

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

Paris, 9–18 September 2014

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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 16 September)****D. EXAMINATION OF MEMBER COUNTRY COMMENTS AND WORK OF RELEVANT EXPERT
GROUPS**

Item 1 General comments of Member Countries

Item 2 Horizontal issues

a) User's guide

b) General obligations related to certification (Chapter 5.1.)

Item 3 Glossary

Item 4 Criteria for listing diseases (Chapter 1.2.)

Item 5 Import risk analysis (Chapter 2.1.)

Item 6 Evaluation of Veterinary Services (Chapter 3.2.)

Item 7 Semen and embryos

a) Collection and processing of bovine, small ruminant and porcine semen (Chapter 4.6.)

b) Collection and processing of *in vivo* derived embryos from livestock and equids (Chapter 4.7.)

Item 8 Certification procedures (Chapter 5.2.)

Item 9 Prevention, detection and control of *Salmonella* in poultry (Chapter 6.5.)

Item 10 Antimicrobial resistance

a) Responsible and prudent use of antimicrobial agents in veterinary medicine (Chapter 6.9.)

b) Risk assessment for antimicrobial resistance arising from the use of antimicrobial agents in animals (Chapter 6.10.)

Annex II (contd)

- Item 11 Animal welfare
- a) Draft new chapter on Animal welfare and dairy cattle production systems (Chapter 7.X.)
 - b) Member Country comments on existing chapters (Chapter 7.10.)
 - c) Report of the meeting of *ad hoc* Group on Disaster Management and Risk Reduction in relation to Animal Health and Welfare and Veterinary Public Health
 - d) Report of the meeting of *ad hoc* Group on the Welfare of Working Equids
 - e) Report of the meeting of Animal Welfare Working Group
- Item 12 Infection with *Taenia solium* (Draft Chapter X.X.)
- Item 13 Foot and mouth disease (Chapters 8.7. and 1.6.)
- Item 14 Infection with Rift valley fever (Chapter 8.13.)
- Item 15 Infection with *Brucella abortus*, *B. melitensis* and *B. suis* (Chapter 8.4.)
- Item 16 Infection with avian influenza viruses (Chapter 10.4.)
- Item 17 Equine diseases
- a) Glanders (Chapter 12.10.)
 - b) High health status horse subpopulation (Chapter 4.16.)
- Item 18 Infection with porcine reproductive and respiratory syndrome (Draft Chapter 15.X.)
- Item 19 Report of the meeting of the *ad hoc* Group on Salmonellosis in Pigs

E. OTHER ISSUES

- Item 20 Update of the Code Commission work programme
- Item 21 Review of applications for recognition as OIE Collaborating Centre
- Safety of bee products (Ukraine)
- Item 22 Other issues
- a) Proposed dates for next meetings
 - b) Prescribed and alternative diagnostic tests for OIE listed diseases (Chapter 1.3.)

JOINT MEETING BETWEEN THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES AND THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

(16 September 2014)

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 16 September 2014 to discuss issues of mutual interest. All members of all Commissions as well as the Director General, Deputy Director General, and his staff participated in the meeting.

The main discussion points were as follows:

1. Procedure for reviewing chapters in the *Terrestrial Code*

Considering the increasing complexity, horizontality, integration and multi-layered inputs and decision-making process to address the issues presented to both Commissions, *ad hoc* groups and the OIE Headquarters required to support the development of new or amended chapters, it was agreed that the OIE Headquarters would establish revised procedures for improving the internal coordination for management of working documents and the provision of comments received from Members to both of the Commissions as appropriate.

2. Foot and mouth disease

The revised foot and mouth disease (FMD) chapter was extensively discussed and both Commissions agreed that the chapter should be circulated for Member Country review in both clean text format and usual 'double underline and strikethrough' format. It was reiterated that Member Countries are advised to consult not only the Code Commission report but also the Scientific Commission report and the associated *ad hoc* group reports when reviewing the revised chapter.

3. International horse movement for equestrian events

Both Commissions noted the work of the *ad hoc* Group on the draft veterinary certificate for horses in the high health status subpopulation. The Scientific Commission explained its view on Chapter 4.16. and the draft certificate to assist the Code Commission in their review of the *ad hoc* Group work.

4. Porcine reproductive and respiratory syndrome

Both Commissions noted the significant volume of comments received from Member Countries on this draft chapter. It will be included in the agendas of the February Commission meetings.

5. Bovine spongiform encephalopathy

Considering the evolution of this disease, in particular in respect of recent cases of atypical bovine spongiform encephalopathy (BSE), both Commissions recognised the need of in-depth analysis and further discussion on how to deal with atypical BSE.

6. Other disease chapters for revision

The Scientific Commission informed the Code Commission on the draft revised chapters on African swine fever and tuberculosis, which would be forwarded to the Code Commission as soon as the Scientific Commission concluded its deliberations and endorsed the *ad hoc* Group reports during the course of the week. Similar procedures would be followed with the proposal of the Headquarters with the harmonisation of chapters on African horse sickness, bluetongue and epizootic haemorrhagic disease.

Annex III (contd)**7. Criteria for listing diseases**

The Director General explained that during the 82nd General Session a commitment was agreed to convene an *ad hoc* group to review the OIE disease listing criteria. Both Commissions recommended that the *ad hoc* group should meet before the February meetings of both Commissions. It was also recommended that, if possible, the Member Countries that had expressed concerns on the current listing criteria should be involved in this *ad hoc* group. Both Commissions also agreed that should the listing criteria be modified by the *ad hoc* group, they would then be reviewed by the Commissions and eventually submitted for adoption by the World Assembly of Delegates. Once adopted, the current OIE listed diseases would be individually reviewed against the new criteria by selected disease-specific experts, rather than all listed diseases being reviewed together by a single group.

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.
- 4) The absence of chapters, articles or recommendations on particular aetiological agents or commodities does not mean that Veterinary Authorities may not apply appropriate animal health measures based on risk analysis conducted in accordance with the *Terrestrial Code*.
- 5) The complete text of the *Terrestrial Code* is available on the OIE website and 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 the chapters of Section 2 are designed to guide the importing country in conducting import risk analysis in the absence of OIE trade standards. The importing country may also use these standards to justify import measures which are ~~more trade restrictive~~ stricter than existing OIE trade 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, disinsection and general hygiene precautions. Some chapters address the specific sanitary measures to be applied for the collection and processing of semen and embryos of animals.

Annex IV (contd)

- 7) The standards in the chapters of Section 5 are designed for the implementation of general sanitary measures for trade. In particular, They chapters address veterinary certification and the measures applicable by the exporting, transit and importing countries. ~~Section 5 also includes A~~ a range of model veterinary certificates are provided for consistent documentation to be used as a harmonised basis of 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 the families 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 the 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 event of epidemiological significance.

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

2) Diagnostic tests and vaccines

The use of specified diagnostic tests and vaccines in *Terrestrial Code* chapters is recommended 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 recommended 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 4.5. 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 health risks. Moreover, in Chapter 4.7. diseases that are not listed diseases are included, and marked as such, for the information of Member Countries.

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

Chapter 6.4. is designed for the implementation of general biosecurity measures in intensive poultry production.

Chapter 6.5. gives 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 of 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 more or less restrictive than those recommended by the *Terrestrial Code*. To scientifically justify more trade restrictive 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 ~~ethics~~ 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. ~~These~~ Chapters 5.3. provides guidance for informal mediation by the OIE.

The OIE aims to include an article listing the commodities that are considered safe for trade without the imposition of pathogen-specific sanitary measures, regardless of the status of the country or zone for the agent in question at the beginning of each disease-specific chapter in Sections 8 to 15. This is a work in progress and some chapters do not yet contain articles listing safe commodities. In those chapters, where a list of safe commodities is present, 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 the Veterinary Authority of an exporting country draws up in accordance with Chapters 5.1. and 5.2. Certificates list the 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 be based upon the standards in the *Terrestrial Code*.

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

- a) list the diseases, infections or infestations ~~for~~ from which the importing country is justified in seeking protection ~~in regards to~~ 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 ~~or eradication~~ programmes;
- b) for commodities capable of transmitting these diseases, infections or infestations through international trade, the importing country should apply the relevant articles ~~addressing the commodity in question~~ in the relevant disease-specific chapters. The application of the articles should be adapted to the disease status of the exporting country, zone or compartment. 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;
- d) Chapters 5.10. to 5.13. provide, as further guidance to Member Countries, model certificates that should be used as a baseline.

Annex IV (contd)

6) Guidance notes for importers and exporters

~~It is recommended that~~ Veterinary Authorities ~~are recommended to~~ 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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CHAPTER 5.1.

GENERAL OBLIGATIONS RELATED TO CERTIFICATION

Article 5.1.1.

Safety of *international trade in animals* and animal products depends on a combination of factors which should be taken into account to ensure unimpeded trade, without incurring unacceptable *risks* to human and animal health.

Because of differences between countries in their animal health situations, various options are offered by the *Terrestrial Code*. The animal health situation in the *exporting country*, in the *transit country* or *countries* and in the *importing country* should be considered before determining the requirements for trade. To maximise harmonisation of the sanitary aspects of *international trade*, *Veterinary Authorities* of Member Countries should base their import requirements on the standards of the OIE.

These requirements should be included in the model certificates approved by the OIE which are included from Chapters 5.10. to 5.12.

Certification requirements should be exact and concise, and should clearly convey the wishes of the *importing country*. For this purpose, prior consultation between *Veterinary Authorities* of *importing* and *exporting countries* may be necessary. It enables the setting out of the exact requirements so that the signing *veterinarian* can, if necessary, be given a note of guidance explaining the understanding between the *Veterinary Authorities* involved.

The certification requirements should not include conditions for *diseases* that are not transmitted by the *commodity* concerned. The certificate should be signed in accordance with the provisions of Chapter 5.2.

When officials of a *Veterinary Authority* wish to visit another country for matters of professional interest to the *Veterinary Authority* of the other country, the latter should be informed.

Article 5.1.2.

Responsibilities of the importing country

- 1) The import requirements included in the *international veterinary certificate* should assure that *commodities* introduced into the *importing country* comply with the standards of the OIE. *Importing countries* should align ~~restrict~~ their requirements with ~~to~~ those recommended in the relevant standards of the OIE necessary to achieve the national appropriate level of protection. If there are no such standards or if the country chooses a level of protection requiring measures ~~these are~~ stricter than the standards of the OIE, these ~~they~~ should be based on an import *risk analysis*.
- 2) The *international veterinary certificate* should not include requirements for the exclusion of pathogens or animal *diseases* which are present in the *importing country* and are not subject to any *official control programme*. The measures imposed on imports to manage the *risks* posed by a specific pathogen or *disease* should not be stricter ~~require a higher level of protection than~~ those ~~that provided by measures~~ applied as part of the *official control programme* operating within the *importing country*.
- 3) The *international veterinary certificate* should not include measures against pathogens or *diseases* which are not OIE listed, unless the *importing country* has demonstrated through import *risk analysis*, carried out in accordance with Section 2, that the pathogen or *disease* poses a significant *risk* to the *importing country*.

Annex V (contd)

- 4) The transmission by the *Veterinary Authority* of certificates or the communication of import requirements to persons other than the *Veterinary Authority* of another country, necessitates that copies of these documents are also sent to the *Veterinary Authority*. This important procedure avoids delays and difficulties which may arise between traders and *Veterinary Authorities* when the authenticity of the certificates or permits is not established.

This information is the responsibility of *Veterinary Authorities*. However, it can be issued by private sector *veterinarians* at the place of origin of the *commodities* when this practice is the subject of appropriate approval and authentication by the *Veterinary Authority*.

- 5) Situations may arise which result in changes to the consignee, identification of the means of transportation, or *border post* after a certificate is issued. Because these do not change the animal or public health status of the consignment, they should not prevent the acceptance of the certificate.

Article 5.1.3.

Responsibilities of the exporting country

- 1) An *exporting country* should, on request, supply the following to *importing countries*:
- a) information on the animal health situation and national animal health information systems to determine whether that country is free or has *zones* or *compartments* free from *listed diseases*, including the regulations and procedures in force to maintain its free status;
 - b) regular and prompt information on the occurrence of *notifiable diseases*;
 - c) details of the country's ability to apply measures to control and prevent the relevant *listed diseases*;
 - d) information on the structure of the *Veterinary Services* and the authority which they exercise according to Chapters 3.1. and 3.2.;
 - e) technical information, particularly on biological tests and vaccines applied in all or part of the national territory.
- 2) *Veterinary Authorities* of *exporting countries* should:
- a) have official procedures for authorisation of certifying *veterinarians*, defining their functions and duties as well as conditions of oversight and accountability, including possible suspension and termination of the authorisation;
 - b) ensure that the relevant instructions and training are provided to certifying *veterinarians*;
 - c) monitor the activities of the certifying *veterinarians* to verify their integrity and impartiality.
- 3) The *Veterinary Authority* of the *exporting country* is ultimately accountable for veterinary certification used in *international trade*.

Article 5.1.4.

Responsibilities in case of an incident related to importation

- 1) *International trade* involves a continuing ethical responsibility. Therefore, if within the recognised *incubation periods* of the various *diseases* subsequent to an export taking place, the *Veterinary Authority* becomes aware of the appearance or reappearance of a *disease* which has been specifically included in the *international veterinary certificate*, there is an obligation for this *Authority* to notify the *importing country*, so that the imported *commodities* may be inspected or tested and appropriate action be taken to limit the spread of the *disease* should it have been inadvertently introduced.

Annex V (contd)

- 2) If a *disease* condition appears in imported *commodities* within a time period after importation consistent with the recognised *incubation period* of the *disease*, the *Veterinary Authority* of the *exporting country* should be informed so as to enable an investigation to be made, since this may be the first available information on the occurrence of the *disease* in a previously free *herd*. The *Veterinary Authority* of the *importing country* should be informed of the result of the investigation since the source of *infection* may not be in the *exporting country*.
- 3) In case of suspicion, on reasonable grounds, that an official certificate may be fraudulent, the *Veterinary Authority* of the *importing country* and *exporting country* should conduct an investigation. Consideration should also be given to notifying any third country(ies) that may have been implicated. All associated consignments should be kept under official control, pending the outcome of the investigation. The *Veterinary Authorities* of all countries involved should fully cooperate with the investigation. If the certificate is found to be fraudulent, every effort should be made to identify those responsible so that appropriate action can be taken according to the relevant legislation.

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GLOSSARY

BIOSECURITY

means the set of management and physical measures designed to reduce the risk of introduction, development and spread of animal diseases, infections or infestations to, from and within an animal population.

DISEASE

means the clinical and/or pathological manifestation of *infection* or *infestation*.

~~HAZARD IDENTIFICATION~~

~~means the process of identifying the pathogenic agents which could potentially be introduced in the commodity considered for importation.~~

~~MODIFIED STAMPING-OUT POLICY~~

~~see stamping-out policy.~~

RISK ANALYSIS

means the process composed of *hazard identification* identification, *risk assessment*, *risk management* and *risk communication*.

RISK ASSESSMENT

means the evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a *hazard* within the territory of an *importing country*.

SAFE COMMODITY

means a commodity which in the form normally traded is considered safe for trade with respect to a listed disease, infection or infestation, without the need for specific risk mitigation measures against the listed disease, infection or infestation and regardless of status of the country or zone of origin for that disease, infection or infestation.

~~STAMPING-OUT POLICY~~

~~means a policy designed to eliminate an outbreak by carrying out under the authority of the Veterinary Authority, in whole or in part, the following on confirmation of a disease:~~

- ~~≡ the killing, in accordance with Chapter 7.6., 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; should be killed and~~
- ~~≡ the destruction of their carcasses destroyed by rendering, burning or burial, or by any other method described in Chapter 4.12. which will eliminate the spread of infection through the carcasses or products of the animals killed;~~
- ~~≡ This policy should be accompanied by the cleansing and disinfection of establishments through procedures defined in the Terrestrial Code Chapter 4.13.~~

~~The terms modified stamping-out policy should be used in communications to the OIE whenever the above animal health measures are not implemented in full and details of the modifications should be given.~~

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CHAPTER 3.2.

EVALUATION OF VETERINARY SERVICES

Article 3.2.1.

General considerations

- 1) Evaluation of *Veterinary Services* is an important element in the *risk analysis* process which countries may legitimately use in their policy formulations directly applying to animal health and sanitary controls of *international trade* in *animals*, animal-derived products, animal genetic material and animal feedstuffs.

Any evaluation should be carried out with due regard for Chapter 3.1.

- 2) In order to ensure that objectivity is maximised in the evaluation process, it is essential for some standards of discipline to be applied. The OIE has developed these recommendations which can be practically applied to the evaluation of *Veterinary Services*. These are relevant for evaluation of the *Veterinary Services* of one country by those of another country for the purposes of *risk analysis* in *international trade*. The recommendations are also applicable for evaluation by a country of its own *Veterinary Services* – the process known as self-evaluation – and for periodic re-evaluation. These recommendations should be used by OIE experts when facilitating an evaluation under the auspices of the OIE, following a request of a Member Country. In applying these recommendations on the evaluation, the *OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool)* should be used.

In carrying out a *risk analysis* prior to deciding the sanitary or zoosanitary conditions for the importation of a *commodity*, an *importing country* is justified in regarding its evaluation of the *Veterinary Services* of the *exporting country* as critical.

- 3) The purpose of evaluation may be either to assist a national authority in the decision-making process regarding priorities to be given to its own *Veterinary Services* (self-evaluation) or to assist the process of *risk analysis* in *international trade* in *animals* and animal-derived products to which official sanitary or zoosanitary controls apply.
- 4) In both situations, the evaluation should demonstrate that the *Veterinary Services* have the capability for effective control of the sanitary and zoosanitary status of *animals* and animal products. Key elements to be covered in this process include adequacy of resources, management capability, legislative and administrative infrastructures, independence in the exercise of official functions and history of performance, including *disease* reporting.
- 5) Good governance is the key to competence, integrity and confidence in organisations. Mutual confidence between relevant official *Veterinary Services* of trading partner countries contributes fundamentally to stability in *international trade* in *animals* and animal-related products. In this situation, scrutiny is directed more at the *exporting country* than at the *importing country*.
- 6) Although quantitative data can be provided on *Veterinary Services*, the ultimate evaluation will be essentially qualitative. While it is appropriate to evaluate resources and infrastructure (organisational, administrative and legislative), it is also appropriate to place emphasis on the evaluation of the quality of outputs and performance of *Veterinary Services*. Evaluation should take into consideration any quality systems used by *Veterinary Services*.
- 7) An *importing country* has a right of assurance that information on sanitary or zoosanitary situations provided by the *Veterinary Services* of an *exporting country* is objective, meaningful and correct. Furthermore, the *Veterinary Services* of the *importing country* are entitled to expect validity in the veterinary certification of export.

Annex VII (contd)

- 8) An *exporting country* is entitled to expect that its *animals* and animal products will receive reasonable and valid treatment when they are subjected to import inspection in the country of destination. The country should also be able to expect that any evaluation of its standards and performance will be conducted on a non-discriminatory basis. The *importing country* should be prepared and able to defend any position which it takes as a consequence of the evaluation.
- 9) As the *veterinary statutory body* is not a part of the *Veterinary Services*, an evaluation of that body should be carried out to ensure that the registration or licensing of *veterinarians* and authorisation of *veterinary para-professionals* is included.

Article 3.2.2.

Scope

- 1) In the evaluation of *Veterinary Services*, the following items may be considered, depending on the purpose of the evaluation:
 - organisation, structure and authority of the *Veterinary Services*;
 - human resources;
 - material (including financial) resources;
 - *veterinary legislation*, regulatory frameworks and functional capabilities;
 - animal health, *animal welfare* and veterinary public health controls;
 - formal quality systems including quality policy;
 - performance assessment and audit programmes;
 - participation in OIE activities and compliance with Member Countries' obligations.
- 2) To complement the evaluation of *Veterinary Services*, the legislative and regulatory framework, the organisational structure and functioning of the *veterinary statutory body* should also be considered.
- 3) Article 3.2.14. outlines appropriate information requirements for:
 - self-evaluation by the *Veterinary Authority* which perceives a need to prepare information for national or international purposes;
 - evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;
 - verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*;
 - evaluation by third parties such as OIE PVS experts or regional organisations.

Article 3.2.3.

Evaluation criteria for the organisational structure of the Veterinary Services

- 1) A key element in the evaluation is the study of the organisation and structure of the official *Veterinary Services*. The *Veterinary Services* should define and set out their policy, objectives and commitment to quality systems and standards. These organisational and policy statements should be described in detail. Organisational charts and details of functional responsibilities of staff should be available for evaluation. The role and responsibility of the Chief Veterinary Officer/Veterinary Director should be clearly defined. Lines of command should also be described.

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- 2) The organisational structure should also clearly set out the interface relationships of government Ministers and departmental Authorities with the Chief Veterinary Officer/Veterinary Director and the *Veterinary Services*. Formal relationships with statutory authorities and with industry organisations and associations should also be described. It is recognised that *Services* may be subject to changes in structure from time to time. Major changes should be notified to trading partners so that the effects of re-structuring may be assessed.
- 3) Organisational components of *Veterinary Services* which have responsibility for key functional capabilities should be identified. These capabilities include epidemiological *surveillance*, *disease control*, import controls, animal disease reporting systems, *animal identification systems*, traceability systems, animal movement control systems, communication of epidemiological information, training, inspection and certification. *Laboratory* and field systems and their organisational relationships should be described.
- 4) To reinforce the reliability and credibility of their services, the *Veterinary Services* may have set up quality systems that correspond with their fields of activity and to the nature and scale of activities that they carry out. Evaluation of such systems should be as objective as possible.
- 5) The *Veterinary Authority* alone speaks for the country as far as official international dialogue is concerned. This is also particularly important to cases where zoning and compartmentalisation are being applied. The responsibilities of the *Veterinary Authority* should be made clear in the process of evaluation of *Veterinary Services*.
- 6) The *Veterinary Authority* is defined in the Glossary. As some countries have some relevant roles of the *Veterinary Authority* vested in autonomous sub-national (state/provincial, municipal) government bodies, there is an important need to assess the role and function of these *Services*. Details of their roles, relationship (legal and administrative) to each other and to the *Veterinary Authority* should be available for evaluation. Annual reports, review findings and access to other information pertinent to the animal health activities of such bodies should also be available.
- 7) Similarly, where the *Veterinary Authority* has arrangements with other providers of relevant services such as universities, *laboratories*, information services, etc., these arrangements should also be described. For the purposes of evaluation, it is appropriate to expect that the organisational and functional standards that apply to the *Veterinary Authority* should also apply to the service providers.

Article 3.2.4.

Evaluation criteria for quality systems

- 1) The *Veterinary Services* should demonstrate a commitment to the quality of the processes and outputs of their services. Where services or components of services are delivered under a formal quality systems programme which is based on OIE recommended standards or, especially in the case of laboratory components of *Veterinary Services* other internationally recognised quality standards, the *Veterinary Services* undergoing evaluation should make available evidence of accreditation, details of the documented quality processes and documented outcomes of all relevant audits undertaken.
- 2) Where the *Veterinary Services* undergoing evaluation make large use of formal quality systems in the delivery of their services, it is appropriate that greater emphasis be placed on the outcomes of evaluation of these quality systems than on the resource and infrastructural components of the services.

Article 3.2.5.

Evaluation criteria for human resources

- 1) The *Veterinary Services* should demonstrate that their human resource component includes an integral core of full-time civil service employees. This core should always include *veterinarians*. It should also include administrative officials and *veterinary para-professionals*. The human resources may also include part-time and private sector *veterinarians* and *veterinary para-professionals*. It is essential that all the above categories of personnel be subject to legal disciplinary provisions. Data relating to the resource base of the *Veterinary Services* undergoing evaluation should be available.

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- 2) In addition to raw quantitative data on this resource base, the functions of the various categories of personnel in the *Veterinary Services* should be described in detail. This is necessary for analysis and estimation of the appropriateness of the application of qualified skills to the tasks undertaken by the *Veterinary Services* and may be relevant, for example, to the roles of *veterinarians* and *veterinary para-professionals* in field services. In this case, the evaluation should provide assurances that *disease* monitoring is being conducted by a sufficient number of qualified, experienced field *veterinarians* who are directly involved in farm visits; there should not be an over-reliance on *veterinary para-professionals* for this task.
- 3) Analysis of these data can be used to estimate the potential of the *Veterinary Services* to have reliable knowledge of the state of animal health in the country and to support an optimal level of animal disease control programmes. A large population of private *veterinarians* would not provide the *Veterinary Services* with an effective epizootiological information base without legislative (e.g. compulsory reporting of *notifiable diseases*) and administrative (e.g. official animal health surveillance and reporting systems) mechanisms in place.
- 4) These data should be assessed in close conjunction with the other information described in this chapter. For example, a large field staff (*veterinarians* and *veterinary para-professionals*) need fixed, mobile and budgetary resources for animal health activities in the livestock farming territory of the country. If deficiencies are evident, there would be reason to challenge the validity of epizootiological information.

Article 3.2.6.

Evaluation criteria for material resources1. Financial

Actual yearly budgetary information regarding the *Veterinary Services* should be available and should include the details set out in the model questionnaire outlined in Article 3.2.14. Information is required on conditions of service for veterinary staff (including salaries and incentives), and should provide a comparison with the private sector and perhaps with other professionals. Information should also be available on non-government sources of revenue available to *veterinarians* in their official responsibilities.

2. Administrative

a) Accommodation

The *Veterinary Services* should be accommodated in premises suitable for efficient performance of their functions. The component parts of the *Veterinary Services* should be located as closely as possible to each other at the central level, and in the regions where they are represented, in order to facilitate efficient internal communication and function.

b) Communications

The *Veterinary Services* should be able to demonstrate that they have reliable access to effective communications systems, especially for animal health surveillance and control programmes. Inadequate communications systems within the field services components of these programmes or between outlying offices and headquarters, or between the *Veterinary Services* and other relevant administrative and professional services, signify an inherent weakness in these programmes. Adequate communications systems between *laboratories* and between field and laboratory components of the *Veterinary Services* should also be demonstrated.

Examples of types of communications which should be routinely available on an adequate country-wide basis are national postal, freight and telephone networks. Rapid courier services, facsimile and electronic data interchange systems such as e-mail and Internet services are examples of useful communication services which, if available, can supplement or replace the others. A means for rapid international communication should be available to the *Veterinary Authority*, to permit reporting of changes in national disease status consistent with OIE recommendations and to allow bilateral contact on urgent matters with counterpart *Veterinary Authorities* in trading-partner countries.

c) Transport systems

The availability of sufficient reliable transport facilities is essential for the performance of many functions of *Veterinary Services*. This applies particularly to the field services components of animal health activities such as emergency response visits. Otherwise, the *Veterinary Services* cannot assure counterpart services in other countries that they are in control of the animal health situation within the country.

Appropriate means of transport are also vital for the satisfactory receipt of samples to be tested at veterinary *laboratories*, for inspection of imports and exports, and for the performance of *animals* and animal product inspection in outlying production or processing establishments.

3. Technical

Details available on *laboratories* should include resources data, programmes under way as well as those recently completed and review reports on the role or functions of the *laboratory*. Information as described in the model questionnaire should be used in the evaluation of laboratory services.

a) Cold chain for laboratory samples and veterinary medicines

Adequate refrigeration and freezing systems should be available and should be used throughout the country to provide suitable low temperature protection for laboratory samples in transit or awaiting analysis, as well as veterinary medical products such as vaccines when these are required for use in animal disease control programmes. If these assurances cannot be given, it may be valid to discount many types of test results, as well as the effectiveness of certain disease control programmes and the export inspection system in the country undergoing evaluation.

b) Diagnostic laboratories

Analysis of the laboratory service component of *Veterinary Services*, which would include official governmental *laboratories* and other *laboratories* authorised by the *Veterinary Services* for specified purposes, is an essential element of the evaluation process. The quality of the veterinary diagnostic *laboratories* of a country underpins the whole control and certification processes of the zoosanitary or sanitary status of exported *animals* and animal products, and therefore these *laboratories* should be subject to rigid quality assurance procedures and should use international quality assurance programmes (wherever available) for standardising test methodologies and testing proficiency. An example is the use of International Standard Sera for standardising reagents.

In countries where there is more than one diagnostic laboratory for a given pathogen, the designation of a National Reference Laboratory for that pathogen may contribute to the quality of analysis performed by the diagnostic laboratories.

Quality of analysis is equally important to the testing performed on individual export consignments as to the broader ongoing testing regimes which are used to determine the animal health and veterinary public health profiles of the country and to support its disease control programmes. For the purposes of evaluation, veterinary diagnostic *laboratories* include those which are concerned with either animal health or veterinary public health activities. The *Veterinary Services* should approve and designate these *laboratories* for such purposes and have them audited regularly.

c) Research

The scope of animal health, welfare disease and veterinary public health problems in the country concerned, the stages reached in the controls which address those problems and their relative importance can be measured to some degree by analysis of information on government priorities and programmes for research in animal health. This information should be accessible for evaluation purposes.

Annex VII (contd)

Article 3.2.7.

Legislation and functional capabilities1. Animal health, animal welfare and veterinary public health

The *Veterinary Authority* should be able to demonstrate that it has the capacity, supported by appropriate legislation, to anticipate and exercise control over all animal health and *animal welfare* matters. These controls should include, where appropriate, compulsory notification of prescribed animal *diseases*, inspection, movement controls through systems which provide adequate traceability, registration of facilities, quarantine of infected premises or areas, testing, treatment, humane *killing* of infected *animals*, disposal of carcasses, or destruction of contaminated materials, controls over the use of veterinary medicines, etc. The scope of the legislative controls should include domestic *animals* and their reproductive material, animal products, *wildlife* as it relates to the transmission of *diseases* to humans and domestic *animals*, and other products subject to veterinary inspection. Arrangements should exist for co-operation with the *Veterinary Authorities* of the neighbouring countries for the control of animal *diseases* in border areas and for establishing linkages to recognise and regulate transboundary activities. Within the structure of *Veterinary Services*, there should be appropriately qualified personnel whose responsibilities include *animal welfare*. Information on the veterinary public health legislation covering the production of products of animal origin for national consumption may be also considered in the evaluation.

2. Export and import inspection

The *Veterinary Authority* should have appropriate legislation and adequate capabilities to prescribe the methods for control and to exercise systematic control over the import and export processes of *animals* and animal products in so far as this control relates to sanitary and zoosanitary matters. The evaluation should also involve the consideration of administrative instructions to ensure the enforcement of *importing country* requirements during the pre-export period.

In the context of production for export of foodstuffs of animal origin, the *Veterinary Authority* should demonstrate that comprehensive legislative provisions are available for the oversight by the relevant authorities of the hygienic process and to support official inspection systems of these *commodities* which function to standards consistent with or equivalent to relevant Codex Alimentarius and OIE standards.

Control systems should be in place which permit the exporting *Veterinary Authority* to approve export premises. The *Veterinary Services* should also be able to conduct testing and treatment as well as to exercise controls over the movement, handling and storage of exports and to make inspections at any stage of the export process. The product scope of this export legislation should include, *inter alia*, *animals* and animal products (including animal semen, ova and embryos), and animal feedstuffs.

The *Veterinary Authority* should be able to demonstrate that they have adequate capabilities and legislative support for zoosanitary control of imports and transit of *animals*, animal products and other materials which may introduce animal *diseases*. This could be necessary to support claims by the *Veterinary Services* that the animal health status of the country is suitably stable, and that cross-contamination of exports from imports of unknown or less favourable zoosanitary status is unlikely. The same considerations should apply in respect of veterinary control of public health. The *Veterinary Services* should be able to demonstrate that there is no conflict of interest when certifying veterinarians are performing official duties.

Legislation should also provide the right to deny or withdraw official certification. Penalty provisions applying to malpractice on the part of certifying officials should be included.

Annex VII (contd)

The *Veterinary Services* should demonstrate that they are capable of providing accurate and valid certification for exports of *animals* and animal products, based on Chapters 5.1. and 5.2. They should have appropriately organised procedures which ensure that sanitary or animal health certificates are issued by efficient and secure methods. The documentation control system should be able to correlate reliably the certification details with the relevant export consignments and with any inspections to which the consignments were subjected.

Security in the export certification process, including electronic documentation transfer, is important. A system of independent compliance review is desirable, to safeguard against fraud in certification by officials and by private individuals or corporations. The certifying *veterinarian* should have no conflict of interest in the commercial aspects of the *animals* or animal product being certified and be independent from the commercial parties.

Article 3.2.8.

Animal health controls1. Animal health status

An updated assessment of the present animal disease status of a country is an important and necessary procedure. For this undertaking, studies of the OIE publications such as *World Animal Health*, the *Bulletin* and *Disease Information* should be fundamental reference points. The evaluation should consider the recent history of the compliance of the country with its obligations regarding international notification of animal *diseases*. In the case of a Member Country, failure to provide the necessary animal health reports consistent with OIE requirements will detract from the overall outcome of the evaluation of the country.

An *exporting country* should be able to provide further, detailed elaboration of any elements of its animal disease status as reported to the OIE. This additional information will have particular importance in the case of animal *diseases* which are foreign to or strictly controlled in the *importing country* or region. The ability of the *Veterinary Services* to substantiate elements of their animal disease status reports with surveillance data, results of monitoring programmes and details of disease history is highly relevant to the evaluation. In the case of evaluation of the *Veterinary Services* of an *exporting country* for *international trade* purposes, an *importing country* should be able to demonstrate the reasonableness of its request and expectations in this process.

2. Animal health control

Details of current animal disease control programmes should be considered in the evaluation. These programmes would include epidemiological *surveillance*, official government-administered or officially-endorsed, industry-administered control or eradication programmes for specific *diseases* or *disease* complexes, and animal disease emergency preparedness. Details should include enabling legislation, programme plans for epidemiological *surveillance* and animal disease emergency responses, quarantine arrangements for infected and exposed *animals* or *herds*, compensation provisions for animal owners affected by disease control measures, training programmes, physical and other barriers between the free country or zone and those infected, incidence and prevalence data, resource commitments, interim results and programme review reports.

3. National animal disease reporting systems

The presence of a functional animal disease reporting system which covers all agricultural regions of the country and all veterinary administrative control areas should be demonstrated.

An acceptable variation would be the application of this principle to specific *zones* of the country. In this case also, the animal disease reporting system should cover each of these *zones*. Other factors should come to bear on this situation, e.g. the ability to satisfy trading partners that sound animal health controls exist to prevent the introduction of *disease* or export products from regions of lesser veterinary control.

Annex VII (contd)

Article 3.2.9.

Veterinary public health controls1. Food hygiene

The *Veterinary Authority* should be able to demonstrate effective responsibility for the veterinary public health programmes relating to the production and processing of animal products. If the *Veterinary Authority* does not exercise responsibility over these programmes, the evaluation should include a comprehensive review of the role and relationship of the organisations (national, state, provincial and municipal) which are involved. In such a case, the evaluation should consider whether the *Veterinary Authority* can provide guarantees of responsibility for an effective control of the sanitary status of animal products throughout the *slaughter*, processing, transport and storage periods.

2. Zoonoses

Within the structure of *Veterinary Services*, there should be appropriately qualified personnel whose responsibilities include the monitoring and control of zoonotic diseases and, where appropriate, liaison with medical authorities.

3. Chemical residue testing programmes

Adequacy of controls over chemical residues in exported *animals*, animal products and feedstuffs should be demonstrated. Statistically-based *surveillance* and monitoring programmes for environmental and other chemical contaminants in *animals*, in animal-derived foodstuffs and in animal feedstuffs should be favourably noted. These programmes should be coordinated nationwide. Correlated results should be freely available on request to existing and prospective trading partner countries. Analytical methods and result reporting should be consistent with internationally recognised standards. If official responsibility for these programmes does not rest with the *Veterinary Services*, there should be appropriate provision to ensure that the results of such programmes are made available to the *Veterinary Services* for assessment. This process should be consistent with the standards set by the Codex Alimentarius Commission or with alternative requirements set by the *importing country* where the latter are scientifically justified.

4. Veterinary medicines

It should be acknowledged that primary control over *veterinary medicinal products* may not rest with the *Veterinary Authority* in some countries, owing to differences between governments in the division of legislative responsibilities. However, for the purpose of evaluation, the *Veterinary Authority* should be able to demonstrate the existence of effective controls (including nationwide consistency of application) over the manufacture, importation, export, registration, supply, sale and use of veterinary medicines, biologicals and diagnostic reagents, whatever their origin. The control of veterinary medicines has direct relevance to the areas of animal health and public health.

In the animal health sphere, this has particular application to biological products. Inadequate controls on the registration and use of biological products leave the *Veterinary Services* open to challenge over the quality of animal disease control programmes and over safeguards against *animal disease* introduction in imported veterinary biological products.

It is valid, for evaluation purposes, to seek assurances of effective government controls over veterinary medicines in so far as these relate to the public health risks associated with residues of these chemicals in *animals* and animal-derived foodstuffs. This process should be consistent with the standards set by the Codex Alimentarius Commission or with alternative requirements set by the *importing country* where the latter are scientifically justified.

5. Integration between animal health controls and veterinary public health

The existence of any organised programme which incorporates a structured system of information feedback from inspection in establishments producing products of animal origin, in particular *meat* or dairy products, and applies this in animal health control should be favourably noted. Such programmes should be integrated within a national disease surveillance scheme.

Veterinary Services which direct a significant element of their animal health programmes specifically towards minimising microbial and chemical contamination of animal-derived products in the human food chain should receive favourable recognition in the evaluation. There should be evident linkage between these programmes and the official control of veterinary medicines and relevant agricultural chemicals.

Article 3.2.10.

Performance assessment and audit programmes

1. Strategic plans

The objectives and priorities of the *Veterinary Services* can be well evaluated if there is a published official strategic plan which is regularly updated. Understanding of functional activities is enhanced if an operational plan is maintained within the context of the strategic plan. The strategic and operational plans, if these exist, should be included in the evaluation.

Veterinary Services which use strategic and operational plans may be better able to demonstrate effective management than countries without such plans.

2. Performance assessment

If a strategic plan is used, it is desirable to have a process which allows the organisation to assess its own performance against its objectives. Performance indicators and the outcomes of any review to measure achievements against pre-determined performance indicators should be available for evaluation. The results should be considered in the evaluation process.

3. Compliance

Matters which can compromise compliance and adversely affect a favourable evaluation include instances of inaccurate or misleading official certification, evidence of fraud, corruption, or interference by higher political levels in international veterinary certification, and lack of resources and poor infrastructure.

It is desirable that the *Veterinary Services* contain (or have a formal linkage with) an independent internal unit, section or commission the function of which is to critically scrutinise their operations. The aim of this unit should be to ensure consistent and high integrity in the work of the individual officials in the *Veterinary Services* and of the corporate body itself. The existence of such a body can be important to the establishment of international confidence in the *Veterinary Services*.

An important feature when demonstrating the integrity of the *Veterinary Services* is their ability to take corrective action when miscertification, fraud or corruption has occurred.

A supplementary or an alternative process for setting performance standards and application of monitoring and audit is the implementation of formal quality systems to some or all activities for which the *Veterinary Services* are responsible. Formal accreditation to international quality system standards should be utilised if recognition in the evaluation process is to be sought.

Annex VII (contd)4. Veterinary Services administration

a) Annual reports

Official government annual reports should be published, which provide information on the organisation and structure, budget, activities and contemporary performance of the *Veterinary Services*. Current and retrospective copies of such reports should be available to counterpart Services in other countries, especially trade partners.

b) Reports of government review bodies

The reports of any periodic or ad hoc government reviews of *Veterinary Services* or of particular functions or roles of the *Veterinary Services* should be considered in the evaluation process. Details of action taken as a consequence of the review should also be accessible.

c) Reports of special committees of enquiry or independent review bodies

Recent reports on the *Veterinary Services* or elements of their role or function, and details of any subsequent implementation of recommendations contained in these reports should be available. The *Veterinary Services* concerned should recognise that the provision of such information need not be detrimental to the evaluation outcome; in fact, it may demonstrate evidence of an effective audit and response programme. The supplying of such information can reinforce a commitment to transparency.

d) In-service training and development programme for staff

In order to maintain a progressive approach to meeting the needs and challenges of the changing domestic and international role of *Veterinary Services*, the national administration should have in place an organised programme which provides appropriate training across a range of subjects for relevant staff. This programme should include participation in scientific meetings of animal health and *animal welfare* organisations. Such a programme should be used in assessing the effectiveness of the Services.

e) Publications

Veterinary Services can augment their reputation by demonstrating that their staff publish scientific articles in refereed veterinary journals or other publications.

f) Formal linkages with sources of independent scientific expertise

Details of formal consultation or advisory mechanisms in place and operating between the *Veterinary Services* and local and international universities, scientific institutions or recognised veterinary organisations should be taken into consideration. These could serve to enhance the international recognition of the *Veterinary Services*.

g) Trade performance history

In the evaluation of the *Veterinary Services* of a country, it is pertinent to examine the recent history of their performance and integrity in trade dealings with other countries. Sources of such historical data may include Customs Services.

Article 3.2.11.

Participation in OIE activities

Questions on a country's adherence to its obligations as a member of the OIE are relevant to an evaluation of the *Veterinary Services* of the country. Self-acknowledged inability or repeated failure of a Member Country to fulfil reporting obligations to the OIE will detract from the overall outcome of the evaluation. Such countries, as well as non-member countries, will need to provide extensive information regarding their *Veterinary Services* and sanitary or zoosanitary status for evaluation purposes.

Article 3.2.12.

Evaluation of the veterinary statutory body1. Scope

In the evaluation of the *veterinary statutory body*, the following items may be considered, depending on the purpose of the evaluation:

- a) objectives and functions;
- b) legislative basis for the *veterinary statutory body*, including autonomy and functional capacity;
- c) the composition of the *veterinary statutory body*, including the organisation represented in it;
- d) accountability and transparency of decision-making;
- e) sources and management of funding;
- f) administration of training programmes and continuing professional development for *veterinarians* and *veterinary para-professionals*.

2. Evaluation of objectives and functions

The policy and the objectives of the *veterinary statutory body*, including details of its power and functions, should be defined, notably with regard to:

- a) the licensing or registration of *veterinarians* and *veterinary para-professionals* to perform the activities of veterinary medicine/science;
- b) the minimum standards of education (initial and continuing) required for degrees, diplomas and certificates entitling the holders thereof to be registered or licensed as *veterinarians* and *veterinary para-professionals*;
- c) the standards of professional conduct and competence of *veterinarians* and *veterinary para-professionals* and ensuring that these standards are met.

3. Evaluation of legislative basis, autonomy and functional capacity

The *veterinary statutory body* should be able to demonstrate that it has the capacity, supported by appropriate legislation, to exercise and enforce control over all *veterinarians* and *veterinary para-professionals* subject to its authority. These controls should include, where appropriate, compulsory licensing or registration, participation in the definition of minimum standards of education (initial and continuing) for the recognition of degrees, diplomas and certificates by the *Competent Authority*, setting standards of professional conduct and competence, investigating complaints and the application of disciplinary procedures.

The *veterinary statutory body* should be able to demonstrate autonomy from undue political and commercial interests.

Where applicable, the implementation of regional agreements for the recognition of degrees, diplomas and certificates for *veterinarians* and *veterinary para-professionals* should be demonstrated.

4. Evaluation of the composition of the veterinary statutory body

Detailed descriptions of the composition, rules and conditions for membership, including duration of appointment and representation of interested third parties, public and private, should be available.

Annex VII (contd)5. Evaluation of accountability and transparency of decision-making

Detailed information should be available on disciplinary procedures regarding the conducting of enquiries into professional misconduct, transparency of decision-making, publication of findings, sentences and mechanisms for appeal.

Additional information regarding the publication at regular intervals of activity reports, lists of registered or licensed persons including deletions and additions should also be taken into consideration.

6. Evaluation of financial sources and financial management

Information regarding income and expenditure, including fee structure(s) for the licensing or registration of persons should be available.

7. Evaluation of training programmes and programmes for continuing professional development, for veterinarians and veterinary para-professionals

Documentary evidence should be available to demonstrate compliance with initial and continuing education requirements, including with OIE recommendations.

8. Evaluation of mechanisms for coordination between Veterinary Authority and veterinary statutory body

The exact mechanisms will vary according to the national governance systems.

Article 3.2.13.

- 1) The *Veterinary Services* of a country may undertake self-evaluation against the above criteria for such purposes as national interest, improvement of internal efficiency or export trade facilitation. The way in which the results of self-evaluation are used or distributed is a matter for the country concerned.
- 2) A prospective *importing country* may undertake an evaluation of the *Veterinary Services* of an *exporting country* as part of a *risk analysis* process, which is necessary to determine the sanitary or zoosanitary measures which the country will use to protect human or animal life or health from *disease* or pest threats posed by imports. Periodic evaluation reviews are also valid following the commencement of trade.
- 3) In the case of evaluation for the purposes of *international trade*, the authorities of an *importing country* should use the principles elaborated above as the basis for the evaluation and should attempt to acquire information according to the model questionnaire outlined in Article 3.2.14. The *Veterinary Services* of the *importing country* are responsible for the analysis of details and for determining the outcome of the evaluation after taking into account all the relevant information. The relative ranking of importance ascribed, in the evaluation, to the criteria described in this chapter will necessarily vary according to case-by-case circumstances. This ranking should be established in an objective and justifiable way. Analysis of the information obtained in the course of an evaluation study should be performed in as objective a manner as possible. The validity of the information should be established and reasonableness should be employed in its application. The assessing country should be willing to defend any position taken on the basis of this type of information, if challenged by the other party.

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.

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*.

Annex VII (contd)

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.

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.

Annex VII (contd)

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.

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.

Annex VII (contd)

- 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. Laboratory services
 - a) Diagnostic Laboratories (~~laboratories engaged primarily in diagnosis~~)
 - a i) Descriptive summary of the organisational structure and role of the government veterinary laboratory service in particular its relevance to the field *Veterinary Services*.
 - b ii) 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 iii) Descriptive summary of accreditation procedures and standards for private *laboratories*.
 - d iv) Human and financial resources allocated to the government veterinary *laboratories*, including staff numbers, graduate and post-graduate qualifications and opportunities for further training.
 - e v) List of diagnostic methodologies available against major *diseases* of farm livestock (including *poultry*).
 - f vi) List of related National Reference Laboratories, if any.
 - g vii) Details of collaboration with external *laboratories* including international reference *laboratories* and details on numbers of samples submitted.
 - h viii) Details of quality control and assessment (or validation) programmes operating within the veterinary laboratory service.
 - i ix) Recent published reports of the official veterinary laboratory service which should include details of specimens received and foreign animal disease investigations made.
 - j x) Details of procedures for storage and retrieval of information on specimen submission and results.
 - k xi) Reports of independent reviews of the laboratory service conducted by government or private organisations (if available).
 - l xii) Strategic and operational plans for the official veterinary laboratory service (if available).

Annex VII (contd)6b) Research laboratories Institutes (laboratories engaged primarily in animal health or animal welfare research)

a i) Numbers of veterinary research *laboratories* operating in the country:

i)– government operated *laboratories*;

ii)– private *laboratories* involved in full time research directly related to animal health and veterinary public health matters involving production animal species.

b ii) Summary of human and financial resources allocated by government to veterinary research.

c iii) Published programmes of future government sponsored veterinary research.

d iv) Annual reports of the government research *laboratories*.

76. 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:

- 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;

Annex VII (contd)

- animal health, animal welfare 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 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.

87. 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.

cb) 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*.
- 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.

Annex VII (contd)

- 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.

98. 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.

109. 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*.

Annex VII (contd)

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.

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.

1140. Membership of the OIE

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

— Text deleted.

CHAPTER 4.6.

COLLECTION AND PROCESSING OF BOVINE,
SMALL RUMINANT AND PORCINE SEMEN

Article 4.6.1.

General considerations

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

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

Artificial insemination centres should comply with recommendations in Chapter 4.5.

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

Article 4.6.2.

Conditions applicable to testing of bulls and teaser animals

Bulls and teaser animals should enter an *artificial insemination centre* only when they fulfil the following requirements.

1. Prior to entering pre-entry isolation facility

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

- a) Brucellosis – point 2 of Article 8.4.14, Chapter 8.4.
- b) Bovine tuberculosis – Point 3 or 4 of Article 11.5.5.
- c) Bovine viral diarrhoea (BVD)

The *animals* should be subjected to:

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

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

- i) come from an IBR/IPV free *herd* as defined in Article 11.10.3.; or
- ii) be subjected, with negative results, to a serological test for IBR/IPV on a blood sample.

Annex VIII (contd)

e) Bluetongue

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

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

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

a) Brucellosis

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

b) BVD

i) The *animals* should be subjected to a virus isolation test or a test for virus antigen, with negative results. Only when all the *animals* in pre-entry isolation have had negative results, may the *animals* enter the semen collection facilities.

ii) All *animals* should be subjected to a serological test to determine the presence or absence of BVD antibodies.

iii) Only if no seroconversion occurs in the *animals* which tested seronegative before entry into the pre-entry isolation facility, may any *animal* (seronegative or seropositive) be allowed entry into the semen collection facilities.

iv) If seroconversion occurs, all the *animals* that remain seronegative should be kept in pre-entry isolation until there is no more seroconversion in the group for a period of three weeks. Serologically positive *animals* may be allowed entry into the semen collection facilities.

c) *Campylobacter fetus* subsp. *venerealis*

i) *Animals* less than six months old or kept since that age only in a single sex group prior to pre-entry isolation should be tested once on a preputial specimen, with a negative result.

ii) *Animals* aged six months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

d) *Tritrichomonas foetus*

i) *Animals* less than six months old or kept since that age only in a single sex group prior to pre-entry isolation, should be tested once on a preputial specimen, with a negative result.

ii) *Animals* aged six months or older that could have had contact with females prior to pre-entry isolation should be tested three times at weekly intervals on a preputial specimen, with a negative result in each case.

Annex VIII (contd)

e) IBR/IPV

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

f) Bluetongue

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

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

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

a) Brucellosis

b) Bovine tuberculosis

c) BVD

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

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

d) *Campylobacter fetus* subsp. *venerealis*

i) A preputial specimen should be tested.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay-off of more than six months should be tested not more than 30 days prior to resuming production.

e) Bluetongue

The *animals* should comply with the provisions referred to in Article 8.3.10. or Article 8.3.11.

f) *Tritrichomonas foetus*

i) A preputial specimen should be cultured.

ii) Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay-off of more than six months should be tested not more than 30 days prior to resuming production.

g) IBR/IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the *animals* should comply with the provisions in point 2 c) of Article 11.10.3.

Annex VIII (contd)4. Testing for BVD prior to the initial dispatch of semen from each serologically positive bull

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

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

Each aliquot of frozen semen should be tested as per Article 11.10.7.

Article 4.6.3.

Conditions applicable to testing of rams/bucks and teaser animals

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

1. Prior to entering pre-entry isolation facility

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

- a) Brucellosis – point 2 of Article 8.4.14 Chapter 8.4.
- b) Ovine epididymitis – Article 14.6.3.
- c) Contagious agalactia – Points 1 and 2 of Article 14.2.1.
- d) Peste des petits ruminants – Points 1, 2 a) or 3 of Article 14.7.10.
- e) Contagious caprine pleuropneumonia – Article 14.3.7., depending on the CCPP status of the country or *zone* of origin of the *animals*.
- f) Paratuberculosis – Free from clinical signs for the past two years.
- g) Scrapie – Comply with Article 14.8.8. if the *animals* do not originate from a scrapie free country or *zone* as defined in Article 14.8.3.
- h) Maedi-visna – Article 14.5.2.
- i) Caprine arthritis/encephalitis – Article 14.1.2. in the case of goats.
- j) Bluetongue

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

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

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

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

Annex VIII (contd)

- a) Brucellosis – two different diagnostic tests on the same blood sample ~~Chapter 8.4.~~
- b) Ovine epididymitis – Point 1 d) of Article 14.6.4.
- c) Maedi-visna and caprine arthritis/encephalitis – Test on *animals*.
- d) Bluetongue

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

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

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

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

The *animals* should comply with the provisions referred to in Article 8.3.10. or Article 8.3.11.

Article 4.6.4.

Conditions applicable to testing of boars

Boars should only enter an *artificial insemination centre* if they fulfil the following requirements.

1. Prior to entering pre-entry isolation facility

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

- a) Brucellosis – point 2 of Article 8.4.15. ~~Chapter 8.4.~~
- b) Foot and mouth disease – Articles 8.7.12., 8.7.13. or 8.7.14.
- c) Aujeszky's disease – Article 8.2.9. or Article 8.2.10.
- d) Transmissible gastroenteritis – Article 15.3.2.
- e) African swine fever – Article 15.1.5. or Article 15.1.6.
- f) Classical swine fever – Article 15.2.7. or Article 15.2.8.
- g) Porcine reproductive and respiratory syndrome – Test complying with the standards in the *Terrestrial Manual*.

Annex VIII (contd)**2. Testing in the pre-entry isolation facility prior to entering the semen collection facilities**

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

- a) Brucellosis –~~Chapter 8.4.~~
- b) Foot and mouth disease – Articles 8.7.15., 8.7.16., 8.7.17. or 8.7.18.
- c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.
- d) Transmissible gastroenteritis – Article 15.3.4.
- e) African swine fever – Article 15.1.8. or Article 15.1.9.
- f) Classical swine fever – Article 15.2.10. or Article 15.2.11.
- g) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

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

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

- a) Brucellosis –~~Chapter 8.4.~~
- b) Foot and mouth disease – Articles 8.7.15., 8.7.16., 8.7.17. or 8.7.18.
- c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.
- d) Transmissible gastroenteritis – Article 15.3.4.
- e) African swine fever – Article 15.1.8. or Article 15.1.9.
- f) Classical swine fever – Article 15.2.10. or Article 15.2.11.
- g) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

Article 4.6.5.

General considerations for hygienic collection and handling of semen

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

Article 4.6.6.

Conditions applicable to the collection of semen

- 1) The floor of the mounting area should be clean and provide safe footing. A dusty floor should be avoided.

Annex VIII (contd)

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

Article 4.6.7.

Conditions applicable to the handling of semen and preparation of semen samples in the laboratory1. Diluents

- a) All receptacles used should have been sterilised.
- b) Buffer solutions employed in diluents prepared on the premises should be sterilised by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.
- c) If the constituents of a diluent are supplied in commercially available powder form, the water used should have been distilled or demineralised, sterilised (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.
- d) Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product should be free of pathogens or sterilised; milk heat-treated at 92°C for 3–5 minutes, eggs from SPF flocks when available. When egg yolk is used, it should be separated from eggs using aseptic techniques.

Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination, may be used. Other additives should also be sterilised before use.

- e) Diluent should not be stored for more than 72 hours at +5°C before use. A longer storage period is permissible for storage at -20°C. Storage vessels should be stoppered.

Annex VIII (contd)

- f) A mixture of antibiotics should be included with a bactericidal activity at least equivalent to that of the following mixtures in each ml of frozen semen: gentamicin (250 µg), tylosin (50 µg), lincomycin–spectinomycin (150/300 µg); penicillin (500 IU), streptomycin (500 µg), lincomycin–spectinomycin (150/300 µg); or amikacin (75 µg), divekacin (25 µg).

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

2. Procedure for dilution and packing

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

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

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

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

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

4. Sperm sorting

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

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

— Text deleted.

CHAPTER 4.7.

**COLLECTION AND PROCESSING OF *IN VIVO*
DERIVED EMBRYOS FROM LIVESTOCK AND EQUIDS**

Article 4.7.1.

Aims of control

The purpose of official sanitary control of *in vivo* derived embryos intended for movement internationally is to ensure that specific pathogenic organisms, which could be associated with embryos, are controlled and transmission of *infection* to recipient *animals* and progeny is avoided.

Article 4.7.2.

Conditions applicable to the embryo collection team

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

- 1) The team should be approved by the *Competent Authority*.
- 2) The team should be supervised by a team *veterinarian*.
- 3) The team *veterinarian* is responsible for all team operations which include verification of donor health status, sanitary handling and surgery of donors and *disinfection* and hygienic procedures.
- 4) Team personnel should be adequately trained in the techniques and principles of *disease* control. High standards of hygiene should be practiced to preclude the introduction of *infection*.
- 5) The collection team should have adequate facilities and equipment for:
 - a) collecting embryos;
 - b) processing and treatment of embryos at a permanent site or mobile laboratory;
 - c) storing embryos.

These facilities need not necessarily be at the same location.

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

Article 4.7.3.

Conditions applicable to processing laboratories

A processing laboratory used by the embryo collection team may be mobile or permanent. It is a facility in which embryos are recovered from collection media, examined and subjected to any required treatments such as washing and being examined and prepared for freezing and storage.

Annex IX (contd)

A permanent laboratory may be part of a specifically designed collection and processing unit, or a suitably adapted part of an existing building. It may be on the premises where the donor *animals* are kept. In either case, the laboratory should be physically separated from *animals*. Both mobile and permanent laboratories should have a clear separation between dirty areas (animal handling) and the clean processing area.

Additionally:

- 1) The processing laboratory should be under the direct supervision of the team *veterinarian* and be regularly inspected by an *official veterinarian*.
- 2) While embryos for export are being handled prior to their storage in ampoules, vials or straws, no embryos of a lesser health status should be processed.
- 3) The processing laboratory should be protected against rodents and insects.
- 4) The processing laboratory should be constructed with materials which permit its effective cleansing and *disinfection*. This should be done frequently, and always before and after each occasion on which embryos for export are processed.

Article 4.7.4.

Conditions applicable to the introduction of donor animals

1. Donor animals

- a) The *Veterinary Authority* should have knowledge of, and authority over, the *herd/ or flock* from which the donor *animals* have been sourced.
- b) The donor *animals* should not be situated in a *herd/ or flock* subject to veterinary restrictions for OIE *listed disease* or pathogens for relevant species (see Chapter 1.2.), other than those that are in International Embryo Transfer Society (IETS) Category 1 for the species of embryos being collected (see Article 4.7.14.).
- c) At the time of collection, the donor *animals* should be clinically inspected by the team *veterinarian*, or by a *veterinarian* responsible to the team *veterinarian* and certified to be free of clinical signs of *diseases*.

2. Semen donors

- a) Semen used to inseminate donor *animals* artificially should have been produced and processed in accordance with the provisions of Chapter 4.6.
- b) When the donor of the semen used to inseminate donor females for embryo production is dead, and when the health status of the semen donor concerning a particular infectious *disease* or *diseases* of concern was not known at the time of semen collection, additional tests may be required of the inseminated donor female after embryo collection to verify that these infectious *diseases* were not transmitted. An alternative may be to test an aliquot of semen from the same collection date.
- c) Where natural service or fresh semen is used, donor sires should meet the health conditions set out in Chapter 4.6. as appropriate to the species.

Article 4.7.5.

Risk management

With regard to *disease* transmission, transfer of *in vivo* derived embryos is a very low risk method for moving animal genetic material. Irrespective of animal species, there are three phases in the embryo transfer process that determine the final level of risk:

- 1) The first phase, which is applicable to *diseases* not included in Category 1 of the IETS categorisation (Article 4.7.14.), comprises the risk potential for embryo contamination and depends on:
 - a) the disease situation in the *exporting country* or *zone*;
 - b) the health status of the *herds* or *flocks* and the donors from which the embryos are collected;
 - c) the pathogenic characteristics of the specified disease agents that are of concern to the *Veterinary Authority* of the *importing country*.
- 2) The second phase covers risk mitigation by use of internationally accepted procedures for processing of embryos which are set out in the IETS Manual. These include the following:
 - a) The embryos should be washed at least ten times with at least 100–fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash.
 - b) Only embryos from the same donor should be washed together, and no more than ten embryos should be washed at any one time.
 - c) Sometimes, for example when inactivation or removal of certain viruses, such as bovine herpesvirus-1 and Aujeszky's disease virus, is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual.
 - d) The zona pellucida of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free of adherent material.
 - e) All shipments of embryos should be accompanied by a statement signed by the team veterinarian certifying that these embryo processing procedures have been completed.
- 3) The third phase, which is applicable to *diseases* not included in Category 1 of the IETS categorisation (Article 4.7.14.) and which are of concern to the *Veterinary Authority* of the *importing country*, encompasses the risk reductions resulting from:
 - a) post-collection *surveillance* of the donors and donor *herd* or *flock* based on the recognised *incubation periods* of the *diseases* of concern to determine retrospectively the health status of donors whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the *exporting country*;
 - b) testing of embryo-collection (flushing) fluids and non-viable embryos, or other samples such as blood, in a laboratory for presence of specified disease agents.

Annex IX (contd)

Article 4.7.6.

Conditions applicable to the collection and storage of embryos1. Media

Any biological product of animal origin used in the media and solutions for collection, processing, washing or storage of embryos should be free of pathogenic micro-organisms. Media and solutions used in the collection and storage of embryos should be sterilised by approved methods according to the IETS Manual and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to collection, processing, washing and storage media as recommended in the IETS Manual.

2. Equipment

- a) All equipment used to collect, handle, wash, freeze and store embryos should ideally be new or at least sterilised prior to use as recommended in the IETS Manual.
- b) Used equipment should not be transferred between countries for re-use by the embryo collection team.

Article 4.7.7.

Optional tests and treatments

- 1) The testing of samples can be requested by an *importing country* to confirm the absence of pathogenic organisms that may be transmitted via *in vivo* derived embryos, or to help assess whether the degree of quality control of the collection team (with regard to adherence to procedures as described in the IETS Manual) is at an acceptable level.

Samples may include:

- a) Non-viable embryos and oocytes

Where the viable, zona pellucida intact embryos from a donor are intended for export, all non-fertilised oocytes and degenerated or zona pellucida compromised embryos collected from that donor should be washed according to the IETS Manual and pooled for testing if requested by the *importing country*. Non-viable embryos and oocytes from the donor should be processed and stored together.

- b) Embryo collection (flushing) fluids

The collection fluid should be placed in a sterile, closed container and, if there is a large amount, it should be allowed to stand undisturbed for one hour. The supernatant fluid should then be removed and the bottom 10–20 ml, along with accumulated debris, decanted into a sterile bottle. If a filter is used in the collection of embryos and oocytes then any debris that is retained on the filter should be rinsed off into the retained fluid.

- c) Washing fluids

The last four washes of the embryos and oocytes should be pooled according to the IETS Manual.

- d) Samples

The samples referred to above should be stored at 4°C and tested within 24 hours. If this is not possible, then samples should be stored frozen at -70°C or lower.

Annex IX (contd)

- 2) When treatment of the viable embryos is modified to include additional washings with the enzyme trypsin (see point 2(c) in Article 4.7.5.), the procedure should be carried out according to the IETS Manual. Enzyme treatment is necessary only when pathogens for which the IETS recommends this additional treatment (such as with trypsin) may be present. It should be noted that such a treatment is not always beneficial and it should not be regarded as a general disinfectant. It may also have adverse effects on embryo viability, for instance in the case of equine embryos where the embryonic capsule could be damaged by the enzyme.

Article 4.7.8.

Conditions applicable to the storage and transport of embryos

- 1) The embryos for export should be stored in sealed sterile ampoules, vials or straws under strict hygienic conditions at a storage place approved by the *Veterinary Authority* of the *exporting country* where there is no risk of contamination of the embryos.
- 2) Only embryos from the same individual donor should be stored together in the same ampoule, vial or straw.
- 3) The embryos should if possible, depending on the species, be frozen, stored with fresh liquid nitrogen in cleaned and sterilised tanks or containers under strict hygienic conditions at the approved storage place.
- 4) Ampoules, vials or straws should be sealed at the time of freezing (or prior to export where cryopreservation is not possible), and they should be clearly identified by labels according to the standardised system recommended in the IETS Manual.
- 5) Liquid nitrogen containers should be sealed under the supervision of the *Official Veterinarian* prior to shipment from the *exporting country*.
- 6) Embryos should not be exported until the appropriate veterinary certificates are completed.

Article 4.7.9.

Procedure for micromanipulation

When micromanipulation of the embryos is to be carried out, this should be done after completion of the treatments described in point 2 of Article 4.7.5. and conducted in accordance with Chapter 4.9.

Article 4.7.10.

Specific conditions applicable to porcine embryos

The *herd* of origin should be free of clinical signs of swine vesicular disease and brucellosis.

The development of effective cryopreservation methods for the storage of zona pellucida-intact porcine embryos is still at a very early stage.

Article 4.7.11.

Specific conditions applicable to equine embryos

The recommendations apply principally to embryos from *animals* continuously resident in national equine populations and therefore may be found unsuitable for those from horses routinely involved in events or competitions at the international level. For instance, in appropriate circumstances horses travelling with an *international veterinary certificate* may be exempt where mutually agreed upon on a bilateral basis between the respective *Veterinary Authorities*.

Annex IX (contd)

Article 4.7.12.

Specific conditions applicable to camelid embryos

South American camelid embryos recovered from the uterine cavity by the conventional non-surgical flushing technique at 6.5 to 7 days post-ovulation are almost invariably at the hatched blastocyst stage, and thus the zona pellucida has already been shed. Since the embryos do not enter the uterus and cannot be recovered before 6.5 to 7 days, it would be unrealistic to stipulate for these species that only zona pellucida-intact embryos can be used in *international trade*.

The development of cryopreservation methods for storage of camelid embryos is still at an early stage, and also that pathogen interaction studies with camelid embryos have not yet been carried out.

Article 4.7.13.

Specific conditions applicable to cervid embryos

The recommendations apply principally to embryos derived from *animals* continuously resident in national domestic or ranched cervid populations and therefore may be found to be unsuitable for those from cervids in feral or other circumstances related to biodiversity or germplasm conservation efforts.

Article 4.7.14.

Recommendations regarding the risk of disease transmission via *in vivo* derived embryos

Based on the conclusions of the IETS, the following ~~listed~~ *diseases* and pathogenic agents are categorised into four categories, which applies only to *in vivo* derived embryos.

1. Category 1

- a) Category 1 *diseases* or pathogenic agents are those for which sufficient evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual.
- b) The following *diseases* or pathogenic agents are in category 1:
 - Infection with Aujeszky's disease virus (pigs): trypsin treatment required
 - Bluetongue (cattle)
 - Bovine spongiform encephalopathy (cattle)
 - *Brucella abortus* (cattle)
 - Enzootic bovine leukosis
 - Foot and mouth disease (cattle)
 - Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis: trypsin treatment required
 - Scrapie (sheep).

2. Category 2

- a) Category 2 *diseases* are those for which substantial evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual, but for which additional transfers are required to verify existing data.

b) The following *diseases* are in category 2:

- Bluetongue (sheep)
- Caprine arthritis/encephalitis
- Infection with Classical swine fever virus.

3. Category 3

a) Category 3 *diseases* or pathogenic agents are those for which preliminary evidence indicates that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual, but for which additional *in vitro* and *in vivo* experimental data are required to substantiate the preliminary findings.

b) The following *diseases* or pathogenic agents are in category 3:

- Atypical scrapie (not a *listed disease*)
- Bovine immunodeficiency virus (not a *listed disease*)
- Bovine spongiform encephalopathy (goats) (not a *listed disease* of goats)
- Bovine viral diarrhoea virus (cattle)
- *Campylobacter fetus* (sheep) (not a *listed disease* of sheep)
- Foot and mouth disease (pigs, sheep and goats)
- *Haemophilus somnus* (cattle) (not a *listed disease*)
- Maedi-visna (sheep)
- *Mycobacterium paratuberculosis* (cattle)
- *Neospora caninum* (cattle) (not a *listed disease*)
- Ovine pulmonary adenomatosis (not a *listed disease*)
- Porcine circovirus (type 2) (pigs) (not a *listed disease*)
- Porcine reproductive and respiratory disease syndrome (PRRS)
- Infection with Rinderpest virus (cattle)
- Swine vesicular disease (not a *listed disease*).

4. Category 4

a) Category 4 *diseases* or pathogenic agents are those for which studies have been done, or are in progress, that indicate:

- i) that no conclusions are yet possible with regard to the level of transmission risk; or
- ii) that the risk of transmission via embryo transfer might not be negligible even if the embryos are properly handled according to the IETS Manual between collection and transfer.

Annex IX (contd)

b) The following diseases or pathogenic agents are in category 4:

- African swine fever
- Akabane (cattle) (not a *listed disease*)
- Bovine anaplasmosis
- Bluetongue (goats)
- Border disease (sheep) (not a *listed disease*)
- Bovine herpesvirus-4 (not a *listed disease*)
- *Chlamydia psittaci* (cattle, sheep)
- Contagious equine metritis
- Enterovirus (cattle, pigs) (not a *listed disease*)
- Infection with equid herpesvirus 1 (Equine rhinopneumonitis)
- Infection with Equine viral arteritis virus
- *Escherichia coli* 09:K99 (cattle) (not a *listed disease*)
- *Leptospira borgpetersenii* serovar *hardjobovis* (cattle) (not a *listed disease*)
- *Leptospira* sp. (pigs) (not a *listed disease*)
- Lumpy skin disease
- *Mycobacterium bovis* (cattle)
- *Mycoplasma* spp. (pigs)
- Ovine epididymitis (*Brucella ovis*)
- Parainfluenza-3 virus (cattle) (not a *listed disease*)
- Parvovirus (pigs) (not a *listed disease*)
- Q fever (*Coxiella burnetii*)
- Scrapie (goats)
- *Tritrichomonas foetus* (cattle)
- *Ureaplasma* and *Mycoplasma* spp. (cattle, goats) (not a *listed disease*)
- Vesicular stomatitis (cattle, pigs) (not a *listed disease*).

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CHAPTER 5.2.

CERTIFICATION PROCEDURES

Article 5.2.1.

Protection of the professional integrity of the certifying veterinarian

Certification should be based on the highest possible ethical standards, the most important of which is that the professional integrity of the certifying *veterinarian* should be respected and safeguarded according to Chapters 3.1. and 3.2.

It is essential to include in any requirements only those specific statements that can be accurately and honestly signed by a certifying *veterinarian*. For example, these requirements should not include certification of an area as being free from *diseases* other than *notifiable diseases*, or the occurrence of which the signing *veterinarian* is not necessarily informed about. It is unacceptable to ask for certification for events which will take place after the document is signed when these events are not under the direct control and supervision of the signing *veterinarian*.

Certification of freedom from *diseases* based on purely clinical freedom and *herd* history is of limited value. This is also true of *diseases* for which there is no specific diagnostic test, or the value of the test as a diagnostic aid is limited.

The note of guidance referred to in Article 5.1.1. is not only to inform the signing *veterinarian* but also to safeguard professional integrity.

Article 5.2.2.

Certifying veterinarians

Certifying *veterinarians* should:

- 1) be authorised by the *Veterinary Authority* of the *exporting country* to sign *international veterinary certificates*;
- 2) only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party;
- 3) sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the certifying *veterinarian* should have verified or be in possession of that documentation before signing;
- 4) have no conflict of interest in the commercial aspects of the *animals* or animal products being certified and be independent from the commercial parties.

Article 5.2.3.

Preparation of international veterinary certificates

Certificates should be drawn up in accordance with the following principles:

- 1) Certificates should be designed so as to minimise the potential for fraud including use of a unique identification number, or other appropriate means to ensure security. Paper certificates should bear the signature of the certifying *veterinarian* and the official identifier (stamp) of the issuing *Veterinary Authority*. Each page of a multiple page certificate should bear the unique certificate number and a number indicating the number of the page out of the total number of pages. Electronic certification procedures should include equivalent safeguards.

Annex X (contd)

- 2) Certificates should be written using terms that are simple, unambiguous and as easy to understand as possible, without losing their legal meaning.
- 3) If so required, certificates should be written in the language of the *importing country*. In such circumstances, they should also be written in a language understood by the certifying *veterinarian*.
- 4) Certificates should require appropriate identification of *animals* and animal products except where this is impractical (e.g. *day-old birds*).
- 5) Certificates should not require a *veterinarian* to certify matters that are outside his/her knowledge or which he/she cannot ascertain and verify.
- 6) Where appropriate, when presented to the certifying *veterinarian*, certificates should be accompanied by notes of guidance indicating the extent of enquiries, tests or examinations expected to be carried out before the certificate is signed.
- 7) The text of a certificate should not be amended except by deletions which should be signed and stamped by the certifying *veterinarian*.
- 8) The signature and stamp should be in a colour different from that of the printing of the certificate. The stamp may be embossed instead of being a different colour.
- 9) Replacement certificates may be issued by a *Veterinary Authority* to replace certificates that have been, for example, lost, damaged, contain errors, or where the original information is no longer correct. These replacements should be provided by the issuing authority and be clearly marked to indicate that they are replacing the original certificate. A replacement certificate should reference the number and the issue date of the certificate that it supersedes. The superseded certificate should be cancelled and, where possible, returned to the issuing authority.
- 10) Only original certificates are acceptable.

Article 5.2.4.

Electronic certification

- 1) Certification may be provided by electronic ~~exchange of data documentation~~ sent directly from the *Veterinary Authority* of the *exporting country* to the *Veterinary Authority* of the *importing country*.
 - a) Systems providing electronic certificates normally provide an interface with the commercial organisation marketing the *commodity* for provision of information to the certifying authority. The certifying *veterinarian* should have access to all information such as *laboratory* results and *animal identification* data.
 - b) When exchanging electronic certificates and in order to fully utilise electronic data exchange the *Veterinary Authorities* should use internationally standardised language, message structure and exchange protocols. Guidance for electronic certification in standardised ~~World Wide Web Consortium (W3C)~~ Extensible Markup Language (XML ~~schemas~~) as well as secure exchange mechanisms between *Veterinary Authorities* is provided by the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT).
 - c) A secure method of electronic data exchange should be ensured by digital authentication of the certificates, encryption, non-repudiation mechanisms, controlled and audited access and firewalls.

Annex X (contd)

- 2) Electronic certificates may be in a different format but should carry the same information as conventional paper certificates.
- 3) The *Veterinary Authority* should have in place systems for the security of electronic certificates against access by unauthorised persons or organisations.
- 4) The certifying *veterinarian* should be officially responsible for the secure use of his/her electronic signature.

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CHAPTER 6.5.

PREVENTION, DETECTION AND CONTROL OF
SALMONELLA IN POULTRY

Article 6.5.1.

Introduction

This chapter provides recommendations on the prevention, detection and control of *Salmonella* in *poultry*.

Salmonellosis is one of the most common food-borne bacterial *diseases* in the world. The great majority of *Salmonella* infections in humans are food-borne with *Salmonella* Enteritidis and *Salmonella* Typhimurium accounting for a major part of the problem. *Salmonella* serotypes and prevalence may vary considerably between localities, districts, regions and countries and therefore, *surveillance* and identification of the prevalent *Salmonella* serotypes in humans and *poultry* should be carried out in order to develop a control programme for the area.

In most food animal species, *Salmonella* can establish a clinically inapparent *infection* of variable duration, which is significant as a potential *zoonosis*. Such *animals* may be important in relation to the spread of *infection* between *flocks* and as causes of human food-borne *infection*. In the latter case, this can occur when *meat* and eggs, or their products, enter the food chain thus producing contaminated food.

Article 6.5.2.

Purpose and scope

This chapter deals with methods for on farm prevention, detection and control of *Salmonella* in *poultry*, and complements the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005), Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976) and Guidelines for the control of *Campylobacter* and *Salmonella* in chicken meat (CAC/GL 78-2011). A pathogen reduction strategy at the farm level is seen as the first step in a continuum that will assist in reducing the presence of food-borne pathogens in eggs and *meat*.

Hygiene and biosecurity procedures to be implemented in *poultry* farms and hatcheries are described in Chapter 6.4. on Biosecurity Procedures in Poultry Production.

The recommendations presented in this chapter are relevant to the control of all *Salmonella* with special attention to *S. Enteritidis* and *S. Typhimurium*, as these are common *Salmonella* serotypes in many countries. It should be noted that the epidemiology of animal and human salmonellosis in a particular locality, district, region or country is important for effective control of *Salmonella*.

Article 6.5.3.

Definitions

Breeders: means *poultry* destined for the production of fertile eggs for incubation for the purpose of producing *day-old birds*.

Competitive exclusion: means the administration of defined or undefined bacterial flora to *poultry* to prevent gut colonisation by enteropathogens, including *Salmonella*.

Culling: means the destruction or *slaughter* of a *flock* before the end of its normal period.

Layers: means *poultry* during the period of laying eggs for human consumption.

Annex XI (contd)

Article 6.5.4.

Surveillance of poultry flocks for *Salmonella*

Where justified by *risk assessment*, *surveillance* should be carried out to identify infected *flocks* in order to take measures that will reduce the prevalence in *poultry* and the risk of transmission of *Salmonella* to humans. Sampling methods, frequency and type of samples required should be determined by the *Veterinary Services* based on a *risk assessment*. Microbiological testing is preferred to serological testing because of its higher sensitivity in broiler *flocks* and higher specificity in breeder and layer *flocks*. In the framework of regulatory programmes for the control of *Salmonella* in *poultry* and salmonellosis in humans, confirmatory testing may be required to exclude false positive or negative results.

1. Available methods for sampling

Drag swabs: sampling is done by dragging swabs throughout the *poultry* house.

Boot swabs: sampling is done by walking throughout the *poultry* house with absorbent material placed over the footwear of the sampler.

Dust samples: sampling is done by collecting dust from exhaust fans, screens and other equipment in the *poultry* house.

Faecal samples: multiple fresh faecal/ or caecal samples collected from different areas in the *poultry* house.

Meconium, chick box liners, dead in shell and culled *day-old birds* at the hatchery.

Hatchery samples: throughout the hatchery, including inside the incubators.

2. Sample size

Refer to the *Terrestrial Manual*.

3. Laboratory methods

Refer to the *Terrestrial Manual*.

4. Time and frequency of testing

Time and frequency of sampling for each *poultry* type are listed below:

a) Breeders and hatcheries

i) Breeder flocks before lay

- Before the end of the first week of life when the status of the breeder *flock* or the hatchery is not known or does not comply with this chapter.
- Within the four weeks before being moved to another house, or before going into production if the birds will remain in the same house for the production period.
- One or more times during the growing period if there is a culling policy in place. The frequency would be determined on commercial considerations.

Annex XI (contd)

- ii) Breeder flocks in lay
 - At least at monthly intervals during the laying period.
 - Additional testing should be determined by the *Veterinary Services*.
- iii) Hatcheries
 - Testing at hatcheries should complement on farm testing.
 - The minimal frequency should be determined by the *Veterinary Services*.
- b) Poultry for the production of eggs for human consumption
 - i) Flocks grown to be layers
 - Before the end of the first week of life when the status of the breeder *flock* or the hatchery is not known or does not comply with this chapter.
 - Within the four weeks before being moved to another house, or before going into production if the birds will remain in the same house for the production period.
 - One or more times during the growing period if there is a culling policy in place. The frequency would be determined by commercial considerations.
 - ii) Layer flocks
 - At expected peak of lay for each production cycle (the period of time in the laying cycle when the production of the *flock* is highest).
 - One or more times if there is a culling policy in place or if eggs are diverted to processing for the inactivation of the pathogen. The minimal frequency should be determined by the *Veterinary Services*.
- c) Poultry for the production of meat
 - i) *Flocks* should be sampled at least once.
 - ii) When sampling occurs on farms and when there is a long period (two weeks or more) between thinning and final depopulation, further testing should be considered.
 - iii) When sampling occurs on farms, *flocks* should be sampled as late as possible before the first birds are transported to the *slaughterhouse*. In order to allow for the implementation of control measures during processing, this should be done at a time that ensures the results are available before *slaughter*.

Whether sampling occurs on the farm which is more appropriate for consequent control measures or at the processing plant, there should be an integrated system in place which allows for investigation of the source of positive *flocks*.

d) Testing of empty poultry houses

Bacteriological monitoring of the efficacy of *disinfection* procedures is recommended when *Salmonella* have been detected in the previous *flock*.

As appropriate, sampling of equipment and surfaces as well as boot swabs or drag swabs of the empty *poultry* house after depopulation, cleaning and *disinfection*.

Annex XI (contd)

Results from *surveillance* may lead to the implementation of additional prevention and control measures to reduce the risk of transmission of *Salmonella* to humans:

- 1) In breeders, control measures may be implemented to reduce the transmission of *Salmonella* to the next generation, especially for trans-ovarian transmitted serotypes such as *S. Enteritidis*.
- 2) In layer *flocks*, control measures will reduce and may eliminate contamination of eggs with *Salmonella*.
- 3) In *poultry* for *meat* production, control measures may be implemented at *slaughter* or further down the food chain.

Article 6.5.5.

Prevention and control measures

Salmonella prevention and control may be achieved by adopting Good Agricultural Practices and Hazard Analysis Critical Control Point (HACCP), and general measures detailed in Chapter 6.4. on Biosecurity Procedures in Poultry Production, in combination with the following additional measures, where appropriate. No single measure used alone will achieve effective *Salmonella* control.

Additional prevention and control measures include *vaccination*, competitive exclusion, use of organic acids, culling and product diversion to processing.

Antimicrobial agents should not be used to control *infection* with *Salmonella* in *poultry* because the effectiveness of the treatment is limited, may mask the *infection* at sampling, has the potential to produce residues in *meat* and eggs and can contribute to the development of antimicrobial resistance. *Antimicrobial agents* may also reduce normal flora in the gut and increase the likelihood of colonisation with *Salmonella*. In special circumstances *antimicrobial agents* may be used to salvage birds with high genetic value.

- 1) *Day-old birds* used to stock a *poultry* house should be obtained from breeder *flocks* and hatcheries that have been monitored according to this chapter and in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected.
- 2) Layer and breeder *flocks* should be stocked from *flocks* that have been monitored according to this chapter and in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected.
- 3) Feed contamination with *Salmonella* is known to be a source of *infection* for *poultry*. Therefore, it is recommended to monitor the *Salmonella* status of *poultry* feed, and if found positive to take corrective measures. Heat treated feeds with or without the addition of other bactericidal or bacteriostatic treatments, e.g. organic acids, are recommended. Where heat treatment is not possible, the use of bacteriostatic or bactericidal treatments is recommended. Feed should be stored in clean closed containers to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents.

Treated feed should be handled and stored in such a way as to avoid recontamination.

- 4) Competitive exclusion may be used in *day-old birds* to reduce colonisation by *Salmonella*. When used, competitive exclusion should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services*.
- 5) Vaccines are used against *Salmonella infections* caused by different serotypes in various *poultry* species, including single or combined vaccines. Vaccines produced according to the *Terrestrial Manual* should be used.

If live vaccines are used, it is important that field and vaccine strains be easily differentiated in the laboratory. If serology is used as the *surveillance* method, it may not be possible to distinguish between *vaccination* and *infection* with a field strain.

Annex XI (contd)

Vaccination can be used as part of an overall *Salmonella* control programme. It is recommended that *vaccination* not be used as the sole control measure.

When the status of the breeder *flock* or the hatchery from which the *flock* originates is not known or does not comply with this chapter, *vaccination of flocks*, starting with *day-old birds*, against the *Salmonella* serotypes known to be significant should be considered.

Vaccination against the *Salmonella* serotypes known to be significant should be considered when moving *day-old birds* to a previously contaminated shed so as to minimise the risk of the birds contracting *Salmonella infection*.

When used, vaccines should be administered according to the instructions provided by the manufacturer and in accordance with the standards and recommendations of the *Veterinary Services*.

Vaccination against *S. Enteritidis* can cause cross-reactions in *Salmonella* Pullorum/*S. Gallinarum* serological tests and needs to be considered when implementing measures for these pathogens.

- 6) Depending on animal health, *risk assessment*, and public health policies, culling is an option to manage infected breeder and layer *flocks*. Infected *flocks* should be destroyed or slaughtered and processed to minimise human exposure to *Salmonella*.

If culling is not applied, eggs for human consumption should be diverted for processing for inactivation of *Salmonella*.

- 7) *S. Enteritidis* is characterised by its ovarian transmission pattern. Countries should set targets for eradicating (or significantly reducing) *S. Enteritidis* from egg-producing *flocks* through a guided policy for eradication from the top of the production pyramid, i.e. from grandparent *flocks* through breeder *flocks* to layer *flocks*.
- 8) The responsible *veterinarian* should evaluate the results of *surveillance* testing for *Salmonella* and supervise the implementation of appropriate control measures. These results should be available to the *veterinarian* before marketing if a veterinary certificate for *flock Salmonella* status is required. When required by the *Competent Authority*, the *veterinarian* or other person responsible for notification should notify the *Competent Authority* if the presence of *Salmonella* of the relevant serotype is confirmed.

Article 6.5.6.

Prevention of *Salmonella* spread from infected flocks

If a *flock* is found infected with specific *Salmonella* serotypes of concern, the following actions should be taken in addition to general measures detailed in Chapter 6.4. on Biosecurity Procedures in Poultry Production:

- 1) According to the epidemiological situation, investigations should be carried out to determine the origin of the *infection*.
- 2) Movement of *poultry flocks* at the end of the production cycle should only be allowed for *slaughter* or destruction. Special precautions should be taken in the transport, *slaughter* and processing of the birds, e.g. they could be sent to a separate *slaughterhouse* or processed at the end of a shift before cleaning and *disinfection* of the equipment.
- 3) Litter should not be reused as such. Used *poultry* litter, carcasses and other potentially contaminated farm waste should be disposed of in a safe manner to prevent the direct or indirect exposure of humans, livestock and *wildlife* to *Salmonella*. Particular care needs to be taken when utilising used *poultry* litter to fertilise plants intended for human consumption. If litter is not removed, it should be treated in a manner to inactivate infectious agents, to prevent the spread from one *flock* to the next.
- 4) Particular care should be taken in cleaning and *disinfection* of the *poultry* house and equipment.

Annex XI (contd)

- 5) Before restocking the facility, a bacteriological examination should be carried out as detailed in this chapter and the *Terrestrial Manual*.

Article 6.5.7.

Recommendations for introduction of live poultry (other than day-old birds)

Introduced live *poultry* (other than *day-old birds*) should:

- 1) originate from a *flock* that participates in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.5.4.;
- 2) originate from a *flock* in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected prior to movement and have had no contact with birds or other material from *flocks* that do not comply with this chapter;
- 3) originate from a *flock* that complies with the recommendations in Chapter 6.4.

Article 6.5.8.

Recommendations for introduction of day-old birds

Introduced *day-old birds* should:

- 1) show no clinical sign of salmonellosis on the day of shipment;
- 2) originate from a breeder *flock* and a hatchery that participate in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.5.4.;
- 3) originate from a breeder *flock* and a hatchery in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected and have had no contact during setting, incubation or hatching with *hatching eggs* or other material from *establishments* that do not comply with this chapter;
- 4) originate from a breeder *flock* and a hatchery that comply with the recommendations in Chapter 6.4.;
- 5) be transported in new ~~and~~ or clean *containers*.

Article 6.5.9.

Recommendations for introduction of hatching eggs

Introduced *hatching eggs* should:

- 1) originate from a breeder *flock* that participates in a *Salmonella surveillance* programme in accordance with the recommendations in Article 6.5.4.;
- 2) originate from a breeder *flock* in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected and have had no contact with *poultry* or other material from *establishments* that do not comply with this chapter;
- 3) originate from a breeder *flock* that complies with the recommendations in Chapter 6.4.;
- 4) be transported in new ~~and~~ or clean packaging materials.

— Text deleted.

DRAFT CHAPTER 7.X.

ANIMAL WELFARE AND DAIRY CATTLE PRODUCTION SYSTEMS

Article 7.X.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.X.2.

Scope

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

Article 7.X.3.

Commercial dairy cattle production systems

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

1. Housed or confined

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

2. Pastured

These are systems where cattle ~~have the freedom to roam~~ live outdoors, and ~~where the cattle~~ have some autonomy over diet selection (through grazing), water consumption and access to shelter. Pastured systems do not involve exclude any housing except that required for milking.

3. Combination systems

These are systems where cattle are managed in exposed to any combination of housed housing, confinement or and pasture husbandry methods production systems, either simultaneously, or varied according to weather changes in climatic conditions or physiological state of the cattle.

Article 7.X.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 stockmanship. The use of these indicators and their appropriate thresholds should be adapted to the different situations where dairy cattle are managed. Consideration should also be given to the design of the system. These criteria can be considered as a tool to monitor the efficiency impact of design and management, given that both of these can affect animal welfare will be affected by both system design and stockmanship.

Annex XII (contd)

Consideration should also be given to the design of the system and stockmanship.

1. Behaviour

Certain behaviours could indicate an *animal welfare* problem. These include decreased feed intake, altered locomotory behaviour and posture, altered lying time, human-animal relationship, altered respiratory rate and panting, coughing, shivering and huddling, grooming and the demonstration of stereotypic, agonistic, aggressive, depressive or other abnormal behaviours (Wiepkema *et al.*, 1983; Moss, 1992; Desire *et al.*, 2002; Appleby, 2006; Mason and Latham, 2004; Lawrence, 2008; Chapinel *et al.*, 2009).

2. Morbidity rates

Morbidity rates, including for infectious and metabolic diseases such as mastitis and metritis, lameness, metabolic diseases, parasitic diseases, post-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 (Blecha, 2000). Mastitis, lameness, reproductive and metabolic diseases are also particularly important animal health problems for adult dairy cows. Scoring systems, such as body condition, lameness scoring and milk quality, can provide additional information (Sprecher *et al.*, 1997; Roche *et al.*, 2004; EFSA, 2012)

Both clinical examination and pathology should be utilised as an indicator of *disease*, injuries and other problems that may compromise *animal welfare*. Post-mortem examination is useful to establish causes of death in cattle.

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 (Moss, 1992). Depending on the production system, estimates of mortality and culling rates can be obtained by analysing the rate and causes of death and culling and the their temporal, temporal and spatial patterns of mortality occurrence. Mortality and culling rates should can be reported recorded regularly, i.e. daily, monthly, annually or with reference to key husbandry activities within the production cycle.

Necropsy is useful in establishing causes of death.

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

In growing animals, body weight gain (failure to achieve appropriate changes outside the expected growth rate curve) especially excessive sudden loss may be are indicators of poor animal health and 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 animals, body condition score outside an acceptable range, significant body weight change and significant decrease in milk yield may be indicators of compromised welfare (Roche *et al.*, 2004; Roche *et al.*, 2009).

In non-lactating animals animals, including bulls, body condition score 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 performance expected standard for that particular breed, can indicate *animal welfare* problems. Examples may include:

- anoestrus or extended post-partum interval ~~prolonged post-partum anoestrus,~~
- 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),
- abnormal swellings, injuries and lesions,
- discharges (e.g. from nose, eyes, reproductive tract).
- feet abnormalities,
- abnormal posture indicating pain (e.g. rounded back, head low),
- emaciation and dehydration.

7. Handling responses

Improper handling can result in fear and distress in cattle. Indicators could 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,
- percentage of animals animals striking restraints or gates,
- percentage of animals injured injuries sustained during handling, such as bruising, lacerations, broken horns or tails and fractured legs,
- percentage of animals animals vocalising abnormally or excessively during restraint and handling,
- disturbed behaviour in the chute or race such as repeated reluctance to enter behaviour,
- percentage of animals animals slipping or falling.

Annex XII (contd)8. Complications due to from routine common procedures management

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

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

Article 7.X.5.

Provisions for good animal welfare

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

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.

1. 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 should be sought (e.g. Milk Development Council, 2006).

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

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.

i) Heat stress

The risk of heat stress for cattle is influenced by environmental factors including air temperature, relative humidity, and wind speed, animal density (area and volume available per animal), lack of sufficient shade, and animal factors including breed, age, body condition, metabolic rate and stage of lactation, and coat colour and density (West, 2003; Bryant *et al.*, 2007).

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 could include provision of shade, fans, ~~easy~~ access to additional drinking water, reduction of animal density, and provision of cooling systems as appropriate for the local conditions (Igono *et al.*, 1987; Kendall *et al.*, 2007; Blackshaw and Blackshaw, 1994).

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

ii) 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 (Manninen *et al.*, 2002).

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, including especially abnormal postures, shivering and huddling, growth rate curve, body condition and weight loss.

b) Lighting

Confined 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 (Arab *et al.*, 1995; Dahl *et al.*, 2000; Phillips *et al.*, 2000). The lighting should not cause discomfort to the animals. Housed dairy cows should be provided with subdued night time lighting. Entrance to restraint devices should be well lit.

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

c) Air quality

Good air quality and ventilation is an important factor for the health and welfare of cattle by and reducing 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. The air composition is influenced by the stocking 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 preventing the build-up of effluent gases (e.g. ammonia and hydrogen sulphide), including those from manure storage systems, and dust in the confinement housing unit. Poor air quality and poor ventilation are risk factors for respiratory discomfort and diseases. 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, behaviour, mortality rate, behaviour, especially respiratory rate or panting, coughing, changes in weight and body condition score or, growth rate curve, physical appearance, especially wet coat.

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 sudden and unexpected noise.

Annex XII (contd)

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

e) Flooring, bedding, resting surfaces and outdoor areas

In all production systems cattle need a well-drained and comfortable place to rest (Baxter *et al.*, 1983; Baxter, 1992; Moberg and Mench, 2000; Bell and Huxley, 2009; O'Driscoll *et al.*, 2007). All cattle in a group should have sufficient space to lie down and rest at the same time (Kondo *et al.*, 2003; Barrientos *et al.*, 2013; Chapinal *et al.*, 2013).

Particular attention should be given to the provisions for calving 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 (Sepúlveda-Varas *et al.* accepted).

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 paddocks field should be selected to provide the cow with a clean and comfortable environment. (See also 7.x.5.1 point 2 point i.)

Floor management in housed production systems can have a significant impact on cattle welfare (Ingvarsen *et al.*, 1993; Rushen and de Passillé, 1992; Barkema *et al.*, 1999; Drissler *et al.*, 2005). Areas that compromise welfare and are not suitable for resting (e.g. places with excessive water and faecal accumulation, wet bedding (Fregonesi *et al.*, 2007)) should not be included in the determination calculation of the area available for cattle to lie down.

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

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

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

Some form of 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 which to lie (Fisher *et al.*, 2003; Zdanowicz *et al.*, 2004; Bell, 2007; Bell and Huxley, 2009; Fregonesi, *et al.*, 2009).

The design of a standing, or cubicle, or free stall, should be such that the animals 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) (Tucker *et al.* 2003; Tucker *et al.*, 2004; Bell 2007; Cook *et al.*, 2008; Tucker *et al.*, 2009; Bernardi *et al.*, 2009; Anderson, 2010). 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 possible, this design should allow for the animal to move its head freely as it stands up. Where individual spaces are provided for cows to rest, there should be at least one space per cow (Fregonesi *et al.*, 2007).

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. Slippery surfaces should be avoided (e.g. grooved concrete; metal grating, not sharp; rubber mats or deep sand) to minimise slipping and falling (Rushen and de Passillé, 2006; Haufe *et al.*, 2009).

Annex XII (contd)

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 (Hinterhofer *et al.*, 2006; Telezhenko *et al.*, 2007).

If cattle have to be tethered whether indoors or outdoors, they should, as a minimum, be able to lie down, ~~and~~ stand up, maintain normal body posture, and turn around 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 (Loberg *et al.*, 2004; Tucker *et al.*, 2009).

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 (e.g. lameness, and injury rates (e.g. hock and knee injuries and skin lesions pressure sores)), behaviour, especially altered posture, grooming and locomotory behaviour, changes in weight and body condition ~~score~~, physical appearance (e.g. hair loss, cleanliness score), growth rate curve.

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.

~~Farms for dairy cattle should be situated in an appropriate geographical location for the health, welfare and productivity of the cattle.~~

All facilities for dairy cattle should be constructed, maintained and operated to minimise the risk to the welfare of the cattle (Grandin, 1980).

In pasture and combination systems tracks and races between the milking area and paddocks field 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 only be used in a way that minimises the risk of injury, pain or distress. Manufacturers of such equipment should consider animal welfare when preparing operating instructions.

Electrified equipment designed to control animal behaviour (e.g. cow trainer, electrified gate) that has been associated with increased incidence of welfare problems should not be used may cause welfare problems if not designed and maintained properly.

Electric Electrified fences and gates should be well-designed and maintained to avoid welfare problems, and used only according to manufacturer's instructions

Cattle in all housed or pastured production systems should be offered adequate space for comfort and socialisation (Kondo *et al.*, 2003).

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 and a decreased risk of lameness.

Annex XII (contd)

In all production systems, feed and water provision should allow all cattle to have ~~unimpeded~~ access to feed and water (DeVries and Keyserlingk, 2005; DeVries *et al.*, 2005, DeVries *et al.*, 2004; Endres *et al.*, 2005). Feeding systems should be designed to minimise agonistic behaviour. Feeders and water providers should be easy to clean and free of spoiled, mouldy, sour, unpalatable feed and faecal contamination.

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

~~Where possible, there should be a separated area to closely examine where individual animals~~ animals, can be examined closely and which should have has restraining facilities.

~~A hospital area for When relevant, sick and injured animals animals should be provided so the animals can be treated away from healthy animals 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 imperative to ensure the system functions properly and safe for the cattle.

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

Dipping baths and spray races are sometimes used in dairy cattle production for ectoparasite control. ~~Where these are used, they~~ 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 crowding 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*, according to 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 score, physical appearance, ~~lameness,~~ growth ~~curve~~ rate.

g) Emergency plans

~~Where~~ the failure of power, water and feed supply systems could compromise *animal welfare,* ~~D~~ 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, ~~access to maintenance providers 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.

~~Dairy producers should have contingency plans to cover the evacuation of animals in case of emergency (e.g. fire, flooding).~~

~~Outcome based measurables: mortality, morbidity, behaviour, vocalization.~~

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.

2. Recommendations on stockmanship and animal management

Good management and stockmanship are critical to providing an acceptable level of *animal welfare*. Personnel involved in handling and caring for dairy cattle should be competent and receive up-to-date appropriate 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.

a) Biosecurity and animal health

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, and implemented and maintained, commensurate with the best possible desired herd health status, available resources and infrastructure, and current *disease risk* and, for OIE listed diseases in accordance with relevant recommendations found 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, and wildlife, and pests,
- people including sanitation practices,
- equipment, tools and facilities,
- vehicles,
- air,
- water supply, feed and bedding,
- manure, waste and dead stock disposal,
- feed,
- semen and embryos.

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

ii) Animal health management

For the purpose of this chapter, animal health management means a system designed to 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, reproduction reproductive and metabolic diseases).

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.

Annex XII (contd)

At national or regional level there should be programmes to gather records and monitor diseases of importance for animal welfare.

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

Lameness can be is a problem in dairy cattle herds. *Animal handlers* should take measures to prevent lameness, and monitor the state of feet and claws, and take measures to prevent lameness and maintain foot health (Sprecher et al., 1997; Flower and Weary, 2006; Chapinal et al., 2009)

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 score), 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 (FAWC, UK, 1993; Ott *et al.*, 1995; Anonymous, 1997; Blecha, 2000; EU-SCAHAW, 2001; Webster, 2004; Mellor and Stafford, 2004; Millman *et al.*, 2004; OIE, 2005; Appleby, 2006; Broom, 2006; Gehring *et al.*, 2006; Fraser, 2008; Blokhuis *et al.*, 2008; Mench, 2008; Fraser, 2009; Ortiz-Pelawz *et al.*, 2008; FAWAC, Ireland; Hart, 1987; Tizard, 2008; Weary *et al.*, 2009).

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.

~~In the event of an OIE listed disease being suspected or diagnosed, the official veterinary services should be notified (see Chapter 1.1. of the Terrestrial Code).~~

Vaccinations and other treatments administered to cattle should be carried out undertaken by veterinarians or other people skilled in the procedures and on the basis of veterinary or other expert advice.

Animal handlers should be competent have experience in 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 ~~except~~ for treatment or diagnosis. Such movements should be done carefully using methods avoiding dragging or excessive lifting.

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

In case of chronic *disease* or injury, when treatment has failed or been attempted and recovery ~~deemed~~ is unlikely (e.g. cattle that are unable to stand up, unaided or refuse to eat or drink), the animal animal should be humanely killed (AABP, 2013; AVMA, 2013) and in accordance with to Chapter 7.5 or Chapter 7.6 as applicable.

~~animals~~ Animals suffering from photosensitisation should be provided with offered 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 ~~seere~~, changes in milk yield.

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.

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 (National Research Council, 2001).

Cattle should be provided with access to an appropriate quantity and quality of balanced nutrition that meets their physiological needs. Feeding systems should be designed to minimise agonistic behaviour.

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 ~~scores~~ scoring systems for their cattle and should not allow body condition to go outside an acceptable range according to breed and physiological status (Roche *et al.*, 2004; Roche *et al.*, 2009).

Feedstuffs and feed ingredients should be of satisfactory quality to meet nutritional needs and stored to minimise contamination and deterioration (CA 2004, CAC/RCP 54-2004). Where appropriate, feed and feed ingredients should be tested for the presence of substances that would adversely impact on animal health (Binder, 2007). 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. Therefore, when grain or new diets is given to dairy cattle it should be introduced slowly and constitute no more than 50% of the daily diet. Palatable fibrous food 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) (Enemark, 2008; Vermunt and Greenough, 1994). 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 (Drackley, 1999; Huzzey *et al.*, 2005; Bertoni *et al.*, 2008; Goldhawk *et al.*, 2009; Jawor *et al.*, 2012; Vickers *et al.*, 2013).

Liquid milk (or milk replacer) is essential for healthy growth and welfare. However, feeding calves all-liquid diets as the sole source of nutrition after 4-6 weeks of age limits the physiological development of the fore-stomach rumen and the normal development of the process of rumination. Calves over two weeks old should have a sufficient daily ration of fibrous food and starter ration (concentrate) to promote rumen development and to reduce abnormal oral behaviours (Reece & Hotchkiss, 1987).

Annex XII (contd)

Dairy producers should become familiar with potential micronutrient deficiencies or excesses for ~~housed and pastured~~ 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 (Lawrence *et al.*, 2004a; Cardot *et al.*, 2008).

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

c) Social environment

Management of cattle should take into account their social environment as it relates to *animal welfare*, particularly in housed systems (Le Neindre, 1989; Sato *et al.*, 1993; Jóhannesson and Sørensen, 2000; Bøe and Færevik, 2003; Bouissou *et al.*, 2001; Kondo *et al.*, 2003). 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 high stocking density, insufficient space at the feeder, insufficient water access and mixing of bulls.

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 animals, such as very young, very old, small or large size for cohort group, for evidence of agonistic behaviour bullying and excessive mounting behaviour. The *animal handler* should understand the risks of increased agonistic interactions between animals animals, particularly after mixing groups. ~~Cattle that are suffering from excessive agonistic activity should be removed from the group~~ (Bøe and Færevik, 2003; Jensen and Kyhn, 2000; von Keyserlingk *et al.*, 2008).

When other measures have failed, cattle that are expressing excessive agonistic activity or excessive mounting behaviour should be removed from the group (Bøe and Færevik, 2003; Jensen and Kyhn, 2000; von Keyserlingk et al., 2008).

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 animals at different production stages that have different dietary needs) (Grandin, 1998; Grandin, 2003; Grandin, 2006; Kondo *et al.*, 2003).

Horned and non-horned cattle should not be mixed because of the risk of injury (Menke *et al.*, 1999). When farmers intend to change the phenotype of their animals, they should take appropriate measures to reduce this risk.

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

d) Stocking density Space allowance

Cattle in all production systems should be offered adequate space for comfort and socialisation (Kondo et al., 2003).

~~High stocking densities~~ Insufficient and inadequate space allowance may increase the occurrence of injuries and have an adverse effect on growth curve rate, feed efficiency, and behaviour such as locomotion, resting, feeding and drinking (Martin and Bateson, 1986; Kondo *et al.*, 2003).

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Space allowance ~~Stocking density~~ should be managed taking into account different areas for lying, standing and feeding, such that ~~Crowding should not~~ does not adversely affect normal behaviour of cattle and durations of time spent lying (Bøe and Færevik, 2003).

~~This includes the ability to~~ All cattle should be able to rest simultaneously, and each animal to lie down freely, stand up and move around ~~freely, without the risk of injuries, move freely around the pen and access feed and water.~~ In growing animals, space allowance ~~Stocking density~~ should also be managed such that weight gain and duration of time spent lying is not adversely affected ~~by crowding~~ (Petherick and Phillips, 2009). If abnormal behaviour is seen, corrective measures should be taken, such as increasing space allowance, reducing stocking density, 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 (Stafford and Gregory, 2008).

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

e) Protection from predators

Cattle should be protected as much as possible from predators.

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

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 (Lawrence *et al.*, 2001; Lawrence *et al.*, 2004b; Boissy and Le Neindre, 1997; Dillon *et al.*, 2006; Boissy *et al.*, 2007; Jensen *et al.*, 2008; Veissier *et al.*, 2008; Macdonald *et al.*, 2008). ~~Examples of these include nutritional maintenance requirement, ectoparasite resistance and heat tolerance.~~

In breeding programmes, at least as much attention should be paid to criteria conducive to the improvement of cattle welfare, including health, as to production criteria. 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 ectoparasite resistance and heat tolerance.

Individual ~~animals~~ 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 curve, body condition ~~score~~ outside an acceptable range.

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.

Annex XII (contd)

Artificial insemination and pregnancy diagnosis should be performed by a competent operator and in accordance with the provisions of Chapter 4.7.

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

h) Dam and Sire selection and calving management

Dystocia ~~is can be~~ a welfare risk to dairy cattle (Proudfoot *et al*, 2009). Heifers should not be bred before they reach ~~are at~~ 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 ~~Animals~~ observed to be having difficulty in calving should be assisted by a competent handler as soon as possible after they are detected.

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

i) Newborn calves (see also 7.x.5.1e)

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, 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.

Where new ~~Recently~~ born calves ~~need to be~~ should not be transported until the navel ~~has healed~~ is dry, and after which time any transport required ~~this~~ should be carried out according to Chapter 7.3.

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

Outcome-based measurables: mortality rate, morbidity rate, growth rate curve.

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 can be~~ stressful for both cow and calf (Newberry and Swanson, 2008; Weary *et al.*, 2008).

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 ~~done~~ 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 (Roth *et al.*, 2009).

~~If necessary,~~ 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 (vocalisations, activity of the cow and calf), physical appearance, changes in weight and body condition ~~score~~, growth rate curve.

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). (Camiloti *et al.*, 2012)

~~Where possible,~~ Replacement stock should be reared in groups. Animals in groups should be of similar age and physical size (Jensen and Kyhn, 2000; Bøe and Færevik, 2003).

Whether reared individually or in group pens ~~When in pens,~~ each calf should have enough space to be able to turn around, rest, stand up and groom comfortably and see and touch other animals. (see also 1.e).

Replacement stock should be monitored for cross-sucking and appropriate measures taken to prevent this occurring (e.g. provision of sucking devices, revise or modify feeding practices, provide other environmental enrichments use of nose guards or temporary separation) (Seo *et al.*, 1998; Jemsem, 2003; De Paula Vieira *et al.*, 2010; Ude *et al.*, 2011).

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 ~~score~~, growth rate curve, ~~reproduction efficiency~~.

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 (Barkema *et al.*, 1999; Breen *et al.*, 2009). 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.

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A regular milking routine should be established relevant to the stage of the lactation and the capacity of the system. (e.g. For example, cows female in full lactation may need more frequent milking to relieve udder pressure.). All milking cows should be checked for abnormal milk at all milking times.

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

~~Where a milking machine is used, it should be maintained, according to the recommendations of the manufacturer, in order to minimise teat and udder damage.~~

Special care should be paid to animals animals being milked for the first time. If possible, 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), behaviour, changes in milk yield, milk quality, physical appearance (e.g. lesions).

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 animal. Example of such interventions include: dehorning, tail docking and identification.

~~Alternative procedures that reduce or avoid pain should be considered.~~

Future options for enhancing *animal welfare* in relation to these procedures include: ceasing the procedure and addressing the current 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*.

Example of such interventions include: dehorning, tail docking and identification.

i) Disbudding and D dehorning (including disbudding)

Horned Ddairy cattle that are naturally horned 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 (Laden *et al.*, 1985; Petrie *et al.*, 1996; Singh *et al.*, 2002; Sutherland *et al.*, 2002; Stafford *et al.*, 2003; Stafford and Mellor, 2005). Where practical and appropriate for the production system, the selection of polled cattle is preferable to dehorning.

Performing disbudding at an early age where practicable, 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 paraprofessional* 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.

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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 because pain management is difficult 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.

~~Where it is necessary to dehorn dairy cattle, producers should seek guidance from veterinary advisers as to the optimum method, use of anesthesia and analgesia, and timing for their type of cattle and production system.~~

~~Performing dehorning or disbudding at an early age, where practicable, and the use of anaesthesia or analgesia, under the supervision of a veterinarian, are strongly recommended.~~

~~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 at an appropriate age before the horn bud has attached to the skull. Other methods of dehorning 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.~~

~~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. Operators removing developed horns from dairy cattle should be trained and competent in the procedure used, and be able to recognise the signs of complications (e.g. excessive bleeding, sinus infection).~~

ii) Tail docking

~~Research shows that tail docking does not improve the health and welfare of dairy cattle animals, and therefore it is not recommended, as a routine procedure, to dock the tails of dairy cattle. As an alternative, trimming of tail hair should be considered where maintenance of hygiene is a problem (Sutherland and Tucker, 2011).~~

iii) Identification

~~Ear-tagging, ear-notching, tattooing, freeze branding and radio frequency identification devices (RFID) are preferred methods of permanently identifying dairy cattle from an animal welfare standpoint. The least invasive approach should be adopted whichever method is chosen (e.g. the least minimum number of ear tags per ear, and the smallest size of notch practical). It should be accomplished quickly, expertly and with proper equipment. In some situations however hot iron branding may be required or be the only practical method of permanent identifying dairy cattle. If cattle are branded, it should be accomplished quickly, expertly and with the proper equipment. Identification systems should be established also according to Chapter 4~~

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

Identification systems should be established also according to Chapter 4.1.

Annex XII (contd)

Outcome-based measurables: ~~postprocedural complication rate~~, morbidity rate (post-procedural complications), abnormal behaviour, vocalisation, physical appearance, ~~changes in weight and body condition score~~.

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. ~~In most circumstances cattle~~ Lactating cows should be inspected at least once a day. Some ~~animals~~ animals may benefit from ~~should be inspected~~ more frequently, ~~inspection~~ for example; neonatal calves (Larson *et al.*, 1998; Townsend, 1994), cows in late gestation (Boadi and Price, 1996; Mee, 2008; Odde, 1996, Proudfoot, K., et al. 2013), 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 ~~and trained~~ 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. ~~sharp prods~~, 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 ~~or persistent~~ 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: human-animal relationship, morbidity rate, mortality rate, behaviour, especially altered locomotory behaviour, vocalisations, ~~reproductive efficiency, changes in weight and body condition score, changes in milk yield~~.

o) Personnel training

All people responsible for dairy cattle should be competent according to 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: human-animal relationship, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight and body condition ~~score~~, changes in milk yield.

p) Disaster management

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

~~Plans should be in place to minimise and mitigate~~ There should also be plans to address the effects of ~~natural disasters or~~ extreme climatic conditions, such as ~~heat stress,~~ drought, blizzard and flooding. ~~Humane killing procedures for sick or injured cattle should be part of the emergency action plan.~~ 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 1 g) and 2a) iii) of Article 7.X.5.

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~~ 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 downers;
- 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; and
- premature calves that are premature and unlikely to survive, ~~or calves that have a~~ debilitating congenital defect, or otherwise unwanted calves; 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.

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CHAPTER 7.10.

**ANIMAL WELFARE AND BROILER CHICKEN
PRODUCTION SYSTEMS**

Article 7.10.1.

Definitions

For the purpose of this chapter:

Broiler: means a bird of the species *Gallus gallus* kept for commercial *meat* production. *Poultry* kept in village or backyard *flocks* are not included.

Harvesting: means the catching and *loading* of birds on farm for transportation to the *slaughterhouse/abattoir*.

Article 7.10.2.

Scope

This chapter covers the production period from arrival of *day-old birds* on the farm to harvesting the broilers in commercial production systems. Such systems involve confinement of the birds, the application of biosecurity measures, and trade in the products of those birds, regardless of scale of production. These recommendations cover broilers kept in cages, on slatted floors, litter or dirt and indoors or outdoors.

Broiler production systems include:

1. Completely housed system

Broilers are completely confined in a poultry house, with or without environmental control.

2. Partially housed system

Broilers are kept in a poultry house with access to a restricted outdoor area.

3. Completely outdoors system

Broilers are not confined inside a poultry house at any time during the production period but are confined in a designated outdoor area.

This chapter should be read in conjunction with Chapters 7.2., 7.3. and 7.4. on the welfare of broilers during *transport* to the *slaughterhouse/abattoir*.

Article 7.10.3.

Criteria or measurables for the welfare of broilers

The welfare of broilers should be assessed using outcome-based measurables. Consideration should also be given to the resources provided and the design of the system. The following outcome-based measurables, specifically animal-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 broilers are managed, also taking into account the strain of bird concerned.

Annex XIII (contd)

Some criteria can be measured in the farm setting, such as gait, mortality and morbidity rates, while others are best measured at the *slaughterhouse/abattoir*. For example, at *slaughter flocks* can be assessed for presence of bruising, broken limbs and other injuries. The age of these lesions can help to determine the source. Back scratching and contact dermatitis and breast blisters are also easily observed at the *slaughterhouse/abattoir*. Other conditions such as ascites, leg deformities, dehydration and *disease* conditions can also be assessed at *slaughter*. It is recommended that values for welfare measurables be determined with reference to appropriate national, sectoral or perhaps regional norms for commercial broiler production.

The following outcome-based criteria and measurables are useful indicators of broiler welfare:

1. Mortality, culling and morbidity

Daily, weekly and cumulative mortality, culling and morbidity rates should be within expected ranges. Any unforeseen increase in these rates could reflect an *animal welfare* problem.

2. Gait

Broilers are susceptible to developing a variety of infectious and non-infectious musculoskeletal disorders. These disorders may lead to lameness and to gait abnormalities. Broilers that are lame or have gait abnormalities may have difficulty reaching the food and water, may be trampled by other broilers, and may experience pain. Musculoskeletal problems have many causes, including genetics, nutrition, sanitation, lighting, litter quality, and other environmental and management factors. There are several gait scoring systems available.

3. Contact dermatitis

Contact dermatitis affects skin surfaces that have prolonged contact with wet litter or other wet flooring surfaces. The condition is manifested as blackened skin progressing to erosions and fibrosis on the lower surface of the foot pad, at the back of the hocks, and sometimes in the breast area. If severe, the foot and hock lesions may contribute to lameness and lead to secondary *infections*. Validated scoring systems for contact dermatitis have been developed for use in *slaughterhouse/abattoir*.

4. Feather condition

Evaluation of the feather condition of broilers provides useful information about aspects of welfare. Plumage dirtiness is correlated with contact dermatitis and lameness for individual birds or may be associated with the environment and production system. Plumage dirtiness can be assessed as part of on-farm inspections, at the time of harvesting or prior to plucking. A scoring system has been developed for this purpose.

5. Incidence of diseases, metabolic disorders and parasitic infestations

Ill-health, regardless of the cause, is a welfare concern, and may be exacerbated by poor environmental or husbandry management.

6. Behaviour

a) Fear behaviour

Fearful broilers show avoidance of humans, and this behaviour is seen in *flocks* where *animal handlers* walk through the poultry house quickly when performing their tasks rather than moving more slowly while interacting with the broilers. Fearfulness (e.g. of sudden loud noises) can also lead to the broilers piling on top of, and even suffocating, one another. Fearful broilers may be less productive. Validated methods have been developed for evaluating fearfulness.

Annex XIII (contd)

b) Spatial distribution

Changes in the spatial distribution (e.g. huddling) of the birds may indicate thermal discomfort or the existence of areas of wet litter or uneven provision of light, food or water.

c) Panting and wing spreading

Excessive panting and wing spreading indicates heat stress or poor air quality, such as high levels of ammonia.

d) Dust bathing

Dust bathing is an intricate body maintenance behaviour performed by many birds, including broilers. During dust bathing, broilers work loose material, such as litter, through their feathers. Dust bathing helps to keep the feathers in good condition, which in turn helps to maintain body temperature and protect against skin injury. Reduced dust bathing behaviour in the *flock* may indicate problems with litter or range quality, such as litter or ground being wet or not friable.

e) Feeding, drinking and foraging

Reduced feeding or drinking behaviour can indicate management problems, including inadequate feeder or drinker space or placement, dietary imbalance, poor water quality, or feed contamination. Feeding and drinking behaviour are often depressed when broilers are ill, and intake may be also reduced during periods of heat stress and increased during cold stress. Foraging is the act of searching for food, typically by walking and pecking or scratching the litter substrate; reduced foraging activity could suggest problems with litter quality or presence of conditions that decrease bird movement.

f) Feather pecking and cannibalism

Feather pecking can result in significant feather loss and may lead to cannibalism. Cannibalism is the tearing of the flesh of another bird, and can result in severe injury. These abnormal behaviours have multi-factorial causes.

7. Water and feed consumption

Monitoring daily water consumption is a useful tool to indicate *disease* and other welfare conditions, taking into consideration ambient temperature, relative humidity, feed consumption and other related factors. Problems with the water supply can result in wet litter, diarrhoea, dermatitis or dehydration.

Changes in feed consumption can indicate unsuitability of feed, the presence of *disease* or other welfare problems.

8. Performance

a) Growth rate (gr) - an index that indicates the average daily gain of weight per average broiler of a *flock*.

b) Feed conversion - an index that measures the quantity of feed consumed by a *flock* relative to the total live weight harvested, expressed as the weight of feed required to produce one kg of broiler body weight.

c) Liveability - an index that indicates the percentage of broilers present at the end of the production period. More commonly this indicator is measured as its opposite, mortality.

Annex XIII (contd)9. Injury rate

The rate of these injuries can indicate welfare problems in the *flock* during production or harvesting. Injuries include those due to other broilers (scratches, feather loss or wounding due to feather pecking and cannibalism) and those due to environmental conditions, such as skin lesions (e.g. contact dermatitis) and those due to human intervention, such as catching. The most prevalent injuries seen during catching are bruises, broken limbs, dislocated hips, and damaged wings.

10. Eye conditions

Conjunctivitis can indicate the presence of irritants such as dust and ammonia. High ammonia levels can also cause corneal burns and eventual blindness. Abnormal eye development can be associated with low light intensity.

11. Vocalisation

Vocalisation can indicate emotional states, both positive and negative. Interpretation of *flock* vocalisations is possible by experienced *animal handlers*.

Article 7.10.4.

Recommendations1. 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.

Annex XIII (contd)

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.

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

Annex XIII (contd)

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.

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.

Annex XIII (contd)

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.

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.

Annex XIII (contd)

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, in addition to productivity and growth rate, should be taken into account when choosing a 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.

Annex XIII (contd)

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.

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.

Annex XIII (contd)

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.

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 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. 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 which are used for traction and transport, for income generation as well as domestic use (non-commercial work). Equids used in sports or competitions, leisure riding or research are excluded.

Article 7.X.3.

Responsibilities and competencies1. Veterinary Authority

The *Veterinary Authority* is the responsible for implementation of animal health and welfare. In the case of working equids, responsibility may be shared with other government agencies and institutions as listed below and including but is not limited to those responsible for agriculture and transport.

Annex XIV (contd)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 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 *zoonosis* such as glanders.

Education authorities have a responsibility in schools and through agricultural, paraveterinary and veterinary training; appropriate education and training can 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 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 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* 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

Non-governmental organisations (NGOs) and intergovernmental organisation 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 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 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.

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.

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, 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*.

Annex XIV (contd)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, temporal and spatial patterns of mortality and relating associated 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).

5. Physical appearance

Observation of physical appearance will often provide an indication of health and welfare. Attributes of physical appearance that may indicate compromised welfare include:

- presence of parasites,
- abnormal coat, texture or hair loss,
- excessive soiling with faeces, mud or dirt,
- dehydration (measured by drinking behaviour) or heat stress,
- emaciation,
- feet abnormalities,
- abnormal discharges,
- wounds or injuries,
- abnormal behaviour, postures and gait.

6. Handling responses

Poor human-animal interactions can lead to improper handling. This may include inappropriate driving and restraint methods such as the use of whips and sticks, and can result in fear and distress. I

ndicators could include:

- aversive responses to fitting of equipments 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.

7. Complications due to management practices

Some management practices, such as castration, are commonly performed in working equids for improving animal performance, facilitating handling and improving human safety and *animal welfare*. They should be accomplished quickly, expertly and with the proper equipment. If these procedures are not performed properly, *animal welfare* can be compromised. Indicators of such problems could include:

- post procedure *infection* and swelling,
- myiasis,
- 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 put on wounds should be identified as indicators of poor welfare.

8. 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 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.

9. 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).

Annex XIV (contd)

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.6. to 7.X.13. 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.

Article 7.X.6.

Nutrition, feeding and watering

Energy, 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 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 short as possible and that mitigation strategies are implemented if health and welfare 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 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.

However, the most important nutrient for the welfare of working equids is water (Heleski *et al.*, 2010). Working equids need an adequate supply and access to palatable, safe water that meets their physiological, work, and environmental requirements which may vary (e.g. increased water need in hot weather).

Outcome-based measurables: mortality and morbidity rates, behaviour, changes in weight and body condition, 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 large enough for the equid to lie down comfortably and to 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.

Outcome-based measurables: largely behavioural, 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).

Outcome-based measurables: mortality rates, physical appearance, behaviour including abnormal postures and huddling.

3. Protection against predators and injury

Good shelter is required to keep equids safe from predators and from road accidents, a common occurrence if equids are left free to roam. If working equids are housed alongside other domestic livestock, care must be taken to protect them from injury by horned cattle (The Brooke WEVM, 2013).

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

Article 7.X.8.

Disease and injury management: management of endemic disease, infectious disease, work-related wounds and injuries, planning for disease outbreaks, health service provision1. 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 and implemented, 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:

Annex XIV (contd)

- a) equids,
- b) other *animals* and disease 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.

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 effective national programme for the prevention and treatment of working equid *diseases* and conditions with clear roles and responsibilities defined for official and private animal health service personnel as well as for owners.

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.

Animals at higher risk of *disease* or distress will require more frequent inspection by *animal handlers*. If *animal handlers* are not able to correct the causes of ill-health or distress or if they suspect the presence of a reportable *disease* 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 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.

Annex XIV (contd)

When treatment is attempted, equids that are unable to stand up unaided and refuse to eat or drink should be euthanised 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, 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 wounds or harness wounds), they may also be indicative of poor human-animal interactions.

c) 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.

Article 7.X.9.

Handling and driving practice, handling facilities, personnel expertise and training, mutilations and other management practice

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 resting periods, working under heat stress, overloads, 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. *Veterinarians* have a role in educating owners and handlers of working equids to cease these inappropriate and ineffective practices and also in encouraging 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.

Annex XIV (contd)

Equids should not be tethered or hobbled permanently; they should not be hobbled for continuous periods of more than 12 hours in any 24-hour period.

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.

Mares in season should not be tethered with stallions; mares about to foal or with a foal should not be tethered.

Equipment used to hobble must be designed for hobbling. 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.

Outcome based measurables: mortality and morbidity rates, physical appearance (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 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.

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 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.

Annex XIV (contd)

- 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).

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 indicative of discomfort or pain, sociability with humans and other equids, alertness, injuries, changes in weight and body condition, willingness to accept equipment and loading for work.

Article 7.X.11.

End of life issues: euthanasia, slaughter (including end of working life, abandonment)

When *euthanasia* is practised in working equids, the general principles in 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. Animals that are subjected to 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 be ridden or worked within three months 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 weather conditions (work should be reduced in very hot weather). Breaks should be given at least every two hours and fresh water should be available.

Annex XIV (contd)

All animals should receive sufficient good quality feed corresponding to their individual requirements. Fresh water 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 agreement 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, dehydration, handling response, gait and lameness.

Article 7.X.13.

Farriery and harnessing1. Farriery

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, most 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 affect:

- 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 tendiopathy, 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.
- c) 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 to the hoof (Turner, 2013).

Outcome based measurables: physical appearance, lameness.

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.

A properly designed, well-fitted and comfortable harness allows the working equid to pull the equipment to the best of its ability 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.

Annex XIV (contd)

There should be enough clean padding on harnesses so the animals do not have to work with open sores.

A good harness; does not have sharp edges which could cause injury to the equid, fits well so that it does not cause wounds or chafing caused by excess movement; is smoothly shaped or padded so that loads imposed on the equids body are spread over a large area; and does not impede the animal's movement or normal breathing or restrict blood supply. Good harnessing also maximises the efficiency of transfer of draught energy from animal to load so that minimum effort is required by the equid.

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 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.

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CHAPTER 3.4.

VETERINARY LEGISLATION

Article 3.4.1.

Introduction and objective

Good governance is a recognised global public good and is of critical importance to Member Countries. Legislation is a key element in achieving good governance.

Veterinary legislation should, at a minimum, provide a basis for *Competent Authorities* to meet their obligations as defined in the *Terrestrial Code* and the relevant recommendations of the Codex Alimentarius Commission. In addition, there is an obligation for World Trade Organization (WTO) Members under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) to notify the WTO of changes in sanitary measures, including changes in legislation that affect trade, and provide relevant information.

For the purposes of the *Terrestrial Code*, *veterinary legislation* comprises all legal instruments necessary for the governance of the veterinary domain.

The objective of this chapter is to provide advice and assistance to Member Countries when formulating or modernising *veterinary legislation* so as to comply with OIE standards, thus ensuring good governance of the entire veterinary domain.

Article 3.4.2.

Definitions

For the purposes of this chapter the following definitions apply:

Hierarchy of legislation: means the ranking of the legal instruments as prescribed under the fundamental law (e.g. the constitution) of a country. Respect for the hierarchy means that each legal instrument must comply with higher order legal instruments.

Legal instrument: means the legally binding rule that is issued by a body with the required legal authority to issue the instrument.

Primary legislation: means the legal instruments issued by the legislative body of a Member Country.

Secondary legislation: means the legal instruments issued by the executive body of a Member Country under the authority of primary legislation.

Stakeholder: means a person, group, or organisation that can affect or be affected by the impacts of *veterinary legislation*.

Veterinary domain: means all the activities that are directly or indirectly related to *animals*, their products and by-products, which help to protect, maintain and improve the health and welfare of humans, including by means of the protection of animal health and *animal welfare*, and food safety.

Article 3.4.3.

General principles1. Respect for the hierarchy of legislation

Veterinary legislation should scrupulously respect the hierarchy between primary legislation and secondary legislation.

2. Legal basis

Competent Authorities should have available the primary legislation and secondary legislation necessary to carry out their activities at all administrative and geographic levels.

Veterinary legislation should be consistent with national and international law, as appropriate, including civil, penal and administrative laws.

3. Transparency

Veterinary legislation should be inventoried and be readily accessible and intelligible for use, updating and modification, as appropriate.

Competent Authorities should ensure communication of *veterinary legislation* and related documentation to stakeholders.

4. Consultation

The drafting of new and revised legislation relevant to the veterinary domain should be a consultative process involving *Competent Authorities* and legal experts to ensure that the resulting legislation is scientifically, technically and legally sound.

To facilitate implementation of the *veterinary legislation*, *Competent Authorities* should establish relationships with stakeholders, including taking steps to ensure that they participate in the development of significant legislation and required follow-up.

5. Quality of legislation and legal certainty

Veterinary legislation should be clear, coherent, stable and transparent and protect citizens against unintended adverse side effects of legal instruments. It should be technically relevant, acceptable to society, able to be effectively implemented and sustainable in technical, financial and administrative terms. A high quality of legislation is essential for achieving legal certainty.

Article 3.4.4.

The drafting of veterinary legislation

Veterinary legislation should:

- 1) be drafted in a manner that establishes clear rights, responsibilities and obligations (i.e. 'normative');
- 2) be unambiguous, with clear and consistent syntax and vocabulary;
- 3) be precise, accurate and consistent in the repeated use of the terminology;
- 4) contain no definitions that create any conflict or ambiguity;
- 5) include a clear statement of scope and objectives;

Annex XIV (contd)

- 6) provide for the application of penalties and sanctions, either criminal or administrative, as appropriate to the situation; and
- 7) make provision for the financing needed for the execution of all activities of *Competent Authorities*; the financing should be ensured in accordance with the national funding system.

Article 3.4.5.

Competent Authorities

Competent Authorities should be legally mandated, capacitated and organised to ensure that all necessary actions are taken quickly and coherently to address animal health, public health and *animal welfare* emergencies effectively.

Veterinary legislation should provide for a chain of command that is as effective as possible (i.e. short, with all responsibilities clearly defined). For this purpose, the responsibilities and powers of *Competent Authorities*, from the central level to those responsible for the implementation of legislation in the field, should be clearly defined. Where more than one *Competent Authority* is involved such as in relation to environmental, food safety or other public health matters a reliable system of coordination and cooperation should be in place.

Competent Authorities should appoint technically qualified officials to take any actions needed for implementation or verification of compliance with the *veterinary legislation*, respecting the principles of independence and impartiality prescribed in Article 3.1.2.

1. Necessary powers of the Competent Authority

The *veterinary legislation* should also ensure that:

- a) officials have the legal authority to intervene in accordance with the legislation and the penal procedures in force;
- b) while executing their legal mandate, officials are protected against legal action and physical harm for actions carried out in good faith;
- c) the powers and functions of officials are explicitly and thoroughly listed to protect the rights of stakeholders and the general public against any abuse of authority. This includes respecting confidentiality, as appropriate; and
- d) at least the following powers are available through the primary legislation:
 - i) access to premises and vehicles for carrying out inspections;
 - ii) access to documents;
 - iii) taking samples;
 - iv) retention (setting aside) of *animals* and goods, pending a decision on final disposition;
 - v) seizure of *animals*, products and food of animal origin;
 - vi) suspension of one or more activities of an inspected establishment;
 - vii) temporary, partial or complete closure of inspected establishments; and
 - viii) suspension or withdrawal of authorisations or approvals.

These essential powers must be identified as they can result in actions that may conflict with individual rights ascribed in fundamental laws.

2. Delegation of powers by the Competent Authority

The *veterinary legislation* should provide the possibility for *Competent Authorities* to delegate specific tasks related to official activities. The specific tasks delegated, the body(ies) to which the tasks are delegated and the conditions of supervision by the *Competent Authority* should be defined.

For this purpose, the *veterinary legislation* should:

- a) define the field of activities and the specific tasks covered by the delegation;
- b) provide for the control, supervision and, when appropriate, financing of the delegation;
- c) define the procedures for making delegation;
- d) define the competencies to be held by persons receiving delegation; and
- e) define the conditions of withdrawals of delegations.

Article 3.4.6.

Veterinarians and veterinary para-professionals

1. Veterinary medicine/science

In order to ensure quality in the conduct of veterinary medicine/science, the *veterinary legislation* should:

- a) define the prerogatives of *veterinarians* and of the various categories of *veterinary para-professionals* that are recognised by the Member Country;
- b) define the minimum initial and continuous educational requirements and competencies for *veterinarians* and *veterinary para-professionals*;
- c) prescribe the conditions for recognition of the qualifications for *veterinarians* and *veterinary para-professionals*;
- d) define the conditions to perform the activities of veterinary medicine/science; and
- e) identify the exceptional situations, such as epizootics, under which persons other than *veterinarians* can undertake activities that are normally carried out by *veterinarians*.

2. The control of veterinarians and veterinary para-professionals

Veterinary legislation should provide a basis for regulation of *veterinarians* and *veterinary para-professionals* in the public interest. To that end, the legislation should:

- a) describe the general system of control in terms of the political, administrative and geographic configuration of the country;
- b) describe the various categories of *veterinary para-professionals* recognised by the Member Country according to its needs, notably in animal health and food safety, and for each category, prescribe its training, qualifications, tasks and extent of supervision;
- c) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to *veterinarians* and *veterinary para-professionals*;

Annex XIV (contd)

- d) provide for the possibility of delegation of powers to a professional organisation such as a *veterinary statutory body*; and
- e) where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organisation.

Article 3.4.7.

Laboratories in the veterinary domain1. Facilities

Veterinary legislation should define the role, responsibilities, obligations and quality requirements for:

- a) reference *laboratories*, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods;
- b) *laboratories* designated by the *Competent Authority* for carrying out the analysis of official samples; and
- c) *laboratories* recognised by the *Competent Authority* to conduct analyses required under the legislation e.g. for the purposes of quality control.

Veterinary legislation should define the conditions for the classification, approval, operations and supervision of *laboratories* at each level.

2. Reagents

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) procedures for authorising reagents that are used to perform official analyses;
- b) quality assurance by manufacturers of reagents used in official analyses; and
- c) surveillance of marketing of reagents, where these can affect the quality of analyses required by the *veterinary legislation*.

Article 3.4.8.

Health provisions relating to animal production1. Identification and traceability

Veterinary legislation should provide a basis for actions to address all the elements in point 6 of Article 4.2.3.

2. Animal markets and other gatherings

Veterinary legislation should address, for animal markets and other commercially or epidemiologically significant animal gatherings, the following elements:

- a) registration of animal markets and other animal gatherings;
- b) health measures to prevent *disease* transmission, including procedures for cleaning and *disinfection*, and *animal welfare* measures; and
- c) provision for veterinary checks.

Annex XIV (contd)3. Animal reproduction

Veterinary legislation should provide a basis for actions to address the health regulation of animal reproduction as appropriate. Health regulations may be implemented at the level of *animals*, genetic material, establishments or operators.

4. Animal feed

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) standards for the production, composition and quality control of animal feed;
- b) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and
- c) recall from the market of any product likely to present a hazard to human health or animal health.

5. Animal by-products

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) definition of the animal by-products subject to the legislation;
- b) rules for collection, processing, use and disposal of animal by-products;
- c) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and
- d) rules to be followed by animal owners.

6. Disinfection

Veterinary legislation should provide a basis for actions to address the regulation and use of products and methods of *disinfection* relating to the prevention and control of animal *diseases*.

Article 3.4.9.

Animal diseases

Veterinary legislation should provide a basis for the *Competent Authority* to manage *diseases* of importance to the country and to list those *diseases*, guided by the recommendations in Chapters 1.1. and 1.2.

1. Surveillance

Veterinary legislation should provide a basis for the collection, transmission and utilisation of epidemiological data relevant to *diseases* listed by the *Competent Authority*.

2. Disease prevention and control

- a) *Veterinary legislation* should include general animal health measures applicable to all *diseases* and, if necessary, additional or specific measures such as *surveillance*, establishment of a regulatory programme or emergency response for particular *diseases* listed in the country.

Annex XIV (contd)

- b) The legislation should also provide a basis for contingency plans to include the following for use in *disease* responses:
- i) administrative and logistic organisation;
 - ii) exceptional powers of the *Competent Authority*; and
 - iii) special and temporary measures to address all identified *risks* to human or animal health.
- c) *Veterinary legislation* should provide for the financing of animal disease control measures, such as operational expenses and, as appropriate, owners' compensation in the event of *killing* or *slaughtering* of *animals* and seizure or destruction of carcasses, *meat*, animal feed or other things.

3. Emerging diseases

Veterinary legislation should provide for measures to investigate and respond to *emerging diseases*.

Article 3.4.10.

Animal welfare1. General provisions

Veterinary legislation should provide a basis for actions to address the *animal welfare* related requirements in Section 7.

To this end, the legislation should contain, as a minimum, a legal definition of cruelty as an offence, and provisions for direct intervention of the *Competent Authority* in the case of neglect by animal keepers.

2. Stray dogs and other free-roaming animals

Veterinary legislation should provide a basis for actions to address the requirements in Chapter 7.7. and, as appropriate, prohibition of the abandonment of *animals*, and management of abandoned *animals*, including transfer of ownership, veterinary interventions and *euthanasia*.

3. Working animals

Veterinary legislation should provide a basis for actions to address the requirements in Chapter 7.X. and, as appropriate, the definition of owner responsibilities for their *animals*, and management of abandoned *animals*, including transfer of ownership, veterinary interventions and *euthanasia*.

Article 3.4.11.

Veterinary medicines and biologicals

Veterinary legislation should provide a basis for assuring the quality of veterinary medicines and biologicals and minimising the *risk* to human, animal and environmental health associated with their use.

1. General measures

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) definition of veterinary medicines and biologicals, including any specific exclusions; and
- b) regulation of the importation, manufacture, distribution and usage of, and commerce in, veterinary medicines and biologicals.

2. Raw materials for use in veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the elements listed below:

- a) quality standards for raw materials used in the manufacture or composition of veterinary medicines and biologicals and arrangements for checking quality;
- b) establishment of the withdrawal periods and maximum residue limits for veterinary medicines and biologicals, as appropriate; and
- c) requirements for substances in veterinary medicines and biologicals that may, through their effects, interfere with the conduct of veterinary checks.

3. Authorisation of veterinary medicines and biologicals

- a) *Veterinary legislation* should ensure that only authorised veterinary medicines and biologicals may be placed on the market.
- b) Special provisions should be made for:
 - i) medicated feed;
 - ii) products prepared by authorised *veterinarians* or authorised pharmacists; and
 - iii) emergencies and temporary situations.
- c) *Veterinary legislation* should address the technical, administrative and financial conditions associated with the granting, renewal, refusal and withdrawal of authorisations.
- d) In defining the procedures for seeking and granting authorisations, the legislation should:
 - i) describe the role of the relevant *Competent Authorities*; and
 - ii) establish rules providing for the transparency in decision making.
- e) *Veterinary legislation* may provide for the possibility of recognition of the equivalence of authorisations made by other countries.

4. Quality of veterinary medicines and biologicals

Veterinary legislation should address the following elements:

- a) the conduct of clinical and non-clinical trials to verify all claims made by the manufacturer;
- b) conditions for the conduct of trials;
- c) qualifications of experts involved in trials; and
- d) surveillance for adverse effects arising from the use of veterinary medicines and biologicals.

5. Establishments producing, storing and wholesaling veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the following elements:

- a) registration or authorisation of all operators manufacturing importing, storing, processing, wholesaling or otherwise distributing veterinary medicines and biologicals or raw materials for use in making veterinary medicines and biologicals;

Annex XIV (contd)

- b) definition of the responsibilities of operators;
- c) *good manufacturing practices* as appropriate;
- d) reporting on adverse effects to the *Competent Authority*; and
- e) mechanisms for traceability and recall.

6. Retailing, use and traceability of veterinary medicines and biologicals

Veterinary legislation should provide a basis for actions to address the following elements:

- a) control over the distribution of veterinary medicines and biologicals and arrangements for traceability, recall and conditions of use;
- b) establishment of rules for the prescription and provision of veterinary medicines and biologicals to end users;
- c) restriction to authorised professionals and, as appropriate, authorised *veterinary para-professionals* of commerce in veterinary medicines and biologicals that are subject to prescription;
- d) the supervision by an authorised professional of organisations approved for holding and use of veterinary medicines and biologicals;
- e) the regulation of advertising claims and other marketing and promotional activities; and
- f) reporting on adverse effects to the *Competent Authority*.

Article 3.4.12.

Human food production chain

Veterinary legislation should provide a basis for actions to safeguard the human food production chain through controls at all critical steps, consistent with national food safety standards. The role of the *Veterinary Services* in food safety is described in Chapter 6.1.

1. General provisions

Veterinary legislation should provide a basis for actions to address the following elements:

- a) controls over all stages of the production, processing and distribution of food of animal origin;
- b) recording all significant animal and public health events that occur during primary production;
- c) giving operators of food production premises the primary responsibility for compliance with food safety requirements, including traceability established by the *Competent Authority*;
- d) inspection for compliance with food standards, where this is relevant to health or safety;
- e) inspection of premises;
- f) prohibition of the marketing of products not fit for human consumption; and
- g) provisions for recall from the marketplace of all products likely to be hazardous for human or animal health.

2. Products of animal origin intended for human consumption

Veterinary legislation should provide a basis for actions to address the following elements:

- a) arrangements for inspection and audit;
- b) the conduct of inspection and audit;
- c) health standards; and
- d) the application of health identification marks that are visible to the intermediary or final user.

The *Competent Authority* should have the necessary powers and means to rapidly withdraw any products deemed to be hazardous from the food chain or to prescribe uses or treatments that ensure the safety of such products for human or animal health.

3. Operators responsible for premises and establishments pertaining to the food chain

Veterinary legislation should provide a basis for actions to address the following elements as appropriate:

- a) registration of premises and establishments by the *Competent Authority*;
- b) the use of *risk*-based management procedures; and
- c) prior authorisation of operations that are likely to constitute a significant *risk* to human or animal health.

Article 3.4.13.

Import and export procedures and veterinary certification

Veterinary legislation should provide a basis for actions to address the elements relating to import and export procedures and veterinary certification referred to in Section 5.

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

Article 7.1.1.

Definition

Animal welfare means how an *animal* is coping with the conditions in which it lives. An *animal* is in a good state of *welfare* if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear, and distress.

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

Article 7.1.2.

Guiding principles for animal welfare

- 1) That there is a critical relationship between animal health and *animal welfare*.
- 2) That the internationally recognised 'five freedoms' (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and *disease*; and freedom to express normal patterns of behaviour) provide valuable guidance in *animal welfare*.
- 3) That the internationally recognised 'three Rs' (reduction in numbers of *animals*, refinement of experimental methods and replacement of *animals* with non-animal techniques) provide valuable guidance for the use of *animals* in science.
- 4) That the scientific assessment of *animal welfare* involves diverse elements which need to be considered together, and that selecting and weighing these elements often involves value-based assumptions which should be made as explicit as possible.
- 5) That the use of *animals* in agriculture, transport and traction, education and research, and for companionship, recreation and entertainment, makes a major contribution to the wellbeing of people.
- 6) That the use of *animals* carries with it an ethical responsibility to ensure the *welfare* of such *animals* to the greatest extent practicable.
- 7) That improvements in farm *animal welfare* can often improve productivity and food safety, and hence lead to economic benefits.
- 8) That, as living assets, working animals play a significant role in supporting the livelihoods of families who own them and in fulfilling socioeconomic functions that benefit animal owning households and the wider community including national economies.
- 9) That equivalent outcomes based on performance criteria, rather than identical systems based on design criteria, be the basis for comparison of *animal welfare* standards and recommendations.

Article 7.1.3.

Scientific basis for recommendations

- 1) *Welfare* is a broad term which includes the many elements that contribute to an *animal's* quality of life, including those referred to in the 'five freedoms' listed above.
- 2) The scientific assessment of *animal welfare* has progressed rapidly in recent years and forms the basis of these recommendations.
- 3) Some measures of *animal welfare* involve assessing the degree of impaired functioning associated with injury, *disease*, and malnutrition. Other measures provide information on *animals'* needs and affective states such as hunger, pain and fear, often by measuring the strength of *animals'* preferences, motivations and aversions. Others assess the physiological, behavioural and immunological changes or effects that *animals* show in response to various challenges.
- 4) Such measures can lead to criteria and indicators that help to evaluate how different methods of managing *animals* influence their *welfare*.

Article 7.1.4.

General principles for the welfare of animals in livestock production systems

- 1) Genetic selection should always take into account the health and *welfare* of *animals*.
- 2) *Animals* chosen for introduction into new environments should be suited to the local climate and able to adapt to local *diseases*, parasites and nutrition.
- 3) The physical environment, including the substrate (walking surface, resting surface, etc.), should be suited to the species so as to minimise risk of injury and transmission of *diseases* or parasites to *animals*.
- 4) The physical environment should allow comfortable resting, safe and comfortable movement including normal postural changes, and the opportunity to perform types of natural behaviour that *animals* are motivated to perform.
- 5) Social grouping of *animals* should be managed to allow positive social behaviour and minimise injury, distress and chronic fear.
- 6) For housed *animals*, air quality, temperature and humidity should support good animal health and not be aversive. Where extreme conditions occur, *animals* should not be prevented from using their natural methods of thermo-regulation.
- 7) *Animals* should have access to sufficient feed and water, suited to the *animals'* age and needs, to maintain normal health and productivity and to prevent prolonged hunger, thirst, malnutrition or dehydration.
- 8) *Diseases* and parasites should be prevented and controlled as much as possible through good management practices. *Animals* with serious health problems should be isolated and treated promptly or killed humanely if treatment is not feasible or recovery is unlikely.
- 9) Where painful procedures cannot be avoided, the resulting pain should be managed to the extent that available methods allow.
- 10) The handling of *animals* should foster a positive relationship between humans and *animals* and should not cause injury, panic, lasting fear or avoidable stress.
- 11) Owners and handlers should have sufficient skill and knowledge to ensure that *animals* are treated in accordance with these principles.

CHAPTER X.X.

INFECTION WITH *TAENIA SOLIUM*

Article X.X.1.

General provisions

Infection with *Taenia solium* is a zoonotic parasitic infection of pigs. *Taenia solium* is a cestode (tapeworm) that is endemic in large areas ~~major parts~~ of Latin America, Asia and sub-Saharan Africa. The adult ~~worm~~ 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 harbour the larval stage when eggs shed in faeces of infected humans are ingested. The most severe form of the infection by the larval stage in humans is neurocysticercosis which causes 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, ~~especially~~ epilepsy.

~~For the purposes of the *Terrestrial Code*, infection with *T. solium* is defined as a zoonotic parasitic infection of pigs.~~

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 component~~ in preventing and controlling *T. solium* transmission.

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

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 X.X.2. *Veterinary Authorities* should apply the recommendations in this chapter.

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

Article X.X.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 or zone*:

Annex XV (contd)

- 1) processed fat;
- 2) casings;
- 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 X.X.3.

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

The *Veterinary Authority* or and other *Competent Authorities* and the public health authority 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 ~~also implement~~ the following measures:

1. Prevention of infection in pigs

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

- 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 food crops;
- d) providing adequate toilet and sanitation facilities for people in pig rearing establishments ~~the involvement of human tapeworm carriers in pig rearing.~~

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 the carcass of a pig has 20 or more cysticerci, 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 the carcass of a pig has ~~less~~ fewer than 20 cysticerci, all pigs from the same establishment of origin should be treated in accordance with Article X.X.6. or 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-;

Annex XV (contd)

- iv) post-mortem examination of pigs for slaughter from known infected establishments should be intensified until the infection has been eliminated from the establishment.

An optimal control programme should include detection and treatment of human tapeworm carriers.

Article X.X.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;
- 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 X.X.3.

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

Article X.X.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;

Annex XV (contd)

or

cb) has been processed to ensure the inactivation of the *T. solium* cysticerci in accordance ~~conformity~~ with one of the procedures referred to in Article X.X.6.

Article X.X.6.

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

For the inactivation of *T. solium* cysticerci 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 ~~below~~ for at least ten days or any time/ and temperature equivalent.

— Text deleted.

NOTE:

The Code Commission proposes the following amendments in this chapter, taking into consideration Member Countries' comments and the technical advices from Scientific Commission, *ad hoc* Groups and other OIE experts. The rationale for the amendments is given in the reports of Scientific Commission and *ad hoc* groups as well as in Part A of this report.

The Code Commission strongly encourages that Member Countries consult all relevant reports when reviewing and preparing comments on this revised chapter.

Relevant reports of Scientific Commission and *ad hoc* groups are:

- [September 2014 report of the Scientific Commission](#)
- [February 2014 report of the OIE *ad hoc* Group on the evaluation of foot and mouth disease status of Member Countries](#)

CHAPTER 8.7.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

Article 8.7.1.

- 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. Infection of dromedaries and South American camelids has not been shown 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 any FMDV.
- 3) The following defines the occurrence of FMDV *infection*:
 - a) FMDV has been isolated from a sample from an animal listed in point 2; or
 - b) viral antigen or viral ribonucleic acid (RNA) specific to a serotype of 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 confirmed or suspected *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 confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.

Annex XVI (A) (contd)

- 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 is 14 days.
- 6) *Infection* with FMDV can give rise to *disease* of variable severity and to FMDV transmission. 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) The chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of FMDV *infection* and transmission, in the absence of clinical signs.
- 8) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.7.2.

FMD free country or zone 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* where *vaccination* is not practised should be protected by the application of animal health 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*.

To qualify for inclusion in the existing list of FMD free countries or *zones* 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 evidence of FMDV *infection* has been found;
 - c) no *vaccination* against FMD has been carried out;
- 3) supply documented evidence that for the past 12 months:
 - a) *surveillance* in accordance with Articles 8.7.40. to 8.7.42. has been implemented to detect clinical signs of FMD and show absence of:
 - i) FMDV *infection* in non-vaccinated animals;
 - ii) FMDV transmission in previously vaccinated animals when transition is made from FMD free country or *zone* where *vaccination* is practised to FMD free country or *zone* where *vaccination* is not practised;
 - b) regulatory measures for the prevention and early detection of FMD have been implemented;

Annex XVI (A) (contd)

- 4) describe in detail and 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 proposed FMD free *zone*;
 - b) the boundaries and measures of a *protection zone*, if applicable;
 - c) the system for preventing the entry of FMDV into the proposed FMD free country or *zone*;
 - 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 8.7.8., 8.7.9. and 8.7.12.;
 - e) no vaccinated animal has been introduced except in accordance with Articles 8.7.8. and 8.7.9.

The Member Country or the proposed free *zone* will be included in the list of FMD free countries or *zones* 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 according to 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* of the 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 a primary purpose to exhibit *animals* or preserve 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 identifiable 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* where *vaccination* is not practised to be assigned to a new *zone* adjacent to another FMD free *zone* where *vaccination* is not practised, it should be indicated 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 8.7.3.

FMD free country or zone where vaccination is practised

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

Annex XVI (A) (contd)

Susceptible animals in the FMD free country or *zone* where *vaccination* is practised should be protected by the application of animal health 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* 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 during the past 12 months;
- 3) supply documented evidence that:
 - a) *surveillance* in accordance with Articles 8.7.40. to 8.7.42. has been implemented to detect clinical signs of FMD and show absence of:
 - i) FMDV *infection* in non-vaccinated animals;
 - ii) FMDV transmission 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) the vaccine used complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection;
- 4) describe in detail and supply 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*;
 - b) the boundaries and measures of a *protection zone*, if applicable;
 - c) the system for preventing the entry of FMDV into the proposed FMD free country or *zone*, in particular the measures described in Articles 8.7.8., 8.7.9. and 8.7.12.;
 - d) the control of the movement of susceptible animals and their products into the proposed FMD free country or *zone*.

The Member Country or the proposed free *zone* will be included in the list of FMD free countries or *zones* 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 according to the requirements in Chapter 1.1.

If a Member Country that meets the requirements of a FMD free country or *zone* where *vaccination* is practised wishes to change its status to FMD free country or *zone* 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. The status of this country or *zone* remains unchanged until compliance with Article 8.7.2. 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 8.7.2., evidence should be provided within three months that it complies with Article 8.7.3. Otherwise the status will be withdrawn.

In the event of the application for the status of a FMD free *zone* where *vaccination* is practised to be assigned to a new *zone* adjacent to another FMD free *zone* where *vaccination* is practised, it should be indicated 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 8.7.4.

FMD free compartment

A FMD free *compartment* 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* 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 according to Articles 8.7.40. to 8.7.42. 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 FMDV *infection* has been found during the past 12 months;
 - 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 should only enter the *compartment* in accordance with relevant articles in this chapter;
 - f) documented evidence shows that *surveillance* in accordance with Articles 8.7.40. to 8.7.42. 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 according to point 1.

Annex XVI (A) (contd)

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 ten-kilometre radius of the *compartment* during the past three months.

Article 8.7.5.

FMD infected country or zone

For the purposes of this chapter, a FMD infected country or *zone* 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 8.7.6.

Establishment of a containment zone within a FMD free country or zone

In the event of limited *outbreaks* within a FMD free country or *zone*, 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, standstill of animal movements has been imposed on the suspected *establishments* and animal movement control has been imposed in the country or *zone*, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;
- 2) on confirmation, standstill of susceptible animals has been imposed in the *containment zone* and movement controls have been reinforced;
- 3) the boundaries of the *containment zone* may only be established once 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 *outbreak* 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 8.7.1. after the application of a *stamping-out policy* to the last detected *case*;
- 7) the susceptible domestic and *captive wild* animal populations within the *containment zone* are clearly identifiable as belonging to the *containment zone*;
- 8) *surveillance* in accordance with Articles 8.7.40.to 8.7.42. is in place in the *containment zone* and in the rest of the country or *zone*;
- 9) animal health 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 8.7.7., once the *containment zone* has been approved, by 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 FMDV transmission in the *containment zone*, the approval of the *containment zone* is withdrawn. The FMD status of the whole country or *zone* is suspended until the relevant requirements of Article 8.7.7. are fulfilled.

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 8.7.7.

Article 8.7.7.

Recovery of free status (see Figures 1 and 2)

- 1) When a FMD case occurs in a FMD free country or *zone* 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 case where a *stamping-out policy*, without emergency *vaccination*, and *surveillance* are applied in accordance with Articles 8.7.40. to 8.7.42.; or
 - b) three months after the disposal of the last case or the *slaughter* of all vaccinated animals whichever occurred last, where a *stamping-out policy*, emergency *vaccination* and *surveillance* in the remaining animals are applied in accordance with Articles 8.7. 40. to 8.7.42.; or
 - c) six months after the disposal of the last case 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* are applied in accordance with Articles 8.7.40. to 8.7.42. However, this requires a serological survey based on the detection of antibodies to nonstructural proteins of FMDV to demonstrate the absence of *infection* in the remaining vaccinated population. This period can be reduced to three months if effectiveness of *vaccination* using vaccine compliant with the *Terrestrial Manual* is demonstrated and additional serological *surveillance* for antibodies to nonstructural proteins is carried out in all vaccinated *herds*. This includes sampling all vaccinated ruminants and their non-vaccinated offspring, and a representative number of animals of other species, based on an acceptable level of confidence.

The country or *zone* will regain the 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 8.7.2.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.7.2. applies.

- 2) When a FMD case occurs in a FMD free country or *zone* where *vaccination* is not practised, the following waiting period is required to gain the status of FMD free country or *zone* where *vaccination* is practised: three months after the disposal of the last case 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 8.7.40. to 8.7.42., and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of FMDV.

The country or *zone* can gain 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.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.7.3. applies.

Annex XVI (A) (contd)

- 3) When a FMD *outbreak* or FMDV transmission occurs in a FMD free country or *zone* 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 *case* where a *stamping-out policy*, with emergency *vaccination*, and *surveillance* in accordance with Articles 8.7.40. to 8.7.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus transmission; 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 8.7.40. to 8.7.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus transmission.

Where an emergency *vaccination* is not applied, the above waiting periods do not apply, and Article 8.7.3. 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*, Article 8.7.4. 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* has been successfully eradicated within the *containment zone*.

Article 8.7.8.

Direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone (where vaccination either is or is not practised)

In order not to jeopardise the status of a free *zone*, FMD susceptible animals should only leave the *infected zone* if transported directly to *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 ten-kilometre radius of the *establishment* of origin for at least four weeks prior to movement;
- 4) the animals should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;
- 5) such a *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 subjected to thorough cleansing and *disinfection* immediately after use.

The animals should have been subjected to ante- and post-mortem inspection for FMD, with favourable results, within 24 hours before and after *slaughter* and the *meat* derived from them treated according to point 2 of Article 8.7.22. or Article 8.7.23. Other products obtained from the animals and any products coming into contact with them should be treated in such a way as to destroy any residual FMDV in accordance with Articles 8.7. 31. to 8.7. 38.

Article 8.7.9.

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

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

- 1) the *containment zone* has been officially established according to the requirements in Article 8.7.6.;
- 2) the animals should be 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 *abattoir* without coming into contact with other susceptible animals;
- 3) such an *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 *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The animals should have been subjected to ante- and post-mortem inspection for FMD, with favourable results, within 24 hours before and after *slaughter* and the *meat* derived from them treated according to point 2 of Article 8.7.22. or Article 8.7.23. Other products obtained from the animals and any products coming into contact with them should be treated in such a way as to destroy any residual FMDV in accordance with Articles 8.7.31. to 8.7.38.

Article 8.7.10.

Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartmentsFor 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* where *vaccination* is not practised or a FMD free *compartment*;
- 3) if transiting an *infected zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*.

Article 8.7.11.

Recommendations for importation from FMD free countries or zones 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* 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*.

Annex XVI (A) (contd)

Article 8.7.12.

Recommendations for importation from FMD infected countries or zonesFor 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) since birth, or
 - b) for the past 30 days, if a *stamping-out policy* is in force in the *exporting country or zone*, or
 - c) for the past 3 months, if a *stamping-out policy* is not in force in the *exporting country or zone*,
- 3) and that FMD has not occurred within the *establishment* of origin for the relevant period as defined in points 2 a) and 2 b) 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 ten-kilometre radius of the *establishment* during that period;
- 5) the animals were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

Article 8.7.13.

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

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

- 1) the donor animals:
 - 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 *zones* where *vaccination* is not practised or FMD free *compartments*;
 - c) were kept in an *artificial insemination centre* where none of the animals had a history of *infection*;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.7.14.

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

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

Annex XVI (A) (contd)

- 1) the donor animals:
 - 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* where *vaccination* is not practised or FMD free *compartments*;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.7.15.

Recommendations for importation from FMD free countries or zones 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 animals:
 - 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* where *vaccination* is practised;
 - c) either
 - i) have been vaccinated at least twice, with the last *vaccination* not less than one month and not more than six months prior to collection, unless protective immunity has been proven for more than six months;
 - 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 the provisions of 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 were kept showed any sign of FMD.

Article 8.7.16.

Recommendations for importation from FMD infected countries or zones

For frozen semen of domestic ruminants and pigs

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

- 1) the donor animals:
 - 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 no animal had been added in the 30 days before collection, and that FMD has not occurred within a ten-kilometre radius of the *artificial insemination centre* for the 30 days before and after collection;

Annex XVI (A) (contd)

- c) either
 - i) have been vaccinated at least twice, with the last *vaccination* not less than one month and not more than six month prior to collection, unless protective immunity has been proven for more than six months;
 - 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 the provisions of Chapters 4.5. and 4.6.;
 - b) was subjected, with negative results, to a test for evidence of FMDV if the donor animal 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 animals were kept showed any sign of FMD.

Article 8.7.17.

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 provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.7.18.

Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartmentsFor *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 *zones* where *vaccination* is not practised or FMD free *compartments*;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.7.13., 8.7.14., 8.7.15. or 8.7.16., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in accordance with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.7.19.

Recommendations for importation from FMD free countries or zones where vaccination is practisedFor *in vitro* produced embryos of cattle

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

Annex XVI (A) (contd)

- 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 *zones* where *vaccination* is practised;
 - c) either
 - i) have been vaccinated at least twice, with the last *vaccination* not less than one month and not more than six months prior to collection, unless protective immunity has been proven for more than six months;

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 8.7.13., 8.7.14., 8.7.15. or 8.7.16., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in accordance with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.7.20.

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

For fresh meat or meat products of FMD susceptible animals

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

- 1) have been kept in a FMD free country or *zones* where *vaccination* is not practised or FMD free *compartments*, or which have been imported in accordance with Article 8.7.10., Article 8.7.11. or Article 8.7.12.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 8.7.21.

Recommendations for importation from FMD free countries, or zones where vaccination is practised

For fresh meat and meat products of ruminants and pigs

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

- 1) have been kept in the FMD free country or *zone* where *vaccination* is practised, or which have been imported in accordance with Article 8.7. 10., Article 8.7. 11. or Article 8.7. 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.

Annex XVI (A) (contd)

Article 8.7.22.

Recommendations for importation from FMD infected countries or zones, 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 proven for more than six months, and not less than one month prior to *slaughter*;
 - c) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;
 - 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 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 to ante- and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;
- 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 above + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi muscle.

Article 8.7.23.

Recommendations for importation from FMD infected countries or zonesFor 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;

Annex XVI (A) (contd)

- 2) the *meat products* have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.7.31.;
- 3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMDV.

Article 8.7.24.

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

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*, or which have been imported in accordance with Article 8.7.10., Article 8.7.11. or Article 8.7.12.

Article 8.7.25.

Recommendations for importation from FMD infected countries or zones where an official control programme exists

For milk and milk products

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 8.7.35. and in Article 8.7.36.;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Article 8.7.26.

Recommendations for importation from FMD infected countries

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 8.7.27.

Recommendations for importation from FMD infected countries

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 8.7.32., 8.7.33. and 8.7.34.;
- 2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMDV.

Annex XVI (A) (contd)

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 8.7.28.

Recommendations for importation from FMD infected countries or zonesFor straw and forage

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

- 1) are free of grossly identifiable 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 minutes,
 - b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35–40 percent 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 8.7.29.

Recommendations for importation from FMD free countries or zones where vaccination either is or is not practisedFor 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* or which have been imported from a country, *zone*, or *compartment* free from FMD.

Article 8.7.30.

Recommendations for importation from FMD infected countries or zonesFor 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 8.7.37.

Article 8.7.31.

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:

Annex XVI (A) (contd)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 70°C or more.

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 ratio between water and protein that is not greater than 2.25:1.

Article 8.7.32.

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) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);
- 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) industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60–70°C;
- 5) storage of wool at 4°C for four months, 18°C for four weeks or 37°C for eight days.

Article 8.7.33.

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

Article 8.7.34.

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).

Annex XVI (A) (contd)

Article 8.7.35.

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 8.7.36.

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;
- 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;
- 3) UHT combined with another physical treatment referred to in point 2 above.

Article 8.7.37

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

For the inactivation of FMDV present in skins and trophies from *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;
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);
- 3) soaking, with agitation, in a 4 % (weight/volume) solution of sodium carbonate (Na_2CO_3) maintained at pH 11.5 or greater for at least 48 hours;
- 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 below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;
- 5) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2 % sodium carbonate (Na_2CO_3).

Article 8.7.38.

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

For the inactivation of FMDV present in casings of ruminants and pigs, the following procedures should be used: treating for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl, $a_w < 0.80$), or with phosphate supplemented salt containing 86.5 % NaCl, 10.7 % Na_2HPO_4 and 2.8 % Na_3PO_4 (weight/weight/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 8.7.39.

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 only towards defined *subpopulations*.

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 according to the requirements in Chapter 1.1.;
- 2) submit documented evidence of the capacity of the *Veterinary Services* to control FMD; one way of providing this evidence is through the OIE PVS Pathway;
- 3) submit a detailed plan of the programme to control and eventually eradicate FMD in the country or *zone* including:
 - a) the timeline;
 - b) the performance indicators for assessing the efficacy of the control measures to be implemented;
 - c) documentation indicating that the *official control programme* for FMD is applicable to the entire country;
- 4) submit a dossier on the epidemiology of FMD in the country describing the following:
 - a) the general epidemiology in the country highlighting the current knowledge and gaps and the progress that has been made in controlling FMD;
 - b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all FMD *outbreaks* in order to reduce the incidence of FMD *outbreaks* and to eliminate FMDV transmission 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) taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter;
 - b) 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;

Annex XVI (A) (contd)

- 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 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 according to 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 8.7.40.

General principles of surveillance

Articles 8.7.40. to 8.7.42. 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 Member Countries seeking endorsement by the OIE of their *official control programme* for FMD, in accordance with Article 8.7.39. *Surveillance* aimed at identifying *disease* and FMDV *infection* or transmission should cover domestic and *wildlife* species indicated in Article 8.7.1. point 2 within the country, *zone* or *compartment*.

A *surveillance* system in accordance with Chapter 1.4. should be the responsibility of the *Veterinary Authority* and provides 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 call for assistance from a team with expertise in FMD diagnosis and control.

The impact and epidemiology of FMD differ widely 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 proving freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMDV should differ significantly from an application designed to prove freedom from FMD for a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*.

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

A Member Country wishing to demonstrate FMD freedom where *vaccination* is not practised should show absence of FMDV *infection*.

A Member Country wishing to demonstrate FMD freedom where *vaccination* is practised should show that FMDV has not been transmitted in any susceptible populations. Within vaccinated populations, serological surveys to demonstrate the absence of FMDV transmission 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. Absence of FMDV *infection* should be demonstrated in any unvaccinated *subpopulations*.

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

Surveillance strategies employed in support of an OIE endorsed *official control programme* should show 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* and transmission and to understand the epidemiology of FMD as part of the *official control programme*.

It is incumbent upon the Member Country to 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*, are identified and managed. This should include provision of scientifically based supporting data.

Surveillance for FMD should be in the form of a continuing programme. *Surveillance* programmes to prove the absence of FMDV *infection* and transmission 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 employed to establish the prevalence of FMDV *infection* or to substantiate freedom from FMDV *infection* or transmission 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* or transmission in accordance with Chapter 1.4. and the epidemiological situation.

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

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.

Annex XVI (A) (contd)

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 positive reactors;
- control of *animal identification* and movements;
- other parameters of regional significance in historic FMDV transmission.

Following the use of routine and emergency *vaccination*, evidence should be provided to show 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 as standard operating procedure within the *surveillance* programme.

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

Article 8.7.41.

Methods of surveillance

1. Clinical surveillance

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

Clinical *surveillance* requires close 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 detected by either of these complementary diagnostic approaches. 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.

3. Serological surveillance

Serological *surveillance* aims at detecting 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* or transmission;
- 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 8.7.42.

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.

Annex XVI (A) (contd)

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* or transmission 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 proteins 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 proteins 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:

- a) *infection* with FMDV;
- b) *vaccination* against FMD;
- c) 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);
- d) non-specific reactivity of the serum in the tests used.

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 reactors. The diagnostic sensitivity of the confirmatory test should approach that of the screening test.

All *herds* with at least one *laboratory* confirmed reactor should be investigated. The investigation should examine all evidence, including the results of virological 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 and should document the status for each positive *herd*. Epidemiological investigation should be continued concurrently.

Clustering of seropositive reactions 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 by demonstrating an increase in the number of seropositive animals or an increase in antibody titre at the second sampling.

Annex XVI (A) (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 identifiable, 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 from the animals tested in the initial survey with emphasis on animals in direct contact with the reactors after an appropriate time has lapsed. 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, sentinel animals may also be used. These can be young, unvaccinated animals 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.

Follow-up of field and laboratory findings:

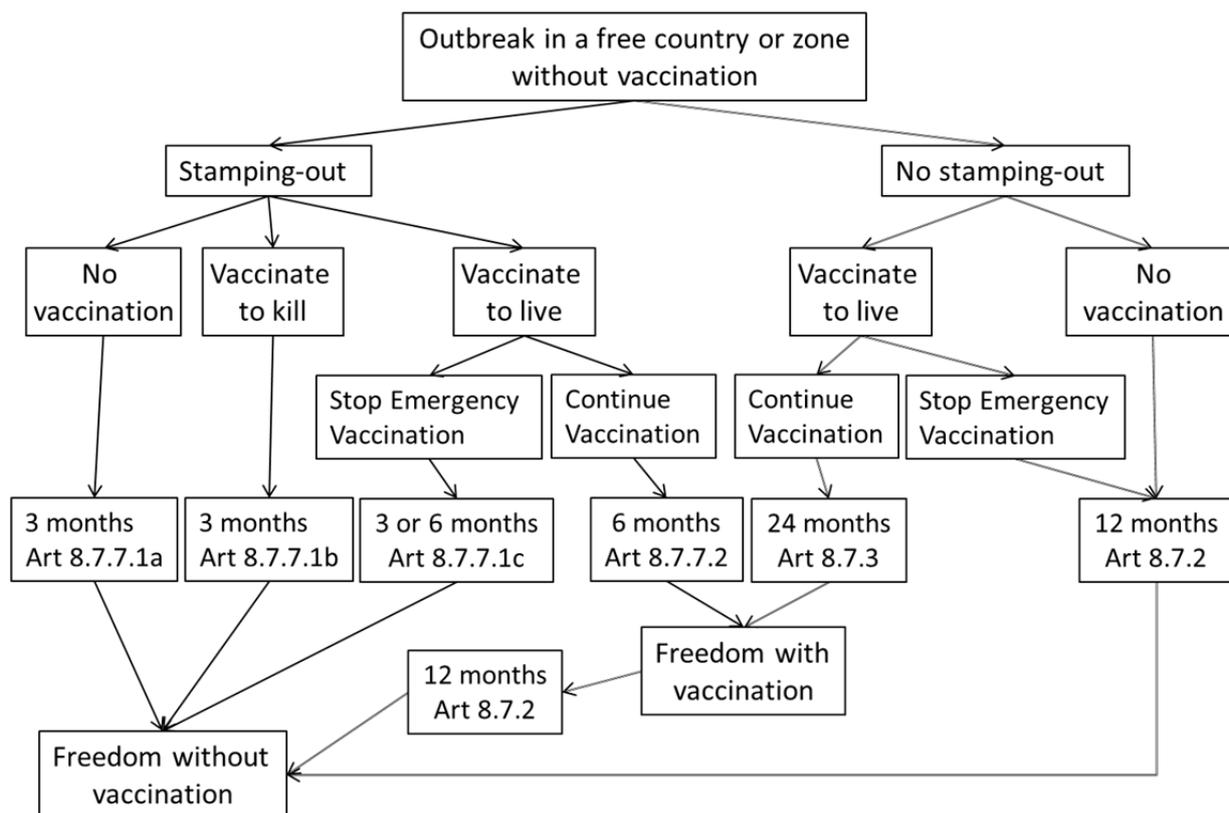
If transmission is proven then an *outbreak* is declared.

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* and transmission, 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 non-specific test system findings expected, susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animals should be investigated further.

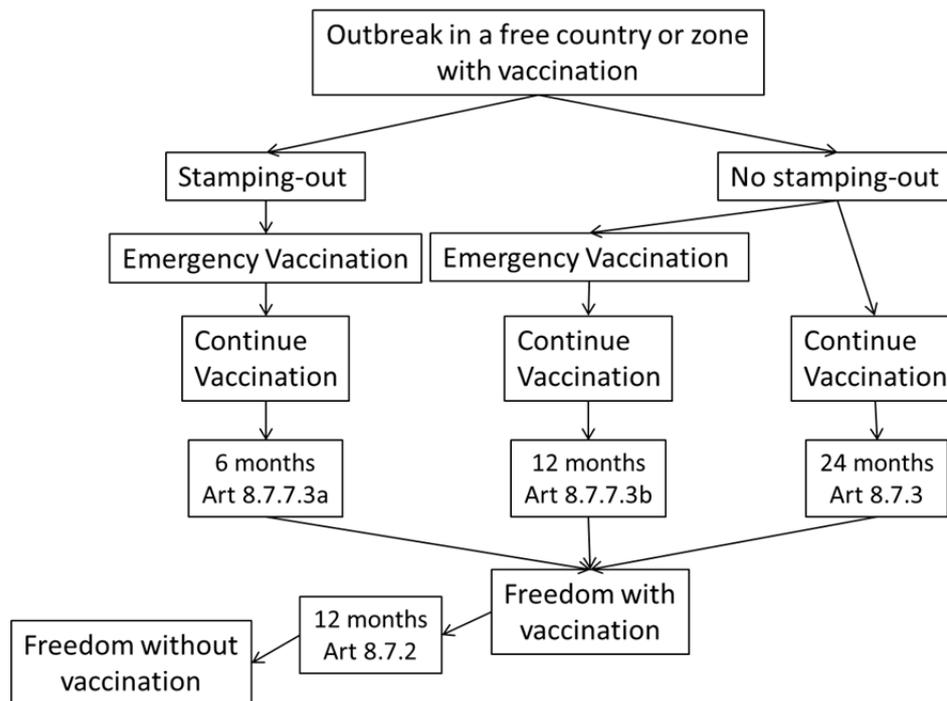
Annex XVI (A) (contd)

Figure 1. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak in a 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.

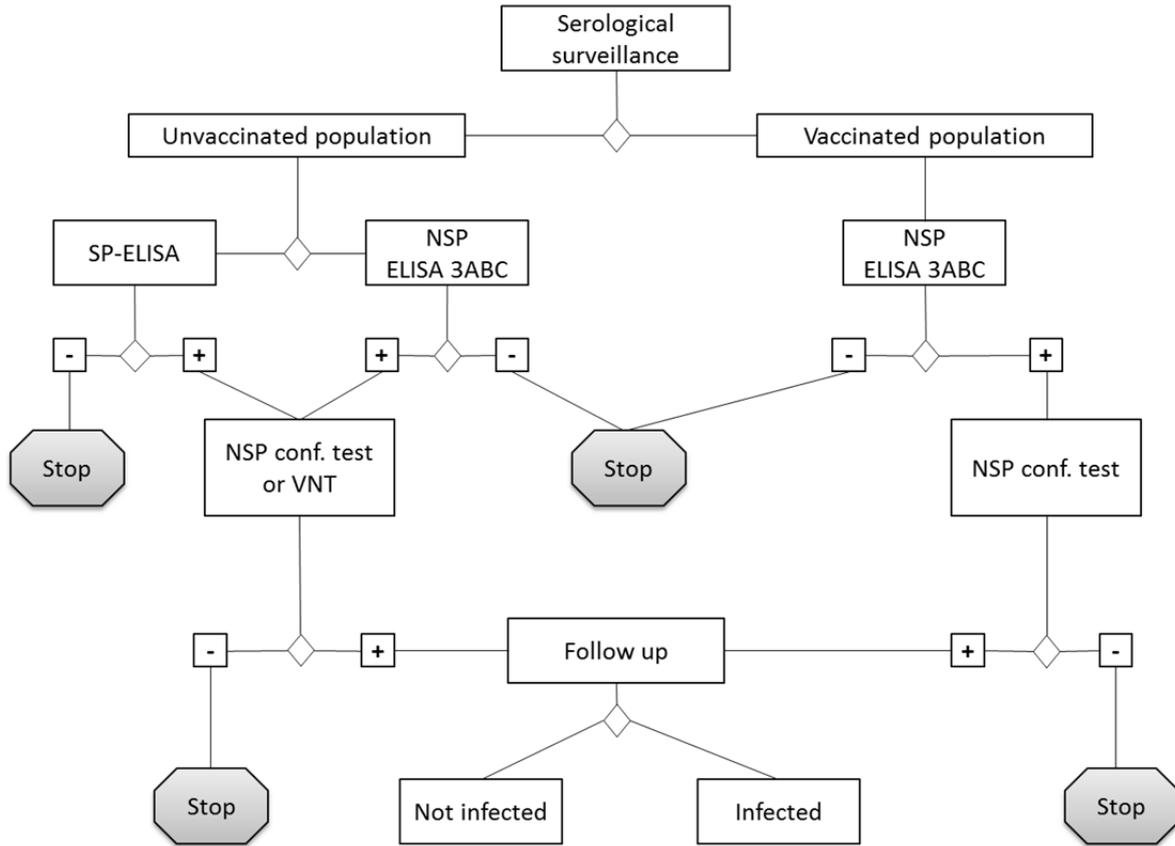
Figure 2. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak in a free country or zone where vaccination is practised



*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.*

Annex XVI (A) (contd)

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



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

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° XXX (administrative procedures) and Resolution N° XXXI (financial obligations) adopted during the 81st General Session in May 2013.

Article 1.6.2.

Endorsement by the OIE of an official control programme for FMD

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

Annex XVI (A) (contd)

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

[Article 1.6.3.]

[Article 1.6.4.]

[Article 1.6.5.]

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 8.7. of the *Terrestrial Code*,
as a FMD free country not practising vaccination

Please 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. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code* and describe how the *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), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, *modified stamping-out policy*, zoning).

Annex XVI (A) (contd)

- c) Vaccines and *vaccination*. Was FMD vaccine ever used? If so, when was the last *vaccination* carried out? What species were vaccinated? What was the fate of these animals?
- 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 detected illegal movements

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 8.7.40. to 8.7.42. 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).

Annex XVI (A) (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? 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 volume 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 XVI (A) (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 FMD risk materials (e.g. stock feed and animal bedding).
- 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 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;

Annex XVI (A) (contd)

- 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 8.7.2. 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 8.7.7., 8.7.2.1, 8.7.2.3 and 8.7.2.4. 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.).

FMD FREE COUNTRY WHERE VACCINATION IS PRACTISED
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Report of a Member Country which applies for recognition of status, under Chapter 8.7. of the <i>Terrestrial Code</i> , as a FMD free country practising vaccination
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Please 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. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code* and describe how the *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), 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.
- 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 detected illegal movements

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 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.

Annex XVI (A) (contd)

- 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 8.7.40. to 8.7.42. 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 8.7.42. 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? 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 volume 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 FMD risk materials (e.g. stock feed and animal bedding).
 - 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.

Annex XVI (A) (contd)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 8.7.3. 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 8.7.40. to 8.7.42. 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 8.7.7., 8.7.3.1, 8.7.3.3 and 8.7.3.4. 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.).

FMD FREE ZONE WHERE VACCINATION IS NOT PRACTISED

Report of a Member Country which applies for recognition of status,
under Chapter 8.7. of the *Terrestrial Code*,
as a FMD free zone not practising vaccination

Please 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. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code* and describe how the *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), 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*. If *vaccination* is used in the rest of the country, 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. of the *Terrestrial Manual*.

Annex XVI (A) (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 8.7.10. 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. 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. 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 8.7.40. to 8.7.42. 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).

Annex XVI (A) (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 animal health 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 volume and quantity.

Annex XVI (A) (contd)

- 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 FMD risk materials (e.g. stock feed and animal bedding).
 - 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;

Annex XVI (A) (contd)

- 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 8.7.4. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:

- 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 8.7.10.

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.7.7., 8.7.2.1, 8.7.2.3 and 8.7.2.4. 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.).

FMD FREE ZONE WHERE VACCINATION IS PRACTISED
 Report of a Member Country which applies for recognition of status,
 under Chapter 8.7. of the *Terrestrial Code*,
 as a FMD free zone practising vaccination

Please 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*.

Annex XVI (A) (contd)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. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code* and describe how the *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), 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. 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.
- 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 8.7.10. 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. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

Annex XVI (A) (contd)

- 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.

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.7.40. to 8.7.42. 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 8.7.42 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.

Annex XVI (A) (contd)

- 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 animal health 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 the country or *zone* of origin, the species and the volume 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:

Annex XVI (A) (contd)

- animals,
 - genetic material (semen and embryos),
 - animal products,
 - *veterinary medicinal products* (i.e. biologics),
 - other FMD risk materials (e.g. stock feed and animal bedding).
- 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 8.7.5. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:

- a) that there has been no *outbreak* of FMD for the past two years,
- b) no evidence of FMDV transmission for the past 12 months,

Annex XVI (A) (contd)

- c) *surveillance* for FMD and FMDV transmission in accordance with Articles 8.7.40 to 8.7.42. is in operation.

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.7.7., 8.7.3.1, 8.7.3.3 and 8.7.3.4. 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.).

[Article 1.6.6.]

[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 8.7. of the *Terrestrial Code*

Please 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 Services* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code* and describe how the *Veterinary Services* supervise, control and maintain all FMD related activities in the country and any *zones*. Provide maps and tables wherever possible.

Annex XVI (A) (contd)

- 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.
- 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 8.7.40 to 8.7.42. of the *Terrestrial Code* and Chapter 2.1.5. of 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.

Annex XVI (A) (contd)

- 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, *slaughterhouse*, 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 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 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.
 - 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.

Annex XVI (A) (contd)

- 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 detected illegal imports, if available.

7. Control measures and emergency response

- a) Give details of any written guidelines, including emergency response plans, available to the *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 in the *Terrestrial Manual* in order to enable demonstration of absence 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 8.7.39. of the *Terrestrial Code*.

CHAPTER 8.7.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

Article 8.7.1.

Introduction

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. Infection of dromedaries and South American camelids has not been shown to be of epidemiological significance.

1-2) 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 any foot and mouth disease virus (FMDV)*.

23) The following defines the occurrence of FMDV *infection*:

Detection in a sample from an animal listed above, of the virus, viral antigen, nucleic acid or virus-specific antibodies that are not a consequence of vaccination by a test as specified in the Terrestrial Manual.

a) *FMDV has been isolated from a sample from an animal listed in point 2); or*

b) *viral antigen or viral ribonucleic acid (RNA) specific to a serotype of 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 confirmed or suspected 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 confirmed or suspected outbreak of FMD, or giving cause for suspicion of previous association or contact with FMDV.*

34) The following defines the occurrence of FMDV *circulation*:

Transmission of FMDV in a vaccinated population, as is demonstrated by clinical signs or change in virological or serological evidence status indicative of recent infection, even in the absence of clinical signs.

45) For the purposes of the *Terrestrial Code*, the *incubation period* for *of* FMD is 14 days.

5) ~~Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection with FMDV*. Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contact between them. Amongst *Camelidae* only Bactrian camels (*Camelus bactrianus*) are of sufficient susceptibility to have potential for epidemiological significance. South American camelids and dromedaries are not considered of epidemiological importance significance.~~

Annex XVI (B) (contd)

For the purposes of this chapter, ruminants include ~~animals~~ of the family of Camelidae (except *Camelus dromedarius*).

For the purposes of this chapter, a case is an ~~animal~~ infected with FMD virus (FMDV).

6) ~~Infection with FMDV can give rise to disease of variable severity and to FMDV circulation transmission. FMDV may persist infection in the pharynx and associated lymph nodes of in ruminants may persist for a variable but limited period of time beyond 28 days. Such animals have been termed carriers leading to carriers. However, the only persistently infected species from which Although live FMDV can be recovered from carriers, transmission of FMDV from these carriers has not been proven is the except from for African buffalo (*Syncerus caffer*).~~

7) The chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of FMDV infection with and transmission, FMDV in the absence of clinical signs.

The following defines the occurrence of FMDV ~~infection~~:

- 1- ~~FMDV has been isolated and identified as such from an animal or a product derived from that animal; or;~~
- 2- ~~viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of FMDV has been identified in samples from one or more animals, whether showing clinical signs consistent with FMD or not, or epidemiologically linked to a confirmed or suspected outbreak of FMD, or giving cause for suspicion of previous association or contact with FMDV; or~~
- 3- ~~antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more animals showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected outbreak of FMD, or giving cause for suspicion of previous association or contact with FMDV.~~

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

Article 8.7.2.

FMD free country or zone 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 where vaccination is not practised should be protected from neighbouring infected countries by the application of animal health measures that effectively prevent the entry of FMDV the virus 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 XVI (B) (contd)

To qualify for inclusion in the existing list of FMD free countries or zones 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 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 since the cessation of vaccination;~~
- 3) supply documented evidence that for at least the past 12 months:
 - a) ~~surveillance for FMD and FMDV infection~~ in accordance with Articles 8.7.4240. to 8.7.5.4742. and Article 8.5.49. is in operation has been implemented to detect clinical signs of FMD and show absence of:
 - i) FMDV infection in non-vaccinated animals;
 - ii) FMDV transmission in previously vaccinated animals when transition is made from FMD free country or zone where vaccination is practised to FMD free country or zone where vaccination is not practised;
 - b) regulatory measures for the prevention and early detection, ~~prevention and control~~ of FMD have been implemented;
- 4) describe in detail and supply documented evidence that for at least the past 12 months the following these have been are properly implemented and supervised: ~~the boundaries and measures of a protection zone, if applicable.~~
 - a) in the case of a FMD free zone, the boundaries of the proposed FMD free zone;
 - b) the boundaries and measures of a protection zone, if applicable;
 - c) the system for preventing the entry of FMDV the virus into the proposed FMD free country or zone;
 - d) the control of the movement of susceptible animals, their meat and other products into the proposed FMD free country or zone, in particular if the measures procedures described in Articles 8.7.8., 8.7.9. and 8.7.12. are implemented;
 - e) no vaccinated animal has been introduced during the past 12 months except in accordance with Articles 8.7.8. and 8.7.9.

The Member Country or the proposed free zone will be included in the list of FMD free countries or zones where *vaccination* is not practised only after the submitted evidence, based on the provisions of Article 1.6.5., 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 according to the requirements in Chapter 1.1.

Annex XVI (B) (contd)

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

- = the zoological collection has a primary purpose to exhibit animals or preserve rare species, and should be identified in advance, 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 identifiable 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 active clinical surveillance for at least 12 months after vaccination.

In the event of the application for the status of an FMD free zone where vaccination is not practised to be assigned to a new zone adjacent to another FMD free zone where vaccination is not practised, it should be indicated 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 8.7.3.

FMD free country or zone 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 where vaccination is practised should be protected from neighbouring infected countries by the application of animal health measures that effectively prevent the entry of FMDV the virus 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 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 outbreak of FMD during the past two years;
 - b) there has been no evidence of FMDV circulation/transmission has been found during the past 12 months;

- 3) supply documented evidence that:
- a) surveillance for FMD and FMDV circulation in accordance with Articles 8.5.4240. to 8.5.4746. and Article 8.5.49. is in operation;
 - a) surveillance in accordance with Articles 8.7.40. to 8.7.42. has been implemented to detect clinical signs of FMD and show absence of:
 - i) FMDV infection in non-vaccinated animals;
 - ii) FMDV transmission in vaccinated animals;
 - b) regulatory measures for the prevention and early detection, prevention and control of FMD have been implemented;
 - c) routine compulsory systematic vaccination in the target population is has been carried out to achieve adequate vaccination coverage and population immunity for the purpose of the prevention of FMD;
 - d) the vaccine used complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection;
- 4) describe in detail and supply documented evidence that these the following have been are properly implemented and supervised the boundaries and measures of a protection zone, if applicable.:
- a) in case of FMD free zone, the boundaries of the proposed FMD free zone;
 - b) the boundaries and measures of a protection zone, if applicable;
 - c) the system for preventing the entry of the virus EMDV into the proposed FMD free country or zone, (in particular if the measures procedure described in Articles 8.7.8., 8.7.9. and 8.7.12. is implemented);
 - d) the control of the movement of susceptible animals animals and their products into the proposed FMD free country or zone.

The Member Country or the proposed free zone will be included in the list of FMD free countries or zones where vaccination is practised only after the submitted evidence, based on the provisions of Article 1.6.5., 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 according to the requirements in Chapter 1.1.

If a Member Country that meets the requirements of an FMD free country or zone where vaccination is practised wishes to change its status to FMD free country or zone 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. The status of this country or zone remains unchanged until compliance with Article 8.7.2. 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 8.7.2., evidence should be provided within 3 three months that it they complies with Article 8.7.3. Otherwise the status will be withdrawn. the status of this country remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV infection has not occurred during that period.

Annex XVI (B) (contd)

In the event of the application for the status of an FMD free zone where vaccination is practised to be assigned to a new zone adjacent to another FMD free zone where vaccination is practised, it should be indicated 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 8.7.4.

FMD free zone where vaccination is not practised

~~An FMD free zone where vaccination is not practised can be established in either an FMD free country where vaccination is practised or in a country of which parts are infected. In defining such a zones the principles of Chapter 4.3. should be followed. Susceptible animals in the FMD free zone should be protected from the rest of the country and from neighbouring countries if they are of a different animal health status by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a protection zone.~~

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

- ~~1. have a record of regular and prompt animal disease reporting;~~
- ~~2. send a declaration to the OIE stating that within the proposed FMD free zone:~~
 - ~~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 8.5.10.;~~
- ~~3. supply documented evidence that:~~
 - ~~a) surveillance for FMD and FMDV infection in accordance with Articles 8.5.42. to 8.5.47. and Article 8.5.49. is in operation;~~
 - ~~b) regulatory measures for the early detection, prevention and control of FMD have been implemented;~~
- ~~4. describe in detail and supply documented evidence that these are properly implemented and supervised:~~
 - ~~a) the boundaries of the proposed FMD free zone;~~
 - ~~b) the boundaries and measures of a protection zone, if applicable;~~
 - ~~c) the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMD free zone (in particular if the procedure described in Article 8.5.10. is implemented).;~~

~~The proposed free zone will be included in the list of FMD free zones where vaccination is not practised only after the submitted evidence has been accepted by the OIE.~~

~~The information required in points 2, 3 and 4 b) c) above should 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 according to the requirements in Chapter 1.1.~~

Article 8.7.5.

FMD free zone where vaccination is practised

An FMD free zone where vaccination is practised can be established in either an FMD free country where vaccination is not practised or in a country of which parts are infected. In defining such zones the principles of Chapter 4.3. should be followed. Susceptible animals in the FMD free zone where vaccination is practised should be protected from neighbouring countries or zones if they are of a lesser animal health status by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a protection zone.

To qualify for inclusion in the list of FMD free zones where vaccination is practised, a Member should:

1. have a record of regular and prompt animal disease reporting;
2. send a declaration to the OIE that within the proposed FMD free zone;
 - a) there has been no outbreak of FMD for the past two years;
 - b) no evidence of FMDV circulation has been found during the past 12 months;
3. supply documented evidence that:
 - a) surveillance for FMD and FMDV infection/circulation in accordance with Articles 8.5.42. to 8.5.47. and Article 8.5.49. is in operation;
 - b) regulatory measures for the early detection, prevention and control of FMD have been implemented;
 - c) routine vaccination is carried out for the purpose of the prevention of FMD;
 - d) the vaccine used complies with the standards described in the *Terrestrial Manual*;
4. describe in detail and supply documented evidence that these are properly implemented and supervised:
 - a) the boundaries of the proposed FMD free zone;
 - b) the boundaries and measures of a protection zone, if applicable;
 - c) the system for preventing the entry of the virus (including the control of the movement of susceptible animals) into the proposed FMD free zone (in particular if the procedure described in Article 8.5.10. is implemented).

The proposed free zone will be included in the list of FMD free zones where vaccination is practised only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3 and 4 b) c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3 b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that has a zone which meets the requirements of a FMD free zone where vaccination is practised wishes to change the status of the zone to FMD free zone where vaccination is not practised, the status of this zone remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV infection has not occurred in the said zone during that period.

Annex XVI (B) (contd)

Article 8.7.46.

FMD free compartment

An FMD free *compartment* can be established in either an 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 an FMD free *compartment* should:

- 1) have a record of regular and prompt animal *disease* reporting and if not FMD free, have an **official control programme** ~~official control programme~~ and a *surveillance* system for FMD in place according to Articles 8.7.4240. to 8.7.4742. and ~~Article 8.56.4946.~~ that allows an accurate 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 outbreak** of FMD during the past 12 months;
 - b) no evidence of FMDV *infection* has been found during the past 12 months;
 - c) **vaccination against FMD is prohibited either:**
 - i) ~~no vaccination against FMD has been carried out during the past 12 months; no vaccinated animal has been introduced during the past 12 months; or~~
 - ii) ~~compulsory systematic vaccination is carried out and the vaccine used complies with the standards described in the Terrestrial Manual, including appropriate vaccine strain selection;~~
 - d) **no animal vaccinated against FMD within the past 12 months is in the compartment;**
 - e) ~~no animal vaccinated against FMD within the past 12 months is in the compartment;~~
 - ede) animals, semen, **and** embryos **and animal products** should only enter the *compartment* in accordance with relevant articles in this chapter;
 - fe) documented evidence shows that *surveillance* in accordance with Articles 8.7.4240. to 8.7.474642. and ~~Article 8.5.49.~~ is in operation **for FMD and FMDV infection;**
 - gfg) 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*; ~~and~~
 - b) the *biosecurity plan* for FMD and FMDV *infection* **and, where applicable, the vaccination plan, to mitigate the risks identified by the surveillance carried out according to point 1 of Article 8.7.4.**

The *compartment* should be approved by the *Veterinary Authority*. The first approval should only be granted when no **case outbreak** of FMD has occurred within a ten-kilometre radius of the zone in which the compartment is situated, during the last past three months.

Article 8.7.5.7.

FMD infected country or zone

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

~~For the purposes of this chapter, an FMD infected zone is a zone that does not fulfil the requirements to qualify as either an FMD free zone where vaccination is not practised or an FMD free zone where vaccination is practised.~~

~~For the purposes of this chapter, a FMD infected country or zone 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 8.7.6.8.

Establishment of a containment zone within an FMD free country or zone

In the event of limited outbreaks within an FMD free country or zone, including within a protection zone, with or without vaccination, a single containment zone, which includes all ~~cases~~ outbreaks, ~~can~~ 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 ~~documented evidence~~ as soon as possible to the OIE, in support of the application, documented evidence that:

- 1) ~~the boundaries of the containment zone are established taking into consideration that~~ the outbreaks are limited based on the following factors:
 - a) ~~immediately~~ on suspicion, standstill of animal movements has been imposed on the suspected establishments and animal movement control has been imposed in the country or zone, and effective controls on the movement of other commodities mentioned in this chapter are in place a rapid response including notification has been made;
 - ~~2b)~~ on confirmation, standstill of susceptible animals has been imposed in the containment zone and movement controls have been reinforced; standstill of animal movements has been imposed, and effective controls on the movement of other commodities mentioned in this chapter are in place;
 - ~~3e)~~ the boundaries of the containment zone may only be established once an epidemiological investigation (trace-back, trace-forward) is able to has demonstrated that the outbreaks are epidemiologically related and limited in number and geographic distribution has been completed;
 - d) ~~the infection~~ has been confirmed;
 - ~~4e)~~ the primary outbreak has been identified, and investigations on into the likely source of the outbreak have been carried out;
 - f) ~~all cases have been shown to be epidemiologically linked;~~

Annex XVI (B) (contd)

- g) ~~no new cases have been found in the containment zone within a minimum of two incubation periods as defined in Article 8.5.1. after the stamping-out of the last detected case is completed;~~
- 52) a stamping-out policy, with or without the use of emergency vaccination, has been applied;
- 63) no new cases have been found in the containment zone within a minimum of one two incubation periods as defined in Article 8.7.1. after the application of a stamping-out policy to the last detected case;
- 3-74) the susceptible domestic and captive wild animal populations within the containment zones should be clearly identifiable as belonging to the containment zone;
- 4-85) ~~increased passive and targeted surveillance in accordance with Articles 8.5.42.3 to 8.5.47. 8.7.40 to 8.7.42. and Article 8.5.49.46. is in place in the containment zone and in the rest of the country or zone has been carried out is in place and has not detected any evidence of FMDV infection;~~
- 5-96) animal health measures that effectively prevent the spread of the FMDV to the rest of the country or zone, taking into consideration physical and geographical barriers, are in place.
6. ~~ongoing surveillance in the containment zone is in place.~~

The free status of the areas outside the containment zone ~~would be~~ is suspended pending the establishment of while the containment zone is being established. The free status of these areas ~~may~~ could be reinstated irrespective of the provisions of Article 8.7.97., once the containment zone has been approved is clearly established, by complying with points 1 to 9 6 above. ~~The containment zone should be managed in such a way that it can~~ It should be demonstrated that Commodities from susceptible animals for international trade can be shown to have originated should be identified as to their origin, either from inside or outside the containment zone.

In the event of recurrence of FMDV circulation transmission in the containment zone, the approval of the containment zone is withdrawn. The FMD status of the whole country or zone is suspended until the relevant requirements of Article 8.7.7. are fulfilled.

The recovery of the FMD free status of the containment zone should follow the provisions of Article 8.7.97.

Article 8.7.9.

Recovery of free status (see Figures 1 and 2)

- 1) When an FMD case outbreak or FMDV infection occurs in an FMD free country or zone where vaccination is not practised, one of the following waiting periods is required to regain the this free status of FMD free country or zone where vaccination is not practised:
- three months after the disposal of the last case where a stamping-out policy, without emergency vaccination, and serological surveillance are applied in accordance with Articles 8.7.42.40. to 8.7.432., 8. 56.45. and 8. 56.49.46.; or
 - three months after the disposal of the last case or the slaughter of all vaccinated animals whichever occurred last, where a stamping-out policy, emergency vaccination and serological surveillance in the remaining animals are applied in accordance with Articles 8.7.42.40. to 8.7.432., 8. 56.45. and 8. 56.49.46.; or

Annex XVI (B) (contd)

- c) six months after the disposal of the last case or the last *vaccination whichever occurred last*, where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated animals, and *serological surveillance* are applied in accordance with Articles 8.7.4240. to 8.7.423., 8. 5.4745. and Article 8. 56.4946., provided that However, this requires a serological survey based on the detection of antibodies to nonstructural proteins of FMDV to demonstrates the absence of *infection* in the remaining vaccinated population. This period can be reduced to three months if effectiveness of vaccination using vaccine compliant with Terrestrial Manual is demonstrated and additional serological surveillance for antibodies to nonstructural proteins is carried out in all vaccinated herds in accordance to Article 8. 56.45. point 2 is carried out. This includes sampling all vaccinated ruminants and their non-vaccinated offspring, and a representative number of animals of other species, based on an acceptable level of confidence.

The country or zone will regain the status of FMD free country or zone where vaccination is not practised only after the submitted evidence, based on the provisions of Article 1.6.5., 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 8.7.2.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.7.2. applies.

- 2) When an FMD case outbreak or FMDV infection occurs in an FMD free country or zone where vaccination is not practised, the following waiting period is required to gain the status of FMD free country or zone where vaccination is practised: 6three months after stamping out of the disposal of the last case where a stamping-out policy has been applied and adoption of a continued vaccination policy has been adopted, provided that serological surveillance is applied in accordance with Articles 8.7.40. to 8.7.42. and Articles 8. 56.44. to 8. 56.46. and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of FMDV circulationtransmission.

The country or zone can gain the status of FMD free country or zone where vaccination is practised only after the submitted evidence, based on the provisions of Article 1.6.5., has been accepted by the OIE.

Where a stamping-out policy is not practised, the above waiting periods do not apply, and Article 8.7.23. applies.

- 2-3) When an FMD outbreak or FMDV infection circulationtransmission occurs in an FMD free country or zone where vaccination is practised, one of the following waiting periods is required to regain the this free status of FMD free country or zone where vaccination is practised:

- a) 6-six months after the disposal of the last case where a *stamping-out policy*, with emergency *vaccination*, and *serological surveillance* in accordance with Articles 8.7.4240. to 8.7.42. and Articles 8. 56.44., 8.6.45 Point 1 and to 8. 56.468.5.45. and Article 8.5.49. are applied, provided that the *serological surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulationtransmission; or
- b) 182 months after the detection of the last case where a *stamping-out policy* is not applied, but where emergency *vaccination* and *serological surveillance* in accordance with Articles 8.7.4240. to 8.7.42. and Articles 8. 56.44., 8.6.45 Point 1 and to 8. 56.46. 8.5.47. and Article 8.5.49. are applied, provided that the *serological surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulationtransmission.

Annex XVI (B) (contd)

Where an emergency vaccination is not applied, the above waiting periods do not apply, and Article 8.7.3. 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 1.6.5., has been accepted by the OIE.

3.4) When an FMD case outbreak or FMDV infection occurs in an FMD free compartment, Article 8.7.64. applies. The waiting period in point 2a) and 2b) of Article 8.6.4. can be reduced to three months provided that the entire compartment has been depopulated, cleansed and disinfected.

5) Member Countries applying for the recovery of status should do so only when as soon as 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 as soon as the disease has been successfully eradicated within the containment zone.

Article 8.7.8-10.

Direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone (where vaccination either is or is not practised)

In order not to jeopardise the status of a free zone, FMD susceptible animals should only leave the *infected zone* if transported directly to *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 ten-kilometre radius of the *establishment* of origin for at least ~~three months~~ four weeks prior to movement;
- 4) the animals should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;
- 5) such a *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 subjected to thorough cleansing and *disinfection* immediately after use.

The ~~meat should be derived from~~ animals that should have been subjected to ante- and post-mortem inspection for FMD, with favourable results, within 24 hours before and after *slaughter* and ~~the meat derived from them~~ treated according to point 2 of Article 8.7.2522. or Article 8.7.2623. Other products obtained from the animals and any products coming into contact with them should be considered infected, and treated in such a way as to destroy any residual FMDV virus in accordance with Articles 8.7.3431. to 8.7.4138.

Animals moved into a free zone for other purposes should be moved under the supervision of the Veterinary Authority and comply with the conditions in Article 8.6.1412.

Article 8.7.9-11.

Direct transfer directly to slaughter of FMD susceptible animals from a containment zone for slaughter in to a free zone (where vaccination either is or is not practised) within a country

In order not to jeopardise the status of a free zone, FMD susceptible animals should only leave the *containment zone* if moved by mechanised transport directly to *slaughter* in the nearest designated *slaughterhouse/abattoir* under the following conditions:

- 1) the *containment zone* has been officially established according to the requirements in Article 8.7.8-9;
- 2) the animals should be 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 a *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 subjected to thorough cleansing and *disinfection* immediately after use.

The ~~meat should be derived from~~ animals ~~that should~~ have been subjected to ante- and post-mortem inspection for FMD, with favourable results, within 24 hours before and after *slaughter* and ~~the meat derived from them~~ treated according to point 2 of Article 8.7.25-22. or Article 8.7.26-23. Other products obtained from the animals and any products coming into contact with them should be treated in such a way as to destroy any residual **FMDV virus** in accordance with Articles 8.7.34-31. to 8.7.44-38.

Article 8.7.10-12.

Recommendations for importation from FMD free countries, or or zones or compartments where vaccination is not practised or FMD free compartments or FMD free compartmentsFor 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 an FMD free country, or or zone or compartment where *vaccination* is not practised; or a FMD free compartment or a FMD free compartment;
- 3) ~~have not been vaccinated;~~
- 4) if transiting an *infected zone*, were not exposed to any source of FMDV **infection** during transportation to the *place of shipment*;

Annex XVI (B) (contd)

Article 8.7.11-13.

Recommendations for importation from FMD free countries, ~~or~~ or zones ~~or compartments~~ 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 an FMD free country, ~~or zone or compartment~~ where *vaccination* is practised; ~~since birth or for at least the past three months~~; and
- 3) ~~when destined to an FMD free country or zone where vaccination is not practised, have not been vaccinated and were subjected, with negative results, to a tests for antibodies against FMD with negative results~~ virus when destined to an FMD free country or zone where vaccination is not practised;
- 4) if transiting an *infected zone*, were not exposed to any source of FMDV *infection* during transportation to the *place of shipment*.

Article 8.7.12-14.

Recommendations for importation from FMD infected countries or zonesFor domestic ruminants and pigs

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

- 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) ~~since birth, or~~ since birth, or
 - b) for ~~the past~~ the past 30 days, ~~or since birth if younger than 30 days~~, if a *stamping-out policy* is in force in the *exporting country* ~~or zone~~, or
 - c) for ~~the past~~ the past 3 months, ~~or since birth if younger than three months~~, if a *stamping-out policy* is not in force in the *exporting country* ~~or zone~~,
- 3) and that FMD has not occurred within ~~a ten kilometre radius of~~ the *establishment* of origin for the relevant period as defined in points 2 a) and b) above;
- 34) ~~the animals~~ were isolated in an *establishment* ~~or a quarantine station~~ for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic *virological and serological* tests (~~virus detection on a probang sample in ruminants or on throat swabs in pigs and serology~~) ~~with negative results on samples collected at least 28 days after the start of isolation~~ ~~the end of that period~~, and that FMD did not occur within a ten-kilometre radius of the *establishment* ~~or a quarantine station~~ during that period; or
- 4) ~~were kept in a quarantine station for the 30 days prior to shipment, all animals in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV infection with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the quarantine station during that period;~~
- 5) ~~the animals~~ were not exposed to any source of FMDV *infection* during their transportation from the *establishment* ~~or quarantine station~~ to the *place of shipment*.

Article 8.7.13,15.

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

For fresh semen of domestic ruminants and pigs

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

- 1) the donor animals:
 - 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 an FMD free country, ~~or~~ or zones ~~or compartments~~ where vaccination is not practised ~~or FMD free compartments~~ or ~~FMD free compartments~~;
 - c) were kept in an artificial insemination centre where none of the animals had a history of infection;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.7.14,16.

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

For frozen semen of domestic ruminants and pigs

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

- 1) the donor animals:
 - 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 an FMD free country, ~~or~~ or zone ~~or compartments~~ where vaccination is not practised ~~or FMD free compartments~~ or ~~FMD free compartments~~;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.7.15,17.

Recommendations for importation from FMD free countries, ~~or~~ or zones ~~or compartments~~ 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 animals:
 - 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 an FMD free country, ~~or~~ or zone ~~or compartment~~ where vaccination is practised;
 - e) ~~if destined to an FMD free country or zone where vaccination is not practised;~~

Annex XVI (B) (contd)

- ii) either
- i) have been vaccinated at least twice, with the last vaccination not less than one month and not more than six months prior to collection, unless protective immunity has been proven for more than six months
- or
- ii) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV virus, with negative results; ~~or~~
- ii)d) had been vaccinated at least twice, with the last vaccination not more than 612 and not less than one month prior to collection;
- 2) ~~no other animal present in the artificial insemination centre has been vaccinated within the month prior to collection;~~
- 23) the semen:
- a) was collected, processed and stored in conformity accordance with the provisions of 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 were kept showed any sign of FMD.

Article 8.7.1618.

Recommendations for importation from FMD infected countries or zones

For frozen semen of domestic ruminants and pigs

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

- 1) the donor animals:
- 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 ~~establishment~~ artificial insemination centre where no animal had been added in the 30 days before collection, and that FMD has not occurred within 40 kilometres a ten-kilometre radius of the artificial insemination centre for the 30 days before and after collection;
- c) either
- i) have been vaccinated at least twice, with the last vaccination not less than one month and not more than six months prior to collection, unless protective immunity has been proven for more than six months
- or
- ii) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV virus, with negative results; ~~or~~
- ii)d) had been vaccinated at least twice, with the last vaccination not more than 612 and not less than one month prior to collection;
- 2- ~~no other animal present in the artificial insemination centre has been vaccinated within the month prior to collection;~~

3.2) the semen:

- a) was collected, processed and stored in conformity accordance with the provisions of Chapters 4.5. and 4.6.;
- b) was subjected, with negative results, to a test for evidence of FMDV ~~infection~~ if the donor animal 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 animals were kept showed any sign of FMD.

Article 8.7.17-19.

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 conformity accordance with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.7.18-20.

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

For *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 at the time of collection in an FMD free country, ~~or~~ ~~or~~ zones ~~or compartments~~ where vaccination is not practised ~~or FMD free compartments~~ ~~or FMD free compartments~~;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.7.5-1413, 8.7.5-1414, 8.7.5-1415. or 8.7.5-1416., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in conformity accordance with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.7.19-21.

Recommendations for importation from FMD free countries, ~~or~~ ~~or~~ zones ~~or compartments~~ where vaccination is practised

For *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 an FMD free country, ~~or~~ ~~or~~ zones ~~or compartments~~ where vaccination is practised;
 - e) if destined for an FMD free country or zone where vaccination is not practised or a FMD free ~~compartment~~;

Annex XVI (B) (contd)

h) either

i) have been vaccinated at least twice, with the last vaccination not less than one month and not more than six months prior to collection, unless protective immunity has been proven for more than six months

or

ii) have not been vaccinated and were subjected, not less than 21 days after collection, to tests for antibodies against FMDV virus, with negative results; or

ii)d) had been vaccinated at least twice, with the last vaccination not more than 612 and not less than one month prior to collection;

- 2) no other animal present in the artificial insemination centre has been vaccinated within the month prior to collection;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.7 .4513., 8.7 .4614., 8.7 .4715. or 8.7 .4816., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in conformity accordance with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.7 .20,22.

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

For fresh meat or meat products of FMD susceptible animals

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

- 1) have been kept in a the FMD free country, or ~~or~~ zones or compartments where *vaccination* is not practised or FMD free compartments ~~or FMD free compartments~~, or which have been imported in accordance with Article 8.7 .4210., Article 8.7 .4311. or Article 8.7 .4412.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.

Article 8.7 .21,23.

Recommendations for importation from FMD free countries, or ~~or~~ zones or compartments where vaccination is practised

For fresh meat and meat products of ruminants and pigs cattle and 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* comes from animals which:

- 1) have been kept in the FMD free country, or ~~or~~ zone or compartment where *vaccination* is practised, or which have been imported in accordance with Article 8.7 .4210., Article 8.7 .4311. or Article 8.7 .4412.;
- 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, ~~have has~~ been excluded from the shipment removed.

Article 8.5.24.

Recommendations for importation from FMD free countries or zones where vaccination is practicedFor fresh meat or meat products of pigs and ruminants other than cattle and buffaloes

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 where vaccination is practised, or which have been imported in accordance with Article 8.5.12., Article 8.5.13. or Article 8.5.14.;
- 2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.

Article 8.7.22,25.

Recommendations for importation from FMD infected countries or zones, where an official control programme for FMD, involving compulsory systematic vaccination of cattle, 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 for at least three months prior to *slaughter*;
 - b) have remained, during this period, in a part of the country where cattle and water buffaloes are regularly vaccinated against FMD and where official controls are an official control programme is in operation;
 - be) have been vaccinated at least twice with the last *vaccination* not more than six months, unless protective immunity has been proven for more than six months, and not less than one month prior to *slaughter*;
 - cd) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;
 - de) 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 to the approved *slaughterhouse/abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;
 - ef) 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;
 - fg) have been subjected to ante- and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;
- 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 above + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi muscle.

Annex XVI (B) (contd)Article 8.7.~~23~~.26.**Recommendations for importation from FMD infected countries or zones**For meat products of domestic ruminants and pigs FMD susceptible animals*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the entire consignment of *meat products* comes from animals which have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results;
- 2) the *meat products* have been processed to ensure the destruction of the FMD virus in accordance conformity with one of the procedures referred to in Article 8.7 .~~343~~.1.;
- 3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 8.7.~~24~~.27.**Recommendations for importation from FMD free countries ~~or~~ or zones ~~or compartments~~ (where vaccination either is or is not practised) ~~or FMD free compartments~~ or FMD free compartments**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 an FMD free country, zone or compartment, or which have been imported in accordance with Article 8.7 .~~421~~.0., Article 8.7 .~~431~~.1. or Article 8.7 .~~441~~.2.Article 8.7.~~25~~.28.**Recommendations for importation from FMD infected countries or zones where an official control programme exists**For milk, cream, milk powder and milk products*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these products:
 - a) originate from *establishments herds or flocks* 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 the FMD virus in accordance conformity with one of the procedures referred to in Article 8.7 .~~383~~.5. and in Article 8.7 .~~393~~.6.;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

Article 8.7.~~26-29~~.

Recommendations for importation from FMD infected countries

For blood-meal and meat-meals from FMD susceptible animals (from domestic or wild ruminants and pigs)

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 8.7.~~27-30~~.

Recommendations for importation from FMD infected countries

For wool, hair, bristles, raw hides and skins from FMD susceptible animals (from domestic or wild ruminants and pigs)

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

- 1) these products have been processed to ensure the destruction of the FMDV virus in accordance conformity with one of the procedures referred to in Articles 8.7. ~~3532~~, 8.7. ~~3633~~ and 8.7. ~~3734~~;
- 2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMDV virus.

Veterinary Authorities ~~can~~ 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 ~~—e.g. 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 8.7.~~28-31~~.

Recommendations for importation from FMD infected countries or zones

For straw and forage

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

- 1) are free of grossly identifiable 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 minutes,
 - b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35–40 percent 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 ~~three~~ four months (~~under study~~) before being released for export.

Annex XVI (B) (contd)

Article 8.7.29.32.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised)

For skins and trophies derived from FMD susceptible wildlife animals

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 or which have been imported from a country or zone or compartment free of from FMD (where vaccination either is or is not practised).

Article 8.7.30.33.

Recommendations for importation from FMD infected countries or zones

For skins and trophies derived from FMD susceptible wildlife animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the FMDV virus in accordance conformity with the procedures referred to in Article 8.7.40.37.

Article 8.7.31.34.

Procedures for the inactivation of the FMDV virus in meat and meat products

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

1. Canning

Meat and meat products is 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 the FMDV virus.

2. Thorough cooking

Meat, previously deboned and defatted, and meat products shall be are subjected to a heat treatment heating that results in so that a core an internal temperature of 70°C or more greater is maintained for a minimum of 30 minutes.

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

3. Drying after salting

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

'Drying Completely dried' is defined in terms of the as a ratio between water and protein which must that is not be greater than 2.25:1.

Article 8.7.32-35.

Procedures for the inactivation of the FMDV virus in wool and hair

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

- 1) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);
- 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. The most practical method is to place potassium permanganate in containers (which must NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber;
- 4) industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60–70°C;
- 5) storage of wool at 48°C for four weeks, or 4°C for four months, 18°C for four weeks or 37°C for eight days.

Article 8.7.33-36.

Procedures for the inactivation of the FMDV virus in bristles

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

- 1) boiling for at least one hour;
- 2) immersion for at least 24 hours in a one percent aqueous solution of formaldehyde prepared from 30 ml commercial formalin per litre of water.

Article 8.7.34-37.

Procedures for the inactivation of the FMDV virus in raw hides and skins

For the inactivation of FMDV viruses present in raw hides and skins for industrial use, the following procedure should be used: treatment salting for at least 28 days in with sea salt (NaCl) containing 2 percent sodium carbonate (Na_2CO_3).

Article 8.7.35-38.

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

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

- 1) a sterilisation 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 sterilisation 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.

Annex XVI (B) (contd)

Article 8.7.36-39.

Procedures for the inactivation of the FMDV virus in milk for animal consumption

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

- 1) the HTST process applied twice;
- 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;
- 3) UHT combined with another physical treatment referred to in point 2 above.

Article 8.7.37-40.

Procedures for the inactivation of the FMDV virus in skins and trophies from wild animals susceptible to the disease

For the inactivation of FMDV viruses present in skins and trophies from *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;
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);
- 3) soaking, with agitation, in a four percent (w/v weight/volume) solution of washing soda (sodium carbonate – (Na₂CO₃)) maintained at pH 11.5 or greater above for at least 48 hours;
- 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 below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;
- 5) in the case of raw hides, treating salting for at least 28 days with sea salt (NaCl) containing two percent washing soda (sodium carbonate – (Na₂CO₃)).

Article 8.7.38-41.

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

For the inactivation of FMDV viruses present in casings of ruminants and pigs, the following procedures should be used: treating salting for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl, $a_w < 0.80$), or with phosphate supplemented dry salt containing 86.5 percent NaCl, 10.7 percent Na₂HPO₄ and 2.8 percent 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 8.7.39.

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 for FMD. The official control programme should be applicable to the entire country even if certain measures are directed only towards defined subpopulations.

Annex XVI (B) (contd)

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 according to the requirements in Chapter 1.1.:
- 2) submit documented evidence of ~~en~~ the capacity of the Veterinary Services to control FMD; ~~one way of providing~~ this evidence ~~can be provided by countries following~~ is through the OIE PVS Pathway;
- 3) submit a detailed plan of ~~en~~ the programme to control and eventually eradicate FMD in the country or zone including:
 - a) the timeline;
 - b) the performance indicators ~~for assessing to assess~~ the efficacy of the control measures to be implemented;
 - c) submit documentation indicating that the official control programme for FMD is applicable to the entire country;
- 4) submit a dossier on the epidemiology of FMD in the country describing the following:
 - a) the general epidemiology in the country highlighting the current knowledge and gaps ~~and the progress that has been made in controlling FMD;~~
 - b) the measures implemented to prevent introduction of infection, the rapid detection of, and response to, all FMD outbreaks in order to reduce the incidence of FMD outbreaks and to eliminate ~~FMDV virus circulationtransmission in domestic ruminants~~ 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) taking into account provisions in Chapter 1.4. and the provisions on surveillance of this chapter;
 - b) 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;

Annex XVI (B) (contd)

- 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 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 according to 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 8.7.40-42.

General principles of surveillance: introduction

Articles 8.75.42-40. to 8.75.47-462. and Article 8.5.49. 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 and or recovery of freedom from FMD at the country, zone or compartment level, either with or without the use of vaccination and or Member Countries seeking endorsement by the OIE of their official control programme for FMD, in accordance with Article 8.75.39. Surveillance aimed at identifying disease and FMDV infection or virus circulation-transmission should cover all the susceptible domestic and wildlife species indicated in Article 8.7.1. point 2, including wildlife, if applicable, within the country, zone or compartment. Guidance is provided for Members seeking reestablishment of freedom from FMD for the entire country or for a zone, either with or without vaccination, or a compartment, following an outbreak and for the maintenance of FMD status.

A surveillance system in accordance with Chapter 1.4. should be the responsibility of the Veterinary Authority and provides 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 call for assistance from a team with expertise in FMD diagnosis and control.

The impact and epidemiology of FMD differ widely in different regions of the world and therefore it is impossible-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 will need to should be adapted to the local situation. For example, the approach to proving freedom from FMD following an outbreak caused by a pig-adapted strain of FMD virus (FMDV) should differ significantly from an application designed to prove freedom from FMD for a country or zone where African buffaloes (*Syncerus caffer*) provide a potential reservoir of infection.

Annex XVI (B) (contd)

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

A Member Country wishing to demonstrate FMD freedom where vaccination is not practised should show absence of FMDV infection.

A Member Country wishing to demonstrate FMD freedom where vaccination is practised should show that FMDV has not been transmitted in any susceptible populations. Within vaccinated populations, serological surveys to demonstrate the absence of FMDV transmission 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. Absence of FMDV infection should be demonstrated in any unvaccinated subpopulations.

Surveillance strategies employed for establishing and maintaining a compartment should also identify the prevalence, distribution and characteristics of FMD outside the compartment in the country or zone.

Surveillance strategies employed in support of an OIE endorsed official control programme should show evidence of the effectiveness of any vaccination used and of the ability to rapidly detect all FMD outbreaks.

There is Therefore considerable latitude is available to Member Countries to design and implement surveillance on the one hand to establish that the whole territory or part of it is free from FMDV infection and circulation/transmission and on the other to understand the epidemiology of FMD as part of the official control programme official FMD control programmes.

It is incumbent upon the Member Country to 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, are identified and managed. This should include provision of scientifically based supporting data. There is therefore considerable latitude available to Members to provide a well-reasoned argument to prove that the absence of FMDV infection (in non-vaccinated populations) or circulation (in vaccinated populations) is assured at an acceptable level of confidence.

Surveillance for FMD should be in the form of a continuing programme. The design of surveillance programmes to prove the absence of FMDV infection and circulation/transmission needs to should be carefully designed and implemented followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or being excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

The strategy employed to establish the prevalence of FMDV infection or to substantiate freedom from demonstrate the absence of FMDV infection or circulation/transmission 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 an appropriate strategy. 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 or circulation/transmission in accordance with Chapter 1.4. and the epidemiological situation.

The design of the sampling strategy should will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing should will need to be adequate large enough to detect infection or circulation/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 must 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.

Annex XVI (B) (contd)

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.

Irrespective of the survey design selected, 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. Ideally, 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 ultimately determine with a high level of confidence, whether or not they are indicative of *infection* or *circulation*. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original *epidemiological unit* as well as 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 *circulation* includes but is not limited to:

- = characterisation of the existing production systems;
- = results of clinical *surveillance* of the suspects and their cohorts;
- = quantification description of number of, and protocol for, of *vaccinations* performed in the area under assessment on the affected sites;
- = biosecurity sanitary protocol and history of the *establishments* with positive reactors;
- = control of *animal identification* and movements;
- = other parameters of regional significance in historic FMDV transmission.

Following the use of routine and emergency *vaccination*, evidence should be provided to show 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 as standard operating procedure within the *surveillance* programme.

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

~~Surveillance for FMD should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from FMDV infection/circulation.~~

For the purposes of this chapter, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.

Article 8.7.41-43.

Methods of surveillance: general conditions and methods general principles

1) A surveillance system in accordance with Chapter 1.4. should be under the responsibility of the Veterinary Authority. A procedure should be in place for the rapid collection and transport of samples from suspect cases of FMD to a laboratory for FMD diagnosis as described in the Terrestrial Manual. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in FMD diagnosis and control.

1.2) The FMD surveillance programme should:

a) include structured non-random surveillance activities as described in Article 1.4.5. with particular reference to an early warning system throughout the production, marketing and processing chain for reporting suspicious suspect cases. Farmers and workers who have day to day contact with livestock, as well as diagnosticians, should report promptly any suspicion of FMD. They should be supported directly or indirectly (e.g. through private veterinarians or veterinary para-professionals) by government information programmes and the Veterinary Authority. All suspect cases of FMD should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted for diagnostic testing a laboratory, unless the suspect case can be confirmed or ruled out by epidemiological and clinical investigation. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in FMD diagnosis and control. Any epidemiological unit within which suspicious animals are detected should be classified as infected until contrary evidence is produced;

b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of animals, such as those adjacent to an FMD infected country or infected zone (for example, bordering a game park in which infected wildlife are present).

b) implement structured population based surveys, when appropriate, as described in Article 1.4.4.

3) The surveillance programme above should:

a) identify the nature of risk factors, including the role of wildlife, to inform targeted surveillance strategies when appropriate;

b) implement, when relevant, an appropriate combination of clinical investigation and other diagnostic procedures in high risk groups.

Annex XVI (B) (contd)

- 34) An effective surveillance system should will periodically identify suspicious suspect cases that require follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Details of the occurrence of suspect cases and how they were investigated and dealt with should be documented. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from FMDV infection/circulation should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of diagnostic laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand still orders, etc.).

Article 8.5.42,44.

Surveillance: methods strategies

1. Introduction

The target population for surveillance aimed at identifying disease and infection should cover all the susceptible species within the country, zone or compartment.

The design of surveillance programmes to prove the absence of FMDV infection/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of FMDV infection/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted surveillance (e.g. based on the increased likelihood of infection in particular localities or species) may be an appropriate strategy. The Member should justify the surveillance strategy chosen as adequate to detect the presence of FMDV infection/circulation in accordance with Chapter 1.4. and the epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member wishes to apply for recognition of a specific zone within the country as being free from FMDV infection/circulation, the design of the survey and the basis for the sampling process would need to be aimed at the population within the zone.

For random surveys, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection/circulation 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 must 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 clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design 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/infection history and production class of animals in the target population.

Irrespective of the testing system employed, 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 needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether they are indicative of infection/circulation or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as herds which may be epidemiologically linked to it.

12- Clinical surveillance

The detection of clinical signs by farmers, veterinary para-professionals and veterinarians is the foundation of an early warning system and of 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 Authority should implement programmes to raise awareness among them.

Clinical surveillance aims at detecting clinical signs of FMD by requires close physical examination of susceptible animals. ~~Whereas~~ Although significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. It may as it can be able to may provide a high level of confidence of detection of *disease* if a sufficiently large number of clinically susceptible animals is examined at an appropriate frequency and investigations are recorded and quantified.

Clinical examination surveillance and laboratory diagnostic testing should always be applied in series to clarify the status of FMD suspected cases detected by either of these complementary diagnostic approaches. Laboratory Diagnostic testing may confirm clinical suspicion, while clinical surveillance may contribute to confirmation of positive serology laboratory test results. Any sampling unit within which suspicious animals are detected should be classified as infected until contrary evidence is produced. Clinical surveillance may be insufficient in case of wildlife and domestic species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such situations cases, 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.

A number of issues must be considered in clinical surveillance for FMD. The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.

Identification of clinical cases is fundamental to FMD surveillance. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such animals. It is essential that FMDV isolates are sent regularly to the regional reference laboratory for genetic and antigenic characterization.

32- 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 materials. It is essential that FMDV isolates are should be sent regularly to an OIE Reference Laboratory.

Virological surveillance using tests described in the *Terrestrial Manual* should be conducted aims to:

- a) to monitor at risk populations;
- b) a) to confirm clinically suspected ed cases;
- eb) to follow up positive serological results;
- c) characterise isolates for epidemiological studies and vaccine matching;
- d) to test 'normal' daily mortality, to ensure early detection of *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.
- d) monitor at risk populations at risk.

Annex XVI (B) (contd)

43) Serological surveillance

Serological *surveillance* aims at detecting antibodies against FMDV caused by resulting from infection or vaccination using either, nonstructural protein (NSP) tests that detect all FMD types or type specific tests that detect structural proteins tests. Positive FMDV antibody test results can have four possible causes:

Serological surveillance with tests described in the *Terrestrial Manual* is may be used to:

- a) estimate the prevalence or substantiate freedom from demonstrate the absence of FMDV infection/ or circulation/transmission;
- b) monitor population immunity.
- a) natural infection with FMDV;
- b) vaccination against FMD;
- e) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to six months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);
- d) heterophile (cross) reactions.

It is important that serological tests, where applicable, contain antigens appropriate for detecting antibodies against viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on nonstructural viral proteins — see below).

It may be possible to use serum collected for other survey purposes can be used for FMD surveillance, provided However, the principles of survey design described in this chapter are met, and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain *infection*. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design. If *vaccination* cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual*.

The results of random or targeted serological surveys are important in providing reliable evidence that FMDV infection is not present in a country, zone or compartment of the FMD situation in a country, zone or compartment. It is therefore essential that the survey be thoroughly documented.

Article 8.5.43.45.**Members applying for recognition of freedom from FMD for the whole a country, or a zone or compartment where vaccination is not practised: additional surveillance procedures**

The strategy and design of the surveillance programme will depend on the historical epidemiological circumstances including whether or not vaccination has been used. In addition to the general conditions described in the above mentioned articles, a Member applying for recognition of FMD freedom for the country, or a zone or compartment where vaccination is not practised 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 will be planned and implemented according to general conditions and methods in this chapter, to demonstrate absence of FMDV circulation in previously vaccinated animals and absence of FMDV infection in non-vaccinated animals, during the preceding 12 months in susceptible populations. This requires the support of a national or other laboratory able to undertake identification of FMDV infection through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

Article 8.5.44.46.**Members applying for recognition of freedom from FMD for the whole a country, or a zone or compartment where vaccination is practised: additional surveillance procedures**

In addition to the general conditions described in the above mentioned articles, a Member applying for recognition of country or zone freedom from FMD with vaccination should show evidence of an effective surveillance programme planned and implemented according to general conditions and methods in this chapter. Absence of clinical disease in the country or zone for the past two years should be demonstrated. Furthermore, surveillance should demonstrate that FMDV has not been circulating in any susceptible populations during the past 12 months. This will require serological surveillance incorporating tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*. Serological surveys to demonstrate the absence of FMDV circulation should target within vaccinated populations, unvaccinated animals or animals that are less likely to show vaccine derived antibodies to NSPs, such as young animals vaccinated a limited number of times, or unvaccinated subpopulations. Vaccination to prevent the transmission of FMDV may be part of a disease control programme. The level of herd immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. However, the aim should be for at least 80 percent of the animals in each vaccinated population to have protective immunity. The vaccine must comply with the *Terrestrial Manual*. Evidence to show the effectiveness of the vaccination programme such as adequate vaccination coverage and population immunity should be provided.

Annex XVI (B) (contd)

In designing serosurveys 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 campaign, 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 to 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.

Based on the epidemiology of FMD in the country or zone, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.

Evidence to show the effectiveness of the vaccination programme should be provided.

~~Article 8.5.6, 45, 47.~~

Members re-applying for recognition of freedom from FMD for the whole a country, or a zone or compartment where vaccination is either practised or not practised, following an outbreak: additional surveillance procedures

In addition to the general conditions described in the above mentioned articles, a country re-applying for country, or zone or compartment freedom from FMD where vaccination is practised or not practised should show evidence of an active surveillance programme for FMD as well as absence of FMDV infection/circulation. This will require serological surveillance incorporating, in the case of a country or a zone practising vaccination or a country or a zone practising tests able to detect antibodies to NSPs, as described in the *Terrestrial Manual*.

Four strategies are recognised by the OIE in a programme to eradicate FMDV infection/circulation following an outbreak:

1. slaughter of all clinically affected and in contact susceptible animals;
2. slaughter of all clinically affected and in contact susceptible animals and vaccination of at risk animals, with subsequent slaughter of vaccinated animals;
3. slaughter of all clinically affected and in contact susceptible animals and vaccination of at risk animals, without subsequent slaughter of vaccinated animals;
4. vaccination used without slaughter of affected animals or subsequent slaughter of vaccinated animals.

The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 8.5.9.

1. Additional surveillance using NSP tests is required to reduce the time period from six to three months in case of slaughter of all clinically affected and in contact susceptible animals and vaccination of at risk animals, without subsequent slaughter of vaccinated animals as mentioned in point 1c) of Article 8.5.7. Additional. This includes serosurveillance of all herds with vaccinated animals by sampling all vaccinated ruminants and their non-vaccinated offspring and a representative number of animals of other species based on an acceptable level of confidence.

In all circumstances, a Member re-applying for country or zone freedom from FMD with vaccination or without vaccination should report the results of an active surveillance programme implemented according to general conditions and methods in this chapter.

Article 8.5.48.

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 free status for FMD.

Members 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's *official control programme* for FMD to be endorsed by the OIE, the Member should:

1. submit documented evidence on the capacity of the *Veterinary Services* to control FMD; this evidence can be provided by countries following the OIE PVS Pathway;
2. submit documentation indicating that the *official control programme* for FMD is applicable to the entire territory;
3. have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;
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;
 - b) the measures to prevent introduction of *infection*;
 - c) the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;
5. submit a detailed plan on the programme to control and eventually eradicate FMD in the country or zone including:
 - a) the timeline;
 - b) the performance indicators to assess the efficacy of the control measures to be implemented;
6. submit evidence that FMD *surveillance*, taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter, is in place;
7. have diagnostic capability and procedures, including regular submission of samples to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the *Terrestrial Manual*;
8. where vaccination is practised as a part of the *official control programme* for FMD, provide evidence (such as copies of legislation) that vaccination of selected populations is compulsory;
9. if applicable, provide detailed information on vaccination campaigns, in particular on:
 - a) target populations for vaccination;
 - b) monitoring of vaccination coverage, including serological monitoring of population immunity;
 - c) technical specification of the vaccines used and description of the licensing procedures in place;
 - d) the proposed timeline for the transition to the use of vaccines, fully compliant with the standards and methods described in the *Terrestrial Manual*;
10. provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.

Annex XVI (B) (contd)

The Member's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence 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 according to 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 8.7.462.49.

The use and interpretation of serological tests (see Figure 123)

The recommended serological tests for FMD surveillance are described in the *Terrestrial Manual*. The selection and interpretation of serological tests should be considered in the context of the epidemiological situation. Information should be provided on the 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. The selection and interpretation of serological tests should be considered in the context of the epidemiological situation.

Animals infected with FMDV produce antibodies to both the structural proteins (SP) and the nonstructural proteins (NSP) of the virus. Tests for SP antibodies to include SP-ELISAs and the virus neutralisation test (VNT). Vaccinated animals produce antibodies mainly or entirely to the SP structural proteins of the virus depending upon vaccine purity. The SP structural protein tests are serotype specific and for optimal sensitivity one should select utilise an antigen or virus closely related to the field strain expected against which antibodies are being sought. Tests for NSP antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests. In unvaccinated populations, SP structural protein tests may be used to screen sera for evidence of FMDV infection or circulation/transmission or to detect the introduction of vaccinated animals. In areas where animals have been vaccinated populations, SP structural protein antibody tests may be used to monitor the serological response to the vaccination and can help to identify infection since vaccinated and infected animals may have higher SP antibody titres than vaccinated only animals.

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

Annex XVI (B) (contd)

Both the NSP + ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.

Serological testing is a suitable tool for FMD surveillance. The choice of a serosurveillance system will depend on, amongst other things, the vaccination status of the country. A country, which is free from FMD without vaccination, may choose serosurveillance of high-risk subpopulations (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV infection/circulation if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical surveillance. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any presumptive positive serological test results. In areas where animals have been vaccinated, SP antibody tests may be used to monitor the serological response to the vaccination. However,

NSP antibody tests should be used to monitor for FMDV infection/circulation. NSP ELISAs may be used for screening sera for evidence of infection/circulation irrespective of the vaccination status of the animal.

Positive FMDV antibody test results can have four possible causes:

- a) infection with FMDV;
- b) vaccination against FMD;
- c) maternal antibodies derived from an immune dam (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);
- d) non-specific reactivity of the serum in the tests used;
- e) lack of specificity of the diagnostic tests used.

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.

All 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 reactors. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The number and strength of sero reactors should be taken into account.

All herds with seropositive at least one laboratory confirmed reactors should be investigated immediately. Epidemiological and supplementary laboratory investigation results should document the status of FMDV infection/circulation for each positive herd. The investigation should examine all evidence, including the results of virological 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 virus circulation/transmission and should document the status of FMDV infection/ circulation for each positive herd. Epidemiological investigation should be continued concurrently in parallel.

Clustering of seropositive reactions should be investigated as it may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of infection/ or circulation/transmission. As clustering may signal infection/ or circulation/transmission, the investigation of all instances should must be incorporated in the survey design.

Annex XVI (B) (contd)

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

The investigation should include the reactor animal(s), susceptible animals of the same epidemiological unit and susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animal(s). The animals sampled should remain in the holding establishment pending test results, should be clearly identifiable, accessible and should not be vaccinated during the investigations, so that they can be retested after an adequate appropriate period of time. Following clinical examination, a second sample should be taken from the animals tested in the initial survey with emphasis on animals in direct contact with the reactor(s) after an adequate appropriate interval of time has lapsed. If the animals are not individually identified, a new serological survey should be carried out in the holding(s) establishments after an adequate appropriate period of 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 if virus is not circulating.

In some circumstances, sSentinel animals can may also be used. These can be young, unvaccinated animals or animals in which maternally conferred immunity has lapsed and preferably belonging to of the same species as resident within the initial 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 virus FMDV is not circulating.

Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.

Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.

- 1- The follow-up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination country or zone where vaccination is not practised

Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and, where possible, virological investigations of the reactor animal at hand, of susceptible animals of the same epidemiological unit and of susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animal. If the follow-up investigations provide no evidence FMDV infection, the reactor animal shall be classified as FMD negative. In all other cases including the absence of such follow-up investigations, the reactor animal should be classified as FMD positive.

Follow-up of field and laboratory findings:

If circulationtransmission is proven then an the outbreak is declared.

~~In the absence of FMDV circulation, an outbreak can be ruled out, but the significance of small numbers of FMD seropositive animals in the absence of current FMDV transmission is difficult to determine/classify. Such findings can may be an indication of past acute infection followed by recovery or by the development of a the carrier state, in ruminants, or due to non-specific serological reactions or lack of specificity of the diagnostic tests used. Antibodies to nonstructural proteins NSP may be induced by repeated vaccination with vaccines that do not comply with the requirements for purity. However, the use of such vaccines is not permissible in for countries, or zones or compartments applying for an official status. In the absence of evidence of FMDV infection and transmission, 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 non-specific test system findings expected, susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animals should be investigated further.~~

~~In the case of a vaccinated herd in a country, or zone or compartment trying to establish or re-establish the status of an FMD free country, or zone or compartment where vaccination is practised, the follow-up investigations may be considered completed where the herd can be declared free of FMDV circulation/transmission. In the case of a number of FMD positive animals at a level above the expected number of non-specific test system findings, susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animal(s) should be investigated.~~

~~In all other cases, when a small number of FMD positive animals are found, at a level consistent with the expected number of non specific test system findings, it is recommended that such reactor animals should be slaughtered, and then the herd declared free of FMDV infection. In the case of a number of FMD positive animals at a level above the expected number of non-specific test system findings, it is recommended that the herd should be slaughtered and susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animal(s) should be investigated.~~

~~2. The follow-up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free country or zone where vaccination is practised status with vaccination~~

~~In case of vaccinated populations, one has to exclude that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on FMD vaccinated populations:~~

~~The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.~~

~~It is suggested that in the primary sampling units where at least one animal reacts positive to the NSP test, the following strategy(ies) should be applied:~~

- ~~a) Following clinical examination, a second serum sample should be taken from the animals tested in the initial survey after an adequate interval of time has lapsed, on the condition that they are individually identified, accessible and have not been vaccinated during this period. The number of animals with antibodies against NSP in the population at the time of retest should be statistically either equal to or less than that observed in the initial test if virus is not circulating.~~

~~The animals sampled should remain in the holding pending test results and should be clearly identifiable. If the three conditions for retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all animals tested are individually identified. These animals should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.~~

Annex XVI (B) (contd)

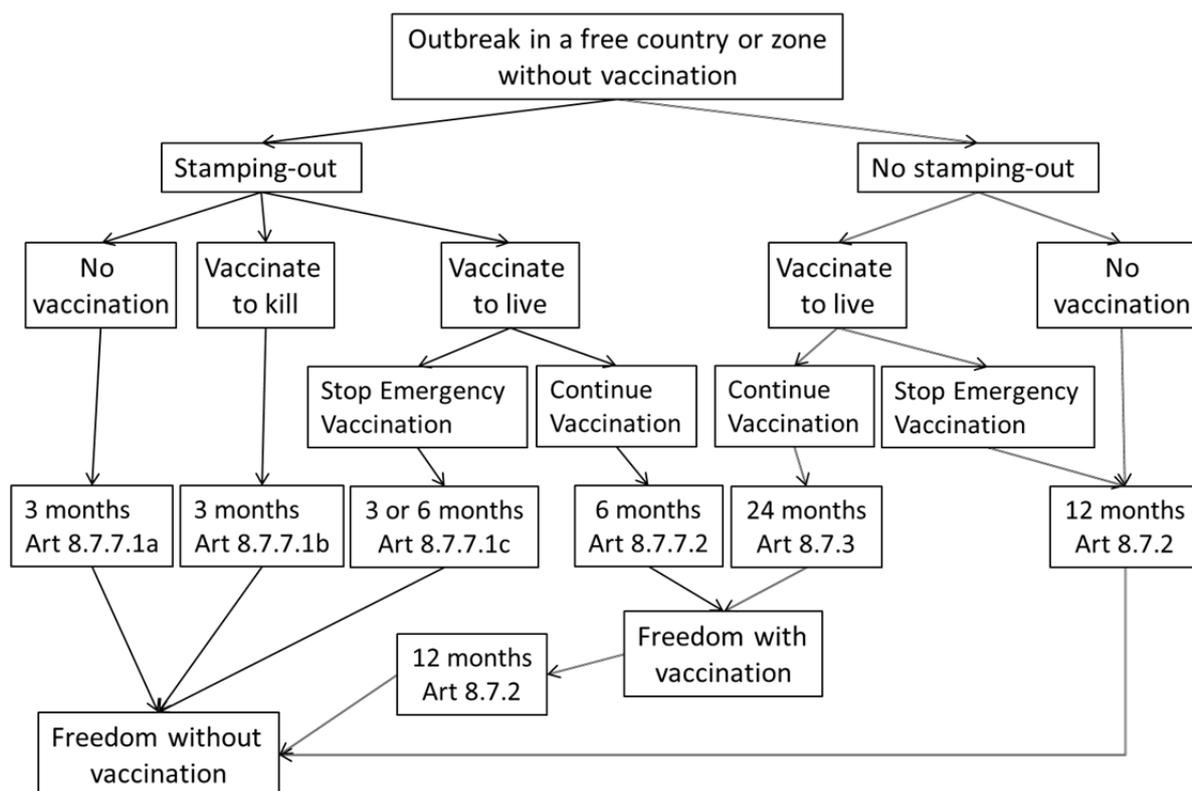
- b) ~~Following clinical examination, serum samples should be collected from representative numbers of susceptible animals that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.~~
- e) ~~Following clinical examination, epidemiologically linked herds should be serologically tested and satisfactory results should be achieved if virus is not circulating.~~
- d) ~~Sentinel animals can also be used. These can be young, unvaccinated animals or animals in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated animals are present, they could act as sentinels to provide additional serological evidence.~~

~~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 circulation includes but is not limited to:~~

- ~~characterization of the existing production systems;~~
- ~~results of clinical surveillance of the suspects and their cohorts;~~
- ~~quantification of vaccinations performed on the affected sites;~~
- ~~sanitary protocol and history of the establishments with positive reactors;~~
- ~~control of animal identification and movements;~~
- ~~other parameters of regional significance in historic FMDV transmission.~~

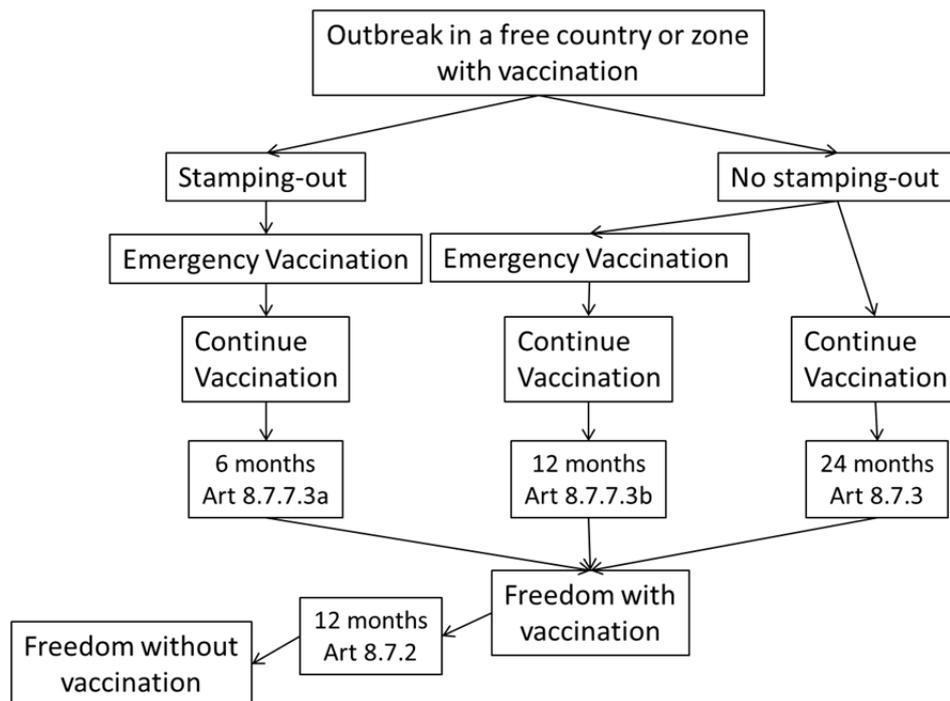
~~The entire investigative process should be documented as standard operating procedure within the surveillance programme.~~

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



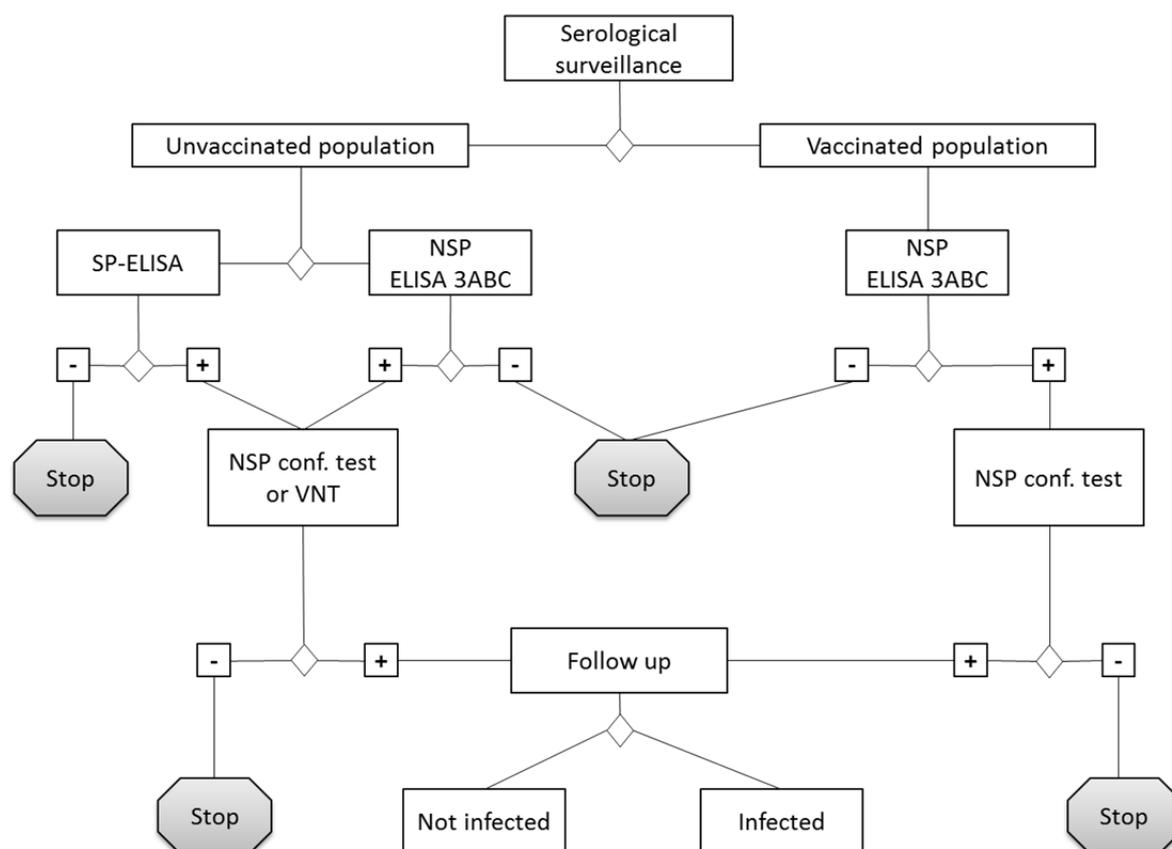
Waiting periods are minima depending upon outcome of surveillance specified in respective Articles. If there are multiple waiting periods because of different control measures, the longest applies.

Figure 2: Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak in a 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.*

Figure 423: Schematic representation of laboratory tests for determining evidence of FMDV infection through or following by means of serological surveys



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

— 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° XXX (administrative procedures) and Resolution N° XXXI (financial obligations) adopted during the 81st General Session in May 2013.

Article 1.6.2.

Endorsement by the OIE of an official control programme for FMD

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

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

[Article 1.6.3.]

[Article 1.6.4.]

[Article 1.6.5.]

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 8.7. of the *Terrestrial Code*,
as an FMD free country not practising vaccination

Please 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. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code Manual* and describe how the *Veterinary Services* supervise, and 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), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, *modified stamping-out policy*, zoning), provide time frame for eradication.

Annex XVI (B) (contd)

- c) Vaccines and *vaccination*. Was FMD vaccine ever used? If so, when was the last *vaccination* carried out? What species were vaccinated? What was the fate of these animals?
- 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 detected illegal movements

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 name(s) 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 participation performance in inter-laboratory validation tests (ring tests) proficiency tests.
 - iii) Is Provide details on the handling of live virus handled?
 - 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 8.7.402. to 8.7.427. ~~and Article 8.6.49.~~ 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 (s) and results (including differential diagnosis).

- b) Serological *surveillance*. Are 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 method(s) 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? 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 volume 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 XVI (B) (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 location(s).
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/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 FMD risk materials (e.g. stock feed and animal bedding).
- 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. Control measures and eContingency 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 an 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 holdings establishments found to be infected with FMD;
 - iii) indicate the control and/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 details on information on access to antigen and vaccine banks;
 - iv) describe the procedures to be used to confirm that an outbreak has been successfully controlled/eradicated control / or eradication, including any restrictions on restocking provisions, sentinel animal and serological surveillance programmes;

Annex XVI (B) (contd)

- 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 8.7.2. 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 8.7.97., 8.7.2.1, 8.7.2.3 and 8.7.2.4 of the *Terrestrial Code* and provide ~~detailed~~ 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.). 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

FMD FREE COUNTRY WHERE VACCINATION IS PRACTISED

Report of a Member Country which applies for recognition of status,

under Chapter 8.7. of the *Terrestrial Code*,

as an FMD free country practising vaccination

Please 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. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code Manual* and describe how the *Veterinary Services* supervise and control and maintain all FMD related activities. Provide maps and tables wherever possible.

Annex XVI (B) (contd)

- 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), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy, modified stamping-out policy, zoning*), provide time frame for eradication.
- c) Vaccines and *vaccination*. What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the *vaccination* programme, including records kept, and provide evidence to show its effectiveness (e.g. *vaccination* coverage, serosurveillance, etc.). 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.
- 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 detected illegal movements

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 name(s) 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 participation performance in inter-laboratory validation tests (ring tests) proficiency tests.
- iii) Is Provide details on the handling of live virus handled?
- 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 8.7.402 to 8.7.427 and Article 8.6.49 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 ed cases, the number of samples tested for FMDV, species, type of sample, testing method(s) 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 8.7.46.2 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 method(s) 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? 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, 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?

Annex XVI (B) (contd)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 volume 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 location(s).
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/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 FMD risk materials (e.g. stock feed and animal bedding).
- 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. Control measures and 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. stock standstills)?
- c) In the event of an 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 holdings establishments found to be infected with FMD;
 - iii) indicate the control and/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 details on information on access to antigen and vaccine banks;
 - iv) describe the procedures to be used to confirm that an outbreak has been successfully controlled/eradicated control or /eradication, including any restrictions on—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

In addition to the documentary evidence that the provisions of Article 8.7.3. 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 circulationtransmission for the past 12 months, with documented evidence that:

- a) *surveillance* for FMD and FMDV circulationtransmission in accordance with Articles 8.7. 40-42. to 8.7. 42-47. and Article 8.7.49. 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 8.7.97, 8.7.3.1, 8.7.3.3 and 8.57.3.4. of the *Terrestrial Code* and provide detailed 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.). 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

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

Report of a Member Country which applies for recognition of status,
under Chapter 8.7. of the *Terrestrial Code*,
as an FMD free zone not practising vaccination

Please 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. of the *Terrestrial Code* and **Article 1.1.3. of the *Terrestrial Code Manual*** and describe how the *Veterinary Services* supervise, **and 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), 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*), **provide time frame for eradication**.
- c) Vaccines and *vaccination*. If *vaccination* is used in the rest of the country, **What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the *vaccination* programme, including records kept, and provide evidence to show its effectiveness (e.g. *vaccination coverage*, *serosurveillance*, etc.). **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*.****

Annex XVI (B) (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 8.7.10. 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. 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 name(s) 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 participation performance in inter-laboratory validation tests (ring tests) proficiency tests.
 - iii) Is Provide details on the handling of live virus handled?
 - 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 8.7.402. to 8.7.427. ~~and Article 8.6.49.~~ 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 method(s) and results (including differential diagnosis).

Annex XVI (B) (contd)

- b) Serological *surveillance*. Are 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 method(s) 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, and 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 an FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

- 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 volume and quantity.

Annex XVI (B) (contd)

- 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 of and the disposal location(s).
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and 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 FMD risk materials (e.g. stock feed and animal bedding).
- 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. Control measures and eContingency 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 an 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 holdings establishments found to be infected with FMD;
 - iii) indicate the control and 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 details on information on access to antigen and vaccine banks;

Annex XVI (B) (contd)

- iv) describe the procedures to be used to confirm that an outbreak has been successfully controlled/eradicated control/ or eradication, including any restrictions on 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*

In addition to the documentary evidence that the provisions of Article 8.7.4. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:

- 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 8.7.10.

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.7.97, 8.7.2.1, 8.7.2.3 and 8.7.2.4. of the *Terrestrial Code* and provide detailed 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.), 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

FMD FREE ZONE WHERE VACCINATION IS PRACTISED

Report of a Member Country which applies for recognition of status,

under Chapter 8.7. of the <i>Terrestrial Code</i> ,

as an FMD free zone practising vaccination
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Please 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. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code Manual* and describe how the *Veterinary Services* supervise, and 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), 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*), provide time frame for eradication.
- c) Vaccines and *vaccination*. What type of vaccine is used? What species are vaccinated? Provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*. Describe the *vaccination* programme in the country and in the *zone*, including records kept, and provide evidence to show its effectiveness (e.g. *vaccination* coverage, serosurveillance, etc.); 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.
- 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 8.7.10. 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. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

Annex XVI (B) (contd)

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) 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 participation performance in inter-laboratory validation tests (ring tests)-proficiency tests.
 - iii) ~~Is~~ Provide details on the handling of live virus handled?
 - 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 8.7.402. to 8.7.427. and Article 8.6.49. 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 method(s) 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 8.7.46.2 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 method(s) 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, and 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 an FMD infected country or borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

- 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 the country or *zone* of origin, the species and the volume 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 location(s).
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow-up of the following:

Annex XVI (B) (contd)

- animals,
 - genetic material (semen and embryos),
 - animal products,
 - *veterinary medicinal products* (i.e. biologics),
 - other FMD risk materials (e.g. stock feed and animal bedding).
- 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. Control measures and 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 an 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 holdings establishments found to be infected with FMD;
 - iii) indicate the control and/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 details on information on access to antigen and vaccine banks;
 - iv) describe the procedures to be used to confirm that an outbreak has been successfully controlled/eradicated control/ or eradication, including any restrictions on 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

In addition to the documentary evidence that the provisions of Article 8.7.5. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:

- a) that there has been no *outbreak* of FMD for the past two years,
- b) no evidence of FMDV circulation/transmission for the past 12 months,

- c) *surveillance* for FMD and FMDV circulation/transmission in accordance with Articles 8.7.40 to 8.7.42, to 8.6.47, and Article 8.6.49 is in operation.

9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.7.97, 8.7.3.1, 8.7.3.3 and 8.7.3.4 of the *Terrestrial Code* and provide ~~detailed~~ 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.), 3.a), 3.b), 3.c) and 5.b) of this questionnaire. Information in relation to other sections need only be supplied if relevant.

[Article 1.6.6.]

[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 8.7. of the *Terrestrial Code*

Please 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 *zone(s)* 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 *zone(s)*.
- 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 Services* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Manual/Code* and describe how the *Veterinary Services* supervise, and control and maintain all FMD related activities in the country and any *zones*. Provide maps and tables wherever possible.

Annex XVI (B) (contd)

- 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 FMD virus 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.
- 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 the virus 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 8.7.40 to 8.7.42. to 8.6.47. and Article 8.6.49. of the *Terrestrial Code* and Chapter 2.1.5. of 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.

Annex XVI (B) (contd)

- 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, *slaughterhouse*, 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 method(s) 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 population(s), 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 population(s), 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 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 laboratories approved by the competent authority to diagnose FMD. If not, provide the name(s) 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*?

Annex XVI (B) (contd)

- 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.
 - 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.

Annex XVI (B) (contd)

- 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 detected illegal imports, if available.

7. Control measures and emergency response

- a) Give details of any written guidelines, including emergency response plans, available to the *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 an *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 *holdings 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.

Annex XVI (B) (contd)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 including 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 in the *Terrestrial Manual* in order to enable demonstration of absence of virus circulationtransmission.

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 8.7.4839 of the *Terrestrial Code*.

 — Text deleted.

CHAPTER 8.13.

INFECTION WITH RIFT VALLEY FEVER VIRUS

Article 8.13.1.

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*:
 - 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, ~~duration~~, with intermittent low level ~~virus 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 8.13.2., *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*.

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Article 8.13.2.

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 8.13.3.

Country or zone free from RVFV infection

A country or a *zone* may be considered free from RVFV *infection* when the *disease* is notifiable in the whole 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* in ruminants in the country or *zone* for a minimum of ten years; and
 - b) 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 8.13.4.

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 8.13.5.

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 8.13.6.

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;

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- 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 8.13.7.

Recommendations for importation from countries or zones free from RVFV infection

For 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 8.13.8.

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

For 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 *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.

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Article 8.13.9.

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 *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 8.13.10.

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 8.13.11.

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:

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- 1) ruminants which showed no clinical sign of RVF within 24 hours before *slaughter*,
- 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 8.13.12.

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 8.13.13.

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 8.13.8. and 8.13.9.) *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 8.4.

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

Article 8.4.1.

General provisions

- 1) The aim of this chapter is to mitigate the risk of spread of, and the risk to human health from, *Brucella abortus*, *B. melitensis* and *B. suis* in animals.
- 2) For the purpose of this chapter:
 - a) 'Brucella' means *B. abortus*, *B. melitensis* or *B. suis*, excluding vaccine strains.
 - b) 'Animals' means domestic and *captive wild* animal populations of the following categories:
 - i) bovids: this term means cattle (*Bos taurus*, *B. indicus*, *B. frontalis*, *B. javanicus* and *B. grunniens*), bison (*Bison bison* and *B. bonasus*) and water buffalo (*Bubalus bubalis*);
 - ii) sheep (*Ovis aries*) and goats (*Capra aegagrus*);
 - iii) pigs (*Sus scrofa*);
 - iv) camelids: this term means dromedary camel (*Camelus dromedarius*), Bactrian camel (*Camelus bactrianus*), llama (*Lama glama*), alpaca (*Lama pacos*), guanaco (*Lama guanicoe*) and vicuna (*Vicugna vicugna*);
 - v) cervids: this term means roe deer (*Capreolus capreolus*), red deer (*Cervus elaphus elaphus*), wapiti/elk (*C. elaphus canadensis*), sika (*C. nippon*), samba (*C. unicolor unicolor*), rusa (*C. timorensis*), fallow deer (*Dama dama*), white-tailed, black-tailed, mule deer (*Odocoileus* spp.) and reindeer/caribou (*Rangifer tarandus*);
 - vi) European hare (*Lepus europaeus*).
- 3) For the purpose of the *Terrestrial Code*, a case is an animal infected with *Brucella*.
- 4) The chapter deals not only with the occurrence of clinical signs caused by *infection* with *Brucella*, but also with the presence of *infection* with *Brucella* in the absence of clinical signs.
- 5) The following defines *infection* with *Brucella*:
 - a) *Brucella* has been isolated from ~~identified in~~ a sample from an animal;

OR

 - b) positive results to a diagnostic test have been obtained, and there is an epidemiological link to a case.
- 6) When authorising import or transit of *commodities* listed in this chapter, with the exception of those listed in Article 8.4.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *Brucella infection* status of the animal population of the exporting country, *zone*, *herd* or *flock*.
- 7) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

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Article 8.4.2.

Safe commodities

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

- 1) skeletal muscle *meat*, brain and spinal cord, digestive tract, thymus, thyroid and parathyroid glands and derived products;
- 2) cured hides and skins;
- 3) gelatine, collagen, tallow and *meat-and-bone meal*.

Article 8.4.3.

Country or zone historically free from infection with *Brucella* in specified animal categories

A country or *zone* may be considered free from *infection* with *Brucella* in specified animal categories when:

- 1) *infection* with *Brucella* in animals is a *notifiable disease* in the entire country;
- 2) historical freedom in the relevant animal categories has been demonstrated as described in point 1 of Article 1.4.6.

Article 8.4.4.

Country or zone free from infection with *Brucella* in bovids without vaccination

- 1) To qualify as free from *infection* with *Brucella* in bovids without *vaccination*, a country or *zone* should satisfy the following requirements:
 - a) *infection* with *Brucella* in animals is a *notifiable disease* in the entire country;
 - b) no case has been recorded in bovids for at least the past three years;
 - c) regular testing of all *herds* has been in place for the past three years; and this testing has demonstrated that during this period, *infection* with *Brucella* was not present in at least 99.8% of the *herds* representing at least 99.9% of bovids in the country or *zone*;
 - d) regulatory measures have been implemented for the early detection of *infection* with *Brucella* in bovids, including at least the regular submission of samples from abortion cases to diagnostic laboratories;
 - e) no bovids have been vaccinated against *infection* with *Brucella* for at least the past three years, and no bovids introduced into the country or *zone* have been vaccinated in the past three years;
 - f) bovids and their genetic materials introduced into the country or *zone* comply with the recommendations in Articles 8.4.14. and 8.4.16. to 8.4.18.
- 2) To maintain the status as free from *infection* with *Brucella* in bovids without *vaccination*, a country or *zone* should satisfy the following requirements:
 - a) the requirements in points 1a), 1b) and 1d) to 1f) above are met;
 - b) a *surveillance* programme based on regular testing of bovids is in place in the country or *zone* to detect *infection* with *Brucella* in accordance with Article 1.4.4.;

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- c) if the *surveillance* programme described in b) above has not detected *infection* with *Brucella* for two consecutive years, *surveillance* may be maintained in accordance with Article 1.4.5.
- 3) The country or *zone* status of free from *infection* with *Brucella* in bovids without *vaccination* is not affected by the occurrence of *infection* with *Brucella* in other animal categories or *feral* or *wild animals* provided that effective measures have been implemented to prevent transmission of *infection* with *Brucella* to bovids.

Article 8.4.5.

Country or zone free from infection with *Brucella* in bovids with vaccination

- 1) To qualify as free from *infection* with *Brucella* in bovids with *vaccination*, a country or *zone* should satisfy the following requirements:
- a) *infection* with *Brucella* in animals is a *notifiable disease* in the entire country;
 - b) no case has been recorded in bovids for at least the past three years;
 - c) regular testing of all *herds* has been in place for the past three years; and this testing has demonstrated that during this period, *infection* with *Brucella* was not present in at least 99.8% of the *herds* representing at least 99.9% of bovids in the country or *zone*;
 - d) regulatory measures have been implemented for the early detection of *infection* with *Brucella* in bovids, including at least the regular submission of samples from abortion cases to diagnostic laboratories;
 - e) vaccinated bovids should be permanently identified as such;
 - f) bovids and their genetic materials introduced into the country or *zone* comply with the recommendations in Articles 8.4.14. and 8.4.16. to 8.4.18.
- 2) To maintain the status as free from *infection* with *Brucella* in bovids with *vaccination*, a country or *zone* should satisfy the following requirements:
- a) the requirements in points 1a), 1b) and 1d) to 1f) above are met;
 - b) a *surveillance* programme based on regular testing of bovids is in place in the country or *zone* to detect *infection* with *Brucella* in accordance with Article 1.4.4.;
 - c) if the *surveillance* programme described in b) above has not detected *infection* with *Brucella* for two consecutive years, *surveillance* may be maintained in accordance with Article 1.4.5.
- 3) The country or *zone* status of free from *infection* with *Brucella* in bovids with *vaccination* is not affected by the occurrence of *infection* with *Brucella* in other animal categories or *feral* or *wild animals* provided that effective measures have been implemented to prevent transmission of *infection* with *Brucella* to bovids.
- 4) The status of a country or *zone* free from *infection* with *Brucella* in bovids with *vaccination* remains unchanged for a period of three years after *vaccination* has ceased, provided that the requirements in points 1a), 1b) and 1d) to 1f) of Article 8.4.4. are met, at which time this status may be changed to free from *infection* with *Brucella* in bovids without *vaccination*.

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Article 8.4.6.

Country or zone free from infection with *Brucella* in sheep and goats without vaccination

- 1) To qualify as free from *infection* with *Brucella* in sheep and goats without *vaccination*, a country or *zone* should satisfy the following requirements:
 - a) *infection* with *Brucella* in animals is a *notifiable disease* in the entire country;
 - b) no case has been recorded in sheep and goats for at least the past three years;
 - c) regular testing of all *flocks* has been in place for the past three years; and this testing has demonstrated that during this period, *infection* with *Brucella* was not present in at least 99.8% of the *flocks* representing at least 99.9% of sheep and goats in the country or *zone*;
 - d) regulatory measures have been implemented for the early detection of *infection* with *Brucella* in sheep and goats, including at least the regular submission of samples from abortion cases to diagnostic laboratories;
 - e) no sheep and goats have been vaccinated against *infection* with *Brucella* for at least the past three years and no sheep and goats introduced into the country or *zone* have been vaccinated in the past three years;
 - f) sheep and goats and their genetic materials introduced into the country or *zone* comply with the recommendations in Articles 8.4.14. and 8.4.16. to 8.4.18.
- 2) To maintain the status as free from *infection* with *Brucella* in sheep and goats without *vaccination*, a country or *zone* should satisfy the following requirements:
 - a) the requirements in points 1a), 1b) and 1d) to 1f) above are met;
 - b) a *surveillance* programme based on regular testing of sheep and goats is in place in the country or *zone* to detect *infection* with *Brucella* in accordance with Article 1.4.4.;
 - c) if the *surveillance* programme described in b) above has not detected *infection* with *Brucella* for two consecutive years, *surveillance* may be maintained in accordance with Article 1.4.5.
- 3) The country or *zone* status of free from *infection* with *Brucella* in sheep and goats without *vaccination* is not affected by the occurrence of *infection* with *Brucella* in other animal categories or *feral* or *wild animals* provided that effective measures have been implemented to prevent transmission of *infection* with *Brucella* to sheep and goats.

Article 8.4.7.

Country or zone free from infection with *Brucella* in sheep and goats with vaccination

- 1) To qualify as free from *infection* with *Brucella* in sheep and goats with *vaccination*, a country or *zone* should satisfy the following requirements:
 - a) *infection* with *Brucella* in animals is a *notifiable disease* in the entire country;
 - b) no case has been recorded in sheep and goats for at least the past three years;
 - c) regular testing of all *flocks* has been in place for the past three years; and this testing has demonstrated that during this period, *infection* with *Brucella* was not present in at least 99.8% of the *flocks* representing at least 99.9% of sheep and goats in the country or *zone*;

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- d) regulatory measures have been implemented for the early detection of *infection* with *Brucella* in sheep and goats, including at least the regular submission of samples from abortion cases to diagnostic laboratories;
 - e) vaccinated sheep and goats should be permanently identified as such;
 - f) sheep and goats and their genetic materials introduced into the country or *zone* comply with the recommendations in Articles 8.4.14. and 8.4.16. to 8.4.18.
- 2) To maintain the status as free from *infection* with *Brucella* in sheep and goats with *vaccination*, a country or *zone* should satisfy the following requirements:
- a) the requirements in points 1a), 1b) and 1d) to 1f) above are met;
 - b) a *surveillance* programme based on regular testing of sheep and goats is in place in the country or *zone* to detect *infection* with *Brucella* in accordance with Article 1.4.4.;
 - c) if the *surveillance* programme described in b) above has not detected *infection* with *Brucella* for two consecutive years, *surveillance* may be maintained in accordance with Article 1.4.5.
- 3) The country or *zone* status of free from *infection* with *Brucella* in sheep and goats with *vaccination* is not affected by the occurrence of *infection* with *Brucella* in other animal categories or *feral* or *wild animals* provided that effective measures have been implemented to prevent transmission of *infection* with *Brucella* to sheep and goats.
- 4) The status of a country or *zone* free from *infection* with *Brucella* in sheep and goats with *vaccination* remains unchanged for a period of three years after *vaccination* has ceased, provided that the requirements in points 1a), 1b) and 1d) to 1f) of Article 8.4.6. are met, at which time this status may be changed to free from *infection* with *Brucella* in sheep and goats without *vaccination*.

Article 8.4.8.

Country or zone free from infection with *Brucella* in camelids

- 1) To qualify as free from *infection* with *Brucella* in camelids, a country or *zone* should satisfy the following requirements:
- a) *infection* with *Brucella* in animals is a *notifiable disease* in the entire country;
 - b) no case has been recorded in camelids for at least the past three years;
 - c) regular testing of all *herds* has been in place for the past three years; and this testing has demonstrated that during this period, *infection* with *Brucella* was not present in at least 99.8% of the *herds* representing at least 99.9% of camelids in the country or *zone*;
 - d) regulatory measures have been implemented for the early detection of *infection* with *Brucella* in camelids, including at least the regular submission of samples of abortion cases to diagnostic laboratories;
 - e) no camelids have been vaccinated against *infection* with *Brucella* for at least the past three years and no camelids introduced into the country or *zone* have been vaccinated in the past three years;
 - f) camelids and their genetic materials introduced into the country or *zone* comply with the recommendations in Articles 8.4.14. and 8.4.16. to 8.4.18.

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- 2) To maintain the status as free from *infection with Brucella* in camelids, a country or *zone* should satisfy the following requirements:
 - a) the requirements in points 1a), 1b) and 1d) to 1f) above are met;
 - b) a *surveillance* programme based on regular testing of camelids is in place in the country or *zone* to detect *infection with Brucella* in accordance with Article 1.4.4.;
 - c) if the *surveillance* programme described in b) above has not detected *infection with Brucella* for two consecutive years, *surveillance* may be maintained in accordance with Article 1.4.5.
- 3) The country or *zone* status of free from *infection with Brucella* in camelids is not affected by the occurrence of *infection with Brucella* in other animal categories or *feral* or *wild animals* provided that effective measures have been implemented to prevent transmission of *infection with Brucella* to camelids.

Article 8.4.9.

Country or zone free from infection with *Brucella* in cervids

- 1) To qualify as free from *infection with Brucella* in cervids, a country or *zone* should satisfy the following requirements:
 - a) *infection with Brucella* in animals is a *notifiable disease* in the entire country;
 - b) no case has been recorded in cervids for at least the past three years;
 - c) regular testing of all *herds* has been in place for the past three years; and this testing has demonstrated that during this period, *infection with Brucella* was not present in at least 99.8% of the *herds* representing at least 99.9% of cervids in the country or *zone*;
 - d) regulatory measures have been implemented for the early detection of *infection with Brucella* in cervids, including at least the regular submission of samples from abortion cases to diagnostic laboratories;
 - e) no cervids have been vaccinated against *infection with Brucella* for at least the past three years and no cervids introduced into the country or *zone* have been vaccinated in the past three years;
 - f) cervids and their genetic materials introduced into the country or *zone* comply with the recommendations in Articles 8.4.14. and 8.4.16. to 8.4.18.
- 2) To maintain the status as free from *infection with Brucella* in cervids, a country or *zone* should satisfy the following requirements:
 - a) the requirements in points 1a), 1b) and 1d) to 1f) above are met;
 - b) a *surveillance* programme based on regular testing of cervids is in place in the country or *zone* to detect *infection with Brucella* in accordance with Article 1.4.4.;
 - c) if the *surveillance* programme described in b) above has not detected *infection with Brucella* for two consecutive years, *surveillance* may be maintained in accordance with Article 1.4.5.
- 3) The country or *zone* status of free from *infection with Brucella* in cervids is not affected by the occurrence of *infection with Brucella* in other animal categories or *feral* or *wild animals* provided that effective measures have been implemented to prevent transmission of *infection with Brucella* to cervids.

Article 8.4.10.

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

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

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

OR

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

OR

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

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

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

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

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

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

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

2) To maintain the free status, the following conditions should be met:

a) the requirements in points 1a) or 1b) or 1c) i) to v) above are met;

b) regular tests, at a frequency depending on the prevalence of *herd* or *flock infection* in the country or *zone*, demonstrate the continuing absence of *infection* with *Brucella*;

c) animals of the relevant category introduced into the *herd* or *flock* are accompanied by a certificate from an *Official Veterinarian* attesting that they come from:

i) a country or *zone* free from *infection* with *Brucella* in the relevant category without *vaccination*;

OR

ii) a country or *zone* free from *infection* with *Brucella* with *vaccination* and the animals of the relevant category have not been vaccinated in the past three years;

Annex XVIII (contd)

OR

- iii) a *herd* or *flock* free from *infection* with *Brucella* with or without *vaccination* and that the animals have not been vaccinated in the past three years and were tested for *infection* with *Brucella* within 30 days prior to shipment with negative results; in the case of post-parturient females, the test is carried out at least 30 days after giving birth. This test is not required for sexually immature animals.

Article 8.4.11.

Herd or flock free from infection with *Brucella* in bovids, sheep and goats with vaccination

- 1) To qualify as free from *infection* with *Brucella* with *vaccination*, a *herd* of bovids or *flock* of sheep and goats should satisfy the following requirements:

- a) the *herd* or *flock* is in a country or *zone* free from *infection* with *Brucella* with *vaccination* for the relevant animal category and is certified free with *vaccination* by the *Veterinary Authority*;

OR

- b) the *herd* or *flock* met the following conditions:

- i) *infection* with *Brucella* in animals is a *notifiable disease* in the entire country;
- ii) vaccinated animals of the relevant categories are permanently identified as such;
- iii) no case has been detected in the *herd* or *flock* for at least the past year;
- iv) animals showing clinical signs consistent with *infection* with *Brucella* such as abortions have been subjected to the necessary diagnostic tests with negative results;
- v) for at least the past year, there has been no evidence of *infection* with *Brucella* in other *herds* or *flocks* of the same *establishment*, or measures have been implemented to prevent any transmission of the *infection* with *Brucella* from these other *herds* or *flocks*;
- vi) two tests have been performed with negative results on all sexually mature animals present in the *herd* at the time of testing, the first test being performed not before 3 months after the *slaughter* of the last case and the second test at an interval of more than 6 and less than 12 months.

- 2) To maintain the free status, the following conditions should be met:

- a) the requirements in points 1 a) or 1b) i) to v) above are met;
- b) regular tests, at a frequency depending on the prevalence of *herd* or *flock infection* in the country or *zone*, demonstrate the continuing absence of *infection* with *Brucella*;
- c) animals of the relevant category introduced into the *herd* or *flock* should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from either:
 - i) a country or *zone* free from *infection* with *Brucella* in the relevant category with or without *vaccination*;

OR

- ii) a *herd* or *flock* free from *infection* with *Brucella* with or without *vaccination* and that the animals were tested for *infection* with *Brucella* within 30 days prior to shipment with negative results; in the case of post-parturient females, the test is carried out at least 30 days after giving birth. This test is not required for sexually immature animals or vaccinated animals less than 18 months of age.

Article 8.4.12.

Herd free from infection with *Brucella* in pigs

- 1) To qualify as free from *infection* with *Brucella*, a *herd* of pigs should satisfy the following requirements:
 - a) *infection* with *Brucella* in animals is a *notifiable disease* in the entire country;
 - b) no case has been detected in the *herd* for at least the past three years;
 - c) animals showing clinical signs consistent with *infection* with *Brucella* such as abortions or orchitis have been subjected to the necessary diagnostic tests with negative results;
 - d) no pigs of the *herd* have been vaccinated for at least the past three years and no pigs introduced into the *herd* have been vaccinated in the past three years;
 - e) for at least the past three years, there has been no evidence of *infection* with *Brucella* in other *herds* or *flocks* of the same *establishment*, or measures have been implemented to prevent any transmission of *infection* with *Brucella* from these other *herds* or *flocks*.

- 2) To maintain the free status, the following conditions should be met:
 - a) the requirements in point 1) above are met;
 - b) animals introduced into the *herd* are accompanied by a certificate from an *Official Veterinarian* attesting that:
 - i) they come from a *herd* free from *infection* with *Brucella*;

OR

 - ii) they come from a *herd* in which a statistically valid sample of the breeding pigs, selected in accordance with the provisions of Article 1.4.4., was tested within 30 days prior to shipment, demonstrating the absence of *infection* with *Brucella*;

OR

- iii) they were tested within 30 days prior to shipment with negative results.

Article 8.4.13.

Recovery of the *Brucella* infection free status in a country or a zone

Should a case of *infection* with *Brucella* in one or more animal categories occur in a free country or *zone* as described in Articles 8.4.4. to 8.4.9., the free status may be recovered once the following requirements are met:

- 1) all infected animals of the relevant category have been slaughtered or destroyed as soon as *infection* with *Brucella* is confirmed;
- 2) an epidemiological investigation has been performed within 60 days of ~~*Brucella infection*~~ confirmation of *infection* with *Brucella* in the *herd* or *flock*, aiming at identifying the likely source and the distribution of the *infection*, and shows that the number of *outbreaks* is limited and all are epidemiologically linked;

Annex XVIII (contd)

- 3) in the index *herd* or *flock* and *herds* or *flocks* identified by the epidemiological investigation:
- a) whole *herd* or *flock* depopulation has been practised; or
 - b) whole *herd* or *flock* depopulation has not been practised, and all remaining sexually mature animals except castrated males have been tested, with negative results, on three occasions, at an interval of not less than two months, then a fourth test six months later and a final fifth test a year later;
- and
- c) no animals are moved from the *herds* or *flocks* except directly for *slaughter* until the processes in point a) or b) above are completed;
- 4) cleansing and *disinfection* procedures have been applied at the end of the *slaughter* process and before new animals are introduced.

If these requirements have not been met, the status is not recovered and Articles 8.4.4. to 8.4.9. apply as relevant.

Article 8.4.14.

Recommendations for the importation of bovids, sheep and goats, camelids or cervids for breeding or rearing

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

- 1) showed no clinical sign of *infection* with *Brucella* on the day of shipment;
- 2) originate from:
 - a) a country or *zone* free from *infection* with *Brucella* as relevant;

OR

 - b) a *herd* or *flock* free from *infection* with *Brucella* and all sexually mature animals were tested for *infection* with *Brucella* with negative results within 30 days prior to shipment;

OR

 - c) a *herd* or *flock* not qualified free from *infection* with *Brucella*:
 - i) in which no case has been reported during the year prior to shipment;
 - ii) the animals were isolated for 30 days prior to shipment and all animals in isolation were tested for *infection* with *Brucella* within that period with negative results; in the case of post-parturient females, the test was carried out at least 30 days after giving birth.

Article 8.4.15.

Recommendations for the importation of pigs for breeding or rearing

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

- 1) showed no clinical sign of *infection* with *Brucella* on the day of shipment;

Annex XVIII (contd)

- 2) either
- a) originate from a *herd* free from *infection* with *Brucella*;
- OR
- b) originate from a *herd* in which a statistically valid sample of the breeding pigs, selected in accordance with the provisions of Article 1.4.4., was tested within 30 days prior to shipment, demonstrating the absence of *infection* with *Brucella*;
- OR
- c) were isolated for 30 days prior to shipment and all pigs in isolation were tested for *infection* with *Brucella* within that period with negative results.

Article 8.4.16.

Recommendations for the importation of animals for slaughter

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

- 1) showed no clinical sign of *infection* with *Brucella* on the day of shipment;
- 2) originate from a country, *zone*, *herd* or *flock* free from *infection* with *Brucella*;
- OR
- 3) are not being culled as part of an eradication programme against *Brucella infection* and in the case of sexually mature bovids, sheep and goats, camelids or cervids, were tested for *infection* with *Brucella* with negative results within 30 days prior to shipment.

Article 8.4.17.

Recommendations for the importation of semen

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

- 1) the donor animals showed no clinical sign of *infection* with *Brucella* on the day of collection of the semen;
- 2) the donor animals were not vaccinated against *infection* with *Brucella* and either:
- a) were kept in an *artificial insemination centre* complying with the provisions of Chapter 4.5.;
- OR
- b) were kept in a *herd* or *flock* free from *infection* with *Brucella* and tested every six months for *infection* with *Brucella* with negative results, 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 8.4.18.

Recommendations for the importation of embryos and oocytes

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

Annex XVIII (contd)

- 1) the donor animals showed no clinical signs of *infection* with *Brucella* on the day of collection;
- 2) the donor animals were not vaccinated against *infection* with *Brucella* in the past three years and either:
 - a) were kept in a country or *zone* free from *infection* with *Brucella*, as relevant;

OR

 - b) were kept in a *herd* or *flock* free from *infection* with *Brucella* and tested every six months for *infection* with *Brucella* with negative results;
- 3) the embryos and oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7. to 4.9.

Article 8.4.19.

Recommendations for the importation of fresh meat and meat products other than mentioned in Article 8.4.2.

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the *meat* and *meat products* come from animals:

- 1) which have been subjected to ante-and post-mortem inspections as described in Chapter 6.2.;
- 2) which:
 - a) originate from a country or *zone* free from *infection* with *Brucella*, as relevant;

OR

 - b) originate from a *herd* or *flock* free from *infection* with *Brucella*;

OR

 - c) have not been culled as part of an eradication programme against *infection* with *Brucella*.

Article 8.4.20.

Recommendations for the importation of milk and milk products

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

- 1) have been derived from animals in a country, *zone*, *herd* or *flock* free from *infection* with *Brucella* as relevant;
- 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 8.4.21.

Recommendations for importation of wool and hair

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

- 1) have not been derived from animals culled as part of an eradication programme against *infection* with *Brucella*;

OR

- 2) have been processed to ensure the destruction of *Brucella*.

— Text deleted.

CHAPTER 10.4.

INFECTION WITH AVIAN INFLUENZA VIRUSES

Article 10.4.1.

General provisions

- 1) For the purposes of the *Terrestrial Code*, avian influenza is defined as an *infection of poultry* caused by any influenza A virus of the H5 or H7 subtypes or by any influenza A virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. These viruses are divided into high pathogenicity avian influenza viruses and low pathogenicity avian influenza viruses:
 - a) high pathogenicity avian influenza viruses have an IVPI in six-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in four-to eight-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other high pathogenicity avian influenza isolates, the isolate being tested should be considered as high pathogenicity avian influenza virus;
 - b) low pathogenicity avian influenza viruses are all influenza A viruses of H5 and H7 subtypes that are not high pathogenicity avian influenza viruses.
- 2) The following defines the occurrence of *infection* with an avian influenza virus: the virus has been isolated and identified as such or specific viral ribonucleic acid has been detected in *poultry* or a product derived from *poultry*.
- 3) *Poultry* is defined as 'all domesticated birds, including backyard *poultry*, used for the production of *meat* or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose'.

Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered to be *poultry*.
- 4) For the purposes of the *Terrestrial Code*, the *incubation period* for avian influenza shall be 21 days.
- 5) This chapter deals not only with the occurrence of clinical signs caused by avian influenza, but also with the presence of *infection* with avian influenza viruses in the absence of clinical signs.
- 6) Antibodies against H5 or H7 subtype, which have been detected in *poultry* and are not a consequence of *vaccination*, should be immediately investigated. In the case of isolated serological positive results, *infection* with avian influenza viruses may be ruled out on the basis of a thorough epidemiological and *laboratory* investigation that does not demonstrate further evidence of such an *infection*.
- 7) For the purposes of the *Terrestrial Code*, 'avian influenza free establishment' means an *establishment* in which the *poultry* have shown no evidence of *infection* with avian influenza viruses, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.
- 8) *Infection* with influenza A viruses of high pathogenicity in birds other than *poultry*, including *wild* birds, should be notified according to Article 1.1.3. However, a Member Country should not impose bans on the trade in *poultry* and *poultry commodities* in response to such a *notification*, or other information on the presence of any influenza A virus in birds other than *poultry*, including *wild* birds.

Annex XIX (contd)

- 9) Standards for diagnostic tests, including pathogenicity testing, are described in the *Terrestrial Manual*. Any vaccine used should comply with the standards described in the *Terrestrial Manual*.

Article 10.4.2.

Determination of the avian influenza status of a country, zone or compartment

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

- 1) avian influenza is notifiable in the whole country, an ongoing avian influenza awareness programme is in place, and all notified suspect occurrences of avian influenza are subjected to field and, where applicable, *laboratory* investigations;
- 2) appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in *poultry*, and the *risk* posed by birds other than *poultry*; this may be achieved through an avian influenza *surveillance* programme in accordance with Articles 10.4.27. to 10.4.33.;
- 3) consideration of all epidemiological factors for avian influenza occurrence and their historical perspective.

Article 10.4.3.

Country, zone or compartment free from avian influenza

A country, *zone* or *compartment* may be considered free from avian influenza when it has been shown that *infection* with avian influenza viruses in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, avian influenza free status can be regained:

- 1) In the case of *infections* with high pathogenicity avian influenza viruses, three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.
- 2) In the case of *infections* with low pathogenicity avian influenza viruses, *poultry* may be kept for *slaughter* for human consumption subject to conditions specified in Article 10.4.19. or a *stamping-out policy* may be applied; in either case, three months after the *disinfection* of all affected *establishments*, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.4.

Country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry

A country, *zone* or *compartment* may be considered free from *infection* with high pathogenicity avian influenza viruses in *poultry* when:

- 1) it has been shown that *infection* with high pathogenicity avian influenza viruses in *poultry* has not been present in the country, *zone* or *compartment* for the past 12 months, although its status with respect to low pathogenicity avian influenza viruses may be unknown; or
- 2) when, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33., it does not meet the criteria for freedom from avian influenza but any virus detected has not been identified as high pathogenicity avian influenza virus.

Annex XIX (contd)

The *surveillance* may need to be adapted to parts of the country or existing *zones* or *compartments* depending on historical or geographical factors, industry structure, population data, or proximity to recent *outbreaks*.

If *infection* has occurred in *poultry* in a previously free country, *zone* or *compartment*, the free status can be regained three months after a *stamping-out policy* (including *disinfection* of all affected *establishments*) is applied, providing that *surveillance* in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.

Article 10.4.5.

Recommendations for importation from a country, zone or compartment free from avian influenzaFor live poultry (other than day-old poultry)

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

- 1) the *poultry* showed no clinical sign of avian influenza on the day of shipment;
- 2) the *poultry* were kept in an avian influenza free country, *zone* or *compartment* since they were hatched or for at least the past 21 days;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be attached to the *certificate*.

Article 10.4.6.

Recommendations for the importation of live birds other than poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) on the day of shipment, the birds showed no clinical sign of *infection* with a virus which would be considered avian influenza in *poultry*;
- 2) the birds were kept in isolation approved by the *Veterinary Services* since they were hatched or for at least 21 days prior to shipment and showed no clinical sign of *infection* with a virus which would be considered avian influenza in *poultry* during the isolation period;
- 3) a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.4.29., was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from *infection* with a virus which would be considered avian influenza in *poultry*;
- 4) the birds are transported in new or appropriately sanitized *containers*.

If the birds have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be attached to the *certificate*.

Article 10.4.7.

Recommendations for importation from a country, zone or compartment free from avian influenzaFor day-old live poultry

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

Annex XIX (contd)

- 1) the *poultry* were kept in an avian influenza free country, *zone* or *compartment* since they were hatched;
- 2) the *poultry* were derived from parent *flocks* which had been kept in an avian influenza free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* or the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be attached to the *certificate*.

Article 10.4.8.

Recommendations for importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry

For day-old live poultry

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

- 1) the *poultry* were kept in a country, *zone* or *compartment* free from *infection* with high pathogenicity avian influenza viruses in *poultry* since they were hatched;
- 2) the *poultry* were derived from parent *flocks* which had been kept in an avian influenza free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* or the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be attached to the *certificate*.

Article 10.4.9.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) on the day of shipment, the birds showed no clinical sign of *infection* with a virus which would be considered avian influenza in *poultry*;
- 2) the birds were hatched and kept in isolation approved by the *Veterinary Services*;
- 3) the parent *flock* birds were subjected to a diagnostic test at the time of the collection of the eggs to demonstrate freedom from *infection* with a virus which would be considered avian influenza in *poultry*;
- 4) the birds are transported in new or appropriately sanitized *containers*.

If the birds or parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be attached to the *certificate*.

Article 10.4.10.

Recommendations for importation from a country, zone or compartment free from avian influenza

For hatching eggs of poultry

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

Annex XIX (contd)

- 1) the eggs came from an avian influenza free country, *zone* or *compartment*;
- 2) the eggs were derived from parent *flocks* which had been kept in an avian influenza free country, *zone* or *compartment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be attached to the *certificate*.

Article 10.4.11.

Recommendations for importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry

For hatching eggs of poultry

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

- 1) the eggs came from a country, *zone* or *compartment* free from *infection* with high pathogenicity avian influenza viruses in *poultry*;
- 2) the eggs were derived from parent *flocks* which had been kept in an avian influenza free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;
- 3) the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
- 4) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be attached to the *certificate*.

Article 10.4.12.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the parent *flock* birds were subjected to a diagnostic test seven days prior to and at the time of the collection of the eggs to demonstrate freedom from *infection* with a virus which would be considered avian influenza in *poultry*;
- 2) the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
- 3) the eggs are transported in new or appropriately sanitized packaging materials.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be attached to the *certificate*.

Article 10.4.13.

Recommendations for importation from a country, zone or compartment free from avian influenza

For eggs for human consumption

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

Annex XIX (contd)

- 1) the eggs were produced and packed in an avian influenza free country, *zone* or *compartment*,
- 2) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.14.

Recommendations for importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry

For eggs for human consumption

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

- 1) the eggs were produced and packed in a country, *zone* or *compartment* free from *infection* with high pathogenicity avian influenza viruses in *poultry*;
- 2) the eggs have had their surfaces sanitized (in accordance with Chapter 6.4.);
- 3) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.4.15.

Recommendations for importation of egg products of poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the *commodity* is derived from eggs which meet the requirements of Articles 10.4.13. or 10.4.14.; or
- 2) the *commodity* has been processed to ensure the destruction of avian influenza virus in accordance with Article 10.4.25.;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 10.4.16.

Recommendations for importation from a country, zone or compartment free from avian influenza

For poultry semen

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

- 1) showed no clinical sign of avian influenza on the day of semen collection;
- 2) were kept in an avian influenza free country, *zone* or *compartment* for at least 21 days prior to and at the time of semen collection.

Article 10.4.17.

Recommendations for the importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry

For poultry semen

Annex XIX (contd)

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

- 1) showed no clinical sign of *infection* with high pathogenicity avian influenza viruses in *poultry* on the day of semen collection;
- 2) were kept in a country, *zone* or *compartment* free from *infection* with high pathogenicity avian influenza viruses in *poultry* for at least 21 days prior to and at the time of semen collection.

Article 10.4.18.

Recommendations for the importation of semen of birds other than poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor birds:

- 1) were kept in isolation approved by the *Veterinary Services* for at least 21 days prior to semen collection;
- 2) showed no clinical sign of *infection* with a virus which would be considered avian influenza in *poultry* during the isolation period;
- 3) were tested within 14 days prior to semen collection and shown to be free from *infection* with a virus which would be considered avian influenza in *poultry*.

Article 10.4.19.

Recommendations for importation from a country, zone or compartment free from avian influenza or free from infection with high pathogenicity avian influenza viruses in poultry

For fresh meat of poultry

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

- 1) which have been kept in a country, *zone* or *compartment* free from *infection* with high pathogenicity avian influenza viruses in *poultry* since they were hatched or for at least the past 21 days;
- 2) which have been slaughtered in an approved *abattoir* in a country, *zone* or *compartment* free from *infection* with high pathogenicity avian influenza viruses in *poultry* and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any signs suggestive of avian influenza.

Article 10.4.20.

Recommendations for the importation of meat products of poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the *commodity* is derived from *fresh meat* which meets the requirements of Article 10.4.19.; or
- 2) the *commodity* has been processed to ensure the destruction of avian influenza virus in accordance with Article 10.4.26.;

Annex XIX (contd)

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 10.4.21.

Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* were processed in an avian influenza free country, *zone* or *compartment* from *poultry* which were kept in an avian influenza free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*, or
- 2) these *commodities* have been processed to ensure the destruction of avian influenza virus using;
 - a) moist heat treatment for 30 minutes at 56°C; or
 - b) any equivalent treatment which has been demonstrated to inactivate avian influenza virus;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 10.4.22.

Recommendations for the importation of feathers and down of poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* originated from *poultry* as described in Article 10.4.19. and were processed in an avian influenza free country, *zone* or *compartment*, or
- 2) these *commodities* have been processed to ensure the destruction of avian influenza virus using one of the following:
 - a) washed and steam-dried at 100°C for 30 minutes;
 - b) fumigation with formalin (10% formaldehyde) for 8 hours;
 - c) irradiation with a dose of 20 kGy;
 - d) any equivalent treatment which has been demonstrated to inactivate avian influenza virus;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza virus.

Article 10.4.23.

Recommendations for the importation of feathers and down of birds other than poultry

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* have been processed to ensure the destruction of any virus which would be considered avian influenza in *poultry* using one of the following:
 - a) washed and steam-dried at 100°C for 30 minutes;
 - b) fumigation with formalin (10% formaldehyde) for 8 hours;
 - c) irradiation with a dose of 20 kGy;
 - d) any equivalent treatment which has been demonstrated to inactivate avian influenza virus;
- 2) the necessary precautions were taken to avoid contact of the *commodity* with any source of viruses which would be considered avian influenza in *poultry*.

Article 10.4.24.

Recommendations for the importation of feather meal and poultry meal

Regardless of the avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these *commodities* were processed in an avian influenza free country, *zone* or *compartment* from *poultry* which were kept in an avian influenza free country, *zone* or *compartment* from the time they were hatched until the time of *slaughter* or for at least the 21 days preceding *slaughter*; or
- 2) these *commodities* have been processed either:
 - a) with moist heat at a minimum temperature of 118°C for minimum of 40 minutes; or
 - b) with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122°C for a minimum of 15 minutes; or
 - c) with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74°C;

AND

- 3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza viruses.

Article 10.4.25.

Procedures for the inactivation of avian influenza viruses in eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of avian influenza viruses present in eggs and egg products:

Annex XIX (contd)

	Core temperature (°C)	Time
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	870 seconds
Liquid egg white	56.7	232 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	20 hours
Dried egg white	54.4	513 hours

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.26.

Procedures for the inactivation of avian influenza viruses in meat

The following times for industry standard temperatures are suitable for the inactivation of avian influenza viruses

	Core temperature (°C)	Time
Poultry meat	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 second

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.27.

Introduction to surveillance

Articles 10.4.27. to 10.4.33. define the principles and provide a guide on the *surveillance* for avian influenza complementary to Chapter 1.4., applicable to Member Countries seeking to determine their avian influenza status. This may be for the entire country, *zone* or *compartment*. Guidance for Member Countries seeking free status following an *outbreak* and for the maintenance of avian influenza status is also provided.

The presence of influenza A viruses in *wild* birds creates a particular problem. In essence, no Member Country can declare itself free from influenza A in *wild* birds. However, the definition of avian influenza in this chapter refers to the *infection* in *poultry* only, and Articles 10.4.27. to 10.4.33. were developed under this definition.

The impact and epidemiology of avian influenza differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from avian influenza at an acceptable level of confidence should be adapted to the local situation. Variables such as the frequency of contacts of *poultry* with *wild* birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific *surveillance* strategies to address each specific situation. It is incumbent upon the Member Country to provide scientific data that explains the epidemiology of avian influenza in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of *infection* with avian influenza viruses is assured at an acceptable level of confidence.

Surveillance for avian influenza should be in the form of a continuing programme designed to establish that the country, *zone* or *compartment*, for which application is made, is free from *infection* with avian influenza viruses.

Article 10.4.28.

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* or *infection* with avian influenza viruses should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of avian influenza to a *laboratory* for avian influenza diagnosis;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
- 2) The avian influenza *surveillance* programme should:
 - a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of avian influenza to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of avian influenza should be investigated immediately. As suspicion cannot always be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in avian influenza diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;
 - b) implement, when relevant, regular and frequent clinical inspection and serological and virological testing of high-risk groups of *animals*, such as those adjacent to an avian influenza infected country or *zone*, places where birds and *poultry* of different origins are mixed, such as live bird markets, *poultry* in close proximity to waterfowl or other potential sources of influenza A viruses.

An effective *surveillance* system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is influenza A viruses. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Documentation for freedom from *infection* with avian influenza viruses should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Annex XIX (contd)

Article 10.4.29.

Surveillance strategies1. Introduction

The target population for *surveillance* aimed at identification of *disease* and *infection* should cover all the susceptible *poultry* species within the country, *zone* or *compartment*. Active and passive *surveillance* for avian influenza should be ongoing. ~~The frequency of active *surveillance* should be at least every six months, with the frequency of active *surveillance* being appropriate to the epidemiological situation in the country.~~ *Surveillance* should be composed of random and targeted approaches using molecular, virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of *infection* with avian influenza viruses at an acceptable level of confidence. Random *surveillance* is conducted using serological tests. Positive serological results should be followed up with molecular or virological methods.

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods should be used concurrently to define the avian influenza status of high risk populations.

A Member Country should justify the *surveillance* strategy chosen as adequate to detect the presence of *infection* with avian influenza viruses in accordance with Chapter 1.4. and the prevailing epidemiological situation, including cases of high pathogenicity influenza A detected in any birds. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member Country wishes to declare freedom from *infection* with avian influenza viruses in a specific *zone* or *compartment*, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone* or *compartment*.

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 *infection* 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 epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular should be clearly based on the prevailing or historical epidemiological situation.

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

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

The principles involved in *surveillance* for *disease* and *infection* are technically well defined. The design of *surveillance* programmes to prove the absence of *infection* with, or circulation of, avian influenza viruses should be carefully followed to avoid producing results that are either insufficiently reliable, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

2. Clinical surveillance

Clinical *surveillance* aims at the detection of clinical signs of avian influenza at the *flock* level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory *disease* or a drop in egg production, is important for the early detection of *infection* with avian influenza viruses. In some cases, the only indication of *infection* with low pathogenicity avian influenza virus may be a drop in feed consumption or egg production.

Clinical *surveillance* and *laboratory* testing should always be applied in series to clarify the status of avian influenza suspects detected by either of these complementary diagnostic approaches. *Laboratory* testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive serology. Any sampling unit within which suspicious *animals* are detected should have restrictions imposed upon it until avian influenza *infection* is ruled out.

Identification of suspect *flocks* is vital to the identification of sources of avian influenza viruses and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that avian influenza virus isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterisation.

3. Virological surveillance

Virological *surveillance* should be conducted:

- a) to monitor at risk populations;
- b) to confirm clinically suspect cases;
- c) to follow up positive serological results;
- d) to test 'normal' daily mortality, to ensure early detection of *infection* in the face of *vaccination* or in *establishments* epidemiologically linked to an *outbreak*.

4. Serological surveillance

Serological *surveillance* aims at the detection of antibodies against avian influenza virus. Positive avian influenza viruses antibody test results can have four possible causes:

- a) natural *infection* with avian influenza viruses;
- b) *vaccination* against avian influenza;
- c) maternal antibodies derived from a vaccinated or infected parent *flock* are usually found in the yolk and can persist in progeny for up to four weeks;
- d) lack of specificity of the test.

It may be possible to use serum collected for other survey purposes for avian influenza *surveillance*. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of avian influenza viruses should not be compromised.

The discovery of clusters of seropositive *flocks* may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or *infection*. As clustering may signal *infection*, the investigation of all instances should be incorporated in the survey design. Clustering of positive *flocks* is always epidemiologically significant and therefore should be investigated.

If *vaccination* cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to *infection* or *vaccination* should be employed.

Annex XIX (contd)

The results of random or targeted serological surveys are important in providing reliable evidence that no *infection* with avian influenza viruses is present in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

5. Virological and serological surveillance in vaccinated populations

The *surveillance* strategy is dependent on the type of vaccine used. The protection against influenza A virus is haemagglutinin subtype specific. Therefore, two broad *vaccination* strategies exist: 1) inactivated whole viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the *surveillance* strategy should be based on virological or serological methods and clinical *surveillance*. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, virus antibody free birds and clearly and permanently identified. Sentinel birds should be used only if no appropriate *laboratory* procedures are available. The interpretation of serological results in the presence of *vaccination* is described in Article 10.4.33.

Article 10.4.30.

Documentation of freedom from avian influenza or freedom from infection with high pathogenicity avian influenza viruses in poultry1. Additional surveillance requirements for Member Countries declaring freedom of the country, zone or compartment from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry

In addition to the general conditions described in above mentioned articles, a Member Country declaring freedom of the entire country, or a *zone* or a *compartment* from avian influenza or from *infection* with high pathogenicity avian influenza viruses in *poultry* should provide evidence for the existence of an effective *surveillance* programme.

The strategy and design of the *surveillance* programme depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter, to demonstrate absence of *infection* with avian influenza viruses or with high pathogenicity avian influenza viruses, during the preceding 12 months in susceptible *poultry* populations (vaccinated and non-vaccinated). This requires the support of a *laboratory* able to undertake identification of *infection* with avian influenza viruses through virus detection and antibody tests. This *surveillance* may be targeted to *poultry* population at specific risks linked to the types of production, possible direct or indirect contact with *wild* birds, multi-age *flocks*, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

2. Additional requirements for countries, zones or compartments that practise vaccination

Vaccination to prevent the transmission of high pathogenicity avian influenza virus may be part of a *disease* control programme. The level of *flock* immunity required to prevent transmission depends on the *flock* size, composition (e.g. species) and density of the susceptible *poultry* population. It is therefore impossible to be prescriptive. Based on the epidemiology of avian influenza in the country, *zone* or *compartment*, it may be that a decision is reached to vaccinate only certain species or other *poultry* subpopulations.

In all vaccinated *flocks* there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every six months or at shorter intervals according to the *risk* in the country, *zone* or *compartment*.

Evidence to show the effectiveness of the *vaccination* programme should also be provided.

Article 10.4.31.

Additional surveillance requirements for countries, zones or compartments declaring that they have regained freedom from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry following an outbreak

In addition to the general conditions described in the above-mentioned articles, a Member Country declaring that it has regained country, *zone* or *compartment* freedom from avian influenza or from *infection* with high pathogenicity avian influenza viruses in *poultry* should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*. This will require *surveillance* incorporating virus detection and antibody tests. The use of sentinel birds may facilitate the interpretation of *surveillance* results.

A Member Country declaring freedom of country, *zone* or *compartment* after an *outbreak* of avian influenza should report the results of an active *surveillance* programme in which the susceptible *poultry* population undergoes regular clinical examination and active *surveillance* planned and implemented according to the general conditions and methods described in these recommendations. The *surveillance* should at least give the confidence that can be given by a randomised representative sample of the populations at risk.

Article 10.4.32.

Additional surveillance requirements for avian influenza free establishments

The declaration of avian influenza free *establishments* requires the demonstration of absence of *infection* with avian influenza viruses. Birds in these *establishments* should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these recommendations. The frequency of testing should be based on the *risk of infection* and at a maximum interval of 21 days.

Article 10.4.33.

The use and interpretation of serological and virus detection tests

Poultry infected with avian influenza virus produce antibodies against haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins is not covered in this chapter. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct and blocking ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI), ELISA and neutralisation (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies against the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype influenza A viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of influenza A viruses.

Poultry can be vaccinated with a variety of influenza A vaccines including inactivated whole virus vaccines, and haemagglutinin expression-based vaccines. Antibodies against the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

Annex XIX (contd)

Influenza A virus *infection* of unvaccinated birds including sentinels is detected by antibodies against the NP/M, subtype specific HA or NA proteins, or NSP. *Poultry* vaccinated with inactivated whole virus vaccines containing a virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies against the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies against NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In *poultry* vaccinated with haemagglutinin expression-based vaccines, antibodies are detected against the specific HA, but not any of the other viral proteins. *Infection* is evident by antibodies against the NP/M or NSP, or the specific NA protein of the field virus.

All *flocks* with seropositive results should be investigated. Epidemiological and supplementary *laboratory* investigation results should document the status of avian influenza *infection* for each positive *flock*.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

1. Procedure in case of positive test results if vaccination is used

In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on vaccinated *poultry*. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated *animals*.

- a) Inactivated whole virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If *poultry* in the population have antibodies against NP/M and were vaccinated with inactivated whole virus vaccine, the following strategies should be applied:
 - i) sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating influenza A virus *infection*, specific HI tests should be performed to identify H5 or H7 virus *infection*;
 - ii) if vaccinated with inactivated whole virus vaccine containing homologous NA to field virus, the presence of antibodies against NSP could be indicative of *infection*. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins;
 - iii) if vaccinated with inactivated whole virus vaccine containing heterologous NA to field virus, presence of antibodies against the field virus NA or NSP would be indicative of *infection*. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.
- b) Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect avian influenza *infection*. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of *infection*. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.

2. Procedure in case of test results indicative of infection with avian influenza viruses

The detection of antibodies indicative of an *infection* with avian influenza virus in unvaccinated *poultry* should result in the initiation of epidemiological and virological investigations to determine if the *infections* are due to low and high pathogenicity viruses.

Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of avian influenza virus, by virus isolation and identification, or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting *infection* by avian influenza virus. All influenza A virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as high or low pathogenicity avian influenza viruses or other influenza A viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and *in vivo* testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as high or low pathogenicity avian influenza viruses. The use of antigen detection systems, because of low sensitivity, should be limited to screening clinical field *cases* for *infection* by influenza A virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

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 circulation includes but is not limited to:

- a) characterisation of the existing production systems;
- b) results of clinical *surveillance* of the suspects and their cohorts;
- c) quantification of *vaccinations* performed on the affected sites;
- d) sanitary protocol and history of the affected *establishments*;
- e) control of *animal identification* and movements;
- f) other parameters of regional significance in historic avian influenza virus transmission.

The entire investigative process should be documented as standard operating procedure within the epidemiological *surveillance* programme.

Figures 1 and 2 indicate the tests which are recommended for use in the investigation of *poultry flocks*.

Key abbreviations and acronyms:	
AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbent assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of avian influenza virus

Annex XIX (contd)

Fig. 1. Schematic representation of laboratory tests for determining evidence of avian influenza infection through or following serological surveys

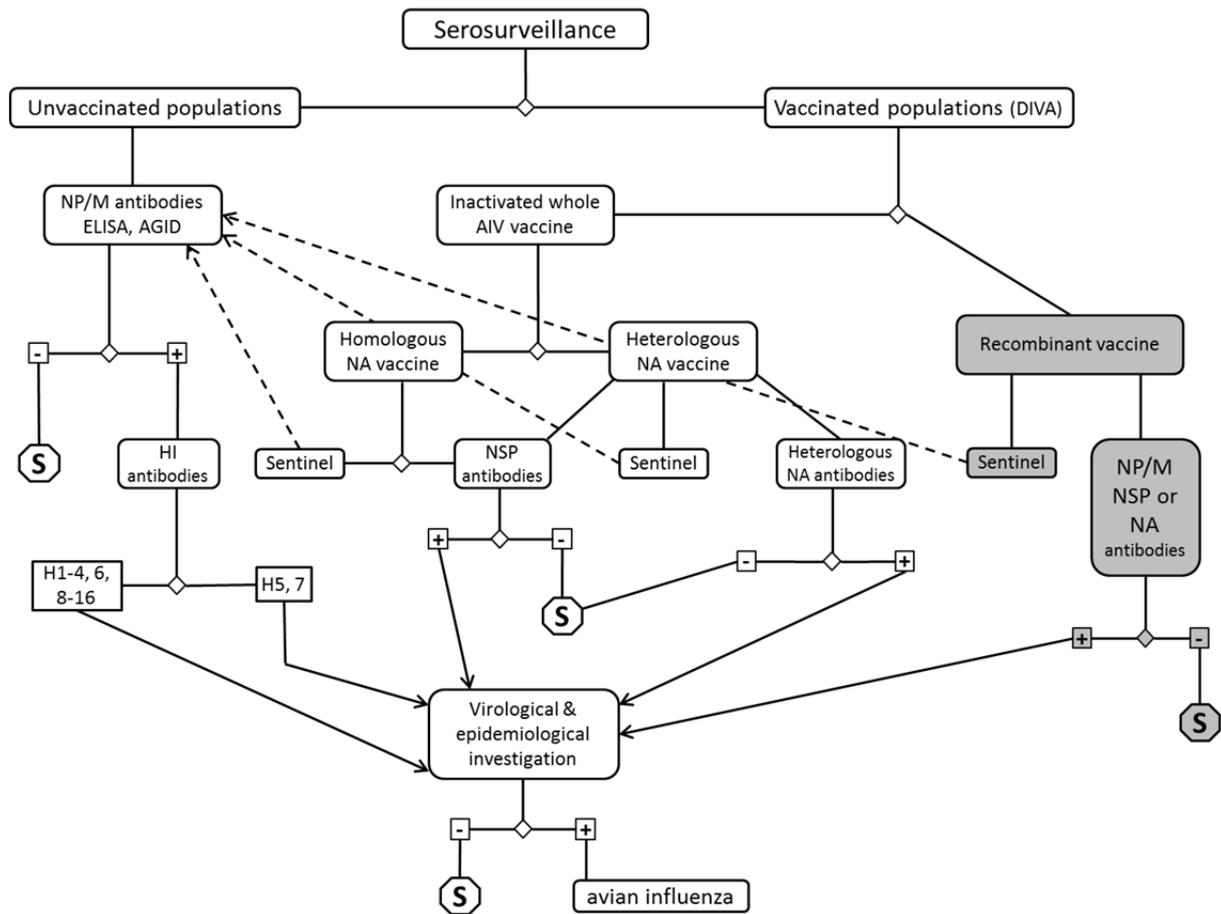
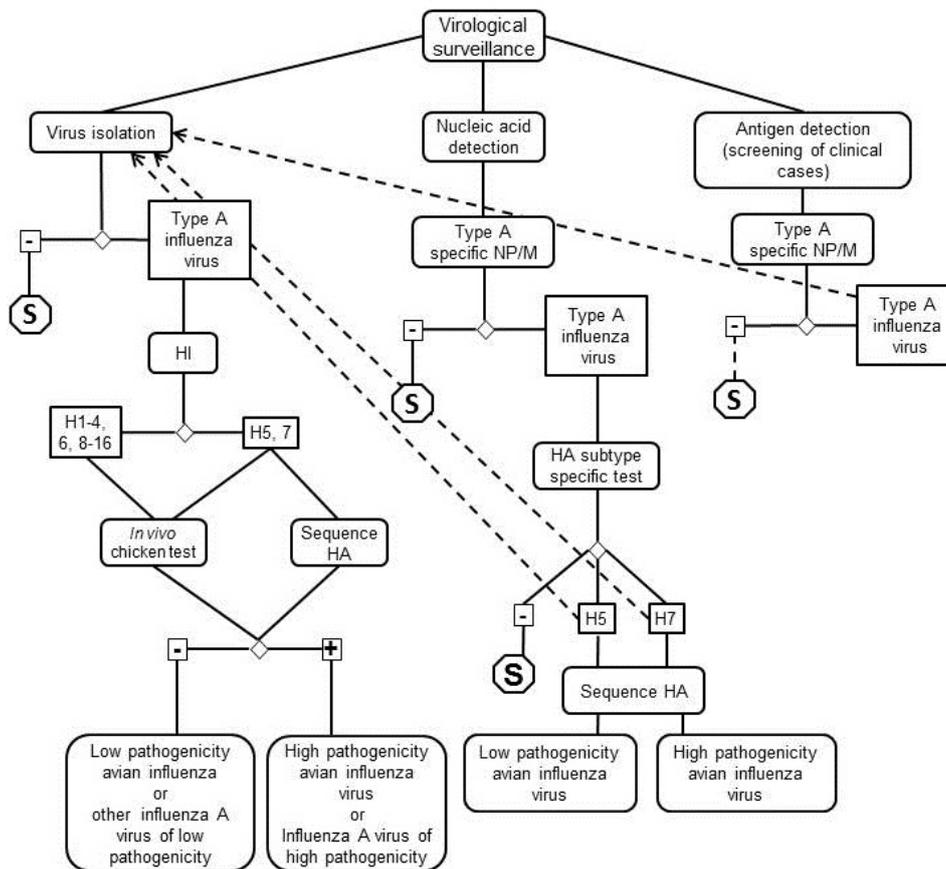


Fig. 2. Schematic representation of laboratory tests for determining evidence of avian influenza infection using virological methods



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CHAPTER 12.10.

INFECTION WITH *BURKHOLDERIA MALLEI* (GLANDERS)

Article 12.10.1.

General provisions

Most glanders susceptible animals are equids. Scientific data are not available for the *infection* in zebras. Camelids and various carnivores including bears, canids and felids can also be infected but play no significant epidemiological role. Glanders is a significant zoonotic disease with fatal outcome if not treated in a timely manner.

For the purpose of the *Terrestrial Code*, glanders is defined as an *infection* with *Burkholderia mallei* in an equid.

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 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 purpose 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 *B. mallei* infection

A country or a *zone* may be considered free from *infection* with *B. mallei* when:

- 1) glanders is notifiable in the country;
- 2) either:
 - a) there has been no *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.;

Annex XX (contd)

and

- 3) imports of equids into the country or *zone* are carried out in accordance with this chapter.

Article 12.10.3.

Recovery of free status

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

- 1) a standstill of movements of equids and their germplasm from *establishments* affected or suspected of being affected has been imposed until the destruction of the last *case*;
- 2) an epidemiological investigation (trace-back, trace-forward), including investigations to determine the likely source of the *outbreak*, have been carried out;
- 3) a *stamping-out policy*, which includes the destruction of all infected equids and cleansing and *disinfection* of the affected *establishments*, has been applied;
- 4) increased *surveillance* in accordance with Article 12.10.8. has been carried out and has not detected any evidence of *infection* in the six months after *stamping-out*;
- 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 *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 the *exporting country* or *zone*; or
 - b) was kept in an *establishment* in the *exporting country* for at least 30 days and was subjected to a prescribed test with negative result on a sample taken during the 10 days prior to shipment.

Article 12.10.5.

Recommendations for importation of equids from countries or zones considered 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 months prior to shipment;
- 3) was subjected to a prescribed test, with negative result on a sample taken during the 30 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 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 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 recommendations in Chapter 4.5.

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 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 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 XX (contd)

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

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

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

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

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

CHAPTER 4.16.

HIGH HEALTH STATUS HORSE SUBPOPULATION

Article 4.16.1.

General provisions

This chapter provides recommendations for the establishment of a *subpopulation* of horses that are moved internationally to compete in equestrian competitions, including thoroughbred races, and that have a high health status certified by the *Veterinary Authority*, in order to facilitate their safe temporary importation, onward movement and return to the country of usual residence.

For the purpose of the *Terrestrial Code*, in line with the provisions in Chapter 4.4., a high health status horse the *subpopulation* is one with a distinct status with respect to specified diseases, which has been established in accordance with the provisions in Chapter 4.4., by the application of documented health management practices and biosecurity measures to create and maintain a functional separation between horses within the defined *subpopulation* and all other equids at all times.

For the purpose of the *Terrestrial Code*, a high health, high performance (HHP) horse means one belonging to high health status *subpopulation* and registered by the International Equestrian Federation (FEI) or the International Federation of Horseracing Authorities (IFHA) as eligible to perform in international competitions and races.

Horses that are moved internationally for the purpose of breeding or any other purpose not linked to competitions are ~~not included~~ excluded from in this the high health status *subpopulation*.

Article 4.16.2.

Criteria for the inclusion of horses in the high health status subpopulation1. High health status

Each horse in the *subpopulation* is subjected to specific measures to establish and maintain its health status, and preserve that of the other horses in the *subpopulation*.

These measures comprise a specific set of *laboratory* tests, treatments and *vaccinations* appropriate to the disease status of the country or region of origin and temporary import of the horse~~horse's region of origin, regions visited and the regions that it will visit~~. Records of all treatments and *vaccinations*, and results of tests and clinical inspections are documented in an individual passport that complies with Chapter 5.12.

2. Identification and traceability

Consistent with the provisions of Chapters 4.1. and 4.2., horses in the *subpopulation* are individually identified as follows:

- a) Each horse bears a permanent unique identifier, preferably a microchip.
- b) Each horse is accompanied at all times by its individual passport that contains information on the horse's unique identifier.
- c) Each horse has an attachment to its passport that identifies it as a member of the high health status *subpopulation*.
- d) Horses are registered in an international database that contains relevant information linked to the passport and the identifier, to which *Veterinary Authorities* should have access to this database.

Annex XXI (contd)3. Management of the subpopulation

- a) In the course of each veterinary examination of a horse, its passport is checked, its identity verified and the details of any tests and treatments, including *vaccinations*, are recorded and signed by the examining *veterinarian*.

For certification purposes, the passport is examined, verified and signed by an *Official Veterinarian*, in accordance with Article 5.2.2. For international movements of not more than 90 days, HHP horses should be accompanied by an international veterinary certificate complying with the *Terrestrial Code*.

- b) The high health status of each horse in the *subpopulation* is maintained by ensuring compliance at all times with an international biosecurity plan approved by the *Veterinary Authorities* of the *importing* and *exporting countries*, in accordance with the relevant recommendations of the OIE. This compliance is assured and validated through continual veterinary supervision of horses at the *establishment* of usual residence, during transport and at competition venues. This supervision is provided by authorised *veterinarians*. Non-compliance results in suspension of the high health status of the horse.
- c) An appropriate qualification period is required for entry or re-entry of a horse into the *subpopulation*. The procedures for qualification should be described in the international biosecurity plan.
- d) A maximum period is set for each absence of a horse from its country or region of usual residence, as specified in the international biosecurity plan.

Article 4.16.3.

Recommendations for the Veterinary Authorities

Organisations that are responsible for ensuring compliance with this chapter should be approved and supervised by the *Veterinary Authorities*. *Veterinary Authorities* are ~~also~~ encouraged to develop specific protocols for the temporary importation of horses of high health status entering the country ~~solely~~ for the purpose of competition at equestrian events or for their onward movement to other such events and for their return to their country of origin.

Veterinary Authorities are encouraged to recognise the international biosecurity plan developed by the FEI International Equestrian Federation and IFHA the International Federation of Horseracing Authorities on the basis of the relevant OIE biosecurity guidelines. (Under study)

 — Text deleted.