

**MEETING OF THE OIE
TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

Paris, 31 August–10 September 2015

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Agenda**A. MEETING WITH THE DIRECTOR GENERAL**

Welcome–Director General

B. ADOPTION OF THE AGENDA**C. JOINT MEETING OF THE CODE COMMISSION AND THE SCIENTIFIC COMMISSION
(Tuesday 8 September)****D. EXAMINATION OF MEMBER COUNTRY COMMENTS AND WORK OF RELEVANT EXPERT
GROUPS**

- Item 1 General comments of OIE Member Countries
- Item 2 User's Guide
- Item 3 Glossary
- Item 4 Notification of diseases, infections and infestations, and provision of epidemiological information (Chapter 1.1.)
- Item 5 Listing diseases
- a) Criteria for the inclusion of diseases, infections and infestations in the OIE list (Chapter 1.2.)
 - b) Disease listed by the OIE (Chapter 1.2.bis)
- Item 6 Prescribed and alternative diagnostic tests for OIE listed diseases (Chapter 1.3.)
- Item 7 Procedures for self-declaration and for official recognition by the OIE (Chapter 1.6.)
- Item 8 Quality of veterinary services
- a) Evaluation of Veterinary Services (Chapter 3.2.)
 - b) Report of the *ad hoc* Group on the evaluation of Veterinary Services
- Item 9 High health status horse subpopulation (Chapter 4.16.) and Model veterinary certificate

Annex 2 (contd)

- Item10 OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (Chapter 5.3.)
- Item 11 Veterinary Public Health: Antimicrobial resistance
- a) Harmonisation of national AMR surveillance and monitoring programme (Chapter 6.7.)
 - b) Updating the chapter on Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals (Chapter 6.8.)
- Item 12 Veterinary Public Health: Zoonoses and Food safety
- a) Draft new chapter on prevention and control of *Salmonella* in cattle (Chapter 6.X.)
 - b) Draft new chapter on prevention and control of *Salmonella* in pig (Chapter 6.X.)
 - c) Infection with *Trichinella* spp. (Chapter 8.16.)
 - d) Infection with *Taenia solium* (Chapter 15.3.)
 - e) Terms of Reference for the Animal Production Food Safety Working Group
- Item 13 Animal welfare
- a) Slaughter of animals (Chapter 7.5.)
 - b) Killing of animals for disease control purposes (Chapter 7.6.)
 - c) Animal welfare and broiler chicken production systems (Chapter 7.10.)
 - d) Animal welfare and dairy cattle production systems (Chapter 7.11.)
 - e) Draft new chapter on the welfare of working equids (Chapter 7.X.)
 - f) Report of the Animal Welfare Working Group
 - g) Disaster risk reduction and management in relation to animal health and welfare and veterinary public health
 - h) Collaborating centre twinning proposal on animal welfare between Italy and South Africa
- Item 14 Harmonisation of vector borne diseases
- a) Infection with bluetongue virus (Chapter 8.3.)
 - b) Infection with epizootic hemorrhagic disease virus (Chapter 8.7.)
 - c) Infection with Rift Valley fever virus (Chapter 8.14.)
- Item 15 Infection with *Brucella abortus*, *B. melitensis* and *B. suis* (Chapter 8.4.)

- Item 16 Infection with foot and mouth disease virus (Chapter 8.8.)
- Item 17 Draft chapter on infection with *Mycobacterium tuberculosis* complex (Chapter 8.X.)
- Item 18 Infection with avian influenza viruses (Chapter 10.4.)
- Item 19 Bovine spongiform encephalopathy (Chapter 11.4.)
- Item 20 Infection with *Burkholderia mallei* (Glanders) (Chapter 12.10.)
- Item 21 Infection with African swine fever virus (Chapter 15.1.)
- Item 22 Draft new chapter on criteria for assessing the safety of commodities (Chapter X.X.)

E. OTHER ISSUES

- Item 23 Update of the Code Commission's work programme
- Item 24 Review of applications for recognition as OIE collaborating centre
- a) Online veterinary education products (USA)
 - b) Infectious reproductive disease (France)
 - c) Capacity building in veterinary service (Thailand)
- Item 25 Report of the *ad hoc* Group on veterinary education
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JOINT MEETING BETWEEN THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES AND THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 8 September 2015

The OIE Scientific Commission for Animal Diseases (the Scientific Commission) and the OIE Terrestrial Animal Health Standards Commission (the Code Commission) held a joint meeting on Tuesday 8 September 2015 to discuss issues of mutual interest. All members of the Commissions as well as the Director General, Deputy Director General, and supporting staff of the Scientific and Technical Department and the International Trade Department of the OIE participated in the meeting.

Dr Bernard Vallat, the Director General of the OIE, emphasised the benefits of having the Scientific Commission and the Code Commission joint meetings to ensure coordination between both Commissions and welcomed the new members of both Commissions to the OIE Headquarters.

The Director General also informed the Commissions of the intention of the OIE Council to increase the transparency and efficiency of the work of all Specialist Commissions by evaluating the performance of their members based on specific criteria still and procedure still being discussed by the Council.

The main discussion points were as follows:

1. Coordination between the two commissions

The Director General first explained the inter-commission coordination mechanisms already established at the OIE Headquarters and reiterated its continued support to the Commissions' work, in particular by providing all the secretarial work to the Commissions.

The Director General emphasised the importance of following a two-year cycle of developing or amending OIE standards. The one-year cycle should only be used in specific circumstances such as emerging diseases or new scientific evidence with impact on disease control or on trade, which requires urgent development or amendment of OIE standards.

The Director General reminded the meeting that there was a natural link between the two Commissions as stipulated in the basic texts of the OIE related to the Terms of Reference of the Specialist Commissions including the Scientific Commission's mandate to provide up-to-date scientific information to the Code Commission.

In this regard, the Director General suggested frequent communication between the Presidents of the Commissions to facilitate the coordination and collaboration between the Commissions with the help from the Headquarters.

The Director General also highlighted the fact that depending on the availability of the budget, the Commissions could request the Director General to convene *ad hoc* Groups to seek experts' opinion in addition to the existing *ad hoc* Groups responsible for official recognition of disease status of Member Countries. When necessary and if budget permitted, a representative of each Commission could be invited to attend the *ad hoc* Group meetings as observer to guide the Group in its work without influencing the Group's position.

In regard to the availability of *ad hoc* Group reports, the Director General reiterated his view that the reports of the *ad hoc* Groups should be available to Specialist Commissions for information but they should not be part of the decision process until the report is validated by the responsible Commission.

The Director General confirmed that experts participating in *ad hoc* Groups are selected based on their scientific excellence and geographical balance, using proposals from Specialist Commissions and when possible within the network of experts from reference centres, endorsed by the World Assembly.

Annex 3 (cont.)

In response to the comments from the Director General, the Presidents of the two Commissions expressed their agreement for his suggestions and asked the Headquarters to continue to provide necessary support with regard to the exchange of working documents.

The two Commissions also agreed to schedule their meetings to enable overlap of their respective meetings, as well as those of the Biological Standards Commission, to allow them to hold joint meetings. When possible, the meeting of the Scientific Commission should coincide with the first week of the Code Commission's meeting.

The Presidents agreed with the Director General on his proposal to find suitable dates decided at least two years in advance for all the meetings of the Specialist Commissions.

2. Glossary

The President of the Code Commission explained that there was a need to clearly define the meaning of "OIE Standards" and "OIE Guidelines" as these could have a direct impact on the process of WTO disputes. For this reason, the Code Commission drafted definitions in consultation with the Scientific Commission and the Biological Standards Commission. He indicated that these draft definitions would be attached to the Code Commission report for Member Countries' comments.

The two Commissions also discussed the new draft definitions for *vaccination programme*, *emergency vaccination*, and *routine vaccination*, which had been developed in collaboration with the two Commissions and the Biological Standards Commission. The Presidents of the two Commissions asked the Headquarters to forward these draft definitions for consideration of the *ad hoc* Group on vaccination which would be convened in near future to draft a new horizontal chapter on vaccination for consideration by the Scientific Commission. It was agreed that the participation of representatives from the Code Commission and Biological Standards Commission would be requested.

3. Procedures for self-declaration and for official recognition by the OIE (Chapter 1.6.)

The President of the Code Commission explained the proposed revision of several references in Chapter 1.6. to the *Terrestrial Manual*. He was informed the revision of Chapter 1.6. was included in the work plan of the Scientific Commission, and informed that the Code Commission had the intention to separate the revised Chapter 1.6. by dedicating one *Terrestrial Code* chapter to each of the disease questionnaires for ease of reference.

4. The model certificate for high health high performance (HHP) horses

The President of the Code Commission noted that a number of Member Countries' comments was received raising concerns on the discrepancies between some requirements of the certificate and the current *Terrestrial Code* chapters and difficulties in interpreting the content of the certificate in absence of the biosecurity guidelines included in the handbook for the management of HHP horses.

The two Commissions agreed to include the Model HHP certificate in the section of certification of the "Handbook for the management of HHP horses" since at this stage the HHP concept as such is complete but the certificate was not yet ready to be proposed for adoption as a *Terrestrial Code* chapter. Further work such as alignment with existing *Terrestrial Code* chapters and testing of the HHP concept in the field was required before a proposal for its adoption as a new *Terrestrial Code* chapter could be reconsidered.

The two Commissions also agreed on the fact that the Model HHP Certificate is an integral part of the HHP concept that would be implemented by those Member Countries wishing to apply it as an OIE guideline. Consequently, the two Commissions decided that the justification for the amendments provided by the Scientific Commission and Code Commission would be annexed to the report of the Scientific Commission.

The Director General agreed with both Commissions noting that it was important to have consistency in developing the OIE standards or guidelines to ensure transparency while enabling Member Countries to adopt and implement the HHP concept.

5. Bovine spongiform encephalopathy (BSE)

The President of the Code Commission informed the Scientific Commission of Member Countries' comments on the revised chapter circulated for comments in the February 2015 Code Commission meeting report and the need for an update of the *Terrestrial Code* and *Terrestrial Manual* chapters on BSE accordingly. The Code Commission suggested to the Director General to convene an *ad hoc* Group to specifically address these Member Country comments by differentiating atypical from classical BSE in the *Terrestrial Manual* and drafting a case definition of both classical and atypical BSE for the *Terrestrial Code*.

The President of the Scientific Commission reminded the Code Commission that the last *ad hoc* Group on BSE proposed some amendments to address the issue of atypical BSE and that the proposed changes still required to be examined. In addition, it was brought to the attention of both Commissions that according to the report of the Biological Standards Commission, the modification of the *Terrestrial Manual* chapter on BSE was already tasked to experts from the OIE Reference Laboratories. The President of the Scientific Commission proposed that the *ad hoc* Group on the evaluation of BSE status dossiers would be capable of undertaking the task of reviewing the concerns from the Member Countries.

The Director General recalled however that a number of Member Countries made strong interventions on the proposed revision of the BSE chapter during the last General Session and agreed to convene a specific *ad hoc* Group with the Terms of Reference of revising the *Terrestrial Code* chapter, in light of those comments and of the revised *Terrestrial Manual* chapter.

6. Porcine reproductive and respiratory syndrome (PRRS)

The President of the Scientific Commission informed the Code Commission that the task of revising Member Countries' comments on the draft chapter was accomplished with the support of the *ad hoc* Group. The amended chapter was forwarded to the Code Commission for further consideration.

The President of the Code Commission suggested that considering its agenda priorities and time constraints, the PRRS draft chapter be reviewed at the next Code Commission meeting.

7. Equine trypanosomiasis including Surra

The President of the Scientific Commission informed the Code Commission that the work of the *ad hoc* Group that was convened to provide an expert opinion on the need to have a specific *Terrestrial Code* Chapter on surra and update the existing chapter on dourine was not accomplished. He suggested to the Director General to reconvene an *ad hoc* Group with additional members experienced in drafting OIE standards. The President of the Code Commission concurred with this decision.

8. Foot and mouth disease (FMD)

The Scientific Commission recalled several pending issues raised by Member Countries when revising the recently adopted chapter on FMD and that were not included in the new chapter.

The President of the Code Commission explained that the Code Commission addressed Member Countries' comments made during the General Session and amended the FMD chapter accordingly, except on the pending issues mentioned, which requested more expertise. The President of the Scientific Commission indicated that the Scientific Commission was not given the opportunity to review these comments during its meeting and requested that those pending issues be forwarded to a forthcoming *ad hoc* Group meeting to seek their expert opinion.

9. Dates of next meeting

The two Commissions agreed on the dates of their next meetings to ensure an overlapping period (during the first week of the Code Commission meeting) and good coordination with other Specialist Commissions. The dates are given in their respective reports.

USER'S GUIDE

A. Introduction

- 1) The OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) sets out standards for the improvement of terrestrial animal health and welfare and veterinary public health worldwide. The purpose of this guide is to advise the Veterinary Authorities of OIE Member Countries on how to use the *Terrestrial Code*.
- 2) Veterinary Authorities should use the standards in the *Terrestrial Code* to set up measures providing for early detection, internal reporting, notification and control of pathogenic agents, including zoonotic ones, in terrestrial animals (mammals, birds and bees) and preventing their spread via international trade in animals and animal products, while avoiding unjustified sanitary barriers to trade.
- 3) The OIE standards are based on the most recent scientific and technical information. Correctly applied, they protect animal health and welfare and veterinary public health during production and trade in animals and animal products, and in the use of animals.
- 4) The absence of chapters, articles or recommendations on particular aetiological agents or commodities does not preclude the application of appropriate sanitary measures by the Veterinary Authorities, provided they are based on risk analyses conducted in accordance with the *Terrestrial Code*.
- 5) The complete text of the *Terrestrial Code* is available on the OIE Web site and individual chapters may be downloaded from: <http://www.oie.int>.

B. *Terrestrial Code* content

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

Annex 4 (contd)

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

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

C. Specific issues

1. Notification

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

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

2. Diagnostic tests and vaccines

It is recommended that specified diagnostic tests and vaccines in *Terrestrial Code* chapters be used with a reference to the relevant section in the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereafter referred to as the *Terrestrial Manual*). Chapter 1.3. provides a table summarising the prescribed and alternative diagnostic tests for OIE listed diseases. Experts responsible for facilities used for disease diagnosis and vaccine production should be fully conversant with the standards in the *Terrestrial Manual*.

3. Prevention and control

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

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

Annex 4 (contd)

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

Chapter 6.4. is designed for the implementation of general biosecurity measures in intensive poultry production. Chapter 6.5. is an example of a specific on-farm prevention and control plan for the non-listed food-borne pathogen *Salmonella* in poultry.

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

4. Trade requirements

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

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

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

5. International veterinary certificates

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

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

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

- a) identify the diseases, infections or infestations from which the importing country is justified in seeking protection because of its own health status. Importing countries should not impose measures in regards to diseases that occur in their own territory but are not subject to official control programmes;
- b) for commodities capable of transmitting these diseases, infections or infestations through international trade, the importing country should apply the relevant articles in the disease-specific chapters. The application of the articles should be adapted to the disease status of the ~~exporting~~ country, zone or compartment of origin. Such status should be established according to Article 1.4.6. except when articles of the relevant disease chapter specify otherwise;
- c) when preparing international veterinary certificates, the importing country should endeavour to use terms and expressions in accordance with the definitions given in the Glossary. As stated in Article 5.2.3., international veterinary certificates should be kept as simple as possible and should be clearly worded, to avoid misunderstanding of the importing country's requirements;

Annex 4 (contd)

- d) Chapters 5.10. to 5.13. provide, as further guidance to Member Countries, model certificates that should be used as a baseline.

6. Guidance notes for importers and exporters

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

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GLOSSARY

ACCEPTABLE RISK

~~means a risk level judged by each Member Country to be compatible with the protection of animal and public health within its territory.~~

APPROPRIATE LEVEL OF PROTECTION

~~means the level of protection deemed appropriate by the country establishing a sanitary measure to protect human or animal life or health within its territory.~~

STAMPING-OUT POLICY

means a policy designed to eliminate an *outbreak* by carrying out under the authority of the *Veterinary Authority* the following:

- a) the *killing* of the *animals* which are affected and those suspected of being affected in the *herd* and, where appropriate, those in other *herds* which have been exposed to *infection* by direct animal to animal contact, or by indirect contact with the causal pathogen; ~~this includes all susceptible animals, vaccinated or unvaccinated, on infected establishments; animals should be killed in accordance with Chapter 7.6.;~~
- b) the destruction of ~~their~~ carcasses and animal products, as relevant, by rendering, burning or burial, or by any other method described in Chapter 4.12.;
- c) the cleansing and *disinfection* of *establishments* through procedures defined in Chapter 4.13.

CASINGS

means bladders and intestines which, after cleaning, have been processed by tissue scraping, and defatting and washing, and have been treated with salt or dried.

OIE STANDARD

means a text that has been formally adopted by the OIE World Assembly of Delegates, published by the OIE, and that describes requirements, recommendations, criteria, specifications and characteristics that should be used consistently to ensure the improvement of animal health, veterinary public health and animal welfare worldwide.

OIE GUIDELINE

means an OIE publication that provides advice to improve animal health, veterinary public health and animal welfare worldwide and that has been endorsed by an OIE Specialist Commission or the OIE Council, but has not been formally adopted by the OIE World Assembly of Delegates.

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CHAPTER 1.1.

NOTIFICATION OF DISEASES, INFECTIONS AND INFESTATIONS, AND PROVISION OF EPIDEMIOLOGICAL INFORMATION

Article 1.1.1.

For the purposes of the *Terrestrial Code* and in terms of Articles 5, 9 and 10 of the OIE Organic Statutes, Member Countries shall recognise the right of the *Headquarters* to communicate directly with the *Veterinary Authority* of its territory or territories.

All *notifications* and all information sent by the OIE to the *Veterinary Authority* shall be regarded as having been sent to the country concerned and all *notifications* and all information sent to the OIE by the *Veterinary Authority* shall be regarded as having been sent by the country concerned.

For the purposes of this chapter, 'event' means a single *outbreak* or a group of epidemiologically related *outbreaks* of a given *disease, infection* or *infestation* that is the object of a *notification*. An event is specific to a pathogen and strain, when appropriate, and includes all related *outbreaks* reported from the time of the immediate *notification* through to the final report. *Notification* of an event includes host species, number and geographical distribution of affected animals and *epidemiological units*.

Article 1.1.2.

- 1) Member Countries shall make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important animal *diseases*, and their aetiological agents, and to assist in achieving better worldwide control of these *diseases*.
- 2) To achieve this, Member Countries shall comply with the *notification* requirements specified in Articles 1.1.3. and 1.1.4.
- 3) To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the official OIE *disease* reporting format.
- 4) The detection of the aetiological agent of a *listed disease* in an *animal* should be reported, even in the absence of clinical signs. Recognising that scientific knowledge concerning the relationship between *diseases* and their aetiological agents is constantly developing and that the presence of an aetiological agent does not necessarily imply the presence of a *disease*, Member Countries shall ensure, through their reports, that they comply with the spirit and intention of point 1 above.
- 5) In addition to notifying new findings in accordance with Articles 1.1.3. and 1.1.4., Member Countries shall also provide information on the measures taken to prevent the spread of *diseases, infections* and *infestations*. Information shall include quarantine measures and restrictions on the movement of *animals*, animal products, biological products and other miscellaneous objects which could by their nature be responsible for their transmission. In the case of *diseases* transmitted by *vectors*, the measures taken against such *vectors* shall also be specified.

Article 1.1.3.

Veterinary Authorities shall, under the responsibility of the Delegate, send to the *Headquarters*:

Annex 6 (contd)

- 1) in accordance with relevant provisions in the *disease-specific* chapters, *notification* through the World Animal Health Information System (WAHIS) or by fax or e-mail, within 24 hours, of any of the following events:
 - a) first occurrence of a *listed disease, infection or infestation* in a country, a *zone* or a *compartment*;
 - b) re-occurrence of a *listed disease, infection or infestation* in a country, a *zone* or a *compartment* following the final report that declared the *outbreak* ended;
 - c) first occurrence of a new strain of a pathogen of a *listed disease, infection or infestation* in a country, a *zone* or a *compartment*;
 - d) a sudden and unexpected change in the distribution or increase in incidence or virulence of, or morbidity or mortality caused by, the aetiological agent of a *listed disease, infection or infestation* present within a country, a *zone* or a *compartment*;
 - e) occurrence of a *listed disease, infection or infestation* in an unusual host species;
- 2) weekly reports subsequent to a *notification* under point 1 above, to provide further information on the evolution of the event which justified the *notification*. These reports should continue until the *disease, infection or infestation* has been eradicated or the situation has become sufficiently stable so that six-monthly reporting under point 3 will satisfy the obligation of the Member Country; for each event notified, a final report **on the event** should be submitted;
- 3) six-monthly reports on the absence or presence, and evolution of *listed diseases, infections or infestations* and information of epidemiological significance to other Member Countries;
- 4) annual reports concerning any other information of significance to other Member Countries.

Article 1.1.4.

Veterinary Authorities shall, under the responsibility of the Delegate, send to the *Headquarters*:

- 1) a *notification* through WAHIS or by fax or e-mail, when an *emerging disease* has been detected in a country, a *zone* or a *compartment*;
- 2) periodic reports subsequent to a *notification* of an *emerging disease*, ~~as described under point 1.~~ These should continue ~~until~~:
 - a) for the time necessary to have reasonable certainty that:
 - i) the *disease, infection or infestation* has been eradicated; or
 - ii) the situation has becomes ~~sufficiently~~ stable; or

OR

 - be) until sufficient scientific information is available to determine whether it meets the criteria for listing inclusion in the OIE list as described in Chapter 1.2.
- 3) once point 2 a) or b) above is complied with, a final report should be submitted.

Article 1.1.5.

- 1) The *Veterinary Authority* of a country in which an *infected zone* was located shall inform the *Headquarters* when this zone is free from the *disease, infection or infestation*.
- 2) An *infected zone* for a particular *disease, infection or infestation* shall be considered as such until a period ~~exceeding the infective period~~ specified in the *Terrestrial Code* has elapsed after the last reported case, and when full prophylactic and appropriate animal health *biosecurity* measures and *surveillance* have been applied to prevent possible recurrence~~appearance~~ or spread of the *disease, infection or infestation*. These measures ~~will be found~~ *are described* in detail in the *various relevant disease-specific* chapters ~~of Volume II~~ of the *Terrestrial Code*.
- 3) A Member Country may be considered to regain freedom from a specific *disease, infection or infestation* when all relevant conditions given in the *Terrestrial Code* have been fulfilled.
- 4) The *Veterinary Authority* of a Member Country which sets up one or several *free zones* shall inform the *Headquarters* giving necessary details, including the criteria on which the free status is based, the requirements for maintaining the status and indicating clearly the location of the *zones* on a map of the territory of the Member Country.

Article 1.1.6.

- 1) Although Member Countries are only required to notify *listed diseases, infections and infestation and emerging diseases*, they are encouraged to *provide inform* the OIE *with* ~~of~~ other important animal health *events information*.
- 2) The *Headquarters* shall communicate by e-mail or World Animal Health Information Database (WAHID) to *Veterinary Authorities* all *notifications* received as provided in Articles 1.1.2. to 1.1.5. and other relevant information.

— Text deleted.

CHAPTER 1.2.

CRITERIA FOR THE INCLUSION OF DISEASES,
INFECTIONS AND INFESTATIONS IN THE OIE LIST

Article 1.2.1.

Introduction

~~The aim of this chapter is to describe~~ This chapter is to describe the criteria for the inclusion of *diseases, infections and infestations* ~~in~~ on the OIE list.

The objective of listing is to support Member Countries ~~by providing information needed to take appropriate action efforts~~ by providing information needed to take appropriate action efforts to prevent the transboundary spread of important animal *diseases*, including *zoonoses*. ~~This is achieved by through transparent, timely and consistent notification reporting.~~ This is achieved by through transparent, timely and consistent notification reporting.

Each *listed disease* normally has a corresponding chapter ~~that~~ that ~~to~~ assists Member Countries in the harmonisation of *disease* detection, prevention and control ~~and provides standards for safe international trade in animals and their products.~~ and provides standards for safe international trade in animals and their products.

Requirements for *notification* are detailed in Chapter 1.1. ~~and notifications are to be made through WAHIS or, if not possible, by fax or e-mail as described in Article 1.1.3.~~

Principles for selection of diagnostic tests are described in Chapter 1.1.5. of the Terrestrial Manual.

Article 1.2.2.

The criteria for the inclusion of a *disease, infection or infestation* in the OIE list are as follows:

- 1) International spread of the agent (via live *animals* or their products, *vectors* or fomites) has been proven.

AND

- 2) At least one country has demonstrated freedom or impending freedom from the *disease, infection or infestation* in populations of susceptible *animals*, based on the ~~animal health surveillance provisions of the Terrestrial Code, in particular those contained in Chapter 1.4.~~ animal health surveillance provisions of the Terrestrial Code, in particular those contained in Chapter 1.4.

AND

- 3) ~~A~~ Reliable means of detection and diagnosis exists and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections and infestations.

AND

~~4)~~

- a) Natural transmission to humans has been proven, and human infection is associated with severe consequences.

OR

- b) The *disease* has been shown to cause a significant impact on the health of morbidity or mortality in domestic animals at the level of a country or a zone taking into account the occurrence and severity of the clinical signs, including direct production losses and mortality.

Annex 7 (contd)

OR

- c) The *disease* has been shown to, or scientific evidence indicates that it would, cause a significant impact on the health of morbidity or mortality in wild *wildlife animal* populations taking into account the occurrence and severity of the clinical signs, including direct production losses and mortality, and ecological any threats to the viability of a *wildlife population*.

AND

- ~~4) A reliable means of detection and diagnosis exists and a precise case definition is available to clearly identify cases and allow them to be distinguished from other *diseases, infections and infestations.*~~

— Text deleted.

CHAPTER 1.2.BIS
DISEASES LISTED BY THE OIE

Article 1.2.3.

Preamble

The following *diseases, infections and infestations* are included in the OIE list.

In case of modifications of this list of animal diseases, infections and infestations adopted by the World Assembly, the new list comes into force on 1 January of the following year.

Article 1.2.bis.1.

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

- Anthrax
- Bluetongue
- Infection with Brucellosis (*Brucella abortus*, *Brucella melitensis*, *Brucella suis*)
- Brucellosis (*Brucella melitensis*)
- Brucellosis (*Brucella suis*)
- Crimean Congo haemorrhagic fever
- Epizootic haemorrhagic disease
- Equine encephalomyelitis (Eastern)
- Infection with Foot and mouth disease virus
- Heartwater
- Infection with Aujeszky's disease virus
- Infection with *Echinococcus granulosus*
- Infection with *Echinococcus multilocularis*
- Infection with rabies virus
- Infection with Rift Valley fever virus
- Infection with rinderpest virus
- Infection with *Trichinella* spp.
- Japanese encephalitis
- New World screwworm (*Cochliomyia hominivorax*)
- Old World screwworm (*Chrysomya bezziana*)
- Paratuberculosis
- Q fever
- Surra (*Trypanosoma evansi*)
- Tularemia
- West Nile fever.

Annex 7 (contd)Article 1.2.bis.2.

2) The following are included within the category of cattle *diseases* and *infections*:

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy
- Bovine tuberculosis
- Bovine viral diarrhoea
- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia)
- Lumpy skin disease
- Theileriosis
- Trichomonosis
- Trypanosomosis (tsetse-transmitted).

Article 1.2.bis.3.

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

- Caprine arthritis/encephalitis
- Contagious agalactia
- Contagious caprine pleuropneumonia
- Infection with *Chlamydophila abortus* (Enzootic abortion of ewes, ovine chlamydiosis)
- Infection with peste des petits ruminants virus
- Maedi–visna
- Nairobi sheep disease
- Ovine epididymitis (*Brucella ovis*)
- Salmonellosis (*S. abortus ovis*)
- Scrapie
- Sheep pox and goat pox.

Article 1.2.bis.4.

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

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

Article 1.2.bis.5.

5) The following are included within the category of swine *diseases* and *infections*:

- African swine fever
- Infection with classical swine fever virus
- Nipah virus encephalitis
- Infection with *Taenia solium* ~~Porcine cysticercosis~~
- Porcine reproductive and respiratory syndrome
- Transmissible gastroenteritis.

Article 1.2.bis.6.

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

- Avian chlamydiosis
- Avian infectious bronchitis
- Avian infectious laryngotracheitis
- Avian mycoplasmosis (*Mycoplasma gallisepticum*)
- Avian mycoplasmosis (*Mycoplasma synoviae*)
- Duck virus hepatitis
- Fowl typhoid
- Infection with avian influenza viruses

Annex 7 (contd)

- Infection with influenza A viruses of high pathogenicity in birds other than poultry including wild birds
- Infection with Newcastle disease virus
- Infectious bursal disease (Gumboro disease)
- Pullorum disease
- Turkey rhinotracheitis.

Article 1.2.bis.7.

7) The following are included within the category of lagomorph *diseases and infections*:

- Myxomatosis
- Rabbit haemorrhagic disease.

Article 1.2.bis.8.

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

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

Article 1.2.bis.9.

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

- Camel pox
- Leishmaniosis.

— Text deleted.

CHAPTER 1.3.

~~PRESCRIBED AND ALTERNATIVE DIAGNOSTIC TESTS FOR OIE LISTED DISEASES~~

NOTE

~~In many of the *Terrestrial Code* chapters relating to specific *diseases*, the reader is referred to the *Terrestrial Manual* for information on OIE standards for the relevant diagnostic tests and vaccines.~~

~~However, some readers of the *Terrestrial Code* may need to know which diagnostic tests are recommended by the OIE for use in the *international trade of animals* or animal products, without requiring the details of how these tests should be performed.~~

~~The tables in this chapter have been included to meet this need. These tables show, for each OIE *listed diseases*, the diagnostic tests which can be used when the *Terrestrial Code* recommends a testing procedure.~~

~~These tests should be performed in accordance with the specifications in the *Terrestrial Manual*, in order to avoid any differences between the *exporting and importing countries* in the interpretation of results.~~

~~In the tables, the diagnostic tests have been divided into two categories – ‘prescribed tests’ and ‘alternative tests’ (a similar categorisation is made in the *Terrestrial Manual*). The ‘prescribed tests’ are those which are considered optimal for determining the health status of *animals* before shipment. ‘Alternative tests’ do not demonstrate the absence of *infection* in the tested *animals* with the same level of confidence as the prescribed tests do. However, the OIE Terrestrial Animal Health Standards Commission considers that an ‘alternative test’, chosen by mutual agreement between the *importing and exporting countries*, can provide valuable information for evaluating the *risks* of any proposed trade in *animals* or animal products. The *disease* for which the *Terrestrial Code* does not require any test are not included in the tables.~~

ABBREVIATIONS AND ACRONYMS

Agent id.	Agent identification
Agg.	Agglutination test
AGID	Agar gel immunodiffusion
BBAT	Buffered <i>Brucella</i> antigen test
CF	Complement fixation (test)
DTH	Delayed type hypersensitivity
ELISA	Enzyme linked immunosorbent assay
FAVN	Fluorescent antibody virus neutralisation
FPA	Fluorescence polarisation assay
HI	Haemagglutination inhibition
IFA	Indirect fluorescent antibody (test)
MAT	Microscopic agglutination test
NPLA	Neutralising peroxidase linked assay
PCR	Polymerase chain reaction
PRN	Plaque reduction neutralisation
VN	Virus neutralisation
–	No test designated yet

Annex 8 (contd)

<i>Terrestrial Code Chapter No.</i>	<i>Terrestrial Manual Chapter No.</i>	Disease name	Prescribed tests	Alternative tests
OIE listed diseases				
Multiple species				
8.2.	2.1.2.	Aujeszky's disease	ELISA, VN	-
8.3.	2.1.3.	Bluetongue	Agent id., ELISA, PCR, VN	AGID
8.8.	2.1.5.	Foot and mouth disease	ELISA, VN	CF
8.9.	2.1.6.	Heartwater	-	ELISA, IFA
	2.1.9.	Leptospirosis	-	MAT
8.11.	2.1.10.	New _____ world _____ screwworm (<i>Cochliomyiahominivorax</i>) and old world screwworm (<i>Chrysomyabezziiana</i>)	-	Agent id.
8.12.	2.1.11.	Paratuberculosis	-	DTH, ELISA
8.13.	2.1.13.	Rabies	ELISA, VN	-
8.14.	2.1.14.	Rift Valley fever	VN	ELISA, HI
8.15.	2.1.15.	Rinderpest	-	VN
8.16.	2.1.16.	Trichinellosis	Agent id.	ELISA
8.17.	2.1.18.	Tularemia	-	Agent id.
	2.1.19.	Vesicular stomatitis	CF, ELISA, VN	-

Annex 8 (contd)

Bovidae				
11.1.	2.4.1.	Bovine anaplasmosis	-	CAT, CF
11.2.	2.4.2.	Bovine babesiosis	PCR	CF, ELISA, IFA
	2.4.3.	Bovine brucellosis	BBAT, CF, ELISA, FPA	-
11.3.	2.4.5.	Bovine genital campylobacteriosis	Agent id.	-
11.5.	2.4.7.	Bovine tuberculosis	Tuberculin test	Interferon-gamma release
11.7.	2.4.9.	Contagious bovine pleuropneumonia	CF, ELISA	-
11.8.	2.4.11.	Enzootic bovine leukosis	AGID, ELISA	PCR
11.9.	2.4.12.	Haemorrhagic septicaemia	-	Agent id.
11.10.	2.4.13.	Infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis	Agent id. (semen only), ELISA, PCR, VN	-
11.11.	2.4.14.	Lumpy skin disease	-	VN
11.12.	2.4.16.	Theileriosis	Agent id., IFA	-
11.13.	2.4.17.	Trichomonosis	Agent id.	Mucus agg.
Caprinae				
-	2.7.2.	Caprine and ovine brucellosis (excluding <i>Brucella ovis</i>)	BBAT, CF, ELISA, FPA	Brucellin test
14.1.	2.7.3.	Caprine arthritis/encephalitis	AGID, ELISA	-
14.5.	2.7.4.	Maedi-visna	AGID, ELISA	-
14.3.	2.7.6.	Contagious caprine pleuropneumonia	-	-
14.4.	2.7.7.	Enzootic abortion of ewes	-	CF
14.6.	2.7.9.	Ovine epididymitis (<i>Brucella ovis</i>)	CF	ELISA
14.7.	2.7.11.	Peste des petits ruminants	VN	ELISA
14.9.	2.7.14.	Sheep pox and goat pox	-	VN

Annex 8 (contd)

Equidae				
12.1.	2.5.1.	African horse sickness	CF, ELISA	Agent id. (real time PCR), VN
12.2.	2.5.2.	Contagious equine metritis	Agent id.	-
12.3.	2.5.3.	Dourine	CF	ELISA, IFA
12.4.	2.5.5.	Equine encephalomyelitis (Eastern and Western)	-	CF, HI, PRN
12.5.	2.5.6.	Equine infectious anaemia	AGID	ELISA
12.6.	2.5.7.	Equine influenza	-	HI
12.7.	2.5.8.	Equine piroplasmiasis	ELISA, IFA	CF
12.8.	2.5.9.	Equine rhinopneumonitis	-	VN
12.9.	2.5.10.	Equine viral arteritis	Agent id. (semen only), VN	-
12.10.	2.5.11.	Glanders	CF	-
12.11.	2.5.13.	Venezuelan equine encephalomyelitis	-	CF, HI, PRN
Suidae				
15.1.	2.8.1.	African swine fever	ELISA	IFA
15.2.	2.8.3.	Classical swine fever	ELISA, FAVN, NPLA	-
	2.8.5.	Porcine brucellosis	BBAT, CF, ELISA, FPA	-
	2.8.9.	Swine vesicular disease	VN	ELISA
15.3.	2.8.11.	Transmissible gastroenteritis	-	ELISA, VN
Aves				
10.2.	2.3.2.	Avian infectious bronchitis	-	ELISA, HI, VN
10.3.	2.3.3.	Avian infectious laryngotracheitis	-	AGID, ELISA, VN
10.4.	2.3.4.	Avian influenza	Virus isolation with pathogenicity testing	AGID, HI
10.5.	2.3.5.	Avian mycoplasmosis (<i>Mycoplasma gallisepticum</i>)	-	Agg., HI
10.7.	2.3.11.	Fowl typhoid and Pullorum disease	-	Agent id., Agg.
10.8.	2.3.12.	Infectious bursal disease	-	AGID, ELISA

Annex 8 (contd)

	2.3.13.	Marek's disease	-	AGID
40.9.	2.3.14.	Newcastle disease	Virus isolation	HI
Leporidae				
13.1.	2.6.1.	Myxomatosis	-	AGID, CF, IFA
13.2.	2.6.2.	Rabbit haemorrhagic disease	-	ELISA, HI

— Text deleted.

CHAPTER 1.6.

PROCEDURES FOR SELF DECLARATION AND FOR
OFFICIAL RECOGNITION BY THE OIE

Article 1.6.1.

General principles

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

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

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

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

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

When requesting official recognition of disease status, the Member Country should submit to the OIE Scientific and Technical Department a dossier providing the information requested (as appropriate) in Articles 1.6.5. (for BSE), 1.6.6. (for FMD), 1.6.7. (for CBPP), 1.6.8. (for AHS), 1.6.9. (for PPR) or 1.6.10. (for CSF).

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

[Article 1.6.2.]

[Article 1.6.3.]

[Article 1.6.4.]

[Article 1.6.5.]

Annex 9 (contd)

Article 1.6.6.

Questionnaires on FMD**FMD FREE COUNTRY WHERE VACCINATION IS NOT PRACTISED**

Report of a Member Country which applies for recognition of status, under Chapter 8.8. of the *Terrestrial Code*, as a FMD free country not practising vaccination

Address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.
- b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
- b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. in the *Terrestrial Code* and Article Chapter 1.1.3. in the *Terrestrial Code Manual* and describe how *Veterinary Services* supervise, control and maintain all FMD related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

- a) History. Provide a description of the FMD history in the country, date of first detection, origin of *infection*, date of eradication (date of last case), and types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, modified stamping-out policy, zoning).
- c) Vaccines and *vaccination*. Was FMD vaccine ever used? If so, when was the last *vaccination* carried out? When was *vaccination* formally prohibited? What species were vaccinated? What was the fate of these animals?

In addition, if *vaccination* was conducted during the past two years, provide a description and justification of the *vaccination* strategy, including the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the *vaccination* of animals was certified or reported and the records maintained. Also provide evidence that the vaccine used complies with Chapter 2.1.5. in the *Terrestrial Manual*.

Annex 9 (contd)

- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe the action taken when an illegal movement is detected. Provide information on illegal movements detected.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the names of and the arrangements with the laboratory (ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
 - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
 - ii) Give details of performance in inter-laboratory proficiency tests.
 - iii) Provide details on the handling of live virus.
 - iv) *Biosecurity* measures applied.
 - v) Details of the type of tests undertaken and their performance for their applied use (specificity and sensitivity).
 - vi) Laboratory capacity in processing tests and samples.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.8.40. to 8.8.42. in the *Terrestrial Code* and Chapter 2.1.5. in the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis).
- b) Serological *surveillance*. Have serological surveys been conducted to demonstrate freedom from *infection*? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are *wildlife* susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

Annex 9 (contd)

- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc. of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) *Wildlife* demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and *wildlife* susceptible species?
- e) *Slaughterhouses* and markets or events associated with the congregation of FMD susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries.
- b) Are there controls in place for the feeding of swill containing animal products to pigs? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.
- c) Import control procedures

From what countries or *zones* does the country authorise the import of susceptible animals or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or *zone* of origin, species and quantity.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
 - ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of and the disposal locations.
 - iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals,
 - genetic material (semen and embryos),
 - animal products,
 - *veterinary medicinal products* (i.e. biologics),
 - other materials at risk of being contaminated with FMDV.
 - iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on illegal imports detected.
- d) Describe and justify the corrective actions that have been implemented to prevent future FMD *outbreaks* in response to any past *disease* incursions.

7. Contingency planning and outbreak response programmes

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases* (e.g. livestock standstills)?
- c) In the event of a FMD *outbreak*:
 - i) indicate the sampling and testing procedures to be used to identify and confirm presence of the causative agent;
 - ii) describe the actions to be taken to report and control the disease situation in and around any *establishments* found to be infected with FMD;
 - iii) indicate the control or eradication procedures (e.g. *vaccination*, *stamping-out policy*, partial slaughter or *vaccination*, methods of disposal of carcasses and other contaminated products and materials, decontamination, etc.) that would be taken. Include information on access to antigen and vaccine banks;
 - iv) describe the procedures to be used to confirm successful control or eradication, including any restocking provisions, sentinel animal and serological *surveillance* programmes;
 - v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control or eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

- a) In addition to the documentary evidence that the provisions of Article 8.8.2. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:
 - i) there has been no *outbreak* of FMD during the past 12 months;
 - ii) no evidence of FMDV *infection* has been found during the past 12 months;
 - iii) no *vaccination* against FMD has been carried out during the past 12 months,
- b) and should confirm that since the cessation of *vaccination* no animals vaccinated against FMD have been imported.

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.8.7., and points 1, 3 and 4 of Article 8.8.2. of the *Terrestrial Code* and provide information as specified in sections 1 - 7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).

Annex 9 (contd)**FMD FREE COUNTRY WHERE VACCINATION IS PRACTISED**

Report of a Member Country which applies for recognition of status,
under Chapter 8.8. of the *Terrestrial Code*,
as a FMD free country practising vaccination

Address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.
- b) Livestock industry. Provide a general description of the livestock industry in the country.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
- b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. in the *Terrestrial Code* and ~~Article Chapter~~ Chapter 1.1.3. in the *Terrestrial Code Manual* and describe how *Veterinary Services* supervise, control and maintain all FMD related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

- a) History. Provide a description of the FMD history in the country, date of first detection, origin of *infection*, date of eradication (date of last case), and types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, modified stamping-out policy, zoning).
- c) Vaccines and *vaccination*. Provide a description and justification of the *vaccination* strategy, including the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the *vaccination* of animals was certified or reported and the records maintained, the date on which the last *vaccination* was performed, and the disposition of vaccinated animals (e.g. removed from or retained in the population). Provide evidence to show its effectiveness (e.g. *vaccination* coverage, serological *surveillance*, etc.). Also provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*.
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

Annex 9 (contd)

- e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability, including *vaccination* data. How are animal movements controlled in the country? Provide evidence on the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe the action taken when an illegal movement is detected. Provide information on illegal movements detected.

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. in the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the names of and the arrangements with the laboratory(ies) samples are sent to and the follow-up procedures and the time frame for obtaining results.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
- i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
 - ii) Give details of performance in inter-laboratory proficiency tests.
 - iii) Provide details on the handling of live virus.
 - iv) *Biosecurity* measures applied.
 - v) Details of the type of tests undertaken and their performance for their applied use (specificity and sensitivity).
 - vi) Laboratory capacity in processing tests and samples.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.8.40. to 8.8.42. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) *Clinical suspicion*. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis).
- b) *Surveillance*. Are serological and virological surveys conducted to demonstrate freedom from *infection*, in particular applying the provisions of Article 8.8.42.? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are susceptible *wildlife* species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

Annex 9 (contd)

- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc. of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) *Wildlife* demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and *wildlife* susceptible species?
- e) *Slaughterhouses*, markets and events associated with the congregation of FMD susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

- b) Are there controls in place for the feeding of swill containing animal products to pigs? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

- c) Import control procedures

From what countries or *zones* does the country authorise the import of susceptible animals or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or *zone* of origin, species and quantity.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
 - ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of and the disposal locations.
 - iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals,
 - genetic material (semen and embryos),
 - animal products,
 - *veterinary medicinal products* (i.e. biologics),
 - other materials at risk of being contaminated with FMDV.
 - iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.
- d) Describe and justify the corrective actions that have been implemented to prevent future FMD *outbreaks* in response to any past *disease* incursions.

7. Contingency planning and outbreak response programmes

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases* (e.g. livestock standstills)?
- c) In the event of a FMD *outbreak*:
 - i) indicate the sampling and testing procedures to be used to identify and confirm presence of the causative agent;
 - ii) describe the actions to be taken to report and control the disease situation in and around any *establishments* found to be infected with FMD;
 - iii) indicate the control or eradication procedures (e.g. *vaccination*, *stamping-out policy*, partial slaughter or *vaccination*, methods of disposal of carcasses and other contaminated products or materials, decontamination, etc.) that would be taken. Include information on access to antigen and vaccine banks;
 - iv) describe the procedures to be used to confirm successful control or eradication, including any restocking provisions, sentinel animal and serosurveillance programmes;
 - v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control or eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.8.3. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating that there has been no *outbreak* of FMD for the past two years and no evidence of FMDV transmission for the past 12 months, with documented evidence that:

- a) *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;
- b) routine *vaccination* is carried out for the purpose of the prevention of FMD;
- c) the vaccine used complies with the standards described in the *Terrestrial Manual*.

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.8.7. and of points 1, 3 and 4 of Article 8.8.3. in the *Terrestrial Code* and provide information as specified in sections 1 - 7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).

Annex 9 (contd)**FMD FREE ZONE WHERE VACCINATION IS NOT PRACTISED**

Report of a Member Country which applies for recognition of status,
under Chapter 8.8. of the *Terrestrial Code*,
as a FMD free zone not practising vaccination

Address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that although may not be adjacent share a link for the potential introduction of *disease*. The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.
- b) Livestock industry. Provide a general description of the livestock industry in the country and the *zone*.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
- b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. in the *Terrestrial Code* and ~~Article Chapter~~ 1.1.3. in the *Terrestrial Code Manual* and describe how *Veterinary Services* supervise, control and maintain all FMD related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

- a) History. Provide a description of the FMD history in the country and *zone*, provide date of first detection, origin of *infection*, date of eradication in the *zone* (date of last *case*), and types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. *stamping-out policy*, modified stamping-out policy).
- c) Vaccines and *vaccination*
 - i) Was *vaccination* ever used in the *zone*? If so, when was the last *vaccination* carried out? When was *vaccination* formally prohibited? What species were vaccinated? What was the fate of those animals?
 - ii) In addition, if *vaccination* was conducted during the past two years, provide a description and justification of the *vaccination* strategy, including the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the *vaccination* of animals was certified or reported and the records maintained. Also provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*.
 - iii) If *vaccination* continues to be used in the rest of the country, give details on the post-*vaccination* monitoring programme.

Annex 9 (contd)

- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability. How are animal movements controlled in and between *zones* of the same or different status, in particular if the provisions of the *Terrestrial Code* in Article 8.8.10. are applied? Provide evidence on the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe the action taken when an illegal movement is detected. Provide information on detected illegal movements

4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. in the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the names of and the arrangements with the laboratory(ies) samples are sent to. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed, the follow-up procedures and the time frame for obtaining results.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
 - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
 - ii) Give details of performance in inter-laboratory proficiency tests.
 - iii) Provide details on the handling of live virus.
 - iv) *Biosecurity* measures applied.
 - v) Details of the type of tests undertaken and their performance for their applied use (specificity and sensitivity).
 - vi) Laboratory capacity in processing tests and samples.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.8.40. to 8.8.42. in the *Terrestrial Code* and Chapter 2.1.5. in the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis).

Annex 9 (contd)

- b) Serological *surveillance*. Have serological surveys been conducted to demonstrate freedom from *infection*? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are *wildlife* susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the *zone*? How many *herds*, *flocks*, etc. of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) *Wildlife* demographics. What susceptible species are present in the country and the *zone*? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and *wildlife* susceptible species?
- e) *Slaughterhouses*, markets and events associated with the congregation of FMD susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the FMD free *zone* without *vaccination* is situated in a FMD infected country or borders an infected country or *zone*, describe the *biosecurity* measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

- b) Are there controls in place for the feeding of swill containing animal products to pigs? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.
- c) Import control procedures

From what countries or *zones* does the country authorise the import of susceptible animals or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or *zone* of origin, species and quantity.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

Annex 9 (contd)

- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of and the disposal locations.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals,
 - genetic material (semen and embryos),
 - animal products,
 - *veterinary medicinal products* (i.e. biologics),
 - other materials at risk of being contaminated with FMDV.
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on illegal imports detected.
- d) Describe and justify the corrective actions that have been implemented to prevent future FMD *outbreaks* in response to any past *disease* incursions.

7. Contingency planning and outbreak response programmes

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases* (e.g. livestock standstills)?
- c) In the event of a FMD *outbreak*:
 - i) indicate the sampling and testing procedures to be used to identify and confirm presence of the causative agent;
 - ii) describe the actions to be taken to report and control the disease situation in and around any *establishments* found to be infected with FMD;
 - iii) indicate the control or eradication procedures (e.g. *vaccination*, *stamping-out policy*, partial slaughter or *vaccination*, methods of disposal of carcasses and other contaminated products or materials, decontamination, etc.) that would be taken. Include information on access to antigen and vaccine banks;
 - iv) describe the procedures to be used to confirm successful control or eradication, including any restocking provisions, sentinel animal and serosurveillance programmes;
 - v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control or eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.8.4. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:

Annex 9 (contd)

- a) there has been no *outbreak* of FMD during the past 12 months;
- b) no evidence of FMDV *infection* has been found during the past 12 months;
- c) no *vaccination* against FMD has been carried out during the past 12 months;
- d) no vaccinated animal has been introduced into the *zone* since the cessation of *vaccination*, except in accordance with Article 8.8.10.

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.8.7. and of points 1, 3 and 4 of Article 8.8.2. in the *Terrestrial Code* and provide information as specified in sections 1 - 7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).

FMD FREE ZONE WHERE VACCINATION IS PRACTISED

Report of a Member Country which applies for recognition of status,
under Chapter 8.8. of the *Terrestrial Code*,
as a FMD free zone practising vaccination

Address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that although may not be adjacent share a link for the potential introduction of *disease*. The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.
- b) Livestock industry. Provide a general description of the livestock industry in the country and the *zone*.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
- b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. in the *Terrestrial Code* and Article Chapter 1.1.3. in the *Terrestrial Code Manual* and describe how *Veterinary Services* supervise, control and maintain all FMD related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

3. FMD eradication

- a) History. Provide a description of the FMD history in the country and *zone*, provide date of first detection, origin of *infection*, date of eradication in the *zone* (date of last case), and types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. *stamping-out policy*, modified stamping-out policy).
- c) Vaccines and *vaccination*. Provide a description and justification of the *vaccination* strategy, including the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the *vaccination* of animals was certified or reported and the records maintained, the date on which the last *vaccination* was performed, and the disposition of vaccinated animals (e.g. removed from or retained in the population). Provide evidence to show its effectiveness (e.g. *vaccination* coverage, serosurveillance, etc.). Also provide evidence that the vaccine used complies with Chapter 2.1.5. in the *Terrestrial Manual*.
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability, including *vaccination* data. How are animal movements controlled in and between *zones* of the same or different status, in particular if the provisions of the *Terrestrial Code* in Article 8.8.10. are applied? Provide evidence on the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe the action taken when an illegal movement is detected. Provide information on detected illegal movements.

4. FMD diagnosis

Provide documentary evidence that the provisions of Chapters 1.1.2., 1.1.3. and 2.1.5. in the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the names of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points.
 - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
 - ii) Give details of performance in inter-laboratory proficiency tests.
 - iii) Provide details on the handling of live virus.
 - iv) *Biosecurity* measures applied.
 - v) Details of the type of tests undertaken and their performance for their applied use (specificity and sensitivity).
 - vi) Laboratory capacity in processing tests and samples.

Annex 9 (contd)5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.8.40. to 8.8.42. in the *Terrestrial Code* and Chapter 2.1.5. in the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis).
- b) *Surveillance*. Are serological and virological surveys conducted to demonstrate freedom from *infection*, in particular applying the provisions of Article 8.8.42.? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are *wildlife* susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the *zone*? How many *herds*, *flocks*, etc. of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) *Wildlife* demographics. What susceptible species are present in the country and in the *zone*? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and *wildlife* susceptible species?
- e) *Slaughterhouses*, markets and events associated with the congregation of FMD susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the FMD free *zone* with *vaccination* is situated in a FMD infected country or borders an infected country or *zone*, describe the *biosecurity* measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

- b) Are there controls in place for the feeding of swill containing animal products to pigs? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

Annex 9 (contd)

c) Import control procedures

From what countries or *zones* does the country authorise the import of susceptible animals or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying the country or *zone* of origin, the species and quantity.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
 - ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of and the disposal locations.
 - iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals,
 - genetic material (semen and embryos),
 - animal products,
 - *veterinary medicinal products* (i.e. biologics),
 - other materials at risk of being contaminated with FMDV.
 - iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on illegal imports detected.
- d) Describe and justify the corrective actions that have been implemented to prevent future FMD *outbreaks* in response to any past *disease* incursions.

7. Contingency planning and outbreak response programmes

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious *cases*, pending final diagnosis? What other procedures are followed regarding suspicious *cases* (e.g. livestock standstills)?
- c) In the event of a FMD *outbreak*:
 - i) indicate the sampling and testing procedures to be used to identify and confirm presence of the causative agent;

Annex 9 (contd)

- ii) describe the actions to be taken to report and control the disease situation in and around any *establishments* found to be infected with FMD;
- iii) indicate the control or eradication procedures (e.g. *vaccination*, *stamping-out policy*, partial slaughter or *vaccination*, methods of disposal of carcasses and other contaminated products or materials, decontamination, etc.) that would be taken. Include information on access to antigen and vaccine banks;
- iv) describe the procedures to be used to confirm successful control or eradication, including any restocking provisions, sentinel animal and serosurveillance programmes;
- v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control or eradication purposes and their prescribed timetable.

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.8.5. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating that:

- a) there has been no *outbreak* of FMD for the past two years,
- b) no evidence of FMDV transmission for the past 12 months,
- c) *surveillance* for FMD and FMDV transmission in accordance with Articles 8.8.40. to 8.8.42. is in operation.

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.8.7., and points 1, 3 and 4 of Article 8.8.3. in the *Terrestrial Code* and provide information as specified in sections 1 - 7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).

[Article 1.6.7.]

[Article 1.6.8.]

[Article 1.6.9.]

[Article 1.6.10.]

Article 1.6.11.

Questionnaire on FMD

COUNTRY WITH AN OIE ENDORSED OFFICIAL CONTROL PROGRAMME FOR FMD

Report of a Member Country which applies for the OIE endorsement
of its official control programme for FMD
under Chapter 8.8. of the *Terrestrial Code*

Annex 9 (contd)

Address concisely the following topics. National laws, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Provide a general description of geographical factors in the country and *zones*, including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that, although not adjacent, present a risk for the introduction of *disease*.
- b) If the endorsed plan is gradually implemented 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 precise text description of the geographical boundaries of the *zones*.
- c) Provide a general description of the livestock industry in the country and any *zones*.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to the FMD control programme.
- b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. in the *Terrestrial Code* and Article Chapter 1.1.3. in the *Terrestrial Code Manual* and describe how *Veterinary Services* supervise, control and maintain all FMD related activities in the country and any *zones*. Provide maps and tables wherever possible.
- c) Provide a description on the involvement and the participation of industry, producers, farmers, including subsistence and small scale producers, community animal health workers and the role of the private veterinary profession in FMD *surveillance* and control. Include a description of training and awareness programmes on FMD.
- d) Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS Pathway.
- e) Provide evidence that the legal framework and budget ensure that control and *surveillance* activities are implemented in an effective and sustainable way.

3. FMD control

- a) Provide a description of the FMD history in the country and any *zones*, including date of first detection, origin of *infection*, date of implementation of the control programme in the country and any *zones*, and types and subtypes of the FMDV present.
- b) Describe the general epidemiology of FMD in the country and the surrounding countries or *zones* highlighting the current knowledge and gaps.
- c) Describe how FMD is controlled in the country or any *zones*.
- d) Provide a description of the legislation, organisation and implementation of the FMD control programme. Indicate if detailed operational guidelines exist and give a brief summary.
- e) Provide information on what types of vaccines are used and which species are vaccinated. Provide information on the licensing process of the vaccines used. Describe the *vaccination* programme in the country and in any *zones*, including records kept, and provide evidence to show its effectiveness, such as *vaccination* coverage, population immunity, etc. Provide details on the studies carried out to determine the population immunity, including the study design.

Annex 9 (contd)

- f) Provide a description of the methods of *animal identification* (at the individual or group level), *herd* registration and traceability and how the movements of animals and products are assessed and controlled, including movement of infected animals to *slaughter*. Describe the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe measures to prevent introduction of FMDV from neighbouring countries or *zones* and through trade.
- g) Provide evidence of the impact of the control measures already implemented in the event of *outbreaks* on the reduction of distribution and numbers of *outbreaks*. If possible, provide information on primary and secondary *outbreaks*.

4. FMD surveillance

Provide documentary evidence on whether *surveillance* for FMD in the country complies with the provisions of Articles 8.8.40. to 8.8.42. in the *Terrestrial Code* and Chapter 2.1.5. in the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Describe the criteria for raising a suspicion of FMD and the procedure to notify (by whom and to whom) and what penalties are involved for failure to report.
- b) Describe how clinical *surveillance* is conducted, including which levels of the livestock production system are included in clinical *surveillance*, such as farms, markets, fairs, *slaughterhouses*, check points, etc. Provide criteria for selection of populations for targeted *surveillance* and numbers of animals examined and samples tested in diagnostic laboratories. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators. Explain whether serological and virological surveys are conducted and, if so, how frequently and for what purpose.
- c) Provide a summary table indicating, for at least the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details on follow-up actions taken on suspicious and positive results.
- d) Provide information on livestock demographics and economics, including the susceptible animal population by species and production systems in the country and the *zone*. Identify how many *herds*, *flocks*, etc. of each susceptible species are in the country and how they are distributed, such as *herd* density, etc. Provide tables and maps as appropriate.
- e) Provide information on the demographics and migration patterns of FMD susceptible *wildlife* species, including which susceptible species are present in the country and any *zones*. Provide estimates of population sizes and geographic distribution. Identify whether susceptible *wildlife* are included in *surveillance*. Identify the measures in place to prevent contact between domestic and susceptible *wildlife*.
- f) Identify the livestock slaughter, marketing and collection centres. Provide information on the patterns of livestock movement within the country, including how animals are transported and handled during these transactions.
- g) Provide information on circulating strains and 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.
- h) 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.

5. FMD laboratory diagnosis

Provide documentary evidence that the provisions of Chapters 1.1.2., 1.1.3. and 2.1.5. in the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of laboratories approved by the *Competent Authority* to diagnose FMD. If not, provide the names of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. If applicable, indicate the laboratory(ies) where samples originating from any *zone* are diagnosed. Is there regular submission of samples from the country or *zone* to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the standards and methods described in the *Terrestrial Manual*?
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
 - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system.
 - ii) Give details on participation in inter-laboratory validation tests (ring tests).
 - iii) Is live virus handled?
 - iv) *Biosecurity* measures applied.
 - v) Details of the type of tests undertaken.

6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country. In particular provide details on:

- a) Coordination with neighbouring countries, trading partners and other countries within the same region. Identify relevant factors about the adjacent countries and *zones* that should be taken into account such as size, distance from adjacent borders to affected *herds* or animals, *surveillance* carried in adjacent countries. Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*. Describe the measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation of the agent within the country or *zone* and through trade. Provide evidence that measures are in place at markets to reduce transmission of FMD such as enhancing awareness of FMD transmission mechanisms and behaviours that can interrupt transmission, implementation of good *biosecurity* practices, hygiene, cleaning and *disinfection* routines at critical points all along the production and marketing networks (typically where animals are being moved, and marketed through the country or region).
- b) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Are there controls in place for the feeding of swill containing animal products to pigs? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.
- c) Provide information on countries or *zones* 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 or *zones*, the controls applied on entry of such animals and products, and subsequent internal movement. Describe the import conditions and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health certificates are required. Describe any other procedures used. Provide summary statistics on imports of susceptible animals and their products for at least the past two years, specifying country or *zone* of origin, the species and the number or volume. Provide evidence that the import policy and the improved border controls have contributed to reducing the number of *outbreaks* or that *outbreaks* are not related to imports or transboundary movements of domestic animals.

Annex 9 (contd)

- i) Provide a map with the number and location of ports, airports and land crossings. Advise whether the service responsible for import controls is part of the official services, or if it is an independent body. If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste food from international traffic, who is responsible to supervise this and provide a summary, for the past two years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and their final destination, concerning the import and follow-up of the following:
 - animals,
 - genetic material (semen and embryos),
 - animal products,
 - *veterinary medicinal products*, i.e. biologics,
 - other livestock related goods potentially contaminated with FMDV including bedding, litter and feeds.
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on illegal imports detected, if available.

7. Control measures and emergency response

- a) Give details of any written guidelines, including emergency response plans, available to *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Advise whether quarantine is imposed on premises with suspicious *cases*, pending final diagnosis and any other procedures followed in respect of suspicious *cases*.
- c) In the event of a FMD *outbreak*:
 - i) provide a detailed description of procedures that are followed in case of an *outbreak* including forward and backward tracing;
 - ii) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
 - iii) describe the actions taken to control the disease situation in and around any *establishments* found to be infected with FMD;
 - iv) indicate the control or eradication procedures, such as *vaccination*, *stamping-out policy*, partial slaughter or *vaccination*, including *vaccination* delivery and cold chain, movement control, control of *wildlife*, pastured livestock and livestock as pets, control of the livestock waste, campaign to promote awareness of farmers, etc. that would be taken;
 - v) describe the procedures used to confirm that an *outbreak* has been successfully controlled or eradicated, including any restrictions on restocking;
 - vi) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control or eradication purposes and their prescribed timetable;
 - vii) describe how control efforts, including *vaccination* and *biosecurity* measures, have been targeted at critical risk control points.

8. Official control programme for FMD submitted for OIE endorsement

Submit a detailed plan on the measures, in addition to those described in point 3, for the control and eventual eradication of FMD in the Member Country, including:

- a) objectives,
- b) expected status to be achieved,
- c) timelines of the control programme,
- d) performance indicators and methods for their measurement and verification, including the progressive reduction in *outbreak* incidence towards elimination of FMDV transmission in all susceptible livestock in at least one *zone* of the country,
- e) description of the funding for the control programme and annual budgets for its duration,
- f) details, if applicable, on a proposed timeline for the transition to the use of vaccines, which are fully compliant with the *Terrestrial Manual* in order to enable demonstration of no evidence of FMDV transmission.

9. Recovery of official endorsement of the national FMD control programme

Member Countries applying for recovery of the official endorsement of the national FMD control programme should provide updated information in compliance with the provisions of Article 8.8.39. in the *Terrestrial Code*.

[Article 1.6.12.]

[Article 1.6.13.]

— Text deleted.

CHAPTER 3.2.

EVALUATION OF VETERINARY SERVICES

[Article 3.2.1.]

[Article 3.2.2.]

[Article 3.2.3.]

[Article 3.2.4.]

[Article 3.2.5.]

[Article 3.2.6.]

[Article 3.2.7.]

[Article 3.2.8.]

[Article 3.2.9.]

[Article 3.2.10.]

[Article 3.2.11.]

[Article 3.2.12.]

[Article 3.2.13.]

Article 3.2.14.

This article outlines appropriate information requirements for the self-evaluation or evaluation of the *Veterinary Services* of a country.

1. Organisation and structure of Veterinary Services

a) National Veterinary Authority

Organisational chart including numbers, positions and numbers of vacancies.

b) Sub-national components of the Veterinary Authority

Organisational charts including numbers, positions and number of vacancies.

c) Other providers of veterinary services

Description of any linkage with other providers of veterinary services.

2. National information on human resources

a) Veterinarians

- i) Total numbers of *veterinarians* registered or licensed by the *Veterinary statutory body* of the country.

Annex 10 (contd)

ii) Numbers of:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- private *veterinarians* authorised by the *Veterinary Services* to perform official veterinary functions [*Describe accreditation standards, responsibilities and limitations applying to these private veterinarians.*];
- other *veterinarians*.

iii) Animal health and welfare:

Numbers associated with farm livestock sector on a majority time basis in a veterinary capacity, by geographical area [*Show categories and numbers to differentiate staff involved in field service, laboratory, administration, import and export and other functions, as applicable.*]:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- other *veterinarians*.

iv) Veterinary public health:

Numbers employed in food inspection on a majority time basis, by commodity [*Show categories and numbers to differentiate staff involved in inspection, laboratory and other functions, as applicable.*]:

- full time government *veterinarians*: national and sub-national;
- part time government *veterinarians*: national and sub-national;
- other *veterinarians*.

v) Numbers of veterinarians relative to certain national indices:

- per total human population;
- per farm livestock population, by geographical area;
- per livestock farming unit, by geographical area.

vi) Veterinary education:

- number of veterinary schools;
- length of veterinary course (years);
- curriculum addressing the minimum competencies of day 1 veterinary graduates and the post-graduate and continuing education topics to assure the delivery of quality veterinary services, as described in the relevant chapter(s) of the *Terrestrial Code*;
- international recognition of veterinary degree.

vii) Veterinary professional associations.

Annex 10 (contd)

b) Graduate personnel (non-veterinary)

Details to be provided by category (including biologists, biometricians, economists, engineers, lawyers, other science graduates and others) on numbers within the *Veterinary Authority* and available to the *Veterinary Authority*.

c) Veterinary para-professionals employed by the Veterinary Services

i) Animal health and welfare:

- Categories and numbers involved with farm livestock on a majority time basis:
 - by geographical area;
 - proportional to numbers of field Veterinary Officers in the *Veterinary Services*, by geographical area.
- Education or training details.

ii) Veterinary public health:

- Categories and numbers involved in food inspection on a majority time basis:
 - *meat* inspection: export *meat* establishments with an export function and domestic *meat* establishments (no export function);
 - dairy inspection;
 - other foods.
- Numbers in import and export inspection.
- Education or training details.

d) Support personnel

Numbers directly available to *Veterinary Services* per sector (administration, communication, transport).

e) Descriptive summary of the functions of the various categories of staff mentioned above

f) Veterinary, *veterinary para-professionals*, livestock owner, farmer and other relevant associations

g) Additional information or comments.

3. Financial management informationa) Total budgetary allocations to the *Veterinary Authority* for the current and past two fiscal years:

- i) for the national *Veterinary Authority*;
- ii) for each of any sub-national components of the *Veterinary Authority*;
- iii) for other relevant government-funded institutions.

Annex 10 (contd)

- b) Sources of the budgetary allocations and amount:
 - i) government budget;
 - ii) sub-national authorities;
 - iii) taxes and fines;
 - iv) grants;
 - v) private services.
- c) Proportional allocations of the amounts in a) above for operational activities and for the programme components of *Veterinary Services*.
- d) Total allocation proportionate of national public sector budget. *[This data may be necessary for comparative assessment with other countries which should take into account the contexts of the importance of the livestock sector to the national economy and of the animal health status of the country.]*
- e) Actual and proportional contribution of animal production to gross domestic product.

4. Administration details

a) Accommodation

Summary of the numbers and distribution of official administrative centres of the *Veterinary Services* (national and sub-national) in the country.

b) Communications

Summary of the forms of communication systems available to the *Veterinary Services* on a nation-wide and local area bases.

c) Transport

- i) Itemised numbers of types of functional transport available on a full-time basis for the *Veterinary Services*. In addition provide details of transport means available part-time.
- ii) Details of annual funds available for maintenance and replacement of motor vehicles.

5. Laboratories engaged in diagnosis

- a) Descriptive summary of the organisational structure and role of the government veterinary laboratory service in particular its relevance to the field *Veterinary Services*.

Annex 10 (contd)

- b) Numbers of veterinary diagnostic laboratories operating in the country:
 - i) government operated *laboratories*;
 - ii) private *laboratories* authorised by *Veterinary Authority* for the purposes of supporting official or officially endorsed animal health control or public health testing and monitoring programmes and import and export testing.
 - c) Descriptive summary of accreditation procedures and standards for private *laboratories*.
 - d) Human and financial resources allocated to the government veterinary *laboratories*, including staff numbers, graduate and post-graduate qualifications and opportunities for further training.
 - e) List of diagnostic methodologies available against major *diseases* of farm livestock (including *poultry*).
 - f) List of related National Reference Laboratories, if any.
 - g) Details of collaboration with external *laboratories* including international reference *laboratories* and details on numbers of samples submitted.
 - h) Details of quality control and assessment (or validation) programmes operating within the veterinary laboratory service.
 - i) Recent published reports of the official veterinary laboratory service which should include details of specimens received and foreign animal disease investigations made.
 - j) Details of procedures for storage and retrieval of information on specimen submission and results.
 - k) Reports of independent reviews of the laboratory service conducted by government or private organisations (if available).
 - l) Strategic and operational plans for the official veterinary laboratory service (if available).
6. Institutes engaged in research
- a) Numbers of veterinary research institutes operating in the country:
 - i) government operated institutes;
 - ii) private institutes involved in full time research directly related to animal health and welfare, and veterinary public health matters involving production animal species.
 - b) Summary of human and financial resources allocated by government to veterinary research.
 - c) Published programmes of future government sponsored veterinary research.
 - d) Annual reports of the government research institutes.
7. Veterinary legislation, regulations and functional capabilities
- a) Animal health and animal welfare and veterinary public health
 - i) Assessment of the adequacy and implementation of relevant legislation (national or sub-national) concerning the following:

Annex 10 (contd)

- animal and veterinary public health controls at national frontiers;
 - control of endemic animal diseases, including *zoonoses*;
 - emergency powers for management of disasters which could have impact on animal health and *animal welfare*, and control of exotic disease *outbreaks*, including *zoonoses*;
 - inspection and registration of facilities;
 - animal feeding;
 - veterinary public health controls of the production, processing, storage and marketing of *meat* for domestic consumption;
 - veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other food of animal origin for domestic consumption;
 - registration and use of veterinary pharmaceutical products including vaccines;
 - *animal welfare*.
- ii) Assessment of ability of *Veterinary Services* to enforce legislation.
- b) Export and import inspection
- i) Assessment of the adequacy and implementation of relevant national legislation concerning:
- veterinary public health controls of the production, processing, storage and transportation of *meat* for export;
 - veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other food of animal origin for export;
 - animal health and veterinary public health controls of the export and import of *animals*, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;
 - animal welfare controls at export and import of *animals*;
 - animal health controls of the importation, use and bio-containment of organisms which are aetiological agents of animal *diseases*, and of pathological material;
 - animal health controls of importation of veterinary biological products including vaccines;
 - administrative powers available to *Veterinary Services* for inspection and registration of facilities for veterinary control purposes (if not included under other legislation mentioned above);
 - documentation and compliance.
- ii) Assessment of ability of *Veterinary Services* to enforce legislation.

8. Animal health, animal welfare and veterinary public health controls

a) Animal health

- i) Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services*.
- ii) Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services*.
- iii) Description and relevant data of current official control programmes including:
 - epidemiological *surveillance* or monitoring programmes;
 - officially approved industry administered control or eradication programmes for specific *diseases*.
- iv) Description and relevant details of animal disease emergency preparedness and response plans.
- v) Recent history of animal disease status:
 - animal *diseases* eradicated nationally or from defined sub-national zones in the last ten years;
 - animal *diseases* of which the prevalence has been controlled to a low level in the last ten years;
 - animal *diseases* introduced to the country or to previously free sub national regions in the last ten years;
 - *emerging diseases* in the last ten years;
 - animal *diseases* of which the prevalence has increased in the last ten years.

b) Animal welfare

- i) Description of major animal welfare issues.
- ii) Description of specific official programmes initiated by the *Veterinary Services* to address animal welfare problems.

c) Veterinary public health

i) Food hygiene

- Annual national *slaughter* statistics for the past three years according to official data by species of *animals* (bovine, ovine, porcine, caprine, *poultry*, farmed game, wild game, equine, other).
- Estimate of total annual slaughterings which occur but are not recorded under official statistics.
- Proportion of total national *slaughter* which occurs in registered export establishments, by category of *animal*.
- Proportion of total national *slaughter* which occurs under veterinary control, by category of *animal*.

Annex 10 (contd)

- Numbers of commercial *fresh meat* establishments in the country which are registered for export by the *Veterinary Authority*:
 - *slaughterhouses* (indicate species of *animals*);
 - cutting or packing plants (indicate *meat* type);
 - *meat* processing establishments (indicate *meat* type);
 - cold stores.
 - Numbers of commercial *fresh meat* establishments in the country approved by other *importing countries* which operate international assessment inspection programmes associated with approval procedures.
 - Numbers of commercial *fresh meat* establishments under direct public health control of the *Veterinary Services* (including details of category and numbers of inspection staff associated with these premises).
 - Description of the veterinary public health programme related to production and processing of animal products for human consumption (including *fresh meat*, *poultry meat*, *meat products*, game *meat*, dairy products, fish, fishery products, molluscs and crustaceans and other foods of animal origin) especially including details applying to exports of these *commodities*.
 - Descriptive summary of the roles and relationships of other official organisations in public health programmes for the products listed above if the *Veterinary Authority* does not have responsibility for those programmes which apply to national production destined to domestic consumption or exports of the *commodities* concerned.
- ii) Zoonoses
- Descriptive summary of the numbers and functions of staff of the *Veterinary Authority* involved primarily with monitoring and control of zoonotic diseases.
 - Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of *zoonoses* to be provided if the *Veterinary Authority* does not have these responsibilities.
- iii) Chemical residue testing programmes
- Descriptive summary of national surveillance and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, *animals* and animal feedstuffs.
 - Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.
 - Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.
- iv) Veterinary medicines
- Descriptive summary of the administrative and technical controls involving registration, supply and use of veterinary pharmaceutical products especially including biological products. This summary should include a focus on veterinary public health considerations relating to the use of these products in food-producing animals.
 - Role and function in these programmes of the *Veterinary Authority* and other *Veterinary Services* to be described in summary form.

9. Quality systems

a) Accreditation

Details and evidence of any current, formal accreditation by external agencies of the *Veterinary Services* of any components thereof.

b) Quality manuals

Documented details of the quality manuals and standards which describe the accredited quality systems of the *Veterinary Services*.

c) Audit

Details of independent (and internal) audit reports which have been undertaken of the *Veterinary Services* of components thereof.

10. Performance assessment and audit programmes

a) Strategic plans and review

i) Descriptive summary and copies of strategic and operational plans of the *Veterinary Services* organisation.

ii) Descriptive summary of corporate performance assessment programmes which relate to the strategic and operational plans - copies of recent review reports.

b) Compliance

Descriptive summary of any compliance unit which monitors the work of the *Veterinary Services* (or elements thereof).

c) Annual reports of the *Veterinary Authority*

Copies of official annual reports of the national (sub-national) *Veterinary Authority*.

d) Other reports

i) Copies of reports of official reviews into the function or role of the *Veterinary Services* which have been conducted within the past three years.

ii) Descriptive summary (and copy of reports if available) of subsequent action taken on recommendations made in these reviews.

e) Training

i) Descriptive summary of in-service and development programmes provided by the *Veterinary Services* (or their parent Ministries) for relevant staff.

ii) Summary descriptions of training courses and duration.

iii) Details of staff numbers (and their function) who participated in these training courses in the last three years.

f) Publications

Bibliographical list of scientific publications by staff members of *Veterinary Services* in the past three years.

Annex 10 (contd)

g) Sources of independent scientific expertise

List of local and international universities, scientific institutions and recognised veterinary organisations with which the *Veterinary Services* have consultation or advisory mechanisms in place.

11. Membership of the OIE

State if country is a member of the OIE and period of membership.

— Text deleted.

CHAPTER 5.3.

OIE PROCEDURES RELEVANT TO THE AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES OF THE WORLD TRADE ORGANIZATION

Article 5.3.1.

The Agreement on the Application of Sanitary and Phytosanitary Measures and role and responsibility of the OIE

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) encourages the Members of the World Trade Organization to base their *sanitary measures* on international standards, guidelines and recommendations, where they exist. Members may choose to implement sanitary measures more stringent ~~adopt a higher level of protection than that provided by those in~~ international standards texts if there is a scientific justification ~~or if the level of protection provided by the relevant international texts is considered to be inappropriate~~. In such circumstances, Members are subject to obligations relating to *risk assessment* and to a consistent approach of *risk management*.

~~The SPS Agreement encourages Governments to make a wider use of risk analysis: WTO Members shall undertake an assessment as appropriate to the circumstances of the actual risk involved.~~

The SPS Agreement, in Article 7, obliges WTO Members to notify changes in, and provide relevant information on, sanitary measures which may, directly or indirectly, affect international trade.

The SPS Agreement recognises the OIE as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live *animals* and animal products.

Article 5.3.2.

Introduction on the judgement of the equivalence of sanitary measures

The importation of *animals* and animal products involves a degree of *risk* to the *animal health status* and human health status of an *importing country*. The estimation of that *risk* and the choice of the appropriate *risk management* option(s) are made more difficult by differences among the animal health management systems and animal production systems in Member Countries. However, it is now recognised that significantly different animal health and production systems can provide equivalent animal and human health protection for the purposes of international trade, with benefits to both the importing country and the exporting country.

These recommendations are to assist Member Countries to determine whether *sanitary measures* arising from different ~~animal health and production~~ systems may provide the same level of animal and human health protection. They discuss principles which might be utilised in a judgement of equivalence, and outline a step-wise process for trading partners to follow in determining ~~facilitating a judgement of~~ equivalence. These provisions are applicable whether equivalence applies ~~at the level of~~ to specific measures or on a systems-wide basis, and whether equivalence applies to specific areas of trade or *commodities*, or generally.

Annex 11 (contd)

Article 5.3.3.

General considerations on the judgement of the equivalence of sanitary measures

Before trade in *animals* or their products may occur, an *importing country* must be satisfied that its *animal health status and human health* will be appropriately protected. In most cases, the *risk management* measures adopted ~~drawn up~~ will rely in part on judgements made about the animal health and production system(s) in the *exporting country* and the effectiveness of *sanitary measures* ~~procedures~~ applied ~~undertaken~~ there. Systems operating in the *exporting country* may differ from those in the *importing country* and from those in other countries with which the *importing country* has traded. Differences may be with respect to infrastructure, policies ~~and/or~~ operating procedures, *laboratory* systems, approaches to control of ~~the pests and diseases~~ present, border security and internal movement controls.

~~International recognition of the legitimacy of different approaches to achieving the importing country's appropriate level of protection (ALOP) has led to the principle of equivalence being included in trade agreements, including the SPS Agreement of the WTO.~~

Benefits of applying equivalence may include:

- 1) minimising costs associated with international trade by tailoring sanitary measures ~~animal health measures~~ to local circumstances;
- 2) maximising animal health outcomes for a given level of resource input;
- 3) facilitating trade by achieving the required health protection through less trade restrictive *sanitary measures*; and
- 4) decreased reliance on relatively costly commodity testing and isolation procedures in bilateral or multilateral agreements.

The *Terrestrial Code* recognises equivalence by recommending alternative *sanitary measures* for many *diseases, infections* and *infestations* ~~pathogenic agents~~. Equivalence may be gained, for example, by enhanced *surveillance* and monitoring, by the use of alternative test, treatment or isolation procedures, or by combinations of the above.

To facilitate the judgement of equivalence, Member Countries should base their *sanitary measures* on the standards, and guidelines ~~and recommendations~~ of the OIE.

~~It is essential to apply a scientific~~ Member Countries should use *risk analysis* ~~to the extent practicable in~~ establishing the basis for a judgement of equivalence.

Article 5.3.4.

Prerequisite considerations in a judgement of equivalence1. Application of risk assessment

~~Application of the discipline of~~ *Risk assessment* provides a structured basis for judging equivalence among different *sanitary measures* as it allows a comparison ~~close examination to be made~~ of the effect of a measure(s) on a particular step(s) in the importation pathway, ~~and the relative~~ with the effects of a proposed alternative measure(s) ~~on the same or related steps~~.

A judgement of equivalence should ~~needs to~~ assess the *sanitary measure* in terms of its effectiveness against ~~regarding~~ the particular *risk* or group of *risks* against which it ~~the~~ measure is designed to protect. ~~Such an assessment may include the following elements: the purpose of the measure, the level of protection achieved by the measure and the contribution the measure makes to achieving the ALOP of the importing country.~~

2. Categorisation of sanitary measures

Proposals for equivalence may be in terms of a measure comprising a single component of a measure (e.g. an isolation procedure, a test or treatment requirement, a certification procedure) or multiple components (e.g. a production system for *commodity*), or a combination of measures. Multiple components or combinations of measures may be applied consecutively or concurrently.

Sanitary measures are ~~those~~ described in each disease-specific chapter of the *Terrestrial Code* which ~~are used for reducing risks reduction and are appropriate for particular posed by that diseases, infection or infestation.~~ *Sanitary measures* may be applied either alone or in combination and include test requirements, processing requirements, inspection or certification procedures, quarantine confinements, and sampling procedures.

For the purposes of judging equivalence, *sanitary measures* can be broadly categorised as:

- a) infrastructure: including the legislative base (e.g. animal health law) and administrative systems (e.g. organisation of Veterinary Services ~~national and regional animal health authorities, emergency response organisations~~);
- b) programme design and implementation: including documentation of systems, performance and decision criteria, *laboratory* capability, and provisions for certification, audit and enforcement;
- c) specific technical requirement: including requirements applicable to the use of secure facilities, treatment (e.g. retorting of cans), specific test (e.g. ELISA) and procedures (e.g. pre-export inspection).

A Sanitary measure(s) proposed for a judgement of equivalence may fall into one or more of these categories, which are not mutually exclusive.

In some cases, such as a method for pathogen inactivation, a comparison of specific technical requirements may suffice. In many instances, however, a judgement as to whether the same level of protection is likely to be achieved may only be ~~able to be~~ determined through an evaluation of all relevant components of an *exporting country's* animal health management systems and animal production system. ~~For example, a judgement of equivalence for a specific sanitary measure at the programme design/implementation level may require a prior examination of infrastructure while a judgement of equivalence for a specific measure at the specific technical requirement level may require that the specific measure be judged in its context through examination of infrastructure and programmes.~~

Article 5.3.5.

Principles for judgement of equivalence

In conjunction with the above considerations, judgement of the equivalence of *sanitary measures* should be based on application of the following principles:

- 1) an *importing country* has the right to set the level of protection it deems appropriate (~~its ALOP~~) in relation to human and animal life and health in its territory; this ALOP may be expressed in qualitative or quantitative terms;
- 2) the *importing country* should be able to describe the reason for each *sanitary measure* i.e. the level of protection intended to be achieved by application of the identified measure against a *hazard*;
- 3) an *importing country* should recognise that *sanitary measures* different from the ones it has proposed may be capable of providing the same level of protection, in particular, it should consider the existence of specified disease-free zones/regions or compartments;
- 4) the *importing country* should, upon request, enter into consultations with the *exporting country* with the aim of facilitating a judgement of equivalence;

Annex 11 (contd)

- 5) any *sanitary measure* or combination of *sanitary measures* can be proposed for judgement of equivalence;
- 6) an interactive process should be followed that applies a defined sequence of steps, and utilises an agreed process for exchange of information, so as to limit data collection to that which is necessary, to minimise administrative burden, and to facilitate resolution of claims;
- 7) the *exporting country* should be able to demonstrate objectively how the alternative *sanitary measure(s)* proposed as equivalent will provide the same level of protection;
- 8) the *exporting country* should present a submission for equivalence in a form that facilitates judgement by the *importing country*;
- 9) the *importing country* should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner, and in accordance with appropriate *risk assessment* principles;
- 10) the *importing country* should take into account any knowledge of and prior experience with the *Veterinary Authority* or other *Competent Authority* of the *exporting country*;
- 11) the *exporting country* should provide access to enable the procedures or systems which are the subject of the equivalence judgement to be examined and evaluated upon request of the *importing country*;
- 12) the *importing country* should be the sole determinant of equivalence, but should provide to the *exporting country* a full explanation for its judgement;
- 13) to facilitate a judgement of equivalence, Member Countries should base their *sanitary measures* on relevant OIE standards, where these exist;
- 14) to allow the judgement of equivalence to be reassessed if necessary, the *importing country* and the *exporting country* should keep each other informed of significant changes to infrastructure, health status or programmes which may bear on the judgement of equivalence; and
- 15) ~~appropriate technical assistance from an importing country, following a should give positive consideration to a request by an exporting developing country, for appropriate technical assistance that would may facilitate the successful completion of a judgement of equivalence.~~

Article 5.3.6.

Sequence of steps to be taken in judgement of equivalence

There is no single sequence of steps which must be followed in all judgements of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. Nevertheless, ~~the~~ interactive sequence of steps described below may be useful for assessing any all sanitary measures irrespective of their categorisation as infrastructure, programme design, and implementation or specific technical requirement components of an animal health management system or and animal production system.

This sequence assumes that the importing country is meeting its obligations under the WTO SPS Agreement and has in place a transparent measure based either on an international standard or a *risk analysis*.

Recommended steps are:

- 1) the *exporting country* identifies the measure(s) for which it wishes to propose an alternative ~~measure(s)~~, and requests from the *importing country* a reason for its *sanitary measure* in terms of the level of protection intended to be achieved against a *hazard(s)*;
- 2) the *importing country* explains the reason for the measure(s), in terms that ~~which~~ would facilitate comparison with an alternative *sanitary measure(s)* and consistent with the principles set out in these provisions;
- 3) the *exporting country* demonstrates the case for equivalence of an alternative *sanitary measure(s)* in a form which facilitates evaluation analysis by an *importing country*;

Annex 11 (contd)

- 4) the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;
- 5) judgement of equivalence by the *importing country* should takes into account as appropriate:
 - a) the impact of biological variability and uncertainty;
 - b) the expected effect of the alternative *sanitary measure(s)* on all relevant hazards;
 - c) OIE standards;
 - d) application of ~~solely qualitative frameworks where it is not possible or reasonable to conduct quantitative risk assessment;~~
- 6) the *importing country* notifies the *exporting country* of its judgement and its ~~the underlying~~ reasons within a reasonable period of time. The judgement:
 - a) ~~recognitions~~ uses of the equivalence of the *exporting country's* alternative *sanitary measure(s)*; or
 - b) ~~requests for~~ further information; or
 - c) ~~rejections~~ of the case for equivalence of the alternative *sanitary measure(s)*;
- 7) an attempt should be made to resolve any differences of opinion over judgement of a case, ~~either interim or final,~~ by using an agreed mechanism such as to reach consensus (e.g. the OIE informal procedure for dispute mediation), ~~or by referral to an agreed expert (Article 5.3.8.);~~
- 8) depending on the category of measures involved, the *importing country* and the *exporting country* may enter into a formal or informal agreement of equivalence ~~agreement~~ giving effect to the judgement ~~or a less formal acknowledgement of the equivalence of a specific measure(s) may suffice.~~

An *importing country* recognising the equivalence of an *exporting country's* alternative *sanitary measure(s)* ~~needs to~~ should ensure that it acts consistently with regard to applications from third countries for recognition of equivalence applying to the same or a very similar measure(s). Consistent action does not mean however that a specific measure(s) proposed by several *exporting countries* should always be judged as equivalent because as a measure(s) should not be considered in isolation but as part of a system of infrastructure, policies and procedures.

Article 5.3.7.

Sequence of steps to be taken in establishing a zone/ ~~or~~ compartment and having it recognised for international trade purposes

The establishment ~~There is no single sequence of steps which should be followed in establishing of a disease-free zone or a compartment is described in Chapter 4.3 and should be considered by trading partners when establishing sanitary measures for trade. The steps that the Veterinary Services of the importing country and the exporting country choose and implement will generally depend on the circumstances existing within the countries and at their borders, and their trading history. The~~ Recommended steps are:

1. For zoning
 - a) The *exporting country* identifies a geographical area within its territory, which it considers to contain an animal *subpopulation* with a distinct health status with respect to a specific ~~disease/specific diseases,~~ infection or infestation, based on surveillance.
 - b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures ~~which are being, or will be,~~ applied to distinguish such an area epidemiologically from other parts of its territory, in accordance with the recommendations in the *Terrestrial Code*.

Annex 11 (contd)

- c) The *exporting country* provides:
 - i) the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separate *zone* for *international trade* purposes;
 - ii) access to enable the procedures or systems that establish the *zone* to be examined and evaluated upon request by the *importing country*.
- d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *animals* and animal products, taking into account:
 - i) an evaluation of the *exporting country's Veterinary Services*;
 - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
 - iii) its own animal health situation with respect to the *disease(s)* concerned; and
 - iv) other relevant OIE standards.
- e) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:
 - i) recognition of the *zone*; or
 - ii) request for further information; or
 - iii) rejection of the area as a *zone* for *international trade* purposes.
- f) An attempt should be made to resolve any differences over recognition of the *zone*, ~~either in the interim or finally~~, by using an agreed mechanism ~~to reach consensus~~ such as the OIE informal procedure for dispute mediation (Article 5.3.8.).
- g) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognising the *zone*.

2. For compartmentalisation

- a) Based on discussions with the relevant industry, the *exporting country* identifies within its territory a *compartment* comprising an animal *subpopulation* contained in one or more *establishments* or other premises operating under common management practices ~~and related to biosecurity~~. The *compartment* contains an identifiable animal *subpopulation* with a distinct health status with respect to a specific *disease(s)*. The *exporting country* describes how this status is maintained through a partnership between the relevant industry and the *Veterinary Authority* of the *exporting country*.
- b) The *exporting country* examines the *compartment's biosecurity plan* and confirms through an audit that:
 - i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and
 - ii) the *surveillance* and monitoring programme in place is appropriate to verify the status of such a *subpopulation* with respect to ~~such~~ the disease(s) in question.
- c) The *exporting country* describes the *compartment*, in accordance with ~~the recommendations in the Terrestrial Code Chapters 4.3. and 4.4.~~

Annex 11 (contd)

- d) The *exporting country* provides:
- i) the above information to the *importing country*, with an explanation of why such a *subpopulation* can be treated as an epidemiologically separate *compartment* for *international trade* purposes; and
 - ii) access to enable the procedures or systems that establish the *compartment* to be examined and evaluated upon request by the *importing country*.
- e) The *importing country* determines whether it accepts such a *subpopulation* as a *compartment* for the importation of *animals* ~~or~~ and animal products, taking into account:
- i) an evaluation of the *exporting country's Veterinary Services*;
 - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
 - iii) its own animal health situation with respect to the disease(s) concerned; and
 - iv) other relevant OIE standards.
- f) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:
- i) recognition of the *compartment*; or
 - ii) request for further information; or
 - iii) rejection of such a *subpopulation* as a *compartment* for *international trade* purposes.
- g) An attempt should be made to resolve any differences over recognition of the *compartment*, ~~either in the interim or finally~~, by using an agreed mechanism ~~to reach consensus~~ such as the OIE informal procedure for dispute mediation (Article 5.3.8.).
- h) The *Veterinary Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognising the *compartment*.
- i) The *Veterinary Authority* of the *exporting country* should promptly inform *importing countries* of any occurrence of a *disease* in respect of which the *compartment* was defined.

Article 5.3.8.

The OIE informal procedure for dispute mediation

OIE shall maintain ~~its existing~~ a voluntary in-house mechanisms for assisting Member Countries to resolve differences. In-house procedures ~~that which~~ will apply are that:

- 1) Both parties agree to give the OIE a mandate to assist them in resolving their differences.
- 2) If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.
- 3) Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.

Annex 11 (contd)

- 4) The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.
- 5) The expert or experts shall submit a confidential report to the Director General of the OIE, who will transmit it to both parties.

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CHAPTER 6.7.

HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

Article 6.7.1.

Objective

This chapter provides criteria for the:

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

Article 6.7.2.

Purpose of surveillance and monitoring

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

Surveillance and monitoring of antimicrobial resistance is necessary to:

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

Article 6.7.3.

The development of antimicrobial resistance surveillance and monitoring programmes

1. General aspects

Surveillance of antimicrobial resistance at targeted intervals or ongoing monitoring of the prevalence of resistance in bacteria from *animals*, food, environment and humans, constitutes a critical part of animal health and food safety strategies aimed at limiting the spread of antimicrobial resistance and optimising the choice of *antimicrobial agents* used in therapy.

Annex 12 (contd)

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

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

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

2. Sampling strategies

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

3. Sample size

The sample size should be large enough to allow detection of existing and emerging antimicrobial resistance phenotypes.

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

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

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

4. Sample sources

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

a) Animal feed

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

b) Food producing animals

Categories of food producing animals considered for sampling should be relevant to the country's production system.

c) Food

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

5. Type of sample to be collected

Feed samples should be collected in amounts sufficient for isolation of resistant bacteria of concern (at least 25 g) and should be linked to pathogen surveillance programmes.

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

Annex 12 (contd)

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

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

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

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

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

6. Bacterial isolates

The following categories of bacteria could be monitored:

a) Animal bacterial pathogens relevant to the countries' priorities

Monitoring of antimicrobial resistance in animal pathogens is important, both to:

- i) detect emerging resistance that may pose a concern for animal and human health;
- ii) guide *veterinarians* in their prescribing decisions.

Information on the occurrence of antimicrobial resistance in animal pathogens is in general derived from routine clinical material sent to veterinary diagnostic *laboratories*. These samples, often derived from severe or recurrent clinical cases including therapy failure, may provide biased information.

b) Zoonotic bacteria

i) *Salmonella*

Salmonella should be sampled from animal feed, food producing animals and animal derived food products. For the purpose of consistency and harmonisation, samples should be preferably taken at the *abattoir*.

Annex 12 (contd)

Surveillance and monitoring programmes may also include bacterial isolates obtained from designated national *laboratories* originating from other sources.

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

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

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

ii) *Campylobacter*

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

iii) Other emerging bacterial pathogens

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

c) Commensal bacteria

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

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

7. Storage of bacterial strains

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

8. Antimicrobial susceptibility testing

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

Appropriately validated antimicrobial susceptibility testing methods should be used in accordance with Guideline 3.1. of the *Terrestrial Manual*, concerning laboratory methodologies for bacterial antimicrobial susceptibility testing. Antimicrobial susceptibility data should be reported quantitatively (minimum inhibitory concentrations [MICs] or inhibition zone diameters), rather than qualitatively.

Annex 12 (contd)9. Recording, storage and interpretation of data

- a) Because of the volume and complexity of the information to be stored and the need to keep these data available for an undetermined period of time, careful consideration should be given to database design.
- b) The storage of raw (primary, non-interpreted) data is essential to allow the evaluation in response to various kinds of questions, including those arising in the future.
- c) Consideration should be given to the technical requirements of computer systems when an exchange of data between different systems (comparability or compatibility of automatic recording of laboratory data and transfer of these data between and within resistance monitoring programmes) is envisaged. Results should be collected in a suitable national database. They should be recorded quantitatively:
 - i) as distributions of MICs in micrograms per millilitre;
 - ii) or inhibition zone diameters in millimetres.
- d) The information to be recorded should include, where possible, the following aspects:
 - i) sampling programme;
 - ii) sampling date;
 - iii) animal species and production type;
 - iv) type of sample;
 - v) purpose of sampling;
 - vi) type of antimicrobial susceptibility testing method used;
 - vii) geographical origin (geographical information system data where available) of *herd, flock or animal*;
 - viii) *animal* factors (e.g. age, condition, health status, identification, sex).
- e) The reporting of *laboratory* data should include the following information:
 - i) identity of *laboratory*,
 - ii) isolation date,
 - iii) reporting date,
 - iv) bacterial species,and, where relevant, other typing characteristics, such as:
 - v) serotype or serovar,
 - vi) phage type,
 - vii) antimicrobial susceptibility result or resistance phenotype,
 - viii) genotype.

Annex 12 (contd)

- f) The proportion of isolates regarded as resistant should be reported, including the defined interpretive criteria used.
- g) In the clinical setting, breakpoints are used to categorise bacterial strains as susceptible, intermediate or resistant. These clinical breakpoints may be elaborated on a national basis and may vary between Member Countries.
- h) The antimicrobial susceptibility testing standards and guidelines used should be recorded.
- i) For surveillance purposes, use of the microbiological breakpoint (also referred to as epidemiological cut-off point), which is based on the distribution of MICs or inhibition zone diameters of the specific bacterial species tested, is preferred. When using microbiological breakpoints, only the bacterial population with acquired resistance that clearly deviates from the distribution of the normal susceptible population will be designated as resistant.
- j) Ideally, data should be collected at the individual isolate level, allowing antimicrobial resistance patterns to be recorded.

10. Reference laboratory and annual reports

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

— Text deleted.

CHAPTER 6.8.

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

Article 6.8.1.

Definition and purpose

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

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

In order to evaluate antimicrobial exposure in food-producing animals, quantitative information should be collected to monitor usage patterns by animal species, antimicrobial agents or class, type of use (therapeutic or non-therapeutic) and route of administration.

Article 6.8.2.

Objectives

The information provided in these recommendations is essential for antimicrobial resistance *risk analyses* and planning purposes and should be read in conjunction with Chapters 6.7. and 6.10. This information is necessary for interpreting antimicrobial resistance surveillance data and can assist in responding to problems of antimicrobial resistance in a precise and targeted way. The continued collection of this basic information will also help to give an indication of trends in the use of *antimicrobial agents* in *animals* over time and potential associations with antimicrobial resistance in *animals*. This information may also assist in *risk management* to evaluate the effectiveness of efforts to ensure responsible and prudent use and mitigation strategies (for example, by identifying changes in veterinary prescribing practices) and to indicate where change of antimicrobial usage practices might be appropriate. The publication of these data is important to ensure transparency and to allow all interested parties to assess trends, to perform *risk assessments* and for *risk communication* purposes.

Article 6.8.3.

Development and standardisation of antimicrobial monitoring systems

Systems to monitor antimicrobial usage consist of the following elements:

1. Sources of antimicrobial data

a) Basic sources

Sources of data will vary from country to country. Such sources may include customs, import and export data, manufacturing and sales data.

b) Direct sources

Data from *veterinary medicinal product* registration authorities, wholesalers, retailers, pharmacists, *veterinarians*, feed stores, feed mills and pharmaceutical industry associations can be efficient and practical sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by pharmaceutical manufacturers to the regulatory authority one of the requirements of antimicrobial registration.

Annex 13 (contd)

c) End-use sources (veterinarians and food animal producers)

This may be appropriate when basic or direct sources cannot be used for the routine collection of the information or when more accurate and locally specific information is required (such as off label use).

Periodic collection of this type of information may be sufficient.

Collection, storage and processing of data from end-use sources should be carefully designed, well managed and have the capability to produce accurate and targeted information.

d) Other sources

Non-conventional sources including Internet sales data related to *antimicrobial agents* could be collected where available.

Member Countries may wish to consider, for reasons of cost and administrative efficiency, collecting medical, food-producing animal, agricultural and other antimicrobial use data in a single programme. A consolidated programme would also facilitate comparisons of animal use with human use data for *risk analysis* purposes and help to promote optimal usage of *antimicrobial agents*.

2. Types and reporting formats of antimicrobial usage data

a) Type of antimicrobial use data

The data collected at minimum should be the weight in kilograms of the active ingredient of the antimicrobial(s) used in food-producing animals per year. It is possible to estimate total usage by collecting sales data, prescribing data, manufacturing data, import and export data or any combination of these.

The total number of food-producing animals by species, type of production and their weight in kilograms for food production per year (as relevant to the country of production) is essential basic information.

Information on dosage regimens (dose, dosing interval and duration of the treatment) and route of administration are elements to include when estimating antimicrobial usage in food-producing animals.

b) Reporting formats of antimicrobial use data

The *antimicrobial agents*, classes or sub-classes to be included in data reporting should be based on current known mechanisms of antimicrobial activity and antimicrobial resistance data.

Nomenclature of *antimicrobial agents* should comply with international standards where available.

For active ingredients present in the form of compounds or derivatives, the mass of active entity of the molecule should be recorded. For *antimicrobial agents* expressed in International Units, the factor used to convert these units to mass of active entity should be stated.

The reporting of antimicrobial use data may be further organised by species, by route of administration (specifically in-feed, in-water, injectable, oral, intramammary, intra-uterine and topical) and by type of use (therapeutic or non-therapeutic).

Regarding data coming from end-use sources, further breakdown of data for analysis of antimicrobial use at the regional, local, *herd* and individual *veterinarian* or veterinary practice levels may be possible.

Article 6.8.4.

Interpretation

According to the OIE *risk assessment* guidelines (refer to Chapter 6.10.), factors such as the number or percentage of *animals* treated, treatment regimes, type of use and route of administration are key elements to consider.

When comparing antimicrobial use data over time, changes in the size and composition of animal populations should also be taken into account.

The interpretation and communication of results should take into account factors such as seasonality and disease conditions, animal species and age affected, agricultural systems (e.g. extensive range conditions and feedlots), animal movements, and dosage regimens with *antimicrobial agents*.

— Text deleted.

CHAPTER 8.16.

INFECTION WITH *TRICHINELLA* SPP.

Article 8.16.1.

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 adult parasite and the larval forms live in the small intestine and muscles (respectively) of many mammalian, avian and reptile host species. Within the genus *Trichinella*, twelve genotypes have been identified, eight 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. infection* 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 domesticus*), 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 authorising the import or transit of the *commodities* covered in this chapter, with the exception of those listed in Article 8.16.2., *Veterinary Authorities* should apply the recommendations in this chapter.

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

Article 8.16.2.

Safe commodities

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

- 1) hides, skins, hair and bristles;
- 2) semen, embryos and oocytes.

Article 8.16.3.

Measures to prevent infection in domestic pig herds kept under controlled management conditions

- 1) Prevention of *infection* is dependent on minimising exposure to potential sources of *Trichinella*:

Annex 14 (contd)

- a) facilities and the surrounding environment should be managed to prevent exposure of pigs to rodents and *wildlife*;
 - b) raw food waste of animal origin should not be present at the farm level and should not be fed to pigs;
 - c) feed should comply with the requirements in Chapter 6.3. and should be stored in a manner to prevent access by rodents and *wildlife*;
 - d) a rodent control programme should be in place;
 - e) dead *animals* should be immediately removed and disposed of in accordance with Chapter 4.12.;
 - f) introduced pigs should originate from *herds* officially recognised as being under controlled management conditions as described in point 2, or from *herds* of a *compartment* with a negligible risk of *Trichinella* infection, as described in Article 8.16.5.
- 2) The *Veterinary Authority* may officially recognise pig *herds* as being under controlled management conditions if:
- a) all management practices described in point 1 are complied with and recorded;
 - b) visits by approved auditors have been made periodically to verify compliance with good management practices described in point 1; the frequency of inspections should be *risk*-based, taking into account historical information, *slaughterhouse* monitoring results, knowledge of established farm management practices and the presence of susceptible *wildlife*;
 - c) a subsequent programme of audits is conducted, taking into account the factors described in point b).

Article 8.16.4.

Prerequisite criteria for the establishment of compartments with a negligible risk of *Trichinella* infection in domestic pigs kept under controlled management conditions

Compartments with a negligible risk of *Trichinella* infection in domestic pigs kept under controlled management conditions can only be established in countries, in which the following criteria, as applicable, are met:

- 1) *Trichinella* infection is notifiable in the whole territory and communication procedures on the occurrence of *Trichinella* infection are established between the *Veterinary Authority* and the public health authority;
- 2) the *Veterinary Authority* has knowledge of, and authority over, all domestic pigs;
- 3) the *Veterinary Authority* has current knowledge of the distribution of susceptible species of *wildlife*;
- 4) an *animal identification* and *animal traceability* system for domestic pigs is implemented in accordance with Chapters 4.1. and 4.2.;
- 5) *Veterinary Services* have the capability to assess the epidemiological situation, detect the presence of *Trichinella* infection (including genotype, if relevant) in domestic pigs and identify exposure pathways.

Article 8.16.5.

Compartment with a negligible risk of *Trichinella* infection in domestic pigs kept under controlled management conditions

The *Veterinary Authority* may recognise a *compartment* in accordance with Chapter 4.4. as having negligible risk of *Trichinella* infection in domestic pigs kept under controlled management conditions if the following conditions are met:

- 1) all *herds* of the *compartment* comply with the requirements in Article 8.16.3.

Annex 14 (contd)

- 2) Article 8.16.4. has been complied with for at least 24 months;
- 3) the absence of *Trichinella infection* in the *compartment* has been demonstrated by a *surveillance* programme which takes into account current and historical information, and *slaughterhouse* monitoring results, as appropriate, in accordance with Chapter 1.4.;
- 4) once a *compartment* is established, a subsequent programme of audits of all *herds* within the *compartment* is in place to ensure compliance with Article 8.16.3.;
- 5) if an audit identifies a lack of compliance with the criteria described in Article 8.16.3. and the *Veterinary Authority* determines this to be a significant breach of *biosecurity*, the *herd(s)* concerned should be removed from the *compartment* until compliance is re-established.

Article 8.16.6.

Recommendations for the importation of meat or meat products of domestic pigs

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

- 1) has been produced in accordance with the Codex Code of Hygienic Practice for Meat (CAC/RCP 58-2005);

AND

- 2) either:
 - a) comes from domestic pigs originating from a *compartment* with a negligible risk for *Trichinella infection* in accordance with Article 8.16.5.;

OR

 - b) comes from domestic pigs that tested negative by an approved method for the detection of *Trichinella* larvae;

OR

 - c) was processed to ensure the inactivation of *Trichinella* larvae in accordance with the Codex Guidelines for the control of *Trichinella* spp. in meat of Suidae (CAC/GL 86-2015) ~~the recommendations of the Codex Alimentarius (under study).~~

Article 8.16.7.

Recommendations for the importation of meat or meat products of wild or feral pigs

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

- 1) has been produced in accordance with the Codex Code of Hygienic Practice for Meat (CAC/RCP 58-2005);

AND

- 2) either:
 - a) comes from *wild* or *feral* pigs that tested negative by an approved method for the detection of *Trichinella* larvae;

OR

Annex 14 (contd)

- b) was processed to ensure the inactivation of *Trichinella* larvae in accordance with the Codex Guidelines for the control of *Trichinella* spp. in meat of Suidae (CAC/GL 86-2015) ~~the recommendations of the Codex Alimentarius (under study).~~

Article 8.16.8.

Recommendations for the importation of meat or meat products of domestic equids

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

- 1) has been produced in accordance with the Codex Code of Hygienic Practice for Meat (CAC/RCP 58-2005);

AND

- 2) comes from domestic equids that tested negative by an approved method for the detection of *Trichinella* larvae.

Article 8.16.9.

Recommendations for the importation of meat or meat products of wild and feral equids

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

- 1) has been inspected in accordance with Chapter 6.2.;

AND

- 2) comes from *wild* or *feral* equids that tested negative by an approved method for the detection of *Trichinella* larvae.

— Text deleted.

CHAPTER 15.3.

INFECTION WITH *TAENIA SOLIUM*

Article 15.3.1.

General provisions

~~Infection with *Taenia solium* is a zoonotic parasitic infection parasite of pigs and occasionally of other animals.~~ *T. solium* is a cestode (tapeworm) that is endemic in large areas of Latin America, Asia and sub-Saharan Africa. The adult cestode occurs in the small intestine of humans (definitive host) causing taeniosis. The larval stage (cysticercus) occurs in striated muscles, subcutaneous tissues and central nervous system of pigs (intermediate hosts), causing cysticercosis. Other suids and dogs can be infected but are not epidemiologically significant. Humans may also become infected with the larval stage through the ingestion of eggs shed in faeces of infected humans. The most severe form of ~~the human~~ infection by the larval stage ~~in humans~~ is neurocysticercosis which causes neurological disorders including seizures (epilepsy) and sometimes death. Cysticercosis, although normally clinically inapparent in pigs, is associated with significant economic losses due to carcass condemnation and decreased value of pigs, and causes a major disease burden in humans.

In humans, taeniosis occurs following ingestion of pig *meat* containing viable cysticerci and can be prevented by avoiding consumption of raw or undercooked contaminated pig *meat*. In humans, cysticercosis occurs following ingestion of *T. solium* eggs and can be prevented by avoiding exposure to *T. solium* eggs through detection and treatment of human tapeworm carriers, community health education, appropriate sanitation, personal hygiene, and good food hygiene. Collaboration between the *Veterinary Authority* and the public health authority is an essential in preventing and controlling *T. solium* transmission.

In pigs, cysticercosis occurs by ingestion of *T. solium* eggs from faeces, or environments contaminated with faeces of humans harbouring adult *T. solium*.

For the purposes of the *Terrestrial Code*, infection with *T. solium* is defined as an infection of pigs.

The aim of this chapter is to reduce the risk of infection with *T. solium* of humans and pigs and to minimise the international spread of *T. solium*. The chapter provides recommendations for prevention, control, and surveillance of infection with *T. solium* in pigs.

This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005).

When authorising the import or transit of the *commodities* covered in this chapter, with the exception of those listed in Article 15.3.2. *Veterinary Authorities* should apply the recommendations in this chapter.

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

Article 15.3.2.

Safe commodities

When authorising import or transit of the following *commodities* of pigs, *Veterinary Authorities* should not require any *T. solium* related conditions regardless of the status of the animal population of the *exporting country*:

- 1) processed fat;
- 2) casings;

Annex 15 (contd)

- 3) semi-processed skins which have been submitted to the usual chemical and mechanical processes in use in the tanning industry;
- 4) bristles, hooves and bones;
- 5) embryos, oocytes and semen.

Article 15.3.3.

Measures to prevent and control infection with *T. solium*

The *Veterinary Authority* and other *Competent Authorities* should carry out community awareness and education programmes on the risk factors associated with transmission of *T. solium* emphasising the role of pigs and humans.

The *Veterinary Authority* or other *Competent Authorities* should promote the following measures:

1. Prevention of infection in pigs

Transmission of *T. solium* eggs from humans to pigs can be avoided by:

- a) preventing the exposure of pigs to environments contaminated with human faeces;
- b) preventing the deliberate use of human faeces as pig feed or the use of pigs as a means of human faeces disposal;
- c) preventing the use of untreated sewage effluent to irrigate or fertilise land to be used by pigs for forage ~~and~~ or for food crops;
- d) ensuring that any treated sewage effluent used to irrigate or fertilise land to be used by pigs for forage or for food crops has been treated in a manner shown to inactivate *T. solium* eggs;
- ~~de~~) providing adequate toilet and sanitation facilities for people in pig rearing establishments to prevent the exposure of pigs and their environment to human faeces.

2. Control of infection in pigs

- a) The *Veterinary Authority* should ensure that all slaughtered pigs are subjected to post-mortem *meat* inspection in accordance with Chapter 6.2., and with reference to Chapter 2.9.5. of the *Terrestrial Manual*.
- b) When cysticerci are detected during post-mortem *meat* inspection:
 - i) if ~~20 or more~~ cysticerci are detected in a carcass of a pig in multiple locations (systemic infection), that carcass and its viscera, as well as all pigs from the same *establishment* of origin should be disposed of in accordance with Article 4.12.6.;
 - ii) if ~~fewer than 20~~ only localised cysticerci are detected in a carcass of a pig, the meat from that carcass and from all pigs from the same *establishment* of origin should be treated in accordance with Article 15.3.6. or may be disposed of in accordance with Article 4.12.6.;
 - iii) an investigation should be carried out by the *Veterinary Authority* and the public health authority to identify the possible source of the *infection* in order to target an intervention;
 - iv) post-mortem examination of pigs at *slaughter* from known infected *establishments* should be intensified until sufficient evidence has been obtained indicating that the *infection* has been eliminated from the *establishment*.

An optimal control programme should include detection and treatment of human tapeworm carriers and control of sewage used for agricultural production.

Article 15.3.4.

Surveillance for infection with *T. solium* in pigs

Communication procedures on the occurrence of *T. solium* should be established between the *Veterinary Authority* and public health authorities.

The *Veterinary Authority* should use information from public health authorities and other sources on human cases of taeniosis or cysticercosis in the initial design and any subsequent modification of *surveillance* programmes.

Surveillance can be conducted by:

- 1) *meat* inspection at *slaughterhouses/abattoirs*;
- 2) tongue inspection of live pigs at markets provided that the methods used do not cause injury and avoid unnecessary suffering;
- 3) other diagnostic tests on live pigs.

The data collected should be used for investigations and for the design or amendment of control programmes as described in Article 15.3.3.

Animal identification and *animal traceability* systems should be implemented in accordance with the provisions of Chapters 4.1. and 4.2.

Article 15.3.5.

Recommendations for the importation of meat and meat products of pigs

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

- 1) has been produced in accordance with the Codex Code of Hygienic Practice for Meat (CAC/RCP 58-2005);

AND

- 2) comes from pigs which have been slaughtered in an approved *slaughterhouse/abattoir*;

AND

- 3) either
 - a) comes from pigs born and raised in a country, *zone* or *compartment* demonstrated to be free from *T. solium* in accordance with Article 1.4.6.;
 - or
 - b) comes from pigs which have been subjected to post-mortem inspections for *T. solium* cysticerci with favourable results;
 - or
 - c) has been processed to ensure the inactivation of the *T. solium* cysticerci in accordance with one of the procedures referred to in Article 15.3.6.

Annex 15 (contd)

Article 15.3.6.

Procedures for the inactivation of *T. solium* cysticerci in meat of pigs

For the inactivation of *T. solium* cysticerci in *meat* of pigs, one of the following procedures should be used:

- 1) heat treatment to a core temperature of at least ~~80~~ 60°C; or
- 2) freezing to minus 10°C or less for at least ten days or any time and temperature equivalent.

— Text deleted.

CHAPTER 7.5.

SLAUGHTER OF ANIMALS

[Article 7.5.1.]

[Article 7.5.2.]

[Article 7.5.3.]

[Article 7.5.4.]

[Article 7.5.5.]

[Article 7.5.6.]

Article 7.5.7.

Stunning methods1. General considerations

The competence of the operators, and the appropriateness, and effectiveness of the method used for *stunning* and the maintenance of the equipment are the responsibility of the management of the *slaughterhouse*, and should be checked regularly by a *Competent Authority*.

Persons carrying out *stunning* should be properly trained and competent, and should ensure that:

- a) the animal is adequately restrained;
- b) animals in *restraint* are stunned as soon as possible;
- c) the equipment used for *stunning* is maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the animal;
- d) the equipment is applied correctly;
- e) stunned animals are bled out (slaughtered) as soon as possible;
- f) animals are not stunned when *slaughter* is likely to be delayed; and
- g) backup *stunning* devices are available for immediate use if the primary method of *stunning* fails. Provision of a manual inspection area and simple intervention like captive bolt or cervical dislocation for *poultry* would help prevent potential *welfare* problems.

In addition, such persons should be able to recognise when an animal is not correctly stunned and should take appropriate action.

2. Mechanical stunning

A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface. For a more detailed explanation on the different methods for mechanical *stunning*, see Chapter 7.6. and Articles 7.6.6., 7.6.7. and 7.6.8. ~~The following diagrams illustrate the proper application of the device for certain species.~~

Signs of correct *stunning* using a mechanical instrument are as follows:

- a) the animal collapses immediately and does not attempt to stand up;

Annex 16 (contd)

- b) the body and muscles of the animal become tonic (rigid) immediately after the shot;
- c) normal rhythmic breathing stops; and
- d) the eyelid is open with the eyeball facing straight ahead and is not rotated.

Captive bolts powered by cartridges, compressed air or spring can be used for *poultry*. The optimum position for *poultry* species is at right angles to the frontal surface.

Firing of a captive bolt in accordance with to the manufacturers' instructions should lead to immediate destruction of the skull and the brain and, as a result, immediate *death*.

3. [...]

4. [...]

5. [...]

Figure 1. The optimum position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.

Cattle



Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 2. The optimum position for pigs is on the midline just above eye level, with the shot directed down the line of the spinal cord.

Pigs



Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 3. The optimum position for hornless sheep and goats is on the midline.

Sheep



Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Annex 16 (contd)

Figure 4. The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

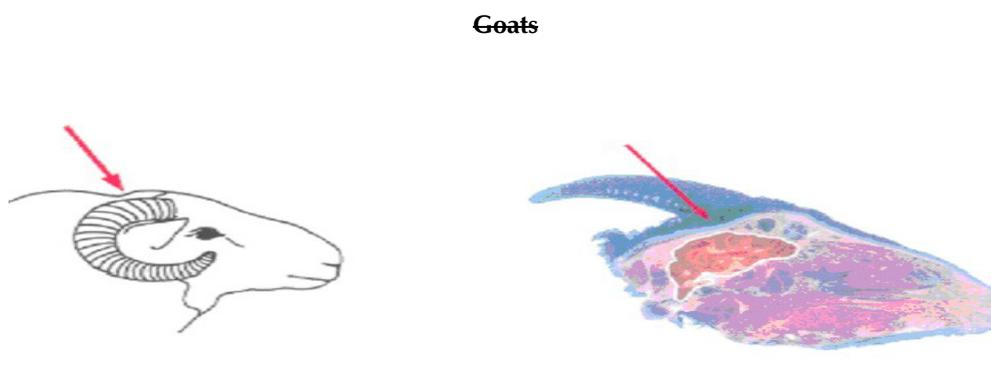


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 5. The optimum position for horses is at right angles to the frontal surface, well above the point where imaginary lines from eyes to ears cross.

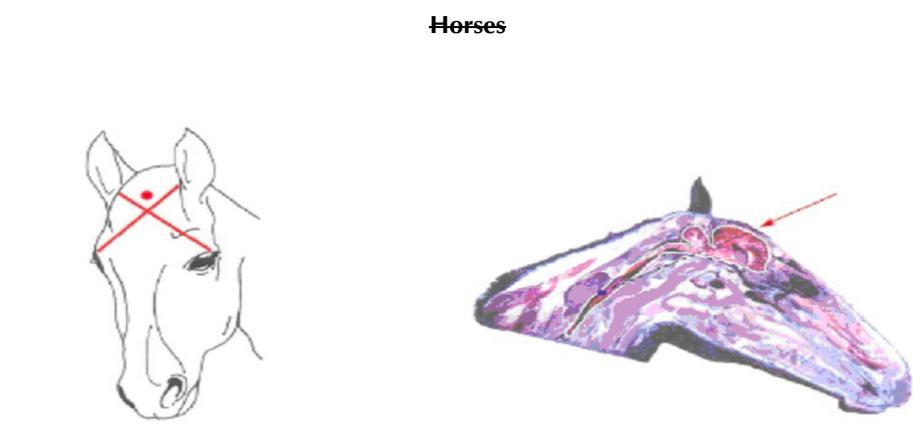


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Signs of correct *stunning* using a mechanical instrument are as follows:

- 1) — the animal collapses immediately and does not attempt to stand up;
- 2) — the body and muscles of the animal become tonic (rigid) immediately after the shot;
- 3) — normal rhythmic breathing stops; and
- 4) — the eyelid is open with the eyeball facing straight ahead and is not rotated.

Poultry



Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Poultry



Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Captive bolts powered by cartridges, compressed air or spring can be used for *poultry*. The optimum position for *poultry* species is at right angles to the frontal surface.

Firing of a captive bolt according to the manufacturers' instructions should lead to immediate destruction of the skull and the brain and, as a result, immediate *death*.

Annex 16 (contd)

[Article 7.5.8.]

— Text deleted.

CHAPTER 7.6.

KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

[Article 7.6.1.]

[Article 7.6.2.]

[Article 7.6.3.]

[Article 7.6.4.]

Article 7.6.5.

Table summarising killing methods described in Articles 7.6.6.-7.6.18.

The methods are described in the order of mechanical, electrical and gaseous, not in an order of desirability from an *animal welfare* viewpoint.

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Cattle	all	free bullet	no	non-lethal wounding	Article 7.6.6.
	all except neonates	penetrating captive bolt - followed by pithing or bleeding	yes	ineffective stunning	Article 7.6.7.
	adults only	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before killing	Article 7.6.8.
	calves only	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	Article 7.6.10.
	calves only	electrical, single application (method 1)	yes	ineffective stunning	Article 7.6.11.
	all	injection with barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	Article 7.6.15.

Annex 17 (contd)

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Sheep and goats	all	free bullet	no	non-lethal wounding	Article 7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	Article 7.6.7.
	all except neonates	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before death	Article 7.6.8.
	neonates	non-penetrating captive bolt	yes	non-lethal wounding	Article 7.6.8.
	all	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	Article 7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	Article 7.6.11.
	neonates only	CO ₂ /air mixture	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO ₂	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	Article 7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	Article 7.6.15.
Pigs	all, except neonates	free bullet	no	non-lethal wounding	Article 7.6.6.

Annex 17 (contd)

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Pigs (contd)	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	Article 7.6.7.
	neonates only	non-penetrating captive bolt	yes	non-lethal wounding	Article 7.6.8.
	all ¹	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	Article 7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	Article 7.6.11.
	neonates only	CO ₂ / air mixture	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO ₂	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	Article 7.6.14.
	all	injection with barbiturates and other	yes	non-lethal dose, pain associated with injection site	Article 7.6.15.
Poultry	adults only	non-penetrating captive bolt	yes	ineffective stunning	Article 7.6.8.
	day-olds and eggs only	maceration	no	non-lethal wounding, non-immediacy	Article 7.6.9.
	adults only	electrical, single application (method 2)	yes	ineffective stunning	Article 7.6.11.

Annex 17 (contd)

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Poultry (contd)	adults only	electrical, single application, followed by killing (method 3)	yes	ineffective stunning; regaining of consciousness before death	Article 7.6.11.
	all	CO ₂ / air mixture Method 1 Method 2	yes no	slow induction of unconsciousness, aversiveness of induction	Article 7.6.12.
	all	nitrogen and/or inert gas mixed with CO ₂	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.13.
	all	nitrogen and/or inert gases	yes	slow induction of unconsciousness	Article 7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	Article 7.6.15.
	all	cervical dislocation	no		Point 1 of 7.6.17.
	all	decapitation	no		Point 2 of 7.6.17.
	adults only	addition of anaesthetics to feed or water, followed by an appropriate killing method	no	ineffective or slow induction of unconsciousness	Article 7.6.16.
<u>Equids</u>	<u>all</u>	<u>free bullet</u>	<u>no</u>	<u>non-lethal wounding</u>	<u>Article 7.6.6.</u>
	<u>all, except neonates</u>	<u>penetrating captive bolt followed by pithing or bleeding</u>	<u>yes</u>	<u>ineffective stunning, non-lethal wounding, regaining of consciousness before killing</u>	<u>Article 7.6.7</u>
	<u>all</u>	<u>injection of barbiturates and other drugs</u>	<u>yes</u>	<u>non-lethal dose, pain associated with injection site</u>	<u>Article 7.6.15.</u>

Article 7.6.6.

Free bullet1. Introduction

- a) A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.
- b) The most commonly used firearms for close range use are:
 - i) humane killers (specially manufactured/adapted single-shot weapons);
 - ii) shotguns (12, 16, 20, 28 bore and .410);
 - iii) rifles (.22 rimfire);
 - iv) handguns (various calibres from .32 to .45).
- c) The most commonly used firearms for long range use are rifles (.22, .243, .270 and .308).
- d) A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the animals (high neck shot) and to cause irreversible concussion and *death* and should only be used by properly trained and competent marksmen.

2. Requirements for effective use

- a) The marksman should take account of human safety in the area in which he/she is operating. Appropriate vision and hearing protective devices should be worn by all personnel involved.
- b) The marksman should ensure that the animal is not moving and in the correct position to enable accurate targeting and the range should be as short as possible (5–50 cm for a shotgun) but the barrel should not be in contact with the head of the animals.
- c) The correct cartridge, calibre and type of bullet for the different species age and size should be used. Ideally, the ammunition should expand upon impact and dissipate its energy within the cranium.
- d) Shot animals should be checked to ensure the absence of brain stem reflexes.

3. Advantages

- a) Used properly, a free bullet provides a quick and effective method for *killing*.
- b) It requires minimal or no *restraint* and can be used to kill from a distance by properly trained and competent marksmen.
- c) It is suitable for *killing* agitated animals in open spaces.

4. Disadvantages

- a) The method is potentially dangerous to humans and other animals in the area.
- b) It has the potential for non-lethal wounding.
- c) Destruction of brain tissue may preclude diagnosis of some *diseases*.
- d) Leakage of bodily fluids may present a *biosecurity* risk.
- e) Legal requirements may preclude or restrict use.
- f) There is a limited availability of competent personnel.

5. Conclusion

The method is suitable for cattle, sheep, goats ~~and~~, pigs, and equids including large animals in open spaces.

Annex 17 (contd)

Figure 1. The optimum shooting position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the opposite horn buds.



Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 2. The optimum position for hornless sheep and goats is on the midline.

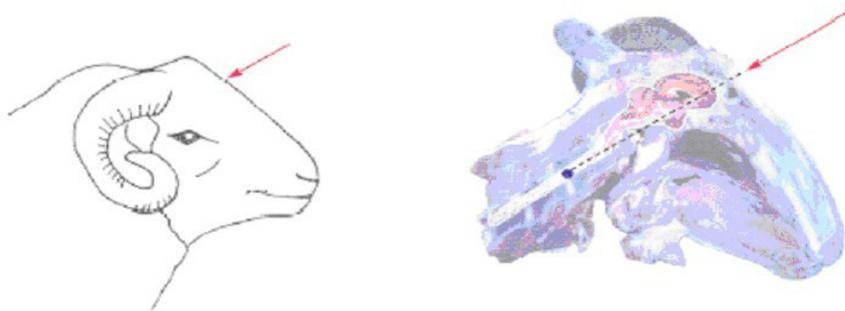


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 3. The optimum shooting position for heavily horned sheep and horned goats is behind the poll aiming towards the angle of the jaw.

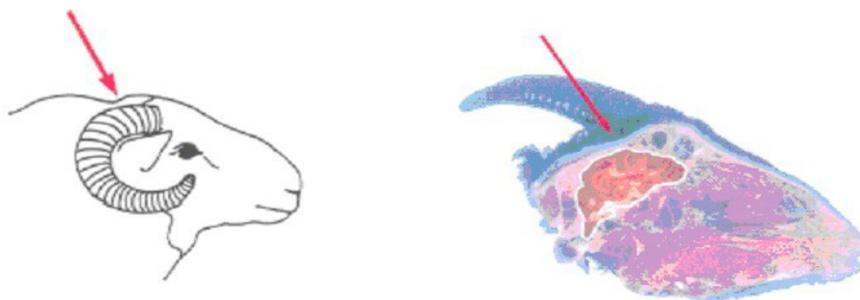


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 4. The optimum shooting position for pigs is just above eye level, with the shot directed down the line of the spinal cord.



Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Article 7.6.7.

Penetrating captive bolt

1. Introduction

A penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The captive bolt should be aimed on the skull in a position to penetrate the cortex and mid-brain of the animal. The impact of the bolt on the skull produces unconsciousness. Physical damage to the brain caused by penetration of the bolt may result in *death*; however, pithing or bleeding should be performed as soon as possible after the shot to ensure the *death* of the animal. Shooting *poultry* species with the captive bolts results in immediate destruction of the skull and brain, causing *death*. For a detailed description on the use of this method, see Chapter 7.5.

Annex 17 (contd)2. Requirements for effective use

- a) For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of animal, in accordance with the recommendations of the manufacturer.
- b) Captive bolt guns should be frequently cleaned and maintained in good working condition.
- c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.
- d) Animals should be restrained; at a minimum, they should be penned for cartridge powered guns and in a race for compressed air guns.
- e) The operator should ensure that the head of the animal is accessible.
- f) The operator should fire the captive bolt at right angles to the skull in the optimal position (~~see figures 1, 3 & 4. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw.~~)
- g) To ensure the *death* of the animal, pithing or bleeding should be performed as soon as possible after *stunning*.
- h) Animals should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

- a) Mobility of cartridge powered equipment reduces the need to move animals.
- b) The method induces an immediate onset of a sustained period of unconsciousness.

4. Disadvantages

- a) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.
- b) Post stun convulsions may make pithing difficult and hazardous.
- c) The method is difficult to apply in agitated animals.
- d) Repeated use of a cartridge powered gun may result in over-heating.
- e) Leakage of bodily fluids may present a *biosecurity* risk.
- f) Destruction of brain tissue may preclude diagnosis of some *diseases*.

5. Conclusions

The method is suitable for *poultry*, cattle, sheep, goats, ~~and~~ pigs and equids (except neonates), when followed by pithing or bleeding.

Article 7.6.8.

Non-penetrating captive bolt1. Introduction

A non-penetrating captive bolt is fired from a gun powered by either compressed air or a blank cartridge. There is no free projectile.

The gun should be placed on the front of the skull to deliver a percussive blow which produces unconsciousness in cattle (adults only), sheep, goats and pigs, and *death* in *poultry* and neonate sheep, goats and pigs. Bleeding should be performed as soon as possible after the blow to ensure the *death* of the animal.

2. Requirements for effective use

- a) For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of animal, in accordance with the recommendations of the manufacturer.
- b) Captive bolt guns should be frequently cleaned and maintained in good working condition.
- c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.
- d) Animals should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.
- e) The operator should ensure that the head of the animal is accessible.
- f) The operator should fire the captive bolt at right angles to the skull in the optimal position (~~figures 1-4~~).
- g) To ensure *death* in non-neonate mammals, bleeding should be performed as soon as possible after *stunning*.
- h) Animals should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

- a) The method induces an immediate onset of unconsciousness, and *death* in birds and neonates.
- b) Mobility of equipment reduces the need to move animals.

4. Disadvantages

- a) As consciousness can be regained quickly in non-neonate mammals, they should be bled as soon as possible after *stunning*.
- b) Laying hens in cages have to be removed from their cages and most birds have to be restrained.
- c) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.
- d) Post stun convulsions may make bleeding difficult and hazardous.

Annex 17 (contd)

- e) Difficult to apply in agitated animals; such animals may be sedated in advance of the *killing* procedure.
- f) Repeated use of a cartridge powered gun may result in over-heating.
- g) Bleeding may present a *biosecurity* risk.

5. Conclusions

The method is suitable for *killing poultry*, and neonate sheep, goats and pigs up to a maximum weight of 10 kg.

[Article 7.6.9.]

Article 7.6.10.

Electrical — two-stage application1. Introduction

A two-stage application of electric current comprises firstly an application of current to the head by scissor-type tongs, immediately followed by an application of the tongs across the chest in a position that spans the heart.

The application of sufficient electric current to the head will induce ‘tonic/clonic’ epilepsy and unconsciousness. Once the animal is unconscious, the second stage will induce ventricular fibrillation (cardiac arrest) resulting in *death*. The second stage (the application of low frequency current across the chest) should only be applied to unconscious animals to prevent unacceptable levels of pain.

2. Requirements for effective use

- a) The stunner control device should generate a low frequency (AC sine wave 50 Hz) current with a minimum voltage and current as set out in the following table:

Animal	Minimum voltage (V)	Minimum current (A)
Cattle	220	1.5
Sheep	220	1.0
Pigs over 6 weeks of age	220	1.3
Pigs less than 6 weeks of age	125	0.5

- b) Appropriate protective clothing (including rubber gloves and boots) should be worn.
- c) Animals should be restrained, at a minimum free-standing in a pen, close to an electrical supply.
- d) Two team members are required, the first to apply the electrodes and the second to manipulate the position of the animal to allow the second application to be made.
- e) A *stunning* current should be applied via scissor-type *stunning* tongs in a position that spans the brain for a minimum of 3 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 3 seconds.
- f) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.
- g) Animals should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

Annex 17 (contd)

- h) Electrodes should be applied firmly for the intended duration of time and pressure not released until the stun is complete.

3. Advantages

- a) The application of the second stage minimises post-stun convulsions and therefore the method is particularly effective with pigs.
- b) Non-invasive technique minimises *biosecurity* risk.

4. Disadvantages

- a) The method requires a reliable supply of electricity.
- b) The electrodes should be applied and maintained in the correct positions to produce an effective stun and kill.
- c) Most stunner control devices utilise low voltage impedance sensing as an electronic switch prior to the application of high voltages; in unshorn sheep, contact impedance may be too high to switch on the required high voltage (especially during stage two).
- d) The procedure may be physically demanding, leading to operator fatigue and poor electrode placement.

5. Conclusion

The method is suitable for calves, sheep and goats, and especially for pigs (over one week of age).

Figure 5. Scissor type tongs.



[Article 7.6.11.]

[Article 7.6.12.]

Annex 17 (contd)

Article 7.6.13.

Nitrogen and/or inert gas mixed with CO₂1. Introduction

CO₂ may be mixed in various proportions with nitrogen or an inert gas (e.g. argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and *death* when the oxygen concentration by volume is <2%, or <5% for chickens. Various mixtures of CO₂ and nitrogen or an inert gas can be administered to kill birds using Methods 1 and 2 described under Article 7.6.12. Whole house gassing with mixtures of CO₂ and nitrogen, or an inert gas, has not been tested owing to the complex issues presented by mixing gases in large quantities. Such mixtures however do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO₂ and the respiratory distress occurring during the induction phase, are important *animal welfare* considerations.

Pigs and *poultry* appear not to find low concentrations of CO₂ strongly aversive, and a mixture of nitrogen or argon with ≤30% CO₂ by volume and ≤2% O₂ by volume can be used for *killing poultry*, neonatal sheep, goats and pigs.

2. Method 1

The animals are placed in a gas-filled *container* or apparatus.

a) Requirements for effective use

- i) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O₂ and CO₂ concentrations accurately measured during the *killing* procedure.
- ii) When animals are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.
- iii) Animals should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with ≤2% O₂), and held in this atmosphere until *death* is confirmed.
- iv) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the *container* or apparatus.
- v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid animals suffocating by climbing on top of each other.

b) Advantages

Low concentrations of CO₂ cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.

c) Disadvantages

- i) A properly designed *container* or apparatus is needed.
- ii) It is difficult to verify *death* while the animals are in the *container* or apparatus.
- iii) There is no immediate loss of consciousness.
- iv) Exposure times required to kill are considerable.

d) Conclusion

The method is suitable for *poultry*, and for neonatal sheep, goats and pigs.

3. Method 2

In this method, the crates or modules holding the birds are loaded into a *container* and gas is introduced into the *container* (refer to Figures under Article 7.6.12.). As shown in the example below, each containerised gassing unit (CGU) typically comprises a gas-tight chamber designed to accommodate *poultry* transport crates or a module. The *container* or chamber is fitted with gas lines and diffusers, with silencers, which in turn are connected via a system of manifolds and gas regulators to gas cylinders. There is a hole at the top of the unit to permit displaced air to escape when filling the *container* with gas.

Procedures involved in the operation of CGU includes (a) position the *container* on a level, solid, open ground; (b) connect gas cylinder to the *container* (c) load a module of birds into the *container*, (d) shut and secure the door, (e) deliver the gas to the point where less than 2% by volume of oxygen is found at the top of the *container*, (f) allow time for the birds to become unconscious and die, (g) open the door and allow the gas to be dispersed in air, (h) remove the module, (i) check each drawer for survivors; (j) humanely kill survivors, if any; and (k) dispose carcasses appropriately.

a) Requirements for effective use of containerised gassing units (CGU)

- i) The birds should be caught gently and placed in crates or modules of appropriate size and at appropriate *stocking densities* to allow all birds to sit down.
- ii) The crates or module of birds should be placed inside the *container* and the door shut only when the operator is ready to administer the gas mixture.
- iii) Ensure the *container* door is locked and administer the gas mixture until <2% residual oxygen is achieved at the top of the crates.
- iv) An appropriate gas meter should be used to ensure a concentration of oxygen <2% is achieved and maintained until it can be confirmed that the birds have been killed.
- v) Sufficient exposure time should be allowed for birds to die before the door is opened. In the absence of a viewing window, which allows direct observation of birds during killing, cessation of vocalisation and wing flapping sounds can be observed by standing close to the *container* and used to determine the onset of *death* in birds. Remove the crates or modules from the *container* and leave them in the open air.
- vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing movements indicate *death*.
- vii) Any survivors should be humanely killed.
- viii) Ducks and geese do not appear to be resilient to the effects of a mixture of 20% carbon dioxide and 80% nitrogen or argon.

b) Advantages

- i) The gas mixture is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.
- ii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house.
- iii) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.
- iv) Mixtures containing up to 20% carbon dioxide in argon are readily available as welding gas cylinders.

Annex 17 (contd)

- v) Birds are exposed to gas in a more uniform manner and they do not smother each other when compared with Method 1.
 - vi) Two CGU can be operated in tandem and throughputs of up to 4,000 chickens per hour are possible.
 - vii) The volume of gas required can be readily calculated.
 - viii) As the units are operated outdoor the gas is dispersed quickly at the end of each cycle by opening the door, improving operators' health and safety.
 - ix) The system uses skilled catching teams and equipment in daily use by the industry.
 - x) Metal *containers* can be readily cleansed and disinfected.
- c) Disadvantages
- i) Requires trained operators, trained catchers, transport modules and a fork lift. However, such equipment and suitable outdoor areas with a hard surface are usually available.
 - ii) The main limiting factors are speed of catching birds and availability of gas mixtures.
 - iii) In the absence of a viewing window, visual confirmation of *death* while the birds are still in the *container* is difficult. However, cessation of vocalisation and convulsive wing flapping can be used to determine the onset of *death*.
 - iv) CGU could be used to kill *poultry* on small to medium farms, e.g. up to 25 thousand birds on a single farm.
- d) Conclusion
- i) Method 2 is suitable for use in *poultry* and in neonatal sheep, goats and pigs.
 - ii) Method 2 is suitable for use in *poultry* in a wide range of *poultry* systems providing that these have access to *vehicles* to carry *containers* and equipment.
 - iii) Animals should be introduced into the *container* or apparatus, which is then sealed and filled as quickly as possible with the gas mixture. A residual oxygen concentration of less than 2% should be achieved and maintained and birds should be held in this atmosphere until *death* is confirmed.

Annex 17 (contd)

Figure source: Department of Clinical Veterinary Science, University of Bristol, United Kingdom.

Annex 17 (contd)

Article 7.6.14.

Nitrogen and/or inert gases1. Introduction

This method involves the introduction of animals into a *container* or apparatus containing nitrogen or an inert gas such as argon. The controlled atmosphere produced leads to unconsciousness and *death* from hypoxia.

Research has shown that hypoxia is not aversive to pigs and *poultry*, and it does not induce any signs of respiratory distress prior to loss of consciousness.

2. Requirements for effective use

- a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O₂ concentration accurately measured.
- b) When animals are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the animals and allow them to be observed.
- c) Animals should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with $\leq 2\%$ O₂), and held in this atmosphere until *death* is confirmed.
- d) Team members should ensure that there is sufficient time allowed for each batch of animals to die before subsequent ones are introduced into the *container* or apparatus.
- e) *Containers* or apparatus should not be overcrowded, and measures are needed to avoid animals suffocating by climbing on top of each other.

3. Advantages

Animals are unable to detect nitrogen or inert gases, and the induction of hypoxia by this method is not aversive to animals.

4. Disadvantages

- a) A properly designed *container* or apparatus is needed.
- b) It is difficult to verify *death* while the animals are in the *container* or apparatus.
- c) There is no immediate loss of consciousness.
- d) Exposure times required to kill are considerable.

5. Conclusion

The method is suitable for *poultry* and neonatal sheep, goats and pigs.

Article 7.6.15.

Lethal injection1. Introduction

A lethal injection using high doses of anaesthetic and sedative drugs causes CNS depression, unconsciousness and *death*. In practice, barbiturates in combination with other drugs are commonly used.

Annex 17 (contd)2. Requirements for effective use

- a) Doses and routes of administration that cause rapid loss of consciousness followed by *death* should be used.
- b) Prior sedation may be necessary for some animals.
- c) Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.
- d) Animals should be restrained to allow effective administration.
- e) Animals should be monitored to ensure the absence of brain stem reflexes.
- f) Personnel performing this method should be trained and knowledgeable in anaesthetic techniques.

3. Advantages

- a) The method can be used in all species.
- b) *Death* can be induced smoothly.

4. Disadvantages

- a) *Restraint* ~~and~~ or sedation may be necessary prior to injection.
- b) Some combinations of drug type and route of administration may be painful, and should only be used in unconscious animals.
- c) Legal requirements and skill~~s~~ and training required may restrict use to *veterinarians*.
- d) Contaminated carcasses may present a risk to other *wild animals* or domestic animals.

5. Conclusion

The method is suitable for *killing* small numbers of cattle, sheep, goats, pigs, equids and *poultry*.

[Article 7.6.16.]

[Article 7.6.17.]

Article 7.6.18.

Pithing and bleeding1. Pithing

- a) Introduction

Pithing is a method of *killing* animals which have been stunned by a penetrating captive bolt, without immediate *death*. Pithing results in the physical destruction of the brain and upper regions of the spinal cord, through the insertion of a rod or cane through the bolt hole.

Annex 17 (contd)

b) Requirements for effective use

- i) Pithing cane or rod is required.
- ii) An access to the head of the *animal* and to the brain through the skull is required.
- iii) Animals should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

The technique is effective in producing immediate *death*.

d) Disadvantages

- i) A delayed ~~and~~ or ineffective pithing due to convulsions may occur.
- ii) The working area is contaminated with body fluids, which increases *biosecurity* risks.

2. Bleeding

a) Introduction

Bleeding is a method of *killing* animals through the severance of the major blood vessels in the neck or chest that results in a rapid fall in blood pressure, leading to cerebral ischaemia and *death*.

b) Requirements for effective use

- i) A sharp knife is required.
- ii) An access to the neck or chest of the animal is required.
- iii) Animals should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

The technique is effective in producing *death* after an effective *stunning* method which does not permit pithing.

d) Disadvantages

- i) A delayed ~~and~~ or ineffective bleeding due to convulsions may occur.
- ii) The working area is contaminated with body fluids, which increases *biosecurity* risks.

— Text deleted.

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- 1 The only preclusion against the use of this method for neonates is the design of the stunning tongs that may not facilitate their application across such a small-sized head or body.

CHAPTER 7.10.

**ANIMAL WELFARE AND
BROILER CHICKEN PRODUCTION SYSTEMS**

[Article 7.10.1.]

[Article 7.10.2.]

[Article 7.10.3.]

Article 7.10.4.

Recommendations

1. Biosecurity and animal health

a) Biosecurity and disease prevention

Biosecurity means a set of measures designed to maintain a *flock* at a particular health status and to prevent the entry (or exit) of specific infectious agents.

Biosecurity programmes should be designed and implemented, commensurate with the best possible *flock* health status and current *disease* risk (endemic and exotic or transboundary) that is specific to each epidemiological group of broilers and in accordance with relevant recommendations found in the *Terrestrial Code*.

These programmes should address the control of the major routes for *disease* and pathogen transmission:

- i) direct transmission from other *poultry*, domesticated and *wild animals* and humans,
- ii) fomites, such as equipment, facilities and *vehicles*,
- iii) *vectors* (e.g. arthropods and rodents),
- iv) aerosols,
- v) water supply,
- vi) feed.

Outcome-based measurables: incidence of *diseases*, metabolic disorders and parasitic *infestations*, mortality, performance.

b) Animal health management, preventive medicine and veterinary treatment

Animal health management means a system designed to optimise the health and welfare of the broilers. It includes prevention, treatment and control of *diseases* and adverse conditions.

Those responsible for the care of broilers should be aware of the signs of ill-health or distress, such as a change in feed and water intake, reduced growth, changes in behaviour, abnormal appearance of feathers, faeces, or other physical features.

Annex 18 (contd)

If persons in charge are not able to identify the causes of *diseases*, ill-health or distress, or to correct these, or if they suspect the presence of a reportable *disease*, they should seek advice from *veterinarians* or other qualified advisers. Veterinary treatments should be prescribed by a *veterinarian*.

There should be an effective programme for the prevention and treatment of *diseases* consistent with the programmes established by *Veterinary Services* as appropriate.

Vaccinations and treatments should be administered, on the basis of veterinary or other expert advice, by personnel skilled in the procedures and with consideration for the welfare of the broilers.

Sick or injured broilers should be humanely killed as soon as possible. Similarly, killing broilers for diagnostic purposes should be done in a humane manner according to Chapter 7.6.

Outcome-based measurables: incidence of *diseases*, metabolic disorders and parasitic *infestations*, mortality, performance, gait.

2. Environment and management

a) Thermal environment

Thermal conditions for broilers should be appropriate for their stage of development, and extremes of heat, humidity and cold should be avoided. For the growing stage, a heat index can assist in identifying the comfort zones for the broilers at varying temperature and relative humidity levels.

When environmental conditions move outside these zones, strategies should be used to mitigate the adverse effects on the broilers. These may include adjusting air speed, provision of heat, evaporative cooling and adjusting stocking density.

Management of the thermal environment should be checked frequently enough so that failure of the system would be noticed before it caused a welfare problem.

Outcome-based measurables: behaviour, mortality, contact dermatitis, water and feed consumption, performance, feather condition.

b) Lighting

There should be ~~also~~ an adequate period of continuous light.

The light intensity during the light period should be sufficient and homogeneously distributed to allow the broilers to find feed and water after they are placed in the poultry house, to stimulate activity, and allow adequate inspection.

There should also be an adequate period of continuous darkness during each 24-hour period to allow the broilers to rest, to reduce stress and to promote normal behaviour, gait and good leg health.

There should be a period for gradual adjustment to lighting changes.

Outcome-based measurables: gait, metabolic disorders, performance, behaviour, eye condition, injury rate.

c) Air quality

Adequate ventilation is required at all times to provide fresh air, to remove waste gases such as carbon dioxide and ammonia, dust and excess moisture content from the environment.

Annex 18 (contd)

Ammonia concentration should not routinely exceed 25 ppm at broiler level.

Dust levels should be kept to a minimum. Where the health and welfare of broilers depend on an artificial ventilation system, provision should be made for an appropriate back-up power and alarm system.

Outcome-based measurables: incidence of respiratory *diseases*, metabolic disorders, eye conditions, performance, contact dermatitis.

d) Noise

Broilers are adaptable to different levels and types of noise. However, exposure of broilers to sudden or loud noises should be minimised where possible to prevent stress and fear reactions, such as piling. Ventilation fans, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in such a way that they cause the least possible amount of noise.

Location of farms should, where possible, take into account existing local sources of noise.

Outcome-based measurables: daily mortality rate, morbidity, performance, injury rate, fear behaviour.

e) Nutrition

Broilers should always be fed a diet appropriate to their age and genetics, which contains adequate nutrients to meet their requirements for good health and welfare.

Feed and water should be acceptable to the broilers and free from contaminants at a concentration hazardous to broiler health.

The water system should be cleaned regularly to prevent growth of hazardous microorganisms.

Broilers should be provided with adequate access to feed on a daily basis. Water should be available continuously. Special provision should be made to enable young chicks access to appropriate feed and water.

Broilers that are physically unable to access feed or water should be humanely killed as soon as possible.

Outcome-based measurables: feed and water consumption, performance, behaviour, gait, incidence of *diseases*, metabolic disorders and parasitic *infestations*, mortality, injury rate.

f) Flooring, bedding, resting surfaces and litter quality

The floor of a poultry house should preferably be easy to clean and disinfect.

The provision of loose and dry bedding material is desirable in order to insulate the chicks from the ground and to encourage dust bathing and foraging.

Litter should be managed to minimise any detrimental effects on welfare and health. Poor litter quality can lead to contact dermatitis and breast blisters. Litter should be replaced or adequately treated when required to prevent *diseases* in the next *flock*.

Litter quality is partly related to the type of substrate used and partly to different management practices. The type of substrate should be chosen carefully. Litter should be maintained so that it is dry and friable and not dusty, caked or wet. Poor litter quality can result from a range of factors including water spillage, inappropriate feed composition, enteric *infections*, poor ventilation and overcrowding.

Annex 18 (contd)

If broilers are kept on slatted floors, where a very humid climate precludes the use of other flooring substrates, the floors should be designed, constructed and maintained to adequately support the broilers, prevent injuries and ensure that manure can fall through or be adequately removed.

To prevent injury and keep them warm, *day-old birds* should be placed on an appropriate type of flooring suitable for their size.

If *day-old birds* are housed on litter, before they enter the poultry house, a layer of uncontaminated substrate, such as wood shavings, straw, rice husk, shredded paper, treated used litter should be added to a sufficient depth to allow normal behaviour and to separate them from the floor.

Outcome-based measurables: contact dermatitis, feather condition, gait, behaviour (dust bathing and foraging), eye conditions, incidence of *diseases*, metabolic disorders and parasitic *infestations*, performance.

g) Prevention of feather pecking and cannibalism

Feather pecking and cannibalism are rarely seen in broilers because of their young age. However, management methods, such as reducing light intensity, providing foraging materials, nutritional modifications, reducing stocking density, selecting the appropriate genetic stock should be implemented where feather pecking and cannibalism are a potential problem.

If these management strategies fail, therapeutic beak trimming is the last resort.

Outcome-based measurables: injury rate, behaviour, feather condition, mortality.

h) Stocking density

Broilers should be housed at a stocking density that allows them to access feed and water and to move and adjust their posture normally. The following factors should be taken into account: management capabilities, ambient conditions, housing system, production system, litter quality, ventilation, *biosecurity* strategy, genetic stock, and market age and weight.

Outcome-based measurables: injury rate, contact dermatitis, mortality, behaviour, gait, incidence of *diseases*, metabolic disorders and parasitic *infestations*, performance, feather condition.

i) Outdoor areas

Broilers can be given access to outdoor areas as soon as they have sufficient feather cover and are old enough to range safely. There should be sufficient exit areas to allow them to leave and re-enter the poultry house freely.

Management of outdoor areas is important in partially housed and completely outdoors production systems. Land and pasture management measures should be taken to reduce the risk of broilers being infected by pathogens or infested by parasites. This might include limiting the stocking density or using several pieces of land consecutively in rotation.

Outdoor areas should be placed on well drained ground and managed to minimise swampy conditions and mud.

Outdoor areas should provide shelter for broilers and be free from poisonous plants and contaminants.

Protection from adverse climatic conditions should be provided in completely outdoors systems.

Outcome-based measurables: behaviour, incidence of *disease*, metabolic disorders and parasitic *infestations*, performance, contact dermatitis, feather condition, injury rate, mortality, morbidity.

j) Protection from predators

Broilers should be protected from predators.

Outcome-based measurables: fear behaviour, mortality, injury rate.

k) Choice of broiler strain

Welfare and health considerations, should balance any decisions on ~~in addition to~~ productivity and growth rate, ~~should be taken into account~~ when choosing a broiler strain for a particular location or production system.

Outcome-based measurables: gait, metabolic disorders, contact dermatitis, mortality, behaviour, performance.

l) Painful interventions

Painful interventions, such as beak trimming, toe trimming and dubbing, should not be routinely practised on broilers.

If therapeutic beak trimming is required, it should be carried out by trained and skilled personnel at as early an age as possible and care should be taken to remove the minimum amount of beak necessary using a method which minimises pain and controls bleeding.

Surgical caponisation should not be performed without adequate pain and *infection* control methods and should only be performed by *veterinarians* or trained and skilled personnel under veterinary supervision.

Outcome-based measurables: mortality, culling and morbidity, behaviour.

m) Handling and inspection

Broilers should be inspected at least daily. Inspection should have three main objectives: to identify sick or injured broilers to treat or cull them, to detect and correct any welfare or health problem in the *flock*, and to pick up dead broilers.

Inspection should be done in such a way that broilers are not unnecessarily disturbed, for example *animal handlers* should move quietly and slowly through the *flock*.

When broilers are handled, they should not be injured or unnecessarily frightened or stressed.

Broilers which have an incurable illness, significant deformity or injury should be removed from the *flock* and killed humanely as soon as possible as described in Chapter 7.6.

Cervical dislocation is an accepted method for killing individual broilers if carried out competently as described in Article 7.6.17.

Outcome-based measurables: behaviour, performance, injury rate, mortality, vocalisation, morbidity.

n) Personnel training

All people responsible for the broilers should have received appropriate training or be able to demonstrate that they are competent to carry out their responsibilities and should have sufficient knowledge of broiler behaviour, handling techniques, emergency killing procedures, *biosecurity*, general signs of *diseases*, and indicators of poor *animal welfare* and procedures for their alleviation.

Outcome-based measurables: all measurables could apply.

o) Emergency plans

Broiler producers should have emergency plans to minimise and mitigate the consequences of natural disasters, *disease outbreaks* and the failure of mechanical equipment. Planning may include the provision of fail-safe alarm devices to detect malfunctions, backup generators, access to maintenance providers, alternative heating or cooling arrangements, ability to store water on farm, access to water cartage services, adequate on farm storage of feed and alternative feed supply and a plan for managing ventilation emergencies.

Annex 18 (contd)

The emergency plans should be consistent with national programmes established or recommended by *Veterinary Services*.

p) Location, construction and equipment of farms

The location of broiler farms should be chosen to be safe from the effects of fires and floods and other natural disasters to the extent practical. In addition farms should be sited to avoid or minimise *biosecurity* risks, exposure of broilers to chemical and physical contaminants, noise and adverse climatic conditions.

Broiler houses, outdoor areas and equipment to which broilers have access should be designed and maintained to avoid injury or pain to the broilers.

Broiler houses should be constructed and electrical and fuel installations should be fitted to minimise the risk of fire and other hazards.

Broiler producers should have a maintenance programme in place for all equipment the failure of which can jeopardise broiler welfare.

q) On farm harvesting

Broilers should not be subject to an excessive period of feed withdrawal prior to the expected *slaughter* time.

Water should be available up to the time of harvesting.

Broilers that are not fit for *loading* or *transport* because they are sick or injured should be killed humanely.

Catching should be carried out by skilled *animal handlers* and every attempt should be made to minimise stress and fear reactions, and injury. If a broiler is injured during catching, it should be killed humanely.

Broilers should not be picked up by their neck or wings.

Broilers should be carefully placed in the *transport container*.

Mechanical catchers, where used, should be designed, operated and maintained to minimise injury, stress and fear to the broilers. A contingency plan is advisable in case of mechanical failure.

Catching should preferably be carried out under dim or blue light to calm the broilers.

Catching should be scheduled to minimise the time to *slaughter* as well as climatic stress during catching, *transport* and holding.

Stocking density in *transport containers* should suit climatic conditions and maintain comfort.

Containers should be designed and maintained to avoid injury, and they should be cleaned and, if necessary, disinfected regularly.

Outcome-based measurables: injury rate, mortality rate at harvesting and on arrival at the *slaughterhouse/abattoir*.

— Text deleted.

CHAPTER 7.11.

ANIMAL WELFARE AND DAIRY CATTLE PRODUCTION SYSTEMS

Article 7.11.1.

Definition

Dairy cattle production systems are defined as all commercial cattle production systems where the purpose of the operation includes some or all of the breeding, rearing and management of cattle intended for production of milk.

Article 7.11.2.

Scope

This chapter addresses the welfare aspects of dairy cattle production systems.

Article 7.11.3.

Commercial dairy cattle production systems

Dairy cattle in commercial production may be kept in housed or pastured systems, or a combination of both:

1. Housed

These are systems where cattle are kept on a formed surface, indoors or outdoors, and are fully dependent on humans to provide for basic animal needs such as food, shelter and water. The type of housing will depend on the environment, climatic conditions and management system. The animals may be housed unrestrained or tethered, within this housing system.

2. Pastured

These are systems where cattle live outdoors, and have some autonomy over diet selection, water consumption and access to shelter. Pastured systems do not involve any housing except that required for milking.

3. Combination systems

These are systems where cattle are managed in any combination of housed and pasture production systems, either simultaneously, or varied in accordance with weather or physiological state of the cattle.

Article 7.11.4.

Criteria (or measurables) for the welfare of dairy cattle

The following outcome-based criteria, specifically animal-based criteria, can be useful indicators of *animal welfare*. Consideration should also be given to the design of the system and animal management practices. The use of these indicators and their appropriate thresholds should be adapted to the different situations where dairy cattle are managed. These criteria can be considered as a tool to monitor the impact of design and management, given that both of these can affect *animal welfare*.

1. Behaviour

Certain behaviours could indicate an *animal welfare* problem. These include decreased feed intake, altered locomotory behaviour and posture, altered lying time, altered respiratory rate and panting, coughing, shivering and huddling, excessive grooming and the demonstration of stereotypic, agonistic, depressive or other abnormal behaviours.

Annex 19 (contd)2. Morbidity rate

Morbidity rates, including for infectious and metabolic *diseases*, lameness, peri-partum and post-procedural complications and injury rates, above recognised thresholds, may be direct or indirect indicators of the *animal welfare* status of the whole *herd*. Understanding the aetiology of the *disease* or syndrome is important for detecting potential *animal welfare* problems. Mastitis, and hoof, reproductive and metabolic diseases are also particularly important animal health problems for adult dairy cows. Scoring systems, such as for body condition, lameness and milk quality, can provide additional information.

Both clinical examination and pathology should be utilised as an indicator of *disease*, injuries and other problems that may compromise *animal welfare*.

3. Mortality and culling rates

Mortality and culling rates affect the length of productive life and, like morbidity rates, may be direct or indirect indicators of the *animal welfare* status. Depending on the production system, estimates of mortality and culling rates can be obtained by analysing ~~the causes of death~~ and culling and their temporal and spatial patterns of occurrence. Mortality and culling ~~rates, and their causes~~, should be recorded regularly, e.g. daily, monthly, annually or with reference to key husbandry activities within the production cycle.

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

4. Changes in body weight, body condition and milk yield

In growing animals, body weight changes outside the expected growth rate, especially excessive sudden loss, are indicators of poor animal health or *animal welfare*. Future performance, including milk yield and fertility, of replacement heifers can be affected by under- or over-nutrition at different stages of rearing.

In lactating animals, body condition outside an acceptable range, significant body weight change and significant decrease in milk yield may be indicators of compromised welfare.

In non-lactating animals, ~~including and~~ bulls, body condition outside an acceptable range and significant body weight change may be indicators of compromised welfare.

5. Reproductive efficiency

Reproductive efficiency can be an indicator of animal health and *animal welfare* status. Poor reproductive performance, compared with the targets expected for a particular breed, can indicate *animal welfare* problems.

Examples may include:

- anoestrus or extended post-partum interval,
- low conception rates,
- high abortion rates,
- high rates of dystocia,
- retained placenta,
- metritis,
- loss of fertility in breeding bulls.

6. Physical appearance

Physical appearance may be an indicator of animal health and *animal welfare*, as well as the conditions of management. Attributes of physical appearance that may indicate compromised welfare include:

- presence of ectoparasites,
- abnormal coat colour, texture or hair loss,
- excessive soiling with faeces, mud or dirt (cleanliness),
- swellings, injuries or lesions,
- discharges (e.g. from nose, eyes, reproductive tract),
- feet abnormalities,
- abnormal posture (e.g. rounded back, head low),
- emaciation or dehydration.

7. Handling responses

Improper handling can result in fear and distress in cattle. Indicators include:

- evidence of poor human-animal relationship, such as excessive flight distance,
- negative behaviour at milking time, such as reluctance to enter the milking parlour, kicking, vocalisation,
- animals striking restraints or gates,
- injuries sustained during handling, such as bruising, lacerations, broken horns or tails and fractured legs,
- animals vocalising abnormally or excessively during restraint and handling,
- disturbed behaviour in the chute or race such as repeated reluctance to enter,
- animals slipping or falling.

8. Complications from common procedures

Surgical and non-surgical procedures may be performed in dairy cattle for facilitating management, improving human safety and *animal welfare* (e.g. disbudding, hoof trimming), and treatment of certain conditions (e.g. displaced abomasum). However, if these procedures are not performed properly, *animal welfare* can be compromised. Indicators of such problems could include:

- post procedure infection, swelling and pain behaviour,
- reduced feed and water intake,
- post procedure body condition and weight loss,
- morbidity and mortality.

Annex 19 (contd)

Article 7.11.5.

Provisions for good animal welfare Recommendations

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

Articles 7.11.6. and 7.11.7. provide recommendations for measures applied to dairy cattle.

Each recommendation includes a list of ~~relevant~~ outcome-based measurables derived from Article 7.11.4. This does not exclude other measures being used where appropriate.

Article 7.11.6.**Recommendations on system design and management including physical environment**4- ~~Recommendations on system design and management including physical environment~~

When new facilities are planned or existing facilities are modified, professional advice on design in regards to animal ~~health and welfare~~ and health should be sought.

Many aspects of the environment can impact the ~~health and welfare~~ and health of dairy cattle. These include thermal environment, air quality, lighting, noise, etc.

1.a) Thermal environment

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

a) Heat stress

The risk of heat stress for cattle is influenced by environmental factors including air temperature, relative humidity, wind speed, animal density (area and volume available per animal), shade availability, animal factors including breed, age, body condition, metabolic rate and stage of lactation, and coat colour and density.

Animal handlers should be aware of the risk that heat stress poses to cattle and of the thresholds in relation to heat and humidity that may require action. As conditions change, routine daily activities that require moving cattle should be amended appropriately. If the risk of heat stress reaches very high levels the *animal handlers* should institute an emergency action plan that gives priority to access to additional water and could include provision of shade, fans, reduction of animal density, and provision of cooling systems as appropriate for the local conditions.

Outcome-based measurables: feed and water intake, behaviour, especially respiratory rate and panting, physical appearance, especially dehydration, morbidity rate, mortality rate, changes in milk yield.

b) Cold stress

Protection from extreme weather conditions should be provided when these conditions are likely to create a serious risk to the welfare of cattle, particularly in neonates and young cattle and others that are physiologically compromised. This could be provided by extra bedding and natural or man-made shelters.

During extreme cold weather conditions, *animal handlers* should institute an emergency action plan to provide cattle with shelter, adequate feed and water.

Outcome-based measurables: mortality and morbidity rates, physical appearance, behaviour, especially abnormal postures, shivering and huddling, growth rate, body condition and weight loss.

2.b) Lighting

Housed cattle that do not have sufficient access to natural light should be provided with supplementary lighting which follows natural periodicity sufficient for their health and welfare, to facilitate natural behaviour patterns and to allow adequate and safe inspection of the cattle. The lighting should not cause discomfort to the animals. Housed dairy cows should be provided with subdued night time lighting. Entrance to and exit from restraint facilities and their surrounding area should be well lit.

Outcome-based measurables: behaviour, especially altered locomotory behaviour, morbidity, physical appearance.

3.e) Air quality

Good air quality and ventilation are important for the health and welfare of cattle and reduce the risk of respiratory discomfort and *diseases*. Air quality is affected by air constituents such as gases, dust and micro-organisms, and is influenced strongly by management and building design in housed systems. Air composition is influenced by animal density, the size of the cattle, flooring, bedding, waste management, building design and ventilation system.

Proper ventilation is important for effective heat dissipation in cattle and to prevent the build-up of effluent gases (e.g. ammonia and hydrogen sulphide), including those from manure and dust in the housing unit. The ammonia level in enclosed housing should not exceed 25 ppm. A useful indicator is that if air quality is unpleasant for humans it is also likely to be a problem for cattle.

Outcome-based measurables: morbidity rate, mortality rate, behaviour, especially respiratory rate or panting, coughing, changes in weight and body condition or growth rate, physical appearance, especially wet coat.

4.d) Noise

Cattle are adaptable to different levels and types of noise. However, exposure of cattle to sudden and unexpected noises, including from personnel, should be minimised where possible to prevent stress and fear reactions. Ventilation fans, alarms, feeding machinery or other indoor or outdoor equipment should be constructed, placed, operated and maintained in a manner that minimises noise.

Outcome-based measurables: behaviour especially agitation and nervousness, changes in milk yield.

5.e) Flooring, bedding, resting surfaces and outdoor areas

In all production systems cattle need a well-drained and comfortable place to rest. All cattle in a group should have sufficient space to lie down and rest at the same time.

Particular attention should be given to the provisions for areas used for calving. The environment in such areas (e.g. floors, bedding, temperature, calving pen and hygiene) should be appropriate to ensure the welfare of calving cows and new born calves.

In housed systems calving areas should be thoroughly cleaned and provided with fresh bedding between each calving. Group pens for calving should be managed based on the principle 'all in - all out'. The group calving pen should be thoroughly cleaned and provided with fresh bedding between each animal group. The time interval between first and last calving of cows kept in the same group calving pen should be minimised.

Outdoor calving pens and fields should be selected to provide the cow with a clean and comfortable environment.

Floor management in housed production systems can have a significant impact on cattle welfare. Areas that compromise welfare and are not suitable for resting (e.g. places with excessive faecal accumulation, or wet bedding) should not be included in the determination of the area available for cattle to lie down.

Slopes of the pens should allow water to drain away from feed troughs and not pool the pens.

Annex 19 (contd)

Flooring, bedding, resting surfaces and outdoor yards should be cleaned as conditions warrant, to ensure good hygiene, comfort and minimise risk of diseases and injuries.

In pasture systems, stock should be rotated between fields to ensure good hygiene and minimise risk of diseases and injuries.

Bedding should be provided to all animals housed on concrete. In straw, sand or other bedding systems such as rubber mats, crumbled-rubber-filled mattresses and waterbeds, the bedding should be suitable (e.g. hygienic, non-toxic) and maintained to provide cattle with a clean, dry and comfortable place ~~in~~ on which to lie.

The design of a standing, or cubicle, or free stall, should be such that the animals can stand and lie comfortably on a solid surface (e.g. length, width and height should be appropriate for the size of the largest animal). There should be sufficient room for the animal to rest and to rise adopting normal postures, to move its head freely as it stands up, and to groom itself without difficulty. Where individual spaces are provided for cows to rest, there should be at least one space per cow.

Alleys and gates should be designed and operated to allow free movement of cattle. Floors should be designed to minimise slipping and falling, promote foot health, and reduce the risk of claw injuries.

If a housing system includes areas of slatted floor, cattle, including replacement stock, should have access to a solid lying area. The slat and gap widths should be appropriate to the hoof size of the cattle to prevent injuries.

If cattle have to be tethered whether indoors or outdoors, they should, as a minimum, be able to lie down, stand up, maintain normal body posture and groom themselves unimpeded. Cows kept in tie stall housing should be allowed sufficient untethered exercise to prevent welfare problems. When tethered outdoors they should be able to walk. *Animal handlers* should be aware of the higher risks of welfare problems where cattle are tethered.

Where breeding bulls are in housing systems, care should be taken to ensure that they have sight of other cattle with sufficient space for resting and exercise. If used for natural mating, the floor should not be slatted or slippery.

Outcome-based measurables: morbidity rates, especially lameness and injuries (e.g. hock and knee injuries and skin lesions), behaviour, especially altered posture, grooming and locomotory behaviour (e.g. not using the intended lying areas), changes in weight and body condition, physical appearance (e.g. hair loss, cleanliness score), growth rate.

6.f) Location, construction and equipment

The impacts of climate and geographical factors on dairy cattle should be evaluated when farms are established. Efforts should be made to mitigate any negative impacts of those factors, including matching dairy breed to location and consideration of alternate sites.

All facilities for dairy cattle should be constructed, maintained and operated to minimise the risk to the welfare of the cattle.

In pasture and combination systems tracks and races between the milking area and fields should be laid out and managed so as to minimise the overall distances walked. Construction and maintenance of tracks and races, including their surface, should minimise any risk to the welfare of the cattle, especially from foot health problems.

Equipment for milking, handling and restraining dairy cattle should be constructed and used in a way that minimises the risk of injury, pain or distress. Manufacturers of such equipment should consider *animal welfare* when designing it and when preparing operating instructions.

Electrified equipment designed to control animal behaviour (e.g. cow trainer) may cause welfare problems if not designed, used and maintained properly.

Annex 19 (contd)

Electrified fences and gates should be well-designed and maintained to avoid welfare problems, and used only in accordance with manufacturer's instructions.

Where access to an outdoor area, including pasture, is possible, there may be additional benefits to dairy cattle from the opportunity to graze and exercise, especially a decreased risk of lameness.

In all production systems, feed and water provision should allow all cattle to have access to feed and water. Feeding systems should be designed to minimise agonistic behaviour. Feeders and water providers should be easy to clean and properly maintained.

Milking parlours, free stalls, standings, cubicles, races, chutes and pens should be properly maintained and be free from sharp edges and protrusions to prevent injury to cattle.

There should be a separated area where individual animals can be examined closely and which has restraining facilities.

When relevant, sick and injured animals should be treated away from healthy animals. When a dedicated space is provided this should accommodate all the needs of the animal e.g. recumbent animals may require additional bedding or an alternative floors surface.

Hydraulic, pneumatic and manual equipment should be adjusted, as appropriate, to the size of cattle to be handled. Hydraulic and pneumatic operated restraining equipment should have pressure limiting devices to prevent injuries. Regular cleaning and maintenance of working parts is essential to ensure the system functions properly and is safe for the cattle.

Mechanical and electrical devices used in facilities should be safe for cattle.

Dipping baths and spray races used for ectoparasite control should be designed and operated to minimise the risk of crowding and to prevent injury and drowning.

Collecting yards (e.g. entry to the milking parlour) should be designed and operated to minimise stress and prevent injuries and lameness.

The loading areas and ramps, including the slope of the ramp, should be designed to minimise stress and injuries for the animals and ensure the safety of the *animal handlers*, in accordance with Chapters 7.2., 7.3. and 7.4.

Outcome-based measurables: handling response, morbidity rate, especially lameness, mortality rate, behaviour, especially altered locomotory behaviour, injury rate, changes in weight and body condition, physical appearance, growth rate.

7.g) Emergency plans

The failure of power, water and feed supply systems could compromise *animal welfare*. Dairy producers should have contingency plans to cover the failure of these systems. These plans may include the provision of fail-safe alarms to detect malfunctions, back-up generators, contact information for key service providers, ability to store water on farm, access to water cartage services, adequate on-farm storage of feed ~~and~~ alternative feed supply, and emergency killing of animals according to chapter 7.6.

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

Annex 19 (contd)Article 7.11.7**Recommendations on animal management practices****2- Recommendations on animal management practices**

Good animal management practices are critical to providing an acceptable level of *animal welfare*. Personnel involved in handling and caring for dairy cattle should be competent with relevant experience or training to equip them with the necessary practical skills and knowledge of dairy cattle behaviour, handling, health, *biosecurity*, physiological needs and welfare. There should be a sufficient number of *animal handlers* to ensure the health and welfare of the cattle.

1.a) Biosecurity and animal health**a)i) Biosecurity and disease prevention**

For the purpose of this chapter, *biosecurity* means a set of measures designed to maintain a *herd* at a particular health status and to prevent the entry or spread of infectious agents.

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

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

- cattle, including introductions to the *herd*,
- calves coming from different sources,
- other domestic animals, *wildlife*, and pests,
- people including sanitation practices,
- equipment, tools and facilities,
- *vehicles*,
- air,
- water supply, feed and bedding,
- manure, waste and dead stock disposal,
- semen and embryos.

Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, changes in weight and body condition, changes in milk yield.

b)ii) Animal health management

Animal health management should optimise the physical and behavioural health and welfare of the dairy *herd*. It includes the prevention, treatment and control of *diseases* and conditions affecting the *herd* (in particular mastitis, lameness, reproductive and metabolic diseases).

Annex 19 (contd)

There should be an effective programme for the prevention and treatment of *diseases* and conditions, formulated in consultation with a *veterinarian*, where appropriate. This programme should include the recording of production data (e.g. number of lactating cows, births, animal movements in and out of the *herd*, milk yield), morbidities, mortalities, culling rate and medical treatments. It should be kept up to date by the *animal handler*. Regular monitoring of records aids management and quickly reveals problem areas for intervention.

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

Lameness can be a problem in dairy cattle. *Animal handlers* should monitor the state of feet hooves and claws, and take measures to prevent lameness and maintain foot health.

Those responsible for the care of cattle should be aware of early specific signs of *disease* or distress (e.g. coughing, ocular discharge, changes in milk appearance, changes in locomotory behaviour), and non-specific signs such as reduced feed and water intake, reduction of milk production, changes in weight and body condition, changes in behaviour or abnormal physical appearance.

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

Vaccinations and other treatments administered to cattle should be carried out by *veterinarians* or other people skilled in the procedures and on the basis of veterinary or other expert advice and with consideration for the welfare of the dairy cattle.

Animal handlers should be competent in identifying and appropriately managing chronically ill or injured cattle, for instance in recognising and dealing with non-ambulatory cattle, especially those that have recently calved. Veterinary advice should be sought as appropriate.

Non-ambulatory cattle should have access to water at all times and be provided with feed at least once daily and milked as necessary. They should be provided shade and protected from predators. They should not be transported or moved unless absolutely necessary for treatment or diagnosis. Such movements should be done carefully using methods avoiding dragging the animal or excessive lifting it in a way that might exacerbate injuries.

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

In case of *disease* or injury, when treatment has failed or recovery is unlikely (e.g. cattle that are unable to stand up, unaided or refuse to eat or drink), the animal should be humanely killed as soon as possible in accordance with Chapter 7.6.

Animals suffering from photosensitisation should be provided with shade and where possible the cause should be identified.

Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, depressive behaviour, altered locomotory behaviour, physical appearance and changes in weight and body condition changes in milk yield.

c)iii) Emergency plans for disease outbreaks

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

Annex 19 (contd)

2.b) Nutrition

The nutrient requirements of dairy cattle have been well defined. Energy, protein, mineral and vitamin content of the diet are major factors determining milk production and growth, feed efficiency, reproductive efficiency, and body condition.

Cattle should be provided with access to an appropriate quantity and quality of balanced nutrition that meets their physiological needs.

Where cattle are maintained in outdoor conditions, short term exposure to climatic extremes may prevent access to nutrition that meets their daily physiological needs. In such circumstances the *animal handler* should ensure that the period of reduced nutrition is not prolonged and that extra food and water supply are provided if welfare would otherwise be compromised.

Animal handlers should have adequate knowledge of appropriate body condition scoring systems for their cattle and should not allow body condition to go outside an acceptable range in accordance with breed and physiological status.

Feedstuffs and feed ingredients should be of satisfactory quality to meet nutritional needs and stored to minimise contamination and deterioration. Where appropriate, feed and feed ingredients should be tested for the presence of substances that would adversely impact on animal health. Control and monitoring of animal feed should be implemented in accordance with relevant recommendations in Chapter 6.3.

The relative risk of digestive upset in cattle increases as the proportion of grain increases in the diet or if quality of silage is poor. Grain or new diets should be introduced slowly and palatable fibrous feed such as silage, grass and hay, should be available *ad libitum* to meet metabolic requirements in a way that promotes digestion and ensures normal rumen function.

Animal handlers should understand the impact of cattle size and age, weather patterns, diet composition and sudden dietary changes in respect to digestive upsets and their negative consequences (displaced abomasum, sub-acute ruminal acidosis, bloat, liver abscess, laminitis). Where appropriate, dairy producers should consult a cattle nutritionist for advice on ration formulation and feeding programmes.

Particular attention should be paid to nutrition in the last month of pregnancy, with regards to energy balance, roughage and micronutrients, in order to minimise calving and post-calving diseases and body condition loss.

Liquid milk (or milk replacer) is essential for healthy growth and welfare of calves. However, feeding calves all-liquid diets as the sole source of nutrition after 4-6 weeks of age limits the physiological development of the rumen. Calves over two weeks old should have a sufficient daily ration of fibrous feed and starter ration (concentrate) to promote rumen development and to reduce abnormal oral behaviours.

Dairy producers should become familiar with potential micronutrient deficiencies or excesses for production systems in their respective geographical areas and use appropriately formulated supplements where necessary.

All cattle, including unweaned calves, need an adequate supply and access to palatable water that meets their physiological requirements and is free from contaminants hazardous to cattle health.

Outcome-based measurables: mortality rates, morbidity rates, behaviour, especially agonistic behaviour (at the feeding area), changes in weight and body condition, reproductive efficiency, changes in milk yield, growth rate and vocalisation.

3.e) Social environment

Management of cattle should take into account their social environment as it relates to *animal welfare*, particularly in housed systems. Problem areas include: agonistic and oestrus activity, mixing of heifers and cows, feeding cattle of different size and age in the same pens, decreased space allowance, insufficient space at the feeder, insufficient water access and mixing of bulls.

Annex 19 (contd)

Management of cattle in all systems should take into account the social interactions of cattle within groups. The *animal handler* should understand the dominance hierarchies that develop within different groups and focus on high risk animals, such as sick or injured, very young, very old, small or large size for cohort group, for evidence of agonistic behaviour and excessive mounting behaviour. The *animal handler* should understand the risks of increased agonistic interactions between animals, particularly after mixing groups.

When other measures have failed, cattle that are expressing excessive agonistic activity or excessive mounting behaviour should be removed from the group.

Animal handlers should be aware of the *animal welfare* problems that may be caused by mixing of inappropriate groups of cattle and provide adequate measures to minimise them (e.g. introduction of heifers in a new group, mixing of animals at different production stages that have different dietary needs).

Horned and non-horned cattle should not be mixed because of the risk of injury.

Outcome-based measurables: behaviour, especially lying times, physical injuries and lesions, changes in weight and body condition, physical appearance (e.g. cleanliness), lameness scores, changes in milk yield, morbidity rate, mortality rate, growth rate, vocalisation.

4.d) Space allowance

Cattle in all production systems should be offered adequate space for comfort and socialisation.

Insufficient and inadequate space allowance may increase the occurrence of injuries and have an adverse effect on growth rate, feed efficiency, and behaviour such as locomotion, resting, feeding and drinking.

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

All cattle should be able to rest simultaneously, and each animal lie down, stand up and move freely. In growing animals, space allowance should also be managed such that weight gain is not adversely affected. If abnormal behaviour is seen, corrective measures should be taken, such as increasing space allowance, redefining the areas available for lying, standing and feeding.

In pastured systems, stocking density should depend on the available feed and water supply and pasture quality.

Outcome-based measurables: behaviour, especially agonistic or depressive behaviour, morbidity rate, mortality rate, changes in weight and body condition, physical appearance, changes in milk yield, parasite burden, growth rate.

5.e) Protection from predators

Cattle should be protected from predators.

Outcome-based measurables: mortality rate, morbidity rate (injury rate), behaviour, physical appearance.

6.f) Genetic selection

Welfare and health considerations, in addition to productivity, should be taken into account when choosing a breed or subspecies for a particular location or production system.

In breeding programmes, attention should be paid to criteria conducive to the improvement of cattle welfare, including health. The conservation and development of genetic lines of dairy cattle, which limit or reduce animal welfare problems, should be encouraged. Examples of such criteria include nutritional maintenance requirement, disease resistance and heat tolerance.

Annex 19 (contd)

Individual animals within a breed should be selected to propagate offspring that exhibit traits beneficial to animal health and welfare by promoting robustness and longevity. These include resistance to infectious and production related *diseases*, ease of calving, fertility, body conformation and mobility, and temperament.

Outcome-based measurables: morbidity rate, mortality rate, length of productive life, behaviour, physical appearance, reproductive efficiency, lameness, human-animal relationship, growth rate, body condition outside an acceptable range.

7.g) Artificial insemination, pregnancy diagnosis and embryo transfer

Semen collection should be carried out by a trained operator in a manner that does not cause pain or distress to the bull and any teaser animal used during collection and in accordance with Chapter 4.6.

Artificial insemination and pregnancy diagnosis should be performed in a manner that does not cause pain or distress by a competent operator.

Embryo transfer should be performed under an epidural or other anaesthesia by a trained operator, preferably a *veterinarian* or a *veterinary para-professional* and in accordance with the provisions of Chapter 4.7. and Chapter 4.8.

Outcome-based measurables: behaviour, morbidity rate, reproductive efficiency.

8.h) Dam and sire selection and calving management

Dystocia is a welfare risk to dairy cattle. Heifers should not be bred before they reach the stage of physical maturity sufficient to ensure the health and welfare of both dam and calf at birth. The sire has a highly heritable effect on final calf size and as such can have a significant impact on ease of calving. Sire selection for embryo implantation, insemination or natural mating, should take into account the maturity and size of the female.

Pregnant cows and heifers should be managed during pregnancy so as to achieve an appropriate body condition range for the breed. Excessive fatness increases the risk of dystocia and metabolic disorders during late pregnancy or after parturition.

Cows and heifers should be monitored when they are close to calving. Animals observed to be having difficulty in calving should be assisted by a competent handler as soon as possible after they are detected. When a caesarean section is required, it must be carried out by a *veterinarian*.

Outcome-based measurables: morbidity rate, mortality rate (cow and calf), reproductive efficiency, especially rate of dystocia, retained placenta and metritis, body condition.

9.i) Newborn calves

Calving aids should not be used to speed the birthing process, only to assist in cases of dystocia, and should not cause undue pain, distress, or further medical problems.

Newborn calves are susceptible to hypothermia. The temperature and ventilation of the birthing area should consider the needs of the newborn calf. Soft, dry bedding and supplemental heat can help prevent cold stress.

Receiving adequate immunity from colostrum generally depends on the volume and quality of colostrum ingested, and how soon after birth the calf receives it.

Animal handlers should ensure that calves receive sufficient colostrum of a satisfactory quality, preferably ~~from their own dam~~, and within 24 hours of birth to provide passive immunity. Colostrum is most beneficial if received during the first six hours after birth. ~~Where there is risk of disease transfer from the dam, colostrum from a healthy cow should be used. Where possible, calves should continue to receive colostrum or equivalent for at least five days after birth.~~

Annex 19 (contd)

Recently born calves should not be transported until the navel is dry, and after which time any transport required should be carried out in accordance with Chapter 7.3.

Calves should be handled and moved in a manner which minimises distress and avoids pain and injury.

Outcome-based measurables: physical appearance, mortality rate, morbidity rate, growth rate.

10.j) Cow-calf separation and weaning

Different strategies to separate the calf from the cow are utilised in dairy cattle production systems. These include early separation (usually within 48 hours of birth) or a more gradual separation (leaving the calf with the cow for a longer period so it can continue to be suckled). Separation is stressful for both cow and calf.

For the purposes of this chapter, weaning means the change from a milk-based diet to a fibrous diet and the weaned calf no longer receives milk in its diet. This change should be made gradually and calves should be weaned only when their ruminant digestive system has developed sufficiently to enable them to maintain growth, health and good welfare.

Dairy cattle producers should seek expert advice on the most appropriate time and method of weaning for their type of cattle and production system.

Outcome-based measurables: morbidity rate, mortality rate, behaviour after separation (vocalisation, activity of the cow and calf), physical appearance, changes in weight and body condition, growth rate.

11.k) Rearing of replacement stock

Young calves are at particular risk of thermal stress. Special attention should be paid to management of the thermal environment (e.g. provision of additional bedding, nutrition or protection to maintain warmth and appropriate growth).

Individual calf-housing facilitates monitoring of health of very young calves and minimises the risk of disease spread. Replacement stock should then be reared in groups. Animals in groups should be of similar age and physical size.

Whether reared individually or in group pens, each calf should have enough space to be able to turn around, rest, stand up and groom comfortably and see other animals.

Replacement stock should be monitored for cross-sucking and appropriate measures taken to prevent this occurring (e.g. provide sucking devices, revise or modify feeding practices, provide other environmental enrichments).

Particular attention should be paid to the nutrition, including trace elements, of growing replacement stock to ensure good health and that they achieve an appropriate growth curve for the breed and farming objectives.

Outcome-based measurables: morbidity rate, mortality rate, behaviour, especially cross-sucking, altered grooming and lying behaviours, injuries, physical appearance, changes in weight and body condition, growth rate.

12.l) Milking management

Milking, whether by hand or machine, should be carried out in a calm and considerate manner in order to avoid pain and distress. Special attention should be paid to the hygiene of personnel, the udder and milking equipment. All cows should be checked for abnormal milk at every milking.

Milking machines, especially automated milking systems, should be used and maintained in a manner which minimises injury to teats and udders. Manufacturers of such equipment should provide operating instructions that consider *animal welfare*.

A regular milking routine should be established relevant to the stage of lactation and the capacity of the system.

Annex 19 (contd)

Animal handlers should regularly check the information provided by the milking system and act accordingly to protect the welfare of the cows.

Special care should be paid to animals being milked for the first time. They should be familiarised with the milking facility prior to giving birth.

Long waiting times before and after milking can lead to health and welfare problems (e.g. lameness, reduced time to eat). Management should ensure that waiting times are minimised.

Outcome-based measurables: morbidity rate (e.g. udder health, milk quality), behaviour, changes in milk yield, physical appearance (e.g. lesions).

13.m) Painful husbandry procedures

Husbandry practices are routinely carried out in cattle for reasons of management, *animal welfare* and human safety. Those practices that have the potential to cause pain should be performed in such a way as to minimise any pain and stress to the animal. Such procedures should be performed at as early an age as possible or using anaesthesia or analgesia under the recommendation or supervision of a veterinarian.

Options for enhancing *animal welfare* in relation to these procedures include: ceasing the procedure and addressing the need for the operation through management strategies; breeding cattle that do not require the procedure; or replacing the current procedure with a non-surgical alternative that has been shown to enhance *animal welfare*.

a)ii) Disbudding and dehorning

Horned dairy cattle are commonly disbudded or dehorned in order to reduce animal injuries and hide damage, improve human safety, reduce damage to facilities and facilitate transport and handling. The selection of polled cattle is preferable to dehorning.

Performing disbudding at an early age is preferred, rather than dehorning older cattle.

Thermal cautery of the horn bud by a trained operator with proper equipment is the recommended method in order to minimise post-operative pain. This should be done at an appropriate age before the horn bud has attached to the skull.

Guidance from a *veterinarian* or *veterinary para-professional* as to the optimum method and timing for the type of cattle and production system should be sought. The use of anaesthesia and analgesia are strongly recommended when performing disbudding, and should always be used when dehorning. Appropriate restraint systems and procedures are required when disbudding or dehorning.

Other methods of disbudding include: removal of the horn buds with a knife and the application of chemical paste to cauterise the horn buds. Where chemical paste is used, special attention should be paid to avoid chemical burns to other parts of the calf or to other calves. This method is not recommended for calves older than two weeks.

Operators should be trained and competent in the procedure used, and be able to recognise the signs of pain and complications that may include excessive bleeding or sinus infection.

Methods of dehorning when horn development has commenced involve the removal of the horn by cutting or sawing through the base of the horn close to the skull.

b)ii) Tail docking

Tail docking does not improve the health and welfare of dairy cattle and therefore it is not recommended. As an alternative, trimming of tail hair should be considered where maintenance of hygiene is a problem.

c)iii) Identification

Ear-tagging, ear-notching, tattooing, branding and radio frequency identification devices (RFID) are methods of permanently identifying dairy cattle. The least invasive approach should be adopted whichever method is chosen (e.g. the least number of ear tags per ear and the smallest notch practical). It should be accomplished quickly, expertly and with proper equipment.

Freeze branding and branding with a hot iron should be avoided where alternative identification methods exist (e.g. electronic identification or ear-tags). When branding is used, the operator should be competent in procedures used and be able to recognise signs of complications.

Identification systems should be established also in accordance with Chapter 4.1.

Outcome-based measurables: morbidity rate (post-procedural complications), abnormal behaviour, vocalisation, physical appearance.

14.n) Inspection and handling

Dairy cattle should be inspected at intervals appropriate to the production system and the risks to the health and welfare of the cattle. Lactating cows should be inspected at least once a day. Some animals should be inspected more frequently, for example, neonatal calves, cows in late gestation, newly weaned calves, cattle experiencing environmental stress and those that have undergone painful husbandry procedures or veterinary treatment.

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

Recommendations on the handling of cattle are also found in Chapter 7.5. In particular handling aids that may cause pain and distress (e.g. electric goads) should be used only in extreme circumstances and provided that the animal can move freely. Dairy cattle should not be prodded in sensitive areas including the udder, face, eyes, nose or ano-genital region. Electric prods should not be used on calves (see also point 3 of Article 7.3.8.).

Where dogs are used as an aid for cattle herding they should be properly trained. *Animal handlers* should be aware that presence of dogs can stress the cattle and cause fear and should keep them under control at all times. The use of dogs is not appropriate in housed systems, collection yards or other small enclosures where the cattle cannot move freely away.

Cattle are adaptable to different visual environments. However, exposure of cattle to sudden movement or changes in visual contrasts should be minimised where possible to prevent stress and fear reactions.

Electroimmobilisation should not be used.

Outcome-based measurables: handling responses, morbidity rate, mortality rate, behaviour, especially altered locomotory behaviour and vocalisation.

15.o) Personnel training

All people responsible for dairy cattle should be competent in accordance with their responsibilities and should understand cattle husbandry, animal handling, milking routines, reproductive management techniques, behaviour, *biosecurity*, signs of *disease*, and indicators of poor *animal welfare* such as stress, pain and discomfort, and their alleviation.

Competence may be gained through formal training or practical experience.

Outcome-based measurables: handling responses, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight and body condition, changes in milk yield.

Annex 19 (contd)16.p) Disaster management

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

In times of drought, animal management decisions should be made as early as possible and these should include a consideration of reducing cattle numbers.

Humane *killing* procedures for sick or injured cattle should be part of the disaster management plan.

Reference to emergency plans can also be found in points 74 g) and 2a) iii) of Article 7.11.56 and point 1c) of Article 7.11.7.

17.q) Humane killing

For sick and injured cattle a prompt diagnosis should be made to determine whether the animal should be treated or humanely killed.

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

Reasons for humane *killing* may include:

- severe emaciation, weak cattle that are non-ambulatory or at risk of becoming non ambulatory;
- non-ambulatory cattle that will not stand up, refuse to eat or drink, have not responded to therapy;
- rapid deterioration of a medical condition for which therapies have been unsuccessful;
- severe, debilitating pain;
- compound (open) fracture;
- spinal injury;
- central nervous system *disease*;
- multiple joint *infections* with chronic weight loss;
- calves that are premature and unlikely to survive, have a debilitating congenital defect, or otherwise unwanted; and
- as part of disaster management response.

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

— Text deleted.

DRAFT CHAPTER 7.X.

WELFARE OF WORKING EQUIDS

Article 7.X.1.

Preamble

In many countries, working equids, used for transport and traction, contribute directly and indirectly to households' livelihoods and benefit communities as a whole.

More specifically, they contribute to agricultural production and food security by transporting, for instance, water and fodder for other livestock, firewood and other daily needs to the homestead, agricultural products to the market; they provide draught power for agricultural work such as ploughing, harrowing and seeding, weeding and transport; they supply manure and, in some cases, *milk*, *meat* and hides for household use or income (FAO, 2014). Working equids may be of direct or indirect use in production and commercial activities.

~~Working equids may be of direct or indirect use in commercial activities such as taxi services, construction, tourism and transporting goods. They can also be rented out and provide an income for the equid's owner and a small business opportunity for the hirer (FAO, 2014). In the case of the latter there can potentially be an increased *animal welfare* risk.~~

~~Finally, working equids relieve the physical burden of women and children and less able people in transport of domestic needs; they may strengthen social relationships within extended families and communities through sharing working animals at times of need, for example during ploughing and harvesting seasons. They transport people to health centres and medical supplies to remote areas and may also form an important part of weddings or ceremonial occasions (FAO, 2014) (The Brooke, 2014).~~

The welfare of these working equids is often poor and this may be as a result of their ownership by poor and marginalised communities who are unable to sufficiently resource their needs ~~or who have insufficient knowledge of the appropriate care of equids.~~ Certain working contexts may present a particular risk to welfare such as working within construction industries ~~(e.g. brick kilns).~~

Article 7.X.2.

Scope and definition

This chapter applies to the following working animals: horses, mules and donkeys ~~that which~~ are destined, used for and retired from for traction and, transport, ~~for~~ and generation of income ~~generation as well as domestic use (non-commercial work).~~ Equids used in sports or competitions, leisure riding or research are excluded.

For the purposes of this chapter, harness means all parts of the driving harness, saddle, bridle and bit that work to control the working equid, act as a braking system when pulling a cart, hold loads in place and transfer power to attached carts or agricultural implements.

Annex 20 (contd)

Article 7.X.3.

Responsibilities and competencies

All those with a defined responsibility as outlined below should have the requisite knowledge and skill to perform their duties.

1. Veterinary Authority

The *Veterinary Authority* is the responsible for implementation of animal health and welfare. ~~However, in the case of working equids, the responsibility may be shared with other government agencies, and institutions and relevant stakeholders as listed below and including but is not limited to those responsible for agriculture and transport.~~

2. Other government agencies

The responsibilities of other government agencies will depend on the range of working equid uses and contexts.

For example those agencies responsible for regulating industrial and construction activities brick kilns, whether for environmental or labour compliance, may also have a responsibility for the working equids involved in the industry.

Particularly in urban areas, the transport or other responsible agency may have legislative authority in dealing with traffic circulation and have a role to play in ensuring a safe environment for working equids as well as other road users.

Environmental protection agencies may regulate and enforce measures to prevent working equids from accessing ~~rubbish or garbage sites or other potential~~ sources of contamination ~~(such as agricultural chemicals or cadavers).~~

The agency responsible for public health may have legislative authority in dealing with *zoonosies* ~~such as glanders.~~

Education authorities have a responsibility in schools and through agricultural, veterinary para-professional ~~para-veterinary~~ and veterinary training; appropriate education and training ~~can will~~ prevent many welfare problems ~~from occurring.~~

3. Local government authorities

Local government authorities are responsible for many services and programmes that relate to health, safety and public good within their jurisdiction. In many countries the legislative framework gives authority to local government agencies with regard to aspects of transport, agriculture, public health, environmental health and inspection, and compliance activities including in relation to animal health measures ~~quarantine~~ and responsibility for abandoned animals.

In many countries local government agencies are responsible for the development and enforcement of legislation relating to equine drawn carts and carried loads in traffic, *animal identification* (registration), licensing and disposal of dead animals.

4. Private sector veterinarians

~~The private sector veterinarians~~ are responsible for providing services and advice to working equid owners or handlers and can play an important role in *disease surveillance* because they may be the first to see an equid suffering from a *notifiable disease*. ~~The private sector veterinarians should follow the procedure established by the Veterinary Authority for reporting a suspected notifiable disease. Private sector veterinarians.~~ They may also play a role (often in liaison with the police or other local authorities) in dealing with cases of neglect that can lead to welfare problems.

~~The private veterinarians should have competence in clinical examination, diagnosis and treatment, preventive procedures such as vaccination (which may include contracted services from the government in the case of certain diseases), animal identification, nutrition, and management advice provision, surgical procedures and euthanasia.~~ Two-way communication between the private sector veterinarians and *Veterinary Authority*, often via the medium of a veterinary professional organisation, is important and the *Veterinary Authority* is responsible for setting up appropriate mechanisms for this interaction.

Private veterinarians may also have a responsibility in supervising and coordination of *veterinary para-professionals* involved in delivering animal health services.

5. Non-governmental organisations

Relevant non-governmental organisations (NGOs) and intergovernmental organisations should understand the role of working equids and may help to collect and provide information to support policy formulation, to advocate for and promote health and welfare of working equids.

Local NGOs are potential partners of the *Veterinary Services* in the development and implementation of working equid health and welfare programmes.

NGOs may also contribute, together with veterinarians and *Competent Authorities*, in educating the public in the importance of *animal welfare* of working equids.

6. Working equid owners and users

Owners and users are ultimately responsible for the welfare of their working equids by ensuring their animals' "five freedoms" ~~should ensure that the welfare of the equid, including behavioural needs, is respected and the equid is protected, as far as possible, from injuries, harm, neglect and infectious diseases (e.g. through vaccination and parasite control). Provision of appropriate feed, water and shelter is also a responsibility of the equid owner.~~

Article 7.X.4.

Criteria or measurables for the welfare of working equids

Although there is no single measure of *animal welfare*, focusing on issues that improve animal health and cater for the needs of working equids will bring about improvements in *animal welfare* in practice and ensure that legislators can make evidence-based decisions (Dawkins, 2006).

The following outcome-based measurables can be useful indicators of *animal welfare*. The use of these indicators and the appropriate thresholds should be adapted to the different situations where working equids are used.

Annex 20 (contd)1. Behaviour

Presence or absence of certain equine behaviours could indicate an *animal welfare* problem, including fear, depression or pain. ~~Non-specific behavioural indicators of pain include aggression, restlessness, agitation, a reluctance to move and a lowered head carriage. Other behaviours have been well documented (at least for horses) for abdominal, limb and dental pain (Ashley *et al.*, 2005). Behaviours differ between donkeys, horses and mules and a good understanding of normal behaviour of each species is required.~~

Some behaviours may not be uniquely indicative of one type of problem; they may be exhibited for a variety of different welfare causes. Depression, apathy, dullness and lethargy in equids that are usually active and alert can be indicative of a welfare problem. Changes in eating or drinking patterns may indicate a welfare problem, especially a decreased feed intake. This might also be an indicator of dental problems, poor feed quality or even feed contamination.

Behaviours indicating discomfort or pain:

- ≡ head pressing, teeth grinding, grunting, food dropping, and inability to eat normally; such behaviours may indicate disease process or pain;
- ≡ depression, circling, foot pawing, flank watching, inability to stand up and rolling; such behaviours may indicate abdominal or other discomfort;
- ≡ disturbance of ground or bedding; such behaviours may indicate disease process, abdominal pain and malnutrition;
- ≡ weight shifting, foot pawing, reluctance to move or abnormal movement; such behaviours may indicate leg, foot or abdominal pain;
- ≡ head shaking or avoidance of head contact; such behaviours may indicate head, ear or ocular discomfort;
- ≡ itching, rubbing and self-inflicted abrasions; such behaviours may indicate skin problems and parasites;
- ≡ restlessness, agitation and anxiety, rigid stance and reluctance to move, lowered head carriage, fixed stare and dilated nostrils, clenched jaw, aggression and reluctance to be handled may indicate non-specific pain in horses; in donkeys, these behaviours are more subtle and may not be recognised;
- ≡ vocalisation, rolling, kicking at abdomen, flank watching and stretching may indicate abdominal pain in horses; in donkeys, dullness and depression;
- ≡ Weight-shifting, limb guarding, abnormal weight distribution, pointing, hanging and rotating limbs, abnormal movement and reluctance to move may indicate limb and foot pain in horses; these signs are more subtle in donkeys, although repeated episodes of lying down are reportedly more indicative;
- ≡ headshaking, abnormal bit behaviour, altered eating, anorexia and quidding may indicate head and dental pain (Ashley *et al.*, 2005).

Behaviours indicating fear or anxiety:

- ≡ avoidance of humans, especially when handlers or objects associated with their handling come close;
- ≡ a reluctance by the working equids to engage in their use for traction or transport or even a cessation and aggressive behaviour, especially when fitting equipment or loading is undertaken.

Behaviours indicating stress:

= oral stereotypies: crib biting, aerophagia (“wind sucking”):

= locomotive stereotypies: stable walking, weaving.

2. Morbidity

Morbidity, including incidence of *disease*, lameness, injuries or post-procedural complications, may be a direct or indirect indicator of the *animal welfare* status.

Understanding the aetiology of the *disease* or syndrome is important for detecting potential *animal welfare* problems. Scoring systems, such as those used to score lameness and body condition, can provide additional information.

~~Post mortem examination is useful to establish causes of death. Both clinical and post mortem pathology may be utilised as indicators of disease, injuries and other problems that may compromise animal welfare.~~

3. Mortality

Mortality, like morbidity, may be a direct or indirect indicator of the *animal welfare* status. Depending on the context, causes of mortality should be investigated including as well as temporal and spatial patterns of mortality and possible relationships associated with husbandry and handling practices.

4. Body condition

~~Poor or changing body condition may be an indicator of compromised animal health and welfare and scoring systems help provide objectivity (Kay G., Pearson R.A. & Ouassat M. (2004); Pearson R. A. & Ouassat M., 1996; Carroll C. L. & Huntington P. J., 1988).~~

4.5. Body condition and physical appearance

Poor or changing body condition may be an indicator of compromised animal welfare and health and scoring systems help to provide objectivity (Kay G., Pearson R.A. & Ouassat M. (2004); Pearson R. A. & Ouassat M., 1996; Carroll C. L. & Huntington P. J., 1988).

Observation of physical appearance ~~will~~ often provides an indication of animal welfare and health. Attributes of physical appearance that may indicate compromised welfare include:

- feet or limb abnormalities,
- wounds or injuries,
- dehydration (~~measured by drinking behaviour~~) or signs of heat stress,
- abnormal discharges,
- presence of parasites,
- abnormal coat, texture or hair loss,
- excessive soiling with faeces, mud or dirt,
- ~~emaciation,~~
- ~~abnormal behaviour, postures and gait.~~

Annex 20 (contd)56. Handling responses

Poor human-animal interactions can lead to or be caused by improper handling. This may include ~~inappropriate~~ poor driving and restraint methods such as the ~~inappropriate~~ use of whips and sticks, and can result in fear and distress.

Indicators ~~could~~ include:

- aversive responses to fitting of equipment and loads,
- defensive responses from the equid to the owner or user such as threatening facial expressions, kicking, biting and avoiding human contact.
- ~~injuries to animals resulting from improper handling.~~

67. Complications due to management practices

Some management practices, such as castration and hoof care, are commonly performed in working equids ~~for improving animal performance, to facilitating~~ handling, and ~~improving~~ human safety and *animal welfare*.

Working equids are shod for two main reasons; to prevent hoof wear and to improve performance. Many equids cope well without shoes and, if they are coping well, are best unshod. However, poor hoof care and farriery predisposes the working equid to injury and infection, and can result in changes to the size, shape and function of the hoof. Untreated abnormalities of the foot can create long-term problems in other parts of the leg due to change in gait and weight bearing.

~~They should be accomplished quickly, expertly and with the proper equipment. If these such~~ management practices ~~procedures~~ are not performed properly, *animal welfare* can may be compromised.

Indicators of such problems ~~could~~ include:

- post-procedure *infection* and swelling;
- post-procedure lameness;
- yiasis;
- behaviour indicating pain or fear;
- mortality.

It is important to note that some “~~management practices~~” are not based on evidence and are inherently bad for welfare. Evidence of firing, nasal slitting, lampas cutting and harmful substances applied to ~~put~~ ~~on~~ wounds should be identified as indicators of poor welfare.

78. Lameness (Gait)

Traditionally, lameness has been defined as any alteration of the horse's gait. In addition, lameness can ~~be~~ manifest in such ways as a change in attitude or performance. These abnormalities can be caused by pain in the neck, withers, shoulders, back, loin, hips, legs or feet. Identifying the source of the problem is essential ~~to~~ for proper treatment (AAEP, 2014). Lameness or gait abnormalities are the most common presenting signs of working equids to *veterinarians*. ~~Ninety to ninety nine per cent of working equids may have hoof and limb problems~~ (Burn *et al.*, 2010; Pritchard *et al.*, 2005).

Indicators of such problems could include:

- hoof conformation abnormalities;
- unequal weight bearing;
- hoof pastern axis and angles;
- lameness grades: there are various gait or lameness scoring systems; an example is one developed by the American Association of Equine Practitioners (AAEP).

The scale ranges from zero to five, with zero being no perceptible lameness, and five being most extreme:

- 0- Lameness not perceptible under any circumstances.
- 1- Lameness is difficult to observe and is not consistently apparent, regardless of circumstances (e.g. under saddle, circling, inclines, hard surface, etc.).
- 2- Lameness is difficult to observe at a walk or when trotting in a straight line but consistently apparent under certain circumstances (e.g. weight carrying, circling, inclines, hard surface, etc.).
- 3- Lameness is consistently observable at a trot under all circumstances.
- 4- Lameness is obvious at a walk.
- 5- Lameness produces minimal weight bearing.

98. Fitness to work

Fitness to work is defined as the state or condition of being physically sound and healthy, especially as a result of exercise and proper nutrition, to perform work well (Saunders Comprehensive Veterinary Dictionary, 3 ed. Elsevier).

Indicators of an equid's inability to carry out the work demanded of it include the presence of heat stress, lameness, poor body condition or weight loss, harness related wounds and aversive behavioural responses to, for example, harness or equipment fitting.

Article 7.X.5.

Recommendations

Articles 7.X.67. to 7.X.134. provide recommendations for measures applied to working equids.

Each recommendation includes a list of relevant outcome-based measurables derived from Article 7.X.4. This does not exclude other measures being used where appropriate.

Annex 20 (contd)

Article 7.X.6.

Nutrition, and Feeding and provision of watering1. Feeding

Working equids are natural grazers that eat little and often. Their natural diet is mainly grasses, which have a high roughage content. Horses should be provided frequently with a predominantly fibre-based diet: either grass, hay or suitable and safe alternative in order to mimic their natural feeding pattern as closely as possible.

Energy, fibre, protein, mineral (including trace minerals) and vitamin contents in the diet of working equids, their balance, safety, digestibility and availability are major factors determining the ~~traction~~ power of the animals, their growth and overall productivity and their health and welfare (FAO, 2014; Pearson, 2005).

Working equids should be provided with access to an appropriate quantity of balanced and safe feed, ~~and water which is safe (edible and with no biological, chemical and physical contaminants)~~ and of adequate quality to meet their physiological and working needs. In case of feed shortages, the *animal handler* should ensure that the period of reduced feeding is as short as possible and that mitigation strategies are implemented if welfare and health are at risk of being compromised (NRC, 2007).

If supplementary feed is not available, steps should be taken to avoid starvation, including *slaughter*, sale or relocation of the animals, or humane *killing*.

Working equids need some of their nutrient requirements to be met by fresh, green forage. For this purpose, owners and handlers should allow them to forage whenever possible and allow for an adequate number of working breaks to allow the animals to eat (Heleski *et al.*, 2010). Cut green forage should be provided when grazing is not possible. Long fibre forage is important as well as green forage and should also be provided even when green forage is not available. Long fibre hay is better than chopped forage ~~to prevent ulcers~~.

Inadequate diets and feeding systems that may contribute to *diseases*, stress, discomfort or to abnormal behaviour in working animals should be avoided. *Animal handlers* should be aware of the importance of the animals' nutritional needs and consult an expert for advice on ration formulation and feeding programmes when needed.

2. Provision of water

~~However, t~~The most important nutrient for the welfare of working equids is water (Heleski *et al.*, 2010). Working equids need regular and adequate ~~supply and~~ access to palatable, safe water that meets their physiological, and work, and environmental requirements which may vary (~~e.g. increased water need in hot weather~~).

Outcome-based measurables: behaviour, morbidity, mortality, and morbidity rates, behaviour, changes in weight and body condition and physical appearance, and fitness to work, ~~dehydration (as measured by drinking behaviour), signs of heat stress.~~

Article 7.X.7.

Shelter: ~~homestead housing, workplace shelter, environmental considerations, protection from predators~~

Effective shelter should be provided for working equids both in the resting and working environments. Shelter should provide protection against adverse weather conditions and against predators and injury as well as good ventilation and the ability to rest comfortably. Resting space should be dry, clean and large enough for the equid to lie down, get up and turn around easily ~~comfortably and turn round.~~

1. Heat stress

Heat stress is a common condition in working equids ~~which are often working~~ in hot, humid environments and *animal handlers* should be aware of the risk that heat stress poses. Equid owners and handlers should be aware of how to prevent it through provision of appropriate shade or shelter along with sufficient drinking water (The Brooke, 2013). Owners may also be trained in effective treatment of hyperthermia as timely veterinary assistance may not be available.

Behaviours which indicate heat stress include increased respiratory rate and effort; flared nostrils; increased head movement and lack of response to environment (Pritchard *et al.*, 2006).

Outcome-based measurables: ~~largely behavioural, morbidity, mortality, body condition and physical appearance and fitness to work including: increased respiratory rate and effort; flared nostrils; increased head movement and lack of response to environment (Pritchard *et al.*, 2006).~~

2. Cold

Protection from extreme cold weather conditions should be provided when these are likely to create a serious risk to the welfare of equids, particularly of neonates and young animals and others that are physiologically compromised. Such a protection could be provided by natural or man-made shelter structures. Care must be taken that, in an attempt to protect against the cold, ventilation and air quality are not compromised. *Animal handlers* should also ensure that equids have access to adequate feed and water during cold weather (The Brooke ~~WEVM~~, 2013).

Behaviour which indicates suffering from cold stress includes huddling.

Outcome-based measurables: behaviour, mortality rates, and body condition and physical appearance, ~~behaviour including abnormal postures and huddling.~~

3. Protection ~~against~~ from predators and injury

~~Good shelter is required to keep~~ Working equids should be kept safe from predators and from road accidents, which are a common occurrences if equids are left free to roam. If working equids are housed alongside ~~other domestic livestock~~ horned cattle, care ~~must~~ should be taken to protect them from injury ~~by horned cattle~~ (The Brooke ~~WEVM~~, 2013).

Outcome based measurables: behaviour, ~~morbidity (injury rate) and, mortality rates,~~ body condition and physical appearance and lameness, behaviour.

Annex 20 (contd)

Article 7.X.8.

~~Disease and injury m~~Management: management of endemic disease, infectious disease, work-related wounds and injuries, ~~planning for disease outbreaks, health service provision~~1. Biosecurity and disease prevention

~~For the purpose of this chapter, biosecurity means a set of measures designed to maintain an equid population or herd at a particular health status and to prevent the entry or spread of infectious agents. Biosecurity plans should be designed, promoted with, and implemented by, stakeholders, commensurate with the desired health status of the equid population or herd and current disease risk and for listed diseases, in accordance with relevant recommendations of the Terrestrial Code. These biosecurity plans should address the control of the major sources and pathways for spread of pathogens by:~~

- a) equids,
- b) other animals and disease vectors vectors,
- c) people,
- d) equipment (e.g. harnessing, handling and grooming equipment, feeding utensils),
- e) vehicles,
- f) air,
- g) water supply,
- h) feed.

~~Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, changes in body condition and physical appearance.~~

2. Animal health management

Animal health management means a system designed to optimise the physical and behavioural health and welfare of the working equid. It includes the prevention, treatment and control of diseases and conditions affecting the individual animal and herd, including the recording of illnesses, injuries, mortalities and medical treatments where appropriate.

~~There should be an e~~Effective national programmes for the prevention and treatment of working equid diseases and conditions require with clear roles and responsibilities to be defined for official and private animal health service personnel as well as for owners.

Owners and handlers of working equids should be aware of signs of ill-health, disease, distress and injuries. If they suspect the presence of disease and are not able to manage it, they should seek advice from veterinarians or other qualified persons.

~~Those responsible for the care of working equids should be aware of the signs of ill health or distress, such as reduced feed and water intake, changes in weight and body condition, changes in behaviour or abnormal physical appearance.~~

Annex 20 (contd)

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

~~Vaccinations and other treatments administered to equids should be undertaken by people skilled in the procedures and on the basis of veterinary or other expert advice.~~

~~Animal handlers should have experience in recognising and managing chronically ill or injured equids, including those that are non-ambulatory.~~

Non-ambulatory working equids should have access to feed and water at all times and be provided with concentrated feed at least once daily and hay or forage *ad libitum*. They should not be transported or moved unless absolutely necessary for treatment or diagnosis. Such movements should be done carefully using methods avoiding dragging or excessive lifting.

When treatment is attempted, equids that are unable to stand up unaided and refuse to eat or drink should be euthanised in accordance with according to the methods indicated in Chapter 7.6., as soon as recovery is deemed unlikely.

Outcome-based measurables: morbidity rate, mortality rate, ~~reproductive efficiency~~, behaviour, body condition and physical appearance, and changes in body condition.

~~Health is a major component of the welfare of an animal, as an animal in poor health is necessarily in a state of decreased well-being. Health may be assessed by:~~

a) ~~The general appearance of the equid~~

~~This is a simple to evaluate and revealing parameter, it suffices to observe the posture, and demeanour of the animal, its body condition, and the appearance of its coat.~~

b) ~~The absence of injury~~

~~A wounded animal is suffering. Pain from wounds decreases welfare. Injuries may result from inappropriate external factors; they may result from a poorly adapted environment (e.g. hobble, bit wounds or harness wounds), they may also be indicative of poor human-animal interactions.~~

e) ~~The absence of disease~~

~~Evolution of diseases: disease patterns change with time and in working equids, overt clinical signs of infectious disease may often be difficult to detect. More commonly seen are multi-factorial syndromes or conditions involving multiple pathogens as well as environmental and management factors.~~

d) ~~The effects of stress~~

~~Stress has a deleterious effect on the immune system; a high incidence of disease may be indicative of too much stress.~~

Annex 20 (contd)

Article 7.X.9.

Handling and driving practice, handling facilities, personnel expertise and training, mutilations and other management practices

Management practices should be accomplished expertly and with the proper equipment and pain relief if appropriate.

Drivers and handlers should be trained to acquire good management practice skills.

Poor management practices include bad handling, inappropriate restraint such as too tight tethering or hobbling, working animals that are unfit or immature, poor housing that does not protect the equids from adverse weather conditions (~~heat stress~~), inadequate handling equipment, excessive number of working hours, ~~being underfed~~, lack of access to water, lack of resting periods, working under heat stress, overloads, beating or whipping and some traditional practices such as firing or, nostril slitting.

~~Some traditional beliefs encourage unsafe, non-effective and inhumane handling of working equids. Firing is carried out in the mistaken belief that it will cure problems such as lameness or respiratory disease and nostrils may be slit in an attempt to increase airflow in hot climates. Competent Authorities and veterinarians have a role in should educate owners and handlers of working equids to cease these unsafe, non-effective and inhumane inappropriate and ineffective practices and also in encourage good management and handling skills.~~

~~Education of veterinarians on working equid health, handling, use and management is currently inadequately covered in most veterinary curricula and training programmes for drivers and operators and this should be addressed if such people are to fulfil their responsibility to train others.~~

Working eEquids should not be tethered or hobbled continuously permanently; they should not be hobbled for continuous periods of more than 12 hours in any 24-hour period. In situations where temporary hobbling is necessary, sufficient distance between the two hobbled legs is required to allow the equid to stand as naturally as possible.

~~The tethering site should have a minimum radius of nine metres, and should be free from obstructions that may entangle the tether. Adequate water, and feed and frequent supervision should be provided; action may be taken if necessary by moving the animals to areas providing shade or shelter.~~

~~Mares in season should not be tethered with near stallions; mares about to foal or with a foal should not be tethered.~~

~~Equipment used to hobble ~~must~~ should be designed for hobbling that purpose. The parts of the hobbles which are in contact with the skin should not be made from material that causes pain or injury (Burn *et al.*, 2008).~~

~~Harness injury should be prevented through daily checking of harness for damage and prompt, effective repair as necessary. Equids should be checked after work for signs of rubbing and hair loss and the source of any problems should be removed through maintenance and padding where required. Bits in particular should have no sharp edges and should be of the appropriate size for the animal.~~

Owners and users of working equids should be discouraged from using whips and harmful goads such as sticks. Instead humane training practices for equids should be promoted which focus on developing good driving practices.

Outcome based measurables: behaviour, morbidity, mortality, and morbidity rates, body condition and physical appearance, lameness and fitness to work (~~firing, harness and hobbling wounds and lameness~~), behavioural signs.

Article 7.X.10.

Behaviour and social interactions

~~Natural behaviours and social interactions differ between horses, mules and donkeys, and *Animal handlers should be familiar* a familiarity with normal and abnormal behaviour of each type of working equid is recommended in order to interpret the welfare implications of what is being observed.~~

Human-animal interaction should be positive in order not to compromise the welfare of the working equid.

Different natural behaviours and social interactions between horses, mules and donkeys should be taken into account.

~~Some behaviours may indicate an *animal welfare* problem but may not be uniquely indicative of one type of problem; they may be exhibited for a variety of different welfare causes. Depression, apathy, dullness and lethargy in equids which are usually active and alert can be indicative of a welfare problem. Changes in eating or drinking habits patterns may indicate a welfare problem, especially a decreased feed intake. This might also be an indicator of dental problems; poor feed quality or even feed contamination.~~

~~A variety of other behaviours may also be observed in working equids.~~

~~Behaviours indicating discomfort or pain such as:~~

- ~~– Head pressing, stable walking, weaving, teeth grinding, grunting, food dropping, and inability to eat normally. Such behaviours may indicate disease process, abdominal or cranial pain.~~
- ~~– Depression, circling, foot pawing, flank watching, inability to stand up, trashing, rolling. Such behaviour may indicate abdominal or other discomfort.~~
- ~~– Disturbance of ground or bedding. Such behaviours may indicate disease process, abdominal pain, malnutrition.~~
- ~~– Weight shifting, foot pawing, reluctance to move or abnormal movement. Such behaviours may indicate leg, foot or abdominal pain.~~
- ~~– Head shaking, discharges or avoidance of head contact. Such behaviours may indicate head, ear or ocular discomfort.~~
- ~~– Itching, rubbing, self inflicted abrasions. Such behaviours may indicate skin problems, parasites.~~
- ~~– Non specific pain in horses: restlessness, agitation and anxiety, rigid stance and reluctance to move, lowered head carriage, fixed stare and dilated nostrils, clenched jaw, aggression and reluctance to be handled. In donkeys these behaviours are more subtle and may not be recognised.~~
- ~~– Abdominal pain in horses: vocalisation, rolling, kicking at abdomen, flank watching, stretching. In donkeys, dullness and depression.~~
- ~~– Limb and foot pain in horses: weight shifting, limb guarding, abnormal weight distribution, pointing, hanging and rotating limbs, abnormal movement, reluctance to move. These signs are more subtle in donkeys, although repeated episodes of lying down are reportedly more indicative.~~
- ~~– Head and dental pain: headshaking, abnormal bit behaviour, altered eating; anorexia, quidding, food pocketing (Ashley *et al.*, 2005).~~

Annex 20 (contd)

Behaviours indicating fear or anxiety such as:

- Avoidance of humans, especially when handlers or objects associated with their handling come close,
- A reluctance by the working equids to engage in their use for traction or transport or even a cessation and aggressive behaviour especially when fitting equipment or loading is undertaken.

Outcome-based measurables: behaviours ~~of discomfort or pain, sociability with humans and other equids, alertness, injuries, changes in weight and body condition and physical appearance, and fitness to work~~ willingness to accept equipment and loading for work.

Article 7.X.11.

End of life issues: euthanasia, slaughter (including end of working life, abandonment)

Consideration should be given to end of life issues.

Abandonment of equids should be discouraged. Competent Authorities should be responsible for developing and implementing guidance or legislation to prevent abandonment while taking steps to make provision for abandoned animals which would ensure their welfare.

When euthanasia or slaughter are is practised in working equids, the ~~general principles in the recommendations in~~ Chapters 7.5 and 7.6. of the Terrestrial Code should be followed. Euthanasia is the humane method of ending an animal's life in the most pain-free and least stressful way possible. Otherwise the working equid may suffer a prolonged and painful *death* by abandonment, neglect or disease or acute, painful death such as being eaten by *wild animals*, or hit by a road vehicle.

Article 7.X.12.

Appropriate workloads

~~No equid under the age of four years should be worked. They are under developed and their bones have not had time to mature sufficiently to cope with the rigours of work. In horses upper fore and hind limb growth plates do not close until four years of age and spinal ones not until five years of age. Equids continue to develop until over the age of five years so consideration should be given, according to workload, as to when working life commences. In general this should be three years of age or more but never less than two years of age.~~ Animals that are subjected to excessive work too young in life will usually suffer from leg and back injuries in later life, resulting in a much-reduced working life.

~~No Mares should~~ not be ridden or worked ~~within~~ three months before and after of foaling.

Special considerations should be given to old animals.

Animals should work a maximum of six hours per day and should be given at least one full day's rest in every seven-day period (preferably two). Consideration should be given to the animal's physical condition and age and the work load should be adjusted accordingly.

Consideration should be given to the weather conditions (work should be reduced in very hot weather). Breaks should be given at least every two hours and fresh drinkable water should be provided available.

All animals should receive sufficient good quality feed corresponding to their individual requirements. Fresh drinkable water and roughage should be available to aid digestion.

Sick or injured animals should not be worked. Any animal that has been under veterinary treatment should not be returned to work until advised by ~~from~~ the *veterinarian* ~~is received~~.

~~Animals should be in good health and fit to do the work that is required of them.~~

Outcome based measurables: behaviour, body condition and physical appearance, ~~dehydration~~, handling response, ~~gait and lameness~~ and fitness to work.

Article 7.X.13.

Farriery and harnessing1. Farriery

Owners and handlers should routinely clean and check the hooves of the working equid before and after work.

Hoof trimming and shoeing of working equids should only be performed by persons with the necessary knowledge and skills.

Equids are shod for two main reasons; to prevent hoof wear and to improve performance. Many equids cope well without shoes and, if they are coping well, are best unshod. However, poor hoof care and farriery predisposes the working equid to injury and infection, and can result in changes to the size, shape and function of the hoof. Untreated abnormalities of the foot can create long term problems in other parts of the leg due to change in gait and weight bearing. Such problems could include:

- a) Conditions of the hoof wall and horn producing tissues: hoof wall defects, such as cracks that involve the sensitive tissue; laminitis, laminar tearing (local, due to hoof imbalance), separation or inflammation of the sensitive laminae from the insensitive laminae; abscess formation; contusions of the hoof causing bruising or corn formation; neoplasia, and pododermatitis (thrush or canker);
- b) Conditions of the third phalanx: third phalanx problems include fractures of the coffin bone, deep digital flexor insertional tendinopathy, pedal osteitis (generalised or localised inflammation of the bone), and disruption of the insertions of the collateral ligaments, cyst like lesion formation, and remodeling disease;
- e) Conditions of the podotrochlear region: these include distal interphalangeal synovitis or capsulitis, deep digital flexor tendinitis, desmitis of the impar (distal navicular ligament) or collateral sesamoidean ligaments, navicular osteitis or osteopathy, and vascular disease of the navicular arteries, and navicular fractures;

These conditions are all characterised by pain that can be localised in the hoof (Turner, 2013).

Outcome based measurables: behaviour, body condition and physical appearance, lameness and fitness to work.

2. Harnessing

For the purpose of this chapter, harnessing includes all parts of the driving harness, saddle, bridle and bit. They work to control the working equid, act as a braking system when pulling a cart, hold loads in place and transfer power to attached carts or agricultural implements.

Annex 20 (contd)

A properly designed, well-fitted and comfortable harness allows the working equid to pull the equipment to the best of its ability, efficiently and without risk of injuries. ~~A poorly designed or ill-fitted harness can cause injury and discomfort to the animal as well as inefficient transfer of power from the animal to the implement or cart and can also be a danger for the handler and other road users.~~

Harness injury should be prevented through properly fitted and adjusted harness which is checked daily for damage and repaired promptly as necessary. Equids should be checked after work for signs of rubbing and hair loss and the source of any problems should be removed through maintenance and padding where required.

~~There should be enough clean padding on harnesses so the animals do not have to work with open sores.~~

~~A good harness; does should not have sharp edges which could cause injury to the equids; should fits well so that it does not cause wounds or chafing caused by excess movement; is should be smoothly shaped or padded so that loads imposed on the working equids' body bodies are spread over a large area; and does should not impede the animal's movement or normal breathing or restrict blood supply. Good harnessing also maximizes the efficiency of transfer of draught energy from animal to load so that minimum effort is required by the working equid.~~

Carts should be maintained to ensure accurate balancing and appropriate tyre pressure. For draught animals the use of swingletrees is recommended so as to balance the pull and thus as a result reduce the risk of sores from the harness.

Owners are responsible for ensuring that effective welfare-friendly harnessing is accompanied by good riding and driving practices.

Bits should be ~~ideally~~ of a simple type (such as a straight bar snaffle), depending on work, but should always be smooth, appropriately sized for the equid and kept clean. Inappropriate materials such as thin cord or wire should ~~not~~ never be used as bits or to repair bits.

~~Wounds caused by poorly maintained or inappropriate harnessing are common in working equids and attention should be paid to prevention of harness related injuries. (Pearson et al., 2003).~~

~~Outcome based measurables: lesions at sites of harness abrasion including abrasion of eye area associated with blinkers; lesions at lip commissures or other parts of the mouth associated with biting; lesions on tail, hindquarters, hind limbs or hocks associated with contact with cart. behaviour, body condition and physical appearance, lameness and fitness to work.~~

— Text deleted.

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CHAPTER 8.3.

INFECTION WITH BLUETONGUE VIRUS

Article 8.3.1.

General provisions

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

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

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

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

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

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

Article 8.3.2.

Safe commodities

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

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

Annex 21 (contd)

Article 8.3.3.

BTV-free country or zone free from bluetongue

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

Article 8.3.4.

BTV seasonally-free zone seasonally free from bluetongue

A ~~BTV seasonally-free zone~~ seasonally free from bluetongue is a part of an infected country or of an infected *zone* for which *surveillance* demonstrates no evidence either of ~~BTV~~ transmission of BTV or of adult *Culicoides* for part of a year.

For the application of Articles 8.3.7., 8.3.9. and 8.3.11., the seasonally free period is taken to commence the day following the last evidence of ~~BTV~~ transmission of BTV (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides*.

For the application of Articles 8.3.7., 8.3.9. and 8.3.11., the seasonally free period is taken to conclude either:

- 1) at least 28 days before the earliest date that historical data show ~~BTV~~ transmission of BTV may recommence; or
- 2) immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of adult *Culicoides*.

Annex 21 (contd)

A ~~BTV~~ seasonally free *zone* in which ongoing *surveillance* has found no evidence that *Culicoides* are present will not lose its free status through the introduction of vaccinated, seropositive or infective ruminants or camelids, or semen, or embryos ~~or oocytes~~ from infected countries or infected *zones*.

Article 8.3.5.

BTV-infected Country or zone infected with BTV

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

Article 8.3.6.

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

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

- 1) the animals showed no clinical sign of ~~BTV~~ bluetongue on the day of shipment;
- 2) the animals were kept in a ~~BTV-free~~ country or zone free from bluetongue since birth or for at least 60 days prior to shipment; or
- 3) the animals were kept in a ~~BTV-free~~ country or zone free from bluetongue for at least 28 days, then were subjected, with negative results, to a serological test to detect antibodies to the BTV group and remained in the ~~BTV free~~ country or zone until shipment; or
- 4) the animals were kept in a ~~BTV-free~~ country or zone free from bluetongue for at least 14 days, then were subjected, with negative results, to an agent identification test, and remained in the ~~BTV free~~ country or zone until shipment; or
- 5) the animals:
 - a) were kept in a ~~BTV-free~~ country or zone free from bluetongue for at least seven days;
 - b) were vaccinated, at least 60 days before the introduction into the free country or zone, against all serotypes demonstrated to be present in the source population through a *surveillance* programme as described in Articles 8.3.14. to 8.3.17.;
 - c) were identified as having been vaccinated;
 - d) remained in the ~~BTV free~~ country or zone until shipment;

AND

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

Annex 21 (contd)

Article 8.3.7.

Recommendations for importation from ~~BTV~~ zones seasonally free ~~zones~~ from bluetongueFor ruminants and camelids

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

- 1) showed no clinical sign of ~~BT~~ bluetongue on the day of shipment;
- 2) were kept during the seasonally free period in a ~~BTV~~-seasonally free *zone* since birth or for at least 60 days prior to shipment; or
- 3) were kept during the ~~BTV~~ seasonally free period in a ~~BTV~~ seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibodies to the BTV group, with negative results, carried out at least 28 days after the commencement of the residence period; or
- 4) were kept during the ~~BTV~~-seasonally free period in a ~~BTV~~ seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test, with negative results, carried out at least 14 days after the commencement of the residence period; or
- 5) were kept during the seasonally free period in a ~~BTV~~ seasonally free *zone* and were vaccinated, at least 60 days before the introduction into the free country or *zone*, against all serotypes demonstrated to be present in the source population through a *surveillance* programme in accordance with Articles 8.3.14. to 8.3.17. and were identified as having been vaccinated and remained in the ~~BTV~~ seasonally free country or *zone* until shipment;

AND

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

Article 8.3.8.

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

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

- 1) showed no clinical sign of ~~BT~~ bluetongue on the day of shipment;
- 2) were protected from attacks from *Culicoides* in a *vector-protected establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or

Annex 21 (contd)

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

Article 8.3.9.

Recommendations for importation from ~~BTV-free~~ countries or zones free or from BTV zones seasonally free zones from bluetongueFor semen of ruminants and camelids

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

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

Article 8.3.10.

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

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

- 1) the donor males:
 - a) showed no clinical sign of bluetongue on the day of collection;
 - b) were kept in a *vector-protected establishment* for at least 60 days before commencement of, and during, collection of the semen; or

Annex 21 (contd)

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

Article 8.3.11.

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

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

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

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

Article 8.3.12.

Recommendations for importation from ~~BTV-infected~~ countries or zones infected with BTV

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

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

- 1) the donor females:
 - a) showed no clinical sign of bluetongue on the day of collection;
 - b) were kept in a *vector-protected establishment* for at least 60 days before commencement of, and during, collection of the embryos ~~or oocytes~~; or
 - c) were subjected to a serological test to detect antibodies to the BTV group, between 28 and 60 days after collection, with negative results; or

Annex 21 (contd)

- d) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;
- 2) the embryos ~~or oocytes~~ were collected, processed and stored in accordance with Chapters 4.7., 4.8. and 4.9., as relevant;
- 3) the semen used to fertilise the oocytes complied with Article 8.3.9.

Article 8.3.13.

Protecting animals from *Culicoides* attacks

1. Vector-protected establishment or facility

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

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

2. During transportation

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

a) Transport by road

Risk management strategies may include:

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

Annex 21 (contd)

b) Transport by air

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

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

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

Article 8.3.14.

Introduction to surveillance

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

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

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

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

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

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

Article 8.3.15.

General conditions and methods for surveillance

- 1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:
 - a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspected cases of *infection* with BTV to a *laboratory* for diagnosis;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

Annex 21 (contd)

2) The bluetongue *surveillance* programme should:

- a) in a free country or zone or seasonally free ~~country or 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 infection with BTV to the *Veterinary Authority*.

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

AND

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

Article 8.3.16.

Surveillance strategies

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

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

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

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

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

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

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

Annex 21 (contd)

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

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following up positive reactions to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

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

1. Clinical surveillance

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

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

2. Serological surveillance

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

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

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

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

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

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

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

3. Virological surveillance

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

Virological *surveillance* can be conducted:

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

4. Sentinel animals

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

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

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

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

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

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

Annex 21 (contd)

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

5. Vector surveillance

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

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

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

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local *vector* species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to domestic ruminants, or the use of drop traps over ruminants.

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

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

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

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

Article 8.3.17.

Documentation of ~~BTV infection~~ bluetongue free status1. Additional surveillance requirements for Member Countries declaring freedom from ~~bluetongue infection with BTV~~

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

2. Additional requirements for countries or zones that practise vaccination

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

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

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CHAPTER 8.7.
**INFECTION WITH EPIZOOTIC HEMORRHAGIC
DISEASE VIRUS**

Article 8.7.1.

General provisions

For the purposes of the *Terrestrial Code*, epizootic hemorrhagic disease (EHD) is defined as an *infection* of cervids and bovids with epizootic hemorrhagic disease virus (EHDV) that is transmitted by *Culicoides* vectors.

The following defines the occurrence of an infection with EHDV:

- 1) EHDV has been isolated from a sample from a cervid or bovid; or
- 2) ~~viral~~ antigen or ~~viral~~ ribonucleic acid specific to EHDV has been identified in samples from a cervid or bovid showing clinical signs consistent with EHD, or epidemiologically linked to a suspected or confirmed case; or
- 3) antibodies to structural or nonstructural proteins of EHDV that are not a consequence of *vaccination* have been identified in a cervid or bovid that either shows clinical signs consistent with EHD, or is epidemiologically linked to a suspected or confirmed case.

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

In the absence of clinical *disease* in a country or *zone*, its EHD status should be determined by an ongoing *surveillance* programme in accordance with Article 8.7.14.

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

Article 8.7.2.

Safe commodities

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

- 1) *milk* and *milk products*;
- 2) *meat* and *meat products*;
- 3) hides, skins, antlers and hooves;
- 4) wool and fibre.

Annex 22 (contd)

Article 8.7.3.

Country or zone free from EHD

- 1) Historical freedom as described in Chapter 1.4. does not apply to EHD.
- 2) A country or a *zone* may be considered free from EHD when *infection* with EHDV is notifiable in the whole country, importation of animals and their semen, or embryos ~~or oocytes~~ is carried out in accordance with this chapter and either:
 - a) a *surveillance* programme in accordance with Article 8.7.14. has demonstrated no evidence of ~~EHDV~~ transmission of EHDV in the country or *zone* during the past two years; or
 - b) an ongoing *surveillance* programme in accordance with Article 8.7.14. and Chapter 4.3. has found no *Culicoides* for at least two years in the country or *zone*.
- 3) A country or *zone* free from EHD in which ongoing *vector surveillance* has found no evidence of *Culicoides* will not lose its free status through the introduction of seropositive or infective animals, or semen, or embryos ~~or oocytes~~ from countries or *zones* infected with EHDV.
- 4) A country or *zone* free from EHD in which *Culicoides* are present will not lose its free status through the introduction of seropositive animals, or semen, or embryos ~~or oocytes~~ provided that:
 - a) an ongoing *surveillance* programme has focused on ~~EHDV~~ transmission of EHDV in domestic bovids and farmed cervids and has demonstrated no evidence of ~~EHDV~~ transmission in the country or *zone*; or
 - b) the animals, semen, and embryos ~~and oocytes~~ were introduced in accordance with this chapter.

Article 8.7.4.

Zone seasonally free from EHD

A seasonally free *zone* is a part of an infected country or of an infected *zone* in which for part of a year, *surveillance* demonstrates no evidence either of ~~EHDV~~ transmission of EHDV or of adult *Culicoides*.

For the application of Articles 8.7.7., 8.7.9. and 8.7.11., the seasonally free period is taken to commence the day following the last evidence of ~~EHDV~~ transmission of EHDV (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides*.

For the application of Articles 8.7.7., 8.7.9. and 8.7.11., the seasonally free period is taken to conclude either:

- 1) at least 28 days before the earliest date that historical data show *vector* activity may recommence; or
- 2) immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of adult *Culicoides*.

A seasonally free *zone* in which ongoing *surveillance* has found no evidence that *Culicoides* are present will not lose its free status through the introduction of vaccinated, seropositive or infective animals, or semen, or embryos ~~or oocytes~~ from countries or *zones* infected with EHDV.

Article 8.7.5.

Country or zone infected with EHDV

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

Article 8.7.6.

Recommendations for importation from countries or zones free from EHDFor bovids and cervids

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

- 1) the animals showed no clinical sign of EHD on the day of shipment;
- 2) the animals were kept in a country or *zone* free from EHD since birth or for at least 60 days prior to shipment; or
- 3) the animals were kept in a country or *zone* free from EHD for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the EHDV group and remained in the free country or *zone* ~~free from EHD~~ until shipment; or
- 4) the animals were kept in a country or *zone* free from EHD for at least 14 days, then were subjected, with negative results, to an agent identification test and remained in the free country or *zone* ~~free from EHD~~ until shipment; or
- 5) the animals:
 - a) were kept in a country or *zone* free from EHD for at least seven days;
 - b) were vaccinated at least 60 days before the introduction into the free country or *zone* ~~free from EHD~~ against all serotypes demonstrated to be present in the source population through a *surveillance* programme as described in Article 8.7.14.;
 - c) were identified as having been vaccinated;
 - d) remained in the free country or *zone* ~~free from EHD~~ until shipment;

AND

- 6) if the animals were exported from a free *zone* within an infected country either:
 - a) did not transit through an infected *zone* during transportation to the *place of shipment*; or
 - b) were protected from attacks from *Culicoides* at all times when transiting through an infected *zone*.

Article 8.7.7.

Recommendations for importation from zones seasonally free from EHDFor bovids and cervids

Annex 22 (contd)

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

- 1) showed no clinical sign of EHD on the day of shipment;
- 2) were kept ~~during the seasonally free period~~ in a *zone* seasonally free from EHD during the seasonally free period since birth or for at least 60 days prior to shipment; or
- 3) were kept ~~during the seasonally free period~~ in a *zone* seasonally free from EHD during the seasonally free period for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibodies to the EHDV group with negative results, carried out at least 28 days after the commencement of the residence period; or
- 4) were kept ~~during the seasonally free period~~ in a *zone* seasonally free from EHD during the seasonally free period for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test with negative results, carried out at least 14 days after the commencement of the residence period; or
- 5) were kept ~~during the seasonally free period~~ in a *zone* seasonally free from EHD during the seasonally free period and were vaccinated, at least 60 days before the introduction into the free country or *zone*, against all serotypes the presence of which in the source population has been demonstrated through a *surveillance* programme in accordance with Article 8.7.14. and were identified as having been vaccinated and remained in the free country or *zone* ~~free from EHD~~ until shipment;

AND

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

Article 8.7.8.

Recommendations for importation from countries or zones infected with EHDV

For bovids and cervids

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

- 1) showed no clinical sign of EHD on the day of shipment;
- 2) were protected from attacks from *Culicoides* in a *vector-protected establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or
- 3) were protected from attacks from *Culicoides* in a *vector-protected establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test to detect antibodies to the EHDV group, with negative results, carried out at least 28 days after introduction into the *vector-protected establishment*; or

Annex 22 (contd)

- 4) were protected from attacks from *Culicoides* in a *vector-protected establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test with negative results, carried out at least 14 days after introduction into the *vector-protected establishment*; or
- 5) were demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Article 8.7.14.

Article 8.7.9.

Recommendations for importation from countries or zones free or zones seasonally free from EHDFor semen of bovids and cervids

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

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

Article 8.7.10.

Recommendations for importation from countries or zones infected with EHDVFor semen of bovids and cervids

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

- 1) the donor males:
 - a) showed no clinical sign of EHD on the day of collection;
 - b) were kept in a *vector-protected establishment* for at least 60 days before commencement of, and during, collection of the semen; or
 - c) were subjected to a serological test to detect antibodies to the EHDV group, with negative results, at least every 60 days throughout the collection period and between 28 and 60 days after the final collection for this consignment; or

Annex 22 (contd)

- d) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every seven days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.7.11.

Recommendations for importation from countries or zones free or zones seasonally free from EHD

For embryos or oocytes of bovids and cervids

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

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

Article 8.7.12.

Recommendations for importation from countries or zones infected with EHDV

For embryos or oocytes of bovids and cervids

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

- 1) the donor females:
 - a) showed no clinical sign of EHD on the day of collection;
 - b) were kept in a *vector-protected establishment* for at least 60 days before commencement of, and during, collection of the embryos ~~or oocytes~~; or
 - c) were subjected to a serological test to detect antibodies to the EHDV group, between 28 and 60 days after collection, with negative results; or
 - d) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;

- 2) the embryos or oocytes were collected, processed and stored in accordance with Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.7.13.

Protecting animals from *Culicoides* attacks

1. Vector-protected establishment or facility

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

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

2. During transportation

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

a) Transport by road

Risk management strategies may include:

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

Annex 22 (contd)

b) Transport by air

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

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

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

Article 8.7.14.

Surveillance

This article is complementary to Chapter 1.4. and, for *vectors*, complementary to Chapter 1.5. and outlines the principles for *surveillance* for EHD applicable to Member Countries seeking to determine the EHD status of a country or a *zone*.

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

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

The purpose of *surveillance* is the detection of transmission of EHDV in a country or *zone* and not determination of the status of an individual animal or *herd*.

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

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

General provisions on *surveillance* for arthropod *vectors* are in Chapter 1.5.

More specific approaches to *surveillance* for *Culicoides* transmitted *Orbivirus infections* are described in Chapters 8.3. and 12.1. Passive *surveillance* for clinical cases of EHD in *wild* cervids can be a useful tool for detecting disease, based on lesions of haemorrhagic *disease* combined with appropriate diagnostic tests.

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CHAPTER 8.14.

INFECTION WITH RIFT VALLEY FEVER VIRUS

Article 8.14.1.

General provisions

- 1) The aim of this chapter is to mitigate the animal and public health risks posed by Rift Valley fever (RVF) and to prevent its international spread.
- 2) Humans and many animal species are susceptible to *infection*. For the purpose of the *Terrestrial Code*, RVF is defined as an *infection* of ruminants with Rift Valley fever virus (RVFV).
- 3) The following defines the occurrence of ~~RVFV~~ *infection with RVFV*:
 - a) RVFV, excluding vaccine strains, has been isolated and identified as such from a sample from a ruminant; or
 - b) antigen or ribonucleic acid specific to RVFV, excluding vaccine strains, has been identified in a sample from a ruminant epidemiologically linked to a confirmed or suspected case of RVF, or giving cause for suspicion of association or contact with RVFV; or
 - c) antibodies to RVFV antigens which are not the consequence of *vaccination*, have been identified in a sample from a ruminant with either epidemiological links to a confirmed or suspected case of RVF, or giving cause for suspicion of association or contact with RVFV.
- 4) For the purposes of the *Terrestrial Code*, the *infective period* for RVF shall be 14 days.
- 5) In areas where RVFV is present, epizootics of RVF may occur following favourable climatic, environmental conditions and availability of susceptible host and competent *vector* populations. Epizootics are separated by inter-epizootic periods.
- 6) For the purposes of this chapter:
 - a) 'area' means a part of a country that experiences epizootics and inter-epizootic periods, but which does not correspond to the definition of *zone*;
 - b) 'epizootic of RVF' means the occurrence of *outbreaks* at an incidence substantially exceeding that during an inter-epizootic period;
 - c) 'inter-epizootic period' means the period of variable duration, often long, with intermittent low level of *vector* activity and low rate of virus transmission, which is often not detected;
 - d) ruminants include dromedary camels.
- 7) The historical distribution of RVF has been parts of the African continent, Madagascar, some other Indian Ocean Islands and the south western Arabian Peninsula. However, *vectors*, environmental and climatic factors, land-use dynamics, and animal movements may modify the temporal and spatial distribution of the *infection*.
- 8) When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.14.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the RVF status of the ruminant population of the *exporting country*.
- 9) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Annex 23 (contd)

Article 8.14.2.

Safe commodities

When authorising import or transit of the following *commodities* and any products made from them, *Veterinary Authorities* should not require any RVF related conditions, regardless of the RVF status of the ruminant population of the *exporting country*:

- 1) hides and skins;
- 2) wool and fibre.

Article 8.14.3.

Country or zone free from RVFV ~~infection~~

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

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

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

Article 8.14.4.

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

A country or *zone* infected with RVFV, during the inter-epizootic period, is one in which virus activity is present at a low level but the factors predisposing to an epizootic are absent.

Article 8.14.5.

Country or zone infected with RVFV during an epizootic

A country or *zone* infected with RVFV, during an epizootic, is one in which *outbreaks* of RVF are occurring at an incidence substantially exceeding that of the inter-epizootic period.

Article 8.14.6.

Strategies to protect from vector attacks during transport

Strategies to protect *animals* from *vector* attacks during transport should take into account the local ecology of the *vectors* and potential *risk management* measures include:

- 1) treating *animals* with insect repellents prior to and during transportation;
- 2) *loading*, transporting and *unloading animals* at times of low *vector* activity;

Annex 23 (contd)

- 3) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the *animals* are held behind insect-proof netting;
- 4) using historical and current information to identify low risk ports and transport routes.

Article 8.14.7.

Recommendations for importation from countries or zones free from RVFV infectionFor ruminants

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

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

AND

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

Article 8.14.8.

Recommendations for importation from countries or zones infected with RVFV during the inter-epizootic periodFor ruminants

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

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

AND

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

Annex 23 (contd)

Article 8.14.9.

Recommendations for importation from countries or zones infected with RVFV during an epizooticFor ruminants

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

- 1) showed no sign of RVF on the day of shipment;
- 2) did not originate in the area of the epizootic;
- 3) were vaccinated against RVF at least 14 days prior to shipment;
- 4) were held for at least 14 days prior to shipment in a vector-protected quarantine station, which is located in an area of demonstrated low *vector* activity outside the area of the epizootic. During this period the *animals* showed no sign of RVF;
- 5) either:
 - a) did not transit through an area experiencing an epizootic during transportation to the *place of shipment*; or
 - b) were protected from *vector* attacks when transiting through an area experiencing an epizootic.

Article 8.14.10.

Recommendations for importation from countries or zones not free from ~~infection with~~ RVFVFor semen and *in vivo* derived embryos of ruminants

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

- 1) showed no sign 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 demonstrated to be seropositive on the day of collection; or
 - c) testing of paired samples has demonstrated that seroconversion did not occur between semen or embryo collection and 14 days after.

Article 8.14.11.

Recommendations for importation of fresh meat and meat products from ruminants from countries or zones not free from ~~infection with~~ RVFV

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

- 1) ruminants which showed no clinical sign of RVF within 24 hours before *slaughter*;

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- 2) ruminants which were slaughtered in an approved *slaughterhouse/abattoir* and were subjected to ante- and post-mortem inspections with favourable results;
- 3) carcasses which were submitted to maturation at a temperature above 2°C for a minimum period of 24 hours following *slaughter*.

Article 8.14.12.

Recommendations for importation from countries or zones not free from ~~infection with~~ RVFV

For milk and milk products

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

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

Article 8.14.13.

Surveillance

Surveillance should be carried out in accordance with Chapter 1.4.

- 1) During an epizootic, *surveillance* should be conducted to define the extent of the affected area.
- 2) During the inter-epizootic period, *surveillance* and monitoring of climatic factors predisposing an epizootic should be carried out in countries or *zones* infected with RVFV.
- 3) Countries or *zones* adjacent to a country or *zone* in which epizootics have been reported should determine their RVFV status through an on-going *surveillance* programme.

To determine areas of low *vector* activity (see Articles 8.14.8. and 8.14.9.) *surveillance* for arthropod *vectors* should be carried out in accordance with Chapter 1.5.

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

— Text deleted.

CHAPTER 8.8.

INFECTION WITH FOOT AND MOUTH DISEASE
VIRUS

Article 8.8.1.

- 1) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with foot and mouth disease virus (FMDV). Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contacts between them. Amongst *Camelidae*, only Bactrian camels (*Camelus bactrianus*) are sufficiently susceptible to have potential for epidemiological significance. Dromedaries (*Camelus dromedarius*) are not susceptible to *infection* with FMDV while South American camelids are not considered to be of epidemiological significance.
- 2) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the suborder *ruminantia* and of the family *suidae* of the order *Artiodactyla*, and *Camelus bactrianus* with FMDV.
- 3) The following defines the occurrence of *infection* with FMDV:
 - a) FMDV has been isolated from a sample from an animal listed in point 2; or
 - b) ~~viral~~ antigen or ~~viral~~ ribonucleic acid specific to FMDV has been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or
 - c) antibodies to structural or nonstructural proteins of FMDV, that are not a consequence of *vaccination*, have been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed *outbreak* 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.
- 5) For the purposes of the *Terrestrial Code*, the *incubation period* of FMD shall be 14 days.
- 6) *Infection* with FMDV can give rise to *disease* of variable severity and to ~~FMDV~~ transmission of FMDV. FMDV may persist in the pharynx and associated lymph nodes of ruminants for a variable but limited period of time beyond 28 days. Such animals have been termed carriers. However, the only persistently infected species from which transmission of FMDV has been proven is the African buffalo (*Syncerus caffer*).
- 7) This chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of *infection* with ~~FMDV~~ and transmission of FMDV in the absence of clinical signs.
- 8) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.8.2.

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

In defining a *zone* where *vaccination* is not practised the principles of Chapter 4.3. should be followed.

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

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

Annex 24 (contd)

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

- 1) have a record of regular and prompt animal *disease* reporting;
- 2) send a declaration to the OIE stating that during the past 12 months, within the proposed ~~FMD~~ free country or *zone*:
 - a) there has been no case of FMD;
 - b) no *vaccination* against FMD has been carried out;
- 3) supply documented evidence that for the past 12 months:
 - a) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. has been implemented to detect clinical signs of FMD and demonstrate no evidence of:
 - i) *infection* with FMDV in unvaccinated animals;
 - ii) ~~FMDV~~ transmission of FMDV in previously vaccinated animals when the ~~FMD~~ free country or *zone* where *vaccination* is practised is seeking to become one where *vaccination* is not practised;
 - b) regulatory measures for the prevention and early detection of FMD have been implemented;
- 4) describe in detail and provide ~~supply~~ documented evidence that for the past 12 months ~~the following have been properly implemented and supervised~~:
 - a) ~~in the case of a FMD free zone~~, the boundaries of the any proposed ~~FMD~~ free *zone* have been established and effectively supervised;
 - b) the boundaries and biosecurity measures of a any protection zone, if applicable have been established and effectively supervised;
 - c) the system for preventing the entry of FMDV into the proposed ~~FMD~~ free country or *zone* has been established and effectively supervised;
 - d) the control of the movement of susceptible animals, their *meat* and other products into the proposed ~~FMD~~ free country or *zone*, in particular the measures described in Articles 8.8.8., 8.8.9. and 8.8.12. has been effectively implemented and supervised;
 - e) measures to prevent the introduction of ~~no~~ vaccinated animals ~~has been introduced~~, except in accordance with Articles 8.8.8. and 8.8.9. have been effectively implemented and supervised.

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

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE in accordance with the requirements in Chapter 1.1.

Provided the conditions of points 1 to 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 in place, including effective separation from other susceptible domestic populations or *wildlife*;

- the animals are identified as belonging to the collection and any movements can be traced;
- the vaccine used complies with the standards described in the *Terrestrial Manual*;
- *vaccination* is conducted under the supervision of the *Veterinary Authority*;
- the zoological collection is placed under *surveillance* for at least 12 months after *vaccination*.

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

Article 8.8.3.

~~FMD free~~ Country or zone free from FMD where *vaccination* is practised

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

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

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

To qualify for inclusion in the list of ~~FMD free~~ countries or zones free from FMD where *vaccination* is practised, a Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting;
- 2) send a declaration to the OIE stating that, based on the *surveillance* described in point 3, within the proposed ~~FMD free~~ country or *zone*:
 - a) there has been no case of FMD during the past two years;
 - b) there has been no evidence of ~~FMDV~~ transmission of FMDV during the past 12 months;
- 3) supply documented evidence that:
 - a) *surveillance* in accordance with Articles 8.8.40. to 8.8.42. has been implemented to detect clinical signs of FMD and demonstrate no evidence of:
 - i) *infection* with FMDV in unvaccinated animals;
 - ii) ~~FMDV~~ transmission of FMDV in vaccinated animals;
 - b) regulatory measures for the prevention and early detection of FMD have been implemented;
 - c) compulsory systematic *vaccination* in the target population has been carried out to achieve adequate *vaccination* coverage and population immunity;
 - d) *vaccination* has been carried out following appropriate vaccine strain selection;

Annex 24 (contd)

- 4) describe in detail and ~~supply~~ provide documented evidence that ~~the following have been properly implemented and supervised:~~
- a) ~~in case of FMD free zone,~~ the boundaries of the proposed FMD free zone have been established and effectively supervised;
 - b) the boundaries and biosecurity measures of any protection zone, if applicable have been established and effectively supervised;
 - c) the system for preventing the entry of FMDV into the proposed FMD free country or zone, in particular the measures described in Articles 8.8.8., 8.8.9. and 8.8.12. has been established and effectively supervised;
 - d) the control of the movement of susceptible animals and their products into the proposed FMD free country or zone has been effectively implemented and supervised.

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

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE in accordance with the requirements in Chapter 1.1.

If a Member Country that meets the requirements of a ~~FMD free~~ country or zone free from FMD where vaccination is practised wishes to change its status to ~~FMD free~~ country or zone free from FMD where vaccination is not practised, it should notify the OIE 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 the OIE. If the dossier for the new status is not provided within 24 months then the status of the country or zone as being free with vaccination will be suspended. If the country does not comply with requirements of Article 8.8.2., evidence should be provided within three months that it complies with Article 8.8.3. Otherwise the status will be withdrawn.

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

Article 8.8.4.

FMD free Compartment free from FMD

A ~~FMD free~~ compartment free from FMD can be established in either a FMD free country or zone or in an infected country or zone. In defining such a compartment the principles of Chapters 4.3. and 4.4. should be followed. Susceptible animals in the ~~FMD free~~ compartment should be separated from any other susceptible animals by the application of an effective biosecurity management system.

A Member Country wishing to establish a ~~FMD free~~ compartment free from FMD should:

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

Annex 24 (contd)

- c) *vaccination* against FMD is prohibited;
 - d) no animal vaccinated against FMD within the past 12 months is in the *compartment*;
 - e) animals, semen, embryos and animal products may only enter the *compartment* in accordance with relevant articles in this chapter;
 - f) documented evidence shows that *surveillance* in accordance with Articles 8.8.40. to 8.8.42. is in operation;
 - g) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;
- 3) describe in detail:
- a) the animal *subpopulation* in the *compartment*;
 - b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out in accordance with point 1.

The *compartment* should be approved by the *Veterinary Authority*. The first approval should only be granted when no case of FMD has occurred within a 10 ~~ten~~-kilometre radius of the *compartment* during the past three months.

Article 8.8.5.

FMD-infected Country or zone infected with FMDV

For the purposes of this chapter, a ~~FMD-infected~~ country or zone infected with FMDV is one that does not fulfil the requirements to qualify as either ~~FMD~~ free where *vaccination* is not practised or ~~FMD~~ free where *vaccination* is practised.

Article 8.8.6.

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

In the event of limited *outbreaks* within a ~~FMD-free~~ country or zone previously free from FMD, including within a *protection zone*, with or without *vaccination*, a single *containment zone*, which includes all *outbreaks*, may be established for the purpose of minimising the impact on the entire 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 the OIE, in support of the application, documented evidence that:

- 1) on suspicion, a strict standstill has been imposed on the suspected *establishments* and in the country or *zone* animal movement control has been imposed and effective controls on the movement of other *commodities* mentioned in this chapter are in place;
- 2) on confirmation, an additional standstill of susceptible animals has been imposed in the entire *containment zone* and the movement controls described in point 1 have been reinforced;
- 3) the definitive boundaries of the *containment zone* have been established after an epidemiological investigation (trace-back, trace-forward) has demonstrated that the *outbreaks* are epidemiologically related and limited in number and geographic distribution;
- 4) investigations into the likely source of the *outbreaks* have been carried out;
- 5) a *stamping-out policy*, with or without the use of emergency *vaccination*, has been applied;
- 6) no new cases have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.8.1. after the application of a *stamping-out policy* to the last detected case;

Annex 24 (contd)

- 7) the susceptible domestic and *captive wild* animal populations within the *containment zone* are clearly identified as belonging to the *containment zone*;
- 8) *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*;
- 9) 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 the OIE as complying with points 1 to 9 above. *Commodities* from susceptible animals for *international trade* should be identified as to their origin, either from inside or outside the *containment zone*.

In the event of recurrence of *infection* with FMDV in unvaccinated animals or ~~FMDV~~ transmission of FMDV in vaccinated animals in the *containment zone*, the approval of the *containment zone* is withdrawn and the FMD status of the whole country or *zone* is suspended until the relevant requirements of Article 8.8.7. are fulfilled.

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

Article 8.8.7.

Recovery of free status (see Figures 1 and 2)

- 1) When a FMD case occurs in a ~~FMD free~~ country or *zone* 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 nonstructural proteins of FMDV to demonstrate no evidence of *infection* in the remaining vaccinated population.

The country or *zone* will regain ~~the its free~~ status of ~~FMD free country or zone where vaccination is not practised~~ only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

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

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

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

Annex 24 (contd)

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

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

- 3) When a case of FMD occurs in a ~~FMD free country or zone~~ free from FMD where *vaccination* is practised, one of the following waiting periods is required to regain this free status:
- a) six months after the disposal of the last animal killed where a *stamping-out policy*, with emergency *vaccination*, and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of ~~virus transmission~~ of FMDV; or
 - b) 12 months after the detection of the last case where a *stamping-out policy* is not applied, but where emergency *vaccination* and *surveillance* in accordance with Articles 8.8.40. to 8.8.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of ~~virus transmission~~ of FMDV.

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

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

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

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

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

Article 8.8.8.

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

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

- 1) no FMD susceptible animal has been introduced into the *establishment* of origin and no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;
- 2) the animals were kept in the *establishment* of origin for at least three months prior to movement;
- 3) FMD has not occurred within a 10 kilometre radius of the *establishment* of origin for at least four weeks prior to movement;
- 4) the animals ~~should be~~ are transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;

Annex 24 (contd)

- 5) such a *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the infected zone;
- 6) *vehicles* and the *slaughterhouse/abattoir* ~~should be~~ are subjected to thorough cleansing and *disinfection* immediately after use.

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

Article 8.8.9.

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

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

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

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

Article 8.8.10.

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

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

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

Article 8.8.11.

Recommendations for importation from ~~FMD-free~~ countries or zones free from FMD where vaccination is practisedFor domestic ruminants and pigs

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

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

Article 8.8.12.

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

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

- 1) the animals showed no clinical sign of FMD on the day of shipment;
- 2) 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*;
- 3) FMD has not occurred within the *establishment* of origin for the relevant period as defined in points 2a) and 2b) above;
- 4) the animals were isolated in an *establishment* for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period, and that FMD did not occur within a 10 kilometre radius of the *establishment* during that period, or the *establishment* is a *quarantine station*;
- 5) the animals were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

Article 8.8.13.

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

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

Annex 24 (contd)

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

Article 8.8.14.

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

For frozen semen of domestic ruminants and pigs

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least three months prior to collection in a ~~FMD-free~~ country or zone free from FMD where *vaccination* is not practised or ~~FMD-free compartments~~ free from FMD;
- 2) the semen was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.8.15.

Recommendations for importation from ~~FMD-free~~ countries or zones free from FMD where vaccination is practised

For frozen semen of domestic ruminants and pigs

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least three months prior to collection in a ~~FMD-free~~ country or zone free from FMD where *vaccination* is practised;
 - c) either
 - i) have been vaccinated at least twice, with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;
 - or
 - ii) were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;

Annex 24 (contd)

- 2) the semen:
- a) was collected, processed and stored in accordance with Chapters 4.5. and 4.6.;
 - b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor ~~animals~~ males were kept showed any sign of FMD.

Article 8.8.16.

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

For frozen semen of domestic ruminants and pigs

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

- 1) the donor males:
- a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept in an *artificial insemination centre* ~~where to which~~ where to which no animal had been added in the 30 days before collection, and within a 10 kilometre radius of which, that FMD has not occurred ~~within a 10 kilometre radius of the artificial insemination centre for~~ in the 30 days before and after collection;
 - c) either
 - i) have been vaccinated at least twice, with the last *vaccination* not ~~less~~ more than ~~one~~ six months ~~and not more than six months prior to collection~~, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to collection;

or

 - ii) were subjected, not less than 21 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 4.5. and 4.6.;
 - b) was subjected, with negative results, to a test for evidence of FMDV if the donor male has been vaccinated within the 12 months prior to collection;
 - c) was stored in the country of origin for a period of at least one month following collection, and that during this period no animal on the *establishment* where the donor males were kept showed any sign of FMD.

Article 8.8.17.

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

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

Annex 24 (contd)

Article 8.8.18.

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

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

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

Article 8.8.19.

Recommendations for importation from ~~FMD-free~~ countries or zones free from FMD where vaccination is practisedFor *in vitro* produced embryos of cattle

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

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

Article 8.8.20.

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

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

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

Article 8.8.21.

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

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

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

Article 8.8.22.

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

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

- 1) comes from animals which:
 - a) have remained, for at least three months prior to *slaughter*, in a zone of the *exporting country* where cattle and water buffaloes are regularly vaccinated against FMD and where an *official control programme* is in operation;
 - b) have been vaccinated at least twice with the last *vaccination* not more than six months, unless protective immunity has been demonstrated for more than six months, and not less than one month prior to *slaughter*;
 - c) were kept for the past 30 days in a quarantine station or in an establishment, within a 10 kilometre radius of which and that FMD has not occurred ~~within a 10 kilometre radius of the establishment~~ during that period, ~~or the establishment is a quarantine station~~;

Annex 24 (contd)

- d) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle and water buffaloes were loaded, directly from the *establishment* of origin or *quarantine station* to the approved *slaughterhouse/abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;
 - e) have been slaughtered in an approved *slaughterhouse/abattoir*:
 - i) which is officially designated for export;
 - ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;
 - f) have been subjected, with favourable results, to ante-mortem inspection within 24 hours of *slaughter* and to post-mortem inspections ~~within 24 hours before and after slaughter with no evidence of FMD;~~
- 2) comes from deboned carcasses:
- a) from which the major lymphatic nodes have been removed;
 - b) which, prior to deboning, have been submitted to maturation at a temperature greater than + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was less than 6.0 when tested in the middle of both the longissimus dorsi muscle.

Article 8.8.23.

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

For meat products of FMD susceptible animals

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

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

Article 8.8.24.

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

For milk and milk products intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

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

Article 8.8.25.

Recommendations for importation from ~~FMD-infected~~ countries or zones infected with FMDV, where an official control programme exists

For milk and milk products

Annex 24 (contd)

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

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

Article 8.8.26.

Recommendations for importation from ~~FMD-infected~~ countries infected with FMDV

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

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.

Article 8.8.27.

Recommendations for importation from ~~FMD-infected~~ countries infected with FMDV

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

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

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

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

Article 8.8.28.

Recommendations for importation from ~~FMD-infected~~ countries infected with FMDV

For straw and forage

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

- 1) are free of grossly identified contamination with material of animal origin;
- 2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:
 - a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ~~ten~~ 10 minutes,

Annex 24 (contd)

- 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 from ~~FMD-free~~ countries or zones free from FMD, where whether vaccination either is practised or is not practised

For skins and trophies derived from FMD susceptible wildlife

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

Article 8.8.30.

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

For skins and trophies derived from FMD susceptible wildlife

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

Article 8.8.31.

Procedures for the inactivation of FMDV in meat and meat products

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

1. Canning

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

2. Thorough cooking

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

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

3. Drying after salting

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

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

Article 8.8.32.

Procedures for the inactivation of FMDV in wool and hair

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

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

Article 8.8.33.

Procedures for the inactivation of FMDV in bristles

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

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

Article 8.8.34.

Procedures for the inactivation of FMDV in raw hides and skins

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

Article 8.8.35.

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

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

- 1) a process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or
- 2) if the *milk* has a pH less than 7.0, a process applying a minimum temperature of 72°C for at least 15 seconds (high temperature - short time pasteurisation [HTST]), or
- 3) if the *milk* has a pH of 7.0 or greater, the HTST process applied twice.

Article 8.8.36.

Procedures for the inactivation of FMDV in milk for animal consumption

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

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

Annex 24 (contd)

Article 8.8.37.

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

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

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed; or
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher); or
- 3) soaking, with agitation, in a 4% (weight/volume) solution of sodium carbonate (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.

OIE endorsed official control programme for FMD

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

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.

For a Member Country's *official control programme* for FMD to be endorsed by the OIE, the Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting in accordance with the requirements in Chapter 1.1.;
- 2) submit documented evidence of the capacity of the *Veterinary Services* to control FMD; one way of providing this evidence is through the OIE PVS Pathway;
- 3) submit a detailed plan of the programme to control and eventually eradicate FMD in the country or *zone* including:
 - a) the timeline;
 - b) the performance indicators for assessing the efficacy of the control measures to be implemented;
 - c) documentation indicating that the *official control programme* for FMD is applicable to the entire country;

Annex 24 (contd)

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

The Member Country's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence, based on the provisions of Article 1.6.11., has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE in accordance with the requirements in Chapter 1.1.

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

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

Article 8.8.40.

General principles of surveillance

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

Annex 24 (contd)1. Early detection

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

2. Demonstration of freedom

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

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

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

A Member Country wishing to substantiate FMD freedom where *vaccination* is not practised should demonstrate no evidence of *infection* with FMDV.

A Member Country wishing to substantiate FMD freedom where *vaccination* is practised should demonstrate that FMDV has not been transmitted in any susceptible populations. Within vaccinated populations, serological surveys to demonstrate no evidence of ~~FMDV~~ transmission of FMDV should target animals that are less likely to show vaccine-derived antibodies to nonstructural proteins, 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. OIE endorsed official control programme

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

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

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

4. Surveillance strategies

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

Annex 24 (contd)

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. The sensitivity and specificity of the tests used should be validated for the *vaccination* or *infection* history and production class of animals in the target population.

The *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following-up positives to determine with a high level of confidence, whether or not they are indicative of *infection* or transmission. This should involve supplementary tests and follow-up investigation to collect diagnostic material from the original *epidemiological unit* and *herds* which may be epidemiologically linked to it.

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

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

6. Demonstration of population immunity

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

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

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.

Annex 24 (contd)

Article 8.8.41.

Methods of surveillance1. Clinical surveillance

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

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

Clinical examination and diagnostic testing should be applied to clarify the status of suspected cases. Diagnostic testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive laboratory test results. Clinical *surveillance* may be insufficient in *wildlife* and domestic species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such situations, serological *surveillance* should be used. Hunting, capture and non-invasive sampling and observation methods can 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 an OIE Reference Laboratory.

Virological *surveillance* aims to:

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

3. Serological surveillance

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

Serological *surveillance* may be used to:

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

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

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

Article 8.8.42.

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

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

Animals infected with FMDV produce antibodies to both the structural proteins and the nonstructural proteins of the virus. Vaccinated animals produce antibodies mainly or entirely to the structural proteins of the virus depending upon vaccine purity. The structural protein tests are serotype specific and for optimal sensitivity one should select an antigen or virus closely related to the field strain expected. In unvaccinated populations, structural protein tests may be used to screen sera for evidence of FMDV infection with, or transmission of FMDV or to detect the introduction of vaccinated animals. In vaccinated populations, structural protein tests may be used to monitor the serological response to the *vaccination*.

Nonstructural protein tests may be used to screen sera for evidence of *infection* or transmission of all serotypes of FMDV regardless of the *vaccination* status of the animals provided the vaccines comply with the standards of the *Terrestrial Manual* with respect to purity. However, although animals vaccinated and subsequently infected with FMDV develop antibodies to nonstructural proteins, the levels may be lower than those found in infected animals that have not been vaccinated. To ensure that all animals that had contact with FMDV have seroconverted, it is recommended that for each *vaccination* area samples for nonstructural protein 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 cattle are usually found only up to six months of age but in some individuals and in some other species, maternal antibodies can be detected for longer periods);
- non-specific reactivity of the serum in the tests used.

1. Procedure in case of positive test results

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

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

All *herds* with at least one ~~laboratory confirmed~~ reactor that has been confirmed in a laboratory should be investigated. The investigation should examine all evidence, which may include the results of virological tests and of any further serological tests that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to FMDV transmission of FMDV. 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 events, including the demographics of the population sampled, vaccinal exposure or the presence of *infection* or transmission. As clustering may signal *infection* or transmission, the investigation of all instances should be incorporated in the survey design.

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

Annex 24 (contd)

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 remain in the *establishment* pending test results, should be clearly identified, accessible and should not be vaccinated during the investigations, so that they can be retested after an appropriate period of time. Following clinical examination, a second sample should be taken, after an appropriate time has lapsed, from the animals tested in the initial survey with emphasis on animals in direct contact with the reactors. If the animals are not individually identified, a new serological survey should be carried out in the *establishments* after an appropriate time, repeating the application of the primary survey design. If FMDV is not circulating, the magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample.

In some circumstances, unvaccinated sentinel animals may also be used. These can be young animals from unvaccinated dams or animals in which maternally conferred immunity has lapsed and preferably of the same species as in the positive sampling units. If other susceptible, unvaccinated animals are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the animals of the *epidemiological unit* under investigation for at least two *incubation periods* and should remain serologically negative if FMDV is not circulating.

2. Follow-up of field and laboratory findings

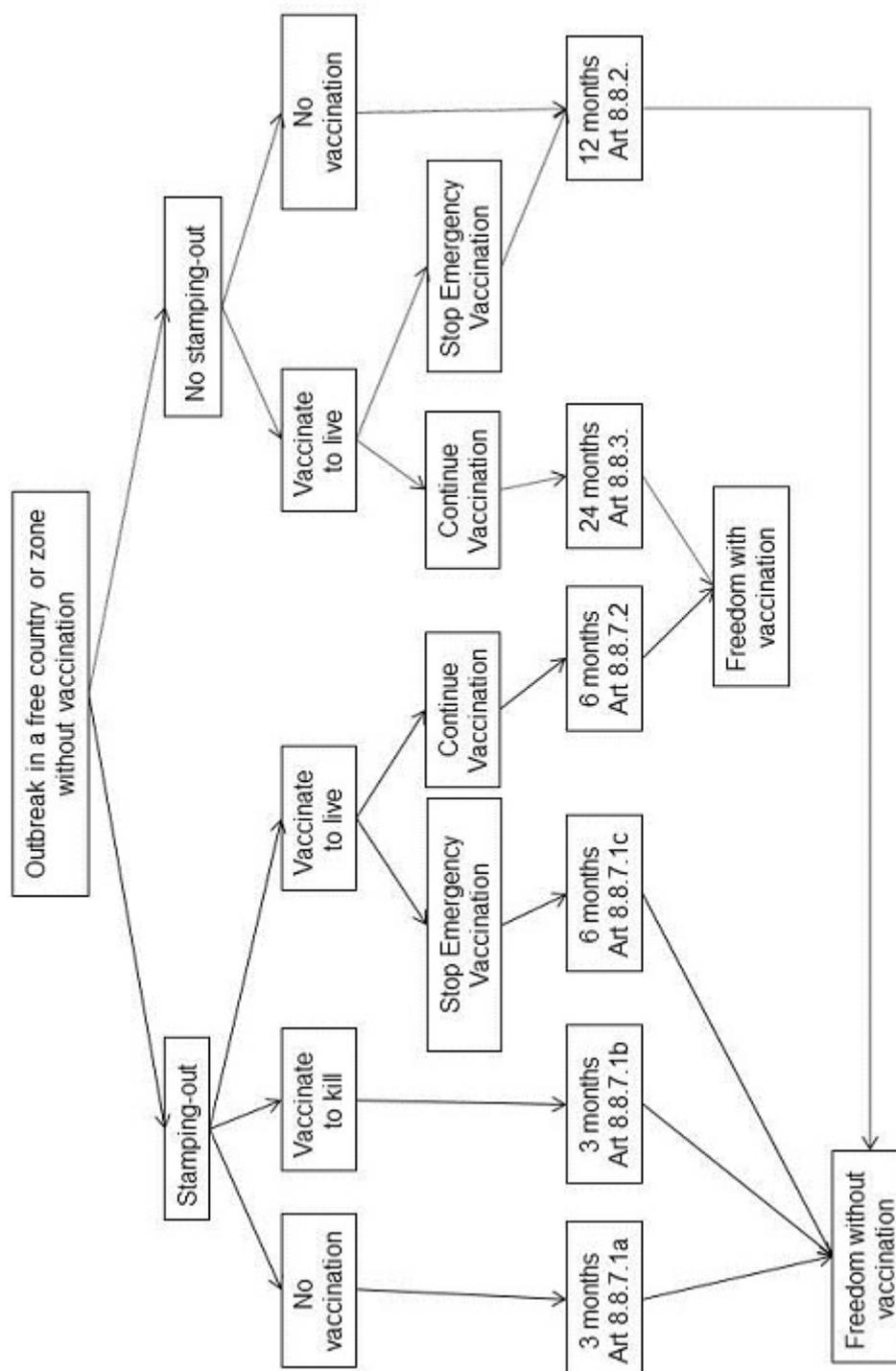
If transmission is demonstrated, an *outbreak* is declared.

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

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

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

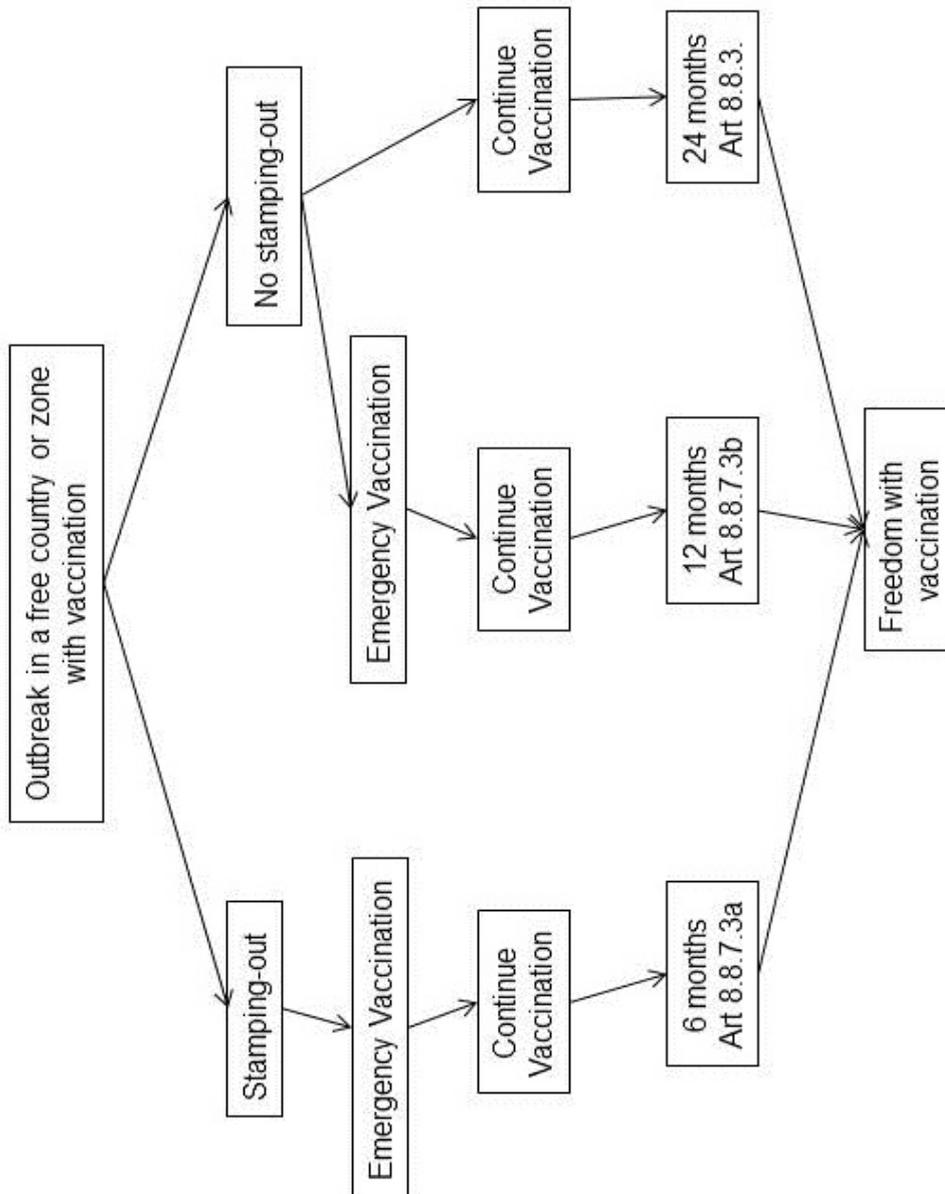
Fig. 1. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak of FMD in a previously free country or zone where vaccination is not practised



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

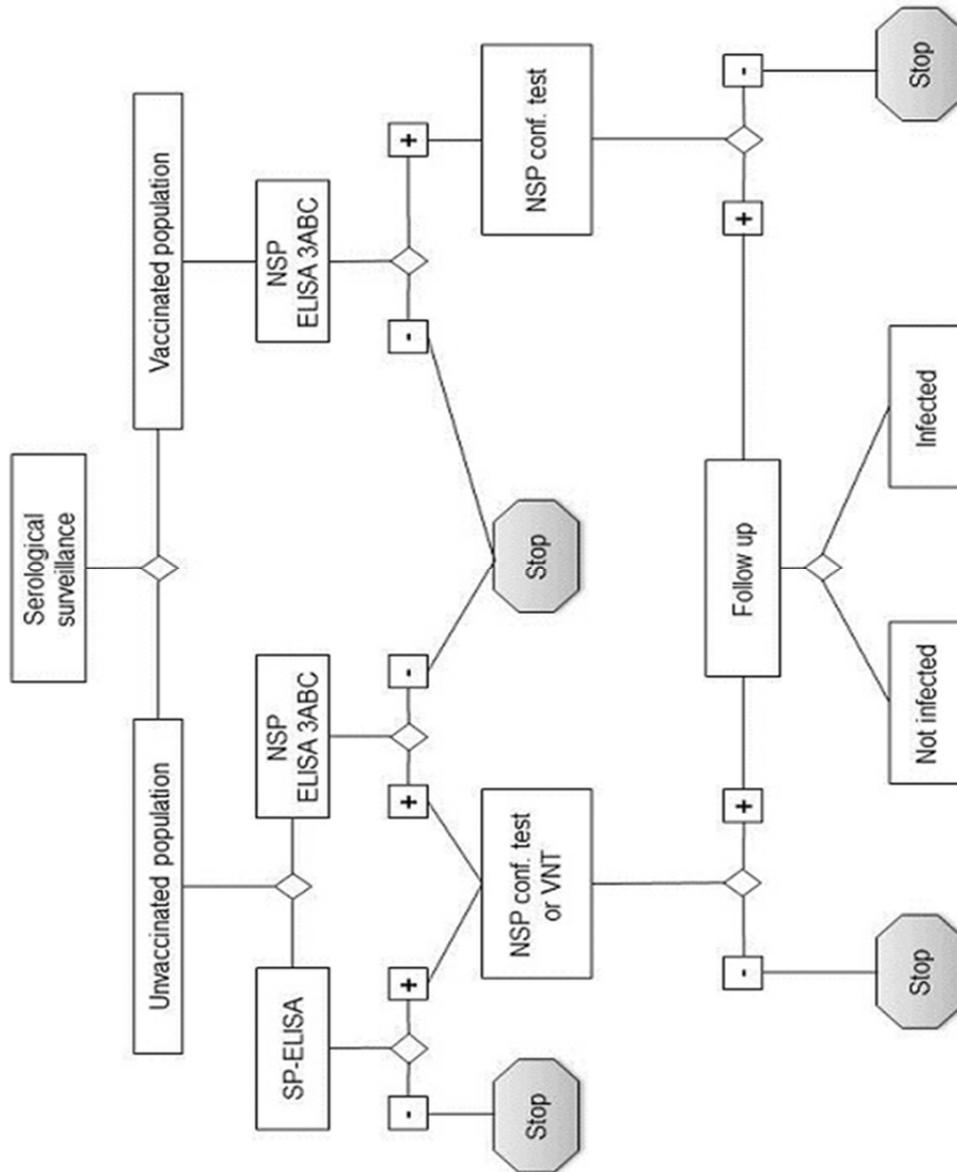
Annex 24 (contd)

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



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

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



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DRAFT CHAPTER 8.X.

INFECTION WITH *MYCOBACTERIUM TUBERCULOSIS* COMPLEX

Article 8.X.1.

General provisions

The recommendations in this chapter are intended to manage the human and animal health risks associated with *infection* of animals with a member of the *Mycobacterium tuberculosis* (*M. tuberculosis*) complex.

For the purposes of this chapter, *M. tuberculosis* complex comprises *M. bovis*, *M. caprae* and *M. tuberculosis*, but excludes vaccine strains.

Many different domestic and *wild animal* species belonging to diverse mammalian taxa are known to be susceptible to *infection* with *M. tuberculosis* complex. Their epidemiological significance depends on the degree of susceptibility, the husbandry system, the density, spatial distribution and ecology of populations as well as the pathogenesis and transmission pathways. In some geographical regions, certain *wild animal* species can act as reservoirs.

For the purposes of this chapter, 'animals' means domestic and *captive wild* animal populations of the following categories:

- 1) Bovids: this term means cattle (*Bos taurus*, *B. indicus*, *B. frontalis*, *B. javanicus* and *B. grunniens*), water buffalo (*Bubalus bubalis*), and bison (*Bison bison* and *B. bonasus*).
- 2) Cervids: this term means red deer (*Cervus elaphus elaphus*), wapiti/elk (*C. elaphus canadensis*), sika (*C. nippon*), samba (*C. unicolor unicolor*), rusa (*C. timorensis*), roe deer (*Capreolus capreolus*), fallow deer (*Dama dama*), white-tailed, black-tailed and mule deer (*Odocoileus* spp.) and reindeer/caribou (*Rangifer tarandus*).
- 3) Goats (*Capra hircus*).
- 4) New World Camelids (under study).

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

For the purposes of the *Terrestrial Code*, the following defines the occurrence of *infection* with *M. tuberculosis* complex:

- A member of *M. tuberculosis* complex has been identified in a sample from an animal or a product derived from that animal;

OR

- positive results to a diagnostic test have been obtained and there is an epidemiological link to a case of *infection* with *M. tuberculosis* complex or there is other reason to suspect *infection* with *M. tuberculosis* complex.

When authorising import or transit of *commodities* listed in this chapter, with the exception of those listed in Article 8.X.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *M. tuberculosis* complex *infection* status of the animal population of the country, *zone* or *herd* of origin.

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

Annex 25 (contd)

Article 8.X.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *M. tuberculosis* complex-related conditions, regardless of the *M. tuberculosis* complex *infection* status of the animal populations of the country, *zone* or *herd* of origin:

- 1) *fresh meat* and *meat products* originating from animals that have been subjected to ante- and post-mortem inspections as described in Chapter 6.2.;
- 2) cured hides, skins and trophies;
- 3) gelatine, collagen, tallow and *meat-and-bone meal*.

Article 8.X.3.

Country or zone historically free from infection with *M. tuberculosis* complex in specified animal categories

A country or *zone* may be considered historically free from *infection* with *M. tuberculosis* complex in specified animal categories when the conditions of point 1a) of Article 1.4.6. have been met for the relevant animal categories.

Article 8.X.4.

Country or zone free from infection with *M. tuberculosis* complex in bovids

- 1) To qualify as free from *infection* with *M. tuberculosis* complex in bovids, a country or *zone* should satisfy the following requirements:
 - a) *infection* in animals is a *notifiable disease* in the entire country;
 - b) regular testing of all *herds* has been in place for at least three years and for the past three years this testing has demonstrated that *infection* with *M. tuberculosis* complex was not present in at least 99.8% of the *herds* representing at least 99.9% of the bovids in the country or *zone*;
 - c) a *surveillance* programme is in place to detect *infection* with *M. tuberculosis* complex in the country or *zone* through ante- and post-mortem inspections as described in Chapter 6.2.;
 - d) regulatory measures have been implemented for the early detection of *infection* with *M. tuberculosis* complex in bovids;
 - e) bovids and their germplasm introduced into the country or *zone* comply with the recommendations in Articles 8.X.7., 8.X.10. and 8.X.12.
- 2) To maintain the status as free from *infection* with *M. tuberculosis* complex in bovids, a country or *zone* should satisfy the following requirements:
 - a) the requirements in points 1a), 1c), 1d) and 1e) are met;
 - b) a *surveillance* programme based on regular testing of bovids is in place in the country or *zone* to detect *infection* with *M. tuberculosis* complex in accordance with Article 1.4.4.;
 - c) once the *surveillance* programme described in point b) has demonstrated that *infection* with *M. tuberculosis* complex has not been present in at least 99.8% of the *herds* representing 99.9% of the bovids in the country or *zone* for two consecutive years, *surveillance* may be maintained through ante- and post-mortem inspections as described in Chapter 6.2.;

Annex 25 (contd)

- 3) The country or *zone* status of free from *infection* with *M. tuberculosis* complex in bovids is not affected by the occurrence of *infection* with *M. tuberculosis* complex in other animal categories or *feral* or *wild animals* provided that measures have been implemented to prevent transmission of *infection* with *M. tuberculosis* complex to bovids.

Article 8.X.5.

Country or zone free from infection with *M. tuberculosis* complex in cervids

- 1) To qualify as free from *infection* with *M. tuberculosis* complex in cervids, a country or *zone* should satisfy the following requirements:
- a) *infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country;
 - b) regular testing of all cervid *herds* has been in place for at least three years and for the past three years this testing has demonstrated that *infection* with *M. tuberculosis* complex was not present in at least 99.8% of the *herds* representing at least 99.9% of the cervids in the country or *zone*;
 - c) a *surveillance* programme is in place to detect *infection* with *M. tuberculosis* complex in the country or *zone* through ante- and post-mortem inspections as described in Chapter 6.2.;
 - d) regulatory measures have been implemented for the early detection of *infection* with *M. tuberculosis* complex in cervids;
 - e) cervids and their germplasm introduced into the country or *zone* comply with the recommendations in Articles 8.X.7., 8.X.11. and 8.X.12.
- 2) To maintain the status as free from *infection* with *M. tuberculosis* complex in cervids, a country or *zone* should satisfy the following requirements:
- a) the requirements in points 1a), 1c), 1d) and 1e) are met;
 - b) a *surveillance* programme based on regular testing of cervids is in place in the country or *zone* to detect *infection* with *M. tuberculosis* complex in accordance with Article 1.4.4.;
 - c) once the *surveillance* programme described in point b) has demonstrated that *infection* with *M. tuberculosis* complex has not been present in at least 99.8% of the *herds* representing 99.9% of the cervids in the country or *zone* for two consecutive years, *surveillance* may be maintained through ante- and post-mortem inspections as described in Chapter 6.2.;
- 3) The country or *zone* status free from *infection* with *M. tuberculosis* complex in cervids is not affected by the occurrence of *infection* with *M. tuberculosis* complex in other animal categories or *feral* or *wild animals* provided that measures have been implemented to prevent transmission of *infection* with *M. tuberculosis* complex to cervids.

Article 8.X.6.

Herd free from infection with *M. tuberculosis* complex in bovids or cervids

- 1) To qualify as free from *infection* with *M. tuberculosis* complex, a *herd* of bovids or cervids should satisfy the following requirements:
- a) the *herd* is in a country or *zone* free from *infection* with *M. tuberculosis* complex in bovids or in cervids and is certified free by the *Veterinary Authority*;
- OR
- b) the *herd* meets the following conditions:

Annex 25 (contd)

- i) *infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country;
 - ii) no evidence of *infection* with *M. tuberculosis* complex has been detected in the *herd* for at least the past 12 months;
 - iii) bovids or cervids in the *herd* have shown no clinical signs of *infection* with *M. tuberculosis* complex or lesions at ante- or post-mortem inspections for at least the past 12 months;
 - iv) two tests have been performed with negative results at a minimum interval of six months on all bovids or cervids over six weeks of age present in the *herd* at the time of testing. The first test was performed at least six months after the removal of the last case;
 - v) bovids or cervids and their germplasm introduced into the *herd* comply with Articles 8.X.7., 8.X.10., 8.X.11. and 8.X.12.;
 - vi) for at least the past 12 months, there has been no evidence of *infection* with *M. tuberculosis* complex in other *herds* of the same *establishments* or measures have been implemented to prevent any transmission of *infection* with *M. tuberculosis* complex from these other *herds*;
- 2) to maintain the free status, either:
- a) the requirements in point 1a) are met;
- OR
- b) the requirements in point 1b i) to iii), v) and vi) are met and bovids or cervids in the *herd*:
 - i) showed a negative result to an annual test to ensure the continuing absence of *infection* with *M. tuberculosis* complex;

OR

 - ii) showed a negative result to a test every two years to ensure the continuing absence of *infection* with *M. tuberculosis* complex if it has been confirmed that the annual percentage of *herds* infected with *M. tuberculosis* complex is not more than 1% of all *herds* in the country or *zone* during the past two years;

OR

 - iii) showed a negative result to a test every three years to ensure the continuing absence of *infection* with *M. tuberculosis* complex if it has been confirmed that the annual percentage of *herds* infected with *M. tuberculosis* complex is not more than 0.2% of all *herds* in the country or *zone* during the past four years;

OR

 - iv) showed a negative result to a test every four years to ensure the continuing absence of *infection* with *M. tuberculosis* complex if it has been confirmed that the annual percentage of *herds* infected with *M. tuberculosis* complex is not more than 0.1% of all *herds* in the country or *zone* during the past six years.

Article 8.X.7.

Recommendations for the importation of bovids and cervids for breeding or rearing

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

- 1) showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of shipment;

Annex 25 (contd)

- 2) a) originate from a *herd* free from *infection* with *M. tuberculosis* complex that is in a country or *zone* free from *infection* with *M. tuberculosis* complex; or
- b) originate from a *herd* free from *infection* with *M. tuberculosis* complex and have been tested for *infection* with *M. tuberculosis* complex with negative results within 30 days prior to shipment; or
- c) have been isolated for at least 90 days prior to shipment including protection from contact with animal reservoirs of *M. tuberculosis* complex and all isolated animals showed negative results to at least two consecutive tests carried out at a six-month interval, with the second test performed within 30 days prior to shipment.

Article 8.X.8.

Recommendations for the importation of goats for breeding or rearing

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

- 1) *infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country;
- 2) the goats showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of shipment;
- 3) the goats were kept in *herds* in which no *case* of *infection* with *M. tuberculosis* complex has been detected for the past three years.

Article 8.X.9.

Recommendations for the importation of bovids and cervids for slaughter

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

- 1) showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of shipment;
- 2) a) originate from a country, *zone* or *herd* free from *infection* with *M. tuberculosis* complex; or
- b) are not being culled as part of an eradication programme against *infection* with *M. tuberculosis* complex and were tested for *infection* with *M. tuberculosis* complex with negative results within 30 days prior to shipment.

Article 8.X.10.

Recommendations for the importation of semen of bovids

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

- 1) the donor males showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of collection of the semen;
- 2) the donor males either:
 - a) were kept in an *artificial insemination centre* complying with the provisions of Chapter 4.5.; or
 - b) were kept in a *herd* free from *infection* with *M. tuberculosis* complex and showed negative results to tests carried out annually and the semen was collected, processed and stored in conformity with the provisions of Articles 4.5.3. to 4.5.5. and Articles 4.6.5. to 4.6.7.

Annex 25 (contd)

Article 8.X.11.

Recommendations for the importation of semen of cervids

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

- 1) the donor males showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of collection of the semen;
- 2) the donor males either:
 - a) were kept in a *herd* free from *infection* with *M. tuberculosis* complex in a country or *zone* free from *infection* with *M. tuberculosis* complex and which only accepts cervids from free *herds* in a free country, or *zone*; or
 - b) were kept in a *herd* free from *infection* with *M. tuberculosis* complex and showed negative results to tests carried out annually and the semen was collected, processed and stored in conformity with the provisions of Articles 4.5.3. to 4.5.5. and Articles 4.6.5. to 4.6.7.

Article 8.X.12.

Recommendations for the importation of embryos of bovids and cervids

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

- 1) the donor females either:
 - a) originated from a *herd* free from *infection* with *M. tuberculosis* complex in a country or *zone* free from *infection* with *M. tuberculosis* complex; or
 - b) were kept in a *herd* free from *infection* with *M. tuberculosis* complex, and were subjected to a test for *infection* with *M. tuberculosis* complex with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;
- 2) the embryos were collected, processed and stored in accordance with the relevant provisions of Chapters 4.7. to 4.9.

Article 8.X.13.

Recommendations for the importation of milk and milk products of bovids

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

- 1) have been derived from bovids in a *herd* free from *infection* with *M. tuberculosis* complex; or
- 2) were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Article 8.X.14.

Recommendations for the importation of milk and milk products of goats

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

Annex 25 (contd)

- 1) *infection with M. tuberculosis* complex in animals is a *notifiable disease* in the entire country and the *milk* or *milk products* have been derived from goats kept in *herds* in which no *case of infection with M. tuberculosis* complex has been detected for the past three years;

OR

- 2) the *milk* or *milk products* were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

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CHAPTER 12.10.

INFECTION WITH *BURKHOLDERIA MALLEI* (GLANDERS)

Article 12.10.1.

General provisions

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

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

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

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

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

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

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

Article 12.10.2.

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

A country or a *zone* may be considered free from *infection with B. mallei* when:

- 1) glanders ~~is~~ has been a notifiable disease in the entire country for at least the past three years;
- 2) ~~either:~~
 - a) there has been no case outbreak and no evidence of infection with *B. mallei* in equids during the past three years ~~following the destruction of the last case; or~~
 - b) ~~no evidence of infection with *B. mallei* has been found during the past six months following the destruction of the last case; and there is a surveillance programme in place demonstrating the absence of infection~~ in accordance with Article 12.10.8. has demonstrated no evidence of infection with *B. mallei* in the past 12 months;

and

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

Annex 26 (contd)

Article 12.10.3.

Recovery of free status

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

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

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

Article 12.10.4.

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

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

- 1) showed no clinical signs of glanders on the day of shipment;
- 2) either:
 - a) was kept for six months prior to shipment, or since birth, in a the exporting country or zone free from infection with B. mallei; or
 - b) was imported in accordance with Article 12.10.5., kept in an establishment in the exporting country for at least 30 days and then was subjected to a ~~prescribed~~ test with negative result ~~on a sample taken during the 10 days prior to shipment.~~

Article 12.10.5.

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

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

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

Article 12.10.6.

Recommendations for the importation of equine semen

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

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

Article 12.10.7.

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

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

- 1) the donor females animals:
 - a) showed no clinical signs of glanders on the day of collection ~~and for the following 21 days;~~
 - b) ~~were kept continuously:~~
 - i) ~~either for a period of at least 21 days before, and for until at least 21 days after, the day of collection of the embryos in a country or a zone free from infection with *B. mallei*, or~~
 - ii) ~~for at least six months prior to the collection and during the collection in an establishment free from infection with *B. mallei* and were subjected to a prescribed test, with a negative result on a sample taken between 21 and 30 days before the collection, or in the case of frozen embryos, between 21 and 30 days after the collection;~~
- 2) the embryos were collected, processed and stored in accordance with the relevant recommendations in Chapters 4.7. and 4.9., ~~as relevant;~~
- 3) semen used to fertilise the oocytes complies with the recommendations in Article 12.10.6.

Article 12.10.8.

Surveillance

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

Annex 26 (contd)

Surveillance should be carried out in accordance with Chapter 1.4.

Populations of *captive wild*, *feral* and *wild* equids should be included in the *surveillance* programme, for example through testing of road kill or of equids culled as part of population control measures.

Clinical *surveillance* aims at detecting signs of glanders by close physical examination of susceptible animals. Clinical inspection is an important component of *surveillance* contributing to the desired level of confidence of detection of *disease*, if so long as a sufficiently large number of clinically susceptible animals is examined. Laboratory investigations should be conducted on all suspected cases.

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

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

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

— Text deleted.

CHAPTER 15.1.

INFECTION WITH AFRICAN SWINE FEVER VIRUS

Article 15.1.1.

General provisions

The Suids (the pig and its close relatives) are the only natural non-arthropod hosts for African swine fever virus (ASFV). These include all varieties of *Sus scrofa* (pig), both domestic and wild, and African wild suid species including warthogs (*Phacochoerus* spp.), bushpigs (*Potamochoerus* spp.) and the giant forest hog (*Hylochoerus meinertzhageni*).

For the purposes of this chapter, a distinction is made among ~~between~~ domestic pigs (permanently captive and farmed free-range pigs) and wild pigs (including feral pigs and wild boar) as well as between *Sus scrofa* and African pig species.

- = domestic and captive wild pigs, permanently captive or farmed free range, used for the production of meat, or other commercial products or use, or for breeding these categories of pigs;
- = wild and feral pigs;
- = African wild suid species.

All varieties of *Sus scrofa* are susceptible to the pathogenic effects of ASFV, while the African wild suids pigs are not and may act as reservoirs of the virus infection. Ticks of the genus *Ornithodoros* are natural arthropods hosts of the virus and act as reservoirs and biological vectors of the infection.

For the purposes of the Terrestrial Code, African swine fever (ASF) is defined as an infection of suids with ASFV.

The following defines infection with ASFV:

1) ASFV has been isolated from samples from a suid;

OR

2) viral antigen has been identified, or viral nucleic acid specific to ASFV has been demonstrated to be present in samples from a suid epidemiologically linked to a suspected or confirmed outbreak of ASF, or giving cause for suspicion of previous association or contact with ASFV, whether or not clinical signs or pathological lesions consistent with ASF are present;

OR

3) antibodies specific to ASFV have been identified in samples from a suid showing clinical signs or pathological lesions consistent with ASF, or epidemiologically linked to a suspected or confirmed outbreak of ASF, or giving cause for suspicion of previous association or contact with ASFV.

A Member Country should not impose bans on the trade in commodities of domestic and or captive wild pigs in response to a notification of infection with ASFV in wild and or feral pigs or African wild suids provided that Article 15.1.2. is implemented.

For the purpose of the *Terrestrial Code*, the incubation period in *Sus scrofa* ~~is~~ shall be 15 days.

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

Article 15.1.2.

General criteria for the Determination of the ASF status of a country, zone or compartment

~~The African swine fever (ASF) status of a country, zone or compartment can only be determined after considering the following criteria in domestic and wild pigs, as applicable:~~

- ~~1) ASF should be is~~ a notifiable disease in the entire whole country, and all suids showing clinical signs suggestive of ASF are subjected to appropriate field and *laboratory* investigations;

Annex 27 (contd)

- 2) an ongoing awareness programme is in place to encourage reporting of all eases suids showing signs suggestive of ASF;
- 3) the *Veterinary Authority* has current knowledge of, and authority over, all domestic and captive wild pig herds in the country, *zone* or *compartment*;
- 4) the *Veterinary Authority* has current knowledge of about the species of wild suids present, their distribution, population and habitat of wild suids pigs in the country or *zone*;
- 5) for domestic and captive wild pigs, an appropriate surveillance programme in accordance with Articles 15.1.22. to 15.1.27. is in place;
- 6) for wild and feral pigs, and for African wild suids, if present in the country or zone, a surveillance programme is in place according to in accordance with Article 15.1.26., taking into account the presence of natural and artificial boundaries, the ecology of the wild and feral pig and African wild suid populations and an assessment of the risks of disease spread including the presence of Ornithodoros ticks;
- 7) based on the assessed risk of spread within the wild and feral pig and African wild suid populations, and according to in accordance with Article 15.1.26., the domestic and captive wild pig population should be separated by appropriate measures from the wild and feral pig and African wild suid populations and from Ornithodoros ticks by appropriate measures.

Article 15.1.3.

Country or zone free from ASF free country, zone or compartment1. Historically free status

A country or *zone* may be considered historically free from ASF without formally applying a specific *surveillance* programme if the provisions of point 1 of Article 1.4.6. are complied with.

2. Free status as a result of an eradication programme

A country or *zone* which does not meet the conditions of point 1 above ~~or a compartment~~ may be considered free from ASF in domestic and captive wild pigs when:

- a) there has been no *outbreak* of ASF in domestic and or captive wild pigs during the past 12 months three years; this period can be reduced to 12 months when there is no evidence of tick involvement in the epidemiology of the infection;
- b) no evidence of ASFV infection with ASFV in domestic and captive wild pigs has been found during the past 12 months;
- be) surveillance in accordance with Articles 15.1.22. to 15.1.27. has been in place in domestic and captive wild pigs for the past 12 months;
- cd) imported domestic and captive wild pigs and pig commodities comply with the requirements of in Articles 15.1.5. or to Article 15.1.617.

AND

Based on *surveillance*, ASF *infection* has been demonstrated not to be present in any wild pig population in the country or *zone*, and:

- e) there has been no clinical evidence, nor virological evidence of ASF in wild pigs during the past 12 months;
- f) no seropositive wild pigs have been detected in the age class 6–12 months during the past 12 months;
- g) imported wild pigs comply with the requirements in Article 15.1.7.

Article 15.1.3.bis**Compartment free from ASF**

The establishment of an ASF free compartment free from ASF should follow the relevant requirements of this chapter and the principles in Chapters 4.3. and 4.4.

Article 15.1.3.ter

Establishment of a containment zone within a country or zone free from ASF

In the event of limited outbreaks of ASF within a country or zone previously free from ASF, including within a protection zone, a containment zone, which includes all outbreaks, can be established for the purpose of minimising the impact on the entire country or zone.

In addition to the requirements for the establishment of a containment zone outlined in point 3 of Article 4.3.3., the surveillance programme should take into account the presence and potential role of *Ornithodoros* ticks and of wild and feral pigs and African wild suids and any measures in place to avoid their dispersion.

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 outside the containment zone may be reinstated irrespective of the provisions of Article 15.1.4., once the containment zone is clearly established. It should be demonstrated that commodities for international trade have originated outside the containment zone unless these commodities comply with the provisions in Articles 15.1.6., 15.1.9., 15.1.11. and Articles 15.1.13. to 15.1.17.

The recovery of the ASF free status of the containment zone should follow the provisions of Article 15.1.4.

Article 15.1.4.

Recovery of free status

Should an ASF outbreak of ASF occur in a previously free country, or zone or compartment, the free its status may be restored three months after the disposal of the last case, provided that:

~~where surveillance has been carried out with negative results, either:~~

- 1) three months after the last case where a stamping-out policy is has been implemented practised and in the case where ticks are suspected to be involved in the epidemiology of the infection, followed by acaricide treatment and the use of sentinel pigs in the infected establishments for two months; or
- 2) surveillance in accordance with Article 15.1.25. has been carried out with negative results.
- 2) where a stamping-out policy is not practised Otherwise, the provisions of point 2 of Article 15.1.3. apply should be followed.

AND

Based on surveillance, ASF infection has been demonstrated not to be present in any wild pig population in the country or zone.

Article 15.1.5.

Recommendations for importation from ASF free countries, zones or compartments free from ASF**For domestic and captive wild pigs**

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

- 1) showed no clinical sign of ASF on the day of shipment;
- 2) were kept in an ASF free country, zone or compartment free from ASF since birth or for at least the past 40 days three months.

Article 15.1.6.

Recommendations for importation from countries or zones considered infected with not free from ASF**For domestic and captive wild pigs**

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

Annex 27 (contd)

- 1) showed no clinical sign of ASF on the day of shipment;
- 2) and either:
 - a) were kept since birth or for the past ~~40 days~~ three months in an ~~ASF free compartment free from ASF;~~ or
 - b) were kept in a quarantine station, isolated for 30 days prior to shipment, and were subjected to a virological test and a serological test performed at least 21 days after entry into the quarantine station, with negative results.

Article 15.1.7.

Recommendations for importation from ASF free countries or zonesFor wild pigs

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

- 1) showed no clinical sign of ASF on the day of shipment;
 - 2) have been captured in an ASF free country or zone;
- and, if the zone where the animal has been captured is adjacent to a zone with infection in wild pigs:
- 3) were kept in a *quarantine station* for 40 days prior to shipment, and were subjected to a virological test and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results.

Article 15.1.8.

Recommendations for importation from ASF free countries, zones or compartments free from ASFFor semen of domestic and captive wild pigs

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

- 1) the donor ~~animals~~ males:
 - a) were kept in an ~~ASF free country, zone or compartment~~ free from ASF since birth or for at least 40 days ~~three months~~ prior to collection;
 - b) showed no clinical sign of ASF on the day of collection of the semen;
- 2) the semen was collected, processed and stored in ~~conformity~~ accordance with the provisions of Chapters 4.5. and 4.6.

Article 15.1.9.

Recommendations for importation from countries or zones considered infected with not free from ASFFor semen of domestic and captive wild pigs

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

- 1) the donor ~~animals~~ males:
 - a) were kept in an ASF free establishment compartment free from ASF since birth or for at least 40 days ~~three months~~ prior to collection in an establishment, in which no case of ASF has occurred in the past three years;
 - b) showed no clinical sign of ASF on the day of collection of the semen and for the following 40 30 days;
 - ~~c) were subjected to a serological test performed at least 21 days after collection, with negative results;~~
- 2) the semen was collected, processed and stored in ~~conformity~~ accordance with the provisions of Chapters 4.5. and 4.6.

Article 15.1.10.

Recommendations for importation from ASF free countries, zones or compartments free from ASFFor in vivo derived embryos of domestic pigs

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

- 1) the donor females:
 - a) ~~were kept in an ASF free country, zone or compartment since birth or for at least 40 days prior to collection;~~
 - a) were kept in a country, zone or compartment free from ASF since birth or for at least three months prior to collection;
 - b) showed no clinical sign of ASF on the day of collection of the embryos;
- 2) the embryos were collected, processed and stored in conformity accordance with the relevant provisions of Chapters 4.7. and 4.9. , as relevant.

Article 15.1.11.

Recommendations for importation from countries or zones considered infected with not free from ASFFor in vivo derived embryos of domestic pigs

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

- 1) the donor females:
 - a) were kept in an ASF free compartment free from ASF since birth or for at least 40 days three months prior to collection in an establishment, in which no case of ASF has occurred in the past three years;
 - b) showed no clinical sign of ASF on the day of collection of the embryos and for the following 40 30 days;
 - c) were subjected to a serological test performed at least 21 days after collection, with negative results;
- 2) the embryos were collected, processed and stored in conformity accordance with the relevant provisions of Chapters 4.7. and 4.9. , as relevant.

Article 15.1.12.

Recommendations for importation from ASF free countries, zones or compartments free from ASFFor fresh meat of domestic and captive wild pigs

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

- 1) have been kept in an ASF free country, zone or compartment free from ASF since birth ~~or for at least the past 40 days,~~ or which have been imported or introduced in accordance with Article 15.1.5. or Article 15.1.6.;
- 2) have been slaughtered in an approved slaughterhouse/abattoir, where they have been subjected with favourable results to ante- and post-mortem inspections in accordance with Chapter 6.2., ~~and have been found free of from any sign suggestive of ASF.~~

Article 15.1.12.bis

Recommendations for importation from countries or zones considered infected with not free from ASFFor fresh meat of domestic and captive wild pigs

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

Annex 27 (contd)

- 1) the entire consignment of fresh meat comes from animals which have been slaughtered in an approved slaughterhouse/abattoir, have been subjected with favourable results to ante- and post-mortem inspections in accordance with Chapter 6.2, and have been found free from any sign suggestive of ASF;
- 2)
 - a) the entire consignment of fresh meat comes from animals which originated from herds in which no case of ASF has occurred in the past three years and samples from a statistically representative number of animals were tested for ASF, with negative results; or
 - b) appropriate samples have been collected from every animal killed slaughtered and been tested subjected to a virological test and a serological test for ASF, with negative results.

Article 15.1.13.

Recommendations for importation ~~from ASF free countries or zones~~ of fresh meat of wild and feral pigs

For fresh meat of wild pigs

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

- 1) the entire consignment of *fresh meat* comes from animals which:
 - a) ~~have been killed in an ASF free country or zone;~~
 - b) have been subjected with favourable results to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre approved by the Veterinary Authority for export purposes, and have been found free of any sign suggestive of ASF;

and,

- 2) if the country or the zone where the animal has been killed does not comply with the conditions of point 1 of Article 1.4.6., or is adjacent to a country or zone with an unknown infection status or with infection in wild or feral pigs or African wild suids,
- 2) appropriate samples has have been collected from every animal killed and has been subjected to a virological test and a serological test for ASF, with negative results.

Article 15.1.14.

Recommendations for the importation of meat products of pigs (either domestic or wild), or for products of animal origin (from fresh meat of pigs) intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use, or for trophies derived from wild pigs

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

- 1) have been prepared:
 - a) exclusively from fresh meat meeting the relevant conditions laid down in Articles 15.1.12. or and 15.1.13., as relevant;
 - b) in a processing establishment:
 - i) approved by the *Veterinary Authority* for export purposes;
 - ii) processing only meat meeting the relevant conditions laid down in Articles 15.1.12. or and 15.1.13., as relevant;

OR

- 2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the ASFV in accordance with Article 15.1.19., and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.15.**Recommendations for the importation of pig products of animal origin (from pigs, but not derived from fresh meat) intended for use in animal feeding and for agricultural or industrial use**

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

- 1) have been prepared: originated from domestic and captive wild pigs in a country, zone or compartment free from ASF and have been prepared in a processing establishment approved by the Veterinary Authority for export purposes;
 - a) exclusively from fresh meat meeting the conditions laid down in Articles 15.1.12. or 15.1.13., as relevant;
 - b) in a processing establishment:
 - i) approved by the Veterinary Authority for export purposes;
 - ii) processing only meat meeting the conditions laid down in Articles 15.1.12. or 15.1.13., as relevant;

OR

- 2) have been processed in an establishment approved by the Veterinary Authority for export purposes so as to ensure the destruction of the ASFV, for swill in accordance with Article 15.1.18., and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.16.

Recommendations for the importation of bristles, litter and manure (from pigs)

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

- 1) originated from domestic and or captive wild pigs in come from an ASF free a country, zone or compartment free from ASF and have been processed in an establishment approved by the Veterinary Authority for export purposes; or
- 2) have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the ASFV in accordance with one of the processes listed in Article 15.1.21.bis, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.17.

Recommendations for the importation of litter and manure (from pigs)

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

- 1) come from an ASF free country, zone or compartment; or
- 2) have been processed in an establishment approved by the Veterinary Authority for export purposes so as to ensure the destruction of the ASFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.17. (Reinstated)**Recommendations for the importation of litter and manure from pigs**

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

- 1) originated from domestic or captive wild pigs in a country, zone or compartment free from ASF; or
- 2) have been processed in an establishment approved by the Veterinary Authority for export purposes so as to ensure the destruction of the ASFV in accordance with one of the processes listed in Article 15.1.21.ter, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Annex 27 (contd)Article 15.1.17.bis**Recommendations for the importation of skins and trophies**

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

- 1) originated from domestic and or captive wild pigs in a country, zone or compartment free from ASF and have been processed in an establishment approved by the Veterinary Authority for export purposes; or
- 2) have been processed in an establishment approved by the Veterinary Authority for export purposes so as to ensure the destruction of ASFV in accordance with one of the procedures referred to in Article 15.1.21., and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.17.ter**Recommendations for the importation of other pig products**

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

- 1) originated from domestic or captive wild pigs in a country, zone or compartment free from ASF and have been prepared in a processing establishment approved by the Veterinary Authority for export purposes;

OR

- 2) have been processed in an establishment approved by the Veterinary Authority for export purposes so as to ensure the destruction of ASFV, and that the necessary precautions were taken after processing to avoid contact of the product with any source of ASFV.

Article 15.1.18.**Procedures for the inactivation of ASFV in swill**

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

- 1) the swill should be maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or
- 2) the swill should be maintained at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of 3 bar.

Article 15.1.19.**Procedures for the inactivation of ASFV in meat**

For the inactivation of ASFV in meat, one of the following procedures should be used:

1. Heat treatment

Meat should be subjected to one of the following treatments:

- a) heat treatment in a hermetically sealed container with a Fo value of 3.00 or more; or
- b) heat treatment for at least 30 minutes at a minimum temperature of 70°C, which should be reached throughout the meat.

2. Dry cured pig meat (under study)

- a) If salted, meat should be cured and dried for a minimum of six months; or
- b) if not salted, meat should be cured and dried for a minimum of 12 months.

Article 15.1.20.

Procedures for the inactivation of ASFV in casings of pigs

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

Article 15.1.21.

Procedures for the inactivation of ASFV in skins and trophies

For the inactivation of ASFV in skins and trophies, one of the following procedures should be used:

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed; or
- 2) soaking, with agitation, in a 4% percent (w/v) solution of washing soda (sodium carbonate – Na_2CO_3) maintained at pH 11.5 or above for at least 48 hours; or
- 3) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added; or
- 4) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% percent washing soda (sodium carbonate – Na_2CO_3); or
- 5) treatment with 1% percent formalin for a minimum of six days.

Article 15.1.21.bis

Procedures for the inactivation of ASFV in bristles

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

- 1) boiling for at least 30 minutes;
- 2) immersion for at least 24 hours in a 1% solution of formaldehyde prepared from 30 ml commercial formalin per litre of water.

Article 15.1.21.ter

Procedures for the inactivation of ASFV in manure and litter from pigs (under study)

For the inactivation of ASFV present in manure of pigs, one of the following procedures should be used:

- 1) moist heat treatment for at least one hour at a minimum temperature of 55°C;
- 2) moist heat treatment for at least 30 minutes at a minimum temperature of 70°C.

Article 15.1.22.

Introduction to surveillance

Articles 15.1.22. to 15.1.27. define the principles and provide a recommendations for guide on the surveillance for ASF, and are complementary to Chapter 1.4. and Chapter 1.5., applicable to Member Countries seeking to determine their ASF status. This may be for the entire country or a zone. Guidance is also provided for Member Countries seeking recovery of ASF free status for the entire country or for a zone following an outbreak and for the maintenance of ASF free status.

Annex 27 (contd)

The impact and epidemiology of ASF may vary in different regions of the world, as do the routine biosecurity measures in different production systems. The surveillance strategies employed for determining demonstrating freedom from ASF status should be adapted to the regional or sub-regional situation. For example, the approach used should take into account be tailored in order to demonstrate freedom from ASF for a country or zone where the presence of wild and feral pigs or African wild suids, the presence of *Ornithodoros* ticks, provide a potential reservoir of infection, or and the presence of where ASF is present in adjacent countries or zones. The method should examine the epidemiology of ASF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is, therefore, latitude available to Member Countries to provide a well reasoned argument to demonstrate that absence of infection with ASFV is assured at an acceptable level of confidence.

Surveillance for ASF should be in the form of an ongoing programme designed to establish that susceptible populations in a country, zone or compartment are free from infection with ASFV or to detect the introduction of ASFV into a free population. Consideration should be given to the specific characteristics of ASF epidemiology which include:

- = the role of swill feeding;
- = the impact of different production systems;
- = the role of wild and feral pigs and African wild suids on the maintenance and spread of the disease;
- = whether *Ornithodoros* ticks are present and the role they may play in the maintenance and spread of the disease;
- = the role of semen in transmission of the ASFV;
- = the lack of pathognomonic gross lesions and clinical signs;
- = the occurrence of apparently healthy carriers;
- = the genotypic variability of ASFV.

Article 15.1.23.**General conditions and methods for surveillance**

- 1) A surveillance system in accordance with Chapter 1.4. and under the responsibility of the Veterinary Authority should address the following:
 - a) a formal and ongoing system for detecting and investigating outbreaks of ASF;
 - b) a procedure for the rapid collection and transport of samples from suspected cases to a laboratory for ASF diagnosis;
 - c) appropriate laboratory testing capability for ASF diagnosis;
 - d) a system for recording, managing and analysing diagnostic and surveillance data.
- 2) The ASF surveillance programme should:
 - a) include an early warning detection 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. The notification system under the Veterinary Authority should be supported directly or indirectly (e.g. through private veterinarians or veterinary para-professionals) by government or private sector information awareness programmes targeted to all relevant stakeholders. Personnel responsible for surveillance should be able to seek expertise in ASF diagnosis, epidemiological evaluation and control;
 - b) conduct, when relevant, regular and frequent clinical inspections and laboratory testing of high-risk groups (for example, where swill feeding is practised), or those adjacent to an ASF infected country or zone (for example, bordering areas where infected wild and feral pigs or African wild suids are present).

Article 15.1.24.

Surveillance strategies1. Introduction

The population covered by surveillance aimed at detecting disease and infection should include domestic and wild and feral suid pig populations within the country or zone. Surveillance should be composed of random and non-random approaches using clinical, virological and serological methods appropriate for the infection status of the country or zone.

The practicality of surveillance in African wild suids should be considered following the guidelines in Chapter 1.4.

The strategy employed to establish the prevalence or absence of infection with ASFV may be based on randomised or non-randomised clinical investigation or sampling at an acceptable level of statistical confidence. If an increased likelihood of infection in particular localities or subpopulations can be identified, targeted sampling may be an appropriate strategy. This may include:

- a) specific high-risk wild and feral suid pig populations and their proximity;
- b) farms which feed swill;
- c) pigs reared outdoors.

Risk factors may include, for example, temporal and spatial distribution of past outbreaks, and pig movements and demographics.

Member Countries should review their surveillance strategies whenever an increase in the risk of incursion of ASFV is perceived. Such changes include but are not limited to:

- = an emergence or an increase in the prevalence of ASF in countries or zones from which live pigs or products are imported;
- = an increase in the prevalence of ASF in wild or feral suids pigs in the country or zone;
- = an increase in the prevalence of ASF in adjacent countries or zones;
- = an increased entry of, or exposure to, infected wild or feral suid pig populations of adjacent countries or zones;
- = evidence of involvement of ticks in the epidemiology of ASF as demonstrated by surveillance implemented in accordance with Chapter 1.5.

2. Clinical surveillance

Clinical surveillance is the most effective tool for detecting ASF due to severe clinical signs and pathology associated with infection with ASFV. However, due to the clinical similarity with other diseases such as classical swine fever, porcine reproductive and respiratory syndrome and erysipelas, and those associated with porcine circovirus 2 infection, clinical surveillance should be supplemented, as appropriate, by serological and virological surveillance.

Clinical signs and pathological findings are useful for early detection; in particular, any cases where clinical signs or lesions suggestive of ASF are accompanied by high mortality should be investigated without delay.

Wild and feral suids pigs rarely present the opportunity for clinical observation, but should form part of any surveillance scheme and should, ideally, be monitored for virus as well as antibodies.

3. Virological surveillance

Virological surveillance is important for early detection, differential diagnosis and for systematic sampling of target populations. It should be conducted:

Annex 27 (contd)

- a) to investigate clinically suspected cases;
- b) to monitor at risk populations;
- c) to follow up positive serological results;
- d) to investigate increased mortality when ASF cannot be ruled out;-
- e) to confirm eradication after a stamping-out policy has been applied.

Molecular detection methods can be applied to large-scale screening for the presence of virus. If targeted at high-risk groups, they provide an opportunity for early detection that can considerably reduce the subsequent spread of ASF. Epidemiological understanding of the pathways of spread of ASFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in outbreaks in ASF-free areas previously free from ASF. Therefore, ASFV isolates should be sent to an OIE Reference Laboratory for further characterisation.

4. Serological surveillance

Serology is an effective and efficient surveillance tool. Serological surveillance aims at detecting antibodies against ASFV. Positive ASFV antibody test results can indicate an ongoing or past outbreaks, since some animals may recover and remain seropositive for a significant period, possibly life. This may include carrier animals. However, ASF serology is not suitable for early detection.

It may be possible to use sera collected for other survey purposes for ASF surveillance. However, the principles of survey design and the requirement for statistical validity should not be compromised.

Article 15.1.25.

Surveillance procedures for recovery of free status

In addition to the general conditions described in Articles 15.1.3. and 15.1.4., a Member Country seeking recovery of free status for the entire country or a zone ASF-free status, including for a containment zone, should show evidence of an active surveillance programme to demonstrate no evidence of infection with ASFV.

The domestic and captive wild pig populations should undergo regular clinical and pathological examinations and virological and serological testing, planned and implemented according to the general conditions and methods described in this chapter.

This surveillance programme should include:

- 1) establishments in the proximity of the outbreaks;
- 2) establishments epidemiologically linked to the outbreaks;
- 3) animals moved from or used as sentinels or to repopulate affected establishments;
- 4) all establishments where contiguous culling has been carried out;
- 5) wild and feral suid pig populations in the area of the outbreaks.

Article 15.1.26.

Surveillance for ASFV in wild and feral pigs and African wild suids

1) The objective of a surveillance programme is either to demonstrate that infection with ASFV is not present in wild and feral suids pigs or, if known to be present, to estimate the geographical distribution of the infection. A similar approach should be taken with respect to African wild suids where appropriate. While the same principles apply, surveillance in wild and feral suids pigs presents additional challenges including:

- a) determination of the distribution, size and movement patterns associated with the wild and feral suid pig population;
- b) relevance and practicality of assessing the possible presence of infection with ASFV within the population;
- c) determination of the practicability of establishing a zone taking into account the degree of interaction with domestic and captive wild pigs within the proposed zone.

The geographic distribution and estimated size of *wild* and *feral* suid pig populations should be assessed as a prerequisite for designing a population monitoring system following Chapter 1.4.

- 2) For implementation of the *surveillance* programme, the limits of the area over which *wild* and *feral* pigs range should be defined. *Subpopulations* of *wild* and *feral* suids pig may be separated from each other by natural or artificial barriers.
- 3) The *surveillance* programme may should include animals found dead, road kills, animals showing abnormal behaviour and or hunted animals.
- 4) There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:
 - a) areas with past history of ASF;
 - b) subregions with large populations of *wild* or and *feral* pigs or African *wild* suids;
 - c) border regions with ASF affected countries or zones;
 - d) interface between *wild* and *feral* pig populations, and domestic and *captive wild* pig populations;
 - e) areas with farms with free-ranging and outdoor pigs;
 - f) areas with a high level of hunting activity, where animal dispersion and feeding as well as inappropriate disposal of waste can occur;
 - g) other risk areas determined by the *Veterinary Authority* such as ports, airports, garbage dumps and picnic and camping areas.

Article 15.1.27.

Surveillance for arthropod vectors

Vector surveillance aims at defining the type and distribution of ticks of the genus *Ornithodoros*, the only known arthropod vectors of ASFV. Any species of *Ornithodoros* ticks should be considered as potential vector or reservoir of ASFV. The virus is generally transmitted transstadially but transovarial transmission has only been observed only in ticks of the *Ornithodoros moubata* complex.

The *Competent Authority* should have knowledge of the presence, distribution and identity of *Ornithodoros* ticks, also taking into account climatic or habitat changes which may affect distribution.

When *vector surveillance* is considered necessary, a sampling plan in accordance with Chapter 1.5. should take into account the biology and ecology of species present and, in particular, the favoured habitat of these species in burrows and structures associated with pig production. The plan should also take into account the distribution and density of pigs in the country or zone.

Sampling methods include CO₂ trapping and vacuuming of burrows or structures.

 — Text deleted.

CHAPTER X.X.

**CRITERIA FOR ASSESSING THE SAFETY OF
COMMODITIES**

Article X.X.1.

Assessing the safety of animal products from a country or zone not free from a specific listed disease

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

In many *disease-specific* chapters, Article X.X.2. lists *animal* products that can be traded from a country or *zone* not free from the specific *listed disease*. The criteria for inclusion of *animal* products in the list of *safe commodities* are based on the absence of the pathogen in the traded *animal* products, either due to its absence in the tissues from which the *animal* products are derived or to its inactivation by the processing or treatment that the *animal* products have undergone.

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

It is assumed that processing or treatment (i) uses standardised protocols, which include the steps considered critical in the inactivation of the pathogen of concern; (ii) is conducted in accordance with Good Manufacturing Practices; and (iii) that any other steps in the treatment, processing and subsequent handling of the *animal* product do not jeopardise its safety.

Article X.X.2.

Criteria

For an *animal* product to be considered a *safe commodity* for *international trade*, it should comply with the following criteria:

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

OR

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

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

or

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

or

- c) biological (e.g. fermentation);

or

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

**TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION
WORK PROGRAMME AS OF SEPTEMBER 2015**

General Topic		
Detailed issue/action (By priority order)	With whom to be managed	Status and further steps
Restructuring of the <i>Terrestrial Code</i>, including Harmonisation of the <i>Terrestrial</i> and <i>Aquatic Codes</i>		
1) Work with AAHSC towards harmonisation, as appropriate, of the horizontal parts of the <i>Codes</i> , notably Glossary, User's Guide, notification and listed diseases, and section 6 Veterinary Public Health (especially AMR) 2) Work with BSC for accurate disease description and diagnostic in the <i>Manual</i> and case definitions in the <i>Code</i> and names of diseases and country/zone disease status 3) Revision and formatting of chapters (articles numbering, tables and figures), especially of Section 7 4) OIE policy on wildlife 5) Use of "Veterinary Services" and "Veterinary Authorities" and "Competent Authorities" in the <i>Code</i>	1) TAHSC & AAHSC & HQs 2) TAHSC & BSC & HQs 3) TAHSC & AWWG & HQs 4) TAHSC & SCAD & WWG & HQs 5) TAHSC & AAHSC & HQs	Ongoing
Glossary		
1) Definitions of OIE 'standards' and 'guidelines' 2) Definition of 'stamping-out policy' 3) Definition of 'casings' 4) Definitions of 'vaccination', 'vaccination programme', 'routine vaccination', 'emergency vaccination' 5) Definitions of 'zone', 'free zone', 'infected zone', 'containment zone', 'protection zone'	1) TAHSC & AAHSC & BSC & SCAD & HQs 2) TAHSC 3) TAHSC 4) TAHSC & BSC & SCAD & AHG & HQs 5) TAHSC & SCAD & HQs	1) Send for MC 2) Review MC 3) Send for MC 4) Send for AHG 5) Preliminary discussions
Horizontal issue not yet in the <i>Terrestrial Code</i>		
1) CH on vaccination strategies 2) CH on contingency planning, outbreak management and stamping-out policy 3) CH on <i>Salmonella</i> in pigs and in cattle 4) CH on working equids 5) CH on international veterinary certificate for HHP horses 6) Disaster management 7) Reptiles 8) CH on pet food	1) TAHSC & BSC & SCAD & AHG & HQs 2) TAHSC & HQs 3) TAHSC & APFSWG 4) TAHSC & AWWG 5) TAHSC & SCAD & AHG 6) AWWG & TAHSC & HQs 7) TAHSC & HQs 8) TAHSC & APFSWG	1) Pending AHG 2) Preliminary discussions 3) Draft CHs (section 6): send for MC 4) Draft CH (section 7): send for MC 5) Send to SCAD for "Handbook on management of HHP horses" 6) Endorsed with comments 7) Preliminary discussions 8) On hold (section 6)

Annex 29 (contd)

General Topic (contd)		
Detailed issue/action (By priority order)	With whom to be managed	Status and further steps
Terrestrial Code texts on horizontal issues in need of revision: Section 1 Notification		
1) Disease notification CH 1.1.	1) TAHSC & SCAD & AAHSC & HQs	1) Send for MC
2) Criteria for listing CH 1.2. and CH 1.2.bis	2) TAHSC & SCAD & AAHSC & HQs	2) Send for MC
3) Prescribed tests CH 1.3. Revise/delete CH in light of <i>Manual</i>	3) TAHSC & BSC	3) Send for MC
4) CH 1.6. on Status: reorganisation	4) TAHSC & SCAD & HQs	4) Ongoing
Terrestrial Code texts on horizontal issues in need of revision: Section 3 Veterinary Services		
Revision of CHs of Section 3 in the light of the return of experience of the PVS Pathway	TAHSC & HQs	Preliminary discussions
Terrestrial Code texts on horizontal issues in need of revision: Section 4 Disease control		
1) CH 4.3. on zoning	1) TAHSC & SCAD & HQs	1) Preliminary discussions
2) CH 4.6. on semen collection	2) TAHSC & BSC	2) Pending BSC advice
Terrestrial Code texts on horizontal issues in need of revision: Section 5 Trade measures		
CH 5.3. on SPS agreement	TAHSC & HQs	Send for MC
Terrestrial Code texts on horizontal issues in need of revision: Section 6 Veterinary Public Health		
Revision of CHs 6.1. and 6.2.	TAHSC & APFSWG	Pending WG report
Terrestrial Code texts on horizontal issues in need of revision: Section 7 Animal welfare		
1) CH 7.11. on dairy cattle production systems	TAHSC & AWWG	1) Send for MC
2) CH 7.5. on slaughter		2) Pending <i>ad hoc</i> Group
3) CH 7.6. on killing		3) Send for MC
4) CH 7.10. on broiler chicken production systems		4) Send for MC
Diseases issues not yet in the Terrestrial Code		
1) New CH 15.X. on PRRS	1) TAHSC & SCAD	1) Review AHG report on MC
2) Non-tsetse transmitted Trypanosomosis (new CH on Surra and revision of CH on Dourine)	2) TAHSC & SCAD & AHG	2) Pending AHG
Terrestrial Code texts on diseases in need of revision: Sections 8 to 15, by priority order		
Revised CH 8.8. on FMD	TAHSC & SCAD & AHG	Adopted May 2015: Send for MC + pending questions to AHG
Revised CH 15.1. on ASF	TAHSC	Send for MC
Revised CH 12.10. on glanders	TAHSC	Send for MC
Revised CH 11.4. on BSE	TAHSC & SCAD & BSC & AHG	Adopted May 2015: Pending questions sent to specific AHG
Update and harmonise CH on vector-borne diseases: BT, EHD, RVF, AHS	TAHSC & HQs	Adopted May 2015: Send for MC (BT, EHD, RVF)

Annex 29 (contd)

General Topic (contd)		
Detailed issue/action (By priority order)	With whom to be managed	Status and further steps
New CH 8.X. on tuberculosis to merge CH 11.5. & CH 11.6.	TAHSC	Send for MC
CH 15.3. on <i>T. Solium</i>	TAHSC & APFSW	Adopted May 2015: Send for MC
Update CH 10.4. on avian influenza viruses	TAHSC & HQs	Pending work on zoning, outbreak management and vaccination
Update CH 10.5. on avian mycoplasmosis	TAHSC & HQs	Pending expert opinion
Update/Revise CH 11.12. on theileriosis	TAHSC & SCAD	Seek expert opinion, AHG
Update CH 11.11. on lumpy skin disease	TAHSC	Seek expert opinion, AHG
Update CH 14.8. on scrapie	TAHSC	Review MC – seek expert opinion

Note: MC: Member comments; CH: chapter; AAHSC: Aquatic Animal Health Standard Commission; BSC: Biological Standard Commission; SCAD: Scientific Commission for Animal Diseases; TAHSC: Terrestrial Animal Health Standard Commission; AHG: ad hoc Group; AWWG: Animal Welfare Working Group; APFSWG: Animal Production Food Safety Working Group; WWG: Wildlife Working Group; HQs: OIE Headquarters.

Annex 29 (contd)

ITEM, ANNEX, CHAPTER NUMBERS AND CURRENT STATUS

Item	Annex	Chapter	Title	Provided for comments	GS83
1			General comments		
2	4		User's guide	Sep 15	C
3	5		Glossary	Sep 15	C
4	6	1.1.	Notification of diseases, infections and infestations	Sep 15	C
5	7	1.2.	Criteria for listing diseases	Sep 15	C
6	8	1.3.	Prescribed and alternative diagnostic tests for OIE listed diseases	Sep 15	C
7	9	1.6.	Procedures for self-declaration and for official recognition by the OIE	Sep 15	C
8	10	3.2.	Evaluation of Veterinary Services	Sep 15	C
	30		Report of the <i>ad hoc</i> Group meeting on evaluation of Veterinary Services	Sep 15	I
9		4.16.	High health status horse subpopulation and model veterinary certificate		E
10	11	5.3.	OIE procedures relevant to the WTO/SPS Agreement	Sep 15	C
11	12	6.7.	Harmonisation of national antimicrobial resistance surveillance and monitoring programmes	Sep 15	C
	13	6.8.	Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals	Sep 15	C
12		6.X.	Draft new chapter on prevention and control of <i>Salmonella</i> in commercial cattle production system		D
		6.X.	Draft new chapter on prevention and control of <i>Salmonella</i> in pig herds		D
	14	8.16.	Infection with <i>Trichinella</i> spp.	Sep 15	C
	15	15.3.	Infection with <i>Taenia solium</i>	Sep 15	C
13	16	7.5.	Slaughter of animals	Sep 15	C
	17	7.6.	Killing of animals for disease control purposes	Sep 15	C
	18	7.10.	Animal welfare and broiler chicken production systems	Sep 15	C
	19	7.11.	Animal welfare and dairy cattle production systems	Sep 15	C
	20	7.X.	Draft new chapter on the welfare of working equids	Sep 15	C
14	21	8.3.	Infection with bluetongue virus	Sep 15	C
	22	8.7.	Infection with epizootic hemorrhagic disease virus	Sep 15	C
	23	8.14.	Infection with Rift Valley fever virus	Sep 15	C
15		8.4.	Infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i>		E
16	24	8.8.	Infection with foot and mouth disease virus	Sep 15	C
17	25	8.X.	Infection with <i>Mycobacterium tuberculosis</i> complex	Sep 15	C
18		10.4.	Infection with avian influenza viruses		E
19		11.4.	Bovine spongiform encephalopathy		E
20	26	12.10.	Infection with <i>Burkholderia mallei</i> (Glanders)	Sep 14	C
21	27	15.1.	Infection with African swine fever virus	Feb 15	C
22	28	X.X.	Draft new chapter on criteria for assessing the safety of commodities	Sep 15	C
23	29		Work programme	Sep 15	C
25	34		Report of the <i>ad hoc</i> Group meeting on veterinary education	Sep 15	I

C: For Member comments; E: under expert consultation (*ad hoc* Groups, Specialist Commissions, etc.), D: deferred to Feb 2016 meeting; I: For Member Country information.