterinarian or other suitably trained person authorised to prescribe VMP-veterinary medicinal products containing antimicrobial agents in accordance with the national legislation and under the supervision of a veterinarian.~~ All products should be appropriately labelled.
- 2) The recommendations on the responsible and prudent use of ~~VMP-veterinary medicinal products~~ containing antimicrobial agents should be reinforced by retail distributors who should keep for an appropriate period detailed sales records of:
 - a) date of supplysale;
 - b) name and contact information of the prescriber;
 - c) name of user;
 - d) name of product;
 - e) batch number;
 - f) expiration date;
 - g) quantity supplied;
 - h) copy of prescription;
 - i) other information as required by national legislation.
- 3) Distributors should also be involved in training programmes on the responsible and prudent use of ~~VMP-veterinary medicinal products~~ containing antimicrobial agents, as defined in point 131 of Article 6.10.3.

Article 6.10.6.

Responsibilities of veterinarians

The *veterinarian's* responsibility is to promote ~~public health, antimicrobial stewardship,~~ animal health and *animal welfare*, as well as public health, through antimicrobial stewardship, including prevention, detection, diagnosis-identification, prevention-control and treatment of animal diseases. The promotion of sound animal husbandry methods, hygiene procedures, *biosecurity* and *vaccination* strategies can help to minimise the need for antimicrobial use in ~~food-producing animals.~~

The veterinarians should only prescribe antimicrobial agents for animals under their care. The veterinarian should consider safe and effective non-antimicrobial options or alternatives to the use of antimicrobials before prescribing antimicrobial agents.

Some of the responsibilities described in this article may be applicable to *veterinary paraprofessionals* or other suitably trained persons according to the national legislation.

1. Use of antimicrobial agentsPre-requisites for using antimicrobial agents

The responsibilities of *veterinarians* are to obtain a detailed history and carry out a proper clinical examination of the animal(s) and then, taking appropriate samples for further testing as necessary. If the provisional or definitive diagnosis is a microbial infection, then the veterinarian should:

- a) administer, or prescribe, dispense or administer antimicrobial agents only when necessary and taking into consideration the WOAH list of antimicrobial agents of veterinary importance to treat, control or prevent infectious diseases in animals;
- b) avoid using the use of antimicrobial agents routinely to compensate for inadequate animal husbandry practices;

- c) take into consideration the WOAH List of Antimicrobial Agents of Veterinary Importance and follow science-based species or sector-specific antimicrobial use guidelines for responsible and prudent use when available and follow the principles of antimicrobial stewardship;
- bd) make an appropriate choice of antimicrobial agent based on clinical experience and available diagnostic laboratory information (pathogenic agent isolation, identification and ~~antibiogram~~ antimicrobial susceptibility testing) where possible;
- ee) provide a detailed treatment protocol, including precautions and withdrawal period times (if applicable), especially when prescribing extra-label or off-label use;
- f) provide appropriate adequate supportive therapy, if appropriate, which may, for example, include fluid therapy, segregation from other animals, administration of anti-inflammatory or analgesic agents.

2. Choosing antimicrobial agents

a- The choice of an effectiveness-effective expected efficacy of the treatment is based on:

- ia) the clinical experience of the veterinarians, their diagnostic insight and therapeutic judgement;
- ib) diagnostic laboratory information (pathogenic agent isolation, identification and ~~antibiogram~~ antimicrobial susceptibility testing);
- ic) pharmacodynamics properties of the selected antimicrobial agent, including the activity towards the pathogenic agents involved;
- id) the appropriate dosage regimen (i.e. dose, frequency of dosing, and route and duration of administration) and route of administration;
- ie) pharmacokinetics and tissue distribution to ensure that the selected therapeutic agent is effective at the site of infection;
- if) the epidemiological history relevant to of the animal or animals being treated rearing unit, particularly in relation to the antimicrobial resistance profiles of the pathogens pathogenic agents involved.

Should a first-line antimicrobial treatment fail or should the disease recur, an investigation a second line treatment should be undertaken based on the results of diagnostic tests. In the absence of such results, an appropriate antimicrobial agent belonging to a different class or sub-class should be used to reassess the circumstances including reviewing the diagnosis, conducting additional diagnostic testing as needed, and then formulate and implement a new treatment plan, which may or may not include another antimicrobial agent.

In emergenciesIn particular situations, a veterinarian may treat animals empirically, before without recourse to an accurate diagnosis and antimicrobial susceptibility testing results are available, to prevent the development of clinical disease and for reasons of animal welfare.

b- Use of combinations of antimicrobial agents should be scientifically supported. Combinations of antimicrobial agents may be used for their synergistic effect to increase therapeutic effectiveness efficacy or to broaden the spectrum of activity, but only when scientifically supported.

When prescribing, dispensing or administering a veterinary medicinal product containing antimicrobial agents intended for veterinary medical use to an individual or a group of animals to treat, control or prevent an infectious disease as defined in Chapter 6.9, the veterinarian should give specific consideration to their categorisation in the WOAH List of Antimicrobial Agents of Veterinary Importance or national lists. Preference should be given to the least important antimicrobial agent as categorised by WHO that is appropriate for use.

3. Appropriate veterinary medical use of the selected VMP veterinary medicinal product containing antimicrobial agents chosen

The A-prescription of a ~~for~~ VMP veterinary medicinal product containing antimicrobial agents should exclude growth promotion and indicate precisely the dosage regimen, the withdrawal period where applicable, and when considering group treatments, the total amount of VMP veterinary medicinal products containing antimicrobial agents to be

provided, which will depend depending on the dosage, duration of treatment, and the number of *animals* to be treated.

When prescribing, dispensing or administering a *veterinary medicinal product* containing *antimicrobial agents* intended for veterinary medical use to an individual or a group of *animals* to treat, control or prevent infectious disease as defined in Chapter 6.9, the *veterinarian* should give specific consideration to their categorisation in the WOAH List of Antimicrobial Agents of Veterinary Importance as well as to the WHO List of Critically Important Antimicrobials. Preference should be given to the least important *antimicrobial agent* as categorised by WHO that is appropriate for use.

The *veterinarian* should ensure that instructions for the administration of the product are clearly explained and understood by the food *animal* breeders, owners, or keepers or any other person responsible for administering the product.

The extra-label or off-label use of a ~~VMP~~ *veterinary medicinal product* and of a compounded product containing *antimicrobial agents* may be permitted in certain appropriate circumstances and should be for treatment, control and prevention of diseases, in agreement with the national legislation in force including the withdrawal periods ~~to be used,~~ as applicable. It is the *veterinarian's* responsibility to define the conditions of responsible and prudent use in such a case including the dosage regimen, the route of administration and the withdrawal period.

The use of compounded ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* and extra-label or off-label use of registered ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* should be limited to circumstances where an appropriate registered product is not available and should take into account recommendations provided in the WOAH List of Antimicrobial Agents of Veterinary Importance.

4. Recording of data

Records of ~~a~~ *VMP* *veterinary medicinal products* containing *antimicrobial agents* should be kept in conformity with the national legislation. ~~Information~~ Records should include the following, as appropriate:

- a) commercial name of the *veterinary medicinal products*;
- b) name of the *antimicrobial agents* in the *veterinary medicinal products*;
- ~~a~~b) quantities of VMP used per *animal species* in *animals* or supplied to each *establishment* or animal breeder, owner or keeper;
- b) a list of all VMP supplied to each food producing animal holding;
- ~~c~~d) route of administration;
- ~~d~~e) animal species;
- ~~e~~f) number of *animals* treated;
- ~~f~~g) clinical condition treated;
- ~~e~~g) treatment schedules including *animal* identification and length of the withdrawal period;
- ~~d~~h) antimicrobial susceptibility data, including laboratory records of pathogenic agent isolation, identification and susceptibility testing obtained from isolates;
- ~~e~~ij) comments concerning the response of the *animal* or *animals* to treatment;
- ~~f~~k) the investigation of adverse reactions associated with ~~to~~ antimicrobial treatment, including lack of effectiveness response due to possible antimicrobial resistance. Suspected adverse reactions should be reported to the holder of the regulatory approval or appropriate *Competent Authority* regulatory authorities in accordance with national legislation.

Veterinarians should also periodically review farm records on the use of ~~VMP~~ *veterinary medicinal products* containing *antimicrobial agents* to ensure compliance with their directions or prescriptions and use these records to evaluate the

effectiveness efficacy of treatments.

5. Labelling

All ~~VMP~~ veterinary medicinal products supplied by a *veterinarian* should be labelled in accordance with the national legislation.

6. Training and ~~continued~~ continuing professional development

Veterinary professional and paraprofessional organisations should participate in the training programmes as defined in point ~~134~~ of Article 6.10.3. It is recommended that veterinary professional and paraprofessional organisations develop for their members species-specific clinical practice recommendations on the responsible and prudent use of ~~VMP~~ veterinary medicinal products containing *antimicrobial agents*.

Article 6.10.~~87~~.

Responsibilities of animal feed manufacturers

1. The manufacturing and supply of medicated *feed* containing *antimicrobial agents* to farmers keeping food-producing *animals* by animal feed manufacturers should be allowed only on the prescription of a *veterinarian*. Alternatively, such medicated *feed* may be prescribed by other suitably trained persons authorised to prescribe ~~VMP~~ veterinary medicinal products containing *antimicrobial agents* in accordance with the national legislation ~~and under the supervision of a veterinarian~~. Animal feed manufacturers preparing medicated *feed* should do so following rules put in place by the *Competent Authority* in accordance with the national legislation. All medicated *feed* and medicated premixes should be appropriately labelled.
2. Keep detailed records for medicated feed and premixes for a suitable period of time according to national legislation.
- ~~2-~~ The ~~regulations and recommendations on the responsible and prudent use of VMP containing antimicrobial agents should be reinforced by animal feed manufacturers who should keep detailed records.~~
3. Use only approved sources of pharmaceutical products ~~medications~~: Animal feed manufacturers preparing medicated *feed* should ensure that only approved sources of medications are added to *feed* at a level, and for a species and purpose as permitted by the medicated drug ~~drug~~ premix label or a veterinary prescription.
4. Ensure appropriate labelling with product identification, direction for use and withdrawal ~~time period~~: animal feed manufacturers preparing medicated *feed* should ensure that medicated animal *feed* are labelled with the appropriate information (e.g., level of medication, approved claim, target intended ~~intended~~ species, directions for use, warning, cautions) ~~so as to ensure effective and safe use by the producer.~~
5. Implement appropriate production practices to prevent contamination of other *feed*: animal feed manufacturers preparing medicated *feed* should implement good manufacturing ~~appropriate production practices~~ to avoid unnecessary carry over and ~~unsafe~~ cross contamination of unmedicated *feed*.
6. Feed manufacturers should participate in training programmes as defined in point 13 of Article 6.10.3.

Article 6.10.~~78~~.

Responsibilities of ~~food animal producers~~ breeders, owners and keepers of food-producing animals

1. ~~Food animal producers~~ Breeders, owners and keepers of food-producing animals with the assistance and guidance of a *veterinarian*, are responsible for implementing animal health and *animal welfare* programmes, including biosecurity and good animal husbandry practices on their farms in order to reduce the need for the use of antimicrobial agents in animals, and to promote animal health and food safety.
2. ~~Food animal producers~~ Breeders, owners and keepers of food-producing animals should:
 - a) draw up a health plan with the attending *veterinarian* that outlines preventive and control measures ~~(e.g., feedlot health plans, mastitis control plans, endo and ectoparasite control, vaccination programmes and other biosecurity measures);~~

- ~~b) address implement on-farm biosecurity measures and take appropriate hygiene precautions as appropriate;~~
- ~~c) isolate sick animals, when appropriate, to avoid the transfer of pathogenic agents;~~
- d) dispose of dead or dying *animals* promptly under conditions approved by the relevant authorities Competent Authorities;
- ~~e) address on-farm biosecurity measures and take basic hygiene precautions as appropriate;~~
- ~~b_e) use veterinary medicinal products VMP containing antimicrobial agents only on the prescription and under the supervision of a veterinarian, veterinary paraprofessional or other suitably trained person authorised to prescribe VMP containing antimicrobial agents in accordance with the national legislation and under the supervision of a veterinarian;~~
- ~~e_f) use veterinary medicinal products VMP containing antimicrobial agents in accordance with product label instructions, including storage conditions, and or the instructions of the attending prescribing veterinarian; extra-label/off-label use of veterinary medicinal products containing antimicrobial agents should be in line with the relevant national legislation and the instructions of the prescribing veterinarian;~~
- ~~f_g) comply with and record the recommended withdrawal periods to ensure that residue levels in animal-derived food do not present a risk for the consumer;~~
- ~~g_h) use VMP veterinary medicinal products containing antimicrobial agents within the expiry date and dispose of unused and expired surplus VMP veterinary medicinal products containing antimicrobial agents under conditions safe for the relevant animal environment according to the summary of product characteristics (SPC) or equivalent, or relevant national legislation;~~
- i) ensure that only medicated premixes containing antimicrobial agents from authorised sources are added to feed at a dose and duration appropriate for the target animal species and purpose of use as permitted by the medicated premix label or a veterinary prescription when preparing medicated feed on-farm;
- ~~h_j) maintain all the laboratory records of bacteriological and susceptibility tests; these data should be made available to the veterinarian responsible for treating the animals;~~
- ~~i_k) keep adequate records of all VMP veterinary medicinal products containing antimicrobial agents used, including the following:~~
- ~~i) name of the product or the active pharmaceutical ingredient and active substance, and batch number and expiry date;~~
 - ii) name and contact details of prescriber and the supplier;
 - iii) date of administration;
 - iv) identification of the *animal* or group of *animals*, and the number of animals to which the *antimicrobial agent* was administered;
 - ~~v) clinical conditions disease treated;~~
 - vi) dosage dose regimen (including dose, dosing interval and duration of treatment);
 - vii) withdrawal periods including the end-date of the withdrawal periods;
 - ~~viii) results of laboratory tests;~~
 - ~~ix) effectiveness of therapy;~~
 - ~~x) suspected adverse events;~~
- j) inform the responsible *veterinarian* of recurrent disease problems.

3. Training

Food animal ~~producers~~ breeders, owners and keepers should participate in the training programmes as defined in in point ~~13~~ of Article 6.10.3.

It is recommended that food animal ~~producer~~ organisations work in cooperation with the veterinary professional organisations to implement existing guidelines for the responsible and prudent use of ~~VMP~~ veterinary medicinal products containing *antimicrobial agents*.

Article 6.10.9.

Responsibilities of breeders, owners and keepers of non-food producing animals

Animal breeders, owners and keepers, with the assistance and guidance of a *veterinarian*, are responsible for the health and welfare of their *animals* and should:

- 1) *implement the wellness plans and preventative health plans recommended by their *veterinarian*;*
- 2) *strictly follow their *veterinarian*'s recommendations and ensure that if any, the administration of *veterinary medicinal products* containing *antimicrobial agents* follows the veterinary prescription;*
- 3) *avoid administering over the counter, leftover and expired human and ~~animal~~ *veterinary antimicrobials agents* to their *animals*;*
- 4) *not administer remaining or expired human and *veterinary antimicrobials agents* to their *animals*;*
- 45) *inform their *veterinarian* or *veterinary paraprofessional* of the administration of any additional medicinal products than those prescribed by the *veterinarian* during the consultation;*
- 56) *inform their *veterinarian* of any observed lack of ~~response~~ effectiveness or ~~other~~ adverse effect.*
- 7) *ensure that only *antimicrobial agents* from authorised sources are administered in accordance with national legislation.*

DRAFT CHAPTER 7.5.

ANIMAL WELFARE DURING SLAUGHTER

Introduction

Providing good welfare to the animals at *slaughter* is ethically and economically beneficial. The implementation of *animal welfare* measures, in addition to giving value to the product directly for ethical reasons, contributes to the improvement of workers' wellbeing, health and safety. This will also contribute to food safety and product quality, and product quality, and is essential for (including food safety) and consequently to the improvement of economical returns [Blokhuis *et al.*, 2008; Lara and Rostagno, 2018].

Article 7.5.2.

Scope

This chapter identifies ~~potential~~ hazards to animal welfare hazards during *slaughter* and provides recommendations for arrival and *unloading, lairage*, handling, *restraint, stunning* and bleeding of animals in *slaughterhouses/abattoirs*. It provides animal-based measures to assess the level of welfare and recommends remedial and corrective actions to be applied, when necessary.

This chapter applies to the *slaughter* in *slaughterhouses/abattoirs* of free-moving animals the following domestic animals, e.g. such as cattle, buffalo, bison, sheep, goats, horses, donkeys, mules, ruminants, camelids, equids and pigs, and animals in containers (e.g. such as rabbits and most poultry species).- hereafter referred as "animals." Recommendations consider whether animals arrive at the slaughterhouse/abattoir in containers or are free moving.

~~The principles underpinning these recommendations should also be applied to the slaughter of other species and those slaughtered in other places.~~

This chapter should be read in conjunction with the guiding principles for *animal welfare* provided in Chapter 7.1., Chapter 7.14. killing of reptiles for their skins, meat and other products and with relevant provisions of Chapters 6.2. and 6.3.

~~The principles underpinning these recommendations may should also be applied apply to the slaughter of other species and those slaughtered in other places.~~

Article 7.5.3.

Definitions for the purpose of this chapter

For the purposes of this chapter:

Bleeding means the act of severing major blood vessels that supply the brain, to ensure death.

Article 7.5.4.

Hazards to aAnimal welfare ~~hazards~~

Hazards to animal welfare during each of the pre-slaughter stages have an ~~additive~~ cumulative effect on the stress of the animals [Moberg and Mench, 2000].

At the *slaughterhouses/abattoirs*, animals are exposed to hazards to animal welfare hazards including fasting feed and water deprivation, mixing of unfamiliar *animals*, handling by humans, exposure to a novel environment (e.g. noise, lighting, flooring and smells), forced movement physical exercise, limited space allowance, extreme adverse weather conditions and ineffective inadequate stunning and bleeding. These *hazards* can have negative impacts on the welfare of the animals that can be assessed through animal-based measures. In the absence of feasible animal-based measures, in addition resource-

~~based measures and management-based measures may be used as a substitute proxy. Hazards to a~~ Animal welfare hazards can be minimised by appropriate design of premises and choice of equipment, and through good management, training and competency of personnel.

Article 7.5.5.

Criteria ~~(or m~~ Measures)

The welfare of animals at *slaughter* should be assessed using ~~outcome animal~~ animal-based measures. Although consideration should be given to the resources provided as well as the design and management of the system, animal-based criteria measures are preferential. However, key stunning parameters need to be considered selected, taking into account alongside animal-based measures.

The routine use of these ~~outcome animal~~ animal-based measures and the appropriate thresholds should be adapted to the different situations in which animals are managed at a *slaughterhouse/abattoir*. It is recommended that target values or thresholds for animal-based measures ~~welfare measurable~~ be based on current scientific ~~knowledge~~ evidence and appropriate national, sectorial or regional standards.

Article 7.5.6.

Management

The *slaughterhouse/abattoir* operator is responsible for the development and ~~enforcement~~ implementation of an dedicated operating plan that should consider the following:

- training and competency of personnel;
- design of premises and choice of equipment;
- standard operating procedure and corrective actions;
- recording, reporting adverse incidents and taking corrective actions;
- ~~training and competency of personnel;~~
- throughput (number of animals slaughtered per hour);
- maintenance and cleaning procedures of equipment and premises;
- ~~contingency emergency plans.~~
- operating procedure and corrective actions.

Article 7.5.7.

Training and competency of personnel

Animal handlers and other personnel have a crucial role to play in ensuring good *animal welfare* conditions from the time of arrival of the animals at the *slaughterhouse/abattoir* through to their *death*. Training for all personnel should emphasise the importance of *animal welfare* and their responsibility in contributing to the welfare of the animals that come through the *slaughterhouse/abattoir*.

Animal handlers should understand the species-specific behavioural patterns of the animals they are working with and their underlying principles ~~to for~~ carrying out the required tasks whilst ensuring good *animal welfare*. They should be experienced and competent in handling and moving the animals with knowledge about animal behaviour and physiology and able that allows them to identify signs of distress, fear, and pain and suffering and take preventive and corrective actions. Personnel in charge of restraint (including pre-stun shackling) and of stunning and bleeding operations should be familiar with the relevant equipment, their and its key working parameters and procedures. Personnel in charge of stunning, post-stun shackling and bleeding animals should be able to identify and take corrective actions in case of: ineffective stunning of the animal and signs of recovery of consciousness, should be able to detect if an animal is still alive prior to dressing or scalding and should be able to take corrective actions, if necessary [EFSA, 2013a; EFSA 2013b]

- a) ineffective stunning of the animal;
- b) recovery of consciousness;
- c) animal is still alive signs of life prior to dressing or scalding.

Competencies may be gained through a combination of formal training and practical experience. These competencies should be assessed by the *Competent Authority* or by an independent body recognised by the *Competent Authority*.

Only the personnel actively working on the slaughter line in areas where live animals are handled should be present in these areas where animals are handled. The presence of visitors or other personnel should be limited in these areas in order to prevent unnecessary noise, shouting, or movement or and to reduce risk of accidents.

Article 7.5.8.

Design of premises and choice of equipment

The design of premises and the choice of equipment used in a *slaughterhouse/abattoir* have an important impacts on the welfare of animals. ~~They should consider the animals' needs~~ should be considered, in terms of their physical comfort including:

- thermal comfort conditions;
- ease of movement;
- protection from injury ~~protection from sudden or excessive noise;~~
- protection from visual, auditory and olfactory overstimulation;
- minimising fear and avoiding distress and pain ;
- and ability to perform natural and social behaviours ; ~~as well as~~
- watering and feeding needs, including the need of sick or injured animals;
- needs arising from illness or injury;
- needs arising from other vulnerabilities (e.g. pregnant, lactating or neonatal animals).

Premises should be designed to eliminate distractions that may cause approaching animals to stop, baulk or turn back.

Flooring should be non-slip to prevent injury and stress due to slipping or falling. There should be Adequate quality and quantity of lighting to allow allowing adequate appropriate ante-mortem inspection of animals and to enable assist the moving of animals utilising low-stress handling techniques.

The design of the *slaughterhouse/abattoir* and choice of equipment should take into consideration the species, categories, quantities, ~~and~~ size or weight and age of the animals. *Restraint, stunning* and bleeding equipment is critical for the welfare of an animal at the time of *slaughter*. Appropriate back-up equipment should be available for immediate use in case of failure of the primary stunning equipment ~~initially used~~.

Article 7.5.9.

~~The throughput is (number of animals slaughtered per hour)~~

The throughput of the *slaughterhouse/abattoir* is the number of animals slaughtered per hour. It should never exceed the maximum specification capacity of the design of the facilities or equipment, and may ~~The slaughterhouse/abattoir operators should continuously monitor throughput and adjust it to any operational changes, such as staff numbers and experience or line breakdowns. #Throughput may also need to be reduced depending on their welfare outcomes are is negatively impacted.~~

Personnel allocation should be adequate for the anticipated throughput and be sufficient to implement the *slaughterhouse/abattoir* operating plan as well as ante- and post-mortem inspections.

Article 7.5.10.

Maintenance and cleaning procedures

All equipment should be clean ~~and~~, well maintained, ~~and including calibration~~, in accordance with the manufacturer's instructions in order to ensure positive outcomes for animal welfare and safety of personnel.

Maintenance and cleaning of handling, unloading, lairage and moving facilities and equipment contribute to ensuring that animals are handled smoothly, preventing minimising pain and fear.

Maintenance and cleaning of handling, restraining, stunning and bleeding equipment are essential to ensure reliable and efficient effective stunning and *slaughter*, thereby minimising *pain*, fear and suffering.

Article 7.5.11.

~~Contingency~~ Emergency plans

~~Contingency~~ Emergency plans should be in place at the *slaughterhouse/abattoir* to protect the welfare of the animals in the event of an emergency. The ~~contingency~~ plans should consider the most likely emergency situations given the species slaughtered and the location of the *slaughterhouse/abattoir*.

~~Contingency~~ Emergency plans should be documented and communicated to all responsible parties; and these plans should be tested regularly.

~~Each p~~Personnel who ~~has~~ have a role to play in implementing ~~contingency~~ the plans should be well trained on the tasks they have to perform in case of emergency.

Article 7.5.12.

Arrival of free-moving animals

On arrival at the *slaughterhouse/abattoir*, animals ~~will~~ would already have been exposed to *hazards* that may have negative impacts on their welfare. Any previous *hazards* will have a cumulative effect that may affect the welfare of the animals throughout the *slaughter* process. Therefore, animals should be transported to the *slaughterhouse/abattoir* in a manner that minimises adverse animal health and welfare ~~outcomes~~, and in accordance with Chapters 7.2. and 7.3.

1-) Animal welfare concerns:

Delay in *unloading* of animals is a major ~~the main~~ *animal welfare* concern at arrival [NAMI, 20172021].

Animals in *vehicles* have smaller space allowances than on farm, undergo water and *feed* deprivation, may have suffered from an injury, and and may be exposed to ~~thermal stress due to~~ adverse weather conditions and to stress and discomfort from social disturbance, noise, vehicle vibration and motion. In addition, stationary *vehicles* may have insufficient ventilation. Delays in *unloading* animals will prolong or exacerbate the impact of these *hazards*. Under these circumstances, injured or sick animals requiring urgent attention ~~will~~ may not be identified or dealt with appropriately and therefore the duration of their suffering will be increased prolonged.

2-) Animal-based and other measurable measures include:

It can be difficult to assess animal-based measures while animals are in the *vehicle*. Some ~~measurable measures~~ that may be assessed include animals with injuries, lameness and / or poor body condition or those that are sick or have died. Panting, shivering and huddling may indicate thermal stress. Drooling and licking may indicate prolonged thirst.

Animals dead or emergency killed (see Article 7.5.19.) on arrival ~~or condemned on arrival~~ should be recorded and monitored as an indicator of *animal welfare* prior to and during transport.

Time from arrival to *unloading* and the environmental temperature and humidity can be used to establish relevant thresholds for corrective action.

3-) Recommendations:

Animals should be unloaded promptly on arrival. This is facilitated by scheduling the arrival of the animals at the *slaughterhouse/abattoir* to ensure that there are sufficient personnel and adequate space in the unloading or lairage area.

Consignments of animals ~~assessed whose welfare is to be~~ at greater risk of being compromised animal welfare hazards should be unloaded first. When no space is immediately available, creating space should be a priority. Provisions should be made to provide shelter, shade or additional ventilation during waiting periods, or animals should be transported to an alternative nearby location where such provision is available.

Animals should not be isolated throughout the slaughter process, except under specific conditions, such as for aggressive or sick animals.

Animals should be provided with drinking water as soon as possible after unloading.

~~Special consideration should be given to a~~Animals that have undergone long or arduous journeys ~~times, are sick or injured animals, are lactating or pregnant animals and young neonatal animals. These animals should be slaughtered as a priority and without delay. If this is not possible, animals should be given appropriate care. arrangements should be made to mitigate or prevent suffering, in particular by: milking dairy animals at intervals of not more than 12 hours and providing appropriate conditions for suckling and the welfare of the newborn neonatal animal in the case of a female having given birth. Mortalities and injuries should be reported to the competent authority.~~

4-) Species-specific recommendations:

Some species such as Ppigs and shorn sheep are especially sensitive to extreme temperatures and therefore special attention should be ~~taken paid~~ when dealing with delays in *unloading* ~~this species~~sensitive animals. This may include careful consideration of transport plans to time arrival and processing, provision of additional means of temperature and humidity control ventilation / heating, etc.

Shorn sheep might be especially sensitive to extreme temperatures and therefore special attention should be taken when dealing with delays in unloading.

Lactating animals should be given special attention and given priority when unloading and processing.

Unweaned animals are especially sensitive to extreme temperatures and can find it difficult to regulate their body temperature. They are very more susceptible to dehydration, illness and stress after transportation and handling. These animals must be given special attention and be given priority when unloading and processing.

Article 7.5.13.

Displacements Handling of free-moving animals

This article addresses the handling of animals during *unloading* and *lairage*, and in the *killing* area.

1-) Animal welfare concerns:

During *unloading*, animals are exposed to similar *hazards* to those encountered when being loaded (see Chapters 7.2. and 7.3). Inappropriate equipment in the *vehicle* or the *slaughterhouse/abattoir*, such as a lack of lateral protection when *unloading*, excessively steep ramps, slippery surfaces, or an absence of foot battens, may result in animals slipping, falling or being trampled, causing injuries. The absence of ramps, or lifts or an unloading bay or dock could ~~can~~ result in animals being pushed or thrown off the vehicle. These *hazards* can also be associated with inappropriate handling and forced physical movement of animals that are unable to move independently as a result of weakness or injuries. Exposure to novel environments (e.g. noise, lighting, flooring, smell) will may cause fear and reluctance to move, or turning back. Poorly designed facilities will increase the risk of such fear and injuries.

2-) Animal-based and other measurable measures include:

- a) animals ~~running~~ slipping and falling and piling up;
- b) animals with broken or otherwise injured limbs;

- c) animals turning-back, attempting to escape and or reluctant to move;
- d) animal vocalisation referring to distress and frequency of (e.g. high pitched vocalisation for in pigs) especially for pigs and cattle;
- e) animals that are unable to move by themselves due to reasons other than those with broken or injured limbs;
- f) animals that ~~strike against the facilities~~ collide with facility structures;
- g) ~~frequency of use of excessive force by personnel;~~
- h) ~~frequency of use of electrical prods~~ goads.

Animals are safely handled when these measures are below an acceptable threshold.

3-) Recommendations:

Ramps or lifts should be provided and used except when the vehicle and the unloading dock are at the same height. Ramps or lifts should be positioned so that the animals can be handled safely. There should be no gap between the vehicle and the ramp unloading dock. Ramps or lifts should be positioned so that the animals can be handled safely. The gradient should not be too so steep as to preventing animals from moving voluntarily moving, and solid side barriers should be in place.

Design of the facilities should promote the natural movements of animals, and, as far as possible, with a minimal minimise human interaction.

Preventive ~~measures~~ equipment such as foot battens, rubber mats and deep-groove flooring can help animals to avoid slipping.

The *unloading* area and raceways should be well lit so that animals can see where they are going.

The design of areas and raceways should aim to minimise the potential for distractions that may cause animals to stop, baulk or turn back when being unloaded (e.g. shadows, changes in flooring, moving objects, loud or sudden noises). For details refer to Chapters 7.2. and 7.3.

Animals that are injured, sick or unable to rise require immediate action and, when necessary, emergency killing should be performed euthanised without moving them and without delay. Refer to Articles 7.5.19. and 7.5.20. Such animals should never be dragged, nor should they be lifted or handled in a way that might cause further pain, and suffering or exacerbate injuries.

Personnel should be calm and patient, assisting the animals to move using a soft voice and slow movements. They should not shout, kick, or use any other means that is likely to cause *distress*, fear or *pain* to the animals. Under no circumstances should *animal handlers* resort to violent acts to move animals (see Article 7.5.20.).

Personnel should not stand between an animal and where they want it to move to as this may cause the animal to baulk. They should keep in mind the flight distance and point of balance of the animal when positioning themselves to encourage movement.

Animals should be moved in small groups as this decreases fear and makes use of their natural tendency to follow other animals.

Mechanical handling aids ~~and electric goads~~ should be used in a manner to encourage and direct movement of the animals without causing *distress*, fear ~~and or~~ *pain*. Preferred mechanical aids include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and ~~metallic~~ rattles.

Other handling aids should not be used as a substitute for good facility design and handling. They should not be used repeatedly if an animal fails to respond or move. In such cases it should be determined whether some physical or other impediment is preventing the animal from moving.

Electric goads should only not be used on a routine basis to move animals. in extreme cases and not on a routine basis to move animals. Electric goads may only be used when other measures have been ineffective, the animal has no injury

or other condition that is impeding mobility and there is room for the animal to move forward without obstruction (e.g. obstacles or other animals).

The use of electric goads should be limited to battery-powered low-voltage goads applied to the hindquarters of adult pigs and large ruminants, and never to sensitive areas such as the eyes, mouth, ears, ano-genital region, udders or belly. Such instruments should not be used on equids, camelids, raites, sheep and goats of any age, pregnant animals or on calves or piglets. Shocks shall not be used repeatedly if the animal fails to respond and should not last longer than one second [Ritter *et al.*, 2008].

Mechanical ~~Other~~ Handling aids and electric goads should not be used as a substitute for good facility design and handling. They should not be used repeatedly if an animal fails to respond or move. In such cases it should be determined whether some physical or other impediment is preventing the animal from moving.

Electric goads should only be used in extreme cases and not on a routine basis to move animals.

The use of electric goads should be limited to battery-powered goads applied to the hindquarters of adult pigs and large ruminants, and never to sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.

The manual lifting of animals should be avoided; if it is necessary, animals should not be grasped or lifted in a manner which causes *pain* or suffering and physical damage (e.g. bruising, fractures, dislocations). (See Article 7.5.20.)

Animals should not be forced to move at a speed greater than their normal walking pace to minimise injury through slipping or falling. Facilities should be designed, constructed and staffed with competent animal handlers, so that less than 1% of the animals fall.

4- Species specific recommendations:

None identified.

Article 7.5.14.

Lairage of free-moving animals

1- Animal welfare concerns:

Animals ~~during lairage~~ may be exposed to several hazards to animal welfare hazards during lairage including:

- a) ~~food feed~~ and water deprivation leading to prolonged hunger and thirst;₂
- b) absence of protection against ~~extremes adverse in weather or climate conditions~~, leading to thermal stress;₂
- c) sudden or excessive noises, including from personnel, machinery, metal yards and gates facilities, and equipment and gates, leading to fear;₂
- d) insufficient space to lie down and move freely leading to fatigue and aggressive behaviour;₂
- e) poor design and maintenance leading to *distress* and injuries;₂
- f) mixing of unfamiliar animals leading to aggressive behaviour; or social stress;₂
- g) limited access to resources (e.g. drinkers, bedding) leading to aggressive behaviour;₂
- h) exposure to hard, sharp or abrasive surfaces leading to injury or lameness (e.g. sharp, abrasive).

2- Animal-based and other measurable measures include:

- a) thermal stress (e.g. panting, sweating, shivering, huddling behaviour);₂

- b) space allowance;₇₂
- c) excessive soiling with faeces (e.g. coat cleanliness, dag score for sheep);₇₂
- d) injuries (e.g. lameness, open wounds, fractures);₇₂
- e) illness (e.g. limping, diarrhoea, coughing);₇₂
- f) aggressive behaviours (e.g. mounting, fighting);₇₂
- g) frequency of animal vocalisation referring to distress especially for pigs and cattle (e.g. hitch high pitched vocalisation in pigs; loud moos or bellows in bovines);₇₂
- h) restlessness (e.g. pacing, walking with continuous ear movements and frequency of snorts – especially for in horses) [Micera et al., 2010 and Visser et al., 2008];₇₂
- i) bruised carcass bruising.

3-) Recommendations:

Animals should have constant access to clean drinking water. Water supply points should be designed according to the species and age of the animal, with environmental conditions that allow for effective consumption. The number and location of the water supply points should minimise competition.

Animals should be provided with feed in lairage if the duration between loading and expected time for slaughter exceeds 24 hours. Animals should be provided with feed in lairage if the duration between loading their last meal and expected time for slaughter exceeds a period appropriate for the species and age of animals. In the absence of information on the transport duration in any case, animals which that are not expected to be slaughtered after within 12 hours of arrival should be fed as appropriate for the age and species and should be given moderate amounts of food at appropriate intervals.

The *lairage* should provide animals with protection against adverse weather conditions including shade and shelter.

Animals should be protected from excessive and sudden noise (e.g. ventilation fans, alarms, or other indoor or outdoor equipment).

Lairage areas should be free from sharp edges and other *hazards* that may cause injury to animals.

The *lairage* should provide enough space for all animals to lie down at the same time, to move freely and to move away in case of aggressive behaviours.

Lairage areas should have adequate lighting levels to allow inspection of the animals.

Animals from different categories (e.g. sexes, sizes, horned or not, species) groups (or different species) should not be mixed except if they are already familiar to each other.

Animals that can move freely but are injured, sick, very young pregnant or are neonates or pregnant should be slaughtered with priority or isolated separated to protect them from other animals and be slaughtered with priority. Animals that are very ill or down or have catastrophic severe injuries should be euthanized without delay (see Article 7.5.1922.).

4-) Species-specific recommendations:

None identified. Pigs should be kept moved in small groups (up to 15) [Barton-Gade and Christensen, 1998] when resting in lairage, when moving to the stunner and when stunned.

Bison and cervids need specific design and construction standards for the unloading and holding prior to slaughter.

Article 7.5.15.

Restraint for stunning or bleeding (free-moving animals)

1-) Animal welfare concerns:

The purpose of *restraint* is to facilitate the correct application of the *stunning* or bleeding equipment. Incorrect *restraint* may not only lead to ineffective *stunning* or bleeding, but also cause distress, fear and pain and ~~distress~~.

Other *hazards* include:

- a) ~~slippery~~ ing or falling of animals entering the restraining area;
- b) ~~struggling or escape attempts caused by~~ insecure *restraint*;
- c) ~~injuries and pain caused by~~ excessive force of *restraint*;
- d) a restraint box that is not appropriate to the size of the animal;
- e) ~~fear caused by~~ prolonged *restraint*, which may exacerbate insecure or excessive *restraint*.

~~In addition, slaughter~~ without *stunning* increases the risk of *pain* and fear due to the need for robust *restraint* of conscious animals for neck cutting, especially if animals are turned on their sides or backs [von Holleben *et al.*, 2010; Pleiter, 2010].

2-) Animal-based and other measurable measures include:

- a) animal slipping or falling;
- b) struggling;
- c) escape attempts;
- d) animal vocalisation referring to distress (cattle and pigs) (e.g. high pitched vocalisation in pigs);
- e) reluctance to enter the restrainer;
- f) frequency of use of electric goods.

3-) Recommendations:

Where individual restraint is used, ~~T~~the restrainer should be narrow enough that the animals cannot move ~~either~~ backwards or forwards or turn around.

The restrainer being used should be appropriate to the size of the animals and the restrainer should not be loaded beyond its design capacity.

In case of slaughter without stunning, the restrainer should restrain the head ~~appropriately~~ and should support the body of the animal appropriately.

The restraining should be maintained until the animal is unconscious.

When restrainers ~~are used~~ that hold an animal with its feet off the floor are used, the animal ~~must~~ should be held in a balanced, comfortable, upright position.

When a restrainer is used to rotate an animal from an upright position, the body and head ~~must~~ should be securely held and supported to prevent struggling and slipping within the device.

Restrainers should not have sharp edges and should be well maintained to minimise risk of injury.

Non-slip flooring should be used to prevent animals from slipping or falling.

Flooring design and handling methods that intentionally cause loss of balance, slipping or falling, i.e. a box with a floor that rises on one side upon entry to the box, should not be used intentionally.

Distractions (e.g. movements of equipment or people, loose chains or objects, shadows, shiny surfaces or floors) should be minimised to prevent baulking balking and improve ease of entry into the restrainer.

No animals should enter the restrainer until equipment and personnel are ready to stun and slaughter that animal.

No animals should be released from the restrainer until the operator has confirmed loss of consciousness.

Animals should not be left in conveyor style single file races or restrainers during work breaks, and in the event of a breakdown animals should be removed from the conveyor restrainer promptly.

The restrainer should be in a clean and non-slip condition.

Animals should not be able to pile on top of each other in the restrainer, nor receive pre-stun shocks from contact with the animal in front, in the case of electrical *stunning*.

Animals subject to specific methods of *stunning* should be individually restrained to ensure precise positioning of the *stunning* equipment. However, this should not apply when restraining is likely to cause additional *distress* or *pain* as well as excessive and unpredictable movements (e.g. animals that cannot move normally due to injuries or sickness, *wild* animals or horses).

4-) Species-specific recommendations:

Gondolas for gas *stunning* of pigs should not be overloaded and pigs should allow pigs be able to stand without being on top of each other.

Head *restraint* is recommended for cattle bovines.

Specialised restraining equipment and methods are required for Bison and cervids, as well as any species which may be processed with or without *stunning*.

Article 7.5.16.

General principles for *stunning* of free-moving animals and animals in containers

1- Animal welfare concerns:

The main *animal welfare* concern associated with *stunning* is '*ineffective *stunning**' which results in *pain, distress* or fear during induction of unconsciousness and possible recovery before *death*.

The most common methods for *stunning* are mechanical, electrical and exposure to controlled atmosphere.

Stunning prior to *slaughter* decreases or avoid prevents *pain* and suffering to animals and also improves workers' *safety*.

Mechanical *stunning* is divided into penetrating *stunning* and non-penetrating non-penetrative percussive *stunning* applications. Both applications use different types of devices aimed to induce immediate loss of consciousness as the impact of the bolt on the skull results in concussion and disruption of normal brain function [Daly *et al.*, 1987; EFSA, 2004]. Penetrative *stunning* devices propel a bolt which penetrates the skull and enters the cranium damaging the brain. Non-penetrative percussive *stunning* devices propel a blunt bolt which does not penetrate the skull, but results in rapid loss of consciousness from impact. The main *hazards* preventing effective mechanical *stunning* are incorrect shooting position and incorrect direction of the impact. These may cause ineffective *stunning* and *pain* or short-lasting unconsciousness. Poor maintenance of the equipment or inadequate cartridge power or air line pressure (in pneumatic stunners) can result in low bolt velocity. Low bolt velocity, misuse/inappropriate use of cartridge Low bolt velocity, narrow bolt diameter or short length of bolt leading to shallow penetration, may also affect the effectiveness of *stunning*. In older animals with a thicker skull, low bolt velocity may result in there is an increase risk of an ineffective *stun*, especially with In non-penetrating non-penetrative percussive *stunning* applications, high bolt velocity may cause fracture of the skull and ineffective *stunning* [Gibson *et al.*, 2014]. If not applied correctly, fracture of the skull and ineffective *stunning* are more likely to occur with young animals such as calves, when a higher bolt velocity is used. Absence of or incorrect restraint can lead to an incorrect shooting position.

Electrical *stunning* involves application of an electric current to the brain of sufficient magnitude to induce immediate

unconsciousness [EFSA, 2004; Grandin, 1980]. The main *hazards* preventing effective electrical *stunning* are: incorrect electrode placement, poor contact, electrical arcing, high contact resistance caused by wool or dirt on the animal surface, dirty or corroded electrode, low voltage/current or high frequency [EFSA, 2004].

Controlled atmosphere *stunning* methods involve the exposure to high concentrations of carbon dioxide (hypercapnia), low concentration of oxygen (hypoxia) or a combination of the two (hypercapnic hypoxia). Loss of consciousness is not immediate following exposure of animals to controlled atmosphere *stunning*. The main *hazards* causing increased *distress* during induction of unconsciousness are irritant or aversive gas mixtures (e.g. CO₂ in high concentrations), low gas temperature and humidity. The main *hazards* causing ineffective controlled atmosphere *stunning* are incorrect gas concentration and too short gas exposure time [Anon, 2018; EFSA, 2004; Velarde *et al.*, 2007].

Gases or gas mixtures that are painful to inhale should preferably not be used to stun or kill pigs.

2. Animal based and other measurables include:

Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, just before and during bleeding until death occurs confirmed neck cutting, and during bleed-out [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

No single indicator should be relied upon alone. Multiple indicators should be used to determine whether a stun is effective and the animal is unconscious.

Mechanical *stunning*:

An effective stun is characterised by the presence of all the following signs: immediate collapse; apnoea; tonic seizure; absence of corneal reflex; absence of eye movements.

The presence of any of the following signs may indicate a high risk of ineffective stun or recovery of consciousness: rapid eye movement or nystagmus, vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

Electrical *stunning*:

An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex.

The presence of any of the following signs may indicate a high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

Gas *stunning*:

An effective stun is characterised by the presence of all the following signs: loss of posture; apnoea; absence of corneal reflex; absence of muscle tone.

The presence of any of the following signs may indicate a high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; rhythmic breathing.

3. Recommendations:

Animals should always be stunned as soon as they are restrained.

When a two-step electrical stun-kill method is used, the electrical current must reach be applied to the brain before it reaches the heart otherwise the animal will experience cardiac arrest while still conscious.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system method. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be used, cleaned, maintained and stored following manufacturer's recommendations.

Regular calibration of the equipment according to the manufacturer's procedure areis recommended. Effectiveness of the stunning should be monitored regularly.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters or and follow the manufacturer's recommendations for stunning, such as:

a) — Mechanical:

- position and direction of the shot [AVMA, 2016];
- grain of the cartridge or air pressure appropriate to the type of animal (captive bolt) [Gibson *et al.*, 2015/2014];
- length and diameter of the bolt (captive bolt);
- calibre and type of gun and ammunition (free bullet).

b) — Electrical:

- shape, size and placement of the electrodes [AVMA, 2016];
- pressure contact between electrode and head;
- wetting point of contact;
- minimum exposure time;
- electrical parameters (current intensity(A), waveform type (AC and DC), voltage(V) and frequency(Hz));
- visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors and displays duration of exposure, voltage and applied current.

c) — Controlled atmosphere:

- gas concentrations and exposure time;
- temperature and humidity;
- rate of decompression (low atmospheric pressure system for stunning);
- animal based measure should be monitored during the induction phase, if possible, because this can be a point of highest welfare risk for animals.
- visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors gas concentration and temperature.
- gases or gas mixtures that are *painful* to inhale should preferably not be used to stun or kill pigs

4. Species-specific recommendations:

Non-penetrating captive bolt should not be used in animals with thick skull (e.g. bison, water buffalo) mature cattle and pigs [Finnie, 1993 and Finnie *et al.*, 2003].

The *Competent Authority* should determine effective electrical parameters, based on scientific evidence for different types of animals.

Where high electrical frequencies is used, the amperage should also be increased.

Gases or gas mixtures that are *painful* to inhale should preferably not be used to stun or kill pigs.

1.) Animal welfare concerns:

The main *animal welfare* concern associated with *stunning* is 'ineffective *stunning*' which results in distress, fear and pain, distress or fear during induction of unconsciousness and possible recovery before *death*.

Animals should only be stunned using *stunning* methods that have been scientifically validated as effective for *stunning* that species. The most common methods for *stunning* are mechanical, electrical and exposure to controlled atmosphere. Animals should only be stunned using *stunning* methods that have been scientifically validated as effective for *stunning* that species.

~~Stunning prior to slaughter decreases or avoid prevents distress, fear and pain and suffering to animals during neck cutting and bleeding and also improves workers' safety.~~

2-) Animal-based and other measurable measures include:

Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, just before and during bleeding until death occurs-is confirmed neck-cutting, and during bleed-out [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

No single indicator should be relied upon alone. Multiple indicators should be used to determine whether a stun is effective and the animal is unconscious.

After *stunning*, the state of consciousness is assessed to identify if animals are successfully rendered unconscious or if they are conscious (e.g. *stunning* was ineffective or they recovered consciousness) and therefore at risk of experiencing *distress*, fear and *pain*. For each animal-based measures of state of consciousness, outcomes either suggesting unconsciousness (e.g. presence of tonic seizures) or suggesting consciousness (e.g. absence of tonic seizures) have been identified for each *stunning* method.

3-) Recommendations:

Animals should always be stunned as soon as they are restrained.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system method. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Effectiveness of *stunning* should be monitored using multiple animal-based measures at different stages: immediately after *stunning*, just before and during bleeding until death occurs-is confirmed neck-cutting, and during bleed-out [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

Stunning equipment should be used, cleaned, maintained and stored following manufacturer's recommendations.

Regular calibration of the equipment according to the manufacturer's procedure are recommended. Effectiveness of the *stunning* should be monitored regularly.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters or and follow the manufacturer's recommendations for *stunning* the species and age group concerned, such as:

4-) Species-specific recommendations:

Article 7.5.17.

Mechanical stunning of free-moving animals

1-) Animal welfare concerns:

Mechanical *stunning* is divided into penetrative *stunning* and non-penetrative percussive *stunning* applications. Both applications use different types of devices aimed to induce immediate loss of consciousness as the impact of the bolt on the skull results in concussion and disruption of normal brain function [Daly *et al.*, 1987; EFSA, 2004]. In addition to the concussive effect, penetrative *stunning* devices propel a bolt which penetrates the skull and enters the cranium causing additional damage to the brain. Non-penetrative percussive *stunning* devices propel a blunt bolt which does not penetrate the skull, but results in rapid loss of consciousness from impact (concussive effect). The main hazards preventing effective mechanical *stunning* are incorrect shooting position and incorrect direction of the impact. These may cause ineffective *stunning* and *pain* or short-lasting unconsciousness. Absence of or incorrect

restraint can lead to an incorrect shooting position. Poor maintenance of the equipment or inadequate cartridge power or air line pressure (in pneumatic stunners) can result in low bolt velocity which delivers less concussive impact to the skull. Low bolt velocity, misuse/inappropriate use of cartridge low bolt velocity, narrow bolt diameter or short length of bolt leading to shallow penetration, may also affect the effectiveness of stunning. In older animals with a thicker skull, low bolt velocity may result in there is an increased risk of an ineffective stun, especially with in non-penetrating non-penetrative percussive stunning applications, high bolt velocity may cause fracture of the skull and ineffective stunning [Gibson et al., 2014]. If not applied correctly, Fracture of the skull which may cause and ineffective stunning are more likely to occur with in young animals such as calves, when a higher bolt velocity is used.

For wild certain extensively reared domestic and captive wild animals or feral animals, on-site shooting with a free bullet in the brain can be an alternative to prevent stressful handling and transport. Under such circumstances, the main objective animal welfare concern is a shot that kills the animal immediately.

2-) Animal-based and other measurable measures include:

Mechanical stunning:

Animal-based measures of an effective stun are characterised by the presence of all the following signs: immediate collapse; apnoea; tonic-clonic seizure; absence of corneal reflex or palpebral reflex and; absence of eye movements.

Animal-based measures The presence of any of the following signs may indicate a high risk of ineffective stun or recovery of consciousness are: absence of collapse or attempts to regain posture rapid eye movement or nystagmus, vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex or palpebral reflex and; rhythmic breathing.

3-) Recommendations:

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters or and follow the manufacturer's recommendations for stunning the species and age group concerned, such as:

Mechanical:

- position and direction of the shot [AVMA, 2016];
- grain of the cartridge or air pressure appropriate to the type of animal (captive bolt) [Gibson et al., 20152014];
- ≡ calibre and type of gun and ammunition (free bullet);
- length and diameter of the penetrating bolt (captive bolt);
- ≡ shape and diameter of the non-penetrating bolt;
- ≡ position and direction of the shot [AVMA, 2016].
- calibre and type of gun and ammunition (free bullet).

4-) Species-specific recommendations:

Non-penetrating captive bolt should not be used in animals with thick skull (e.g. bison, water buffalo), mature cattle and pigs [Finnie, 1993 and Finnie et al., 2003].

Water buffaloes should be stunned with penetrative captive bolt in the occipital position using a heavy-duty contact-fired captive bolt gun directed at the nose or using large-calibre firearms and deformation ammunition (e.g. 0.357 Magnum).

Article 7.5.18.

Electrical stunning in free-moving animals

1-) Animal welfare concerns:

Electrical *stunning* involves application of an electric current ~~across~~ to the brain of sufficient magnitude to induce immediate unconsciousness [EFSA, 2004; Grandin, 1980]. The main *hazards* preventing effective electrical *stunning* are: incorrect electrode placement, poor contact, electrical arcing, high contact resistance caused by wool or dirt on the animal surface, dirty or corroded electrode, low voltage/current or high electrical frequency [EFSA, 2004]. Excessively wet hides or fleeces may result in ineffective *stunning* due to electrical current taking the path of least resistance and flowing around the outside of the body rather than through the skull. This may paralyse the animal, or cause pre-stun shocks, rather than *stunning* the animal. If electrodes are energised prior to ensuring they have good contact with the animal, this results in *pain* from the shock.

2-) Animal-based and other measures:

Electrical *stunning*:

Animal-based measures of an effective stun are: An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex; or palpebral reflex.

Animal-based measures of ineffective stun or recovery of consciousness are: The presence of any of the following signs may indicate a high risk of ineffective stun or recovery of consciousness: absence of tonic-clonic seizures; vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; or palpebral reflex; rhythmic breathing.

3-) Recommendations:

When a two-step head to body electrical stun-kill method is used, the electrical current should reach be applied to the brain before it reaches the heart otherwise the animal will experience cardiac arrest while still conscious.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters and follow the manufacturer's recommendations for *stunning* the species and age group concerned, such as:

When a two-step electrical stun-kill method is used, the electrical current must reach be applied to the brain before it reaches the heart otherwise the animal will experience cardiac arrest while still conscious.

Electrical:

- shape, size and placement of the electrodes [AVMA, 2016];
- pressure contact between electrode and head;
- = wetting moisten point of contact;
- = minimum exposure time;
- electrical parameters (current intensity [A], waveform type [AC and DC], voltage [V] and frequency [Hz]);
- = maximum stun to stick interval;
- visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors and displays duration of exposure, voltage and applied current.

4-) Species-specific recommendations:

The ~~Competent Authority~~ should determine eEffective electrical parameters, should be determined based on scientific evidence for different types of animals.

For head-only *stunning*, minimum parameters are recommended for the following species:

- = 1.15 [AVMA] to 1.28 A for bovines [EFSA 2020b],
- = 1.25 A for slaughter (finished) pigs [AVMA],
- = 1.8 A for sows and boars [AVMA],

= 1 A for small ruminants [EFSA 2013c, and EFSA 2015, AVMA].

The minimum parameters above are recommended to be used with an electrical frequency of 50Hz. Where higher electrical frequencies is are used, the amperage should also be increased.

Article 7.5.19.

Controlled atmosphere stunning in free-moving animals

1-) Animal welfare concerns:

Controlled atmosphere *stunning* methods involve the exposure to high concentrations of carbon dioxide (hypercapnia), low concentration of oxygen (hypoxia) or a combination of the two (hypercapnic hypoxia). Loss of consciousness is not immediate following exposure of animals to controlled atmosphere *stunning*. The main *hazards* causing increased *distress* during induction of unconsciousness are irritant or aversive gas mixtures (e.g. CO₂ in high concentrations), low gas temperature and humidity, and overloading of the gondola or restraint. The main *hazards* causing ineffective controlled atmosphere *stunning* are incorrect gas concentration and too short gas exposure time [Anon, 2018; EFSA, 2004; Velarde *et al.*, 2007].

Gases or gas mixtures that are painful to inhale should preferably not be used to stun or kill pigs.

2-) Animal-based and other measurable measures include:

Gas stunning:

Animal-based measures of an effective stun are: An effective stun is characterised by the presence of all the following signs: loss of posture; apnoea; absence of corneal reflex or palpebral reflex; absence of muscle tone.

Animal-based measures of an ineffective stun or recovery of consciousness are: The presence of any of the following signs may indicate a high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex or palpebral reflex; rhythmic breathing.

3-) Recommendations:

e) Controlled atmosphere:

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters and follow the manufacturer's recommendations for *stunning* the species and age group concerned, such as:

– gas concentrations and exposure time;

– temperature and humidity;

– rate of decompression (low atmospheric pressure system for stunning);

– stocking density of the gondola or restraint for pigs;

– animal based measures should be monitored during the induction phase, if possible, because this can be a point of highest welfare risk for animals;

– since animal based measures are difficult to monitor and adapt during the induction phase, resource based measures should be used such as monitoring of gas concentration(s) and exposure time. Gas concentrations and exposure time, temperature and humidity must should be monitored continuously at the level of the animal inside the chamber;

– visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors gas concentration and temperature.

– gases or gas mixtures that are painful to inhale should preferably not be used to stun or kill pigs

Animal-based measures should be monitored during the induction phase, because this can be a point of highest welfare risk for animals. Since animal-based measures are difficult to monitor and adapt during the induction phase, resource-based measures should be used such as monitoring of gas concentration(s) and exposure time. Gas concentrations and exposure time, temperature and humidity should be monitored continuously at the level of the animal inside the chamber.

4-) Species-specific recommendations:

Pigs:

Gases or gas mixtures that are painful to inhale should preferably not be used to stun or kill pigs. However except, if such methods allow animals-pigs to be stunned in groups and it has a short induction phase, as they could can present a certain animal welfare benefits compared to methods requiring individual restraint.

Article 7.5.20.17

Bleeding of free-moving animals

1-) Animal welfare concerns:

The main *animal welfare* concern at the time of bleeding following *stunning* is the recovery of consciousness due to prolonged *stun-to-stick* interval or due to incomplete severance of the main blood vessels.

Bleeding without prior *stunning* increases the causes risk of animal suffering because the incision to sever blood vessels results in substantial tissue damage in areas well supplied with nociceptors. The activation of these nociceptors causes the animal to experience *pain* [Gregory, 2004; Gibson *et al.*, 2009]. Loss of consciousness due to bleeding is not immediate and there is a period during which the animals can feel experience fear, *pain* and *distress* [Gregory, 2004; Johnson *et al.*, 2015]. This period will be reduced by applying *stunning* immediately after neck cutting.

Absence of or ineffective *stunning* may result in animals being released from the *restraint*, shackled, and bled and/or further processed while they are still conscious or have the potential to recover consciousness.

2-) Animal-based and other measurable measures include:

The main animal-based measurable is the blood flow (rate and duration). For animal-based and other measurable measures of return of consciousness after *stunning*, see Article 7.5.16.

In cases of bleeding without *stunning* the animal-based and other measurable measures that indicate loss of consciousness include all the following: absence of muscle tone; absence of corneal reflex or and palpebral reflex; absence of rhythmic breathing. Unconsciousness should be reassessed until death is confirmed. In addition, cessation of bleeding after a continuous and rapid blood flow can be used as an indicator of *death*.

3-) Recommendations:

a) both carotid arteries or the blood vessels from which they arise should be severed;

a-b) continuous and rapid blood flow should be assured after bleeding;

b-c) ~~cessation of blood flow~~ death should be assured before further processing;

e d) bleeding knives should be sharpened for each animal as necessary to fulfil recommendations a) and b).

In addition, the following should be considered:

Slaughter with stunning:

a) the *stun-to-stick* interval should be short enough to ensure that the animal will ~~die before~~ not recovering consciousness before it dies;

b) unconsciousness should be confirmed before bleeding;

- c) animals who are stunned with a reversible method should be bled without delay to avoid them regaining consciousness during bleeding.

Slaughter without stunning:

- a) bleeding should be carried out by a single incision; any second intervention should be recorded and analysed to improve procedures.
- b) further processing may only be carried out when the *death* of the animal has been ascertained and no movement can be detected.

4) Species-specific recommendations:

~~None identified.~~

Cattle Bovines are at risk of prolonged bleed out times and regaining consciousness as the bilateral vertebral arteries are not cut during a neck cut. If As they are not cut, the vertebral arteries will continue to provide blood to the brain. Furthermore and can cause any occlusion of the cut major arteries, will slowing exsanguination. Therefore, bleeding with a cut of the brachiocephalic trunk should always be preferred in cattle bovines.

Article 7.5.2118.

Slaughter of pregnant free-moving animals

1-) Animal welfare concerns:

Fetuses in the uterus ~~are considered not to cannot~~ achieve consciousness [EFSA, 2017; Mellor, D. J. *et al.*, 2005; ~~Diesch *et al.*, 2005~~]. However, if removed from the uterus the fetus may perceive *pain* or other negative impacts-effects.

2-) Animal-based and other measurable measures include:

~~None identified.~~ Signs of consciousness in the foetus neonate after removal from the uterus, such as breathing [Mellor, 2003; Mellor, 2010; EFSA, 2017].

3-) Recommendations:

~~Under normal circumstances~~ WOAH recommendations (Chapter 7.3. Animal transport by land), pregnant animals that would be in the final 10% of their gestation period at the planned time of *unloading* at the *slaughterhouse/abattoir* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that pregnant females are handled separately.

The fetus should be left undisturbed in utero for at least 30 minutes after the *death* of the dam [EFSA, 2017; Anon, 2017]. The uterus could be removed as a whole, clamped and kept intact such that there is no possibility for the fetus to breathe.

In cases where the fetus is removed before 30 minutes has elapsed *euthanasia (captive bolt followed by bleeding)* should be carried out immediately.

4-) Species-specific recommendations:

~~None identified.~~

Article 7.5.2219.

Emergency killing of free-moving animals

This article addresses animals that show signs of severe *pain* or other types of severe suffering before being unloaded or within the *slaughterhouse/abattoir*. These animals may correspond to animals unfit to travel as listed in Article 7.3.7. Principles described below should be described in the emergency plan and may also apply to animals that are not suitable for *slaughter* for commercial reasons, even if they do not present signs of *distress, pain* or suffering.

1-) Animal welfare concerns:

Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause ~~undue~~ distress and pain and suffering. ~~This is more likely in animals of low economic value.~~

2-) Animal-based and other measurable measures include:

Animals requiring emergency *killing* are unable to walk independently or present severe injuries such as fractures, large open wounds, or prolapses. They may also present clinical signs of serious illness or being in a state of extreme weakness. New-born animals or animals that gave birth within the last 48 hours may also belong to this category.

3-) Recommendations:

Animals should not be moved unless it can be done without causing further distress, pain or suffering.

Animal handlers should euthanise the animal as soon as possible.

Emergency *killing* should be systematically recorded and analysed in order to improve procedures and prevent recurrences.

4-) Species specific recommendations:

~~None identified.~~

Article 7.5.2320.

Methods, procedures or practices that should not be used ~~unacceptable on animal welfare grounds~~ for free-moving animals

1) ~~None of the~~ The following practices for handling animals are unacceptable and should not be used under any circumstances:

- a) crushing, twisting or breaking tails of animals;
- b) applying pressure using an injurious object or applying an irritant substance to any part of an animal to sensitive areas such as eyes, mouth, ears, anogenital region or belly;
- c) hitting animals with instruments such as large sticks, sticks with sharp ends, ~~metal~~-piping, stones, fencing wire or leather belts;
- d) kicking, throwing or dropping animals;
- e) grasping, lifting or dragging animals only by ~~some~~ body parts such as their tail, head, horns, ears, limbs, wool or hair;
- f) dragging animals by any body part, by any means, including with chains, or ropes or by hand;
- g) forcing animals to walk over other animals;
- h) interfering with any sensitive area (e.g. eyes, mouth, ears, anogenital region, udder or belly).

2) ~~None of the~~ The following practices for restraining conscious animals are unacceptable and should not be used under any circumstances:

- a) mechanical clamping of the legs or feet of the animals as the sole method of restraint, including tying limbs together or lifting one or more limbs off the ground;
- b) breaking legs, cutting leg tendons or blinding animals;
- c) severing the spinal cord, by using for example a puntilla or dagger;
- d) applying electrical current that does not span the brain;

- e) suspending or hoisting ~~conscious animals~~them by the feet or legs;
 - f) severing brain stem by piercing through the eye socket or skull bone;
 - g) forcing animals to the ground sit or lay down by one or more handlers jumping on and lying across the animal's back;
 - h) trip floor boxes that are designed to make animals fall.
- 3) Breaking the neck while the animal is still conscious during bleeding is also an unacceptable practice.

Article 7.5. ~~2421~~.

Arrival of animals in containers

On arrival at the *slaughterhouse/abattoir*, animals ~~will~~would already have been exposed to *hazards* that may have negative impacts on their welfare. Any previous *hazards* will have a cumulative effect that may impair the welfare of the animals throughout the *slaughter* process. Therefore, animals should be transported to the *slaughterhouse/abattoir* in a manner that minimises adverse animal health and welfare outcomes, and in accordance with Chapters 7.2. and 7.3.

1-) Animal welfare concerns:

Animals in *containers* have smaller space allowances than on farm, undergo water and *feed* deprivation, may have suffered from injury and may be exposed to thermal stress due to adverse weather conditions and stress from social disturbance, noise, vehicle vibration and motion. In addition, stationary *vehicles* may have insufficient ventilation. Delays in *unloading containers* will prolong or exacerbate the impact of these *hazards*. Under these circumstances, injured or sick animals requiring urgent attention will not be identified and therefore the duration of their suffering will be increased.

2-) Animal-based and other measurable measures include:

It can be difficult to assess animal-based measures while animals are in the *containers* and especially when the *containers* are on the *vehicle* or when many containers are stacked on top of each other. Some measurable measures that may be assessed include animals with injuries, or those that are sick or have died. Panting, reddening of the ears (heat stress in rabbits), shivering and huddling may indicate thermal stress. In rabbits drooling and licking may indicate prolonged thirst.

Time from arrival to *unloading* and *slaughter*, the environmental temperature and humidity (e.g. ambient, inside the vehicle) can be used to establish relevant thresholds for corrective action.

3-) Recommendations:

Animals should be slaughtered as soon as they arrive at the *slaughterhouse/abattoir*. If not possible, *containers* should be unloaded, or *vehicles* should be placed in *lairage* or in sheltered and adequately ventilated area, promptly on arrival. This is facilitated by scheduling the arrival of the animals at the *slaughterhouse/abattoir* to ensure that there are sufficient personnel and adequate space in the *lairage* area. Time at lairage should be kept at a minimum.

Consignments of animals assessed to be at greater risk of compromised animal welfare hazards (e.g. from long journeys, prolonged *lairage*, end-of-lay hens) should be unloaded first or should be considered for prioritised *slaughter*. When no available space is immediately available, creating space should be a priority. Provisions should be made to provide shelter, shade, cooling or heating systems or additional ventilation during waiting periods, or animals should be transported to an alternative nearby location where such provisions are available. Mortalities and injuries should be reported to the competent authority.

4-) Species-specific recommendations:

~~Poultry is especially sensitive to extreme temperatures and therefore special attention should be taken when dealing with delays in unloading this species in extreme temperatures.~~

Birds may get trapped or their wings or claws may get caught in the fixtures, mesh or holes in poorly designed, constructed or maintained transport systems. Similarly, rabbits may trap their paws in the fixtures mesh or holes in

poorly designed, constructed or maintained transport systems. Under these situations, operators *unloading* birds or rabbits should ensure gentle release of trapped animals.

Article 7.5.2522.

Moving of animals in containers

This article addresses the handling of ~~containerised~~ animals in containers during *unloading* and *lairage*, and into the *killing* area.

1-) Animal welfare concerns:

During *unloading* and moving *containers*, animals can be exposed to *pain, stress* and fear due to tilting, dropping or shaking of the *containers*.

During unloading and moving containers, animals can be exposed to adverse weather or climate conditions and experience pain and distress, face heat stress, frost bite, or death. [EFSA, 2019].

2-) Animal-based and other measurable measures include:

- a) animals with broken limbs or dislocated joints;
- b) animals that ~~strike against the facilities~~ collide with facility structures ~~strike against the facilities~~;
- c) animals vocalising vocalisations referring to distress;
- d) body parts (i.e. wings, limbs, feet, paws or heads) stuck between *containers*;
- e) animals injured by sharp projections inside *containers*.

3-) Recommendations:

Containers in which animals are transported should be handled with care, moved slowly, and should not be thrown, dropped or knocked over. Where possible, they should be horizontal while being loaded or unloaded mechanically and stacked to ensure ventilation and prevent animals piling on one another. In any case, *containers* should be moved and stored in an upright position as indicated by specific marks.

Animals delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care to avoid injury by crushing or jamming of body parts.

Animals that are injured, jammed or sick require immediate action and, when necessary, should be taken from the *containers* and euthanised without delay. Refer to Articles 7.5.34 ~~7.5.8, 7.5.9, 7.6.8 and 7.6.1724~~.

Staff should routinely inspect the *containers* and remove the broken *containers* that should not be re-used.

4-) Species-specific recommendations:

~~None identified.~~

Article 7.5.2623.

Lairage of animals in containers

1-) Animal welfare concerns:

Animals during *lairage* may be exposed to several hazards to animal welfare ~~hazards during lairage~~ including:

- a) ~~feed~~ feed and water deprivation leading to prolonged hunger and thirst;
- b) poor ventilation;

- ~~cb)~~ absence of protection against adverse weather or climate conditions ~~extremes in climate~~ leading to thermal stress;₂
- ~~de)~~ sudden or excessive noises, including from personnel, leading to fear;₂
- ~~ed)~~ insufficient space to lie down and move freely leading to fatigue and aggressive behaviour;₂
- ~~fe)~~ not being inspected or accessible for emergency killing when necessary.

2-) Animal-based and other measurable measures include:

- a) thermal stress (e.g. panting, shivering, huddling behaviour, reddening of the ears);₂
- b) space allowance;₂
- c) excessive soiling with faeces;₂
- d) injuries (e.g. splay leg, open wounds, fractures, dislocations);₂
- e) sick or dead animals.

3-) Recommendations:

Animals should be slaughtered upon arrival at the *slaughterhouse/abattoir*.

Staff should routinely inspect and monitor containers while in the lairage to observe animals for signs of distress, fear and pain suffering and distress and take appropriate corrective action to address any concerns.

The *lairage* should provide animals with protection against adverse weather conditions.

Animals should be protected from sudden and excessive noise (e.g. ventilation fans, alarms, or other indoor or outdoor equipment).

4-) Species-specific recommendations:

~~None identified.~~

Article 7.5.2724.

Unloading animals from containers before stunning

1-) Animal welfare concerns:

Animals are removed manually or ~~automatically~~ mechanically by tilting (~~poultry~~) from the transport *containers*.

When the *containers* with ~~birds~~ animals are manually or mechanically emptied by tipping, animals fall on to conveyors. Dumping, piling up and shock ~~might happen~~ may occur, especially for the last ~~birds~~ animals, which are often removed by manual or mechanical shaking of the *containers*.

Other *hazards* include:

- a) narrow openings or doors of the *containers*;
- b) *containers* placed too far away from the place of shackling or stunning;
- c) inappropriate handling and removal of animals from *containers* before stunning;
- ~~ed)~~ incorrect design of manual or mechanical tipping manually or using mechanical equipment that cause animals to falling from a height and conveyor belts that are running too fast or too slow resulting in piling or injured animals;
- e) conveyor belts that are running too fast or too slowly or are not properly aligned resulting in piling or injury.

2-) Animal-based and other measurable measures include:

- a) animals falling;
- b) struggling, including wing flapping;
- c) escape attempts;
- d) vocalisation referring to distress;
- e) injuries, dislocations, fractures;
- f) pilling-off of animals.

3-) Recommendations:

Removal of animals from ~~the~~ containers in a way that causes pain, e.g. by one leg, wings, neck or ears, should be avoided.

Animals should be removed from containers by the body or by both legs using both hands and one animal at a time. Animals should not be grabbed and lifted by one leg, the ears, wings or fur and they should not be thrown, swing or dropped.

Animals should not be mistreated in the process of unloading and shackling prior to stunning (e.g. excessive force used when shackling, punching, kicking, or otherwise hurting).

Modular systems that involve tipping of live birds animals are not conducive to maintaining good animal welfare. These systems, when used, should be have an incorporated with a mechanism to facilitate birds animals sliding out of the transport system, rather than being dropped or dumped on top of each other from heights of more than a metre.

It should be ensured that every animal is removed from the containers before they are returned.

4-) Species-specific recommendations:

Any animal Birds with broken bones and/or dislocated joints should be humanely/emergency killed before being hung on shackles for processing.

Article 7.5.2825.

Restraint for stunning animals from containers

1-) Animal welfare concerns:

The purpose of restraint is to facilitate the correct application of the stunning and/or bleeding procedures equipment. Incorrect restraint and/or handling cause distress, fear and pain fear and distress and may lead to ineffective stunning and/or bleeding.

Other hazards include:

- a) Inversion can provoke compression of the heart and lungs or air sacs by the viscera and might compromise breathing and cardiac activity. This might will cause distress, fear and pain and fear in conscious birds and rabbits.
- b) Shackling hanging birds animals upside down by inserting both legs into metal shackles. During shackling, the birds animals are also subjected to compression of their legs and wing flapping by their neighbour(s), leading to distress, pain and fear.
- c) Inappropriate shackling (e.g. shackles are too narrow or too wide, birds animals are hung shackled by one leg, or when one bird animals is shackled on two different adjacent shackles) leads to distress, pain and fear when shackles are too narrow or too wide, when the birds are hung by one leg, or when one bird is shackled on two different adjacent shackles. Line speed, without a concomitant increase in workforce, can contribute to poor shackling outcomes.

- d) Drops, curves and inclination of the shackle line or high speed of the shackle line create fear and possible *pain* due to the sudden changes in position as well as increased effects of inversion.

2-) Animal-based and other measurable measures include:

- a) struggling (wing flapping for birds;
b) escape attempts;
c) high frequency vocalisations referring to (distress calls) of high frequency (poultry);
d) injuries and pain caused by excessive force of restraint or shackling;
e) respiratory distress.
e-) fear caused by prolonged restraint, which may exacerbate insecure or excessive restraint.

3-) Recommendations:

Stunning methods that avoid handling, shackling and inversion of conscious animals should always be preferred.

Where this is not possible, animals should be handled and restrained to minimise without provoking struggling or attempts to escape.

Avoid inversion of conscious animals.

Avoid shackling of conscious animals but there is no real way to prevent or correct shackling, however, as it is a part of some of the stunning methods most commonly used in slaughter plants.

Shackle lines must should be constructed and maintained so they do not jolt birds/animals as because this is likely to stimulate wing flapping (poultry) or struggling. Shackle line speeds must should be optimised so that they do not cause the birds/animals to struggle. Shackling duration prior to stunning should be kept to a minimum.

To minimise wing flapping (poultry) or struggling, breast support should be provided to the birds from the shackling point up to the stunner.

Inappropriate shackling, such as shackles that are too narrow or too wide shackles, birds/animals being pushed into the shackles with force, birds/animals shackled by one leg, or shackled on two different adjacent shackles, should be avoided.

Inappropriate shackling can be prevented by the appropriate training of the relevant staff, by rotating the staff to avoid boredom and fatigue training staff to handle birds/animals with care and compassion, by an competent professional, shackling birds/animals gently by both legs and killing injured birds/animals before shackling, by rotating staff at regular intervals to avoid boredom and fatigue and by using shackles that are appropriate and adjustable for to the species and size of the birds/animals.

4-) Species-specific recommendations:

Rabbits:

Restraining for head-only electrical stunning is manual and involves holding the rabbit with one hand supporting its belly, and the other hand guiding the head into the stunning tongs or electrodes.

Rabbits should not be lifted or carried by the ears, head, hair or, one leg, or by the skin at the back of the neck without supporting the body.

Poultry:

Shackling should not be used with heavy birds like such as parent flocks, turkeys or with birds that are more susceptible to fractures like (e.g. end-of-lay hens).

Poultry should not be lifted or carried by the head, neck, wings or one leg.

Article 7.5.2926.

Head-only electrical stunning of animals in containers

1-) Animal welfare concerns:

Electrical *stunning* involves application of an electric current ~~to~~ across the brain of sufficient ~~magnitude~~ magnitude current and intensity to induce immediate unconsciousness [EFSA, 2004; Grandin, 1980]. The main *hazards* preventing effective electrical *stunning* are: incorrect electrode placement, poor contact, dirty or corroded electrode, electrical arcing, high contact resistance caused by hair and feathers ~~wet~~ or dirt on the animal surface, and inappropriate electrical parameters (low voltage/current or high frequency [EFSA, 2004]).

2-) Animal-based and other measurable measures include:

~~Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, and just before and during bleeding until death occurs is confirmed [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].~~

~~No indicator should be relied upon alone. Multiple indicators should be used to determine whether a stun is effective and the animal is unconscious.~~

~~Animal-based measures of an effective stun are: An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal or reflex; ~~absence of and palpebral reflex.~~~~

~~Animal-based measures of ineffective stun or recovery of consciousness are: The presence of any of the following signs indicate a high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex; or palpebral reflex; rhythmic breathing-; spontaneous swallowing and head shaking.~~

3-) Recommendations:

Animals should be stunned as soon as they are restrained.

~~To minimise any disturbance to birds during shackling, where shackles are wet to improve conductivity, they should be wet only prior to birds' legs being placed in them.~~

In the case of ineffective *stunning* or recovery, animals should be re-stunned ~~immediately~~ using a backup system or ~~and or~~ be immediately killed immediately. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be used, cleaned, maintained and stored following the manufacturer's recommendations.

~~Constant current stunners ensure that the minimum current is provided to the animal independently from individual impedance and should always be preferred to constant voltage stunners since because the first ones former ensure that the minimum current is provided to the animal independently from individual impedance.~~

Regular calibration of the equipment according to the manufacturer's procedure ~~are~~ is recommended. Effectiveness of the *stunning* should be monitored regularly.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters and/or follow the manufacturer's recommendations for *stunning*, such as:

- shape, size and placement of the electrodes [AVMA, 2016];
- contact between electrode and head;
- electrical parameters (current intensity [A], waveform type [AC and DC], voltage [V] and frequency [Hz]);
- visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors and displays voltage and applied current.

4.) Species-specific recommendations:

~~The Competent Authority should determine Effective electrical parameters, should be determined based on scientific evidence data on the welfare outcomes for different types of animals in accordance with point 5 of Article 7.1.4.~~

For head-only stunning, minimum parameters are recommended for the following species:

- 240 mA for hens and broiler chicken [EFSA, 2019],
- 400 mA for turkeys [EFSA, 2019],
- 600 mA for geese and ducks [EFSA, 2019],
- 140 mA for rabbits (100V of a 50 Hz sine wave AC) [EFSA, 2020a].

Article 7.5.3027.

Electrical water-bath stunning for poultry

1.) Animal welfare concerns:

In electrical water-bath *stunning* poultry are inverted and ~~hung~~ shackled by the legs from a shackle line. The bird's head has direct contact with the water-bath, and an electric current is passed from the water through the bird to the leg shackle. *Hazards* that may prevent effective electrical *stunning* are: lack of contact between head and water, differences in individual bird resistance, improper system grounding, pre-stun shocks due to wings contacting water before the head, and the use of inappropriate electrical parameters (low voltage/current or high frequency [AVMA 2016]).

Hazards that increase the likelihood of animals experiencing pre-stun shocks are: poor handling at shackling, inappropriate line speed, physical contact between birds, incorrect angle of entry ramp, ~~wet~~ entry ramp wetted by charged water, incorrect water-bath height, and shallow immersion.

Factors affecting individual bird resistance include the resistance between the shackle and the leg (leg/shackle interface), shackling on top of a severed foot, shackling by one leg, poor shackle position, incorrect shackle size, dry shackles, scale on the shackle surface, and keratinised skin on the legs (e.g. older birds).

Where ~~inappropriate~~ insufficient electrical *stunning* parameters (e.g. high frequency) are used, conscious animals are at risk of being electro-immobilised or paralysed causing *pain* and suffering.

2.) Animal-based and other measurable measures include:

~~Effectiveness of *stunning* should be monitored at different stages: immediately after *stunning*, and just before and during bleeding until death occurs is confirmed [EFSA, 2019; EFSA, 2013a; EFSA, 2013b; AVMA, 2016].~~

~~No indicator should be relied upon alone. Multiple indicators should be used to determine whether a stun is effective and the animal is unconscious.~~

~~Animal-based measures of an effective stun are An effective stun is characterised by the presence of all the following signs: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal reflex; ~~absence of or~~ palpebral reflex.~~

~~Animal-based measures of ineffective stun or recovery of consciousness are The presence of any of the following signs indicate a high risk of ineffective stun or recovery of consciousness: vocalisation; spontaneous blinking; righting reflex; presence of corneal reflex or palpebral reflex; rhythmic breathing; ~~spontaneous swallowing; and head shaking.~~~~

3.) Recommendations:

The height of the water-bath stunner ~~must~~ should be adjusted so that the birds' heads are completely immersed in the water cannot pull themselves up and avoid the stunner. Avoid distractions such as people walking under the birds as because this can cause birds to pull up.

Personnel should watch for short or stunted birds as these birds will not be able to make contact with the water and will not be stunned. These birds should be stunned in the slaughter line (e.g. penetrative captive bolt) or removed and euthanised.

The rail of the shackle line should run smoothly. Sudden movement such as jolts, drops or sharp curves in the line may cause birds to flap and avoid the stunner.

To minimise any disturbance to birds during shackling, where shackles are wet to improve conductivity, they ~~could~~ should be wetted only prior to birds' legs being placed in them.

Pre-stun shocks should be avoided and can be reduced by having a smooth shackle line and entry in to the water-bath and by adjusting the water level of the bath to minimise overflow.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system and or be killed immediately. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be used, cleaned, maintained and stored following the manufacturer's recommendations.

Constant current stunners should always be preferred to constant voltage stunners since the first ones because the former ensure that the minimum current is provided to the animals independently from individual their impedance.

Regular calibration of the equipment according to the manufacturer's procedure are is recommended. Effectiveness of the *stunning* should be monitored regularly.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters or follow the manufacturer's recommendations for *stunning*, such as:

- water level;
- number of birds in the water-bath;
- contact between water and head, as well as between the legs and the leg shackle;
- electrical parameters (current intensity [A], waveform type [AC and DC], voltage [V] and frequency [Hz]);
- visual or auditory warning system to alert the operator to proper or improper function, such as a device that monitors and displays voltage and applied current.

Ensure an optimum combination of voltage and frequency during electrical water-bath *stunning* practices, to maximise the effectiveness of *stunning*.

Hazards to animal welfare hazards such as inversion of conscious inversion of birds, pre-stun shocks, and variability in electrical current delivered to each bird are inherent risks of electrical water-bath stunning. The use of electrical water-bath stunning should be avoided and replaced by Thus, alternative stunning systems which avoid these associated animal welfare hazards should be preferred.

4-) Species-specific recommendations:

~~The Competent Authority should determine effective~~ Effective electrical parameters, should be based on scientific evidence for different types and species of birds.

~~The Competent Authority should determine~~ Effective electrical parameters should be based on scientific evidence data on the welfare outcomes for different types and species of animals birds in accordance with point 5 of Article 7.1.4.

For water-bath stunning depending on the frequency, minimum parameters are recommended for the following species [EFSA, 2019]:

- For fFrequency below 200 Hz:
 - 100 mA for chicken,

- 250 mA for turkeys,
- 130 mA for ducks and geese,
- 45 mA for quails.
- For frequency from 200 to 400 Hz:
 - 150 mA for chicken,
 - 400 mA for turkeys.
- For frequency from 400-600 Hz:
 - 200 mA for chicken,
 - 400 mA for turkeys.

Birds should receive the current for at least 4 seconds.

Ducks, geese and quails should not be stunned at frequencies higher than 200 Hz [EFSA, 2019].

Chicken and turkeys should not be stunned at frequencies higher than 600 Hz [EFSA, 2019].

Article 7.5.3128.

Mechanical stunning of animals arriving in containers

The mechanical methods described here are penetrative and non-penetrative captive bolt systems, ~~percussive blow to the head, cervical dislocation and decapitation.~~ Effective mechanical *stunning* requires a severe and immediate damage to the brain caused by the application of mechanical force. For that reason, cervical dislocation and decapitation cannot be considered as *stunning* methods.

1-) Animal welfare concerns:

Mechanical methods required precision and often physical strength to restrain and stun the animals. A ~~€~~Common causes ~~for of the~~ misapplication of these methods ~~is are the a~~ lack of proper skill and ~~the~~ operator fatigue.

Penetrative and non-penetrative captive bolt

An incorrect shooting position or incorrect captive bolt parameters (not hitting the skull with sufficient force) will mis-stunned the animal, leaving it conscious and leading to serious wounds and consequently distress, fear and pain, ~~suffering, and fear.~~

Improper captive bolt parameters may be linked to: the use of an inappropriate ~~improper~~ gun (bolt diameter); inappropriate ~~improper~~ cartridges; or an overheated or badly maintained gun.

Percussive blow to the head

An incorrect application of the blow, by not hitting the brain with sufficient force will also mis-stunned the animals leading to serious wounds and consequently pain and fear.

In addition, the blow might not be consistently effective when delivered to an animal held upside down by its legs (part of the energy is dissipated by the movement of the body instead of damaging the brain).

Cervical dislocation and decapitation

~~Because neither method applies to the brain, †The loss of consciousness may be delayed, is not immediate and, in some cases, † when the method is not properly applied there. There is a risk of neck crushing and the~~ distress, fear and pain and fear of the animal might be prolonged.

Decapitation

In addition, ~~d~~Decapitation is associated with an open wound leading to intense ~~pain~~ and delayed loss of consciousness, leading to intense ~~distress, fear and pain~~ [EFSA, 2019].

2-) Animal-based and other measurable measures include:

Penetrative and non-penetrative Captive bolt: ~~and percussive blow to the head~~

~~With birds, s~~Severe convulsions (wing flapping ~~[poultry]~~ and leg kicking ~~i.e. uncontrolled muscular movements~~) occur immediately after ~~shooting or percussive blow~~ the mechanical stunning intervention. This is due to the loss of control of the brain over the spinal cord. Since mechanical stunning is applied ~~on~~ to individual animals, its efficacy can be assessed immediately after the stun [Nielsen *et al.*, 2018].

Effectiveness of stunning should be monitored at different stages: immediately after stunning, and just before and during bleeding until death is confirmed occurs [EFSA, 2019; EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

Animal-based measures of an effective stun are: An effective stun is characterised the following signs: the absence of corneal reflex; ~~or~~ or palpebral reflex; apnoea; the absence of rhythmic breathing and the presence of immediate collapse/loss of posture; presence of tonic-clonic seizure.

Animal-based measures of ineffective stun or recovery of consciousness are: The presence of any of the following signs indicates a high risk of ineffective stun or recovery of consciousness: vocalisations; spontaneous blinking; righting reflex; presence of corneal reflex ~~or~~ or palpebral reflex; rhythmic breathing.

Cervical dislocation and decapitation

Death can be confirmed from several indicators: complete severance between the brain and the spinal cord (i.e. gap between neck vertebrae and base of skull), permanent absence of breathing, absence of corneal or palpebral reflex, dilated pupil, or relaxed carcass [EFSA, 2013a].

Decapitation

ABM for death by decapitation: ~~d~~Death can be confirmed by complete severance between the head and the body

3-) Recommendations:

Penetrative and non-penetrative Captive bolt ~~and percussive blow to the head~~ should only be used as backup or for small-scale throughput slaughtering as in small slaughterhouses/abattoirs or on-farm slaughter or for emergency killing.

Penetrative and non-penetrative Captive bolt:

The captive bolt gun should be used, cleaned, maintained and stored following the manufacturer's recommendations.

The power of the cartridge, compressed air line pressure or spring should be appropriate for the species and size of birds. Cartridges should be kept dry and the gun regularly inspected and maintained.

Effectiveness of the stunning should be monitored regularly.

Because it requires precision, this method should only be applied with proper restraint of the head of the animals. In addition, in the case of birds, they should be restrained in a bleeding cone to contain wing flapping.

The captive-bolt should be pointing perpendicularly on the parietal bones of birds.

Placement is different for birds with ~~or~~ and without combs:

Without comb:

The placement of the device should be directly on the midline of the skull and at the highest/widest point of the head with the captive bolt aimed directly down towards the brain [AVMA, 2020].

With comb:

As far as captive bolt in chickens (and other poultry with comb development) is concerned, the placement of the device should be directly behind the comb and on the midline of the skull with the captive bolt aimed directly down towards the brain of the bird [AVMA, 2020].

The power of the cartridge, compressed air line pressure or spring should be appropriate for the species and size of birds. Cartridges should be kept dry and the gun regularly inspected and maintained.

This method should be dealt with a single sufficiently strong hit the frontoparietal region of the head and should result in loss of auditory evoked potentials when using an EEG in broilers and broiler breeders.

Fatigue of the operator can lead to inconsistency in application, creating concern that the technique may be difficult to apply humanely to large numbers of birds. It should not be done with the animal's head hanging down since inversion is stressful and part of the energy of the blow will be dissipated by the movement of the body.

It should not be used as a routine method and should be limited as a back-up method limited to small animals (e.g. up to 3kg liveweight manually and up to 5 kg mechanical).

Rabbits:

The device should be placed in the centre of the forehead, with the barrel in front of the ears and behind the eyes. The device should be discharged twice in rapid succession at the pressure recommended for the age and size of the rabbit [Walsh *et al.*, 2017].

The power of the cartridge, compressed air line pressure or spring should be appropriate for the animal species and size of birds. Cartridges should be kept dry and the gun regularly inspected and maintained.

As an indication for broiler chickens, the appropriate specifications for captive bolt *stunning* are a minimum of 6 mm bolt diameter driven at an air pressure of 827 kPa to a penetration depth of 10 mm [Raj and O'Callaghan, 2001].

There should be a sufficient bolt number of bolt guns such that they are allowed to cool between operations, and they should be cleaned and maintained according to manufacturer's instructions.

Percussive blow to the head

This method The blow should be dealt with a single sufficiently strong hit placed in the frontoparietal region of the head resulted in loss of auditory evoked potentials in broilers and broiler breeders.

Fatigue of the operator can lead to inconsistency in application, creating concern that the technique may be difficult to apply humanely to large numbers of birds. It should not be done with the animal's head hanging down since inversion is stressful and part of the energy of the blow will be dissipated by the movement of the body.

Considering that the application of this method is entirely manual and prone to error, percussive blow might be used only when no other *stunning* method is available and, by establishing a maximum number of animals per operator in time to avoid errors due to operator fatigue.

It should not be used as a routine method and should be limited as a back-up method limited to small size animals (e.g. up to 3kg liveweight manually and up to 5 kg mechanical).

This method should not be used in rabbits because of the difficulties to apply this method efficiently.

Cervical dislocation

Cervical dislocation is not recommended in conscious animals and should only be used when there are no other options available, should not be used in conscious birds under any circumstances, avoided since it does not render the animal unconscious immediately.

It should not be used as a routine method and should be limited to use as a back-up method limited to for small size animals (e.g. up to 3kg liveweight manually and up to 5 kg mechanically).

Mechanical dislocation should be preferred to manual dislocation as because the efficiency of the firstformer is less dependent on the operator's strength than the latter.

~~Cervical dislocation should not be undertaken performed with tools such as pliers as they cause neck crushing tools (e.g. pliers), rather than concussion, and consequently pain and fear. These tools may not cause complete severance between the brain and the spinal cord.~~

Decapitation

~~Decapitation should not be used in conscious rabbits because it does not render the animal unconscious immediately.~~

4-) Species-specific recommendations:

Because of their size, heavy animals such as turkeys, geese or mature rabbits should not be stunned through percussive blow to the head or cervical dislocation.

Turkeys, ducks and geese and chickens may be also properly stunned by non-penetrative captive bolt [Walsh et al., 2017; Woolcott et al., 2018; Gibson et al., 2019, Stiewert et al. 2021; HSA, 2023].

Article 7.5.32~~29~~.

Controlled atmosphere stunning for animals in containers poultry

Animals may be exposed to controlled atmosphere *stunning* methods either directly in crates or after being unloaded on a conveyor belt. Animals are not subject to restraint. Controlled atmosphere *stunning* includes exposure to carbon dioxide, inert gases, mixtures of carbon dioxide with inert gases or low atmosphere pressure (LAPS). The effectiveness and animal welfare impacts of LAPS are still being evaluated as it is a newer form of controlled atmosphere stunning in comparison with other methods, ; so far it has only been demonstrated to be effective for the stunning of chickens been studied in poultry and therefore is not suitable for use in rabbits or other animals without further study.

1-) Animal welfare concerns:

A common concern of all controlled atmosphere *stunning* methods is the risk of insufficient exposure of animals to the modified atmosphere, which can result in animals recovering returning to consciousness before or during bleeding and cause causing respiratory distress respiratory, fear and pain and fear. The insufficient exposure to the modified atmosphere may be due to either a too short exposure time, a too low concentration of gas, too high stocking density or a combination of these variables.

These variables are critical because animals being stunned in large groups need special attention to ensure unconsciousness prior to neck cutting. For this reason, the duration of unconsciousness induced needs to be longer than required by other *stunning* methods to ensure that animals do not recover consciousness prior to being killed.

Furthermore, hazards causing increased distress during induction of unconsciousness are irritant or aversive gas mixtures, low gas temperature and humidity. In the case of exposure to carbon dioxide, there is a risk that animals are exposed to a too high a concentration of this gas, leading to pain and distress. Exposure of conscious animals to more than 40% carbon dioxide (CO₂) will cause painful stimulation of the nasal mucosa and aversive reactions.

Low atmospheric pressure systems (LAPS) should not be confused with decompression-; LAPS utilise a slow removal of air where animals exhibit minimal to no aversive behaviours. Decompression is a fast process that is associated with induction of pain and respiratory distress.

2-) Animal-based and other measurable measures include:

It may be difficult to monitor the effectiveness of controlled atmosphere *stunning* due to because of limited access to observation observe of animals during the *stunning* process. All chamber-type systems should have either windows or video cameras so that problems with induction can be observed. If problems are observed, there is a need to take immediately any corrective measures that could alleviate the suffering of the animals concerned.

Therefore, it is essential that the unconsciousness death of animals is confirmed at the end of the exposure to the controlled atmosphere.

Death Unconsciousness can be confirmed from by permanent absence of breathing apnoea, absence of corneal reflex or palpebral reflex, dilated pupils and relaxed carcass.

Since animal-based measures are difficult to monitor, resource-based measures should also be used such as monitoring of gas concentration(s), exposure time, gas displacement rate, and decompression rate of air removal (for LAPS low atmosphere pressure).

3-) Recommendations:

Conscious animals should not be exposed to carbon dioxide concentrations exceeding 40%. Any compressed gas should also be vaporised prior to administration and humidified at room temperature to prevent the risk of animals experiencing thermal shock.

The duration of exposure and the gas concentration should be designed and implemented in such a way that all animals are rendered unconscious until death ~~dead before being shackled.~~

Gas concentrations and exposure time, temperature and humidity ~~must~~ should be monitored continuously at the level of the animal inside the chamber.

Stunning systems should have visual and auditory warning system to alert the operator to improper function, such as inappropriate gas concentration or decompression rate.

In the case of low atmosphere pressure ~~stunning-decompression~~ the rate of air removal should be monitored continuously. The decompression rate should not be greater than or equivalent to a reduction in pressure from standard sea level atmospheric pressure (760 Torr) to 250 Torr in not less than 50 s. During a the second phase, a minimum atmospheric pressure of 160 Torr ~~shall~~ should be reached within the following 210 s.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

4-) Species-specific recommendations:

The use of Low aAtmosphere pPressure stunning should be restricted to broilers and newly hatched chicks. has only been scientifically studied on commercial broilers chickens [Gurung et al., 2018; Jongman and Fisher, 2021] and therefore should not be used for other animals until further information is available.

The recommended CO₂ displacement rate for rabbits is 50-60% of the chamber or cage volume/min as this results in a significantly shorter time to insensibility and death [Walsh et al., 2016, AVMA 2020]. Exposure to CO₂ at high concentrations can reduce pre-stun handling and produce irreversible *stunning* in rabbits. With a stun-to-stick interval of up to 2 min, 200 s of exposure at 80%, 150 s at 90% and 110 s at 98% are recommended [Dalmau et al., 2016]. While there are advantages to high CO₂ exposure in rabbits, it is not without welfare concerns (aversion, vocalisation).

Article 7.5. ~~3330~~.

Bleeding ~~in~~ of animals arriving in containers

1-) Animal welfare concerns

~~In poultry, t~~ The most common animal welfare concern at the time of bleeding is recovery of consciousness due to ineffective electric water bath stunning practices or an ineffective bleeding. There are ~~a lot~~ many of factors that determine the efficacy of a *stunning* procedure such as type of ~~chicken-animal (broiler, breeder, layer),~~ animal weight, voltage, frequency, impedance and duration of stunning or gas (mixture) concentration and exposure [Zulkifli et al., 2013; Raj, 2006; Wotton & Wilkins, 2004].

Improper *stunning* practice leads to the risk of animals ~~suffering-experiencing~~ distress, fear and pain ~~fear, distress, and pain,~~ during ~~and after slaughter~~ if they regain consciousness. There is ~~also~~ an additional risk of injury ~~on~~ to bones (coracoid and scapula), wings and joints due to ~~flapping struggling~~ if birds animals regain consciousness.

Bleeding without prior *stunning* ~~increases the risk of~~ causes animal suffering because the incision to sever blood vessels results in substantial tissue damage in areas well supplied with nociceptors. The activation of these nociceptors causes the animal to experience *pain* [Gregory, 2004; Gibson et al., 2009]. Loss of consciousness due to bleeding is not immediate and there is a period during which the animals ~~can feel~~ experience distress, fear, and pain and distress [Gregory, 2004; Johnson et al., 2015].

In case of bleeding without *stunning*, ~~higher more~~ cases of injury, bruising, haemorrhage and broken body parts are expected to occur due to wing flapping and violent muscular contractions [McNeal *et al.*, 2003].

Bleeding duration also plays an integral part in processing, where animals that have not undergone a sufficient bleeding period (~~a minimum 40 sec~~), may still be alive upon reaching the scalding tank. Live and conscious birds, if not removed prior to scalding, will then be subjected to additional *pain* ~~stimulators~~ from the heat inside the scalding tank and death by drowning.

2-) Animal-based and other measurable measures include:

The main animal-based measurable measure is the blood flow (rate and duration). For animal-based and other measurable measures of return of consciousness after *stunning* (see ~~Article 7.5.16~~ Article 7.5.26. to Article 7.5.29).

One of the most common parameters in determining bleeding efficiency is the percentage of blood loss, where the amount of blood loss is estimated ~~through~~ from the difference between pre-slaughter weight and post-slaughter weight [Velarde *et al.*, 2003; Sabow *et al.*, 2015].

For poultry birds, the presence of 'red-skin' carcasses may be the result of ineffective killing and with live birds entering the scalding tank.

~~The effectiveness of a stunning procedure on birds can be seen through the following signs: absence of corneal reflex, loss of posture tonic-clonic seizures and apnoea. Presence of one or more signs during bleeding may be the result of ineffective stunning procedure.~~

3-) Recommendations:

The *slaughterhouse/abattoir* operators should ensure that:

- = both carotid arteries should be severed;
- qualified personnel take random samples of ~~birds-animals~~ between after the end of *stunning* and before bleeding to ensure ~~birds animals~~ are not showing signs of consciousness;
- immediately after bleeding, qualified personnel ~~right after bleeding~~ check that the jugular veins, carotid arteries and trachea windpipe were cut thoroughly, guaranteeing ~~a well~~ an efficient bleeding process ~~afterwards~~.
- the slaughter line speed allows a minimum bleeding period of 90 seconds (for chickens) so that there is minimum blood loss of 60 % before reaching the scalding tank or other potentially *painful* operation;
- qualified personnel check that at the bleeding line, especially before scalding, birds are completely dead. Birds that are still alive need to be euthanised immediately removed from shackle.

Decapitation should ~~not be applied~~ as bleeding method ~~only in~~ to unconscious birds-animals used as a bleeding technique because it does not allow monitoring possible return of consciousness.

4-) Species-specific recommendations:

- = for chicken, the slaughter line speed should allow a minimum bleeding period of 90 seconds (for chickens) so that there is minimum blood loss of 60 % before reaching the scalding tank or other potentially painful operation;
- = qualified personnel should check that at the bleeding line, especially before scalding, birds are completely dead. Birds that are still alive need to be euthanised immediately and removed from shackle.

~~None identified.~~

Article 7.5.34.31

Emergency killing of ~~an~~ animals arriving in containers

This article addresses animals that show signs of severe *distress or pain* ~~or other types of severe suffering~~ before being unloaded or within the *slaughterhouse/abattoir*. These animals may correspond to animals unfit to travel as listed in Article

7.3.7. Principles described may also apply to animals that are not suitable for *slaughter* for commercial reasons, even if they do not present signs of *pain* or suffering.

1-) Animal welfare concerns:

Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause undue *distress, pain and suffering-suffering.*

2-) Animal-based and other measurable measures include:

Animals requiring emergency *killing* are those, ~~among others that present with~~ with severe injuries such as fractures, bone dislocations, and large open wounds.

They may also present clinical signs of serious illness or being in a state of extreme weakness.

3-) Recommendations:

Animal handlers should euthanise the animals as soon as they are identified at arrival, during lairage or at the time of shackling.

Emergency *killing* should be systematically recorded and analysed to improve procedures and prevent recurrences.

4-) Species-specific recommendations:

~~None identified yet.~~

Article 7.5.3532.

Methods, procedures or practices that should not be used ~~unacceptable on animal welfare grounds~~ for animals arriving in containers

1) ~~None of €~~ The following practices for handling animals are unacceptable and they should not be used under any circumstances:

- a) applying pressure using an injurious object or applying an irritant substance to any part of the body of ~~the~~ an animal;
- b) hitting animals including with instruments such as large sticks, notably sticks with sharp ends, ~~metal~~-piping, stones, fencing wire or leather belts;
- c) kicking, throwing or dropping animals;
- d) stepping on or crushing animals;
- ~~e)~~ grasping, lifting or dragging animals only by ~~some~~ body parts such as their tail, head, ears, limbs, hair or feathers.
- ~~e)~~ dragging animals by any body parts.

2) ~~None of €~~ The following practices for restraining animals are unacceptable and should not be used:

- a) mechanical clamping of the legs or feet of the animals as the sole method of *restraint*;
- b) breaking legs, cutting leg tendons or blinding animals;
- c) applying electrical current that does not span the brain; ~~such as the use of the electrical stunning method with a single application leg to leg~~
- d) severing the brain stem by piercing through the eye socket or skull bone;
- e) crushing the neck crushing.

In poultry birds, electro-immobilisation for neck-cutting or preventing wing flapping during bleeding, or the method of brain piercing through the skull without prior *stunning* should not be used under any circumstances ~~are unacceptable~~.

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DRAFT CHAPTER 7.5.

ANIMAL WELFARE DURING SLAUGHTER

Introduction

Providing good welfare to animals at *slaughter* is ethically and economically beneficial. The implementation of *animal welfare* measures, in addition to giving value to the product directly for ethical reasons, contributes to the improvement of workers' wellbeing, health and safety. This will also contribute to food safety and product quality, and consequently to the improvement of economic returns [Blokhuis *et al.*, 2008; Lara and Rostagno, 2018].

Article 7.5.2.

Scope

This chapter identifies *hazards to animal welfare* during *slaughter* and provides recommendations for arrival and *unloading*, *lairage*, handling, *restraint*, *stunning* and bleeding of animals in *slaughterhouses/abattoirs*. It provides animal-based measures to assess the level of welfare and recommends remedial and corrective actions to be applied, when necessary.

This chapter applies to the *slaughter* in *slaughterhouses/abattoirs* of free-moving animals, such as ruminants, camelids, equids and pigs, and animals in *containers* such as rabbits and most *poultry* species. This chapter should be read in conjunction with the guiding principles for *animal welfare* provided in Chapter 7.1., Chapter 7.14. and with relevant provisions of Chapters 6.2. and 6.3.

Article 7.5.3.

Definition

For the purposes of this chapter:

Bleeding means the act of severing major blood vessels that supply the brain, to ensure death.

Article 7.5.4.

Hazards to animal welfare

Hazards to animal welfare during each of the pre-slaughter stages have a cumulative effect on the stress of the animals [Moberg and Mench, 2000].

At *slaughterhouses/abattoirs*, animals are exposed to *hazards to animal welfare* including *feed* and water deprivation, mixing of unfamiliar *animals*, handling by humans, exposure to a novel environment (e.g. noise, lighting, flooring and smells), forced movement, limited space allowance, adverse weather conditions and ineffective *stunning* and bleeding. These *hazards* can have negative impacts on the welfare of the animals that can be assessed through animal-based measures. In the absence of feasible animal-based measures, resource-based measures and management-based measures may be used as a proxy. *Hazards to animal welfare* can be minimised by appropriate design of premises and choice of equipment, and through good management, training and competency of personnel.

Article 7.5.5.

Measures

The welfare of animals at *slaughter* should be assessed using animal-based measures. Although consideration should be given to the resources provided as well as the design and management of the system, animal-based measures are preferential. However, key *stunning* parameters should be selected, taking into account animal-based measures.

The routine use of these animal-based measures and the appropriate thresholds should be adapted to the different situations in which animals are managed at a *slaughterhouse/abattoir*. It is recommended that target values or thresholds for animal-based measures be based on current scientific evidence and appropriate national, sectorial or regional standards.

Article 7.5.6.

Management

The *slaughterhouse/abattoir* operator is responsible for the development and implementation of an operating plan that should consider the following:

- training and competency of personnel;
- design of premises and choice of equipment;
- standard operating procedure;
- recording, reporting adverse incidents and taking corrective actions;
- throughput (number of animals slaughtered per hour);
- maintenance and cleaning procedures of equipment and premises;
- emergency plans.

Article 7.5.7.

Training and competency of personnel

Animal handlers and other personnel have a crucial role to play in ensuring good *animal welfare* conditions from the time of arrival of the animals at the *slaughterhouse/abattoir* through to their *death*. Training for all personnel should emphasise the importance of *animal welfare* and their responsibility in contributing to the welfare of the animals that come through the *slaughterhouse/abattoir*.

Animal handlers should understand the species-specific behavioural patterns of the animals they are working with and the underlying principles for carrying out the required tasks whilst ensuring good *animal welfare*. They should be experienced and competent in handling and moving the animals with knowledge that allows them to identify signs of *distress*, fear, and *pain* and take preventive and corrective actions. Personnel in charge of *restraint* (including pre-stun shackling) and of *stunning* and bleeding operations should be familiar with the relevant equipment, and its key working parameters and procedures. Personnel in charge of *stunning*, post-stun shackling and bleeding animals should be able to identify and take corrective actions in case of: [EFSA, 2013a; EFSA 2013b]

- a) ineffective *stunning* of the animal;
- b) recovery of consciousness;
- c) signs of life prior to dressing or scalding.

Competencies may be gained through a combination of formal training and practical experience. These competencies should be assessed by the *Competent Authority* or by an independent body recognised by the *Competent Authority*.

Only the personnel actively working in areas where live animals are handled should be present in these areas. The presence of visitors or other personnel should be limited in these areas in order to prevent unnecessary noise, shouting and movement and to reduce risk of accidents.

Article 7.5.8.

Design of premises and choice of equipment

The design of premises and the choice of equipment used in a *slaughterhouse/abattoir* have important impacts on the welfare of animals. The animals' needs should be considered including:

- thermal comfort;
- ease of movement;
- protection from injury;
- protection from visual, auditory and olfactory overstimulation;
- minimising fear and avoiding *distress* and *pain*;
- ability to perform natural and social behaviours;
- water and *feed*;
- needs arising from illness or injury;
- needs arising from other vulnerabilities (e.g. pregnant, lactating or neonatal animals).

Premises should be designed to eliminate distractions that may cause approaching animals to stop, baulk or turn back.

Flooring should be non-slip to prevent injury and stress due to slipping or falling. There should be adequate quality and quantity of lighting to allow appropriate ante-mortem inspection of animals and to enable the moving of animals utilising low-stress handling techniques.

The design of the *slaughterhouse/abattoir* and choice of equipment should take into consideration the species, categories, quantities, size or weight and age of the animals. *Restraint*, *stunning* and bleeding equipment is critical for the welfare of an animal at the time of *slaughter*. Appropriate back-up equipment should be available for immediate use in case of failure of the primary *stunning* equipment.

Article 7.5.9.

Throughput

The throughput of the *slaughterhouse/abattoir* is the number of animals slaughtered per hour. It should never exceed the maximum capacity of the design of the facilities or equipment. The *slaughterhouse/abattoir* operators should continuously monitor throughput and adjust it to any operational changes, such as staff numbers and experience or line breakdowns. Throughput may need to be reduced if welfare is negatively impacted.

Personnel allocation should be adequate for the anticipated throughput and be sufficient to implement the *slaughterhouse/abattoir* operating plan as well as ante- and post-mortem inspections.

Article 7.5.10.

Maintenance and cleaning procedures

All equipment should be clean, well maintained and calibrated, in accordance with the manufacturer's instructions in order to ensure positive outcomes for *animal welfare*.

Maintenance and cleaning of handling, *unloading*, *lairage* and moving facilities and equipment contribute to ensuring that animals are handled smoothly, minimising *pain* and fear.

Maintenance and cleaning of handling, *restraining*, *stunning* and bleeding equipment are essential to ensure reliable and effective *stunning* and *slaughter*, thereby minimising *pain*, fear and suffering.

Article 7.5.11.

Emergency plans

Emergency plans should be in place at the *slaughterhouse/abattoir* to protect the welfare of the animals in the event of an emergency. The plans should consider the most likely emergency situations given the species slaughtered and the location of the *slaughterhouse/abattoir*.

Emergency plans should be documented and communicated to all responsible parties and these plans should be tested regularly.

Personnel who have a role to play in implementing the plans should be well trained on the tasks they have to perform.

Article 7.5.12.

Arrival of free-moving animals

On arrival at the *slaughterhouse/abattoir*, animals would already have been exposed to *hazards* that may have negative impacts on their welfare. Any previous *hazards* will have a cumulative effect that may affect the welfare of the animals throughout the *slaughter* process. Therefore, animals should be transported to the *slaughterhouse/abattoir* in a manner that minimises adverse animal health and welfare, and in accordance with Chapters 7.2. and 7.3.

1) Animal welfare concerns:

Delay in *unloading* of animals is a major *animal welfare* concern at arrival [NAMI, 2021].

Animals in *vehicles* have smaller space allowances than on farm, undergo water and *feed* deprivation, may have suffered from an injury, and may be exposed to adverse weather conditions and to stress and discomfort from social disturbance, noise, vehicle vibration and motion. In addition, stationary *vehicles* may have insufficient ventilation. Delays in *unloading* animals will prolong or exacerbate the impact of these *hazards*. Under these circumstances, injured or sick animals requiring urgent attention may not be identified or dealt with appropriately and therefore the duration of their suffering will be prolonged.

2) Animal-based and other measures:

It can be difficult to assess animal-based measures while animals are in the *vehicle*. Some measures that may be assessed include animals with injuries, lameness or poor body condition or those that are sick or have died. Panting, shivering and huddling may indicate thermal stress. Drooling and licking may indicate prolonged thirst.

Animals dead or emergency killed (see Article 7.5.19.) on arrival should be recorded and monitored as an indicator of *animal welfare* prior to and during transport.

Time from arrival to *unloading* and the environmental temperature and humidity can be used to establish relevant thresholds for corrective action.

3) Recommendations:

Animals should be unloaded promptly on arrival. This is facilitated by scheduling the arrival of the animals at the *slaughterhouse/abattoir* to ensure that there are sufficient personnel and adequate space in the *unloading or lairage* area.

Consignments of animals whose welfare is at greater risk of being compromised should be unloaded first. When no space is immediately available, creating space should be a priority. Provision should be made to provide shelter, shade or additional ventilation during waiting periods, or animals should be transported to an alternative nearby location where such provisions available.

Animals should not be isolated throughout the *slaughter* process, except under specific conditions, such as for aggressive or sick animals.

Animals should be provided with drinking water as soon as possible after *unloading*.

Animals that have undergone long or arduous journeys, are sick or injured, are lactating or pregnant and neonatal animals should be slaughtered as a priority and without delay.

4) Species-specific recommendations:

Some species such as pigs and shorn sheep are especially sensitive to extreme temperatures and therefore special attention should be paid when dealing with delays in *unloading* sensitive animals. This may include careful

consideration of transport plans to time arrival and processing, provision of additional means of temperature and humidity control.

Article 7.5.13.

Handling of free-moving animals

This article addresses the handling of animals during *unloading* and *lairage*, and in the *killing* area.

1) Animal welfare concerns:

During *unloading*, animals are exposed to similar *hazards* to those encountered when being loaded (see Chapters 7.2. and 7.3.). Inappropriate equipment in the *vehicle* or the *slaughterhouse/abattoir*, such as a lack of lateral protection when *unloading*, excessively steep ramps, slippery surfaces or an absence of foot battens, may result in animals slipping, falling or being trampled, causing injuries. The absence of ramps, lifts or an *unloading* bay or dock could result in animals being pushed or thrown off the *vehicle*. These *hazards* can also be associated with inappropriate handling and forced physical movement of animals that are unable to move independently as a result of weakness or injuries. Exposure to novel environments (e.g. noise, lighting, flooring, smell) may cause fear and reluctance to move, or turning back. Poorly designed facilities will increase the risk of such fear and injuries.

2) Animal-based and other measures:

- a) animals slipping, falling and piling up;
- b) animals with broken or otherwise injured limbs;
- c) animals turning-back, attempting to escape or reluctant to move;
- d) animal vocalisation referring to *distress*;
- e) animals that are unable to move by themselves due to reasons other than broken or injured limbs;
- f) animals that collide with facility structures;
- g) use of force by personnel;
- h) use of electrical goads.

Animals are safely handled when these measures are below an acceptable threshold.

3) Recommendations:

Ramps or lifts should be provided and used except when the *vehicle* and the *unloading* dock are at the same height. There should be no gap between the *vehicle* and *unloading* dock. Ramps or lifts should be positioned so that the animals can be handled safely. The gradient should not be so steep as to prevent animals from moving, and solid side barriers should be in place.

Design of the facilities should promote the natural movements of animals, and, as far as possible, minimise human interaction.

Preventive equipment such as foot battens, rubber mats and deep-groove flooring can help animals to avoid slipping.

The *unloading* area and raceways should be well lit so that animals can see where they are going.

The design of areas and raceways should aim to minimise the potential for distractions that may cause animals to stop, baulk or turn back when being unloaded (e.g. shadows, changes in flooring, moving objects, loud or sudden noises). For details refer to Chapters 7.2. and 7.3.

Animals that are injured, sick or unable to rise require immediate action and, when necessary, emergency *killing* should be performed without moving them and without delay. Refer to Articles 7.5.19. and 7.5.21. Such animals should never

be dragged, nor should they be lifted or handled in a way that might cause further *pain* and suffering or exacerbate injuries.

Personnel should be calm and patient, assisting animals to move using a soft voice and slow movements. They should not shout, kick, or use any other means that is likely to cause *distress*, fear or *pain* to the animals. Under no circumstances should *animal handlers* resort to violent acts to move animals (see Article 7.5.20.).

Personnel should not stand between an animal and where they want it to move to as this may cause the animal to balk. They should keep in mind the flight distance and point of balance of the animal when positioning themselves to encourage movement.

Animals should be moved in small groups as this decreases fear and makes use of their natural tendency to follow other animals.

Mechanical handling aids should be used in a manner to encourage and direct movement of the animals without causing *distress*, fear or *pain*. Preferred mechanical aids include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and rattles.

Other handling aids should not be used as a substitute for good facility design and handling. They should not be used repeatedly if an animal fails to respond or move. In such cases it should be determined whether some physical or other impediment is preventing the animal from moving.

Electric goads should not be used on a routine basis to move animals. Electric goads may only be used when other measures have been ineffective, the animal has no injury or other condition that is impeding mobility and there is room for the animal to move forward without obstruction (e.g. obstacles or other animals).

The use of electric goads should be limited to low-voltage goads applied to the hindquarters of adult pigs and large ruminants, and never to sensitive areas such as the eyes, mouth, ears, ano-genital region, udders or belly. Such instruments should not be used on equids, camelids, ratites, sheep and goats, pregnant animals or on calves or piglets. Shocks should not be used repeatedly if the animal fails to respond and should not last longer than one second [Ritter *et al.*, 2008].

The manual lifting of animals should be avoided; if it is necessary, animals should not be grasped or lifted in a manner which causes *pain* or suffering and physical damage (e.g. bruising, fractures, dislocations). (See Article 7.5.20.)

Animals should not be forced to move at a speed greater than their normal walking pace to minimise injury through slipping or falling. Facilities should be designed, constructed and staffed with competent *animal handlers*, so that less than 1% of the animals fall.

Article 7.5.14.

Lairage of free-moving animals

1) Animal welfare concerns:

Animals may be exposed to several *hazards* to *animal welfare* during lairage including:

- b) *feed* and water deprivation leading to prolonged hunger and thirst;
- b) absence of protection against adverse weather conditions, leading to thermal stress;
- c) sudden or excessive noises, including from personnel, facilities, equipment and gates, leading to fear;
- d) insufficient space to lie down and move freely leading to fatigue and aggressive behaviour;
- e) poor design and maintenance leading to *distress* and injuries;
- f) mixing of unfamiliar animals leading to aggressive behaviour or social stress;
- g) limited access to resources (e.g. drinkers, bedding) leading to aggressive behaviour;

h) exposure to surfaces leading to injury or lameness (e.g. sharp, abrasive).

2) Animal-based and other measures:

- a) thermal stress (e.g. panting, sweating, shivering, huddling behaviour);
- b) space allowance;
- c) excessive soiling with faeces (e.g. coat cleanliness, dag score for sheep);
- d) injuries (e.g. lameness, open wounds, fractures);
- e) illness (e.g. diarrhoea, coughing);
- f) aggressive behaviours (e.g. mounting, fighting);
- g) animal vocalisation referring to *distress*;
- h) restlessness (e.g. pacing, walking with continuous ear movements and frequency of snorts – especially in horses) [Micera *et al.*, 2010 and Visser *et al.*, 2008];
- i) bruised carcass.

3) Recommendations:

Animals should have constant access to drinking water. Water supply points should be designed according to the species and age of the animal, with environmental conditions that allow for effective consumption. The number and location of the water supply points should minimise competition.

Animals should be provided with *feed in lairage* if the duration between their last meal and expected time for *slaughter* exceeds a period appropriate for the species and age of animals. In the absence of information on the transport duration, animals that are not expected to be slaughtered within 12 hours of arrival should be fed as appropriate for the age and species.

The *lairage* should provide animals with protection against adverse weather conditions including shade and shelter.

Animals should be protected from excessive and sudden noise (e.g. ventilation fans, alarms, or other indoor or outdoor equipment).

Lairage areas should be free from sharp edges and other *hazards* that may cause injury to animals.

The *lairage* should provide enough space for all animals to lie down at the same time, to move freely and to move away in case of aggressive behaviours.

Lairage areas should have adequate lighting levels to allow inspection of the animals.

Animals from different categories (e.g. sexes, sizes, horned or not, species) should not be mixed except if they are already familiar to each other.

Animals that are injured, sick, pregnant or are neonates should be slaughtered with priority or separated to protect them from other animals. Animals that are very ill or down or have severe injuries should be euthanised without delay (see Article 7.5.22.).

4) Species-specific recommendations:

Pigs should be moved in groups up to 15 [Barton-Gade and Christensen,1998].

Bison and cervids need specific design and construction standards for unloading and holding prior to *slaughter*.

Article 7.5.15.

Restraint for stunning or bleeding (free-moving animals)

1) Animal welfare concerns:

The purpose of *restraint* is to facilitate the correct application of the *stunning* or bleeding equipment. Incorrect *restraint* may not only lead to ineffective *stunning* or bleeding, but also cause *distress*, fear and *pain*.

Other *hazards* include:

- a) slippery restraining area;
- b) insecure *restraint*;
- c) excessive force of *restraint*;
- d) a restraint box that is not appropriate to the size of the animal;
- e) prolonged *restraint*, which may exacerbate insecure or excessive *restraint*.

Slaughter without *stunning* increases the risk of *pain* and fear due to the need for robust *restraint* of conscious animals for neck cutting, especially if animals are turned on their sides or backs [von Holleben *et al.*, 2010; Pleiter, 2010].

2) Animal-based and other measures:

- a) animal slipping or falling;
- b) struggling;
- c) escape attempts;
- d) animal vocalisation referring to *distress*;
- e) reluctance to enter the restrainer;
- f) use of electric goads.

3) Recommendations:

Where individual restraint is used, the restrainer should be narrow enough that the animals cannot move backward, forward or turn around.

The restrainer being used should be appropriate to the size of the animals and the restrainer should not be loaded beyond its design capacity.

In case of *slaughter* without *stunning*, the restrainer should restrain the head and should support the body of the animal.

The restraint should be maintained until the animal is unconscious.

When restrainers that hold an animal with its feet off the floor are used, the animal should be held in a balanced, comfortable, upright position.

When a restrainer is used to rotate an animal from an upright position, the body and head should be securely held and supported to prevent struggling and slipping within the device.

Restrainers should not have sharp edges and should be well maintained to minimise risk of injury.

Non-slip flooring should be used to prevent animals from slipping or falling.

Flooring design and handling methods that cause loss of balance, slipping or falling, i.e. a box with a floor that rises on one side upon entry to the box, should not be used.

Distractions (e.g. movements of equipment or people, loose chains or objects, shadows, shiny surfaces or floors) should be minimised to prevent baulking and improve ease of entry into the restrainer.

No animal should enter the restrainer until equipment and personnel are ready to stun and slaughter that animal.

No animal should be released from the restrainer until the operator has confirmed loss of consciousness.

Animals should not be left in single file races or restrainers during work breaks, and in the event of a breakdown animals should be removed from the restrainer promptly.

The restrainer should be in a clean and non-slip condition.

Animals should not be able to pile on top of each other in the restrainer, nor receive pre-stun shocks from contact with the animal in front, in the case of electrical *stunning*.

Animals subject to specific methods of *stunning* should be individually restrained to ensure precise positioning of the *stunning* equipment. However, this should not apply when restraining is likely to cause additional *distress* or *pain* as well as excessive and unpredictable movements (e.g. animals that cannot move normally due to injuries or sickness, *wild* animals or horses).

4) Species-specific recommendations:

Gondolas for gas *stunning* of pigs should not be overloaded and should allow pigs to stand without being on top of each other.

Head *restraint* is recommended for bovines.

Specialised restraining equipment and methods are required for bison and cervids.

Article 7.5.16.

General principles for stunning of free-moving animals and animals in containers

1) Animal welfare concerns:

The main *animal welfare* concern associated with *stunning* is 'ineffective *stunning*' which results in *distress*, fear and *pain*, during induction of unconsciousness and possible recovery before *death*.

Animals should only be stunned using *stunning* methods that have been scientifically validated as effective for *stunning* that species. The most common methods for *stunning* are mechanical, electrical and exposure to controlled atmosphere. Animals should only be stunned using *stunning* methods that have been scientifically validated as effective for *stunning* that species.

Stunning prior to *slaughter* prevents *distress*, fear and *pain* to animals during neck cutting and bleeding.

2) Animal-based and other measures:

Multiple indicators should be used to determine whether a stun is effective and the animal is unconscious. After *stunning*, the state of consciousness is assessed to identify if animals are successfully rendered unconscious or if they are conscious (e.g. *stunning* was ineffective or they recovered consciousness) and therefore at risk of experiencing *distress*, fear and *pain*. For each animal-based measures of state of consciousness, outcomes either suggesting unconsciousness (e.g. presence of tonic seizures) or suggesting consciousness (e.g. absence of tonic seizures) have been identified for each *stunning* method.

3) Recommendations:

Animals should always be stunned as soon as they are restrained.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup method. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Effectiveness of *stunning* should be monitored using multiple animal-based measures at different stages: immediately after *stunning*, just before and during bleeding until *death* is confirmed [EFSA, 2013a; EFSA, 2013b; AVMA, 2016].

Stunning equipment should be used, cleaned, maintained and stored following manufacturer's recommendations.

Regular calibration of the equipment according to the manufacturer's procedure is recommended.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters and follow the manufacturer's recommendations for *stunning* the species and age group concerned.

Article 7.5.17.

Mechanical stunning of free-moving animals

1) Animal welfare concerns:

The main *hazards* preventing effective mechanical *stunning* are incorrect shooting position and incorrect direction of the impact. These may cause ineffective *stunning* or short-lasting unconsciousness. Absence of or incorrect restraint can lead to an incorrect shooting position. Poor maintenance of the equipment or inadequate cartridge power or air line pressure can result in less concussive impact to the skull. Inappropriate use of cartridge, narrow bolt diameter or short length of bolt may also affect the effectiveness of *stunning*. In animals with a thicker skull, there is an increased risk of an ineffective stun, especially with non-penetrative percussive *stunning*. Fracture of the skull which may cause ineffective *stunning* are more likely to occur in young animals such as calves.

For certain extensively reared domestic and *captive wild* animals, on-site shooting with a free bullet in the brain can be an alternative to prevent stressful handling and transport. Under such circumstances, the main objective is a shot that kills the animal immediately.

2) Animal-based and other measures:

Animal-based measures of an effective stun are: immediate collapse; apnoea; tonic-clonic seizure; absence of corneal or palpebral reflex; absence of eye movements.

Animal-based measures of ineffective stun or recovery of consciousness are: absence of collapse or attempts to regain posture rapid eye movement or nystagmus, vocalisation; spontaneous blinking; righting reflex; presence of corneal or palpebral reflex; rhythmic breathing.

3) Recommendations:

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters and follow the manufacturer's recommendations for *stunning* the species and age group concerned, such as:

- grain of the cartridge or air pressure (captive bolt) [Gibson *et al.*, 2015];
- calibre and type of gun and ammunition (free bullet);
- length and diameter of the penetrating bolt;
- shape and diameter of the non-penetrating bolt;
- position and direction of the shot [AVMA, 2016].

4) Species-specific recommendations:

Non-penetrative captive bolt should not be used in animals with thick skull (e.g. bison, water buffalo).

Water buffaloes should be stunned with penetrative captive bolt in the occipital position using a heavy-duty contact-fired captive bolt gun directed at the nose or using large-calibre firearms and deformation ammunition (e.g. 0.357 Magnum).

Article 7.5.18.

Electrical stunning in free-moving animals

1) Animal welfare concerns:

Electrical *stunning* involves application of an electric current across the brain of sufficient magnitude to induce immediate unconsciousness [EFSA, 2004; Grandin, 1980]. The main *hazards* preventing effective electrical *stunning* are: incorrect electrode placement, poor contact, electrical arcing, high contact resistance caused by wool or dirt on the animal surface, dirty or corroded electrode, low voltage/current or high electrical frequency [EFSA, 2004]. Excessively wet hides or fleeces may result in ineffective *stunning* due to electrical current taking the path of least resistance and flowing around the outside of the body rather than through the skull. This may paralyse the animal, or cause pre-stun shocks, rather than *stunning* the animal. If electrodes are energised prior to ensuring they have good contact with the animal, this results in *pain* from the shock.

2) Animal-based and other measures:

Animal-based measures of an effective stun are: tonic-clonic seizures; loss of posture; apnoea; and absence of corneal or palpebral reflex.

Animal-based measures of ineffective stun or recovery of consciousness are: absence of tonic-clonic seizures; vocalisation; spontaneous blinking; righting reflex; presence of corneal or palpebral reflex; rhythmic breathing.

3) Recommendations:

When a head to body electrical stun-kill method is used, the electrical current should be applied to the brain before it reaches the heart otherwise the animal will experience cardiac arrest while still conscious.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters and follow the manufacturer's recommendations for *stunning* the species and age group concerned, such as:

- shape, size and placement of the electrodes [AVMA, 2016];
- contact between electrode and head;
- moisten point of contact;
- minimum exposure time;
- electrical parameters (current intensity [A], waveform type [AC and DC], voltage [V] and frequency [Hz]);
- maximum stun to stick interval;
- visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors and displays duration of exposure, voltage and applied current.

4) Species-specific recommendations:

Effective electrical parameters should be determined based on scientific evidence for different types of animals.

For head-only *stunning*, minimum parameters are recommended for the following species:

- 1.15 [AVMA] to 1.28 A for bovines [EFSA 2020b],
- 1.25 A for finished pigs [AVMA],
- 1.8 A for sows and boars [AVMA],
- 1 A for small ruminants [EFSA 2013c, and EFSA 2015, AVMA].

The minimum parameters above are recommended to be used with an electrical frequency of 50Hz. Where higher frequencies are used, the amperage should also be increased.

Article 7.5.19.

Controlled atmosphere stunning in free-moving animals

1) Animal welfare concerns:

Controlled atmosphere *stunning* methods involve the exposure to high concentrations of carbon dioxide (hypercapnia), low concentration of oxygen (hypoxia) or a combination of the two (hypercapnic hypoxia). Loss of consciousness is not immediate following exposure of animals to controlled atmosphere *stunning*. The main *hazards* causing increased *distress* during induction of unconsciousness are irritant or aversive gas mixtures (e.g. CO₂ in high concentrations), low gas temperature and humidity, and overloading of the gondola or restraint. The main *hazards* causing ineffective controlled atmosphere *stunning* are incorrect gas concentration and too short gas exposure time [Anon, 2018; EFSA, 2004; Velarde *et al.*, 2007].

2) Animal-based and other measures:

Animal-based measures of an effective stun are: loss of posture; apnoea; absence of corneal or palpebral reflex; absence of muscle tone.

Animal-based measures of an ineffective stun or recovery of consciousness are: vocalisation; spontaneous blinking; righting reflex; presence of corneal or palpebral reflex; rhythmic breathing.

3) Recommendations:

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters and follow the manufacturer's recommendations for *stunning* the species and age group concerned, such as:

- gas concentrations and exposure time;
- temperature and humidity;
- stocking density of the gondola or restraint for pigs;
- visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors gas concentration and temperature.

Animal-based measures should be monitored during the induction phase because this can be a point of highest welfare risk for animals. Since animal-based measures are difficult to monitor and adapt during the induction phase, resource-based measures should be used such as monitoring of gas concentration(s) and exposure time. Gas concentrations and exposure time, temperature and humidity should be monitored continuously at the level of the animal inside the chamber.

4) Species-specific recommendations:

Pigs:

Gases or gas mixtures that are painful to inhale should not be used except if such methods allow pigs to be stunned in groups, as they can present animal welfare benefits compared to methods requiring individual *restraint*.

Article 7.5.20.

Bleeding of free-moving animals

1) Animal welfare concerns:

The main *animal welfare* concern at the time of bleeding following *stunning* is the recovery of consciousness due to prolonged stun-to-stick interval or due to incomplete severance of the main blood vessels.

Bleeding without prior *stunning* causes animal suffering because the incision to sever blood vessels results in substantial tissue damage in areas well supplied with nociceptors. The activation of these nociceptors causes the animal to experience *pain* [Gregory, 2004; Gibson *et al.*, 2009]. Loss of consciousness due to bleeding is not immediate

and there is a period during which the animals experience fear, *pain* and *distress* [Gregory, 2004; Johnson *et al.*, 2015]. This period will be reduced by applying *stunning* immediately after neck cutting.

Absence of or ineffective *stunning* may result in animals being released from the *restraint*, shackled, and bled and/or further processed while they are still conscious or have the potential to recover consciousness.

2) Animal-based and other measures:

The main animal-based measure is the blood flow (rate and duration). For animal-based and other measures of return of consciousness after *stunning*, see Article 7.5.16.

In cases of bleeding without *stunning* the animal-based and other measures that indicate loss of consciousness include all the following: absence of muscle tone; absence of corneal or palpebral reflex; absence of rhythmic breathing. Unconsciousness should be reassessed until *death* is confirmed. In addition, cessation of bleeding after a continuous and rapid blood flow can be used as an indicator of *death*.

3) Recommendations:

- a) both carotid arteries or the blood vessels from which they arise should be severed;
- b) continuous and rapid blood flow should be assured after bleeding;
- c) *death* should be assured before further processing;
- d) bleeding knives should be sharpened for each animal as necessary to fulfil recommendations a) and b).

In addition, the following should be considered:

Slaughter with stunning:

- d) the stun-to-stick interval should be short enough to ensure that the animal will not recover consciousness before it dies;
- e) unconsciousness should be confirmed before bleeding;
- f) animals who are stunned with a reversible method should be bled without delay to avoid them regaining consciousness during bleeding.

Slaughter without stunning:

- c) bleeding should be carried out by a single incision; any second intervention should be recorded and analysed to improve procedures;
- d) further processing may only be carried out when the *death* of the animal has been ascertained.

4) Species-specific recommendations:

Bovines are at risk of prolonged bleed out times and regaining consciousness as the bilateral vertebral arteries are not cut during a neck cut. The vertebral arteries will continue to provide blood to the brain. Furthermore, any occlusion of the cut major arteries will slow exsanguination. Therefore, bleeding with a cut of the brachiocephalic trunk should be preferred in bovines.

Article 7.5.21.

Slaughter of pregnant free-moving animals

1) Animal welfare concerns:

Fetuses in the uterus are considered not to achieve consciousness [EFSA, 2017; Mellor, D. J. *et al.*, 2005]. However, if removed from the uterus the fetus may perceive *pain* or other negative effects.

2) Animal-based and other measures:

Signs of consciousness in the neonate after removal from the uterus, such as breathing [Mellor, 2003; Mellor, 2010; EFSA, 2017].

3) Recommendations:

Under WOA recommendations (Chapter 7.3. Animal transport by land), pregnant animals that would be in the final 10% of their gestation period at the planned time of *unloading* at the *slaughterhouse/abattoir* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that pregnant females are handled separately.

The fetus should be left undisturbed in utero for at least 30 minutes after the *death* of the dam [EFSA, 2017; Anon, 2017]. The uterus could be removed as a whole, clamped and kept intact such that there is no possibility for the fetus to breathe.

In cases where the fetus is removed before 30 minutes has elapsed *euthanasia* should be carried out immediately.

Article 7.5.22.

Emergency killing of free-moving animals

This article addresses animals that show signs of severe *pain* or other types of severe suffering before being unloaded or within the *slaughterhouse/abattoir*. These animals may correspond to animals unfit to travel as listed in Article 7.3.7. Principles described below should be described in the emergency plan and may also apply to animals that are not suitable for *slaughter* for commercial reasons, even if they do not present signs of *distress, pain* or suffering.

1) Animal welfare concerns:

Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause *distress* and *pain* and suffering.

2) Animal-based and other measures:

Animals requiring emergency *killing* are unable to walk independently or present severe injuries such as fractures, large open wounds, or prolapses. They may also present clinical signs of serious illness or being in a state of extreme weakness. New-born animals or animals that gave birth within the last 48 hours may also belong to this category.

3) Recommendations:

Animals should not be moved unless it can be done without causing *distress, pain* or suffering.

Animal handlers should euthanise the animal as soon as possible.

Emergency *killing* should be systematically recorded and analysed in order to improve procedures and prevent recurrences.

Article 7.5.23.

Methods, procedures or practices that should not be used for free-moving animals

1) The following practices for handling animals should not be used under any circumstances:

- a) crushing, twisting or breaking tails of animals;
- b) applying pressure using an injurious object or applying an irritant substance to any part of an animal;
- c) hitting animals with instruments such as large sticks, sticks with sharp ends, piping, stones, fencing wire or leather belts;
- d) kicking, throwing or dropping animals;

- e) grasping, lifting or dragging animals only by body parts such as their tail, head, horns, ears, limbs, wool or hair;
 - f) dragging animals by any body part, by any means, including chains, ropes or by hand;
 - g) forcing animals to walk over other animals;
 - h) interfering with any sensitive area (e.g. eyes, mouth, ears, anogenital region, udder or belly).
- 2) The following practices for restraining conscious animals are unacceptable and should not be used under any circumstances:
- a) mechanical clamping of the legs or feet of the animals as the sole method of *restraint*, including tying limbs together or lifting one or more limbs off the ground;
 - b) breaking legs, cutting leg tendons or blinding animals;
 - c) severing the spinal cord, by using for example a puntilla or dagger;
 - d) applying electrical current that does not span the brain;
 - e) suspending or hoisting them by the feet or legs;
 - f) severing brain stem by piercing through the eye socket or skull bone;
 - g) forcing animals to sit or lay down by one or more handlers jumping on and lying across the animal's back;
 - h) trip floor boxes that are designed to make animals fall.
- 3) Breaking the neck while the animal is still conscious during bleeding is also an unacceptable practice.

Article 7.5.24.

Arrival of animals in containers

On arrival at the *slaughterhouse/abattoir*, animals would already have been exposed to *hazards* that may have negative impacts on their welfare. Any previous *hazards* will have a cumulative effect that may impair the welfare of the animals throughout the *slaughter* process. Therefore, animals should be transported to the *slaughterhouse/abattoir* in a manner that minimises adverse animal health and welfare outcomes, and in accordance with Chapters 7.2. and 7.3.

1) Animal welfare concerns:

Animals in *containers* have smaller space allowances than on farm, undergo water and *feed* deprivation, may have suffered from injury and may be exposed to thermal stress due to adverse weather conditions and stress from social disturbance, noise, *vehicle* vibration and motion. In addition, stationary *vehicles* may have insufficient ventilation. Delays in *unloading containers* will prolong or exacerbate the impact of these *hazards*. Under these circumstances, injured or sick animals requiring urgent attention will not be identified and therefore the duration of their suffering will be increased.

2) Animal-based and other measures:

It can be difficult to assess animal-based measures while animals are in the *containers* and especially when the *containers* are on the *vehicle* or when many *containers* are stacked on top of each other. Some measures that may be assessed include animals with injuries, or those that are sick or have died. Panting, reddening of the ears (heat stress in rabbits), shivering and huddling may indicate thermal stress. In rabbits drooling and licking may indicate prolonged thirst.

Time from arrival to *unloading* and *slaughter*, the environmental temperature and humidity (e.g. ambient, inside the *vehicle*) can be used to establish relevant thresholds for corrective action.

3) Recommendations:

Animals should be slaughtered as soon as they arrive at the *slaughterhouse/abattoir*. If not possible, *containers* should be unloaded, or *vehicles* should be placed in *lairage* or in sheltered and adequately ventilated area, promptly on arrival. This is facilitated by scheduling the arrival of the animals at the *slaughterhouse/abattoir* to ensure that there are sufficient personnel and adequate space in the *lairage* area. Time at *lairage* should be kept to a minimum.

Consignments of animals assessed to be at greater risk of compromised *animal welfare* (e.g. from long journeys, prolonged *lairage*, end-of-lay hens) should be unloaded first or should be considered for prioritised *slaughter*. When no available space is immediately available, creating space should be a priority. Provisions should be made to provide shelter, shade, cooling or heating systems or additional ventilation during waiting periods, or animals should be transported to an alternative nearby location where such provisions are available.

4) Species-specific recommendations:

Birds may get trapped or their wings or claws may get caught in the fixtures, mesh or holes in poorly designed, constructed or maintained transport systems. Similarly, rabbits may trap their paws in the fixtures mesh or holes in poorly designed, constructed or maintained transport systems. Under these situations, operators *unloading* birds or rabbits should ensure gentle release of trapped animals.

Article 7.5.25.

Moving of animals in containers

This article addresses the handling of animals in *containers* during *unloading* and *lairage*, and into the *killing* area.

1) Animal welfare concerns:

During *unloading* and moving *containers*, animals can be exposed to *pain*, stress and fear due to tilting, dropping or shaking of the *containers*.

During *unloading* and moving *containers*, animals can be exposed to adverse weather conditions and experience *pain* and *distress* [EFSA, 2019].

2) Animal-based and other measures:

- a) animals with broken limbs or dislocated joints;
- b) animals that collide with facility structures;
- c) animal vocalisations referring to *distress*;
- d) body parts (i.e. wings, limbs, feet, paws or heads) stuck between *containers*;
- e) animals injured by sharp projections inside *containers*.

3) Recommendations:

Containers in which animals are transported should be handled with care, moved slowly, and should not be thrown, dropped or knocked over. Where possible, they should be horizontal while being loaded or unloaded mechanically and stacked to ensure ventilation and prevent animals piling on one another. In any case, *containers* should be moved and stored in an upright position as indicated by specific marks.

Animals delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care to avoid injury by crushing or jamming of body parts.

Animals that are injured, jammed or sick require immediate action and, when necessary, should be taken from the *containers* and euthanised without delay. Refer to Article 7.5.34.

Staff should routinely inspect the *containers* and remove the broken *containers* that should not be re-used.

Article 7.5.26.

Lairage of animals in containers

1) Animal welfare concerns:

Animals may be exposed to several *hazards* to *animal welfare* during *lairage* including:

- c) *feed* and water deprivation leading to prolonged hunger and thirst;
- d) poor ventilation;
- c) absence of protection against adverse weather conditions leading to thermal stress;
- d) sudden or excessive noises, including from personnel, leading to fear;
- e) insufficient space to lie down and move freely leading to fatigue and aggressive behaviour;
- f) not being inspected or accessible for emergency *killing* when necessary.

2) Animal-based and other measures:

- a) thermal stress (e.g. panting, shivering, huddling behaviour, reddening of the ears);
- b) space allowance;
- c) excessive soiling with faeces;
- d) injuries (e.g. splay leg, open wounds, fractures, dislocations);
- e) sick or dead animals.

3) Recommendations:

Animals should be slaughtered upon arrival at the *slaughterhouse/abattoir*.

Staff should routinely inspect and monitor *containers* while in the *lairage* to observe animals for signs of *distress*, fear and *pain* and take appropriate corrective action to address any concerns.

The *lairage* should provide animals with protection against adverse weather conditions.

Animals should be protected from sudden and excessive noise (e.g. ventilation fans, alarms, or other indoor or outdoor equipment).

Article 7.5.27.

Unloading animals from containers before stunning

1) Animal welfare concerns:

Animals are removed manually or mechanically by tilting the transport *containers*.

When the *containers* with animals are manually or mechanically emptied by tipping, animals fall on to conveyors. Dumping, piling up and shock may occur, especially for the last animals, which are often removed by manual or mechanical shaking of the *containers*.

Other *hazards* include:

- a) narrow openings or doors of the *containers*;
- b) *containers* placed too far away from the place of shackling or *stunning*;
- c) inappropriate handling and removal of animals from *containers*;

- d) incorrect design of manual or mechanical tipping equipment that cause animals to fall from a height;
- e) conveyor belts that are running too fast or too slowly or are not properly aligned resulting in piling or injury.

2) Animal-based and other measures:

- a) falling;
- b) struggling, including wing flapping;
- c) escape attempts;
- d) vocalisation referring to *distress*;
- e) injuries, dislocations, fractures;
- f) piling up of animals.

3) Recommendations:

Removal of animals from *containers* in a way that causes *pain*, e.g. by one leg, wings, neck or ears, should be avoided.

Animals should be removed from *containers* by the body or by both legs using both hands and one animal at a time. Animals should not be grabbed and lifted by one leg, the ears, wings or fur and they should not be thrown, swung or dropped.

Animals should not be mistreated in the process of *unloading* and shackling prior to *stunning*.

Modular systems that involve tipping of live animals are not conducive to maintaining good animal welfare. These systems, when used, should have an incorporated mechanism to facilitate animals sliding out of the transport system, rather than being dropped or dumped on top of each other.

It should be ensured that every animal is removed from the *containers*.

Article 7.5.28.

Restraint for stunning animals from containers

1) Animal welfare concerns:

The purpose of *restraint* is to facilitate the correct application of the *stunning* and bleeding procedures. Incorrect *restraint* or handling cause *distress*, fear and *pain* and may lead to ineffective *stunning* and bleeding.

Other *hazards* include:

- e) Inversion can provoke compression of the heart and lungs or air sacs by the viscera and might compromise breathing and cardiac activity. This will cause *distress*, fear and *pain* in conscious birds and rabbits.
- f) Shackling animals upside down by inserting both legs into shackles. During shackling, the animals are also subjected to compression of their legs and wing flapping by their neighbour(s), leading to *distress*, *pain* and fear.
- g) Inappropriate shackling (e.g. shackles are too narrow or too wide, animals are shackled by one leg, or when one animal is shackled on two different adjacent shackles) leads to *distress*, *pain* and fear. Line speed, without a concomitant increase in workforce, can contribute to poor shackling outcomes.
- h) Drops, curves and inclination of the shackle line or high speed of the shackle line create fear and possible *pain* due to the sudden changes in position as well as increased effects of inversion.

2) Animal-based and other measures:

- a) wing flapping for birds;

- b) escape attempts;
- c) vocalisations referring to *distress*;
- d) injuries;
- e) respiratory distress.

3) Recommendations:

Stunning methods that avoid handling, shackling and inversion of conscious animals should always be preferred.

Where this is not possible, animals should be handled and restrained to minimise struggling or attempts to escape.

Shackle lines should be constructed and maintained so they do not jolt animals because this is likely to stimulate wing flapping or struggling. Shackle line speeds should be optimised so that they do not cause the animals to struggle. Shackling duration prior to *stunning* should be kept to a minimum.

To minimise wing flapping or struggling, breast support should be provided to the birds from the shackling point up to the stunner.

Inappropriate shackling can be prevented by the appropriate training of relevant staff, by rotating the staff to avoid boredom and fatigue and by using shackles that are appropriate and adjustable for the species and size of the animals.

4) Species-specific recommendations:

Rabbits:

Restraining for head-only electrical *stunning* is manual and involves holding the rabbit with one hand supporting its belly, and the other hand guiding the head into the *stunning* tongs or electrodes.

Rabbits should not be lifted or carried by the ears, head, hair or, one leg, or by the skin at the back of the neck without supporting the body.

Poultry:

Shackling should not be used with heavy birds such as parent *flocks*, turkeys or with birds that are more susceptible to fractures (e.g. end-of-lay hens).

Poultry should not be lifted or carried by the head, neck, wings or one leg.

Article 7.5.29.

Head-only electrical stunning of animals in containers

1) Animal welfare concerns:

Electrical *stunning* involves application of an electric current across the brain of sufficient magnitude to induce immediate unconsciousness [EFSA, 2004; Grandin, 1980]. The main *hazards* preventing effective electrical *stunning* are: incorrect electrode placement, poor contact, dirty or corroded electrode, electrical arcing, high contact resistance caused by hair and feathers or dirt on the animal surface and inappropriate electrical parameters (low voltage/current or high frequency [EFSA, 2004]).

2) Animal-based and other measures:

Multiple indicators should be used to determine whether a stun is effective and the animal is unconscious.

Animal-based measures of an effective stun are: tonic-clonic seizures; apnoea; absence of corneal or palpebral reflex.

Animal-based measures of ineffective stun or recovery of consciousness are: vocalisation; spontaneous blinking; righting reflex; presence of corneal or palpebral reflex; rhythmic breathing; spontaneous swallowing and head shaking.

3) Recommendations:

Animals should be stunned as soon as they are restrained.

In the case of ineffective *stunning* or recovery, animals should be re-stunned using a backup system or be killed immediately. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be used, cleaned, maintained and stored following the manufacturer's recommendations.

Constant current stunners ensure that the minimum current is provided to the animal independently from individual impedance and should always be preferred to constant voltage stunners.

Regular calibration of the equipment according to the manufacturer's procedure is recommended. Effectiveness of the *stunning* should be monitored regularly.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters and follow the manufacturer's recommendations for *stunning*, such as:

- shape, size and placement of the electrodes [AVMA, 2016];
- contact between electrode and head;
- electrical parameters (current intensity [A], waveform type [AC and DC], voltage [V] and frequency [Hz]);
- visual or auditory warning system to alert the operator to proper or improper function such as a device that monitors and displays voltage and applied current.

4) Species-specific recommendations:

Effective electrical parameters should be determined based on scientific data on the welfare outcomes for different types of animals in accordance with point 5 of Article 7.1.4.

For head-only *stunning*, minimum parameters are recommended for the following species:

- 240 mA for hens and broiler chicken [EFSA, 2019],
- 400 mA for turkeys [EFSA, 2019],
- 600 mA for geese and ducks [EFSA, 2019],
- 140 mA for rabbits (100V of a 50 Hz sine wave AC) [EFSA, 2020a].

Article 7.5.30.

Electrical water-bath stunning for poultry

1) Animal welfare concerns:

In electrical water-bath *stunning* poultry are inverted and shackled by the legs from a shackle line. The bird's head has direct contact with the water-bath, and an electric current is passed from the water through the bird to the leg shackle. *Hazards* that may prevent effective electrical *stunning* are: lack of contact between head and water, differences in individual bird resistance, improper system grounding, pre-stun shocks due to wings contacting water before the head, and the use of inappropriate electrical parameters (low voltage/current or high frequency [AVMA 2016]).

Hazards that increase the likelihood of animals experiencing pre-stun shocks are: poor handling at shackling, inappropriate line speed, physical contact between birds, incorrect angle of entry ramp, entry ramp wetted by charged water, incorrect water-bath height, and shallow immersion.

Factors affecting individual bird resistance include the resistance between the shackle and the leg (leg/shackle interface), shackling on top of a severed foot, shackling by one leg, poor shackle position, incorrect shackle size, dry shackles, scale on the shackle surface, and keratinised skin on the legs (e.g. older birds).

Where insufficient electrical *stunning* parameters are used, conscious animals are at risk of being electro-immobilised or paralysed causing *pain* and suffering.

2) Animal-based and other measures:

Multiple indicators should be used to determine whether a stun is effective and the animal is unconscious.

Animal-based measures of an effective stun are: tonic-clonic seizures; apnoea; and absence of corneal or palpebral reflex.

Animal-based measures of ineffective stun or recovery of consciousness are: vocalisation; spontaneous blinking; righting reflex; presence of corneal or palpebral reflex; rhythmic breathing; spontaneous swallowing; and head shaking.

3) Recommendations:

The height of the water-bath stunner should be adjusted so that the birds' heads are completely immersed in the water. Avoid distractions such as people walking under the birds because this can cause birds to pull up.

Personnel should watch for short or stunted birds as these birds will not be able to make contact with the water and will not be stunned. These birds should be stunned in the slaughter line (e.g. penetrative captive bolt) or removed and euthanised.

The rail of the shackle line should run smoothly. Sudden movement such as jolts, drops or sharp curves in the line may cause birds to flap and avoid the stunner.

To minimise any disturbance to birds during shackling, where shackles are wet to improve conductivity, they should be wetted only prior to birds' legs being placed in them.

Pre-stun shocks should be avoided and can be reduced by having a smooth shackle line and entry to the water-bath and by adjusting the water level of the bath to minimise overflow.

In the case of ineffective *stunning* or recovery, animals should be re-stunned using a backup system or be killed immediately. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

Stunning equipment should be used, cleaned, maintained and stored following the manufacturer's recommendations.

Constant current stunners should be preferred to constant voltage stunners because the former ensure that the minimum current is provided to the animals independently from their impedance.

Regular calibration of the equipment according to the manufacturer's procedure is recommended. Effectiveness of the *stunning* should be monitored regularly.

Slaughterhouses/abattoirs should have standard operating procedures that define key operating parameters or follow the manufacturer's recommendations for *stunning*, such as:

- water level;
- number of birds in the water-bath;
- contact between water and head, as well as between the legs and the leg shackle;
- electrical parameters (current intensity [A], waveform type [AC and DC], voltage [V] and frequency [Hz]);
- visual or auditory warning system to alert the operator to proper or improper function, such as a device that monitors and displays voltage and applied current.

Ensure an optimum combination of voltage and frequency during electrical water-bath *stunning* practices, to maximise the effectiveness of *stunning*.

Hazards to animal welfare such as inversion of conscious birds, pre-stun shocks, and variability in electrical current delivered to each bird are inherent risks of electrical water-bath *stunning*. Thus, alternative *stunning* systems which avoid these associated *hazards* should be preferred.

4) Species-specific recommendations:

Effective electrical parameters should be based on scientific evidence for different species of birds.

Effective electrical parameters should be based on scientific data on the welfare outcomes for different types of animals in accordance with point 5 of Article 7.1.4.

For water-bath *stunning* depending on the frequency, minimum parameters are recommended for the following species [EFSA, 2019]:

- For frequency below 200 Hz:
 - 100 mA for chicken,
 - 250 mA for turkeys,
 - 130 mA for ducks and geese,
 - 45 mA for quails.
- For frequency from 200 to 400 Hz:
 - 150 mA for chicken,
 - 400 mA for turkeys.
- For frequency from 400-600 Hz:
 - 200 mA for chicken,
 - 400 mA for turkeys.

Birds should receive the current for at least 4 seconds.

Ducks, geese and quails should not be stunned at frequencies higher than 200 Hz [EFSA, 2019].

Chicken and turkeys should not be stunned at frequencies higher than 600 Hz [EFSA, 2019].

Article 7.5.31.

Mechanical stunning of animals arriving in containers

The mechanical methods described here are penetrative and non-penetrative captive bolt systems. Effective mechanical *stunning* requires a severe and immediate damage to the brain caused by the application of mechanical force. For that reason, cervical dislocation and decapitation cannot be considered as *stunning* methods.

1) Animal welfare concerns:

Mechanical methods require precision and often physical strength to restrain and stun the animals. Common causes of the misapplication of these methods are a lack of proper skill and operator fatigue.

Penetrative and non-penetrative captive bolt

An incorrect shooting position or incorrect captive bolt parameters (not hitting the skull with sufficient force) will mis-stun the animal, leaving it conscious and leading to serious wounds and consequently *distress*, fear and *pain*.

Improper captive bolt parameters may be linked to: the use of an inappropriate gun (bolt diameter); inappropriate cartridges; or an overheated or badly maintained gun.

2) Animal-based and other measures:

Penetrative and non-penetrative captive bolt:

Severe convulsions (wing flapping and leg kicking i.e. uncontrolled muscular movements) occur immediately after the mechanical *stunning* intervention. This is due to the loss of control of the brain over the spinal cord. Since mechanical *stunning* is applied to individual animals, its efficacy can be assessed immediately after the stun [Nielsen *et al.*, 2018].

Animal-based measures of an effective stun are: the absence of corneal or palpebral reflex; apnoea; loss of posture; presence of tonic-clonic seizure.

Animal-based measures of ineffective stun or recovery of consciousness are: vocalisations; spontaneous blinking; righting reflex; presence of corneal reflex or palpebral reflex; rhythmic breathing.

3) Recommendations:

Penetrative and non-penetrative captive bolt should only be used as backup or for small- throughput slaughtering as in small *slaughterhouses/abattoirs* or on-farm slaughter or for emergency *killing*.

Penetrative and non-penetrative captive bolt:

The captive bolt gun should be used, cleaned, maintained and stored following the manufacturer's recommendations.

The power of the cartridge, compressed air line pressure or spring should be appropriate for the species and size of birds. Cartridges should be kept dry and the gun regularly inspected and maintained.

Effectiveness of the *stunning* should be monitored.

Because it requires precision, this method should only be applied with proper restraint of the head of the animal. In addition, in the case of birds, they should be restrained in a bleeding cone to contain wing flapping.

The captive bolt should be pointing perpendicularly on the parietal bones of birds.

Placement is different for birds with and without combs:

Without comb:

The placement of the device should be directly on the midline of the skull and at the highest/widest point of the head with the captive bolt aimed directly down towards the brain [AVMA, 2020].

With comb:

The placement of the device should be directly behind the comb and on the midline of the skull with the captive bolt aimed directly down towards the brain of the bird [AVMA, 2020].

Rabbits:

The device should be placed in the centre of the forehead, with the barrel in front of the ears and behind the eyes. The device should be discharged twice in rapid succession at the pressure recommended for the age and size of the rabbit [Walsh *et al.*, 2017].

There should be a sufficient number of bolt guns such that they are allowed to cool between operations.

4) Species-specific recommendations:

Turkeys, ducks, geese and chickens may be also properly stunned by non-penetrative captive bolt [Walsh *et al.*, 2017; Woolcott *et al.*, 2018; Gibson *et al.*, 2019, Stiewert *et al.* 2021; HSA, 2023].

Article 7.5.32.

Controlled atmosphere stunning for animals in containers

Animals may be exposed to controlled atmosphere *stunning* methods either directly in crates or after being unloaded on a conveyor belt. Animals are not subject to restraint. Controlled atmosphere *stunning* includes exposure to carbon dioxide, inert gases, mixtures of carbon dioxide with inert gases or low atmosphere pressure (LAPS).

1) Animal welfare concerns:

A common concern of all controlled atmosphere *stunning* methods is the risk of insufficient exposure of animals to the modified atmosphere, which can result in animals recovering consciousness before or during bleeding and causing respiratory distress, fear and *pain*. The insufficient exposure to the modified atmosphere may be due to either too short exposure time, a too low concentration of gas, too high stocking density or a combination of these variables.

These variables are critical because animals being stunned in large groups need special attention to ensure unconsciousness prior to neck cutting. For this reason, the duration of unconsciousness induced needs to be longer than required by other *stunning* methods to ensure that animals do not recover consciousness prior to being killed.

Furthermore, *hazards* causing increased *distress* during induction of unconsciousness are irritant or aversive gas mixtures, low gas temperature and humidity. In the case of exposure to carbon dioxide, there is a risk that animals are exposed to too high a concentration of this gas, leading to *pain* and *distress*. Exposure of conscious animals to more than 40% carbon dioxide (CO₂) will cause painful stimulation of the nasal mucosa and aversive reactions.

Low atmospheric pressure systems (LAPS) should not be confused with decompression: LAPS utilise a slow removal of air where animals exhibit minimal to no aversive behaviours. Decompression is a fast process that is associated with *pain* and respiratory distress.

2) Animal-based and other measures:

It may be difficult to monitor the effectiveness of controlled atmosphere *stunning* because of limited access to observe animals during the *stunning* process. All chamber-type systems should have either windows or video cameras so that problems with induction can be observed. If problems are observed, there is a need to take immediate corrective measures that could alleviate the suffering of the animals concerned.

Therefore, it is essential that the unconsciousness of animals is confirmed at the end of the exposure to the controlled atmosphere.

Unconsciousness can be confirmed by apnoea, absence of corneal or palpebral reflex, dilated pupils and relaxed carcass.

Since animal-based measures are difficult to monitor, resource-based measures should also be used such as monitoring of gas concentration(s), exposure time, gas displacement rate, and rate of air removal (for LAPS).

3) Recommendations:

Conscious animals should not be exposed to carbon dioxide concentrations exceeding 40%. Any compressed gas should also be vaporised prior to administration and humidified at room temperature to prevent the risk of animals experiencing thermal shock.

The duration of exposure and the gas concentration should be designed and implemented in such a way that all animals are rendered unconscious until *death*.

Gas concentrations and exposure time, temperature and humidity should be monitored continuously at the level of the animal inside the chamber.

Stunning systems should have visual and auditory warning system to alert the operator to improper function, such as inappropriate gas concentration or decompression rate.

In the case of low atmosphere pressure *stunning* the rate of air removal should be monitored continuously. The decompression rate should not be greater than or equivalent to a reduction in pressure from standard sea level atmospheric pressure (760 Torr) to 250 Torr in not less than 50 s. During the second phase, a minimum atmospheric pressure of 160 Torr should be reached within the following 210 s.

In the case of ineffective *stunning* or recovery, animals should be re-stunned immediately using a backup system. Ineffective *stunning* or return to consciousness should be systematically recorded and the cause of the failure identified and rectified.

4) Species-specific recommendations:

The use of Low Atmosphere Pressure *stunning* should be restricted to broilers and newly hatched chicks [Gurung *et al.*, 2018; Jongman and Fisher, 2021] and therefore should not be used for other animals until further information is available.

Article 7.5.33.

Bleeding of animals arriving in containers

1) Animal welfare concerns:

The most common animal welfare concern at the time of bleeding is recovery of consciousness due to ineffective *stunning* practices or an ineffective bleeding. There are many of factors that determine the efficacy of a *stunning* procedure such as type of animal, animal weight, voltage, frequency, impedance and duration of *stunning* or gas (mixture) concentration and exposure [Zulkifli *et al.*, 2013; Raj, 2006; Wotton & Wilkins, 2004].

Improper *stunning* practice leads to the risk of animals experiencing *distress*, fear and *pain*, during *slaughter* if they regain consciousness. There is an additional risk of injury to bones, wings and joints due to struggling if animals regain consciousness.

Bleeding without prior *stunning* causes animal suffering because the incision to sever blood vessels results in substantial tissue damage in areas well supplied with nociceptors. The activation of these nociceptors causes the animal to experience *pain* [Gregory, 2004; Gibson *et al.*, 2009]. Loss of consciousness due to bleeding is not immediate and there is a period during which the animals experience *distress*, fear and *pain* [Gregory, 2004; Johnson *et al.*, 2015].

In case of bleeding without *stunning*, more cases of injury, bruising, haemorrhage and broken body parts are expected to occur due to wing flapping and violent muscular contractions [McNeal *et al.*, 2003].

Bleeding duration also plays an integral part in processing, where animals that have not undergone a sufficient bleeding period, may still be alive upon reaching the scalding tank. Live and conscious birds, if not removed prior to scalding, will then be subjected to additional *pain* from the heat inside the scalding tank and *death* by drowning.

2) Animal-based and other measures:

The main animal-based measure is the blood flow (rate and duration). For animal-based and other measures of return of consciousness after *stunning* (see Article 7.5.26. to Article 7.5.29).

One of the most common parameters in determining bleeding efficiency is the percentage of blood loss, where the amount of blood loss is estimated from the difference between pre-slaughter weight and post-slaughter weight [Velarde *et al.*, 2003; Sabow *et al.*, 2015].

For birds, the presence of 'red-skin' carcasses may be the result of ineffective *killing* with live birds entering the scalding tank.

3) Recommendations:

The *slaughterhouse/abattoir* operators should ensure that:

- both carotid arteries are severed;

- qualified personnel take random samples of animals after the end of *stunning* and before bleeding to ensure animals are not showing signs of consciousness;
- immediately after bleeding, qualified personnel check that the jugular veins, carotid arteries and trachea were cut thoroughly, guaranteeing an efficient bleeding process.

Decapitation should be applied as bleeding method only to unconscious animals.

4) Species-specific recommendations:

- for chicken, the slaughter line speed should allow a minimum bleeding period of 90 seconds so that there is minimum blood loss of 60 % before reaching the scalding tank or other potentially painful operation;
- qualified personnel should check that at the bleeding line, especially before scalding, birds are completely dead. Birds that are still alive need to be euthanised immediately and removed from shackle.

Article 7.5.34.

Emergency killing of animals arriving in containers

This article addresses animals that show signs of severe *distress* or *pain* before being unloaded or within the *slaughterhouse/abattoir*. These animals may correspond to animals unfit to travel as listed in Article 7.3.7. Principles described may also apply to animals that are not suitable for *slaughter* for commercial reasons, even if they do not present signs of *pain* or suffering.

1) Animal welfare concerns:

Some animals can arrive at *slaughterhouses/abattoirs* with injuries or severe illnesses that can cause undue *distress*, *pain* suffering.

2) Animal-based and other measures:

Animals requiring emergency *killing* are those with severe injuries such as fractures, bone dislocations, and large open wounds.

They may also present clinical signs of serious illness or be in a state of extreme weakness.

3) Recommendations:

Animal handlers should euthanise the animals as soon as they are identified at arrival, during lairage or at the time of shackling.

Emergency *killing* should be systematically recorded and analysed to improve procedures and prevent recurrences.

Article 7.5.35.

Methods, procedures or practices that should not be used for animals arriving in containers

1) The following practices for handling animals should not be used under any circumstances:

- a) applying pressure using an injurious object or applying an irritant substance to any part of the body of an animal;
- b) hitting animals including with instruments such as sticks, notably sticks with sharp ends, piping, stones, fencing wire or leather belts;
- c) kicking, throwing or dropping animals;
- d) stepping on or crushing animals;
- e) grasping, lifting or dragging animals only by body parts such as their tail, head, ears, limbs, hair or feathers.

- 2) The following practices for restraining animals should not be used:
- a) mechanical clamping of the legs or feet of the animals as the sole method of *restraint*;
 - b) breaking legs, cutting leg tendons or blinding animals;
 - c) applying electrical current that does not span the brain;
 - d) severing the brain stem by piercing through the eye socket or skull bone;
 - e) crushing the neck.

In birds, electro-immobilisation for neck-cutting or preventing wing flapping during bleeding, or the method of brain piercing through the skull without prior *stunning* should not be used under any circumstances.

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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 the following animals (hereafter 'susceptible animals') with FMDV:
 - animals of the families *Suidae* and *Cervidae*;
 - animals of the subfamilies *bovinae*, *caprinae* and *antilopinae* of the family *Bovidae* and family *Cervidae* (hereafter 'ruminants'); and
 - *Camelus bactrianus* with FMDV (hereafter 'susceptible animals').
- 2bis) ~~For the purposes of this chapter, a 'bovine' means an animal 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 susceptible animal listed in point 2; or
 - b) antigen or nucleic acid specific to FMDV has been detected in a sample from an susceptible animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *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 detected in a sample from an susceptible animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *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 WOAHP 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 transmission of FMDV. FMDV may persist in the pharynx and associated lymph nodes of some ruminants for a variable but limited period of time beyond 28 days after *infection*, but not indefinitely. Such animals have been termed carriers. However, ~~the~~ the only species for which transmission of FMDV has been proven from persistently infected individuals ~~carriers~~ is the African buffalo (*Syncerus caffer*).~~ However, and transmission of FMDV from African buffalo to domestic livestock is rare.
- 7) Standards for ~~diagnostic tests~~ diagnosis and vaccines, as well as information on the epidemiology, 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 *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 F_0 value of 3 or above;
- 3) *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 animals can be traded safely if in accordance with the relevant articles in this chapter.

Article 8.8.2.

Country or zone free from FMD where vaccination is not practised

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:

- 1) 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 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) Articles 8.8.40. to 8.8.42. where historical freedom cannot be demonstrated, which includes the detection of clinical signs of FMD and demonstrates:
 - i) no *infection* with FMDV in unvaccinated animals;
 - ii) no transmission of FMDV in previously vaccinated animals;
- 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*. **Unless otherwise specified in this chapter, movements of commodities within a country between zones of different animal health status should comply with the same requirements as for importation.** ~~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~~
 - b) ~~for slaughter in accordance with Articles 8.8.8. and 8.8.9.bis.; 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 or *zone* will be included in the list of countries or *zones* free from FMD, where *vaccination* is not practised in accordance with Chapter 1.6.

Retention on the list requires annual reconfirmation of compliance with all points above and provisions under point 4 of Article 1.4.6. Documented evidence should be resubmitted annually for all points above. Any changes in the epidemiological situation or other significant events should be notified to WOA in accordance with Chapter 1.1.

Provided the conditions of point 4 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~~ is in place, including effective separation from other susceptible domestic *populations* or *wildlife*;
- the susceptible 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*.

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

Article 8.8.3.

Country or zone free from FMD where vaccination is practised

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*:

- 1) for at least the past 12 months:
 - a) there has been no transmission of FMDV;
 - b) there has been no *infection* ~~of~~ with FMDV ~~in the unvaccinated subpopulations~~;
 - c) 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 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~~ the target population should be defined in accordance with Chapter 4.18.
 - 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*;

2) for the past 24 months:

appropriate *surveillance* has been implemented in accordance with Articles 8.8.40. to 8.8.42. and demonstrates points 1 a) and 1 b) above.

The country or *zone* will be included in the list of countries or *zones* free from FMD where *vaccination* is practised in accordance with Chapter 1.6.

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 annually for all points above. Any changes in the epidemiological situation or other significant events should be notified to WOAHP in accordance with 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 country or *zone* free from FMD where *vaccination* is practised and is recognised by WOAHP as such, wishes to change its status to country or *zone* free from FMD where *vaccination* is not practised, it should notify WOAHP 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 WOAHP. If the application for the new status is not provided within 24 months of the cessation or if the compliance is not approved by WOAHP, then evidence should be provided that it complies with Article 8.8.3. Otherwise, the status of the country or zone as being free from FMD where vaccination is practised will be is suspended. If the country or zone does not comply with requirements of Article 8.8.2., evidence should be provided that it complies with Article 8.8.3. Otherwise the status will be 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 WOAHP as such, wishes to change its status to country or *zone* free from FMD where *vaccination* is practised, it should provide WOAHP with an application ~~and a plan following the structure of the Questionnaire in accordance with Chapter 1.11.~~ The status ~~as of the country or zone as~~ free from FMD where *vaccination* is not practised remains unchanged until the application and plan are approved by WOAHP. As soon as it is recognised as free from FMD where *vaccination* is practised, the country or *zone* ~~will should~~ begin the *vaccination*. ~~Then the Member Country should provide evidence within six months that it has complied with Article 8.8.3. for this time period. Otherwise, the status will be is~~ suspended.

Article 8.8.4.

Compartment free from FMD where vaccination is not practised

A *compartment* free from FMD where *vaccination* is not practised can be established in any country or *zone*. In defining such a *compartment* the principles of Chapters 4.4. and 4.5. should be followed. Susceptible animals in the free *compartment* should be separated from any other susceptible animals by the effective application of a *biosecurity plan*.

A Member Country wishing to establish a *compartment* free from FMD where *vaccination* is not 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* that:
 - a) no *infection* with FMDV has occurred during the past 12 months;
 - b) *vaccination* against FMD is prohibited;
 - c) no animal vaccinated against FMD within the past 12 months is in the *compartment*;
 - d) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;

- e) documented evidence shows that *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation;
 - f) an *animal identification and traceability* system in accordance with Chapters 4.2. and 4.3. 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 approval should only be granted when no *infection with* or transmission of FMDV has occurred within a 10-kilometre radius of the *compartment* during the three months prior to the ~~effective establishment~~ application 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 4.4. and 4.5. 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) no *infection* or transmission of FMDV has occurred during the past 12 months;
 - b) 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;
 - c) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;
 - d) 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 or transmission* at an early stage with a high level of confidence;
 - e) an *animal identification and traceability* system in accordance with Chapters 4.2. and 4.3. 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 b), 2 d) and 2 e).

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

Article 8.8.5.

Country or zone infected with FMDV

A country or *zone* shall be considered as infected with FMDV when the requirements for acceptance as a country or *zone* free from FMD either where *vaccination* is not practised or 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 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 an application to WOA, ~~in supported of the application, by~~ 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~~ increased surveillance in accordance with Articles 8.8.40. to 8.8.42. is in place in the *protection zone* and enhanced awareness in the rest of the country or *zone*;
- 4) intensified *biosecurity* in the *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* is in place, which may include 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 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. 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~~ not last more than 24 months from the date of its approval by WOA. During this period, the Member Country should either apply for inform WOA of the removal/lifting of the protection zone or apply for its official recognition of the protection zone as a separate zone within 24 months from the date of its approval by WOA in accordance with either Article 8.8.2. or 8.8.3.

Article 8.8.6.

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

In the event of *outbreaks* within a country or *zone* previously free from FMD where *vaccination* is either practised or not, including within a *protection zone*, a *containment zone*, which includes all epidemiologically linked *outbreaks*, may be established, in accordance with Article 4.4.7., to minimise the impact on the country or *zone*.

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. documented evidence that:

- 1) on suspicion, a standstill has been imposed on the suspected *establishments* and effective controls on the movement of animals and other *commodities* are in place in the country or *zone*;
- 2) on confirmation, the standstill and movement controls described in point 1 have been reinforced;
- 3) epidemiological investigations into the likely source of the *outbreaks* have been carried out;
- 4) *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*;
- 5) 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 these areas 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 5 above.

In the event of recurrence of *infection* with FMDV in unvaccinated animals or 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 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 b) 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 free status of the *containment zone* should be achieved within 24 months of its approval and follow the provisions of Article 8.8.7. otherwise the status of the rest of the country or zone is suspended.

Article 8.8.7.

Recovery of free status

- 1) When *infection* with FMDV occurs in a 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 NSP of FMDV to demonstrate no transmission of FMDV in the 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.

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

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 *infection* with FMDV occurs in a country or *zone* previously free from FMD where *vaccination* is not practised, the following waiting period is required to gain the status of 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 NSP of FMDV demonstrates no transmission of FMDV.

The country or *zone* can gain the status of free from FMD where *vaccination* is practised only after the submitted evidence, based on the provisions of Chapter 1.11. has been accepted by WOA. H.

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

- 3) When *infection* with FMDV or transmission of FMDV occurs in a 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 NSP of FMDV demonstrates no 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 Article 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 NSP of FMDV demonstrates no evidence of transmission of FMDV.

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

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

- 4) When *infection* with FMDV occurs in a *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 only when 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., 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 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 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) 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* 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. For ruminants, the head, including the pharynx, tongue and associated lymph nodes, was either destroyed or treated in accordance with Article 8.8.31. 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~~ inactivate any FMDV potentially present.

Article 8.8.9bis.

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

~~In order not to jeopardise the status of a zone free from FMD zone where *vaccination* is not practised, FMD vaccinated susceptible animals should only leave the *free zone* if transported directly for *slaughter* in a 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 *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 countries, zones or compartments free from FMD where vaccination is not practised

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 country, *zone* or *compartment* free from FMD where *vaccination* is not practised;
- 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 susceptible animals ~~domestic ruminants and pigs~~ from countries, zones or compartments free from FMD where vaccination is practised

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 country, *zone* or *compartment* free from FMD where *vaccination* is practised;

- 3) if not vaccinated were subjected to ~~virological~~ a virological and serological tests for FMD with negative results on a samples collected not earlier than 14 days before 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 shipment;
- 5) if transiting an infected *zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article 8.8.11bis.

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

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 susceptible animals ~~domestic ruminants and pigs~~ from countries or zones infected with FMDV, where an official control programme exists

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) if pigs, they have not been fed swill not complying with Article 8.8.31bis.;
- 3) 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*;
- 4) the *establishment* of origin is covered by the *official control programme* and FMD has not occurred within it for the relevant period as defined in points 3 a) and 3 b) above;
- 5) the animals were isolated for the 30 days prior to shipment:
 - a) in a *quarantine station*, 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
 - b) in an establishment that is not a *quarantine station*, infection with FMDV 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;

- 6) the animals were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

Article 8.8.14.

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

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 country, *zone* or *compartment* free from FMD where *vaccination* is not practised;
 - ~~e) were kept in an artificial insemination centre;~~
- 2) the semen was collected, processed and stored in accordance with Chapters 4.6. and 4.7.

Article 8.8.15.

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

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 country, *zone* or *compartment* free from FMD where *vaccination* is practised;
 - c) either
 - i) 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 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 4.6. and 4.7.;
 - 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 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 countries or zones infected with FMDV

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* to which no animal had been added in the 30 days before collection, and within a 10-kilometre radius of which, FMD has not occurred in the 30 days before and after collection;
 - c) either
 - i) 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 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 4.6. and 4.7.;
 - 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 8.8.18.

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

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 country, *zone* or *compartment* free from FMD where *vaccination* is not practised;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 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., 4.9., and 4.10. as relevant.

Article 8.8.19.

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

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 country, *zone* or *compartment* free from FMD where *vaccination* is practised;
 - c) either

- i) 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 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 8.8.14., 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., 4.9., and 4.10. as relevant.

Article 8.8.20.

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

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 country, *zone* or *compartment* free from FMD where *vaccination* is not practised or have been imported in accordance with Article 8.8.10., Article 8.8.11., Article 8.8.11bis. 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 susceptible animals ~~ruminants and pigs~~ from countries, zones or compartments free from FMD where vaccination is practised

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

- 1) ~~ruminants or pigs~~ that have been kept in the country, *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., Article 8.8.11bis. 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 with favourable results;
- 3) if 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 countries or zones infected with FMDV, where an official control programme exists

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

EITHER

- b) comes from bovines that comply with Article 8.8.10., 8.8.11., 8.8.11bis. or 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

2) a) comes from ~~animals~~ bovines which:

- ai) 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;
- bii) 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*;
- €iii) were kept for the past 30 days in:
 - a *quarantine station*; or
 - an *establishment*, within a 10-kilometre radius of which FMD has not occurred during that period;
- div) have been transported, in a *vehicle* which was ~~cleaned~~ cleansed and disinfected before ~~the bovines and water buffaloes were loadinged~~, 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;
- ev) 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;
- fvi) were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable results;

2b) comes from deboned carcasses:

- ai) from which feet, head, viscera and the major lymphatic nodes have been removed;
- bii) 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

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

- 1) the *meat* comes from ~~animals~~ pigs complying with Article 8.8.10., 8.8.11., 8.8.11bis. or 8.8.12.;
- 2) the ~~animals~~ pigs were transported, in a *vehicle* which was cleaned and disinfected before ~~the pigs were loadinged~~, 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~~ pigs 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~~ pigs were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., 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 (~~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) ~~sheep and goats 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) ~~sheep and goats 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) ~~sheep and goats animals~~ that were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., with favourable results; and

EITHER,

- 4) ~~sheep and goats animals~~ that comply with Article 8.8.10., 8.8.11., 8.8.11bis. or 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) ~~sheep and goats 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 feet, head, viscera and 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 countries or zones infected with FMDV

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

- 1) the entire consignment of *meat products* comes from animals which have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results;
- 2) the *meat products* come from *meat* that complies with Articles 8.8.22., 8.8.22bis. or 8.8.22ter., or they have been processed to ensure the ~~destruction~~ inactivation 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 ~~products of animal~~ products origin (other than those covered by other articles) from countries, zones or compartments free from FMD whether vaccination is practised or not

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

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

- 1) these products:
 - a) originate from establishments herds which at the time of *milk* collection were not infected or suspected of being infected with FMDV; and comes from milk that:
 - b) i) have been processed to ensure the destruction inactivation of FMDV in accordance with one of the procedures in Article 8.8.35.; or
 - ii) comes from milk that has a pH less than 7 or has been tested for FMDV with negative results; and heated at a minimum temperature of 72 C for at least 15 seconds;
 - ii) has been heated at a minimum temperature of 72 C for at least 15 seconds;
 - or
 - b) have been processed to ensure the inactivation of FMDV in accordance with one of the procedures in Article 8.8.35.
- 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 countries or zones infected with FMDV

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

- 1) these products have been processed to ensure the ~~destruction~~ inactivation 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 and processing to avoid contact of the products with any potential source of FMDV.

Article 8.8.28.

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

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 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 animals (other than those listed in Article 8.8.1bis.) from countries, zones or compartments free from FMD, whether vaccination is practised or not

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been killed in 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 animals (other than those listed in Article 8.8.1bis.) from countries or zones infected with FMDV

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

Article 8.8.31.

Procedures for the inactivation of FMDV in meat and meat products of susceptible animals

For the inactivation of FMDV present in *meat* and *meat products* of susceptible animals, 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', so that the moisture protein ratio is not greater than 2.25:1 or the water activity (a_w) is not greater than 0.85. 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 (A_w) that is not greater than 0.85.~~

4. Any equivalent treatment which has been demonstrated to inactivate FMDV in *meat* and *meat products*

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, one of the following procedures should be used:

- 1) for wool, industrial washing, which consists of the immersion in a series of baths of water, soap and sodium hydroxide (NaOH) or potassium hydroxide (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 in a water-soluble detergent held at 60-70°C;
- 5) for wool, storage 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, 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, the following procedure should be used: treatment for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na_2CO_3).

Article 8.8.35.

Procedures for the inactivation of FMDV in milk and milk products

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

- 1) ~~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]) applied twice; or~~
- 2) ~~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 in milk.~~

Article 8.8.37.

Procedures for the inactivation of FMDV in skins and trophies from susceptible animals

For the inactivation of FMDV present in skins and trophies from susceptible *animals*, 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 (Na₂CO₃) 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 [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 (Na₂CO₃).

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% Na₂HPO₄ and 2.8% Na₃PO₄ (weight/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

A Member Country may, on a voluntary basis, apply for endorsement of its *official control programme* for FMD in accordance with Chapter 1.6., when 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.

The country will be included in the list of countries having a WOAHA 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.

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 WOAHA of their *official control programme* for FMD, in accordance with Article 8.8.39. *Surveillance* aimed at identifying disease and *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, and transmission of, FMDV should be carefully designed and implemented to avoid producing results that are insufficient to be accepted by WOA 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 *vaccination* has been 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 **populations** 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 transmission of FMDV should target animals that are less likely to show vaccine-derived antibodies to 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 WOA 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 *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 WOA 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 *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 and pigs). The Member Country should justify the *surveillance* strategy chosen and the frequency of sampling as adequate to detect *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 *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 positive 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. 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 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 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 status free from FMD where vaccination is not practised or early recovery of status free from FMD where 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* 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 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 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 movements 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 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 status free from FMD where 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 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 movements 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 movements 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* 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 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 WOAHP 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 NSP tests or SP tests.

Serological *surveillance* may be used to:

- a) estimate the prevalence or substantiate freedom from *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

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 SP and the NSP of the virus. Vaccinated *animals* produce antibodies mainly or entirely to the SP of the virus depending upon vaccine purity. In unvaccinated *populations*, SP tests may be used to screen sera for evidence of *infection* with FMDV or to detect the introduction of vaccinated *animals*. In vaccinated *populations*, SP tests may be used to monitor the serological response to the *vaccination*. The SP tests are serotype specific. For optimal sensitivity an antigen or virus closely related to the field strain expected should be selected.

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 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 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 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 reactor that has been confirmed in a *laboratory* should be investigated. The investigation should examine all evidence, which may include the results of any further serological tests used to confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to 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 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 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*. If there is no transmission of FMDV, they will remain serologically negative.

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. 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 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 *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.

CHAPTER 1.11.

APPLICATION FOR OFFICIAL RECOGNITION BY WOAHP
OF FREE STATUS FOR FOOT AND MOUTH DISEASE

Article 1.11.1.

Country free from infection with foot and mouth disease virus where vaccination is not practised

The following information should be provided by WOAHP Member Countries to support applications for official recognition of status as a country where *vaccination* is not practised that is free from *infection* with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

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

The terminology defined in the WOAHP *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

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

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

The Delegate of the Member Country applying for recognition of FMD freedom for a country where *vaccination* is not practised must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.2. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that for at least the past 12 months:

- 1) there has been no case of infection with FMDV during the past 12 months;
- 2) there has been no evidence of FMDV transmission of FMDV in previously vaccinated animal populations;
- 3) surveillance in accordance with Articles 8.8.40. to 8.8.42. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;
- 24) no vaccination against FMD has been prohibited and the prohibition has been effectively implemented and supervised carried out during the past 12 months.

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

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and, where relevant, of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of the *infection*. Provide maps identifying the features above. Specify whether the application includes any noncontiguous territories.
- b) Livestock demographics. Describe the composition of the livestock industry in the country. In particular, describe:

- i) the susceptible animal *population* by species and types of production systems;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (attach relevant documents if available). Provide tables and maps.
- c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country? Provide estimates of *population sizes*, and geographic distribution and a summary description of their habitat. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.2. and 3.3. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are movements of all susceptible species controlled in the country? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

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

1.4.6. of the *Terrestrial Code*.

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

- b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of FMD in response to any past incursions of FMD virus.
- c) Vaccines and *vaccination*. Briefly answer the following:
- i) Is there any legislation that prohibits *vaccination*? If so:
 - Provide the date when *vaccination* was formally prohibited;
 - Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.
 - ii) Was *vaccination* ever used in the country? If so:
 - Provide the date when the last *vaccination* was carried out;
 - What type of vaccine was used?
 - What species were vaccinated?
 - How were vaccinated animals identified?
 - What was the fate of those animals?
 - iii) In addition, if *vaccination* was applied during the past 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following:
 - the vaccine strains;
 - potency and formulation, purity, details of any vaccine matching performed;
 - the species vaccinated;
 - identification of vaccinated animals;
 - the way in which the *vaccination* of animals was certified or reported and the records maintained;
 - evidence that the vaccine used complies with Chapter 3.1.8. of the *Terrestrial Manual*.
- d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 3.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

- a) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following:
- i) How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up

procedures and the time frame for reporting results;

- ii) Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the last 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - iii) Procedures for quality assurance and for the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - iv) Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - v) Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - vi) Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.
- b) If FMD *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 3.1.8. of the *Terrestrial Manual*. The following information should be included:

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

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

- c) Serological or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are surveys conducted? Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale. Describe how previously vaccinated or newly introduced vaccinated animal populations are considered in the strategy and design of the surveillance programme, if applicable.

Provide a summary table indicating, for the past 24 months, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and on how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.
- e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, including details of:

- a) Coordination with other countries. Describe any relevant factors in neighbouring countries that should be taken into account (e.g. size, distance from the border to affected *herds, flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).

- c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

- d) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species, vaccination status, and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.
- ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?
- iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
- animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - *veterinary medicinal products*;

- other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the WOAH official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed FMD *outbreak*:
 - i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 8.8.7. and points 4, 5 and 6-1, 3 and 4 of Article 8.8.2. of the *Terrestrial Code* and provide detailed information as specified in Sections 3, 5 and 6-1-7 (inclusive) of this questionnaire.

Article 1.11.2.

Country free from infection with foot and mouth disease virus where vaccination is practised

The following information should be provided by WOAH Member Countries to support applications for official recognition of status as a country where *vaccination* is practised that is free from *infection* with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

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

The terminology defined in the WOAH *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

National legislation, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the WOAH official languages. Weblinks to supporting documents in one of the official languages of WOAH may

also be provided, where they exist.

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

The Delegate of the Member Country applying for recognition of FMD freedom for a country where *vaccination* is practised must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that for at least the past 12 months:

- 1) there has been no case of infection with FMDV for the past 24 months;
- 2) no evidence of FMDV transmission of FMDV for the past 12 months;
- 3) surveillance for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;
- 4) routine compulsory systematic vaccination is carried out in the target population for the purposes of the prevention of FMD;
- 5) the vaccine used complies with the standards described in the *Terrestrial Manual*.

And, for at least the past 24 months, surveillance in accordance with Articles 8.8.40. to 8.8.42. is in operation, and regulatory measures for the prevention and control of FMD have been implemented.

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

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and, where relevant, of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of the *infection*. Provide maps identifying the features above. Specify whether the application includes any noncontiguous territories.
- b) Livestock demographics. Describe the composition of the livestock industry in the country. In particular, describe:
 - i) the susceptible animal *population* by species and types of production systems;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (attach relevant documents if available). Provide tables and maps.
- c) *Wildlife* demographics. What susceptible *captive wild, wild* or *feral* species are present in the country? Provide estimates of *population sizes*, and geographic distribution and a summary description of their habitat. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as

appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.2. and 3.3. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are movements of all susceptible species controlled in the country? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

- a) History. Provide a description of the FMD history in the country, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last *case* or *eradication*, and the types and strains in the country.
- b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, modified stamping-out policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of FMD in response to any past incursions of FMD virus.
- c) Vaccines and *vaccination*. Describe any legislation regulating *vaccination*. Provide a description and justification of the *vaccination* strategy and programme, including the following:
 - i) the vaccine strains;
 - ii) potency and formulation, purity, details of any vaccine matching performed;
 - iii) the species vaccinated;
 - iv) identification of vaccinated animals;
 - v) the way in which the *vaccination* of animals was certified or reported and the records maintained;

- vi) the date on which the last *vaccination* was performed;
 - vii) evidence that the vaccine used complies with Chapter 3.1.8. of the *Terrestrial Manual*.
- d) Provide detailed evidence of *vaccination* coverage and population immunity as follows:

Describe how the number of animals intended for *vaccination* and the number of vaccinated animals are estimated.

For serological surveys to estimate population immunity, provide detailed information on the sampling frame (target population, age, species and *vaccination* status) and survey design (expected prevalence, acceptable error, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How long after *vaccination* are samples collected? Describe how the threshold for protective immunity has been established.

Provide the results of the *vaccination* coverage and population immunity by year, serotype, species, as relevant.

Provide details of any additional methods applied for monitoring the performance of *vaccination*.

- e) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 3.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

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

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 3.1.8. of the *Terrestrial Manual*. The following information should be included:

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

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

- c) Serological or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are surveys conducted? Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.
- e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.
- f) Provide evidence that surveys are carried out to assess *vaccination* coverage and population immunity of the target *populations*, show laboratory evidence that the vaccine strains used is appropriate.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, including details of:

- a) Coordination with other countries. Describe any relevant factors in neighbouring countries that should be taken into account (e.g. size, distance from the border to affected *herds*, *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).
- c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

d) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.
- ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?
- iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - *veterinary medicinal products*;
 - other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the WOAH official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed FMD *outbreak*:
 - i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination,

campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;

- v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
- vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
- vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a country should comply with the provisions of Article 8.8.7. and points 1 e), f), g) and 2, 3 and 4 of Article 8.8.3. of the *Terrestrial Code* and provide detailed information as specified in Sections 3, 5 and 6 1-7 (inclusive) of this questionnaire.

Article 1.11.3.

Zone free from infection with foot and mouth disease virus where vaccination is not practised

The following information should be provided by WOAH Member Countries to support applications for official recognition of status as a *zone* where *vaccination* is not practised that is free from *infection* with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

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

The terminology defined in the WOAH *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

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

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

The Delegate of the Member Country applying for recognition of FMD zonal freedom must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.2. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating ~~that~~ for at least the past 12 months:

- 1) there has been no case of infection with FMDV during the past 12 months;
- 2) there has been no evidence of FMDV transmission of FMDV in previously vaccinated animals populations;
- 3) surveillance for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;
- 4) no vaccination against FMD has been prohibited and the prohibition has been effectively implemented and supervised carried out during the past 12 months.

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

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of the *infection*.

The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide maps identifying the features above, including a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.

- b) Livestock demographics. Describe the composition of the livestock industry in the country and the *zone*. In particular, describe:
- i) the susceptible animal *population* by species and types of production systems in the country and the *zone*;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (attach relevant documents if available).

Provide tables and maps.

- c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country and the *zone*? Provide estimates of *population* sizes, and geographic distribution and a summary description of their *habitat*. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country or *zone*, and between *zones* of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.2. and 3.3. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal*

identification and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are movements of all susceptible species controlled in and between *zones* of the same or different status for all production systems? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

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

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

- b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. *stamping-out policy*, modified stamping-out policy, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of FMD in response to any past incursions of FMD virus.

- c) Vaccines and *vaccination*. Briefly answer the following:

- i) Is there any legislation that prohibits *vaccination*? If so:

- Provide the date when *vaccination* was formally prohibited;
- Provide information on cases of detection of illegal *vaccination* during the reporting period and actions taken in response to the detection.

- ii) Was *vaccination* ever used in the *zone*? If so:

- Provide the date when the last *vaccination* was carried out;
- What type of vaccine was used?
- What species were vaccinated?
- How were vaccinated animals identified?
- What was the fate of those animals?

- iii) In addition, if *vaccination* was applied during the past 24 months, provide a description and justification of the *vaccination* strategy and programme, including the following:

- the vaccine strains;
- potency and formulation, purity, details of any vaccine matching performed;
- the species vaccinated;
- identification of vaccinated animals;

- the way in which the *vaccination* of animals was certified or reported and the records maintained;
 - evidence that the vaccine used complies with Chapter 3.1.8. of the *Terrestrial Manual*.
- iv) If *vaccination* continues to be used in the rest of the country, give details of the species vaccinated and on the post-*vaccination* monitoring programme.
- d) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 3.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

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

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 3.1.8. of the *Terrestrial Manual*. The following information should be included:

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

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

- c) Serological or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are surveys conducted? Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale. Describe how previously vaccinated or newly introduced vaccinated animals **populations** are considered in the strategy and design of the surveillance programme, if applicable.

Provide a summary table indicating, for the past 24 months, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.
- e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country or *zone*, including details of:

- a) Coordination with other countries. Describe any relevant factors in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds*, *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem. If the FMD free *zone* without *vaccination* is established in a FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Are *protection zones* in place? If so, indicate whether or not the *protection zone* are included in the proposed FMD free *zones*. Provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.
- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).
- c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.
- d) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the *zone*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin,

species, vaccination status, and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.
- ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What are the biosecurity measures in place at waste disposal sites?
- iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - *veterinary medicinal products*;
 - other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the WOAHP official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed FMD *outbreak*:
 - i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control

points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a *zone* where *vaccination* is not practised should comply with the provisions of Article 8.8.7. and points 4, 5 and 6-1, 3 and 4 of Article 8.8.2. of the *Terrestrial Code* and provide detailed information as specified in Sections 3, 5 and 6-1-7 (inclusive) of this questionnaire.

Article 1.11.4.

Zone free from infection with foot and mouth disease virus where vaccination is practised

The following information should be provided by WOAH Member Countries to support applications for official recognition of status as a *zone* where *vaccination* is practised that is free from *infection* with foot and mouth disease (FMD) virus in accordance with Chapter 8.8. of the *Terrestrial Code*.

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

The terminology defined in the WOAH *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

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

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

The Delegate of the Member Country applying for recognition of FMD zonal freedom must demonstrate compliance with the *Terrestrial Code*. That is, the Delegate should submit documentary evidence that the provisions of Article 8.8.3. have been properly implemented and supervised.

In addition, the Delegate of the Member Country must submit a declaration indicating that for at least the past 12 months:

- 1) there has been no case of infection with FMDV for the past 24 months;
- 2) no evidence of FMDV transmission of FMDV for the past 12 months;
- 3) surveillance for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;
- 4) routine compulsory systematic vaccination is carried out in the target population for the purposes of the prevention of FMD;
- 5) the vaccine used complies with the standards described in the *Terrestrial Manual*.

And, for at least the past 24 months, surveillance in accordance with Articles 8.8.40. to 8.8.42. is in operation, and regulatory measures for the prevention and control of FMD have been implemented.

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

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and the *zone*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of the *infection*.

The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide maps identifying the features above, including a digitalised, geo-referenced map with a description of the geographical boundaries of the *zone*.

- b) Livestock demographics. Describe the composition of the livestock industry in the country and the *zone*. In particular, describe:
- i) the susceptible animal *population* by species and types of production systems in the country and the *zone*;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (attach relevant documents if available).

Provide tables and maps.

- c) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country and the *zone*? Provide estimates of *population sizes*, and geographic distribution and a summary description of their habitat. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?
- d) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country or *zone*, and between *zones* of the same or different status? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The table should include, but not be limited to, the legislation on disease control measures and compensation systems.
- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.2. and 3.3. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are movements of all susceptible species controlled in and between *zones* of the same or different status? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal

migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. FMD eradication

- a) History. Provide a description of the FMD history in the country and *zone*, with emphasis on recent years. If applicable, provide tables and maps showing the date of first detection, the sources and routes of introduction of *infection*, the temporal and spatial distribution (number and location of *outbreaks* per year), the susceptible species involved, the date of last *case* or *eradication* and the types and strains in the country.
- b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. *stamping-out policy*, zoning, *vaccination*, movement control). Provide the time frame for *eradication*. Describe and justify the corrective actions that have been implemented to prevent future *outbreaks* of FMD in response to any past incursions of FMD virus.
- c) Vaccines and *vaccination*. Describe any legislation regulating *vaccination*. Provide a description and justification of the *vaccination* strategy and programme, including the following:
 - i) the vaccine strains;
 - ii) potency and formulation, purity, details of any vaccine matching performed;
 - iii) the species vaccinated;
 - iv) identification of vaccinated animals;
 - v) the way in which the *vaccination* of animals was certified or reported and the records maintained;
 - vi) the date on which the last *vaccination* was performed;
 - vii) evidence that the vaccine used complies with Chapter 3.1.8. of the *Terrestrial Manual*.
- d) Provide detailed evidence of *vaccination* coverage and population immunity as follows:

Describe how the number of animals intended for *vaccination* and the number of vaccinated animals are estimated.

For serological surveys to estimate population immunity, provide detailed information on the sampling frame (target population, age, species and *vaccination* status) and survey design (expected prevalence, acceptable error, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How long after *vaccination* are samples collected? Describe how the threshold for protective immunity has been established.

Provide the results of the *vaccination* coverage and population immunity by year, serotype, species, as relevant.

Provide details of any additional methods applied for monitoring the performance of *vaccination*.

- e) Provide a description of the legislation, organisation and implementation of the *eradication* campaign. Outline the legislation applicable to the *eradication* and how the campaign was organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.

4. FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 3.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

- a) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country. Indicate the *laboratories* where samples originating from the *zone* are diagnosed.

Address the following points:

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

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the *zone* complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 3.1.8. of the *Terrestrial Manual*. The following information should be included:

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

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

- c) Serological or virological *surveillance*. Are serological or virological surveys conducted? If so, provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. How frequently are surveys conducted? Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for the past 24 months, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide details of follow-up actions taken on all suspicious and positive results and how these findings are acted upon. Provide criteria for selection of *populations* for targeted surveillance based on the risk and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

- d) Provide information on risks in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.). Provide evidence of how the knowledge acquired through these activities assisted in more effective implementation of control measures.
- e) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training

programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.

- f) Provide evidence that surveys are carried out to assess *vaccination* coverage and population immunity of the target *populations*, show laboratory evidence that the vaccine strains used is appropriate.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, including details of:

- a) Coordination with other countries. Describe any relevant factors in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds* or *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

If the FMD free *zone* with *vaccination* is established in a FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

Are *protection zones* in place? If so, indicate whether or not the *protection zone* are included in the proposed FMD free *zones*. Provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species) and provide a geo-referenced map of the *zones*.

- b) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).
- c) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

- d) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country or *zone*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products, and subsequent internal movement. Describe the import measures (e.g. quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and if so, the duration and location of quarantine. Advise whether import permits and *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.
- ii) Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What are the *biosecurity* measures in place at waste disposal sites?
- iii) Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the *zone* or their final destination, concerning the import and

follow-up of the following:

- animals;
- genetic material (semen, oocytes and embryos);
- animal products;
- *veterinary medicinal products*;
- other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.

7. Control measures and contingency planning

- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the WOAH official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the past five years.
- b) In the event of a suspected or confirmed FMD *outbreak*:
- i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed with respect to suspected *cases* (e.g. livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Provide a detailed description of the control or *eradication* procedures (e.g. forward and backward tracing, movement control, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including vaccine delivery and cold chain, *stamping-out policy*, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vi) Give details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.

8. Recovery of free status

Member Countries applying for recognition of recovery of free status for a *zone* where *vaccination* is practised should comply with the provisions of Article 8.8.7. and points 1 e), f), g) and 2, 3 and 4 of Article 8.8.3. of the *Terrestrial Code* and provide detailed information as specified in Sections 3, 5 and 6-1-7 (inclusive) of this questionnaire.

Article 1.11.5.

Application for endorsement by WOAH of an official control programme for foot and mouth disease

The following information should be provided by WOAH Member Countries to support applications for endorsement by WOAH of an *official control programme* for foot and mouth disease (FMD) in accordance with Chapter 8.8. of the *Terrestrial Code*.

The dossier provided to WOAAH should address concisely all the topics under the headings provided in Sections 1 to 4 to describe the actual situation in the country and the procedures currently applied, explaining how these comply with the *Terrestrial Code*.

In Sections 3 f) to 3 i) describe concisely the work plan and timelines of the control programme for the next five years.

The terminology defined in the WOAAH *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.

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

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

The Delegate of the Member Country applying for endorsement of the *official control programme* should submit documentary evidence that the provisions of Article 8.8.39. have been properly implemented and supervised. In addition, the Delegate of the Member Country must submit the detailed national official control programme for FMD.

1. Introduction

- a) Geographical features (rivers, mountain ranges, etc.). Provide a general description of the country and *zones*, and where relevant of the region, including physical, geographical and other factors that are relevant to introduction of *infection* and spread of FMD virus, taking into account the countries or *zones* sharing common borders and other epidemiologic pathways for the potential introduction of *infection*. Provide maps identifying the features above. Specify whether the application includes any noncontiguous territories.
- b) If the endorsed plan is implemented in stages to specific parts of the country, the boundaries of the *zones* should be clearly defined, including the *protection zone* if applied. Provide a digitalised, geo-referenced map with a description of the geographical boundaries of the *zones*.
- c) Livestock demographics. Describe the composition of the livestock industry in the country and any *zones*. In particular, describe:
 - i) the susceptible animal *population* by species and types of production systems;
 - ii) the number of *herds* or *flocks*, etc. of each susceptible species;
 - iii) their geographical distribution;
 - iv) *herd* or *flock* density;
 - v) the degree of integration and role of producer organisations in the different production systems;
 - vi) any recent significant changes observed in the production (attach relevant documents if available). Provide tables and maps.
- d) *Wildlife* demographics. What susceptible *captive wild*, *wild* or *feral* species are present in the country and any *zones*? Provide estimates of *population* sizes, and geographic distribution and a summary description of their habitat. What are the measures in place to prevent contact between domestic and susceptible *wildlife* species?
- e) *Slaughterhouses/abattoirs*, markets and events associated with the congregation of susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of movement of susceptible domestic species for marketing within the country? How are the susceptible animals sourced, transported and handled during these transactions? Provide maps as appropriate.

2. Veterinary system

- a) Legislation. Provide a table (and when available a weblink) listing all relevant veterinary legislation, regulations and *Veterinary Authority* directives in relation to FMD and a brief description of the relevance of each. The

table should include, but not be limited to, the legislation on disease control measures and compensation systems.

- b) *Veterinary Services*. Describe how the *Veterinary Services* of the country comply with Chapters 1.1., 3.2. and 3.3. of the *Terrestrial Code*. Describe how the *Veterinary Services* supervise, control, enforce and monitor all FMD-related activities. Provide maps, figures and tables wherever possible.
- c) Provide information on any PVS evaluation conducted in the country and follow-up steps within the PVS Pathway and highlight the results relevant to FMD and the susceptible species.
- d) Provide a description of the involvement and the participation of industry, producers, farmers, including subsistence and small-scale producers, keepers, *veterinary paraprofessionals* including community animal health workers, and other relevant groups in FMD *surveillance* and control. Provide a description of the role and structure of the private veterinary sector, including the number of *veterinarians* and their distribution, in FMD *surveillance* and control. Include a description of continuing education and awareness programmes on FMD at all relevant levels.
- e) *Animal identification*, registration, traceability and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the traceability system, including methods of *animal identification* and *establishment* or *herd* or *flock* registration, applicable to all susceptible species. How are animal movements controlled in the country for all susceptible species? Provide evidence of the effectiveness of *animal identification* and movement controls and a table describing the number, species, origin and destination of the animals and their products moved within the country in the past 24 months. Provide information on pastoralism, transhumance and related paths of movement.

Describe the *risk management* strategy for uncontrolled movements of susceptible species (e.g. seasonal migration).

Describe the actions available under national legislation. Provide information on illegal movements detected in the past 24 months and the action taken.

3. Official control programme for FMD submitted for WOAHA endorsement

Submit a concise plan of the measures for the control and eventual *eradication* of FMD in the country, including:

- a) Epidemiology
 - i) Describe the FMD history in the country, with emphasis on recent years. Provide tables and maps showing the date of first detection, the number and location of *outbreaks* per year, the sources and routes of introduction of *infection*, the types and strains present, the susceptible species involved and the date of implementation of the control programme in the country.
 - ii) Describe the epidemiological situation of FMD in the country and the surrounding countries or *zones* highlighting the current knowledge and gaps. Provide maps of:
 - the geography of the country with the relevant information concerning FMD situation;
 - livestock density and movements and estimated FMD prevalence.

b) FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*, and Chapter 3.1.8. of the *Terrestrial Manual*. The following information should be included:

- i) What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what incentives are there for reporting and what penalties are involved for failure to report?
- ii) Describe how clinical *surveillance* is conducted, including which sectors of the livestock production system are included in clinical *surveillance*, such as *establishments*, markets, fairs, *slaughterhouses/abattoirs*, check points, etc. Provide details of follow-up actions taken on clinical suspicions.

- iii) Serological or virological *surveillance*. Explain whether or not serological or virological surveys are conducted and, if so, how frequently and for what purpose. Provide detailed information on the target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*. Are susceptible *wildlife* species included in serological or virological surveys? If not, explain the rationale.

Provide a summary table indicating, for at least the past 24 months, the number of suspected *cases*, the number of samples tested for FMD, species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details of follow-up actions taken on suspicious and positive results and on how these findings are interpreted and acted upon.

Provide criteria for selection of *populations* for targeted surveillance and numbers of animals examined and samples tested in diagnostic *laboratories*. Provide details of the methods selected and applied for monitoring the performance of the *surveillance* programme including indicators.

- iv) Provide information on circulating strains and the level of *risk* in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active *surveillance*, participatory epidemiology studies, *risk assessments*, etc.) and that the acquired knowledge assists in more effective implementation of control measures.
- v) Provide details of the oversight of *surveillance* programmes by the *Veterinary Services* including training programmes for personnel involved in clinical, serological and virological *surveillance*, and the approaches used to increase community involvement in FMD *surveillance* programmes.
- vi) Provide evidence that surveys are carried out to assess *vaccination* coverage and population immunity of the target *populations*, show laboratory evidence that the vaccine used is appropriate for circulating strains of virus, show analysis of *surveillance* data to assess the change in FMD prevalence over time in the target *populations*, assess the control measures (cost effectiveness, degree of implementation, impact). Provide information on outcomes of *outbreak* investigations including *outbreaks* that have occurred despite control measures, documented inspections showing compliance with biosecurity and hygiene requirements.

c) FMD diagnosis

Provide documentary evidence that the relevant provisions of Chapters 1.1.2., 1.1.3. and 3.1.8. of the *Terrestrial Manual* are applied. The following points should be addressed:

- i) Is FMD *laboratory* diagnosis carried out in the country? If so, provide an overview of the FMD-approved *laboratories* in the country, including the following:
- How the work is shared between different *laboratories*, logistics for shipment of samples, the follow-up procedures and the time frame for reporting results;
 - Details of test capability and the types of tests undertaken and their performance for their applied use (specificity and sensitivity per type of test). Provide details of the number of FMD tests performed in the past 24 months in national *laboratories* and in *laboratories* in other countries, if relevant;
 - Procedures for quality assurance and, if available, the official accreditation of *laboratories*. Give details of formal internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the *laboratory* system;
 - Provide details of performance in inter-*laboratory* validation tests (ring trials), including the most recent results and, if applicable, the corrective measures applied;
 - Provide details of the handling of live pathogenic agent, including a description of the biosecurity and biosafety measures applied;
 - Provide a table identifying the tests carried out by each of the *laboratories* where they are performed, the quality accreditation and biosecurity standards followed and the proficiency tests carried out.

- ii) If FMD *laboratory* diagnosis is not carried out in the country, provide the names of the *laboratories* in other countries providing the service as well as the arrangements in place, including logistics for shipment of samples and the time frame for reporting results.
- d) Strategies
- i) Provide a description of the legislation, organisation and implementation of the current FMD control programme. Outline the legislation applicable to the control programme and how its implementation is organised at different levels. Indicate if detailed operational guidelines exist and give a brief summary.
 - ii) Describe FMD control strategies in the country or any *zones*, including in terms of animal movement control, fate of infected and in-contact animals and *vaccination*. Strategies should be based on the assessment of the FMD situation in the *zones*, country and region.
 - iii) Provide information on what types of vaccines are used and which species are vaccinated. Provide information on the licensing process for the vaccines used. Describe the *vaccination* programme in the country and any *zones*, including records kept, and provide evidence to show its effectiveness, such as *vaccination* coverage, population immunity, etc. Provide details of the studies carried out to determine the *vaccination* coverage and the population immunity, including the study designs and the results.
 - iv) Describe how the *stamping-out policy* is implemented in the country or any *zones* and under which circumstances.
 - v) In the event of *outbreaks*, provide evidence of the impact of the control measures already implemented on the reduction in number of *outbreaks* and their distribution. If possible, provide information on primary and secondary *outbreaks*.
- e) FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country, including details of:

- i) Coordination with other countries. Describe any relevant factors in neighbouring countries and *zones* that should be taken into account (e.g. size, distance from the border to affected *herds* or *flocks* or animals). Describe coordination, collaboration and information-sharing activities with other countries and *zones* in the same region or ecosystem.

Are *protection zones* in place? If so, provide details of the measures that are applied (e.g. *vaccination*, intensified *surveillance*, density control of susceptible species), and provide a geo-referenced map of the *zones*.

- ii) Describe the measures implemented to effectively prevent the introduction of the pathogenic agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the spread of the pathogenic agent within the country or *zone*. Provide evidence that measures to reduce transmission of FMD are in place at markets, such as enhancing awareness of FMD transmission mechanisms and human behaviour that can interrupt transmission, and implementation of good *biosecurity*, hygiene and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved and marketed through the country or region).
- iii) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Is the feeding of swill to pigs regulated? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

- iv) Import control procedures

Provide information on countries, *zones* or *compartments* from which the country authorises the import of susceptible animals or their products into the country or any *zones*. Describe the criteria applied to approve such countries, *zones* or *compartments*, the controls applied to entry of such animals and products and subsequent internal movement. Describe the import measures (e.g. quarantine) and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and *international veterinary certificates* are required.

Describe any other procedures used for assessing the *risks* posed by import of susceptible animals or their products. Provide summary statistics on imports of susceptible animals and their products for at least the past 24 months, including temporary import and re-entry, specifying countries, *zones* or *compartments* of origin, species and the quantity or volume and eventual destination in the country. Provide information on whether or not *outbreaks* have been related to imports or transboundary movements of domestic animals.

- Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the *border posts*, and between *border posts*.
 - Provide a description of the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past 24 months, of the quantity disposed of and the disposal locations. What *biosecurity* is in place at waste disposal sites?
 - Cite the regulations and describe procedures, type and frequency of checks, and management of noncompliance at the points of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals;
 - genetic material (semen, oocytes and embryos);
 - animal products;
 - *veterinary medicinal products*;
 - other materials at risk of being contaminated with FMD virus, including bedding, litter and *feed*.
- v) Describe the actions available under legislation when an illegal import is detected. Provide information on illegal imports detected and the action taken.
- f) Work plan and timelines of the control programme for the next five years, including cessation of *vaccination*. Describe the progressive objectives including expected status to be achieved in the next five years: for *zones* (if applicable) and for the whole country.
- g) Performance indicators and timeline. The performance indicators should relate to the most important areas and steps where improvements in the programme are needed. These may include, but are not restricted to, strengthening *Veterinary Services*, legislation, reporting, availability and quality of vaccines, *animal identification* systems, *vaccination* coverage, population immunity, movement control, disease awareness, livestock owners' participatory perception on the effectiveness of the programme, etc. The progressive reduction of *outbreak* incidence towards elimination of FMD virus transmission in all susceptible livestock in at least one *zone* of the country should also be measured and monitored.
- h) Assessment of the evolution of the *official control programme* since the first date of implementation. This should include documented evidence demonstrating that the control programme has been implemented and that the first results are favourable. Measurable evidence of success such as the performance indicators should include, but not be limited to, *vaccination* data, decreased prevalence, successfully implemented import measures, control of animal movements and finally decrease or elimination of FMD *outbreaks* in the whole country or selected *zones* as described in the programme. Where relevant, the transition to the use of vaccines, which are fully compliant with the *Terrestrial Manual* in order to enable demonstration of no evidence of FMD virus transmission, should be included in the timeline. This should include documented evidence of the effective implementation of Sections 3 d) and 3 e) above.
- i) Describe the funding for the control programme and annual budgets for its duration.
4. Control measures and emergency response
- a) List any written guidelines, including contingency plans, available to the *Veterinary Services* for dealing with

suspected or confirmed *outbreaks* of FMD. The contingency plan should be attached as an annex in one of the WOAHA official languages. If not available, provide a brief summary of what is covered. Provide information on any simulation exercise for FMD that was conducted in the country in the last five years.

- b) In the event of a suspected or confirmed FMD *outbreak*:
- i) Are quarantine measures imposed on *establishments* with suspected *cases*, pending final diagnosis? What other procedures are followed regarding suspected *cases* (e.g. livestock standstills)?
 - ii) Indicate the sampling, dispatch and testing procedures that would be used to identify and confirm presence of the pathogenic agent;
 - iii) Describe the actions that would be taken to control the disease situation in and around the *establishments* where the *outbreak* is confirmed;
 - iv) Describe in detail the control or *eradication* procedures (e.g. forward and backward tracing, *disinfection* of *establishments*, *vehicles* and equipment, including verification methods, *vaccination* including *vaccination* delivery and cold chain, *stamping-out policy*, movement control, control of *wildlife*, pastured livestock and livestock as pets, methods of disposal of carcasses and other contaminated products or materials, decontamination, campaigns to promote awareness of farmers) that would be taken. In the case of emergency *vaccination*, indicate the source and type of vaccine and provide details of any vaccine supply scheme and stocks;
 - v) Describe the criteria and procedures that would be used to confirm that an *outbreak* has been successfully controlled or eradicated, including restocking strategies, use of sentinel animals, serological *surveillance* programmes, etc.;
 - vi) Provide details of any compensation that would be made available to owners, farmers, etc. when animals are slaughtered for disease control or *eradication* purposes and the prescribed timetable for payments;
 - vii) Describe how control efforts, including *vaccination* and *biosecurity*, would target critical risk control points.
-

CHAPTER 8.16.

INFECTION WITH RIFT VALLEY FEVER VIRUS

[...]

Article 8.16.8.

Recommendations for importation of semen and *in vivo* derived embryos of susceptible animals from countries or zones infected with RVFV

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 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; or
 - d) were subjected to a test for the detection of the agent with negative result on the day of collection.

[...]

CHAPTER 8.18.

INFECTION WITH *TRICHINELLA* SPP.

Article 8.18.1.

General provisions

Trichinellosis is a widely distributed zoonosis caused by eating raw or undercooked *meat* from *Trichinella* infected food-producing animals or *wildlife*. Given that clinical signs of trichinellosis are not generally recognised in animals, the importance of trichinellosis lies exclusively in the *risk* posed to humans and costs of control in *slaughter* populations.

~~The~~ While the adult parasite and the larval forms live in the small intestine, and the L1 larval stage also lives in the muscles (respectively) of many mammalian, avian and reptile host species. Within the genus *Trichinella*, twelve genotypes have been identified, nine of which have been designated as species. There is geographical variation amongst the genotypes.

Prevention of *infection* in susceptible species of domestic animals intended for human consumption relies on the prevention of exposure of those animals to the *meat* and *meat products* of *Trichinella* infected animals. This includes consumption of food waste of domestic animal origin, rodents and *wildlife*.

Meat and *meat products* derived from *wildlife* should be considered a potential source of *infection* for humans. Therefore, untested *meat* and *meat products* of *wildlife* may pose a public health *risk*.

For the purposes of the *Terrestrial Code*, *infection* with *Trichinella* spp. is defined as an *infection* of suids or equids by parasites of the genus *Trichinella*.

This chapter provides recommendations for on-farm prevention of *Trichinella infection* in domestic pigs (*Sus scrofa domestica*), and safe trade of *meat* and *meat products* derived from suids and equids. This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005) and Guidelines for the control of *Trichinella* spp. in meat of Suidae (CAC/GL 86-2015).

~~Methods for the detection of *Trichinella infection* in pigs and other animal species include direct demonstration of *Trichinella* larvae in muscle samples. Demonstration of the presence of *Trichinella* specific circulating antibodies using a validated serological test may be useful for epidemiological purposes.~~

When authorizing the import or transit of the *commodities* covered in this chapter, with the exception of those listed in Article 8.18.2., *Veterinary Authorities* should apply the recommendations in this chapter.

Standards for ~~diagnostic tests~~ diagnosis and information on the epidemiology are described in the *Terrestrial Manual*.

[...]

CHAPTER 8.X.

INFECTION WITH *COXIELLA BURNETII* (Q FEVER)

Article 8.X.1.

General provisions

Various animal species and humans can be affected by Q fever, but many of them, including *wild and feral animals* are considered not to, do not play an epidemiologically significant role in the epidemiology of the disease. For the purposes of the *Terrestrial Code*, Q fever is defined as an *infection* of domestic and *captive wild* ruminants, dogs, and cats (hereafter 'susceptible animal') with *Coxiella burnetii*.

The following defines the occurrence of *infection* with *C. burnetii*:

- 1) *C. burnetii* has been isolated and identified as such in a sample from a susceptible animal; or
- 2) nucleic acid specific to *C. burnetii* has been detected in a sample from a susceptible animal showing clinical signs or pathological lesions consistent with infection with *C. burnetii*, or that is epidemiologically linked to a confirmed or suspected case; or
- 3) antibodies specific to *C. burnetii*, that are not the consequence of *vaccination*, have been detected in a sample from a susceptible animal showing clinical signs or pathological lesions consistent with infection with *C. burnetii*, or that is epidemiologically linked to a confirmed or suspected case.

Standards for diagnosis, diagnostic tests and vaccines, as well as information on the epidemiology are described in the *Terrestrial Manual*.

CHAPTER 8.Z.

INFECTION WITH *TRYPANOSOMA EVANSI* (SURRA)

Article 8.Z.1.

General provisions

Surra is a disease caused by *Trypanosoma evansi* of the subgenus *Trypanozoon* and may manifest in acute, chronic or clinically inapparent forms.

T. evansi is a blood and tissue parasite that occasionally invades the nervous system. It can infect a large range of domestic and *wild* mammals. The disease has a significant socio-economic impact on animal production, especially in ~~horses, camels, donkeys, buffaloes and cattle~~ equids, camelids and bovines; it can also affect goats, sheep, deer, pigs, rodents and elephants. It has a serious clinical impact in dogs, cats and non-human primates, and may occasionally infect humans.

T. evansi is mainly transmitted mechanically by several biting flies ~~(e.g. such as tabanids and Stomoxys spp.)~~, but can also be transmitted vertically, iatrogenically and possibly venereally. Additionally, it is transmitted perorally (especially to carnivores) and it can be transmitted biologically by the bite of vampire bats (*Desmodus* spp.), which may act as host, reservoir or vector.

Co-infection of *T. evansi* with other *Trypanosoma* species (including *T. vivax*, *T. brucei*, *T. congolense*, *T. simiae*, *T. equiperdum* and *T. cruzi*) may occur although this may not always be detected using routine testing methods.

For the purposes of the *Terrestrial Code*, surra is defined as an *infection* of susceptible animals with *T. evansi*.

For the purposes of this chapter, 'susceptible animals' means domestic and *wild* animals from the following families: Equidae, Camelidae, Bovidae, Suidae, Canidae, and Felidae; the orders Rodentia and Lagomorpha; and non-human primates.

The following defines the occurrence of *Infection* with *T. evansi*:

- 1) trypanosomes with *Trypanozoon* morphology have been observed in a sample from a susceptible animal and identified as *T. evansi* by the detection of nucleic acid; or
- 2) trypanosomes with *Trypanozoon* morphology have been observed in a sample from a susceptible animal either epidemiologically linked to a confirmed *case* of *infection* with *T. evansi* or ~~with relevant epidemiological context (including clinical signs, endemicity, origin of the host, absence of other *Trypanosoma* spp., absence of tsetse transmission)~~ to support surra suspected of previous association or contact with *T. evansi*; or
- 3) nucleic acid specific to *Trypanozoon* has been detected in a sample from a susceptible animal either epidemiologically linked to a confirmed *case* of *infection* with *T. evansi* or ~~with relevant epidemiological context (including clinical signs, endemicity, origin of the host, absence of other *Trypanosoma* spp., absence of tsetse transmission)~~ to support surra suspected of previous association or contact with *T. evansi*; or
- 4) antibodies specific to *Trypanosoma* spp. have been detected in a sample from a susceptible animal epidemiologically linked to a confirmed *case* of *infection* with *T. evansi* ~~or with relevant epidemiological context (including clinical signs, endemicity, origin of the host, absence of other *Trypanosoma* spp., absence of tsetse transmission)~~ to support surra.

For the purposes of the *Terrestrial Code*, the *incubation period* of *infection* with *T. evansi* shall be 90 days in all species of susceptible animals.

For the purposes of this chapter, a temporary importation of horses 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.

Standards for ~~diagnostic tests~~ diagnosis and information on the epidemiology are described in the *Terrestrial Manual*.

Article 8.Z.2.

Safe commodities

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

- 1) pasteurised *milk* and pasteurised *milk products*;
- 2) hair, wool and fibre;
- 3) gelatine and collagen;
- 4) horns, hooves and claws;
- 5) meat from animals that have been slaughtered in a slaughterhouse/abattoir and have been subjected to ante- and post-mortem inspections with favourable results;
- 6) meat products;
- 7) hides and skins (except raw);
- 8) embryos or oocytes collected, processed and stored in accordance with Chapters 4.8. to 4.10.

Article 8.Z.3.

Country or zone free from surra

A country or *zone* may be considered free from surra when:

- 1) the *infection* is notifiable in the entire country for at least the past two years;
- 2) measures to prevent the introduction of *infection* have been in place; in particular, the importations or movements of susceptible animals and other *commodities* into the country or *zone* have been carried out in accordance with this chapter and other relevant chapters of the *Terrestrial Code*;
- 3) and either:
 - a) the country or *zone* is historically free as described in point 2 b) of Article 1.4.6.; or
 - b) for at least the past two years, *surveillance* in accordance with Articles 8.Z.126. to 8.Z.159. has been in place in the entire country or *zone* and there has been no *case* in the country or *zone*.

In order to maintain its status, a country or *zone* free from ~~infection with *T. evansi*~~ surra should:

- 1) comply with points 1 and 2 above;
- 2) if adjacent to an infected country or zone, should include an area along the border, in which *surveillance* is conducted in accordance with Articles 8.Z.12. to 8.Z.15.

Article 8.Z.4.

Compartment free from surra

The establishment of a *compartment* free from surra should follow the provisions laid down in this chapter and in Chapters 4.4. and 4.5.

Susceptible animals in the free *compartment* should be protected against the *vectors* by the application of an effective *biosecurity* management system.

Susceptible animals in the free *compartment* should be protected against both iatrogenic and venereal transmission.

Article 8.Z.5.

Recovery of free status

Should a *case of infection* with *T. evansi* occur in a previously free country or *zone*, its status may be recovered after the following:

- 1) *cases* have been isolated and then immediately treated, killed or slaughtered and appropriately disposed of;
- 2) animals in contact with *cases* have been put immediately under protection from *vector* contact and tested;
- 3) appropriate *biosecurity* is in place, including *vector* control or protection from *vector* contacts in the affected area in accordance with Articles 1.5.2. and 1.5.3.;
- 4) *surveillance* in accordance with Articles 8.Z.12. to 8.Z.15. has been carried out with negative results;
- 5) for six consecutive months, either:
 - a) after the last *case* was killed or slaughtered, the animals in contact have undergone monthly repeated serological antibody detection and agent identification (microscope and molecular) tests with negative results in all tests; or
 - b) if appropriate trypanocide treatment is applied to the *cases*, after the last *case* was killed, slaughtered or treated, whichever occurred last, both treated and in contact animals have undergone monthly repeated agent identification tests (microscope and molecular) with negative results, and serological antibody detection tests with decreasing titres.

If points 1 to 5 are not applied, Article 8.Z.3. applies.

Article 8.Z.6.

Recommendations for importation of equids, camelids, bovids and suids ~~susceptible animals (except dogs and cats)~~ from countries, zones or compartments free from *surra*

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

- 1) showed no clinical sign of ~~*infection with T. evansi surra*~~ on the day of shipment;
- 2) were kept since birth or at least ~~six months~~ 90 days prior to shipment in a free country, *zone* or *compartment*;
- 3) did not transit through an *infected zone* during transportation to the *place of shipment* or were protected from *vectors* or any source of *T. evansi* by the application of effective *biosecurity* during transportation to the place of shipment.

Article 8.Z.7.

Recommendations for importation of equids, bovids and suids ~~susceptible animals (except dogs and cats)~~ from countries or zones infected with *T. evansi*

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

- 1) showed no clinical sign of ~~*infection with T. evansi surra*~~ during isolation and on the day of shipment;
- 2) were isolated in a *quarantine station* for at least ~~90~~ 45 days prior to shipment, and all animals from the same ~~group flock or herd~~ were subjected to antibody detection tests ~~serological and agent identification (microscope and molecular)~~ on samples taken on two occasions, with an interval of 30 days, immediately prior to entering quarantine and within 15 days before being released from quarantine, with negative results.

Article 8.Z.8.

Recommendations for importation of susceptible animals from countries or zones infected with *T. evansi* for ~~immediate direct~~ slaughter

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

- 1) showed no clinical sign of ~~infection with *T. evansi* surra~~ on the day of the shipment;
- 2) a) were kept for the six months prior to shipment in an establishment in which surveillance in accordance with Articles 8.Z.12., 8.Z.13. and 8.Z.14. demonstrates that no case had occurred during that period; or
b) were negative in an agent identification (microscope and molecular) and an antibody detection serological-test within 15 days prior to shipment;
- ~~3) were kept for the six months prior to shipment in an establishment in which surveillance in accordance with Articles 8.Z.12., 8.Z.13. and 8.Z.14. demonstrates that no case had occurred during that period;~~
- 4) were permanently identified and transported under the supervision of the *Veterinary Services* in a *vector-protected vehicle*, which underwent *disinfection* and *disinsection* before *loading*, directly from the *establishment* of origin to the *place of shipment* without coming into contact with other susceptible animals.

Article 8.Z.9.

Recommendations for the temporary importation of horses

~~When importing on a temporary basis horses that do~~ If the importation of horses on a temporary basis does not comply with the recommendations in Article 8.Z.6. or Article 8.Z.7., *Veterinary Authorities* of *importing countries* should:

- 1) require:
 - a) the equids 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 equids horses:
 - i) showed no clinical sign of surra on the day of shipment;
 - ii) belong to a high health status subpopulation or were negative in an antibody detection test within 15 days prior to departure from the country of origin;
 - ii) ~~showed no clinical sign of infection with *T. evansi* on the days of shipments;~~
 - c) the duration of the temporary importation period and the destination after this period, and the conditions required to leave the country or *zone* be defined;
- 2) ensure that during their stay in the country or *zone*:
 - a) measures are taken to protect the horses from *vectors* or any source of *T. evansi* by the application of effective *biosecurity*;
 - b) the equids horses ~~we~~ are not subjected to any practice that may represent a risk of iatrogenic transmission of ~~infection with *T. evansi* surra~~;
 - c) the equids horses are kept and transported individually in stalls and *vehicles/vessels* which are subsequently cleaned and *disinsected* before re-use.

Article 8.Z.10.

Recommendations for importation of semen of susceptible animals from countries, zones or compartments free from surra

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

- 1) the donor males:
 - a) showed no clinical sign of ~~infection with *T. evansi* surra~~ on the day of semen collection;
 - b) have been kept for at least ~~six months~~ 90 days prior to semen collection in a free country, *zone* or *compartment*; and
- 2) the semen was collected, processed and stored in a *semen collection centre* in accordance with Chapters 4.6. and 4.7.

Article 8.Z.11.

Recommendations for importation of semen of susceptible animals from countries or zones infected with *T. evansi*

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

- 1) the donor males:
 - a) have been kept for at least ~~six months~~ 90 days prior to semen collection in an *establishment* in which *surveillance* in accordance with Articles 8.Z.12., 8.Z.13. and 8.Z.14. demonstrates that no *case* had occurred during that period;
 - b) showed no clinical sign of ~~infection with *T. evansi* surra on the day of semen collection~~ during that period;
 - c) were ~~negative in an agent identification (microscopic) and subjected to an serological antibody detection test on a blood sample taken on two occasions, with an interval of 30 days, with negative results collected on the day of collection of the semen;~~
- 2) ~~molecular examination of semen for *T. evansi* was negative;~~
- 3) the semen was collected, processed and stored in a *semen collection centre* in accordance with Chapters 4.6. and 4.7.

Article 8.Z.11bis.

Recommendations for importation of fresh meat from susceptible animals from countries or zones infected with *T. evansi*

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

- 1) the entire consignment of *meat* comes from:
 - a) susceptible animals that showed no clinical signs of *surra* within 24 hours before *slaughter*;
 - b) 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;
 - c) carcasses that were submitted to maturation for a minimum period of 48 hours following *slaughter*;
- 2) the necessary precautions were taken to avoid contact of the *meat* with any potential source of *T. evansi*;

Article 8.Z.12.

Introduction to surveillance

Articles 8.Z.12. to 8.Z.14. define the principles and provide guidance on *surveillance* for ~~infection with *T. evansi* surra~~, complementary to Chapter 1.4. and Chapter 1.5.

The purpose of *surveillance* could be the demonstration of the absence of *infection*, the early detection of *cases*, or the measurement and monitoring of the *prevalence* and distribution of the *infection* in a country, *zone* or *compartment*.

An important component of the epidemiology of surra is the capability of its *vectors*, which provides a measure of disease risk that incorporates *vector* competence, abundance, biting rates, survival rates, host affinity and in the case of biological *vectors*, the extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context. Therefore, *surveillance* for ~~infection with *T. evansi* surra~~ should focus on transmission of *T. evansi* in susceptible animals.

The impact and epidemiology of surra widely differs between different regions of the world and therefore, it is not appropriate to provide specific recommendations for all situations. Member Countries should provide scientific data explaining the epidemiology of the disease in the country or *zone* concerned, such as host susceptibility and co-infections with other *Trypanosoma* spp., and adapt the *surveillance* strategies for defining their status to the local conditions. There is considerable latitude available to Member Countries to justify their status at an acceptable level of confidence.

~~Consideration should be given to risk factors such as susceptibility, co-infections with other *Trypanosoma* spp. and climate change.~~

Although *surveillance* in susceptible *wild animals* presents challenges that may differ significantly from those in domestic *animals*, *wildlife* should be considered in the *surveillance* system as they are included in the ~~case~~ definition of the occurrence and can serve as reservoirs of *infection* and as indicators of *risk* to domestic *animals*.

Article 8.Z.13.

General conditions and methods of surveillance

The *surveillance* system for ~~infection with *T. evansi* surra~~ should be in accordance with Chapter 1.4. and be under the responsibility of the *Veterinary Authority*.

- 1) It should include:
 - a) formal and ongoing system for detecting and investigating ~~outbreaks of disease~~;
 - ~~b) each country should establish a surveillance system or integrate activities into already established animal health surveillance programmes for purposes of sustainability;~~
 - eb) the collection and transport of samples from suspected *cases* to a *laboratory* for diagnosis or a procedure for the rapid diagnosis in the field;
 - ec) appropriate tools, for collection, recording, managing and analysis of data; reporting and dissemination for decision making.
- 2) In addition, it should, at least:
 - a) in a free country or *zone*, have an *early warning system* capable of detecting *T. evansi* which obliges animal owners and keepers and other stakeholders who have regular contact with susceptible animals, as well as *veterinarians* or *veterinary paraprofessionals*, to report promptly any suspicion of ~~infection with *T. evansi* surra~~ to the *Veterinary Authority Services*;
 - b) include representative or risk-based serological or parasitological surveys appropriate to the status of the country, *zone* or *compartment*.

An effective *surveillance* system will periodically identify suspected *cases* that require follow-up and investigation to confirm or exclude whether the cause of the condition is *T. evansi*. The rate at which such suspected *cases* are likely to occur will differ between epidemiological situations and cannot therefore be reliably predicted. All suspected *cases* should be investigated immediately, and samples should be taken and submitted to a *laboratory*.

Article 8.Z.14.

Surveillance strategies

The target *population* should include domestic and *wild* susceptible animals of epidemiological significance within the country, *zone* or *compartment*. Active and passive *surveillance* for surra should be ongoing as epidemiologically appropriate.

Surveillance should be composed of representative or risk-based approaches using parasitological, serological, clinical and entomological methods appropriate for the status of the country, *zone* or *compartment*.

In a free country, *zone* or *compartment*, it is appropriate to focus *surveillance* in an area adjacent to an infected country, *zone* or *compartment*, considering relevant ecological or geographical features likely to interrupt the transmission of surra.

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of *infection* with *T. evansi* in accordance with Chapter 1.4. and Chapter 1.5., and with the prevailing epidemiological situation.

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

For random surveys, the sample size selected for testing should be large enough to detect evidence of *infection* if it were to occur at a predetermined minimum expected *prevalence*. The sample size and expected *prevalence* determine the level of confidence in the results of the survey. The Member Country should justify the choice of the minimum expected *prevalence* and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *infection* history and the different *Trypanosoma* species and other Kinetoplastid species (*T. vivax*, *T. congolense*, *T. brucei*, *T. equiperdum*, *T. cruzi* and *Leishmania* spp.) present in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of cross reactions. There should be an effective procedure for following up cross reactions to determine, with a high level of confidence, whether they are indicative of *infection* with *T. evansi* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

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

The results of random or targeted surveys are important in providing reliable evidence that no *infection* with *T. evansi* is present in a country, *zone* or *compartment*. It is, therefore, essential that the survey is thoroughly documented. It is critical to consider the movement history of the animals being sampled when interpreting the results.

An active programme of *surveillance* of susceptible populations to detect evidence of ~~*infection with T. evansi surra*~~ is essential to establish the *animal health status* of a country, *zone* or *compartment*.

1. Clinical surveillance

Clinical *surveillance* aims to detect clinical signs of ~~*infection with T. evansi surra*~~ in susceptible animals, particularly during a newly introduced *infection*. However, neither clinical nor post-mortem signs of ~~*infection with T. evansi surra*~~ are pathognomonic. Therefore, suspected *cases* of *infection* with *T. evansi* detected by clinical *surveillance* should always be confirmed by direct or indirect laboratory tests that confirm the presence of *T. evansi*.

2. Parasitological surveillance

Parasitological examination (or agent identification) can be conducted to:

- a) detect active *infection*;
- b) confirm clinically suspected *cases*;
- c) identify parasites at the subgenus level;
- d) confirm active *infection* after positive serological results.

3. Molecular techniques

Molecular techniques can be conducted to:

- a) increase the sensitivity of the detection of active *infections*;
- b) confirm clinically suspected *cases*;
- c) identify parasites at the subgenus level (Trypanozoon), or at the species level (*T. evansi*); (in the host and/or the *vector*);
- d) confirm active *infection* after positive serological results.

4. Serological surveillance

- a) Serological testing of susceptible animals is one of the most effective methods for detecting exposure to *T. evansi*. The host species tested should reflect the epidemiology of the disease. Management variables that may influence likelihood of *infection*, such as animal treatment, should be considered.
- b) Owing to cross reactions with other Kinetoplastid species, co-infections with these pathogenic agents should be considered when interpreting the results of the serological *surveillance* system.
- c) Serological techniques can be ~~conducted~~ used to:
 - i) demonstrate individual or population freedom;
 - ii) detect subclinical or latent *infection* by *T. evansi*;
 - iii) determine by seroprevalence the magnitude of *infection* by *T. evansi* in the host population.
- d) Positive test results can have different possible causes:
 - i) current *infection*;
 - ii) antibodies from previous *infection* (after effective treatment or self-cure);
 - iii) maternal antibodies;
 - iv) cross reactions with other Kinetoplastid species.

5. Sentinel animals

Sentinel *surveillance* may provide evidence of freedom from *infection* or provide data on *prevalence* and *incidence* as well as the distribution of the *infection*. Sentinel *surveillance* may consist of:

- a) the identification and regular testing of one or more of sentinel animal units of known health or immune status in a specified geographical location to detect the occurrence of *infection* with *T. evansi*;
- b) the investigation of clinical suspect *cases* targeting highly susceptible animals such as dogs (hunting dogs and dogs living around *slaughterhouses/abattoirs*), camels, donkeys or horses.

6. Vector surveillance

This point should be read in conjunction with Chapter 1.5.

For the purposes of this chapter, *vector surveillance* aims at determining different levels of *risk* by identifying the presence and abundance of various *vector* species (biting flies and vampire bats) in an area.

The most effective way of gathering *vector surveillance* data should consider the biology and behavioural characteristics of the local *vector* species and include traps, net, sticky targets or other collection tools. The choice of the number and type of collecting tools to be used and the frequency of their use should be made by considering the size and ecological characteristics of the area to be surveyed. In the *surveillance* of *wildlife* species, molecular techniques may be applied to *vectors*.

When sentinel animals are used, *vector surveillance* should be conducted at the same locations.

Article 8.2.15.

Additional surveillance procedures for recovery of free status

In addition to the general conditions described in this chapter, a Member Country seeking recovery of country or *zone* free status, including a *containment zone* established in accordance with Article 4.4.7., should show evidence of an active *surveillance* programme to demonstrate absence of *infection* with *T. evansi*.

Populations under this *surveillance* programme should include:

- 1) *establishments* in the proximity of the *outbreak*;
 - 2) *establishments* epidemiologically linked to the *outbreak*;
 - 3) *animals* moved from previously affected *establishments*;
 - 4) *animals* used to re-populate previously affected *establishments*.
-

CHAPTER 13.2.

INFECTION WITH PATHOGENIC RABBIT LAGOVIRUSES (RABBIT HAEMORRHAGIC DISEASE)

Article 13.2.1.

General provisions

For the purposes of the Terrestrial Code, rabbit haemorrhagic disease (RHD) is defined as an infection of leporids with Rabbit haemorrhagic disease virus type 1 (RHDV) and/or Rabbit haemorrhagic disease virus type 2 (RHDV2) (hereafter 'pathogenic rabbit lagoviruses').

The following defines the occurrence of infection with pathogenic rabbit lagoviruses:

- 1) antigen or nucleic acid specific to pathogenic rabbit lagoviruses has been detected in a sample from a leporid showing clinical signs or pathological lesions consistent with infection with pathogenic rabbit lagoviruses, or epidemiologically linked to a confirmed or suspected case; or
- 2) antibodies specific to pathogenic rabbit lagoviruses, which are not the consequence of vaccination, have been detected in a sample from a leporid showing clinical signs or pathological lesions consistent with infection with pathogenic rabbit lagoviruses, or epidemiologically linked to a confirmed or suspected case.

For the purposes of the Terrestrial Code, the *infective period* for rabbit haemorrhagic disease (RHD) shall be 60 days.

Standards for ~~diagnostic tests~~ diagnosis and vaccines, as well as information on the epidemiology, are described in the Terrestrial Manual.

Article 13.2.2.

Country free from RHD free country

A country may be considered free from RHD when it has been ~~demonstrated~~ shown that no case has occurred ~~the disease has not been present~~ for at least the past 12 months ~~one year~~, that no *vaccination* has been carried out in the ~~past~~ previous 12 months, and that virological or serological surveillance surveys in both domestic and ~~wild rabbits~~ leporids have confirmed the absence of the infection ~~disease~~.

This period may be reduced to six months after the last case has been ~~destroyed~~ eliminated and *disinfection* procedures have been completed in countries adopting a *stamping-out policy*, and where the serological surveillance surveys confirmed that no case ~~the disease had not occurred~~ in the ~~wild rabbits~~ leporids.

[...]

CHAPTER 15.1.
INFECTION WITH AFRICAN SWINE FEVER VIRUS

[...]

Article 15.1.2.

Safe commodities

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

- 1) heat-treated meat products in a hermetically sealed container with a F_0 value of 3 or above;
- 2) gelatine;
- 3) extruded dry pet food;
- 4) protein meal.

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

[...]

CHAPTER ~~X~~16. Z.

INFECTION WITH CAMELPOX VIRUS

Article ~~X~~16.Z.1.

General provisions

For the purposes of the *Terrestrial Code*, infection with eCamelpox virus is defined as an infection of dromedary and bactrian camels (hereafter 'susceptible animals') with eCamelpox virus of genus Orthopoxvirus, family Poxviridae.

The following defines the occurrence of infection with eCamelpox virus:

- 1) eCamelpox virus has been isolated and identified as such in a sample from a susceptible animal; or
- 2) characteristic eOrthopox virions have been observed in a sample from a susceptible animal showing clinical signs ~~suggestive of~~ consistent with infection with eCamelpox virus or epidemiologically linked to a confirmed or suspected case; or
- 3) antigen or nucleic acid specific to eCamelpox virus has been detected in a sample from a susceptible animal showing clinical signs ~~suggestive of~~ consistent with infection with eCamelpox virus, or epidemiologically linked to a confirmed or suspected case; or
- 4) antibodies specific to eCamelpox virus, that are not the consequence of *vaccination*, have been detected in a sample from a susceptible animal showing clinical signs ~~suggestive of~~ consistent with infection with eCamelpox virus, or epidemiologically linked to a confirmed or suspected case.

Standards for ~~diagnostic tests~~ diagnosis and vaccines, as well as information on the epidemiology, are described in the *Terrestrial Manual*.

TERMINOLOGY: USE OF THE TERMS 'COMPETENT AUTHORITY', 'VETERINARY AUTHORITY' AND 'VETERINARY SERVICES'

GLOSSARY

[...]

ANIMAL FOR SLAUGHTER

means an *animal* intended for *slaughter* within a short time, under the control of the relevant ~~Veterinary~~ Competent Authority.

[...]

SLAUGHTERHOUSE/ABATTOIR

means premises, including facilities for moving or lairaging *animals*, used for the *slaughter* of *animals* to produce animal products and approved by the ~~Veterinary Services or other relevant~~ Competent Authority.

Article 1.7.1.

[...]

6. AHS prevention

c) Import control procedures

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central Veterinary Services~~ Veterinary Authority. Describe the communication systems between the ~~central authorities~~ Veterinary Authority and the *border posts*, and between *border posts*.

[...]

Article 1.7.2.

[...]

6. AHS prevention

c) Import control procedures

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central Veterinary Services~~ Veterinary Authority. Describe the communication systems between the ~~central authorities~~ Veterinary Authority and the *border posts*, and between *border posts*.

[...]

Article 1.9.1.

[...]

6. CSF prevention

d) Import control procedures

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central Veterinary Services~~ Veterinary Authority. Describe the communication systems between the ~~central authorities~~ Veterinary Authority and the *border posts*, and between *border posts*.

[...]

Article 1.10.1.

[...]

6. CBPP prevention

c) Import control procedures

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central Veterinary Services~~ Veterinary Authority. Describe the communication systems between the ~~central authorities~~ Veterinary Authority and the *border posts*, and between *border posts*.

[...]

Article 1.10.2.

[...]

6. CBPP prevention

c) Import control procedures

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central Veterinary Services~~ Veterinary Authority. Describe the communication systems between the ~~central authorities~~ Veterinary Authority and the *border posts*, and between *border posts*.

[...]

Article 1.10.3.

[...]

3. Official control programme for CBPP submitted for WOAHA endorsement

e) CBPP prevention

- iii) Import control procedures

- Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central Veterinary Services~~ Veterinary Authority. Describe the communication systems between the ~~central authorities~~ Veterinary Authority and the *border posts*, and between *border posts*.

[...]

Article 1.11.1.

[...]

6. FMD prevention

d) Import control procedures

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central Veterinary Services~~ Veterinary Authority. Describe the communication systems between the ~~central authorities~~ Veterinary Authority and the *border posts*, and between *border posts*.

[...]

Article 1.11.2.

[...]

6. FMD prevention

d) Import control procedures

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central Veterinary Services~~ Veterinary Authority. Describe the communication systems between the ~~central authorities~~ Veterinary Authority and the *border posts*, and between *border posts*.

[...]

Article 1.11.3.

[...]

6. FMD prevention

d) Import control procedures

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central Veterinary Services~~ Veterinary Authority. Describe the communication systems between the ~~central authorities~~ Veterinary Authority and the *border posts*, and between *border posts*.

[...]

Article 1.11.4.

[...]

6. FMD prevention

d) Import control procedures

- i) Provide a map with the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central Veterinary Services~~ Veterinary Authority. Describe the communication systems between the ~~central authorities~~ Veterinary Authority and the *border posts*, and between *border posts*.

[...]

Article 1.11.5.

[...]

3. Official control programme for FMD submitted for WOAH endorsement

e) FMD prevention

iv) Import control procedures

- Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central Veterinary Services~~ Veterinary Authority. Describe the communication systems between the ~~central authorities~~ Veterinary Authority and the *border posts*, and between *border posts*.

[...]

Article 1.12.1.

[...]

6. PPR prevention

c) Import control procedures

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central Veterinary Services~~ Veterinary Authority. Describe the communication systems between the ~~central authorities~~ Veterinary Authority and the *border posts*, and between *border posts*.

[...]

Article 1.12.2.

[...]

6. PPR prevention

c) Import control procedures

- i) Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its

accountability to the ~~central Veterinary Services~~ Veterinary Authority. Describe the communication systems between the ~~central authorities~~ Veterinary Authority and the *border posts*, and between *border posts*.

[...]

Article 1.12.3.

[...]

3. Official control programme for PPR submitted for WOAHA endorsement

e) PPR prevention

iii) Import control procedures

- Provide a map showing the number and location of all ports, airports and land border crossings. Describe the management structure, staffing levels and resources of the service responsible for import controls and its accountability to the ~~central Veterinary Services~~ Veterinary Authority. Describe the communication systems between the ~~central authorities~~ Veterinary Authority and the *border posts*, and between *border posts*.

[...]

Article 3.2.3.

[...]

- 8) formal external coordination mechanisms with clearly described procedures or agreements for activities (including preparedness and response mechanisms) between the *Veterinary Authority*, other Competent Authorities, other relevant governmental authorities and stakeholders, incorporating a One Health approach;

[...]

Article 4.1.1.

[...]

Prerequisites for developing such programmes include:

- quality *Veterinary Services* including legislative framework, *laboratory* capacity and adequate and committed funding;
- appropriate education and training to secure *veterinarians* and *veterinary paraprofessionals*;
- close links with research institutions;
- effective awareness of, and active cooperation with, private stakeholders;
- public-private partnerships;
- cooperation between ~~Veterinary Authorities~~ the Veterinary Authority and other *Competent Authorities*;

– regional cooperation among *Veterinary Authorities* on transboundary animal diseases.

Article 4.13.2.

[...]

4) any need to transfer the ownership of *animals* to the ~~competent authority~~ Competent Authority;

[...]

Should the chosen option for the disposal of dead *animals* be applied near the border of a neighbouring country, the ~~competent authorities~~ relevant Competent Authority of that country should be consulted.

Article 4.19.1.

[...]

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~~ other Competent Authorities in close collaboration with the relevant stakeholders and other authorities, as appropriate.

[...]

Article 5.1.4.

[...]

3) In case of suspicion, on reasonable grounds, that an official certificate may be fraudulent, the *Veterinary Authorities* of the *importing country* and *exporting country* should conduct an investigation. Consideration should also be given to notifying any third country that may have been implicated. All associated consignments should be kept under official control, pending the outcome of the investigation. The *Veterinary Authorities* of all countries involved should fully cooperate with the investigation. If the certificate is found to be fraudulent, every effort should be made to identify those responsible so that appropriate action can be taken in accordance with the relevant legislation.

Article 5.6.4.

[...]

3) a list of airports in its territory which are provided with an area of direct transit, approved by the ~~relevant~~ *Veterinary Authority* and placed under its immediate control, where *animals* stay for a short time pending further transport to their final destination.

Article 6.3.3.

[...]

The CHPM does not provide inspection measures for specific *hazards*, which remain the responsibility of ~~national competent authorities~~ *Competent Authorities*. The animal and public health *risks* associated with livestock populations vary across regions and animal husbandry systems, and ante- and post-mortem inspection needs to be tailored to the individual country situation and its animal and public health objectives.

[...]

Article 6.3.6.

[...]

The ~~national competent authority(ies)~~ *Competent Authority(ies)* should provide an appropriate institutional environment to allow *Veterinary Services* to develop the necessary policies and standards.

[...]

Article 7.4.4.

[...]

1. Health and customs requirements

[...]

Contact the ~~Veterinary Authorities~~ *in the country of origin regarding veterinary certification.*

[...]

Article 7.7.6.

[...]

DPM activities performed by *Veterinary Services* or ~~other relevant~~ *Competent Authorities* should be integrated, to the greatest extent possible, with the activities of all other responsible agencies.

[...]

Article 8.3.15.

[...]

2) The bluetongue *surveillance* programme should:

- a) in a free country or *zone* or seasonally free *zone*, have an *early warning system* which obliges farmers and workers, who have regular contact with domestic ruminants, as well as diagnosticians, to report promptly any suspicion of bluetongue to the ~~Veterinary Authority~~ Services.

[...]

Article 8.18.8.

[...]

2) The *surveillance* programme for the pathogenic agent should, at least:

- a) in a free country or *zone*, have an *early warning system* which obliges animal owners and keepers and other stakeholders who have regular contact with susceptible animals, as well as *veterinarians* or *veterinary paraprofessionals*, to report promptly any suspicion of *infection* with *T. brucei*, *T. congolense*, *T. simiae* and *T. vivax* to the ~~Veterinary Authority~~ Services.

[...]

Article 10.4.27.

[...]

2) The high pathogenicity avian influenza *surveillance* programme should include the following.

- a) An *early warning system* for reporting suspected *cases*, in accordance with Article 1.4.5. throughout the production, marketing and processing chain. Farmers and workers who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of avian influenza to the ~~Veterinary Authority~~ Services. All suspected *cases* of high pathogenicity avian influenza should be investigated immediately and samples should be ~~taken~~ collected and submitted to a *laboratory* for appropriate tests.

[...]

Article 10.4.29.

[...]

Passive *surveillance*, i.e. sampling of birds found dead, is an appropriate method of *surveillance* in *wild* birds because *infection* with high pathogenicity avian influenza can be associated with mortality in some species. Mortality events, or clusters of birds found dead should be reported to the ~~Local Veterinary Authorities~~ Veterinary Services and investigated, including through the collection and submission of samples to a *laboratory* for appropriate tests.

[...]

Article 12.2.8.

[...]

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

Article 12.7.8.

[...]

The *Veterinary Services* should implement programmes to raise awareness among *veterinarians*, horse breeders, owners, keepers, and riders who have day-to-day contact with equids, as well as *veterinary paraprofessionals* and diagnosticians, who should report promptly to them any suspicion of infection with *T. equi* and any suspicion of infection with *B. caballi* ~~to the *Veterinary Authority Services*~~.

Article 15.1.29.

[...]

- 2) The ASF *surveillance* programme should:
- a) include an *early warning system* throughout the production, marketing and processing chain for reporting suspected *cases*. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of ASF to the ~~*Veterinary Authority Services*~~. The reporting system under the *Veterinary Authority* should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary paraprofessionals*) by government or private sector awareness programmes targeted to all relevant stakeholders. Personnel responsible for *surveillance* should be able to seek expertise in ASF diagnosis, epidemiological evaluation and control;

[...]

Article 15.2.29.

[...]

- 2) The CSF *surveillance* programme should:
- a) include an *early warning system* throughout the production, marketing and processing chain for reporting suspected *cases*. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of CSF to the ~~*Veterinary Authority Services*~~. The reporting system under the *Veterinary Authority* should be

supported directly or indirectly (e.g. through private *veterinarians* or *veterinary paraprofessionals*) by information programmes. Given that many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, *cases* in which CSF cannot be ruled out should be immediately investigated. Other important diseases such as African swine fever should also be considered in any differential diagnosis.

[...]

Article 15.3.14.

[...]

2) Any PRRS *surveillance* programme should:

- a) include the reporting and investigation of suspected *cases*. Diagnosticians and those with regular contact with pigs should report promptly any suspicion of PRRS to the ~~Veterinary Authority~~ Services;

[...]
