

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

Paris, 10–19 February 2015

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B. ADOPTION OF THE AGENDA

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Item 10 Report of the meeting of the *ad hoc* Group on *Salmonella* in cattle (Chapter 6.X.)

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Item 14 Foot and mouth disease (Chapters 8.7. and 1.6.)

Item 15 Infection with Rift valley fever virus (Chapter 8.13.)

Item 16 Infection with *Brucella abortus*, *B. melitensis* and *B. suis* (Chapter 8.4.)

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- a) Glanders (Chapter 12.10.)
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- c) Model veterinary certificate for the international movement of not more than 90 days of a high health high performance horse for competition or races

Item 19 Infection with African swine fever virus (Chapter 15.1.)

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

Paris, 12 February 2015

The OIE Scientific Commission for Animal Diseases (the Scientific Commission) and the OIE Terrestrial Animal Health Standards Commission (the Code Commission) held a joint meeting on Thursday 12 February 2015 to discuss issues of mutual interest. All members of Commissions as well as the Director General, Deputy Director General, and supporting staff of the Scientific and Technical Department and the International Trade Department of the OIE participated in the meeting.

Dr Bernard Vallat, the Director General of the OIE, reiterated the importance of the OIE international standards and appreciated both the quality work of the achieved by the two Commissions as well as their increased collaboration in the development of science-based OIE standards adopted by Member Countries. He also thanked all Commission members on behalf of the Member Countries for their full commitment during the three-year period of their mandate. With elections of the Specialist Commissions scheduled for May he wished those standing for re-election good luck and advised those not standing for re-election that their expertise will continue to be sought on *ad hoc* groups and working groups.

The main discussion points were as follows:

1. Better documentation of the reasons for decisions made by the Commissions

The two Commissions discussed the recent significant improvement in providing rationale when addressing Member Countries' comments. The two Commissions reminded and encouraged Member Countries to review all relevant reports on the subject matter, including Code Commission report, Scientific Commission report and their annexes which include the *ad hoc* Group reports. Both Commissions would continue making clear references to the relevant documents in their reports.

The Deputy Director General suggested taking the opportunity of the training for new Delegates and focal points to ensure that Member Countries understand how to use relevant reports and annexes for reviewing revised chapters.

2. Coordination of the working programmes of both Commissions

The Commissions identified as a number of priorities including drafting a chapter on trypanosomosis, updating the existing chapter on theileriosis and amending the chapter on BSE to consider the impact of atypical BSE in risk status recognition. Both Commissions agreed that their working programmes would be followed up by the OIE Headquarters. The Deputy Director General proposed that once the new members of Specialist Commissions are elected at the forthcoming General Session, the four Presidents would meet with him and the Heads of the OIE Departments to ensure horizontal coordination and clarification of operating procedures. He also mentioned the potential new work under an OIE initiative for developing standards covering the animal health, food safety and welfare of reptiles, particularly with respect to humane slaughter.

3. Glossary

The two Commissions discussed the need for defining the term 'OIE standard' recognising that the meaning of this term has been repeatedly sought in the WTO SPS Committee. Considering the legal implication of the definition, both Commissions recognised that the term 'OIE standard' should be defined within the OIE context regardless of whatever definition is used in other contexts, such as the WTO SPS Agreement. It was reiterated that in the OIE context, the standard should refer to any text drafted by one of the Specialist Commissions and formally adopted by the World Assembly of Delegates. The Deputy Director General pointed out that special consideration should then be given to those texts endorsed by Delegates without formal adoption. Both Commissions agreed that the Code Commission would work on a draft that would be discussed between all Commissions before being sent for Member Countries' comment.

Annex III (contd)

The two Commissions also discussed a proposal from an industry organisation requesting a definition of 'biofortified animal product'. While recognising that biofortified animal products might fall under the mandate of the OIE, both Commissions considered that the impact of this issue on Member Countries and on the OIE workload should be cautiously evaluated. They agreed to closely monitor the discussion of the Codex Committee on Nutrition and Foods for Special Dietary Uses on this issue and establishing a coordination procedure with the Committee when appropriate.

4. Notification of animal diseases and disease listing of pathogenic agents

The two Commissions commended the report of the *ad hoc* Group and appreciated the clarifications provided to the criteria for listing the diseases. The Code Commission informed of its intention to create a specific chapter with the list of the diseases currently included in Article 1.2.3., as is currently the case in the *Aquatic Animal Health Code* where the listing criteria and the list of diseases are separate.

5. High health status subpopulation and model certificate for high health high performance (HHP) horses

Both Commissions noted that Member Countries and stakeholders must clearly understand the intention of the chapter, which is to provide the general principles that define a specific horse subpopulation or compartment for the purpose of temporary international movements for competition purposes. The general principles would be supported by detailed guidance in separate documents. The President of the Scientific Commission informed that the detailed guidance would be available shortly and that a modified chapter will be proposed for adoption.

Regarding the model certificate for HHP horses, it was noted that the model was considered to be finalised from the scientific point of view, thanks to the support of the *ad hoc* Group. Further elaboration of this draft prior to submission for adoption by Member Countries would be handled by the Code Commission. Thus, it would not be necessary to request the help of the *ad hoc* Group to address Member Countries' comments.

Both Commissions agreed that the model certificate needed to be circulated for comments by Member Countries. If adopted, it would be included in Section 5 of the *Terrestrial Code*. To this point in time, the draft model certificate has only been presented to Member Countries as part of the *ad hoc* Group report, not as part of the Code Commission report. The Deputy Director General reminded that the certificate was intended to act as a model for Member Countries and, therefore, not having an adopted model certificate would not preclude the implementation of the HHP concept. Member Countries are entitled to adapt model certificates to their own needs.

6. Horizontal chapter on vaccination

During the review of Member Countries' comments on the revised FMD chapter, both Commissions considered that it was an appropriate time to further develop guidance in the *Terrestrial Code* on disease control. It was noted that clear guidance on vaccination programmes (e.g. demonstration of 'effectiveness of vaccination', vaccination procedures, etc.) should be included in the *Terrestrial Code*, while standards on 'vaccines' were already provided in the *Terrestrial Manual*. The two Commissions suggested that the Director General convene an *ad hoc* Group to draft a horizontal chapter on vaccination. To this end, the two Commissions requested the OIE Headquarters to undertake a brainstorming session to develop appropriate Terms of Reference for the *ad hoc* Group in collaboration with the two Commissions and the Biological Standards Commission and Aquatic Animal Health Standards Commission.

7. Foot and mouth disease

The two Commissions extensively discussed the revised foot and mouth disease Chapter and considered that Member Country comments received had been addressed and the chapter could be presented for adoption by the Word Assembly at the 83rd General Session in May 2015. Both Commissions agreed to give detailed explanations on the rationale when addressing Member Countries' comments in the reports of both Commissions.

8. Porcine reproductive and respiratory syndrome

Considering the technical aspects of the majority of the Member Countries' comments, the Commissions agreed that the Director General should be asked to re-convene an *ad hoc* Group to address these comments.

9. Antimicrobial resistance

The two Commissions were informed of the state of play of the OIE activities related to AMR which are mainly focused on amending the current *Terrestrial Code* Chapter and also on developing a database for collecting data on the use of antimicrobial agents.

The Commissions acknowledged with appreciation the coordination effort that the OIE was carrying out in the framework of the Tripartite (FAO/OIE/WHO).

10. Bovine spongiform encephalopathy

Both Commissions noted the urgent need to address the issue of 'atypical' bovine spongiform encephalopathy (BSE), given the possible suspension of 'negligible risk status' due to a single case of 'atypical' BSE, despite the fact that the disease is considered to be a spontaneously occurring condition, likely to occur in any cattle subpopulation at a low rate regardless of the control measures against 'classical' BSE.

They noted the revision of Chapter 11.4., differentiating atypical from BSE when referring to status recognition, proposed by the *ad hoc* Group on BSE. The Commissions agreed that the revision of Chapter 11.4. on BSE should follow sequential steps with regards to surveillance and specified risk materials, the first focusing on minimising the impact of atypical BSE on disease status.

11. Dates of next meeting

The two Commissions agreed on the dates of their next meetings to ensure an overlapping period and good coordination with other Specialist Commissions. The dates are given in their respective reports.

USER'S GUIDE

A. Introduction

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

B. *Terrestrial Code* content

- 1) Key terms and expressions used in more than one chapter in the *Terrestrial Code* are defined in the Glossary. The reader should be aware of the definitions given in the Glossary when reading and using the *Terrestrial Code*. Defined terms appear in italics. In the on-line version of the *Terrestrial Code*, a hyperlink leads to the relevant definition.
- 2) The term '(under study)' is found in some rare instances, with reference to an article or part of an article. This means that this part of the text has not been adopted by the World Assembly of OIE Delegates and the particular provisions are thus not part of the *Terrestrial Code*.
- 3) The standards in the chapters of Section 1 are designed for the implementation of measures for the diagnosis, surveillance and notification of pathogenic agents. The standards include procedures for notification to the OIE, tests for international trade, and procedures for the assessment of the health status of a country, zone or compartment.
- 4) The standards in the chapters of Section 2 are designed to guide the importing country in conducting import risk analysis in the absence of OIE trade standards recommendations on particular aetiological agents or commodities. The importing country may should also use these standards to justify import measures which are more trade restrictive stricter more stringent 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 range of model veterinary certificates is are provided to facilitate for consistent documentation to be used as a harmonised basis of in~~ international trade.
- 8) The standards in the chapters of Section 6 are designed for the implementation of preventive measures in animal production systems. These measures are intended to assist Member Countries in meeting their veterinary public health objectives. They include ante- and post-mortem inspection, control of hazards in feed, biosecurity at the animal production level, and the control of antimicrobial resistance in animals.
- 9) The standards in the chapters of Section 7 are designed for the implementation of animal welfare measures. The standards cover production, transport, and slaughter or killing, as well as the animal welfare aspects of stray dog population control and the use of animals in research and education.
- 10) The standards in each of the chapters of Sections 8 to 15 are designed to prevent the aetiological agents of OIE listed diseases, infections or infestations from being introduced into an importing country. The standards take into account the nature of the traded commodity, the animal health status of the exporting country, zone or compartment, and the risk reduction measures applicable to each commodity.

These standards assume that the agent is either not present in the importing country or is the subject of a control or eradication programme. Sections 8 to 15 each relate to the host species of the pathogenic agent: multiple species or single species of ~~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 events 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~~ current list. Diseases are divided into nine categories based on the host species of the aetiological agents.

2) Diagnostic tests and vaccines

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

3) Prevention and control

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

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

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

Chapter 6.5. gives is an example of a specific on-farm prevention and control plan for the non-listed food-borne pathogen *Salmonella* in poultry.

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

4) Trade requirements

Animal health measures related to international trade should be based on OIE standards. A Member Country may authorise the importation of animals or animal products into its territory under conditions different from more or less restrictive than those recommended by the *Terrestrial Code*. To scientifically justify more stringent 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. also provide describes guidance the OIE for informal procedure for dispute 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 exporting 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 When a list of safe commodities is present in a chapter, importing countries should not apply trade restrictions to such commodities with respect to the agent in question.

5) International veterinary certificates

An international veterinary certificate is an official document that the Veterinary Authority of an exporting country draws up issues in accordance with Chapters 5.1. and 5.2. It Certificates lists 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) identify 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;

Annex IV (contd)

- 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.
- 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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GLOSSARY

ANIMAL HEALTH MANAGEMENT

means a system designed to optimise the physical and behavioural health and welfare of animals. It includes the prevention, treatment and control of diseases and conditions affecting the individual animal and herd, including the recording of illness, injuries, mortalities and medical treatments where appropriate.

BIOSECURITY

means the a set of management and physical measures designed to reduce the risk of introduction, development establishment 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.

LISTED DISEASES

means the list of a transmissible disease, infection or infestation listed in Article 1.2.3. after agreed adoption by the World Assembly of OIE Delegates and set out in Chapter 1.2.

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 can be 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 specifically directed against a particular the listed disease, infection or infestation and regardless of the 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, in whole or in part, under the authority of the Veterinary Authority, in whole or in part, the following on confirmation of a disease,;

Annex V (contd)

- ≡ the ~~the~~ 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; animals should be killed in accordance with Chapter 7.6; ~~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.~~

— Text deleted.

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 VI (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.

Annex VI (contd)

- 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.

Annex VI (contd)

- 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 VI (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.

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 controls

1. 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 VI (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 VI (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 VI (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 VI (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.

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 VI (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 servicesa) 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).

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

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

i)– government operated institutes laboratories;

ii)– private institutes laboratories involved in full time research directly related to animal health and welfare, 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 institutes 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 VI (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.

c) Veterinary public health

i) Food hygiene

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

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 4.7.

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 VII (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 VII (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.

- 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 VII (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*)
- Infection with Rinderpest virus (cattle)
- 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)
- 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) 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 VII (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 5.1.

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 requirements 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 the recommendations in the relevant standards of the OIE ~~necessary to achieve the national appropriate level of protection~~. If there are no such standards recommendations or if the country chooses a level of protection requiring measures ~~these are~~ stricter more stringent than the standards of the OIE, ~~these they~~ should be based on an import *risk analysis* conducted in accordance with Chapter 2.1.
- 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 more stringent~~ 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*.
- 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.

Annex VIII (contd)

This **information procedure** is **under** the responsibility of *Veterinary Authorities*. However, it can be **issued undertaken** 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.
- 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*.

Annex VIII (contd)

- 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.

— Text deleted.

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 VIII (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 VIII (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.

— Text deleted.

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 IX (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 or caecal samples collected at the slaughterhouse/abattoir.

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.

- 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 should be carried out after depopulation, cleaning and *disinfection*.

Annex IX (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) **principles**, 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,** **C**ompetitive exclusion **p**roducts 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.

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

Annex IX (contd)

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.

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NOTE:

The Code Commission encourages Member Countries to review all relevant reports when reviewing this document including the following:

- November 2013 report of the OIE *ad hoc* Group on Animal Welfare on Dairy Cattle Production Systems (http://www.oie.int/fileadmin/Home/eng/International_Standard_Setting/docs/pdf/A_TAHSC_Feb_2014_Part_C.pdf)

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 feed, 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 animal management systems. 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, the impact of design and management, given that both of these can affect animal welfare ~~will be affected by both system design and stockmanship.~~

~~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, excessive 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).

Annex X (contd)2. Morbidity rates

Morbidity rates, including for infectious and metabolic diseases such as mastitis and metritis, lameness, metabolic diseases, parasitic diseases, post peri-partum and post-procedural complications and injury rates, above recognised thresholds, may be direct or indirect indicators of the *animal welfare* status of the whole *herd*. Understanding the aetiology of the *disease* or syndrome is important for detecting potential *animal welfare* problems (Blecha, 2000). Mastitis, lameness and hoof, reproductive and metabolic diseases are also particularly important animal health problems for adult dairy cows. Scoring systems, such as for body condition, lameness 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 tempore 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 the 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 an 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 targets expected standard for that a 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 or lesions,
- discharges (e.g. from nose, eyes, reproductive tract),
- feet abnormalities,
- abnormal posture indicating pain (e.g. rounded back, head low),
- emaciation and or 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.

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.

Annex X (contd)

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 thermal environment, 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 availability, 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 gives priority to access to additional water and 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 and exit to from restraint facilities devices and their surrounding area 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~~ are 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~~ 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.

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

Annex X (contd)

Floor management in housed production systems can have a significant impact on cattle welfare (Ingvarlsen *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, or 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).

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 injuries) 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 fields should be laid out and managed so as to minimise the overall distances walked. Construction and maintenance of tracks and races, including their surface, should minimise any risk to the welfare of the cattle, especially from foot health problems.

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

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

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 properly maintained** and free of spoiled, mouldy, sour, ~~unpalatable food and faecal contamination.~~

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

~~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 **is** 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.

Annex X (contd)

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*. 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 and practices

Good management and stockmanship practices 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, bBiosecurity 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, a~~ Animal health management ~~means a system should 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.

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

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

Annex X (contd)

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 the 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 ~~score~~, 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 feed 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 feed such as silage, grass and hay, should be available *ad libitum* to meet metabolic requirements in a way that promotes digestion and ensures normal rumen function.

Animal handlers should understand the impact of cattle size and age, weather patterns, diet composition and sudden dietary changes in respect to digestive upsets and their negative consequences (displaced abomasum, sub-acute ruminal acidosis, bloat, liver abscess, laminitis) (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 of calves. However, feeding calves all-liquid diets as the sole source of nutrition after 4-6 weeks of age limits the physiological development of the 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 feed and starter ration (concentrate) to promote rumen development and to reduce abnormal oral behaviours (Reece & Hotchkiss, 1987).

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 and 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, such as sick or injured, 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, 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 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 rate curve, feed efficiency, and behaviour such as locomotion, resting, feeding and drinking (Martin and Bateson, 1986; Kondo *et al.*, 2003).

Annex X (contd)

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.

Artificial insemination and pregnancy diagnosis should be performed in a manner that does not cause pain or distress 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. When a caesarean section is required, it must be carried out by a veterinarian.

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: physical appearance, 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, d~~ 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.

Annex X (contd)

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, R~~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.

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, milk quality), 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 ~~D~~dairy 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~~ 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.

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 anaesthesia 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).~~

Annex X (contd)

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.

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: handling responses human-animal relationship, morbidity rate, mortality rate, behaviour, especially altered locomotory behaviour, and 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: handling responses 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, fire, drought, flooding, blizzard, hurricane). Such plans may include evacuation procedures, identifying high ground, maintaining emergency feed and water stores, destocking and humane killing when necessary.

~~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~~

Annex X (contd)

- ~~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.

Scientific references

- American Association of Bovine Practitioners. 2013. Practical Euthanasia of Cattle. www.aabp.org/resources/euth.asp accessed Nov 28, 2013.
- American Veterinary Medical Association. 2013. AVMA Guidelines on Euthanasia. http://www.avma.org/issues/animal_welfare/euthanasia.pdf; accessed Nov 28, 2013.
- Anderson, N., 2010. Freestall dimensions for dairy cows. Ontario Ministry of Agriculture, Food and Rural Affairs (<http://www.omafra.gov.on.ca/english/livestock/dairy>)
- Anonymous, 1997. Treaty of Amsterdam amending the treaty on European Union, the treaties establishing the European communities and related acts, Official Journal, 340, available at <http://eur-lex.europa.eu/en/treaties/dat/11997D/htm/11997D.html>
- Appleby, M.C., 2006. Animal sentience in US farming. In: Turner, J., D'Silva, J. (Eds.), *Animals, Ethics and Trade: The Challenge of Animal Sentience*. Earthscan, London, pp. 159–165.
- Arab TM, CJC Phillips and PN Johnson, 1995. The effect of supplementary light on the behavior of housed cattle. Pp 143-144, Proceedings of the 29th International Congress of the International Society for Applied Ethology.
- Barrientos, A.C., N. Chapinal, D.M. Weary, E. Galo, M.A.G. von Keyserlingk. 2013. Herd-level risk factors for hock injuries in freestall housed dairy cows in the Northeastern US and California. *J. Dairy Sci.* 96:3758-3765.
- Barkema HW, YH Schukken, TJ Lam, Beiboer ML, G Benedictus, and A Brand, 1999. Management practices associated with the incidence rate of clinical mastitis. *J. Dairy Sci.* 82(8):1643-1654
- Baxter, S.H., Baxter, M.R., MacCormack, J.A.C. (Eds.), 1983. *Farm Animal Housing and Welfare*. Martinus, Nijhoff, The Hague.
- Baxter, M. R. 1992. The space requirements of housed livestock. In: Phillips, C. and Piggins, D (Eds). *Farm animals and the environment*. P 67-91. CAB International, Wallingford, UK.
- Bell, N, 2007. Cubicle bedding from The Healthy Feet project, University of Bristol, United Kingdom,. <http://www.cattle-lameness.org.uk/contendocs/Cubicle%20bedding.pdf>
- Bell, NJ, JN Huxley, 2009. The use of rubber floor matting on dairy units: a critical review. *Cattle Practice* 17(2): 142-147
- Bernardi F., J. Fregonisi, C. Winckler, C. M. Veira, M. A. G. von Keyserlingk, and D. M. Weary, 2009. The stall-design paradox: Neck rails increase lameness but improve udder and stall hygiene. *J. Dairy Sci.* 92(7): 3074-3080
- Bertoni, G., E. Trevisi, X. Han, and M. Bionaz, 2008. Effects of inflammatory conditions on liver activity in puerperium period and consequences for performance in dairy cows. *J. Dairy Sci.*, 91: 3300-3310.
- Binder, E.M. 2007. Managing the risk of mycotoxins in modern feed production *Animal Feed Science and Technology*, 133: (1-2), 149-166.
- Blackshaw, J. K., A. W. Blackshaw, 1994. Heat stress in cattle and the effect of shade on production and behaviour: a review. *Australian Journal of Experimental Agriculture* 34: 285-295.
- Blecha, F. 2000. Immune system response to stress. In: Moberg, G.P., Mench, J.A. (Eds.), *The Biology of Animal Stress. Basic Principles and Implications for Animal Welfare*. CABI Publishing, Wallingford. UK, pp. 111-121.
- Blokhuis, H.J., Keeling, L.J., Gavinelli, A. and Serratos, J. 2008. Animal welfare's impact on the food chain. *Trends in Food Science & Technology*, 19: Supplement 1, S79-S87.
- Boadi D, Price MA. 1996. *Canadian Journal of Animal Science*. 76:337-342.
- Boissy, A. and P. Le Neindre. 1997. Behavioral, cardiac and cortisol responses to brief peer separation and reunion in cattle. *Physiol. Behav.* 61:693-699.

Annex X (contd)

- Boissy, A., Manteuffel, G., Jensen, M.B., Oppermann Moe, R., Spruijt, B.M., Keeling, L., Winckler, C., Forkman, B., Dimitrov, I., Langbein, J., Bakken, M., Veissier, I. and Aubert, A. 2007. Assessment of positive emotions in animals to improve their welfare. *Physiol. Behav.* 92: 375–397.
- Bøe, K. E., and G. Færevik. 2003. Grouping and social preferences in calves, heifers and cows. *App. Anim. Behav. Sci.* 80:175-190.
- Bouissou, M.F., Boissy, A., Le Neindre, P. and Veissier I. 2001. The social behaviour of cattle. In: Keeling L, Gonyou H, editors. *Social behaviour in farm animals*. Wallingford, UK: CABI Publishing; 2001. p. 113–45.
- Breen, J. E., M. J. Green, A. J. Bradley, 2009. Quarter and cow risk factors associated with the occurrence of clinical mastitis in dairy cows in the United Kingdom. *J. Dairy Sci.* 92(6): 2551-2561
- Broom, D.M. 2006. Behaviour and welfare in relation to pathology *Applied Animal Behaviour Science*, 97: (1), 73-83.
- Bryant, J. R., N. López-Villalobos, J. E. Pryce, C. W. Holmes, D. L. Johnson, 2007. Quantifying the effect of thermal environment on production traits in three breeds of dairy cattle in New Zealand. *New Zealand Journal of Agricultural Research* 50: 327-338.
- CA, Codex Alimentarius 2004, CAC/RCP 54-2004 Code of Practice on Good Animal Feeding (http://www.codexalimentarius.org/input/download/standards/10080/CXP_054e.pdf)
- Camiloti, T.V., J.A. Fregonesi, M.A.G. von Keyserlingk and D.M. Weary. 2012. Short communication: Effects of bedding quality on lying behavior of dairy calves. *J. Dairy Sci.* 95:3380–3383).
- Cardot, V., Y. Le Roux, S. Jurjanz, 2008. Drinking behaviour of lactating dairy cows and prediction of their water intake. *J Dairy Sci* 91: 2257-2264.
- Chapinal, N., A. M. de Pasillé, D. M., Weary, M. A. G. von Keyserlingk, and J. Rushen, 2009. Using gait score, walking speed and lying behaviour to detect hoof lesions in dairy cows. *J. Dairy Sci.*, 92: 4365-4374.
- Chapinal, N., A. Barrientos, M.A.G. von Keyserlingk, E. Galo, and D.M. Weary. 2013. Herd-level risk factors for lameness in freestall farms in North Eastern US and California. *J. Dairy Sci.* 96: 318-328)
- Cook, N.B., M. J. Marin, R. L. Mentink, T. B. Bennett, M. J. Schaefer, 2008. Comfort-zone design freestalls: do they influence the stall use behavior of lame cows? *J. Dairy Sci.* 91(12): 4673-4678.
- Dahl G. E., B. A. Buchanan, H.A. Tucker, 2000. Photoperiodic effects on dairy cattle: a review. *J. Dairy Sci.* 83: 885-893.
- De Paula Vieira, A., Von Keyserlingk, M. A. G., & Weary, D. M. (2010). Effects of pair versus single housing on performance and behavior of dairy calves before and after weaning from milk. *Journal of dairy science*, 93(7), 3079-3085.
- Desire, L., A. Boissy and Veissier, I. 2002. Emotions in farm animals: a new approach to animal welfare in applied ethology. *Behav. Process.* 60:165–180.
- DeVries T.J., M. A. von Keyserlingk, 2005. Time of feed delivery affects the feeding and lying patterns of dairy cattle. *J. Dairy Sci.*, 88: 625-631. DeVries T.J., M. A. von Keyserlingk, K.A. Beauchemin, 2005. Frequency of feed delivery affects the behaviour of lactating dairy cows. *J Dairy Sci* 88: 3553-3562
- DeVries T.J., M. A. von Keyserlingk, D. M. Weary, 2004. Effect of feeding space on the inter-cow distance, aggression and feeding behavior of free-stall housed lactating dairy cows. *J. Dairy Sci* 87: 1432-1438
- Dillon, P.D., P. R. Berry, D. Evans, F. Buckley, B. Horan, 2006. Consequences of genetic selection for increased milk production in European seasonal pasture based systems for milk production. *Livestock Sciences* 99: 141-158.
- Drackley, J. R., 1999. Biology of dairy cows during the transition period: The final frontier? *J. Dairy Sci* 82: 2259-2273.
- Drissler, M., M. Gaworski, C. B. Tucker, D. M. Weary, 2005. Freestall maintenance: effects on lying behavior of dairy cattle. *J. Dairy Sci.*, 88(7): 2381-2387.
- EFSA Panel on Animal Health and Welfare (AHAW) Scientific Opinion on the use of animal-based measures to assess welfare of dairy cows. *EFSA Journal* 2012; 10(1):2554.
- Endres, M.I., T. J. DeVries, M. A. G. von Keyserlingk, D. M. Weary, 2005. Effect of feed barrier design on the behavior of loose-housed lactating dairy cows. *J Dairy Sci.*, 88: 2377-2380.

- Enemark, J.M.D. 2008. The monitoring, prevention and treatment of sub-acute ruminal acidosis (SARA): A review. *The Veterinary Journal*, 76: (1), 32-43.
- EU-SCAHAW, Scientific Committee on Animal Health and Animal Welfare, 2001. *The Welfare of Cattle Kept for Beef Production*. (http://europa.eu.int/comm/food/fs/sc/scah/out54_en.pdf).
- FAWAC, Ireland, <http://www.fawac.ie/publications.htm>
- FAWC. 1993. *Second Report on Priorities for Research and Development in Farm Animal Welfare*. Farm Animal Welfare Council (FAWC), Ministry of Agriculture Fisheries and Food, Tolworth, UK.
- Fisher, A.D., M. Stewart, G. A. Verkerk, C. J. Morrow, L. R. Matthews, 2003. The effects of surface type on lying behaviour and stress responses of dairy cows during periodic weather-induced removal from pasture. *Applied Animal Behaviour Science* 81(1):1-11.
- Flower and Weary, 2006, Effect of hoof pathologies on subjective assessments of dairy cow gait, *J. Dairy Sci.*, 89 (2006), pp. 139–146).
- Fraser, D., 2008. Toward a global perspective on farm animal welfare. *Applied Animal Behaviour Science*, 113: (4), 330-339.
- Fraser, D., 2009. Animal behaviour, animal welfare and the scientific study of affect. *Applied Animal Behaviour Science*, 118: (3-4), 108-117.
- Fregonesi, J. A., C. B., Tucker, and D. M. Weary, 2007. Overstocking reduces lying time in dairy cows. *J Dairy Sci.*, 90: 3349-3354.
- Fregonesi, J.A., M.A.G von Keyserlingk, D.M. Veira, and D.M. Weary. 2009. Cow preference and usage of free stalls versus an open lying area. *J. Dairy Sci.* 92: 5497-5502
- Gehring, R, Baynes R.E. and Riviere, E. 2006. Application of risk assessment and management principles to the extralabel use of drugs in food-producing animals. *J Vet Pharm Ther*; 29:5-14.
- Goldhawk, C., N. Chapinal, D.M. Veira, D.M. Weary, and M.A.G. von Keyserlingk. 2009. Parturition feeding behavior is an early indicator of subclinical ketosis. *J. Dairy Sci.* 92:4971-4977
- Grandin, T. 1980. Observations of cattle behaviour applied to design of cattle-handling facilities. *Appl Anim Ethol* 6:19-31.
- Grandin, T. 1998. Review: Reducing handling stress improves both productivity and welfare. *Prof. Anim. Sci.* 14: 1-10.
- Grandin, T. 2003. Transferring results of behavioral research to industry to improve animal welfare on the farm, ranch and the slaughter plant. *Applied Animal Behaviour Science*, 81: (3) 215-228.
- Grandin, T. 2006. Progress and challenges in animal handling and slaughter in the U.S. *Applied Animal Behaviour Science*, 100: (1-2), 129-139.
- Hart, B.L., 1987. Behavior of sick animals. *Vet Clin North Am Food Anim Pract.* 3 (2): 383-391.
- Haufe, H. C., L. Gygax, B. Steiner, K. Friedli, M. Stauffacher, B. Wechsler, 2009. Influence of floor type in the walking area of cubicle housing systems on the behaviour of dairy cows. *Applied Animal Behaviour Science* 116: 21-27.
- Hinterhofer, C., J. C. Ferguson, V. Apprich, H. Halder, C. Stanek, 2006. Slatted floors and solid floors: stress and strain on the bovine hoof capsule analyzed in finite element analysis, *J. Dairy Sci.*, 89: 155-162.
- Huzzey, J. M., M. A. G. von Keyserlingk, D. M. Weary, 2005. Changes in feeding, drinking and standing behavior of dairy cows during the transition period. *J. Dairy Sci.* 88: 2454-2461.
- Igono, M. O., H. D. Johnson, B. J. Steevens, G. F. Krause, M. D. Shanklin, 1987. Physiological, productive and economic benefits of shade, spray and fan system versus shade for Holstein cows during summer heat. *J Dairy Sci* 70: 1069-1079.
- Ingvartsen, K. L. and Andersen, H.R. 1993. Space allowance and type of housing for growing cattle. *Acta. Agric. Scand. Sect. A. Animal Sci.* 43:65-80.

Annex X (contd)

Jawor, P., J.A. Huzzey, S. J. LeBlanc and M.A.G. von Keyserlingk. 2012. Associations of subclinical hypocalcemia at calving with milk yield and feeding, drinking and standing behavior around parturition in Holstein cows. *J. Dairy Sci.* 95:1240–1248

Jensen, P., Buitenhuis, B., Kjaer, J., Zanella, A., Mormède, P. and Pizzari, T. 2008. Genetics and genomics of animal behaviour and welfare—Challenges and possibilities. *Applied Animal Behaviour Science*, 113: (4), 383-403.

Jensen, M. B. (2003). The effects of feeding method, milk allowance and social factors on milk feeding behaviour and cross-sucking in group housed dairy calves. *Applied Animal Behaviour Science*, 80(3), 191-206.

Jensen, M. B., R. Kyhn, 2000. Play behaviour in group-housed dairy calves, the effect of space allowance. *Applied Animal Behaviour Science* 67: 35-46.

Jóhannesson T. and Sørensen, J.T. 2000. Evaluation of welfare indicators for the social environment in cattle herds. *Anim. Welfare.* 9:297-316.

Kendall, P. E., G.A. Verkerk, J. R. Webster, C. B. Tucker, 2007. Sprinklers and shade cool cows and reduce insect-avoidance behaviour in pasture-based dairy cows. *J Dairy Sci.* 90: 3671-3680.

Kondo, S., J. Sekine, M. Okubo, and Y. Asahida. 2003. The effect of group size and space allowance on the agonistic and spacing behavior of cattle. *Applied Animal Behavior Science* 24:127-135

Laden, S.A., Wohlt, J.E., Zajac, P.K. and Carsia, R.V. 1985. Effects of stress from electrical dehorning on feed intake, growth, and blood constituents of Holstein heifer calves. *Journal of Dairy Science.* 68: 3062–3066.

Larson, R.L., Pierce, V.L., Randle, R.F., 1998. Economic evaluation of neonatal health protection programs for cattle. *JAVMA* 213(6): 810-816.

Lawrence, A.B., Pryce, J.E. and Simm, G., 2001. G x EEE: the missing link when breeding for welfare. In: Garner, J.P., Mench, J.A., Heekin, S.P. (Eds.), *Proceedings of the 35th Congress of the International Society for Applied Ethology*, The Center for Animal Welfare, University of Davis, CA, pp. 90–91.

Lawrence, A.B., Tolkamp, B., Cockram, M.S., Ashworth, C.J., Dwyer, C.M. and Simm, G., 2004a. Food, water and malnutrition: perspectives on nutrient requirements for health and welfare in farm animals. In: *Proceedings of Global Conference on Animal Welfare: An OIE Initiative*, OIE, Paris, pp. 189–197.

Lawrence, A.B., Conington, J. and Simm, G., 2004b. Breeding and animal welfare: practical and theoretical advantages of multi-trait selection. *Anim. Welf.* 13: (Suppl.), S191–S196.

Lawrence, A.B. 2008. Applied animal behaviour science: Past, present and future prospects. *Applied Animal Behaviour Science*, 115: (1-2), 1-24.

Le Neindre, P. Influence of rearing conditions and breed on social behaviour and activity of cattle in novel environments. *Appl Anim Behav. Sci* 1989; 23:129–40.

Loberg, J., E. Telezhenko, C. Bergsten, L. Lidfors, 2004. Behaviour and claw health in tied dairy cows with varying access to exercise in an outdoor paddock. *Applied Animal Behaviour Science* 89: 1-16.

Macdonald, K., G.A. Verkerk, B. S. Thorrold, J. E. Pryce, J. W. Penno, L. R. McNaughton, L.J. Burton, J. Lancaster, J.H. Williamson, C. W. Holmes, 2008. A comparison of three strains of Holstein-Friesian grazed on pasture and managed under different feed allowances. *J Dairy Sci* 91: 1693-1707.

Manninen E., A. M. de Passillé, J. Rushen, M. Norring, H. Saloniemi, 2002. Preferences of dairy cows kept in unheated buildings for different kinds of cubicle flooring. *Applied Animal Behaviour Science* 75: 281-292.

Martin, P. and Bateson, P. 1986. *Measuring behaviour*. Cambridge Univ. Press, London, UK.

Mason, G.J. and Latham, N.R., 2004. Can't stop, won't stop: is stereotypy a reliable animal welfare indicator? *Anim. Welf.* 13 (Suppl.), S57–S69 (Feb).

Mellor, D.J. and Stafford, K.J. 2004. Animal welfare implications of neonatal mortality and morbidity in farm animals. *The Veterinary Journal*, 168: 118-133.

- Mench, J.A. Farm animal welfare in the U.S.A.: Farming practices, research, education, regulation, and assurance programs. 2008. *Applied Animal Behaviour Science*, 113: (4), 298-312
- Millman, S. T., Duncan, I. J. H., Stauffacher, M., and Stookey, J. M. 2004. The impact of applied ethologists and the international society for applied ethology in improving animal welfare. *Applied Animal Behaviour Science*, 86, 299-311.
- Mee JF. 2008. [Managing the cow at calving time](#). Proceedings of the 41st Annual Conference of the American Association of Bovine Practitioners. 35-43.
- Menke, C., S. Waiblinger, D. W. Fölsch, P. R. Wiepkema, 1999. Social behaviour and injuries of horned cows in loose housing systems. *Animal Welfare* 8: 243-258.
- Moberg, G.P., Mench, J.A., 2000. *The Biology of Animal Stress: Basic Principles and Implications for Animal Welfare*. CABI Publishing, Wallingford, Oxon, UK.
- Moss, R. 1992. Definition of health and welfare. In: R. Moss (Ed.) *Livestock Health and Welfare*. p 1. Longman Scientific and Technical, Essex, UK.
- National Research Council, 2001. *Nutrient requirements of dairy cattle*. National Academy Press, Washington DC
- Newberry, R.C. and Swanson, J.C. 2008. Implications of breaking mother–young social bonds. 2008. *Applied Animal Behaviour Science*, 110:(1-2), 3-23.
- Odde KG. 1996. [Reducing neonatal calf losses through selection, nutrition and management](#). *Agri-Practice*. 17:12-15
- O'Driscoll, K., L. Boyle, P. French, A. Hanlon, 2007. The effect of out-wintering pad design on hoof health and locomotion score of dairy cows. *J Dairy Sci* 91: 544-553.
- OIE, 2005. *Terrestrial Animal Health Code (2005)*. World Organization for Animal Health (OIE), Paris, France.
- Ortiz-Pelaez, A., Pritchard, D.G., Pfeiffer, D.U., Jones, E., Honeyman, P. and Mawdsley, J.J. 2008. Calf mortality as a welfare indicator on British cattle farms. *The Veterinary Journal*, Volume 176: (2), 177-181
- Ott, S.L., Hillberg Seitzinger, A., and Hueston, W.D. 1995. Measuring the national economic benefits of reducing livestock mortality. *Preventive Veterinary Medicine*, 24:(3), 203-211
- Petrie, N.J., Mellor, D.J., Stafford, K.J., Bruce, R.A. and Ward, R.N. 1996. cortisol responses of calves to two methods of disbudding used with or without local anaesthetic. *New Zealand Veterinary Journal* 44: 9–14.
- Petherick, J.C. and Phillips, J.C. 2009. Space allowances for confined livestock and their determination from allometric principles. *Applied Animal Behaviour Science*, 117: (1-2), 1-12.
- Phillips, C. J. C., I. D.A Lomas, S J Lockwood, 2000. The locomotion of dairy cows in passageways with different light intensities. *Animal Welfare* 9: 421-41.
- Proudfoot, K.L., J.M. Huzzey and M.A.G. von Keyserlingk. 2009. The effect of dystocia on dry matter intake and behavior of Holstein cows. *J Dairy Sci*. 92:4937-4944
- Proudfoot, K., M. Bak-Jensen, P. M. H. Heegaard and M.A.G. von Keyserlingk. 2013. Effect of moving dairy cows at different stages of labor on behavior during parturition. *J. Dairy Sci*. 96: 1638-1646;
- Reece & Hotchkiss. 1987. Blood studies and performance among calves reared by different methods. *Journal of Dairy Science* 70:1601-1611.
- Roche, J. R., P. G. Dillon, C. R. Stockdale, L. H. Baumgard, and M. J. VanBaale, 2004. Relationships among international body scoring systems. *J. Dairy Sci.*, 87: 3076-3079.
- Roche, J. R., N. C. Friggens, J.Kay, M. W. Fisher, K.J. Stafford, and D. P. Berry. 2009. Invited review: Body condition score and its association with dairy cow productivity, health, and welfare. *J. Dairy Sci*. 92: 5769-5801.
- Roth, B. A., N. M. Keil, L. Gygas, E. Hillmann, 2009. Influence of weaning method on health status and rumen development in dairy calves. *J Dairy Sci*: 92: 645-656.
- Rushen, J., and de Passillé, A.M. 1992. The scientific assessment of the impact of housing on animal welfare: a critical review. *Can. J. Anim. Sci.* 72:721–743.
- Rushen, J., A. M. de Passillé, 2006. Effects of roughness and compressibility of flooring on cow locomotion. *J Dairy Sci*. 89: 2965-2972.

Annex X (contd)

Sato, S., K. Tatumizu, K. Hatae, 1993. The influence of social factors on allogrooming in cows. *Applied Animal Behaviour Science* 38: 235-244.

Seo, T., Sato, S., Kosaka, K., Sakamoto, N., Tokumoto, K., & Katoh, K. (1998). Development of tongue-playing in artificially reared calves: effects of offering a dummy-teat, feeding of short cut hay and housing system. *Applied Animal Behaviour Science*, 56(1), 1-12.

Sepúlveda-Varas, P., J. M. Huzzey, D. M. Weary and M. A. G. von Keyserlingk. (accepted). Invited Review: Behavioural changes related to illness during the periparturient period in dairy cattle. *Anim. Product. Sci.*

Sprecher, D. J., D. E. Hostetler, J. B. Kaneene, 1997. A lameness scoring system that uses posture and gait to predict dairy cattle reproductive performance. *Theriogenology* 47: 1179-1187.

Singh, S., Saini, A.L., Randhawa, S.S. and Jindal, R. 2002. Plasma cortisol and other blood constituents in relation to age of disbudding with and without cornual block in Murrah buffalo calves, *SARAS Journal of Livestock and Poultry Production*, 18: 1-8.

Stafford, K.J., Mellor D.J., Todd S.E., Ward R.N. and McMeekan C.M. 2003. The effect of different combinations of lignocaine, ketoprofen, xylazine and tolazoline on the acute cortisol response to dehorning in calves. *New Zealand Veterinary Journal*, 51: (5) 219-226.

Stafford, K.J. and Mellor, D.J. 2005. Dehorning and disbudding distress and its alleviation in calves, *The Veterinary Journal*, 169: 337-349.

Stafford, K.J. and Gregory, N.G. 2008. Implications of intensification of pastoral animal production on animal welfare. *New Zealand Veterinary Journal*, 56: 274-280.

Sutherland, M.A., Mellor, D.J., Stafford, K.J., Gregory, N.G., Bruce, R.A., and Ward, R. N. 2002. Modification of cortisol responses to dehorning in calves using a 5-hour local anaesthetic regimen plus phenylbutazone, ketoprofen or adrenocorticotrophic hormone injected prior to dehorning, *Research in Veterinary Science*, 73: 115-123.

Sutherland MA and Tucker C. 2011. The long and short of it: a review of tail docking in farm animals. *Applied Animal Behaviour Science* 135: 179-191

Telezhenko, E., L Lidfors, C Bergsten, 2007. Dairy cow preferences for soft or hard flooring when standing or walking. *J Dairy Sci* 90: 3716-3724.

Tizard, I., 2008. Sickness behavior, its mechanisms and significance. *Anim Health Res Rev* 9(1): 87-99.

Townsend, H. G. (1994). Environmental factors and calving management practices that affect neonatal mortality in the beef calf. *The Veterinary clinics of North America. Food animal practice*, 10(1), 119-126

Tucker, C. B., D. M. Weary, D. Fraser, 2003. Effects of three types of free stall surfaces on preferences and stall usage by dairy cows. *J Dairy Sci* 86: 521-529.

Tucker, C. B., D. M. Weary, D. Fraser, 2004. Free-stall dimensions: effects on preference and usage. *J Dairy Sci* 87: 1208-1216.

Tucker, C. B., D. M. Weary, M. A. G. von Keyserlingk, K. A. Beauchemin, 2009. Cow comfort in tie-stalls: increased depth of shavings or straw bedding increases lying time. *J. Dairy Sci.* 92: 2684-2690.

Ude, G., Georg, H., & Schwalm, A. (2011). Reducing milk induced cross-sucking of group housed calves by an environmentally enriched post feeding area. *Livestock Science*, 138(1), 293-298.

Veissier, I., Butterworth, A., Bock, B. and Roe, E. 2008. European approaches to ensure good animal welfare. *Applied Animal Behaviour Science*, 113, (4), 279-297.

Vermunt, J.J. and Greenough, P.R. 1994. Predisposing factors of laminitis in cattle, *British Veterinary Journal*, 150:(2) 151-164.

Vickers, L.A., D.M. Weary, D.M. Veira and M.A.G. von Keyserlingk. 2013. Feeding a higher forage diet prepartum decreases incidence of subclinical ketosis in transition dairy cows. *J. Anim. Sci.* 91:886-894).

Von Keyserlingk, M. A. G., D. Olenick, D. M. Weary, 2008. Acute behavioural effects of regrouping dairy cows. *J. Dairy Sci.*, 91: 1011-1016.

Annex X (contd)

Weary, D.M., Jasper, J. and Hötzel, M.J., 2008. Understanding weaning distress. *Appl. Anim. Behav. Sci.* 10: 24-41.

Weary, D.M., Huzzey, J.M., von Keyserlingk, A.G., 2009. Board-Invited Review: Using behavior to predict and identify ill health in animals. *J Anim Sci* 87:770-777.

Webster, A.J.F., Main, D.C.J. and Whay, H.R., 2004. Welfare assessment: Indices from clinical observation. *Anim. Welfare* 13:S93-S98.

West, J. W., 2003. Effects of heat stress on production in dairy cattle. *J. Dairy Sci.* 86: 2131-2144.

Wiepkema, P.R., Broom, D.M., Duncan, E.J.H. and van Putten, G., 1983. *Abnormal Behaviours in Farm Animals*. Report of the CEC, Brussels.

Zdanowicz, M., J. A. Shelford, C. B. Tucker, D. M. Weary, M.A.G. von Keyserlingk, 2004. Sand and sawdust bedding affect bacterial populations on teat ends of dairy cows housed in freestalls. *J. Dairy Sci* 87: 1694-1701.

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 XI (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.

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 XI (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 XI (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, to reduce stress and to promote normal behaviour, gait and good leg health.

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

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

Annex XI (contd)

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.

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*.

Annex XI (contd)

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.

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

Annex XI (contd)

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

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

m) Handling and inspection

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

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

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

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

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

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

Annex XI (contd)

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.

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.

Annex XI (contd)

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

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

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

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

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

— Text deleted.

CHAPTER 7.5.

SLAUGHTER OF ANIMALS

Article 7.5.1.

General principles

1. Object

These recommendations address the need to ensure the *welfare* of food *animals* during pre-slaughter and *slaughter* processes, until they are dead.

These recommendations apply to the *slaughter* in *slaughterhouses* of the following domestic *animals*: cattle, buffalo, bison, sheep, goats, camelids, deer, horses, pigs, ratites, rabbits and *poultry*. Other *animals*, wherever they have been reared, and all *animals* slaughtered outside *slaughterhouses* should be managed to ensure that their *transport*, *lairage*, *restraint* and *slaughter* is carried out without causing undue stress to the *animals*; the principles underpinning these recommendations apply also to these *animals*.

2. Personnel

Persons engaged in the *unloading*, moving, *lairage*, care, *restraint*, *stunning*, *slaughter* and bleeding of *animals* play an important role in the *welfare* of those *animals*. For this reason, there should be a sufficient number of personnel, who should be patient, considerate, competent and familiar with the recommendations outlined in the present chapter and their application within the national context.

Competence may be gained through formal training and/or practical experience. This competence should be demonstrated through a current certificate from the *Competent Authority* or from an independent body accredited by the *Competent Authority*.

The management of the *slaughterhouse* and the *Veterinary Services* should ensure that *slaughterhouse* staff are competent and carry out their tasks in accordance with the principles of *animal welfare*.

3. Animal behaviour

Animal handlers should be experienced and competent in handling and moving farm livestock, and understand the behaviour patterns of *animals* and the underlying principles necessary to carry out their tasks.

The behaviour of individual *animals* or groups of *animals* will vary, depending on their breed, sex, temperament and age and the way in which they have been reared and handled. Despite these differences, the following behaviour patterns which are always present to some degree in domestic *animals*, should be taken into consideration in handling and moving the *animals*.

Most domestic livestock are kept in groups and follow a leader by instinct.

Animals which are likely to harm each other in a group situation should not be mixed at *slaughterhouses*.

The desire of some *animals* to control their personal space should be taken into account in designing facilities.

Domestic *animals* will try to escape if any person approaches closer than a certain distance. This critical distance, which defines the flight zone, varies among species and individuals of the same species, and depends upon previous contact with humans. *Animals* reared in close proximity to humans i.e. tame have a smaller flight zone, whereas those kept in free range or extensive systems may have flight zones which may vary from one metre to many metres. *Animal handlers* should avoid sudden penetration of the flight zone which may cause a panic reaction which could lead to aggression or attempted escape.

Animal handlers should use the point of balance at the *animals* shoulder to move *animals*, adopting a position behind the point of balance to move an *animal* forward and in front of the point of balance to move it backward.

Annex XII (contd)

Domestic *animals* have wide-angle vision but only have limited forward binocular vision and poor perception of depth. This means that they can detect objects and movements beside and behind them, but can only judge distances directly ahead.

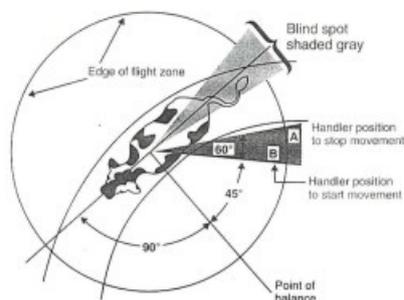
Although most domestic *animals* have a highly sensitive sense of smell, they react in different ways to the smells of *slaughterhouses*. Smells which cause fear or other negative responses should be taken into consideration when managing *animals*.

Domestic *animals* can hear over a greater range of frequencies than humans and are more sensitive to higher frequencies. They tend to be alarmed by constant loud noise and by sudden noises, which may cause them to panic. Sensitivity to such noises should also be taken into account when handling *animals*.

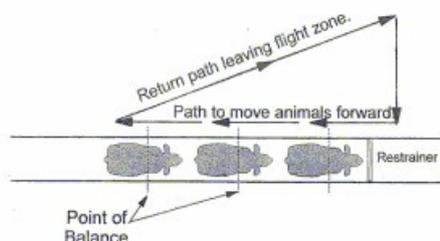
4. Distractions and their removal

Distractions that may cause approaching *animals* to stop, baulk or turn back should be designed out from new facilities or removed from existing ones. Below are examples of common distractions and methods for eliminating them:

- a) reflections on shiny metal or wet floors – move a lamp or change lighting;
- b) dark entrances to chutes, races, stun boxes or conveyor restrainers – illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals* or create areas of sharp contrast;
- c) *animals* seeing moving people or equipment up ahead – install solid sides on chutes and races or install shields;
- d) dead ends – avoid if possible by curving the passage, or make an illusory passage;
- e) chains or other loose objects hanging in chutes or on fences – remove them;
- f) uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers – avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface;
- g) sounds of air hissing from pneumatic equipment – install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;
- h) clanging and banging of metal objects – install rubber stops on gates and other devices to reduce metal to metal contact;
- i) air currents from fans or air curtains blowing into the face of *animals* – redirect or reposition equipment.

An example of a flight zone (cattle) Handler movement pattern to move cattle forward

Moving and handling animals



Article 7.5.2.

1. General considerations

Each *slaughterhouse* should have a dedicated plan for *animal welfare*. The purpose of such plan should be to maintain good level of *animal welfare* at all stages of the handling of *animals* until they are killed. The plan should contain standard operating procedures for each step of animal handling as to ensure that *animal welfare* is properly implemented based on relevant indicators. It also should include specific corrective actions in case of specific risks, like power failures or other circumstances that could negatively affect the *welfare of animals*.

Animals should be transported to *slaughter* in a way that minimises adverse animal health and *welfare* outcomes, and the transport should be conducted in accordance with the OIE recommendations for the transportation of *animals* (Chapters 7.2. and 7.3.).

The following principles should apply to *unloading animals*, moving them into *lairage* pens, out of the *lairage* pens and up to the *slaughter* point:

- a) The conditions of the animals should be assessed upon their arrival for any animal welfare and health problems.
- b) Injured or sick *animals*, requiring immediate *slaughter*, should be killed humanely and without delay, in accordance with the recommendations of the OIE.
- c) *Animals* should not be forced to move at a speed greater than their normal walking pace, in order to minimise injury through falling or slipping. Performance standards should be established where numerical scoring of the prevalence of *animals* slipping or falling is used to evaluate whether animal moving practices and/or facilities should be improved. In properly designed and constructed facilities with competent *animal handlers*, it should be possible to move 99% of *animals* without their falling.
- d) *Animals* for *slaughter* should not be forced to walk over the top of other *animals*.
- e) *Animals* should be handled in such a way as to avoid harm, distress or injury. Under no circumstances should *animal handlers* resort to violent acts to move *animals*, such as crushing or breaking tails of *animals*, grasping their eyes or pulling them by the ears. *Animal handlers* should never apply an injurious object or irritant substance to *animals* and especially not to sensitive areas such as eyes, mouth, ears, anogenital region or belly. The throwing or dropping of *animals*, or their lifting or dragging by body parts such as their tail, head, horns, ears, limbs, wool, hair or feathers, should not be permitted. The manual lifting of small *animals* is permissible.
- f) When using goads and other aids, the following principles should apply:
 - i) *Animals* that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move *animals*. The use and the power output should be restricted to that necessary to assist movement of an *animal* and only when an *animal* has a clear path ahead to move. Goads and other aids should not be used repeatedly if the *animal* fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the *animal* from moving.

Annex XII (contd)

- ii) The use of such devices should be limited to battery-powered goads on the hindquarters of pigs and large ruminants, and never on sensitive areas such as the eyes, mouth, ears, anogenital region or belly. Such instruments should not be used on horses, sheep and goats of any age, or on calves or piglets.
- iii) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the *animals* without causing undue stress.
- iv) Painful procedures (including whipping, kicking, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move *animals*.
- v) Excessive shouting at *animals* or making loud noises (e.g. through the cracking of whips) to encourage them to move should not occur, as such actions may make the *animals* agitated, leading to crowding or falling.
- vi) *Animals* should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young *animals* or small species, and in a manner appropriate to the species; grasping or lifting such *animals* only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where *animal welfare* or human safety may otherwise be compromised.
- vii) Conscious *animals* should not be thrown, dragged or dropped.
- g) Performance standards should be established to evaluate the use of such instruments. Numerical scoring may be used to measure the percentage of *animals* moved with an electric instrument and the percentage of *animals* slipping or falling at a point in the *slaughterhouse*. Any risk of compromising *animal welfare*, for example slippery floor, should be investigated immediately and the defect rectified to eliminate the problem. In addition to resource-based measures, outcome-based measures (e.g. bruises, lesions, behaviour, and mortality) should be used to monitor the level of *welfare* of the *animals*.

2. Specific considerations for poultry

Stocking density in transport crates should be optimum to suit climatic conditions and to maintain species-specific thermal comfort within *containers*.

Care is especially necessary during *loading* and *unloading* to avoid body parts being caught on crates, leading to dislocated or broken bones in conscious birds. Such injuries will adversely affect *animal welfare*, carcass and *meat* quality.

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

Birds may get trapped or their wings or claws may get caught in the fixtures, mesh or holes in poorly designed, constructed or maintained transport systems. Under this situation, operators *unloading* birds should ensure gentle release of trapped birds.

Drawers in modular systems and crates should be stacked and de-stacked carefully so as to avoid injury to birds.

Birds should have sufficient space so that all can lie down at the same time without being on top of each other.

Annex XII (contd)

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

The number of *poultry* arriving at the processing plant with broken bones and/or dislocated joints should be recorded in a manner that allows for verification. For *poultry*, the percentage of chickens with broken or dislocated wings should not exceed 2%, with less than 1% being the goal (under study).

3. Provisions relevant to animals delivered in containers

- a) *Containers* in which *animals* are transported should be handled with care, and should not be thrown, dropped or knocked over. Where possible, they should be horizontal while being loaded and unloaded mechanically, and stacked to ensure ventilation. In any case they should be moved and stored in an upright position as indicated by specific marks.
- b) *Animals* delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care in order to avoid injury. Where appropriate, *animals* should be unloaded from the *containers* individually.
- c) *Animals* which have been transported in *containers* should be slaughtered as soon as possible; mammals and ratites which are not taken directly upon arrival to the place of *slaughter* should have drinking water available to them from appropriate facilities at all times. Delivery of *poultry* for *slaughter* should be scheduled such that they are not deprived of water at the premises for longer than 12 hours. *Animals* which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.

4. Provisions relevant to restraining and containing animals

- a) Provisions relevant to restraining animals for stunning or slaughter without stunning, to help maintain animal welfare, include:
 - i) provision of a non-slippery floor;
 - ii) avoidance of excessive pressure applied by restraining equipment that causes struggling or vocalisation in animals;
 - iii) equipment engineered to reduce noise of air hissing and clanging metal;
 - iv) absence of sharp edges in restraining equipment that would harm animals;
 - v) avoidance of jerking or sudden movement of restraining device.
- b) Methods of restraint causing avoidable suffering should not be used in conscious animals because they cause severe pain and stress:
 - i) suspending or hoisting animals (other than poultry) by the feet or legs;
 - ii) indiscriminate and inappropriate use of stunning equipment;
 - iii) mechanical clamping of the legs or feet of the animals (other than shackles used in poultry and ostriches) as the sole method of restraint;
 - iv) breaking legs, cutting leg tendons or blinding animals in order to immobilise them;
 - v) severing the spinal cord, for example using a puntilla or dagger, to immobilise animals using electric currents to immobilise animals, except for proper stunning.

Annex XII (contd)

Article 7.5.3.

Lairage design and construction1. General considerations

The *lairage* should be designed and constructed to hold an appropriate number of *animals* in relation to the throughput rate of the *slaughterhouse* without compromising the *welfare* of the *animals*. In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the *animals*, the *lairage* should be designed and constructed so as to allow the *animals* to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight zone. The following recommendations may help to achieve this.

2. Design of lairage

- a) The *lairage* should be designed to allow a one-way flow of *animals* from *unloading* to the point of *slaughter*, with a minimum number of abrupt corners to negotiate.
- b) In red meat *slaughterhouses*, pens, passageways and races should be arranged in such a way as to permit inspection of *animals* at any time, and to permit the removal of sick or injured *animals* when considered to be appropriate, for which separate appropriate accommodation should be provided.
- c) Each *animal* should have room to stand up and lie down and, when confined in a pen, to turn around, except where the *animal* is reasonably restrained for safety reasons (e.g. fractious bulls). Fractious *animals* should be slaughtered as soon as possible after arrival at the *slaughterhouse* to avoid *welfare* problems. The *lairage* should have sufficient accommodation for the number of *animals* intended to be held. Drinking water should always be available to the *animals*, and the method of delivery should be appropriate to the type of *animal* held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in *animals*, and should not hinder the movement of *animals*.
- d) Holding pens should be designed to allow as many *animals* as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all *animals* to feed. The feed trough should not hinder the movement of *animals*.
- e) Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress to the *animals* and should also allow the *animals* to stand, lie down and access any food or water that may need to be provided.
- f) Passageways and races should be either straight or consistently curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race, the shared partition should allow adjacent *animals* to see each other. For pigs and sheep, passageways should be wide enough to enable two or more *animals* to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the *animals*.
- g) *Animal handlers* should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of *animals* to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of *animals* without injury.
- h) In *slaughterhouses* with high throughput, there should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of *stunning* or *slaughter*, to ensure a steady supply of *animals* for *stunning* or *slaughter* and to avoid having *animal handlers* trying to rush *animals* from the holding pens. The waiting pen should preferably be circular, but in any case, so designed that *animals* cannot be trapped or trampled.
- i) Ramps or lifts should be used for the *loading* and *unloading* of *animals* where there is a difference in height or a gap between the floor of the *vehicle* and the *unloading* area. Unloading ramps should be designed and constructed so as to permit *animals* to be unloaded from *vehicles* on the level or at the minimum gradient achievable. Lateral side protection should be available to prevent *animals* escaping or falling. They should be well drained, with secure footholds and adjustable to facilitate easy movement of *animals* without causing distress or injury.

Annex XII (contd)3. Construction of lairage

- a) *Lairages* should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the *animals*.
- b) Floors should be well drained and not slippery; they should not cause injury to the feet of the *animals*. Where necessary, floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where *animals* would have to cross them. Discontinuities or changes in floor, wall or gate colours, patterns or texture which could cause baulking in the movement of *animals* should be avoided.
- c) *Lairages* should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the *animals* or affect their movement. The fact that *animals* will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.
- d) *Lairages* should be adequately ventilated to ensure that waste gases (e.g. ammonia) do not build up and that draughts at animal height are minimised. Ventilation should be able to cope with the range of expected climatic conditions and the number of *animals* the *lairage* will be expected to hold.
- e) Care should be taken to protect the *animals* from excessively or potentially disturbing noises, for example by avoiding the use of noisy hydraulic or pneumatic equipment, and muffling noisy metal equipment by the use of suitable padding, or by minimising the transmission of such noises to the areas where *animals* are held and slaughtered.
- f) Where *animals* are kept in outdoor *lairages* without natural shelter or shade, they should be protected from the effects of adverse weather conditions.

Article 7.5.4.

Care of animals in lairages

Animals in *lairages* should be cared for in accordance with the following recommendations:

- 1) As far as possible, established groups of *animals* should be kept together and each *animal* should have enough space to stand up, lie down and turn around. *Animals* hostile to each other should be separated.
- 2) Where tethers, ties or individual stalls are used, they should allow *animals* to stand up and lie down without causing injury or distress.
- 3) Where bedding is provided, it should be maintained in a condition that minimises risks to the health and safety of the *animals*, and sufficient bedding should be used so that *animals* do not become soiled with manure.
- 4) *Animals* should be kept securely in the *lairage*, and care should be taken to prevent them from escaping and from predators.
- 5) Suitable drinking water should be available to the *animals* on their arrival and at all times to *animals* in *lairages* unless they are to be slaughtered without delay.
- 6) Waiting time should be minimised and should not exceed 12 hours. If *animals* are not to be slaughtered within this period, suitable feed should be available to the *animals* on arrival and at intervals appropriate to the species. Unweaned *animals* should be slaughtered as soon as possible.
- 7) In order to prevent heat stress, *animals* subjected to high temperatures, particularly pigs and *poultry*, should be cooled by the use of water sprays, fans or other suitable means. However, the potential for water sprays to reduce the ability of *animals* to thermoregulate (especially *poultry*) should be considered in any decision to use water sprays. The risk of *animals* being exposed to very cold temperatures or sudden extreme temperature changes should also be considered.
- 8) The *lairage* area should be well lit in order to enable the *animals* to see clearly without being dazzled. During the night, the lights should be dimmed. Lighting should also be adequate to permit inspection of all *animals*. Subdued lighting, and for example blue light, may be useful in *poultry lairages* in helping to calm birds.

Annex XII (contd)

- 9) The condition and state of health of the *animals* in a *lairage* should be inspected at least every morning and evening by a *veterinarian* or, under the *veterinarian's* responsibility, by another competent person, such as an *animal handler*. *Animals* which are sick, weak, injured or showing visible signs of distress should be separated, and veterinary advice should be sought immediately regarding treatment or the *animals* should be humanely killed immediately if necessary.
- 10) Lactating dairy *animals* should be slaughtered as soon as possible. Dairy *animals* with obvious udder distension should be milked to minimise udder discomfort.
- 11) *Animals* which have given birth during the *journey* or in the *lairage* should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling for their *welfare* and the *welfare* of the newborn. Under normal circumstances, *animals* which are expected to give birth during a *journey* should not be transported.
- 12) *Animals* with horns, antlers or tusks capable of injuring other *animals*, if aggressive, should be penned separately.
- 13) *Poultry* awaiting *slaughter* should be protected from adverse weather conditions and provided with adequate ventilation.
- 14) *Poultry* in transport *containers* should be examined at the time of arrival. *Containers* should be stacked with sufficient space between the stacks to facilitate inspection of birds and air movement.
- 15) Forced ventilation or other cooling systems may be necessary under certain conditions to avoid buildup of temperature and humidity. Temperature and humidity should be monitored at appropriate intervals.

Recommendations for specific species are described in detail in Articles 7.5.5. to 7.5.9.

Article 7.5.5.

Management of fetuses during slaughter of pregnant animals

Under normal circumstances, pregnant *animals* that would be in the final 10% of their gestation period at the planned time of *unloading* at the *slaughterhouse* should be neither transported nor slaughtered. If such an event occurs, an *animal handler* should ensure that females are handled separately, and the specific procedures described below are applied. In all cases, the *welfare* of fetuses and dams during *slaughter* should be safeguarded.

Foetuses should not be removed from the uterus sooner than 5 minutes after the maternal neck or chest cut, to ensure absence of consciousness. A foetal heartbeat will usually still be present and foetal movements may occur at this stage, but these are only a cause for concern if the exposed foetus successfully breathes air.

If a live mature foetus is removed from the uterus, it should be prevented from inflating its lungs and breathing air (e.g. by clamping the trachea).

When uterine, placental or foetal tissues, including foetal blood, are not to be collected as part of the post-*slaughter* processing of pregnant *animals*, all fetuses should be left inside the unopened uterus until they are dead. When uterine, placental or foetal tissues are to be collected, where practical, fetuses should not be removed from the uterus until at least 15–20 minutes after the maternal neck or chest cut.

If there is any doubt about consciousness, the foetus should be killed with a captive bolt of appropriate size or a blow to the head with a suitable blunt instrument.

The above recommendations do not refer to foetal rescue. Foetal rescue, the practice of attempting to revive foetuses found alive at the evisceration of the dam, should not be attempted during normal commercial *slaughter* as it may lead to serious *welfare* complications in the newborn *animal*. These include impaired brain function resulting from oxygen shortage before rescue is completed, compromised breathing and body heat production because of foetal immaturity, and an increased incidence of infections due to a lack of colostrum.

Annex XII (contd)

Article 7.5.6.

Summary analysis of handling and restraining methods and the associated animal welfare issues

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
No restraint	Animals are grouped	Group container	Gas stunning	Specific procedure is suitable only for gas stunning	Competent animal handlers in lairage; facilities; stocking density	Pigs, poultry
		In the field	Free bullet	Inaccurate targeting and inappropriate ballistics not achieving outright kill with first shot	Operator competence	Deer
		Group stunning pen	Head-only electrical Captive bolt	Uncontrolled movement of animals impedes use of hand operated electrical and mechanical stunning methods	Competent animal handlers in lairage and at stunning point	Pigs, sheep, goats, calves
	Individual animal confinement	Stunning pen/box	Electrical and mechanical stunning methods	Loading of animal; accuracy of stunning method, slippery floor and animal falling down	Competent animal handlers	Cattle, buffalo, sheep, goats, horses, pigs, deer, camelids, ratites
Restraining methods	Head restraint, upright	Halter/ head collar/bridle	Captive bolt Free bullet	Suitable for halter-trained animals; stress in untrained animals	Competent animal handlers	Cattle, buffalo, horses, camelids
	Head restraint, upright	Neck yoke	Captive bolt Electrical-head only Free bullet Slaughter without stunning	Stress of loading and neck capture; stress of prolonged restraint, horn configuration; unsuitable for fast line speeds, animals struggling and falling due to slippery floor, excessive pressure	Equipment; competent animal handlers, prompt stunning or slaughter	Cattle
	Leg restraint	Single leg tied in flexion (animal standing on 3 legs)	Captive bolt Free bullet	Ineffective control of animal movement, misdirected shots	Competent animal handler	Breeding pigs (boars and sows)
	Upright restraint	Beak holding	Captive bolt Electrical-head only	Stress of capture	Sufficient competent animal handlers	Ostriches
		Head restraint in electrical stunning box	Electrical-head only	Stress of capture and positioning	Competent animal handler	Ostriches

Annex XII (contd)

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Restraining methods (contd)	Holding body upright-manual	Manual restraint	Captive bolt Electrical-head only Slaughter without stunning	Stress of capture and restraint; accuracy of stunning/ slaughter	Competent animal handlers	Sheep, goats, calves, raites, small camelids, poultry
	Holding body upright mechanical	Mechanical clamp/crush/ squeeze/ V-restrainer (static)	Captive bolt Electrical methods Slaughter without stunning	Loading of animal and overriding; excessive pressure	Proper design and operation of equipment	Cattle, buffalo, sheep, goats, deer, pigs, ostriches
	Lateral restraint-manual or mechanical	Restrainer/ cradle/crush	Slaughter without stunning	Stress of restraint	Competent animal handlers	Sheep, goats, calves, camelids, cattle
	Upright restraint mechanical	Mechanical straddle (static)	Slaughter without stunning Electrical methods Captive bolt	Loading of animal and overriding	Competent animal handlers	Cattle, sheep, goats, pigs
	Upright restraint-manual or mechanical	Wing shackling	Electrical	Excessive tension applied prior to stunning	Competent animal handlers	Ostriches
Restraining and /or conveying methods	Mechanical – upright	V-restrainer	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding; excessive pressure, size mismatch between restrainer and animal	Proper design and operation of equipment	Cattle, calves, sheep, goats, pigs
	Mechanical – upright	Mechanical straddle-band restrainer (moving)	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding, size mismatch between restrainer and animal	Competent animal handlers, proper design and layout of restraint	Cattle, calves, sheep, goats, pigs
	Mechanical – upright	Flat bed/deck Tipped out of containers on to conveyors	Presentation of birds for shackling prior to electrical stunning Gas stunning	Stress and injury due to tipping in dump-module systems height of tipping conscious poultry broken bones and dislocations	Proper design and operation of equipment	Poultry
	Suspension and/or inversion	Poultry shackle	Electrical stunning Slaughter without stunning	Inversion stress; pain from compression on leg bones	Competent animal handlers; proper design and operation of equipment	Poultry
	Suspension and/or inversion	Cone	Electrical – head-only Captive bolt Slaughter without stunning	Inversion stress	Competent animal handlers; proper design and operation of equipment	Poultry
	Upright restraint	Mechanical leg clamping	Electrical – head-only	Stress of resisting restraint in ostriches	Competent animal handlers; proper equipment design and operation	Ostriches
Restraining by inversion	Rotating box	Fixed side(s) (e.g. Weinberg pen)	Slaughter without stunning	Inversion stress; stress of resisting restraint, prolonged restraint, inhalation of blood and ingesta Keep restraint as brief as possible	Proper design and operation of equipment	Cattle

Annex XII (contd)

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key Animal welfare requirements	Applicable species
Restraining by inversion (contd)	Rotating box (contd)	Compressible side(s)	Slaughter without stunning	Inversion stress, stress of resisting restraint, prolonged restraint. Preferable to rotating box with fixed sides. Keep restraint as brief as possible	Proper design and operation of equipment.	Cattle
Body restraint	Casting/hobbling	Manual	Mechanical stunning methods. Slaughter without stunning	Stress of resisting, restraint; animal temperament; bruising. Keep restraint as short as possible.	Competent animal handlers	Sheep, goats, calves, small camelids, pigs
		Rope casting	Mechanical stunning methods. Slaughter without stunning.	Stress of resisting, restraint; prolonged restraint, animal temperament; bruising. Keep restraint as short as possible.	Competent animal handlers	Cattle, camelids
Leg restraints		Tying of 3 or 4 legs	Mechanical stunning methods. Slaughter without stunning.	Stress of resisting restraint; prolonged restraint, animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Sheep, goats, small camelids, pigs

Article 7.5.7.

Stunning methods1. General considerations

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

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

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

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

Annex XII (contd)2. Mechanical stunning

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

3. Electrical stunning

a) General considerations

An electrical device should be applied to the *animal* in accordance with the following recommendations.

Electrodes should be designed, constructed, maintained and cleaned regularly to ensure that the flow of current is optimal and in accordance with manufacturing specifications. They should be placed so that they span the brain. The application of electrical currents which bypass the brain is unacceptable unless the *animal* has been stunned. The use of a single current leg-to-leg is unacceptable as a *stunning* method.

If, in addition, it is intended to cause cardiac arrest, the electrodes should either span the brain and immediately thereafter the heart, on the condition that it has been ascertained that the *animal* is adequately stunned, or span brain and heart simultaneously.

Electrical *stunning* equipment should not be applied on *animals* as a means of guidance, movement, *restraint* or immobilisation, and shall not deliver any shock to the *animal* before the actual *stunning* or *killing*. Electrical *stunning* apparatus should be tested prior to application on *animals* using appropriate resistors or dummy loads to ensure the power output is adequate to stun *animals*.

The electrical *stunning* apparatus should incorporate a device that monitors and displays voltage (true RMS) and the applied current (true RMS) and that such devices are regularly calibrated at least annually.

Appropriate measures, such as removing excess wool or wetting the skin only at the point of contact, can be taken to minimise impedance of the skin and facilitate effective *stunning*.

The *stunning* apparatus should be appropriate for the species. Apparatus for electrical *stunning* should be provided with adequate power to achieve continuously the minimum current level recommended for *stunning* as indicated in the table below.

In all cases, the correct current level shall be attained within one second of the initiation of stun and maintained at least for between one and three seconds and in accordance with the manufacturer's instructions. Minimum current levels for head-only stunning are shown in the following table.

Species	Minimum current levels for head-only stunning
Cattle	1.5. amps
Calves (bovines of less than 6 month of age)	1.0 amps
Pigs	1.25 amps
Sheep and goats	1.0 amps
Lambs	0.7 amps
Ostriches	0.4 amps

b) Electrical stunning of birds using a waterbath

There should be no sharp bends or steep gradients in the shackle line and the shackle line should be as short as possible consistent with achieving acceptable line speeds, and ensuring that birds have settled by the time they reach the water bath. A breast comforter can be used effectively to reduce wing flapping and calm birds. The angle at which the shackle line approaches the entrance to the water bath, and the design of the entrance to the water bath, and the draining of excess 'live' water from the bath are all important considerations in ensuring birds are calm as they enter the bath, do not flap their wings, and do not receive pre-stun electric shocks.

Annex XII (contd)

In the case of birds suspended on a moving line, measures should be taken to ensure that the birds are not wing flapping at the entrance of the stunner. The birds should be secure in their shackle, but there should not be undue pressure on their shanks. The shackle size should be appropriate to fit the size of the shanks (metatarsal bones) of birds.

Birds should be hung on shackles by both legs.

Birds with dislocated or broken legs or wings should be humanely killed rather than shackled.

Standard procedures should be implemented to ensure that small birds do not go on the line amongst bigger birds and that these small birds are stunned separately.

The duration between hanging on shackles and *stunning* should be kept to the minimum. In any event, the time between shackling and *stunning* should not exceed one minute.

Waterbaths for *poultry* should be adequate in size and depth for the type of bird being slaughtered, and their height should be adjustable to allow for the head of each bird to be immersed. The electrode immersed in the bath should extend the full length of the waterbath. Birds should be immersed in the bath up to the base of their wings.

The waterbath should be designed and maintained in such a way that when the shackles pass over the water, they are in continuous contact with the earthed rubbing bar.

The control box for the waterbath stunner should incorporate an ammeter which displays the total current flowing through the birds.

The shackle-to-leg contact should be wetted preferably before the birds are inserted in the shackles. In order to improve the electrical conductivity of the water, it is recommended that salt be added in the waterbath as necessary. Additional salt should be added regularly as a solution to maintain suitable constant concentrations in the waterbath.

Using waterbaths, birds are stunned in groups and different birds will have different impedances. The voltage should be adjusted so that the total current is the required current per bird as shown in the table hereafter, multiplied by the number of birds in the waterbath at the same time. The following values in the following table have been found to be satisfactory when employing a 50 Hertz sinusoidal alternating current, but are indicative only, as there are many parameters that will affect stun efficiency.

The effective current for a particular slaughterhouse/abattoir's operation should be adjusted through monitoring specific indicators.

Birds should receive the current for at least 4 seconds.

Minimum average current for stunning poultry when using 50Hz is as follows:

<u>Type of bird</u>	<u>Minimum average current (milliamperes per bird)</u>
<u>Broilers</u>	<u>100 mA</u>
<u>Layers (spent hens)</u>	<u>100 mA</u>
<u>Turkeys</u>	<u>150mA</u>
<u>Ducks and geese</u>	<u>130 mA</u>

Because of issues of product quality, lower currents are sometimes used. This is not recommended unless all other measures to solve quality issues have failed. In such a situation, operators should be aware of the higher risk of stun failure and a sampling plan to monitor stun efficiency should be implemented.

While a lower current may also be satisfactory, in any case, the current shall should in any case be such as to ensure that unconsciousness occurs immediately and lasts until the bird has been killed by cardiac arrest or by bleeding. When higher electrical frequencies are used, higher currents may be required.

Annex XII (contd)

Minimum average current for stunning poultry when using high frequencies is as follows:

Frequency (Hz)	Minimum average current (milliamperes per bird)	
	Chickens	Turkeys
From 50 to 200 Hz	100 mA	250 mA
From 200 to 400 Hz	150 mA	400 mA
From 400 to 1500 Hz	200 mA	400 mA

The effectiveness of the stun depends on the interaction of several parameters in the stunning process such as current type and strength, frequency, electrical wave form, and size, age and condition of the birds. The management of these parameters to ensure all birds are effectively stunned should be set out as standard operating procedures in the slaughterhouse/abattoir's dedicated plan for animal welfare, taken into account manufacturers' instructions.

The means of assessing the welfare outcomes of the stunning process should also be set out in the standard operating procedures in the slaughterhouse/abattoir's plan for animal welfare. An operator should be present to monitor the effectiveness of the stun by assessing the following indicators of the state of consciousness of birds immediately after exiting the water bath:

- a) Tonic seizures; effective electrical head to body stunning will result in tonic seizure, which in shackled birds, is recognised by an arched neck and wings held tightly to the body.
- b) Breathing; effective stunning will result in apnoea (absence of breathing). Ineffectively stunned birds and those recovering consciousness will start to breathe in a rhythmic pattern. Rhythmic breathing is recognised from the regular abdominal movement in shackled birds.
- c) Spontaneous blinking without stimulation indicates consciousness and an ineffective stun.

For an accurate assessment of outcomes, more than one indicator should be evaluated at the same time. Additional indicators may be included such as the presence or absence of corneal or palpebral reflex and vocalisation.

If the monitoring of indicators of the state of consciousness of birds shows that an effective stun is not being delivered then the operator should take immediate corrective action by adjusting the stun parameters to ensure birds are rendered unconscious until death by bleeding occurs. In case of repetitive failure, the management of the slaughterhouse/abattoir should develop an improvement plan.

Every effort shall be made to ensure that no conscious or live birds enter the scalding tank.

In the case of automatic systems, until fail-safe systems of *stunning* and bleeding have been introduced, a manual back-up system should be in place to ensure that any birds which have missed the waterbath stunner and/or the automatic neck-cutter are immediately stunned and/or killed immediately, and they are dead before entering scald tank.

To lessen the number of birds that have not been effectively stunned reaching neck cutters, steps should be taken to ensure that small birds do not go on the line amongst bigger birds and that these small birds are stunned separately. The height of the waterbath stunner should be adjusted according to the size of birds to ensure even the small birds are immersed in the water bath up to the base of the wings.

Waterbath *stunning* equipment should be fitted with a device which displays and records the details of the electrical key parameter.

Minimum current for *stunning* poultry when using 50Hz is as follows:

Species	Current (milliamperes per bird)
Broilers	100
Layers (spent hens)	100
Turkeys	150
Ducks and geese	130

Minimum current for stunning poultry when using high frequencies is as follows:

Frequency (Hz)	Minimum current (milliamperes per bird)	
	Chickens	Turkeys
From 50 to 200 Hz	100 mA	250 mA
From 200 to 400 Hz	150 mA	400 mA
From 400 to 1500 Hz	200 mA	400 mA

4. Gas stunning (under study)a) Stunning of pigs by exposure to carbon dioxide (CO₂)

The concentration of CO₂ for *stunning* should be preferably 90% by volume but in any case no less than 80% by volume. After entering the *stunning* chamber, the *animals* should be conveyed to the point of maximum concentration of the gas as rapidly as possible and be kept until they are dead or brought into a state of insensibility which lasts until *death* occur due to bleeding. Ideally, pigs should be exposed to this concentration of CO₂ for 3 minutes. Sticking should occur as soon as possible after exit from the gas chamber. In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the *animal* prior to loss of consciousness.

The chamber in which *animals* are exposed to CO₂ and the equipment used for conveying them through it shall be designed, constructed and maintained in such a way as to avoid injury or unnecessary stress to the *animals*. The animal density within the chamber should be such to avoid stacking *animals* on top of each other.

The conveyor and the chamber shall be adequately lit to allow the *animals* to see their surroundings and, if possible, each other.

It should be possible to inspect the CO₂ chamber whilst it is in use, and to have access to the *animals* in emergency cases.

The chamber shall be equipped to continuously measure and display register at the point of *stunning* the CO₂ concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO₂ falls below the required level.

Emergency *stunning* equipment should be available at the point of exit from the *stunning* chamber and used on any pigs that do not appear to be completely stunned.

b) Inert gas mixtures for stunning pigs

Inhalation of high concentration of carbon dioxide is aversive and can be distressing to *animals*. Therefore, the use of non-aversive gas mixtures is being developed. Such gas mixtures include: i) a maximum of 2% by volume of oxygen in argon, nitrogen or other inert gases, or ii) to a maximum of 30% by volume of carbon dioxide and a maximum of 2% by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases. Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before *death* supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

The main objective of gas *stunning* is to avoid the pain and suffering associated with shackling conscious *poultry* under water bath *stunning* and *killing* systems. Therefore, gas *stunning* should be limited to birds contained in crates or on conveyors only. The gas mixture should be non-aversive to *poultry*.

Live *poultry* contained within transport modules or crates may be exposed to gradually increasing concentrations of CO₂ until the birds are properly stunned. No bird should recover consciousness during bleeding.

Gas *stunning* of *poultry* in their transport *containers* will eliminate the need for live birds' handling at the processing plant and all the problems associated with the electrical *stunning*. Gas *stunning* of *poultry* on a conveyor eliminates the problems associated with the electrical water bath *stunning*.

Annex XII (contd)

Live *poultry* should be conveyed into the gas mixtures either in transport crates or on conveyor belts.

The following gas procedures have been properly documented for chickens and turkeys but do not necessarily apply for other domestic birds. In any case the procedure should be designed as to ensure that all *animals* are properly stunned without unnecessary suffering. Some monitoring points for gas *stunning* could be the following:

- ensure smooth entry and passage of crates or birds through the system;
 - avoid crowding of birds in crates or conveyors;
 - monitor and maintain gas concentrations continuously during operation;
 - provide visible and audible alarm systems if gas concentrations are inappropriate to the species;
 - calibrate gas monitors and maintain verifiable records;
 - ensure that duration of exposure is adequate to prevent recovery of consciousness;
 - make provision to monitor and deal with recovery of consciousness;
 - ensure that blood vessels are cut to induce *death* in unconscious birds;
 - ensure that all birds are dead before entering scalding tank;
 - provide emergency procedures in the event of system failure.
- i) Gas mixtures used for stunning *poultry* include:
- a minimum of 2 minutes exposure to 40% carbon dioxide, 30% oxygen and 30% nitrogen, followed by a minimum of one minute exposure to 80% carbon dioxide in air; or
 - a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30% by volume and the residual oxygen concentration does not exceed 2% by volume; or
 - a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2% residual oxygen by volume; or
 - a minimum of 2 minutes exposure to a minimum of 55% carbon dioxide in air; or
 - a minimum of one minute exposure to 30% carbon dioxide in air, followed by a minimum of one minute exposure to at least 60% carbon dioxide in air.
- ii) Requirements for effective use are as follows:
- Compressed gases should be vaporised prior to administration into the chamber and should be at room temperature to prevent any thermal shock; under no circumstances, should solid gases with freezing temperatures enter the chamber.
 - Gas mixtures should be humidified.
 - Appropriate gas concentrations of oxygen and carbon dioxide should be monitored and displayed continuously at the level of the birds inside the chamber to ensure that anoxia ensues.

Under no circumstances, should birds exposed to gas mixtures be allowed to regain consciousness. If necessary, the exposure time should be extended.

Annex XII (contd)5. Bleeding

From the point of view of *animal welfare*, *animals* which are stunned with a reversible method should be bled without delay. Maximum stun-stick interval depends on the parameters of the *stunning* method applied, the species concerned and the bleeding method used (full cut or chest stick when possible). As a consequence, depending on those factors, the *slaughterhouse* operator should set up a maximum stun-stick interval that ensures that no *animals* recover consciousness during bleeding. In any case the following time limits should be applied.

Stunning method	Maximum–stun stick interval
Electrical methods and non-penetrating captive bolt	20 seconds
CO ₂	60 seconds (after leaving the chamber)

All *animals* should be bled out by incising both carotid arteries, or the vessels from which they arise (e.g. chest stick). However, when the *stunning* method used causes cardiac arrest, the incision of all of these vessels is not necessary from the point of view of *animal welfare*.

It should be possible for staff to observe, inspect and access the *animals* throughout the bleeding period. Any *animal* showing signs of recovering consciousness should be re-stunned.

After incision of the blood vessels, no scalding carcass treatment or dressing procedures should be performed on the *animals* for at least 30 seconds, or in any case until all brain-stem reflexes have ceased.

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

Cattle



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

Annex XII (contd)

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

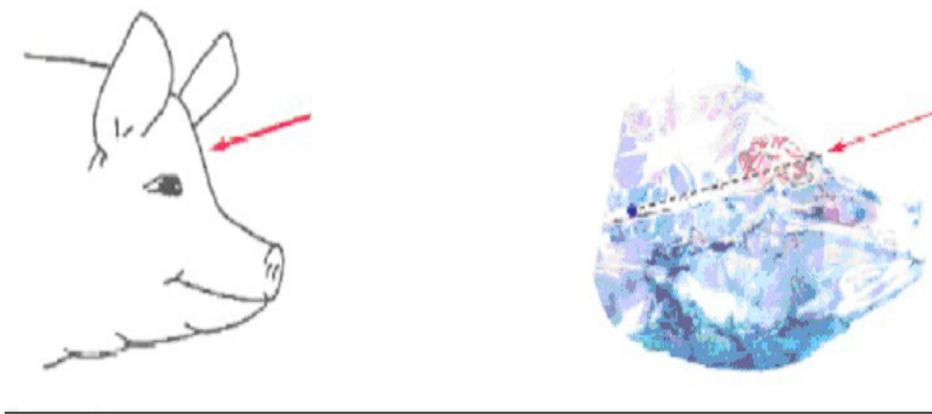
Pigs

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

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

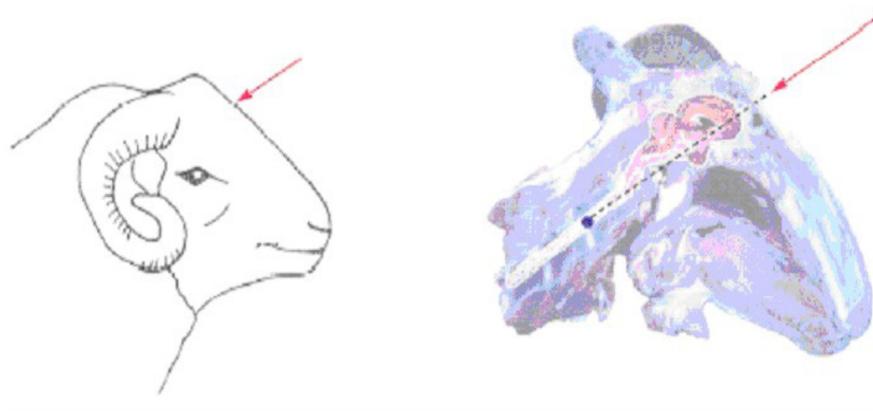
Sheep

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

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

Goats

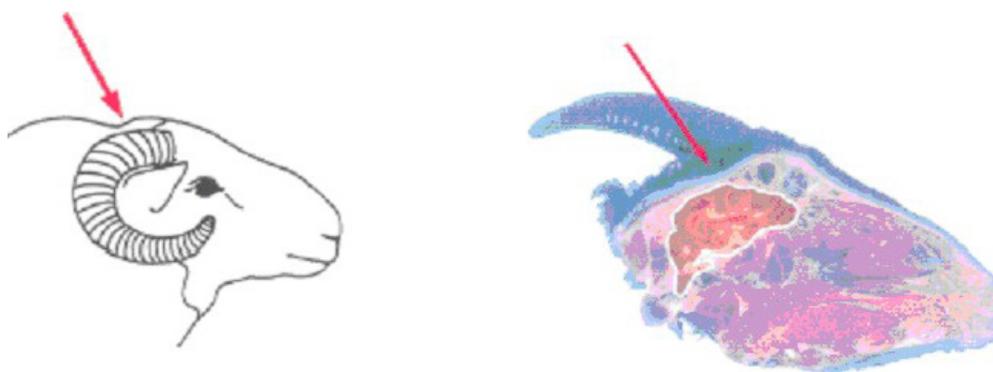


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

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

Horses



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

Annex XII (contd)

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

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

Figure 6. Captive bolts powered by cartridges, compressed air or spring can be used for *poultry*. The optimum position for *poultry* species is at right angles to the frontal surface.

Poultry

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

Poultry

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

Annex XII (contd)

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

Article 7.5.8.

Summary analysis of stunning methods and the associated animal welfare issues

Method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements applicable	Species	Comment
Mechanical	Free bullet	In accurate targeting and inappropriate ballistics	Operator competence; achieving outright kill with first shot	Cattle, calves, buffalo, deer, horses, pigs (boars and sows)	Personnel safety
	Captive bolt – penetrating	Inaccurate targeting, velocity and diameter of bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, buffalo, sheep, goats, deer, horses, pigs, camelids, ratites, poultry	(Unsuitable for specimen collection from TSE suspects). A back-up gun should be available in the event of an ineffective shot
	Captive bolt – non-penetrating	Inaccurate targeting, velocity of bolt, potentially higher failure rate than penetrating captive bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, deer, pigs, camelids, ratites, poultry	Presently available devices are not recommended for young bulls and animals with thick skull. This method should only be used for cattle and sheep when alternative methods are not available.
	Manual percussive blow	Inaccurate targeting; insufficient power; size of instrument	Competent animal handlers; restraint; accuracy. Not recommended for general use	Young and small mammals, ostriches and poultry	Mechanical devices potentially more reliable. Where manual percussive blow is used, unconsciousness should be achieved with single sharp blow delivered to central skull bones
Electrical	Split application: 1. across head then head to chest; 2. across head then across chest	Accidental pre-stun electric shocks; electrode positioning; application of a current to the body while animal conscious; inadequate current and voltage	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats and pigs, ratites and poultry	Systems involving repeated application of head-only or head-to-leg with short current durations (<1 second) in the first application should not be used.
	Single application: 1. head only; 2. head to body; 3. head to leg	Accidental pre-stun electric shocks; inadequate current and voltage; wrong electrode positioning; recovery of consciousness	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, pigs, ratites, poultry	
	Waterbath	Restraint, accidental pre-stun electric shocks; inadequate current and voltage; recovery of consciousness	Competent operation and maintenance of equipment	Poultry only	
Gaseous	CO ₂ air/O ₂ mixture; CO ₂ inert gas mixture	Aversiveness of high CO ₂ ; respiratory distress; inadequate exposure	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	

Annex XII (contd)

Method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements applicable	Species	Comment
Gaseous (contd)	Inert gases	Recovery of consciousness	Concentration; duration of exposure; design, maintenance and operation of equipment; density management	Pigs, poultry	

Article 7.5.9.

Summary analysis of slaughter methods and the associated animal welfare issues

Slaughter methods	Specific methods	Animal welfare concerns/ implications	Key requirements	Species	Comments
Bleeding out by severance of blood vessels in the neck without stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut	High level of operator competency. A very sharp blade or knife of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. The incision should not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats, poultry, ratites	No further procedure should be carried out before the bleeding out is completed (i.e. at least 30 seconds for mammals). The practice to remove hypothetical blood clots just after the bleeding should be discouraged since this may increase animal suffering.
Bleeding with prior stunning	Full frontal cutting across the throat	Failure to cut both common carotid arteries; occlusion of cut arteries; pain during and after the cut.	A very sharp blade or knife of sufficient length so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. The incision should not close over the knife during the throat cut.	Cattle, buffalo, horses, camelids, sheep, goats	
	Neck stab followed by forward cut	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Neck stab alone	Ineffective stunning; failure to cut both common carotid arteries; impaired blood flow; delay in cutting after reversible stunning	Prompt and accurate cutting	Camelids, sheep, goats, poultry, ratites	
	Chest stick into major arteries or hollow-tube knife into heart	Ineffective stunning; inadequate size of stick wound inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate sticking	Cattle, sheep, goats, pigs	

Annex XII (contd)

Slaughter methods	Specific methods	Animal welfare concerns/ implications	Key requirements	Species	Comments
Bleeding with prior stunning (contd)	Neck skin cut followed by severance of vessels in the neck	Ineffective stunning; inadequate size of stick wound; inadequate length of sticking knife; delay in sticking after reversible stunning	Prompt and accurate cutting of vessels	Cattle	
	Automated mechanical cutting	Ineffective stunning; failure to cut and misplaced cuts. Recovery of consciousness following reversible stunning systems	Design, maintenance and operation of equipment; accuracy of cut; manual back-up	Poultry only	
	Manual neck cut on one side	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness under slaughter without stunning
	Oral cut	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness in non-stun systems
Other methods without stunning	Decapitation with a sharp knife	Pain due to loss of consciousness not being immediate		Sheep, goats, poultry	This method is only applicable to Jhatka slaughter
	Manual neck dislocation and decapitation	Pain due to loss of consciousness not being immediate; difficult to achieve in large birds	Neck dislocation should be performed in one stretch to sever the spinal cord	Poultry only	Slaughter by neck dislocation should be performed in one stretch to sever the spinal cord. Acceptable only when slaughtering small numbers of small birds.
Cardiac arrest in a waterbath electric stunner	Bleeding by evisceration		Induction of cardiac arrest	Quail	
	Bleeding by neck cutting			Poultry	

Article 7.5.10.

Methods, procedures or practices unacceptable on animal welfare grounds

- 1) The restraining methods which work through electro-immobilisation or immobilisation by injury such as breaking legs, leg tendon cutting, and severing the spinal cord (e.g. using a puntilla or dagger) cause severe pain and stress in *animals*. Those methods are not acceptable in any species.
- 2) The use of the electrical *stunning* method with a single application leg to leg is ineffective and unacceptable in any species.
- 3) The *slaughter* method of brain stem severance by piercing through the eye socket or skull bone without prior *stunning* is not acceptable in any species.

 — Text deleted.

NOTE:

The Code Commission encourages Member Countries to review all relevant reports when reviewing this document including the following:

- September 2013 report of the Scientific Commission
(http://www.oie.int/fileadmin/Home/eng/International_Standard_Setting/docs/pdf/SCAD/A_SCAD_Sept2013.pdf)
- March 2011 report of the OIE *ad hoc* Group on Epizootic Hemorrhagic Disease attached to the Scientific Commission report
(http://www.oie.int/fileadmin/Home/eng/International_Standard_Setting/docs/pdf/SCAD/A_SCAD_Aug-Sept2011.pdf)

CHAPTER 8.X.

INFECTION WITH EPIZOOTIC
HEMORRHAGIC DISEASE VIRUS

Article 8.X.1.

General provisions

For the purposes of the *Terrestrial Code*, epizootic hemorrhagic disease (EHD) is defined as an infection of cervids and bovids cattle with one of several serotypes of epizootic hemorrhagic disease virus (EHDV) that is transmitted by *Culicoides* vectors. Outbreaks of disease due to EHDV are sporadic and geographically restricted. Although EHDV is not regarded as a significant pathogen of livestock in many countries in which it is present, outbreaks of disease have caused significant economic loss to the cattle industry in some countries.

The following defines an infection with the occurrence of EHDV infection:

- 1) EHDV has been isolated and identified as such from a sample from a cervid or bovid or a product derived from it; or
- 2) viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of EHDV has been identified in samples from a cervid or bovid showing clinical signs consistent with EHD, or epidemiologically linked to a confirmed or suspected or confirmed case, or giving cause for suspicion of previous association or contact with EHDV; or
- 3) antibodies to structural or nonstructural proteins of EHDV that are not a consequence of vaccination have been identified in a cervid or bovid that either shows clinical signs consistent with EHD, or is epidemiologically linked to a confirmed or suspected or confirmed case, or gives cause for suspicion of previous association or contact with EHDV.

For the purposes of international trade, a distinction is made between a case as defined above and an animal that is potentially infectious to vectors.

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

For countries that do not meet the provisions of point 1 of Article 1.4.6, and in the absence of clinical disease in a country or zone, its EHDV status should be determined by an ongoing surveillance programme (in accordance with Article x.x.1612). The programme may need to be adapted to target parts of the country or zone at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology.

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

Article 8.X.2.

Safe commodities

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

Annex XIII (contd)

- 1) *milk and milk products*;
- 2) *meat and meat products*;
- 3) *hides, skins, antlers and hooves*;
- 4) *wool and fibre*.

Article 8.X.3.

EHDV-free Country or zone free from EHD

- 1) Historical freedom as described in Chapter 1.4. does not apply to with EHDV.
- 24) A country or a *zone* may be considered free from EHDV when infection with EHDV epizootic haemorrhagic disease is notifiable in the whole country, importation of animals and their semen, embryos, or oocytes is carried out in accordance with this chapter and either:
 - a) historical freedom has been demonstrated as described in Article 1.4.6.; or
 - ba) a surveillance programme in accordance with Article 8.X.12. has demonstrated no evidence of EHDV transmission in the country or zone during the past two years; or
 - bb) an ongoing surveillance programme in accordance with Article 8.X.12. and Chapter 4.3 has found demonstrated no evidence of *Culicoides* for at least two years in the country or zone.
- 32) An EHDV-free country or zone free from EHD in which ongoing vector surveillance has found no evidence of *Culicoides* will not lose its free status through the importation introduction of seropositive or infective animals, or semen, embryos or ova oocytes from infected countries or infected zones infected with EHD.
- 43) An EHDV-free country or zone free from EHD in which surveillance has found evidence that *Culicoides* are present will not lose its free status through the importation introduction of seropositive animals, or semen, embryos, or oocytes provided that: they were imported in accordance with Article X.X.6.
 - a) an ongoing surveillance programme has focused on EHDV transmission in domestic bovids and farmed cervids and has demonstrated no evidence of EHDV transmission in the country or zone; or
 - b) the animals, semen, embryos and oocytes were introduced in accordance with this chapter.

Article X.X.4.

EHDV seasonally free zone

An EHDV seasonally free zone is a part of an infected country or an *infected zone* for which for part of a year surveillance demonstrates no evidence either of EHDV transmission or of adult *Culicoides*.*

Article 8.X.3.bis**Zone seasonally free from EHD**

A seasonally free zone is a part of an infected country or an infected zone in which for part of a year, surveillance demonstrates no evidence either of EHDV transmission or of adult *Culicoides*.

Annex XIII (contd)

For the application of Articles 8.X.5.bis, 8.X.7. and 8.X.9., the seasonally free period is taken to commence the day following the last evidence of EHDV transmission (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides*.

For the application of Articles 8.X.5.bis, 8.X.7. and 8.X.9., the seasonally free period is taken to conclude either:

- 1) at least 28 days before the earliest date that historical data show vector activity may recommence; or
- 2) immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of adult *Culicoides*.

A seasonally free zone in which ongoing *surveillance* has found no evidence that *Culicoides* are present will not lose its free status through the introduction of vaccinated, seropositive or infective animals, or semen, embryos or oocytes from countries or zones infected with EHD.

Article 8.X.54.

EHDV-infected Country or zone infected with EHD

For the purpose of this chapter, an EHDV-infected country or infected zone infected with EHD is a clearly defined area where evidence of EHDV transmission has been reported during the past two years. Such a country or zone may contain an EHDV seasonally free zone, one that does not fulfil the requirements to qualify as either a country or zone free from EHD or a zone seasonally free from EHD.

Article 8.X.65.

Recommendations for importation from EHDV free countries or zones free from EHD

For ~~cattle-bovids~~ and cervids

Where EHDV is of concern, Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the animals showed no clinical sign of EHD on the day of shipment;
- 24) the animals were kept in an EHDV free country or zone free from EHD since birth or for at least 60 days prior to shipment; or
- 32) the animals were kept in an EHDV free country or zone free from EHD for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the EHDV group and remained in the EHDV free country or zone until shipment; or
- 43) the animals were kept in an EHDV free country or zone free from EHD for at least seven¹⁴ days, then were subjected, with negative results, to an agent identification test and remained in the EHDV free country or zone free from EHD until shipment; or
- 5) the animals:
 - a) were kept in a country or zone free from EHD for at least seven days;
 - b) were vaccinated at least 60 days before the introduction into the country or zone free from EHD against all serotypes demonstrated to be present in the source population through a *surveillance* programme as described in Article 8.X12.;
 - c) were identified as having been vaccinated;
 - d) remained in the country or zone free from EHD until shipment;

AND

Annex XIII (contd)

- 64) if the animals were exported from a free zone within an infected country either:
- a) did not transit through an infected zone during transportation to the *place of shipment*, or
 - b) were protected from attacks by *Culicoides* at all times when transiting through an infected zone.

Article X.X.7.

Recommendations for importation from EHDV seasonally free zonesFor cattle and cervids

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

- 1) ~~were kept during the seasonally free period in an EHDV seasonally free zone since birth or for at least 60 days prior to shipment; or~~
- 2) ~~were kept during the EHDV seasonally free period in an EHDV seasonally free zone for at least 28 days prior to shipment, and were subjected during the residence period in the zone to a serological test to detect antibody to the EHDV group with negative results, carried out at least 28 days after the commencement of the residence period; or~~
- 3) ~~were kept during the EHDV seasonally free period in an EHDV seasonally free zone for at least 14 days prior to shipment, and were subjected during the residence period in the zone to an agent identification test with negative results, carried out at least 14 days after the commencement of the residence period;~~

AND

- 4) either:
 - a) did not transit through an *infected zone* during transportation to the *place of shipment*, or
 - b) were protected from attacks by *Culicoides* at all times when transiting through an *infected zone*.

Article 8.X.5.bis**Recommendations for importation from zones seasonally free from EHD**For bovids and cervids

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

- 1) showed no clinical sign of EHD on the day of shipment;
- 2) were kept during the seasonally free period in a zone seasonally free from EHD since birth or for at least 60 days prior to shipment; or
- 3) were kept during the seasonally free period in a zone seasonally free from EHD for at least 28 days prior to shipment, and were subjected during the residence period in the zone to a serological test to detect antibodies to the EHDV group with negative results, carried out at least 28 days after the commencement of the residence period; or

Annex XIII (contd)

- 4) were kept during the seasonally free period in a zone seasonally free from EHD for at least 14 days prior to shipment, and were subjected during the residence period in the zone to an agent identification test with negative results, carried out at least 14 days after the commencement of the residence period; or
- 5) were kept during the seasonally free period in a zone seasonally free from EHD and were vaccinated, at least 60 days before the introduction into the free country or zone, against all serotypes the presence of which in the source population has been demonstrated through a surveillance programme in accordance with Article 8.X.12, and were identified as having been vaccinated and remained in the country or zone free from EHD until shipment;

AND

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

Article 8.X.86.

Recommendations for importation from EHDV-infected countries or zones infected with EHD

For cattle bovids and cervids

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

- 1) showed no clinical sign of EHD on the day of shipment;
- 24) were protected from attacks by *Culicoides* in a vector-protected establishment for at least 60 days prior to shipment and during transportation to the place of shipment; or
- 32) were protected from attacks by *Culicoides* in a vector-protected establishment for at least 28 days prior to shipment and during transportation to the place of shipment, and were subjected during that period to a serological test to detect antibodies to the EHDV group, with negative results, carried out at least 28 days after introduction into the vector-protected establishment; or
- 43) were protected from attacks by *Culicoides* in a vector-protected establishment for at least 14 days prior to shipment and during transportation to the place of shipment, and were subjected during that period to an agent identification test with negative results, carried out at least 14 days after introduction into the vector-protected establishment; or
- 54) were demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes whose presence has been demonstrated in the source population through a surveillance programme in accordance with Article 8.x.4612.

Article 8.X.97.

Recommendations for importation from EHDV-free countries or zones free or seasonally free from EHD

For semen of cattle bovids and cervids

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

Annex XIII (contd)

- 1) the donor **animals males**:
 - a) **showed no clinical sign of EHD on the day of collection;**
 - ba) were kept in an ~~EHDV free~~ country or zone **free from EHD or in a seasonally free zone during the seasonally free period** for at least 60 days before commencement of, and during, collection of the semen; or
 - cb) were subjected to a serological test to detect antibody **ies** to the EHDV group, between **21-28** and 60 days after the last collection for this consignment, with negative results; or
 - de) were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
- 2) the semen was collected, processed and stored in **conformity accordance** with ~~the provisions of~~ Chapters 4.5. and 4.6.

Article X.X.10.

Recommendations for importation from ~~EHDV seasonally free zones~~For semen of cattle and cervids

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

- 1) ~~the donor animals:~~
 - a) ~~were kept during the EHDV seasonally free period in a seasonally free zone for at least 60 days before commencement of, and during, collection of the semen; or~~
 - b) ~~were subjected to a serological test to detect antibody to the EHDV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or~~
 - c) ~~were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;~~
- 2) ~~the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.~~

Article 8.X.11g.

Recommendations for importation from **EHDV infected countries or zones **infected with EHD****For semen of **cattle bovids** and cervids

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

- 1) the donor **animals males**:
 - a) **showed no clinical sign of EHD on the day of collection;**
 - ba) were kept in a *vector-protected establishment* for at least 60 days before commencement of, and during, collection of the semen; or

Annex XIII (contd)

- cb)** were subjected to a serological test to detect antibody~~ies~~ to the EHDV group, with negative results, at least every 60 days throughout the collection period and between ~~24 28~~ and 60 days after the final collection for this consignment; or
 - de)** were subjected to an agent identification test on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
- 2) the semen was collected, processed and stored in ~~conformity~~ ~~accordance~~ with ~~the provisions of~~ Chapters 4.5. and 4.6.

Article 8.X.129.

Recommendations for importation from ~~EHDV free~~ countries or zones ~~free or seasonally free from EHD~~

For embryos or oocytes of ~~cattle~~ ~~bovids~~ and cervids

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

- 1) the donor females:
 - a)** ~~showed no clinical sign of EHD on the day of collection;~~
 - ba)** were kept in an ~~EHDV free~~ country or zone ~~free from EHD~~ ~~or in a seasonally free zone during the~~ ~~seasonally free period~~ for at least the 60 days prior to, and at the time of, collection of the embryos or oocytes; or
 - cb)** were subjected to a serological test to detect antibody~~ies~~ to the EHDV group, between ~~24 28~~ and 60 days after collection, with negative results; or
 - de)** were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;
- 2) the embryos or oocytes were collected, processed and stored in ~~conformity~~ ~~accordance~~ with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article X.X.13.

Recommendations for importation from ~~EHDV seasonally free zones~~

For embryos or oocytes of ~~cattle~~ and ~~cervids~~

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

- 4) ~~the donor females:~~
 - ~~a)~~ ~~were kept during the seasonally free period in a seasonally free zone for at least 60 days before commencement of, and during, collection of the embryos or oocytes; or~~
 - ~~b)~~ ~~were subjected to a serological test to detect antibody to the EHDV group, between 21 and 60 days after collection, with negative results; or~~
 - ~~e)~~ ~~were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;~~

Annex XIII (contd)

- 2) ~~the embryos or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.~~

Article 8.X.4410.

Recommendations for importation from EHDV-infected countries or zones infected with EHD

For embryos or oocytes of cattle bovids and cervids

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

- 1) the donor females:
 - a) showed no clinical sign of EHD on the day of collection;
 - ba) were kept in a *vector-protected establishment* for at least 60 days before commencement of, and during, collection of the embryos or oocytes; or
 - cb) were subjected to a serological test to detect antibodyies to the EHDV group, between 24 28 and 60 days after collection, with negative results; or
 - de) were subjected to an agent identification test on a blood sample taken on the day of collection, with negative results;
- 2) the embryos or oocytes were collected, processed and stored in conformity accordance with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.X.4511.

Protecting animals from Culicoides attacks

1. Vector-protected establishment or facility

~~Where movement of animals or collection of genetic material requires a vector-protected facility, the establishment or facility should be approved by the Veterinary Authority and the means of protection should at least comprise the following criteria apply:~~

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

2. During transportation

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

- a) Transport by road

Risk management strategies may include:

- i) treating animals with insect repellents prior to and during transportation;
- aii) *loading*, transporting and *unloading* animals at times of low *vector* activity (i.e. bright sunshine, low temperature);

Annex XIII (contd)

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

b) Transport by air

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

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

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

Article 8.X.4612.

Surveillance

This article is complementary to Chapters 1.4. and for vectors, complementary to Chapter 1.5. and outlines the principles for surveillance for EHDV applicable to Member Countries seeking to determine the EHDV status of a country or a zone.

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

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

The purpose of surveillance is the detection of transmission of EHDV in a country or zone and not determination of the status of an individual animal or herd.

The impact and epidemiology of EHD differ widely in different regions of the world and therefore it is impossible not appropriate to provide specific recommendations for all situations. It is incumbent upon Member Countries should to provide scientific data that explain the epidemiology of EHD infection in the region country or zone concerned and adapt the surveillance strategies for defining their infection status (free, seasonally free or infected country or zone) to the local conditions. There is considerable latitude available to Member Countries to justify their infection status at an acceptable level of confidence.

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

General provisions on surveillance for arthropod vectors are in Chapter 1.5.

Annex XIII (contd)

More specific approaches to *surveillance* for *Culicoides*-transmitted *Orbivirus infections* are described in Chapters 8.3. and 12.1. Passive *surveillance* for clinical cases of EHD in susceptible wild ruminants cervids can be a useful tool for detecting disease, based on lesions of haemorrhagic disease combined with appropriate diagnostic tests detection techniques.

— Text deleted.

NOTE:

The Code Commission encourages Member Countries to review all relevant reports when reviewing this document including the following:

- September 2014 report of the Scientific Commission for the rationale on the proposed amendments (http://www.oie.int/fileadmin/Home/eng/International_Standard_Setting/docs/pdf/SCAD/A_SCAD_Sept2014.pdf)
- August 2013 report of the *ad hoc* Group on Harmonization of Vector-Borne Diseases attached to the Scientific Commission report (http://www.oie.int/fileadmin/Home/eng/International_Standard_Setting/docs/pdf/SCAD/A_SCAD_Sept2013.pdf)

CHAPTER 8.3.

INFECTION WITH BLUETONGUE VIRUSES

Article 8.3.1.

General provisions

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

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

- 1) BTV, including naturally transmitted vaccine strains, has been isolated and identified as such from an *animal ruminant or camelid* or a product derived from that *animal ruminant or camelid*, or
- 2) viral antigen or viral ribonucleic acid (RNA) specific to *one or more of the serotypes of BTV* has been identified in samples from *one or more animals a ruminant or camelid* showing clinical signs consistent with bluetongue BT, or epidemiologically linked to a *confirmed/suspected or suspected confirmed case, or giving cause for suspicion of previous association or contact with BTV*, or
- 3) *antibodies to structural or nonstructural proteins of BTV that are not a consequence of vaccination* have been identified in *one or more animals a ruminant or camelid* that either shows clinical signs consistent with BT-bluetongue, or is epidemiologically linked to a *suspected confirmed or suspected confirmed case, or give cause for suspicion of previous association or contact with BTV*.

For the purposes of *international trade*, a distinction should be made between a case as defined above and an *animal that is potentially infectious to vectors*.

For the purposes of the *Terrestrial Code*, the *infective period* for *bluetongue viruses (BTV)* shall be 60 days. Historically, the global BTV distribution has been confined between the latitudes of approximately 53°N and north of 34°S with a recent extension in Northern Europe.

In the absence of clinical *disease* in a country or *zone*, its BTV status should be determined by an ongoing *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.). The programme may need to be adapted to target parts of the country or *zone* at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology, or proximity to enzootic or incursional zones as described in Articles 8.3.16. to 8.3.21.

All countries or *zones* adjacent to a country or *zone* not having free status should be subjected to similar *surveillance*. The *surveillance* should be carried out over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of BTV or a bluetongue *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.) in the country or *zone* not having free status supports a lesser distance.

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

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

Article 8.3.2.

Safe commodities

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

Annex XIV (contd)

- 1) *milk* and *milk products*;
- 2) *meat* and *meat products*;
- 3) hides and skins;
- 4) wool and fibre;
- 5) *in vivo* derived bovine embryos and oocytes collected, processed and stored in conformity accordance with the provisions of Chapter 4.7. except for BTV8 (under study).

Article 8.3.3.

BTV free country or zone

- 1) Historical freedom as described in Chapter 1.4. does not apply to infection with BTV.
- 24) A country or a zone may be considered free from BTV when bluetongue infection with BTV is notifiable in the whole country and either:
 - a) a surveillance programme in accordance with Articles 8.3.1614. to 8.3.2117. has demonstrated no evidence of BTV infection in the country or zone during the past two years; or
 - b) an ongoing surveillance programme has demonstrated found no evidence of *Culicoides* for at least two years in the country or zone.
- 32) A BTV free country or zone in which ongoing vector surveillance, performed according to point 5 of Article 8.3.1916., has found no evidence of *Culicoides* will not lose its free status through the importation introduction of vaccinated, seropositive or infective animals ruminants or camelids, or their semen, or embryos, or oocytes from infected countries or infected zones.
- 43) A BTV free country or zone in which surveillance has found evidence that *Culicoides* are present will not lose its free status through the importation introduction of vaccinated or seropositive or vaccinated animals ruminants or camelids, or semen, embryos, or oocytes from infected countries or infected zones, provided:
 - a) an ongoing surveillance programme focused on BTV transmission and a consideration of the epidemiology of BTV infection, in accordance with Articles 8.3.14. to 8.3.17. and Chapter 4.3., has demonstrated no evidence of BTV transmission in the country or zone; or
 - b) the ruminants or camelids, their semen, embryos and oocytes were introduced in accordance with this chapter.
 - a) the animals have been vaccinated, at least 60 days prior to dispatch, in accordance with the *Terrestrial Manual* with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a surveillance programme in accordance with Articles 8.3.16. to 8.3.21., and the animals are identified in the accompanying certification as having been vaccinated; or
 - b) the animals are not vaccinated and, at least 60 days prior to dispatch, are demonstrated to have specific antibodies against the bluetongue virus serotypes whose presence has been demonstrated in the exporting country or zone.
- 54) A BTV free country or zone adjacent to an infected country or infected zone should include a zone as described in Article 8.3.1. in which surveillance is conducted in accordance with Articles 8.3.1614. to 8.3.2117. Animals within this zone should be subjected to continuing surveillance. The boundaries of this zone should be clearly defined, and should take account of geographical and epidemiological factors that are relevant to BTV transmission.

Article 8.3.4.

BTV seasonally free zone

A BTV seasonally free zone is a part of an infected country or an infected zone for which ~~for part of a year,~~ surveillance demonstrates no evidence either of BTV transmission or of adult *Culicoides* ~~for part of a year.~~

For the application of Articles 8.3.7., 8.3.409. and 8.3.431., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the surveillance programme), and of the cessation of activity of adult *Culicoides*.

For the application of Articles 8.3.7., 8.3.409. and 8.3.431., the seasonally free period is taken to conclude either:

- 1) at least 28 days before the earliest date that historical data show ~~bluetongue virus~~ BTV activity ~~transmission~~ ~~has~~ ~~may~~ recommenced; or
- 2) immediately if current climatic data or data from a surveillance programme indicate an earlier resurgence of activity of adult *Culicoides*.

A BTV seasonally free zone in which ongoing surveillance has found no evidence that *Culicoides* are present will not lose its free status through the ~~importation~~ ~~introduction~~ of vaccinated, seropositive or infective ~~animals ruminants or camelids~~, or semen, ~~or~~ embryos ~~or~~ ovaocytes from infected countries or infected zones.

Article 8.3.5.

BTV infected country or zone

For the purposes of this chapter, a BTV infected country or infected zone is ~~a clearly defined area where evidence of BTV has been reported during the past two years. one that does not fulfil the requirements to qualify as either BTV free country or zone or BTV seasonally free zone. Such a country or zone may contain a BTV seasonally free zone.~~

Article 8.3.6.

Recommendations for importation from BTV free countries or zones

For ruminants and ~~camelids~~ ~~other BTV susceptible herbivores~~

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

- 1) ~~the animals showed no clinical sign of BT on the day of shipment;~~
- 2) the animals were kept in a BTV free country or zone since birth or for at least 60 days prior to shipment; or
- 3) the animals were kept in a BTV free country or zone for at least 28 days, then were subjected, with negative results, to a serological test to detect antibodies to the BTV group ~~according to the Terrestrial Manual~~ and remained in the BTV free country or zone until shipment; or
- 4) the animals were kept in a BTV free country or zone for at least ~~seven~~ 14 days, then were subjected, with negative results, to an agent identification test ~~according to the Terrestrial Manual~~, and remained in the BTV free country or zone until shipment; or
- 5) the animals:
 - a) were kept in a BTV free country or zone for at least seven days;
 - b) were vaccinated, at least 60 days before the introduction into the free country or zone, ~~in accordance with the Terrestrial Manual~~ against all serotypes ~~whose presence demonstrated to be present~~ in the source population ~~has been demonstrated~~ through a surveillance programme as described in Articles 8.3.4614. to 8.3.2417.;
 - c) were identified as having been vaccinated; ~~and~~
 - d) remained in the BTV free country or zone until shipment;

Annex XIV (contd)

AND

- 65)** if the animals were exported from a free *zone* within an infected country, either:
- a) did not transit through an infected *zone* during transportation to the *place of shipment*; or
 - b) were protected from attack from *Culicoides* at all times when transiting through an infected *zone*; or
 - c) had been vaccinated in accordance with point **54** above.

Article 8.3.7.

Recommendations for importation from BTV seasonally free zonesFor ruminants and other BTV susceptible herbivores/camelids

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

- 1)** showed no clinical sign of BT on the day of shipment;
- 24)** were kept during the seasonally free period in a BTV seasonally free *zone* since birth or for at least 60 days prior to shipment; or
- 32)** were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibodies to the BTV group ~~according to the *Terrestrial Manual*~~, with negative results, carried out at least 28 days after the commencement of the residence period; or
- 43)** were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test ~~according to the *Terrestrial Manual*~~, with negative results, carried out at least 14 days after the commencement of the residence period; or
- 54)** were kept during the seasonally free period in a BTV seasonally free *zone* and were vaccinated, at least 60 days before the introduction into the free country or *zone*, in accordance with the *Terrestrial Manual* against all serotypes whose presence demonstrated to be present in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.1614. to 8.3.2417. and were identified as having been vaccinated and remained in the BTV seasonally free country or *zone* until shipment;

AND

- 65)** either:
- a) did not transit through an infected *zone* during transportation to the *place of shipment*; or
 - b) were protected from attack from *Culicoides* at all times when transiting through an infected *zone*; or
 - c) were vaccinated in accordance with point **54** above.

Article 8.3.8.

Recommendations for importation from BTV infected countries or zonesFor ruminants and other BTV susceptible herbivores/camelids

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

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

Annex XIV (contd)

- 24) were protected from attack from *Culicoides* in a vector-protected establishment for at least 60 days prior to shipment and during transportation to the place of shipment; or
- 32) were protected from attack from *Culicoides* in a vector-protected establishment for at least 28 days prior to shipment and during transportation to the place of shipment, and were subjected during that period to a serological test according to the Terrestrial Manual to detect antibodies to the BTV group, with negative results, carried out at least 28 days after introduction into the vector-protected establishment; or
- 43) were protected from attack from *Culicoides* in a vector-protected establishment for at least 14 days prior to shipment and during transportation to the place of shipment, and were subjected during that period to an agent identification test according to the Terrestrial Manual, with negative results, carried out at least 14 days after introduction into the vector-protected establishment; or
- 54) were vaccinated, at least 60 days before shipment, according to the Terrestrial Manual against all serotypes whose presence demonstrated to be present in the source population has been demonstrated through a surveillance programme in accordance with Articles 8.3.1614. to 8.3.2417.7, and were identified in the accompanying certification as having been vaccinated or, if demonstrated to have antibodies, have been protected from vectors for at least 60 days prior to shipment; or
- 65) were demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes whose presence has been demonstrated to be present in the source population through a surveillance programme in accordance with Articles 8.3.1614. to 8.3.2417.

Article 8.3.9.

Recommendations for importation from BTV free countries or zones or from BTV seasonally free zones

For semen of ruminants and camelids/other BTV susceptible herbivores

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

- 1) the donor animals/males:
 - a) showed no clinical sign of bluetongue on the day of collection;
 - ba) were kept in a BTV free country or zone or during the BTV seasonally free period in a BTV seasonally free zone for at least 60 days before commencement of, and during, collection of the semen; or
 - cb) were subjected to a serological test according to the Terrestrial Manual to detect antibodies to the BTV group, with negative results, between 2428 and 60 days after the last collection for this consignment with negative results, and, in case of a BTV seasonally free zone, at least every 60 days throughout the collection period; or
 - de) were subjected to an agent identification test according to the Terrestrial Manual on blood samples collected at commencement and conclusion of, and at least every 7 seven days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
- 2) the semen was collected, processed and stored in conformity accordance with the provisions of Chapters 4.5. and 4.6.

Article 8.3.10.

Recommendations for importation from BTV seasonally free zones

For semen of ruminants and other BTV susceptible herbivores

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

- 1) the donor animals:

Annex XIV (contd)

- a) were kept during the BTV seasonally free period in a seasonally free zone for at least 60 days before commencement of, and during, collection of the semen; or
 - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or
 - c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.3.11.10.

Recommendations for importation from BTV infected countries or zones

For semen of ruminants and camelids other BTV susceptible herbivores

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

- 1) the donor animals males:
- a) showed no clinical sign of bluetongue on the day of collection;
 - ba) were kept in a vector-protected establishment for at least 60 days before commencement of, and during, collection of the semen; or
 - cb) were subjected to a serological test according to the *Terrestrial Manual* to detect antibodies to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21-28 and 60 days after the final collection for this consignment; or
 - de) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 seven days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;
- 2) the semen was collected, processed and stored in conformity accordance with the provisions of Chapters 4.5. and 4.6.

Article 8.3.12.11.

Recommendations for importation from BTV free countries or zones or from BTV seasonally free zonesFor *in vivo* derived embryos of ruminants (other than bovine embryos) and other BTV susceptible herbivores and for *in vitro* produced bovine embryosVeterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females:
- a) showed no clinical sign of bluetongue on the day of collection;
 - ba) were kept in a BTV free country or zone or during the seasonally free period in a seasonally free zone for at least the 60 days prior to, and at the time of, collection of the embryos; or
 - cb) were subjected to a serological test according to the *Terrestrial Manual* to detect antibodies to the BTV group, between 21-28 and 60 days after collection, with negative results; or
 - de) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;
- 2) the embryos were collected, processed and stored in conformity accordance with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.13.

Recommendations for importation from BTV seasonally free zones

For *in vivo* derived embryos/ or oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

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

- 1) the donor females:
 - a) were kept during the seasonally free period in a seasonally free zone for at least 60 days before commencement of, and during, collection of the embryos/ or oocytes; or
 - b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or
 - c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;
- 2) the embryos/ or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.

Article 8.3.14.

Recommendations for importation from BTV infected countries or zones

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

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

- 1) the donor females:
 - a) showed no clinical sign of bluetongue on the day of collection;
 - ba) were kept in a vector-protected establishment for at least 60 days before commencement of, and during, collection of the embryos/ or oocytes; or
 - cb) were subjected to a serological test according to the *Terrestrial Manual* to detect antibodies to the BTV group, between 2428 and 60 days after collection, with negative results; or
 - dc) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;
- 2) the embryos/ or oocytes were collected, processed and stored in conformity accordance with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant;
- 3) semen used to fertilise the oocytes complied with Article 8.3.9.

Annex XIV (contd)Article 8.3. 1513.**Protecting animals from *Culicoides* attack**1. Vector-protected establishment or facility

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

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

2. During transportation

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

a) Transport by road

Potential Risk management strategies may include:

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

b) Transport by air

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

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

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

Article 8.3.16-14.

Introduction to surveillance: introduction

The purpose of surveillance is the detection of virus circulation in a country or zone and not determination of the status of an individual animal or herds. Surveillance deals not only with the occurrence of clinical signs caused by BTV, but also with the evidence of infection with BTV in the absence of clinical signs.

Articles 8.3.16-14. to 8.3.24-17. define the principles and provide a guide guidance on the surveillance for infection with BTV, complementary to Chapter 1.4. and for vectors complementary to Chapter 1.5., applicable to Members seeking to determine their BT status. This may be for the entire country or zone. Guidance for Members seeking free status following an outbreak and for the maintenance of BT status is also provided.

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

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

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

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

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

Article 8.3.17.

Surveillance: case definition

For the purposes of surveillance, a case refers to an animal infected with BT virus (BTV).

For the purposes of international trade, a distinction should be made between a case as defined below and an animal that is potentially infectious to vectors. The conditions for trade are defined in Articles 8.3.1. to 8.3.15. of this chapter.

The purpose of surveillance is the detection of virus circulation in a country or zone and not determination of the status of an individual animal or herds. Surveillance deals not only with the occurrence of clinical signs caused by BTV, but also with the evidence of infection with BTV in the absence of clinical signs.

The following defines the occurrence of BTV infection:

1. BTV 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 BTV has been identified in samples from one or more animals showing clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected case, or giving cause for suspicion of previous association or contact with BTV, or
3. antibodies to structural or nonstructural proteins of BTV that are not a consequence of vaccination have been identified in one or more animals that either show clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected case, or give cause for suspicion of previous association or contact with BTV.

Annex XIV (contd)

Article 8.3.1815.

Surveillance: General conditions and methods for surveillance

- 1) A surveillance system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:
 - a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* should be in place;
 - b) a procedure should be in place for the rapid collection and transport of samples from suspected cases of *infection with* BT~~V~~ to a *laboratory* for ~~BT~~ diagnosis ~~as described in the *Terrestrial Manual*~~;
 - c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.
- 2) The ~~BT~~bluetongue surveillance programme should:
 - a) in a ~~country/ zone~~ free or seasonally free ~~country or zone~~, ~~have include~~ an early warning system ~~which obliges for reporting suspicious cases~~. Farmers and workers, who have regular contact with domestic ruminants, as well as diagnosticians, ~~should to~~ report promptly any suspicion of *infection with* BT~~V~~ 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. An effective surveillance system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that whether the cause of the condition is BT~~V~~. The rate at which such suspicious suspected cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected cases of ~~BT~~ bluetongue should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are be available for those responsible for surveillance;~~

AND

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

~~Generally, the conditions to prevent exposure of susceptible animals to BT~~V~~ infected vectors will be difficult to apply. However, under specific situations, in establishments such as artificial insemination centres or quarantine stations exposure to vectors may be preventable. The testing requirements for animals kept in these facilities are described in Articles 8.3.11. and 8.3.14.~~

Article 8.3.1916.

Surveillance strategies

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

~~The strategy employed may be based on surveillance using randomised sampling that would demonstrate the absence of BT~~V~~ infection at an acceptable level of confidence. The frequency of sampling should be dependent on the epidemiological situation. Random surveillance is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results may be followed up with virological methods as appropriate.~~

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 may be used concurrently to define the BTV status of targeted populations.

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

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

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

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

If a Member Country wishes to declare freedom from BTV infection with BTV in a specific zone, the design of the surveillance strategy would need to should be aimed at the population within the zone.

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

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

Irrespective of the testing system employed, surveillance system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to should be an effective procedure for following up positive reactions to ultimately determine with a high level of confidence, whether they are indicative of infection or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in surveillance for disease or infection are technically well defined. The design of surveillance programmes to prove the absence of BTV infection with BTV and circulation transmission needs to should be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

1. Clinical surveillance

Clinical surveillance aims at the detection of to detect clinical signs of BT bluetongue at the flock or herd level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated, particularly during a newly introduced infection. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

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

Annex XIV (contd)2. Serological surveillance

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

~~Surveillance may include serological surveys, for example abattoir surveys, the use of cattle as sentinel animals (which should be individually identifiable), or a combination of methods. Surveillance may also be conducted by sampling and testing of bulk milk using an ELISA, as prescribed in the Terrestrial Manual.~~

~~The objective of serological surveillance is to detect evidence of BTV circulation. Samples should be examined for antibodies against BTV using tests prescribed in the Terrestrial Manual. Positive BTV antibody test results can have four possible causes:~~

- a) natural *infection* with BTV,
- b) *vaccination* against BTV,
- c) maternal antibodies,
- d) ~~positive results due to~~ the lack of specificity of the test.

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

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

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

~~A protection zone within a free country or zone should separate it from a potentially infected country or infected zone. Serological surveillance in a free country or zone should be carried out over an appropriate distance from the border with a potentially infected country or infected zone, based upon geography, climate, history of infection and other relevant factors.~~

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

3. Virological surveillance

Isolation and genetic analysis of BTV from a proportion of infected animals ~~is beneficial in terms of providing~~ provides information on serotype and genetic characteristics of the viruses concerned.

Virological surveillance using tests described in the *Terrestrial Manual* can be conducted:

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

4. Sentinel animals

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

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

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

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

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

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

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

5. Vector surveillance

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

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

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

Annex XIV (contd)

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local *vector* species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to domestic ruminants, or the use of drop traps over ruminants animals.

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

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

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

Other surveillance strategies (e.g. the use of sentinel animals of domestic ruminants) are preferred to detect virus circulation.

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

Article 8.3.192017.

Documentation of BTV infection free status

1. Additional surveillance requirements for Member Countries declaring freedom from BTV infection with BTV for the country or zone: additional surveillance procedures

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

2. Additional requirements for countries or zones that practise vaccination

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

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

Article 8.3.2021.

The use and interpretation of serological and virus detection tests

1. Serological testing

Ruminants infected with BTV produce antibodies to structural and non-structural viral proteins, as do animals vaccinated with current modified live virus vaccines. Antibodies to the BTV serogroup antigen are detected with high sensitivity and specificity by competitive ELISA (c-ELISA) and to a lesser extent by AGID as described in the Terrestrial Manual. Positive c-ELISA results can be confirmed by neutralization assay to identify the infecting serotype(s); however, BTV infected ruminants can produce neutralizing antibodies to serotypes of BTV other than those to which they were exposed (false positive results), especially if they have been infected with multiple serotypes.

2- Virus detection

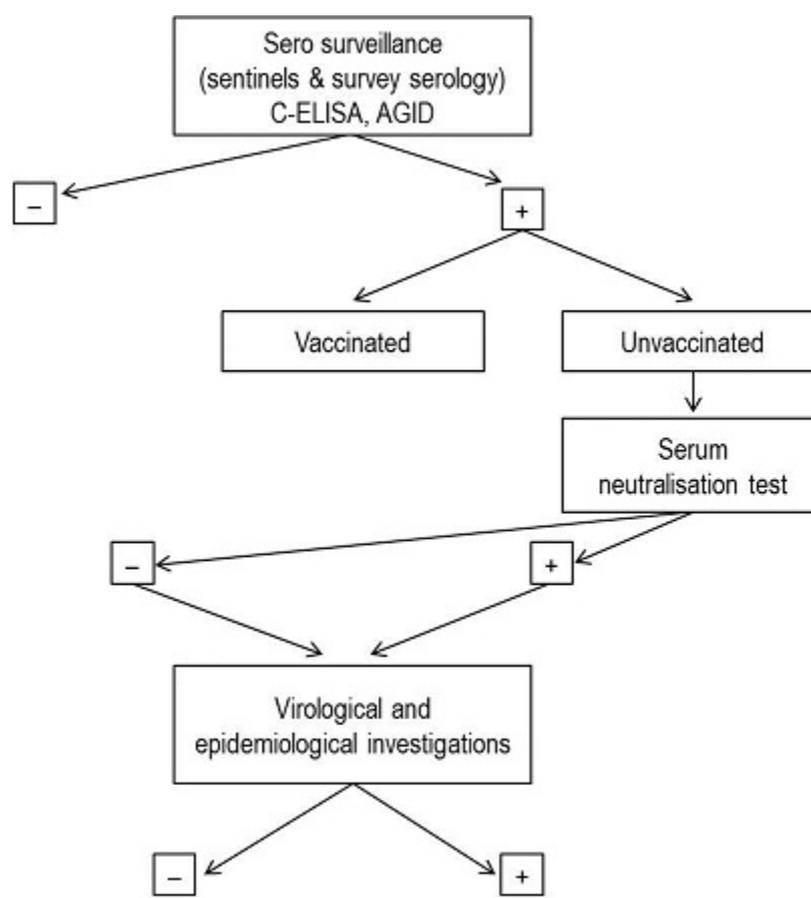
The presence of BTV in ruminant blood and tissues can be detected by virus isolation or polymerase chain reaction (PCR) as described in the *Terrestrial Manual*.

Interpretation of positive and negative results (both true and false) differs markedly between these tests because they detect different aspects of BTV *infection*, specifically (1) infectious BTV (virus isolation) and (2) nucleic acid (PCR). The following are especially relevant to interpretation of PCR assays:

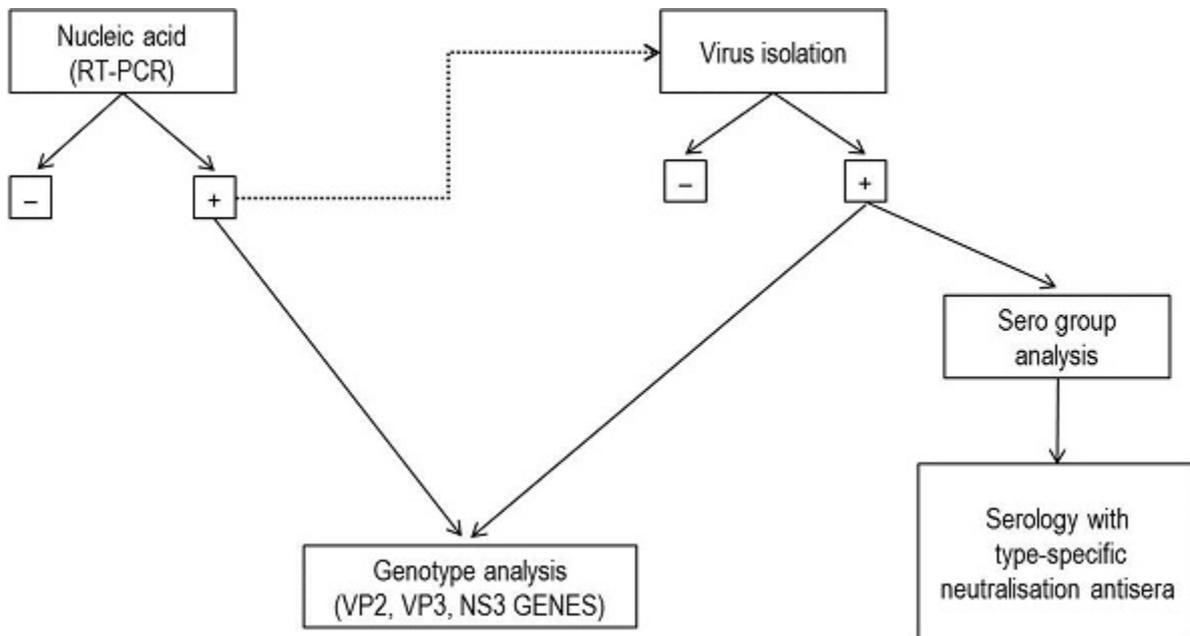
- a) The nested PCR assay detects BTV nucleic acid in ruminants long after the clearance of infectious virus. Thus positive PCR results do not necessarily coincide with active *infection* of ruminants. Furthermore, the nested PCR assay is especially prone to template contamination, thus there is considerable risk of false positive results.
- b) PCR procedures other than real time PCR allow sequence analysis of viral amplicons from ruminant tissues, insect vectors or virus isolates. These sequence data are useful for creating data bases to facilitate important epidemiological studies, including the possible distinction of field and vaccine virus strains of BTV, genotype characterization of field strains of BTV, and potential genetic divergence of BTV relevant to vaccine and diagnostic testing strategies.

It is essential that BTV isolates are sent regularly to the OIE Reference Laboratories for genetic and antigenic characterization.

Fig. 1. Application of laboratory tests in serological surveillance



Annex XIV (contd)

Fig 2. Application of laboratory tests in virological surveillance

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CHAPTER 15.X.

INFECTION WITH *TAENIA SOLIUM*

Article 15.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 become infected with ~~harbour~~ the larval stage when through the ingestion of 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 neurological disorders including seizures (epilepsy) and sometimes death. Cysticercosis, although normally clinically inapparent in pigs, is associated with significant economic losses due to carcass condemnation and decreased value of pigs, and causes a major *disease* burden in humans, ~~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, ~~from~~ or environments contaminated with faeces, ~~from~~ or 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 15.X.2. *Veterinary Authorities* should apply the recommendations in this chapter.

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

Article 15.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 15.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 are detected in a carcass of a pig, 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 are detected in a carcass of a pig, the meat from that carcass and from all pigs from the same establishment of origin should be treated in accordance with Article 15.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-;
 - iv) post-mortem examination of pigs for at slaughter from known infected establishments should be intensified until sufficient evidence has been obtained indicating that the infection has been eliminated from the establishment.

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

Article 15.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 provided that the methods used do not cause injury and avoid unnecessary suffering;
- 3) other diagnostic tests on live pigs.

The data collected should be used for investigations and for the design or amendment of control programmes as described in Article 15.X.3.

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

Article 15.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;
 - 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 15.X.6.

Annex XV (contd)

Article 15.X.6.

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

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

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

— Text deleted.

NOTE:

The Code Commission encourages Member Countries to review all relevant reports when reviewing this document including the following:

- February 2015 report of the Scientific Commission for the rationale on the proposed amendments
- September–October 2014, November 2014 and January 2015 reports of the OIE *ad hoc* Group on the Evaluation of Foot and Mouth Disease Status of Member Countries attached to the February 2015 report of the Scientific Commission

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. Dromedaries (*Camelus dromedarius*) are not susceptible to FMDV *infection* while South American camelids are not considered to be of epidemiological significance.
- 2) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the suborder *ruminantia* and of the family *suidae* of the order *Artiodactyla*, and *Camelus bactrianus* with FMDV.
- 3) The following defines the occurrence of 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 specific to FMDV has been identified in a sample from an animal listed in point 2), showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or
 - c) antibodies to structural or nonstructural proteins of FMDV, that are not a consequence of *vaccination*, have been identified in a sample from an animal listed in point 2), showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.
- 4) Transmission of FMDV in a vaccinated population is demonstrated by change in virological or serological evidence indicative of recent *infection*, even in the absence of clinical signs.
- 5) For the purposes of the *Terrestrial Code*, the *incubation period* of FMD shall be 14 days.
- 6) *Infection* with FMDV can give rise to *disease* of variable severity and to FMDV transmission. FMDV may persist in the pharynx and associated lymph nodes of ruminants for a variable but limited period of time beyond 28 days. Such animals have been termed carriers. However, the only persistently infected species from which transmission of FMDV has been proven is the African buffalo (*Syncerus caffer*).
- 7) This chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of 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.

Annex XVI (A) (contd)

Susceptible animals in the FMD free country or *zone* where *vaccination* is not practised should be protected by the application of biosecurity measures that prevent the entry of FMDV into the free country or *zone*. Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*.

To qualify for inclusion in the 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 *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 demonstrate no evidence of:
 - i) FMDV *infection* in unvaccinated animals;
 - ii) FMDV transmission in previously vaccinated animals when the FMD free country or *zone* where *vaccination* is practised is seeking to become one where *vaccination* is not practised;
 - b) regulatory measures for the prevention and early detection of FMD have been implemented;
- 4) describe in detail and 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* to FMD susceptible animals in zoological collections in the face of a FMD threat identified by the *Veterinary Authorities*, provided that the following conditions are met:

Annex XVI (A) (contd)

- the zoological collection has the primary purpose of exhibiting *animals* or preserving rare species, has been identified, including the boundaries of the facility, and is included in the country's contingency plan for FMD;
- appropriate biosecurity measures are in place, including effective separation from other susceptible domestic populations or *wildlife*;
- the animals are identified as belonging to the collection and any movements can be traced;
- the vaccine used complies with the standards described in the *Terrestrial Manual*;
- *vaccination* is conducted under the supervision of the *Veterinary Authority*;
- the zoological collection is placed under *surveillance* for at least 12 months after *vaccination*.

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

Article 8.7.3.

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 by the application of biosecurity measures that prevent the entry of FMDV into the free country or *zone*. Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*.

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

To qualify for inclusion in the list of FMD free countries or *zones* 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 demonstrate no evidence of:
 - i) FMDV *infection* in unvaccinated animals;
 - ii) FMDV transmission in vaccinated animals;

Annex XVI (A) (contd)

- b) regulatory measures for the prevention and early detection of FMD have been implemented;
 - c) compulsory systematic *vaccination* in the target population has been carried out to achieve adequate *vaccination* coverage and population immunity;
 - d) *vaccination* has been carried out following appropriate vaccine strain selection;
- 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 of the cessation. 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 stated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of animals between the *zones* of the same status in accordance with Chapter 4.3.

Article 8.7.4.

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*;

Annex XVI (A) (contd)

- 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 may 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).

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, a strict standstill has been imposed on the suspected *establishments* and in the country or *zone* animal movement control has been imposed and effective controls on the movement of other *commodities* mentioned in this chapter are in place;
- 2) on confirmation, an additional standstill of susceptible animals has been imposed in the entire *containment zone* and the movement controls described in point 1) have been reinforced;

Annex XVI (A) (contd)

- 3) the definitive boundaries of the *containment zone* have been established after an epidemiological investigation (trace-back, trace-forward) has demonstrated that the *outbreaks* are epidemiologically related and limited in number and geographic distribution;
- 4) investigations into the likely source of the *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 identified 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) 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 the OIE as complying with points 1) to 9) above. *Commodities* from susceptible animals for *international trade* should be identified as to their origin, either from inside or outside the *containment zone*.

In the event of recurrence of FMDV *infection* in unvaccinated animals or FMDV transmission in vaccinated animals in the *containment zone*, the approval of the *containment zone* is withdrawn and the FMD status of the whole country or *zone* is suspended until the relevant requirements of Article 8.7.7. are fulfilled.

The recovery of the FMD free status of the *containment zone* should be achieved within 12 months of its approval and follow the provisions of Article 8.7.7.

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 animal killed 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 animal killed or the *slaughter* of all vaccinated animals, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* and *surveillance* in accordance with Articles 8.7. 40. to 8.7.42. are applied; or
 - c) six months after the disposal of the last animal killed or the last *vaccination* whichever occurred last, where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated animals, and *surveillance* in accordance with Articles 8.7.40. to 8.7.42. are applied. However, this requires a serological survey based on the detection of antibodies to nonstructural proteins of FMDV to demonstrate no evidence of *infection* in the remaining vaccinated population.

The country or *zone* will regain the 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.

Annex XVI (A) (contd)

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: six months after the disposal of the last animal killed where a *stamping-out policy* has been applied and a continued *vaccination* policy has been adopted, provided that *surveillance* is applied in accordance with Articles 8.7.40. to 8.7.42., and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates no evidence of FMDV transmission.

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.

- 3) When a case of FMD 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 animal killed 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 no evidence 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 no evidence of virus transmission.

Where 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*.

For Member Countries not applying for recovery within 24 months after suspension, the provisions of Article 8.7.2., Article 8.7.3. or Article 8.7.4. apply.

Article 8.7.8.

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

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

Annex XVI (A) (contd)

- 1) no FMD susceptible animal has been introduced into the *establishment* of origin and no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;
- 2) the animals were kept in the *establishment* of origin for at least three months prior to movement;
- 3) FMD has not occurred within a 10 kilometre radius of the *establishment* of origin for at least four weeks prior to movement;
- 4) the animals should be 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 within 24 hours before and after *slaughter* with no evidence of FMD, 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 accordance with Articles 8.7.31. to 8.7.38 in order to destroy any FMDV potentially present.

Article 8.7.9.

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

In order not to jeopardise the status of a free zone, FMD susceptible animals should only leave the *containment zone* if transported directly to *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 *slaughterhouse/abattoir* without coming into contact with other susceptible animals;
- 3) such an *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the *containment zone*;
- 4) *vehicles* and the *slaughterhouse/abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The animals should have been subjected to ante- and post-mortem inspection within 24 hours before and after *slaughter* with no evidence of FMD and the *meat* derived from them treated 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 accordance with Articles 8.7.31. to 8.7.38. in order to destroy any FMDV potentially present.

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

Annex XVI (A) (contd)

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 practised

For domestic ruminants and pigs

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

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

Article 8.7.12.

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

For domestic ruminants and pigs

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

- 1) the animals showed no clinical sign of FMD on the day of shipment;
- 2) prior to isolation, the animals were kept in the *establishment* of origin:
 - a) for 30 days, or since birth if younger than 30 days, if a *stamping-out policy* is applied to control FMD in the *exporting country* or *zone*, or
 - b) for three months, or since birth if younger than three months if a *stamping-out policy* is not applied to control FMD in the *exporting country* or *zone*;
- 3) FMD has not occurred within the *establishment* of origin for the relevant period as defined in points 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 10 kilometre radius of the *establishment* during that period, or the *establishment* is a *quarantine station*;
- 5) the animals were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

Annex XVI (A) (contd)

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 males:
 - a) showed no clinical sign of FMD on the day of collection of the semen;
 - b) were kept for at least three months prior to collection in a FMD free country or zone 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* with FMDV ;
- 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:

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least three months prior to collection in a FMD free country or zone 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 practisedFor frozen semen of domestic ruminants and pigs

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

- 1) the donor males:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least three months prior to collection in a FMD free country or zone 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 demonstrated 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;

Annex XVI (A) (contd)

- 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 males:
- a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept in an *artificial insemination centre* where no animal had been added in the 30 days before collection, and that FMD has not occurred within a 10 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 demonstrated 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 male has been vaccinated within the 12 months prior to collection;
 - c) was stored in the country of origin for a period of at least one month following collection, and that during this period no animal on the *establishment* where the donor males were kept showed any sign of FMD.

Article 8.7.17.

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 compartments

For *in vitro* produced embryos of cattle

Annex XVI (A) (contd)

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

- 1) the donor females:
 - a) showed no clinical sign of FMD at the time of collection of the oocytes;
 - b) were kept for at least three months prior to collection in a FMD free country or *zone* 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 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 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 demonstrated 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 *zone* where *vaccination* is not practised or FMD free *compartment*, 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 practisedFor fresh meat and meat products of ruminants and pigs

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

- 1) have been kept in the FMD free country or *zone* 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.

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 demonstrated 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 10 kilometre radius of the *establishment* during that period, or the *establishment* is a *quarantine station*;
 - d) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle and water buffaloes were loaded, directly from the *establishment* of origin or *quarantine station* to the approved *slaughterhouse/abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;
 - e) have been slaughtered in an approved *slaughterhouse/abattoir*.
 - i) which is officially designated for export;
 - ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;
 - f) have been subjected to ante- and post-mortem inspections within 24 hours before and after *slaughter* with no evidence of FMD;

Annex XVI (A) (contd)

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

Article 8.7.23.

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;
- 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 compartmentsFor 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 existsFor 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 countriesFor 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 countriesFor 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.

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 identified contamination with material of animal origin;
- 2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:
 - a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ten 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 zones

Annex XVI (A) (contd)For skins and trophies derived from FMD susceptible wildlife

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of FMDV in accordance with the procedures in Article 8.7.37.

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:

1. Canning

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

2. Thorough cooking

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

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

3. Drying after salting

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

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

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:

Annex XVI (A) (contd)

- 1) boiling for at least one hour; or
- 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).

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

Article 8.7.37

Procedures for the inactivation of FMDV in skins and trophies from wildlife 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; or
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher); or
- 3) soaking, with agitation, in a 4 % (weight/volume) solution of sodium carbonate (Na₂CO₃) maintained at pH 11.5 or greater for at least 48 hours; or
- 4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at pH less than 3.0 for at least 48 hours; wetting and dressing agents may be added; or

Annex XVI (A) (contd)

- 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 towards defined *subpopulations* only.

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.

For a Member Country's *official control programme* for FMD to be endorsed by the OIE, the Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting 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;
 - b) detailed information on *vaccination* campaigns, in particular on:
 - i) target populations for *vaccination*;
 - ii) monitoring of *vaccination* coverage, including serological monitoring of population immunity;
 - iii) technical specification of the vaccines used, including matching with the circulating FMDV strains, and description of the licensing procedures in place;
 - iv) the proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;
- 7) provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.

The Member Country's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence, based on the provisions of Article 1.6.11., has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE 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 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, where appropriate, *wildlife* species as indicated in point 2) of Article 8.7.1.

1. Early detection

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

Annex XVI (A) (contd)2. Demonstration of freedom

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 demonstrating freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMDV should differ significantly from an approach designed to demonstrate freedom from FMD in a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*.

Surveillance for FMD should be in the form of a continuing programme. Programmes to demonstrate no evidence of 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 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 substantiate FMD freedom where *vaccination* is not practised should demonstrate no evidence of FMDV *infection*.

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

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

3. OIE endorsed official control programme

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

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

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

4. Surveillance strategies

The strategy employed to establish the prevalence of 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.

5. Follow up of suspected cases and interpretation of results

An effective *surveillance* system will identify suspected cases that require immediate follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Samples should be taken and submitted for diagnostic testing, unless the suspected case can be confirmed or ruled out by epidemiological and clinical investigation. Details of the occurrence of suspected cases and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the control measures to which the animals concerned were subjected during the investigation.

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

The *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following-up positives to determine with a high level of confidence, whether or not they are indicative of *infection* or transmission. This should involve supplementary tests and follow-up investigation to collect diagnostic material from the original *epidemiological unit* and *herds* which may be epidemiologically linked to it.

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

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

6. Demonstration of population immunity

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

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

Annex XVI (A) (contd)

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

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

Article 8.7.41.

Methods of surveillance1. Clinical surveillance

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

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

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

2. Virological surveillance

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

Virological *surveillance* aims to:

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

3. Serological surveillance

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

Serological *surveillance* may be used to:

- a) estimate the prevalence or substantiate freedom from FMDV *infection* 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.

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

Positive FMDV antibody test results can have four possible causes:

- 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 results. 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, which may include the results of virological tests and of any further serological tests that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to FMDV transmission. This investigation should document the status for each positive *herd*. Epidemiological investigation should be continued concurrently.

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

Annex XVI (A) (contd)

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.

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

In some circumstances, unvaccinated sentinel animals may also be used. These can be young animals from unvaccinated dams or animals in which maternally conferred immunity has lapsed and preferably of the same species as in the positive sampling units. If other susceptible, unvaccinated animals are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the animals of the *epidemiological unit* under investigation for at least two *incubation periods* and should remain serologically negative if FMDV is not circulating.

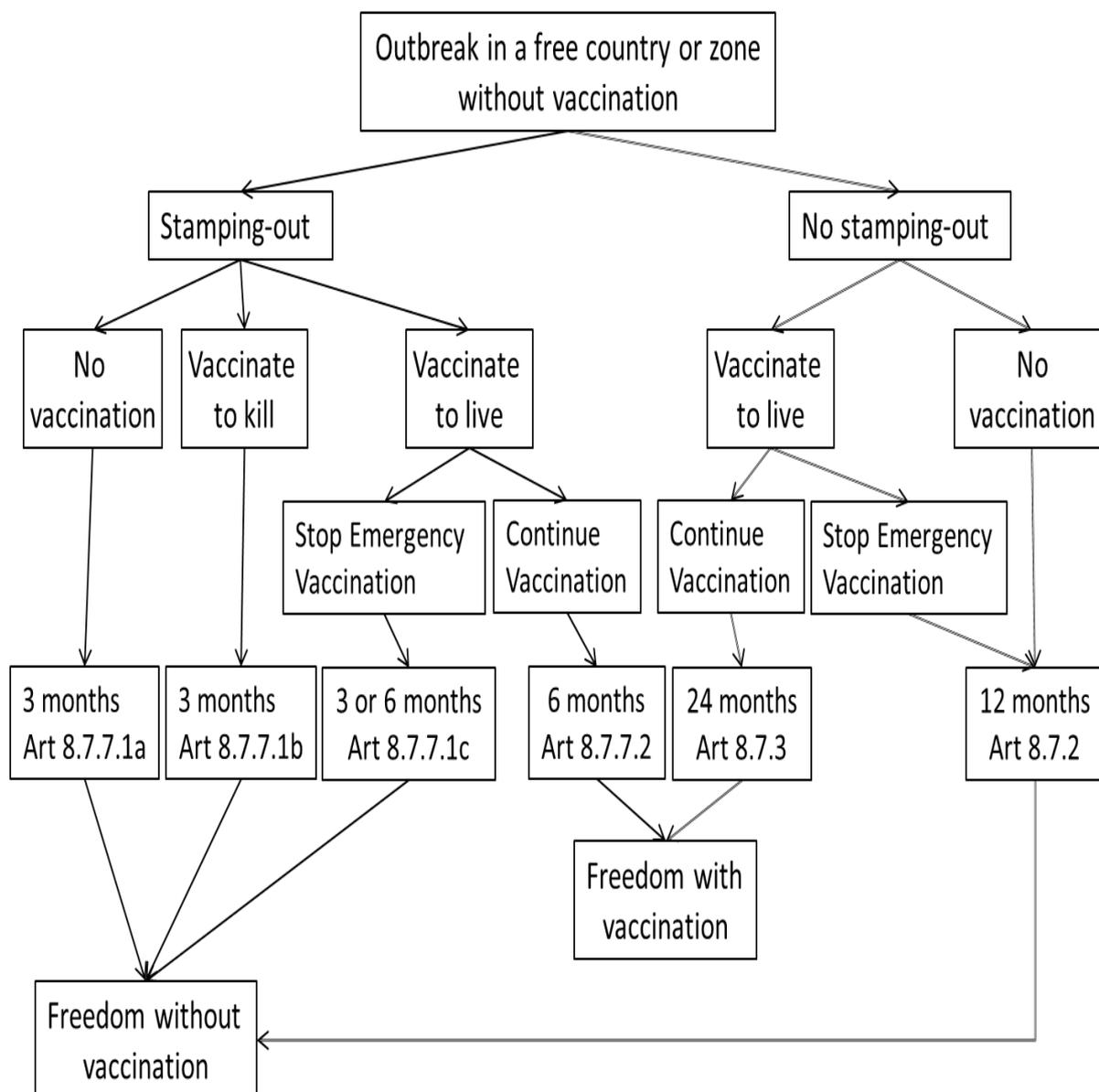
Follow-up of field and laboratory findings:

If transmission is demonstrated, 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 false positive results expected from the specificity of the diagnostic tests used, susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animals should be investigated further.

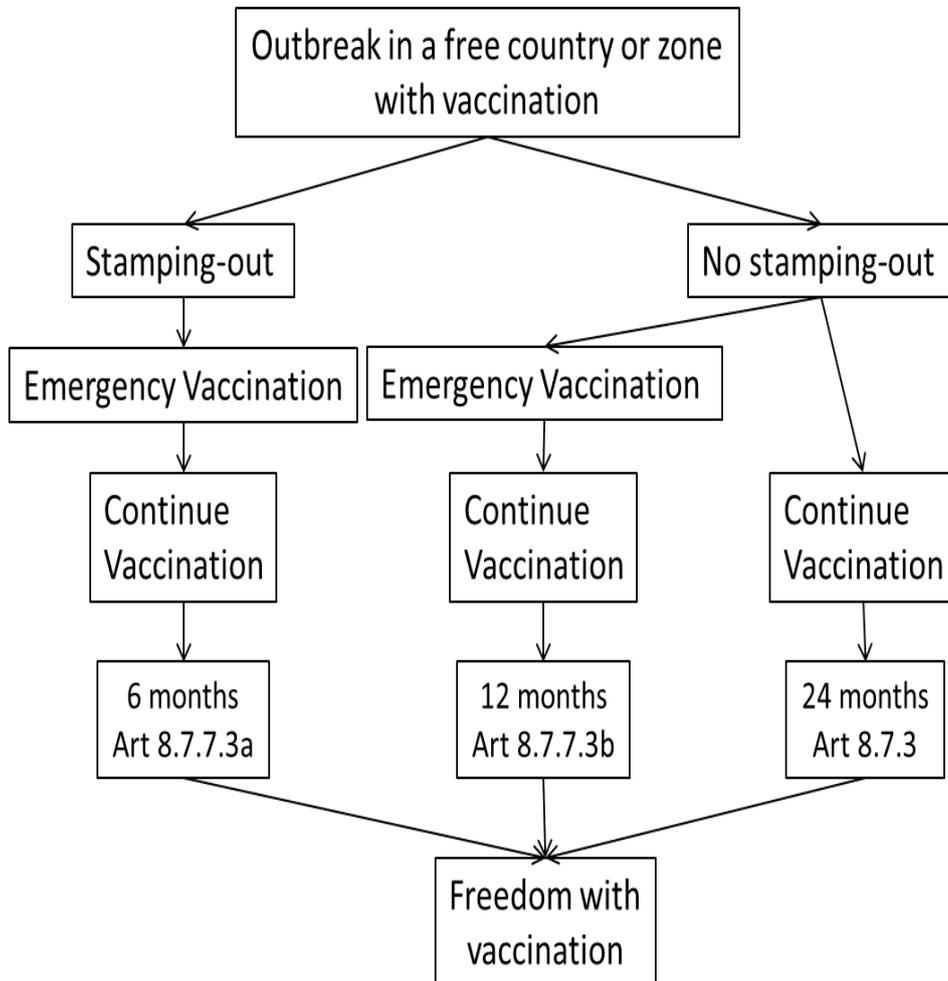
Figure 1. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak in a free country or zone where vaccination is not practised



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.

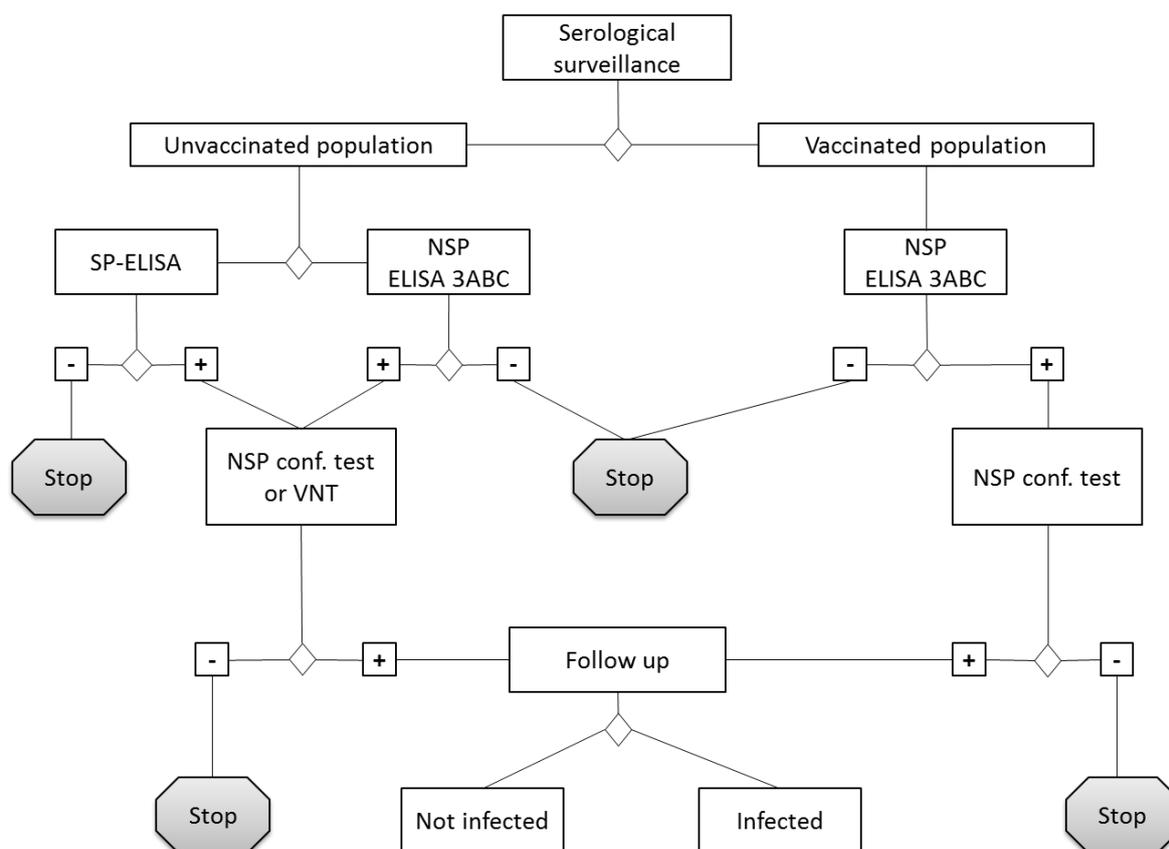
Annex XVI (A) (contd)

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 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° XXVI (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.

Annex XVI (A) (contd)

[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

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*. Was FMD vaccine ever used? If so, when was the last *vaccination* carried out? When was *vaccination* formally prohibited? What species were vaccinated? What was the fate of these animals?

In addition, if *vaccination* was conducted during the past two years, provide a description and justification of the *vaccination* strategy, including the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the *vaccination* of animals was certified or reported and the records maintained. Also provide evidence that the vaccine used complies with Chapter 2.1.5. 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 the country? Provide evidence on the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe the action taken when an illegal movement is detected. Provide information on illegal movements detected.

4. FMD diagnosis

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

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

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.7.40. 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) Serological *surveillance*. Have serological surveys been conducted to demonstrate freedom from *infection*? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are *wildlife* susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.

Annex XVI (A) (contd)

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

6. FMD prevention

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

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

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of and the disposal locations.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals,
 - genetic material (semen and embryos),
 - animal products,
 - *veterinary medicinal products* (i.e. biologics),
 - other materials at risk of being contaminated with FMDV

Annex XVI (A) (contd)

- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on illegal imports detected.
 - d) Describe and justify the corrective actions that have been implemented to prevent future FMD outbreaks in response to any past disease incursions.
7. Contingency planning and outbreak response programmes
- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
 - b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases (e.g. livestock standstills)?
 - c) In the event of a FMD *outbreak*:
 - i) indicate the sampling and testing procedures to be used to identify and confirm presence of the causative agent;
 - ii) describe the actions to be taken to report and control the disease situation in and around any *establishments* found to be infected with FMD;
 - iii) indicate the control or eradication procedures (e.g. *vaccination, stamping-out policy, partial slaughter or vaccination*, methods of disposal of carcasses and other contaminated products and materials, decontamination, etc.) that would be taken. Include information on access to antigen and vaccine banks;
 - iv) describe the procedures to be used to confirm successful control or eradication, including any restocking provisions, sentinel animal and serological surveillance programmes;
 - v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control or eradication purposes and their prescribed timetable.
8. Compliance with the *Terrestrial Code*
- a) In addition to the documentary evidence that the provisions of Article 8.7.2. 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.).

Annex XVI (A) (contd)

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 a FMD free country practising vaccination

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

1. Introduction

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

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
- b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. 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 illegal movements detected.

4. FMD diagnosis

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

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

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.7.40. 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 susceptible *wildlife* species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- 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?

Annex XVI (A) (contd)

- e) *Slaughterhouses*, markets and events associated with the congregation of FMD-susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

6. FMD prevention

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

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

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

7. Contingency planning and outbreak response programmes

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

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.7.3. 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.).

Annex XVI (A) (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 a FMD free zone not practising vaccination

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

1. Introduction

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

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
- b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. 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*.
 - i) Was *vaccination* ever used in the *zone*? If so, when was the last *vaccination* carried out? When was *vaccination* formally prohibited? What species were vaccinated? What was the fate of those animals?
 - ii) In addition, if *vaccination* was conducted during the past 2 years, provide a description and justification of the *vaccination* strategy, including, the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the *vaccination* of animals was certified or reported and the records maintained. Also provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*.
 - ii) If *vaccination* continues to be used in the rest of the country, give details on the post-*vaccination* monitoring programme.

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

Annex XVI (A) (contd)

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

6. FMD prevention

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

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

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

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

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

Annex XVI (A) (contd)

- *veterinary medicinal products* (i.e. biologics),
 - other materials at risk of being contaminated with FMDV.
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on illegal imports detected.
- d) Describe and justify the corrective actions that have been implemented to prevent future FMD outbreaks in response to any past disease incursions.

7. Contingency planning and outbreak response programmes

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

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.7.4. 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.).

Annex XVI (A) (contd)

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

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*. 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.

Annex XVI (A) (contd)

- e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability, including *vaccination* data. How are animal movements controlled in 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, 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.

Annex XVI (A) (contd)

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

6. FMD prevention

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

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

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

- c) Import control procedures

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

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of and the disposal locations.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:
 - animals,
 - genetic material (semen and embryos),
 - animal products,
 - *veterinary medicinal products* (i.e. biologics),
 - other materials at risk of being contaminated with FMDV.

Annex XVI (A) (contd)

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

In addition to the documentary evidence that the provisions of Article 8.7.5. 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,
- 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 1.6.7.]

[Article 1.6.8.]

[Article 1.6.9.]

[Article 1.6.10.]

Annex XVI (A) (contd)

Article 1.6.11.

Questionnaire on FMD

<p>COUNTRY WITH AN OIE ENDORSED OFFICIAL CONTROL PROGRAMME FOR FMD</p> <p>Report of a Member Country which applies for the OIE endorsement</p> <p>of its official control programme for FMD</p> <p>under Chapter 8.7. of the <i>Terrestrial Code</i></p>

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.
- 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*.

Annex XVI (A) (contd)

- 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.
- 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.

Annex XVI (A) (contd)

- 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).

Annex XVI (A) (contd)

- b) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Are there controls in place for the feeding of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and *surveillance* measures.
- c) Provide information on countries or *zones* from which the country authorises the import of susceptible animals or their products into the country or *zone*. Describe the criteria applied to approve such countries or *zones*, the controls applied on entry of such animals and products, and subsequent internal movement. Describe the import conditions and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health certificates are required. Describe any other procedures used. Provide summary statistics on imports of susceptible animals and their products for at least the past two years, specifying country or *zone* of origin, the species and the number or volume. Provide evidence that the import policy and the improved border controls have contributed to reducing the number of outbreaks or that *outbreaks* are not related to imports or transboundary movements of domestic animals.
- i) Provide a map with the number and location of ports, airports and land crossings. Advise whether the service responsible for import controls is part of the official services, or if it is an independent body. If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste food from international traffic, who is responsible to supervise this and provide a summary, for the past two years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and their final destination, concerning the import and follow up of the following:
- animals,
 - genetic material (semen and embryos),
 - animal products,
 - *veterinary medicinal products*, i.e. biologics,
 - other livestock related goods potentially contaminated with FMDV including bedding, litter and feeds.
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on illegal imports detected, if available.

7. Control measures and emergency response

- a) Give details of any written guidelines, including emergency response plans, available to 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;

Annex XVI (A) (contd)

- 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 no evidence of FMDV transmission.

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

Member Countries applying for recovery of the official endorsement of the national FMD control programme should provide updated information in compliance with the provisions of Article 8.7.39. of the *Terrestrial Code*.

NOTE:

The Code Commission encourages Member Countries to review all relevant reports when reviewing this document including the following:

- February 2015 report of the Scientific Commission for the rationale on the proposed amendments
- September–October 2014, November 2014 and January 2015 reports of the OIE ad hoc Group on the Evaluation of Foot and Mouth Disease Status of Member Countries attached to the February 2015 report of the Scientific Commission

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. Dromedaries (*Camelus dromedarius*) are not susceptible to FMDV infection of dromedaries and while South American camelids are has not been shown considered to be of epidemiological significance.
- 2) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the suborder *ruminantia* and of the family *suidae* of the order *Artiodactyla*, and *Camelus bactrianus* with 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 suspected or 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 suspected or confirmed or suspected outbreak of FMD, or giving cause for suspicion of previous association or contact with FMDV.
- 4) Transmission of FMDV in a vaccinated population is demonstrated by change in virological or serological evidence indicative of recent *infection*, even in the absence of clinical signs.
- 5) For the purposes of the *Terrestrial Code*, the *incubation period* of FMD is shall be 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) Theis 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.

Annex XVI (B) (contd)

Susceptible animals in the FMD free country or *zone* where *vaccination* is not practised should be protected by the application of **animal health biosecurity** measures that prevent the entry of FMDV into the free country or *zone*. Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*.

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;**
 - e)** 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 demonstrate no evidence** of:
 - i) FMDV *infection* in **non-un**vaccinated animals;
 - ii) FMDV transmission in previously vaccinated animals when **transition is made from the** FMD free country or *zone* where *vaccination* is practised **is seeking to become one 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;
- 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.

Annex XVI (B) (contd)

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 to FMD susceptible animals in zoological collections in the face of a FMD threat identified by the *Veterinary Authorities*, provided that the following conditions are met:

- the zoological collection has a the primary purpose to of exhibiting animals or preserveing 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 stated if the new zone is being merged with the adjacent zone to become one enlarged zone. If the two zones remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate zones and particularly on the identification and the control of the movement of animals between the zones of the same status in accordance with Chapter 4.3.

Article 8.7.3.

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 by the application of animal health biosecurity measures that prevent the entry of FMDV into the free country or zone. Taking into consideration physical or geographical barriers with any neighbouring infected country or zone, these measures may include a protection zone.

Based on the epidemiology of FMD in the country, it may be decided to vaccinate only a defined subpopulation 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 demonstrate no evidence of:

Annex XVI (B) (contd)

- i) FMDV *infection* in ~~non-un~~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 *vaccination* has been carried out following e-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 ~~of the cessation~~. 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 stated~~ if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of *animals* between the *zones* of the same status in accordance with Chapter 4.3.

Article 8.7.4.

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.

Annex XVI (B) (contd)

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** may 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).

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:

Annex XVI (B) (contd)

- 1) on suspicion, a strict standstill of animal movements has been imposed on the suspected establishments and in the country or zone 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, an additional standstill of susceptible animals has been imposed in the entire containment zone and the movement controls described in point 1) have been reinforced;
- 3) the definitive boundaries of the *containment zone* may only be have been established once after an epidemiological investigation (trace-back, trace-forward) has demonstrated that the *outbreaks* are epidemiologically related and limited in number and geographic distribution;
- 4) investigations into the likely source of the *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 the OIE as complying with points 1) to 9) above. *Commodities* from susceptible animals for *international trade* should be identified as to their origin, either from inside or outside the *containment zone*.

In the event of recurrence of FMDV infection in unvaccinated animals or FMDV transmission in vaccinated animals in the *containment zone*, the approval of the *containment zone* is withdrawn, and the FMD status of the whole country or *zone* is suspended until the relevant requirements of Article 8.7.7. are fulfilled.

The recovery of the FMD free status of the *containment zone* should be achieved within 12 months of its approval and follow the provisions of Article 8.7.7.

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 animal killed 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 animal killed 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. are applied; or

Annex XVI (B) (contd)

- c) six months after the disposal of the last case animal killed or the last *vaccination* whichever occurred last, where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated animals, and *surveillance* ~~are applied~~ are applied in accordance with Articles 8.7.40. to 8.7.42. are applied. However, this requires a serological survey based on the detection of antibodies to nonstructural proteins of FMDV to demonstrate ~~the absence~~ no evidence 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~~ six months after the disposal of the last case animal killed where a *stamping-out policy* has been applied and a continued *vaccination* policy has been adopted, provided that *surveillance* is applied in accordance with Articles 8.7.40. to 8.7.42., and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates ~~the absence~~ no evidence of FMDV transmission.

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.

- 3) When a case of 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 animal killed 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~~ no evidence 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~~ no evidence 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.

Annex XVI (B) (contd)

- 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*.

For Member Countries not applying for recovery within 24 months after suspension, the provisions of Article 8.7.2., Article 8.7.3. or Article 8.7.4. apply.

Article 8.7.8.

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

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

- 1) no FMD susceptible animal has been introduced into the *establishment* of origin and no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;
- 2) the animals were kept in the *establishment* of origin for at least three months prior to movement;
- 3) FMD has not occurred within a 10 kilometre radius of the *establishment* of origin for at least four weeks prior to movement;
- 4) the animals should be 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* with no evidence of FMD, 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 accordance with Articles 8.7.31. to 8.7.38 in order such a way as to destroy any residual FMDV potentially present 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 whether vaccination either is or is not is practised or not)

In order not to jeopardise the status of a free zone, FMD susceptible animals should only leave the *containment zone* if transported directly to *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 *slaughterhouse/abattoir* without coming into contact with other susceptible animals;
- 3) such an *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the *containment zone*;

Annex XVI (B) (contd)

- 4) *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 with no evidence of FMD* 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 accordance with Articles 8.7.31. to 8.7.38. in order such a way as* to destroy any *residual FMDV potentially present* 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 compartments

For FMD susceptible animals

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

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept since birth or for at least the past three months in a FMD free country or *zone* 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 practised

For domestic ruminants and pigs

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

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

Article 8.7.12.

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

For domestic ruminants and pigs

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

- 1) the animals showed no clinical sign of FMD on the day of shipment;
- 2) prior to isolation, the animals were kept in the *establishment* of origin:
 - a) *since birth, or*
 - b) *for the past 30 days, or since birth if younger than 30 days*, if a *stamping-out policy* is *applied to control FMD in force* in the *exporting country or zone*, or

Annex XVI (B) (contd)

- be) for the past three months, or since birth if younger than three months if a stamping-out policy is not applied to control FMD 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 10 kilometre radius of the *establishment* during that period, or the *establishment* is a *quarantine station*;
- 5) the animals were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

Article 8.7.13.

Recommendations for importation from FMD free countries or zones where vaccination is not practised 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 males:
- a) showed no clinical sign of FMD on the day of collection of the semen;
 - b) were kept for at least three months prior to collection in a FMD free country or 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 with FMDV ;
- 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 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 males:
- a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least three months prior to collection in a FMD free country or zone 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

Annex XVI (B) (contd)

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

- 1) the donor **animals males**:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept for at least three months prior to collection in a FMD free country or *zone* 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 demonstrated** 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 males**:
 - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
 - b) were kept in an *artificial insemination centre* where no animal had been added in the 30 days before collection, and that FMD has not occurred within a 10 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 demonstrated** 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 male** has been vaccinated within the 12 months prior to collection;

Annex XVI (B) (contd)

- 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** **males** 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:

- 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 demonstrated** 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;

Annex XVI (B) (contd)

- 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.

Article 8.7.22.

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

For 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;

Annex XVI (B) (contd)

- b) have been vaccinated at least twice with the last *vaccination* not more than six months, unless protective immunity has been ~~proven~~ demonstrated 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 10 kilometre radius of the *establishment* during that period, or the establishment is a quarantine station;
 - d) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle and water buffaloes were loaded, directly from the *establishment* of origin or quarantine station to the approved *slaughterhouse/abattoir* without coming into contact with other animals which do not fulfil the required conditions for export;
 - e) have been slaughtered in an approved *slaughterhouse/abattoir*:
 - i) which is officially designated for export;
 - ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;
 - f) have been subjected to ante- and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter* with no evidence of FMD;
- 2) comes from deboned carcasses:
- a) from which the major lymphatic nodes have been removed;
 - b) which, prior to deboning, have been submitted to maturation at a temperature above greater than + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below less than 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 zones

For meat products of FMD susceptible animals

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

- 1) the entire consignment of *meat products* come from animals which have been slaughtered in an *approved slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results;
- 2) the *meat products* have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.7.31.;
- 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 existsFor 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 countriesFor 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 countriesFor 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.

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:

Annex XVI (B) (contd)

- 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% 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:

1. Canning

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

2. Thorough cooking

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

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

3. Drying after salting

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

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

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; **or**
- 2) immersion for at least 24 hours in a % 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).

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.

Annex XVI (B) (contd)

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

Article 8.7.37

Procedures for the inactivation of FMDV in skins and trophies from ~~wild animals~~ **wildlife 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; **or**
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher); **or**
- 3) soaking, with agitation, in a 4% (weight/volume) solution of sodium carbonate (Na_2CO_3) maintained at pH 11.5 or greater for at least 48 hours; **or**
- 4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at **below** pH **less than** 3.0 for at least 48 hours; wetting and dressing agents may be added; **or**
- 5) in the case of raw hides, treating for at least 28 days with salt (NaCl) containing 2% sodium carbonate (Na_2CO_3).

Article 8.7.38.

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* **only**.

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.

Annex XVI (B) (contd)

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;
 - 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*.

Annex XVI (B) (contd)

The Member Country's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence, based on the provisions of Article 1.6.11., has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE 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, where appropriate, *wildlife* species as indicated in point 2) of Article 8.7.1. within the country, zone or compartment.

1. Early detection

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

2. Demonstration of freedom

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 demonstrating freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMDV should differ significantly from an application approach designed to prove demonstrate freedom from FMD for in a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*.

Surveillance for FMD should be in the form of a continuing programme. Programmes to demonstrate no evidence of 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 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 substantiate demonstrate FMD freedom where *vaccination* is not practised should show absence demonstrate no evidence of FMDV *infection*.

A Member Country wishing to **substantiate demonstrate** FMD freedom where *vaccination* is practised should **show demonstrate** that FMDV has not been transmitted in any susceptible populations. Within vaccinated populations, serological surveys to demonstrate **the absence no evidence** 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. **In any unvaccinated subpopulation, surveillance should demonstrate no evidence** 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*.

3. OIE endorsed official control programme

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

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

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

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.

4. Surveillance strategies

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.

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

An effective *surveillance* system will identify suspected cases that require immediate follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Samples should be taken and submitted for diagnostic testing, unless the suspected case can be confirmed or ruled out by epidemiological and clinical investigation. Details of the occurrence of suspected cases and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the control measures to which the animals concerned were subjected during the investigation.

Annex XVI (B) (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;**
- **identification and traceability of animals and control of their movements;**
- other parameters of regional significance in historic FMDV transmission.

6. Demonstration of population immunity

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

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

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

Clinical examination and diagnostic testing should be applied to clarify the status of suspected cases ~~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 **for the presence and transmission of the virus**.

3. Serological surveillance

Serological *surveillance* aims **at to** 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.

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*.

Annex XVI (B) (contd)

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

Positive FMDV antibody test results can have four possible causes:

- a) *infection* with FMDV;
- b) *vaccination* against FMDV;
- 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 results**. 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 which may include** the results of virological tests **and of any further serological tests** that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to FMDV transmission, **and This investigation** should document the status for each positive *herd*. Epidemiological investigation should be continued concurrently.

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

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

The investigation should include the reactor animals, susceptible animals of the same *epidemiological unit* and susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animals. The animals sampled should 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, **after an appropriate time has lapsed**, 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.

Annex XVI (B) (contd)

In some circumstances, unvaccinated sentinel animals may also be used. These can be young, unvaccinated animals from unvaccinated dams or animals in which maternally conferred immunity has lapsed and preferably of the same species as in the positive sampling units. If other susceptible, unvaccinated animals are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the animals of the *epidemiological unit* under investigation for at least two *incubation periods* and should remain serologically negative if FMDV is not circulating.

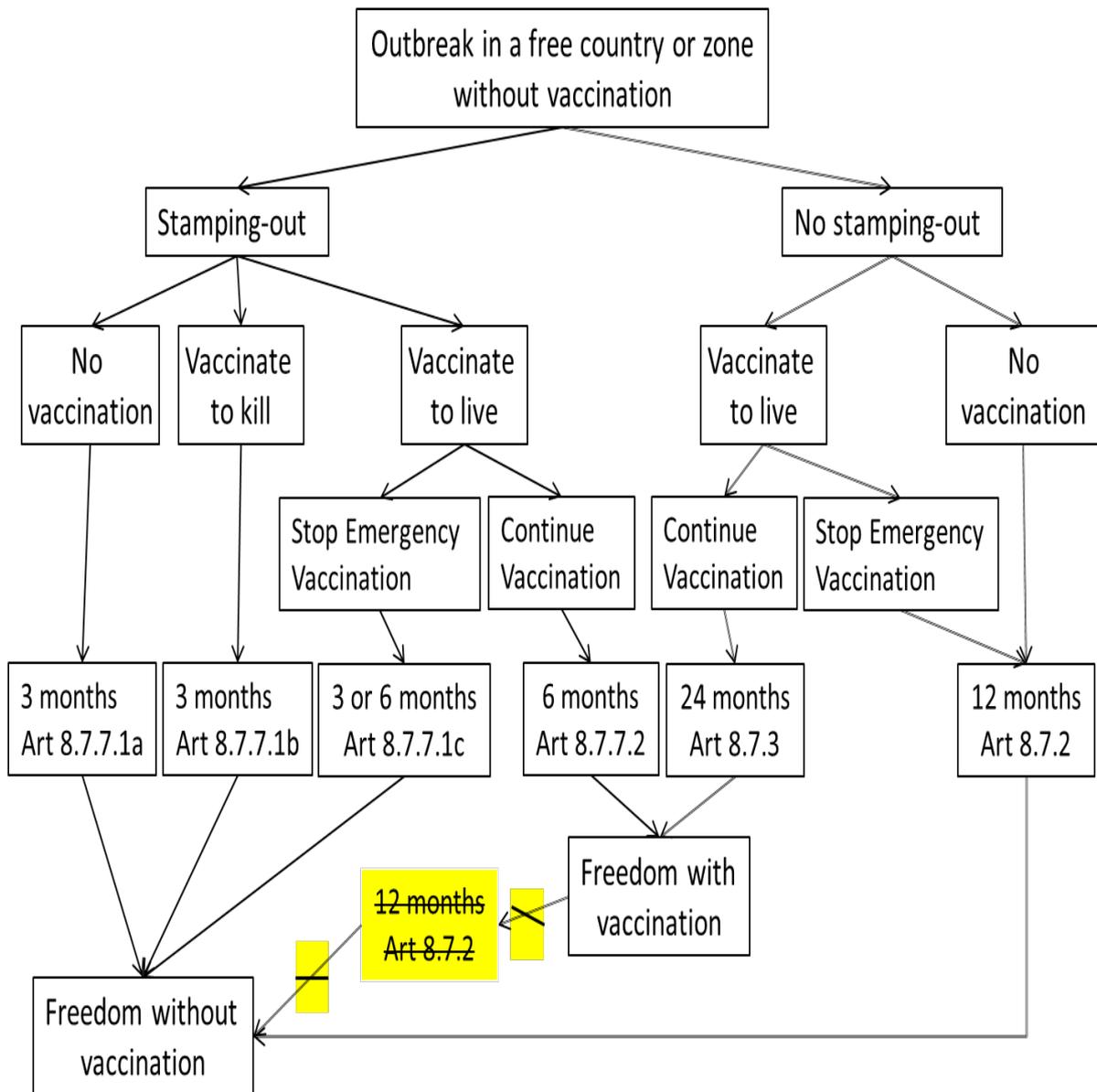
Follow-up of field and laboratory findings:

If transmission is proven demonstrated, 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.

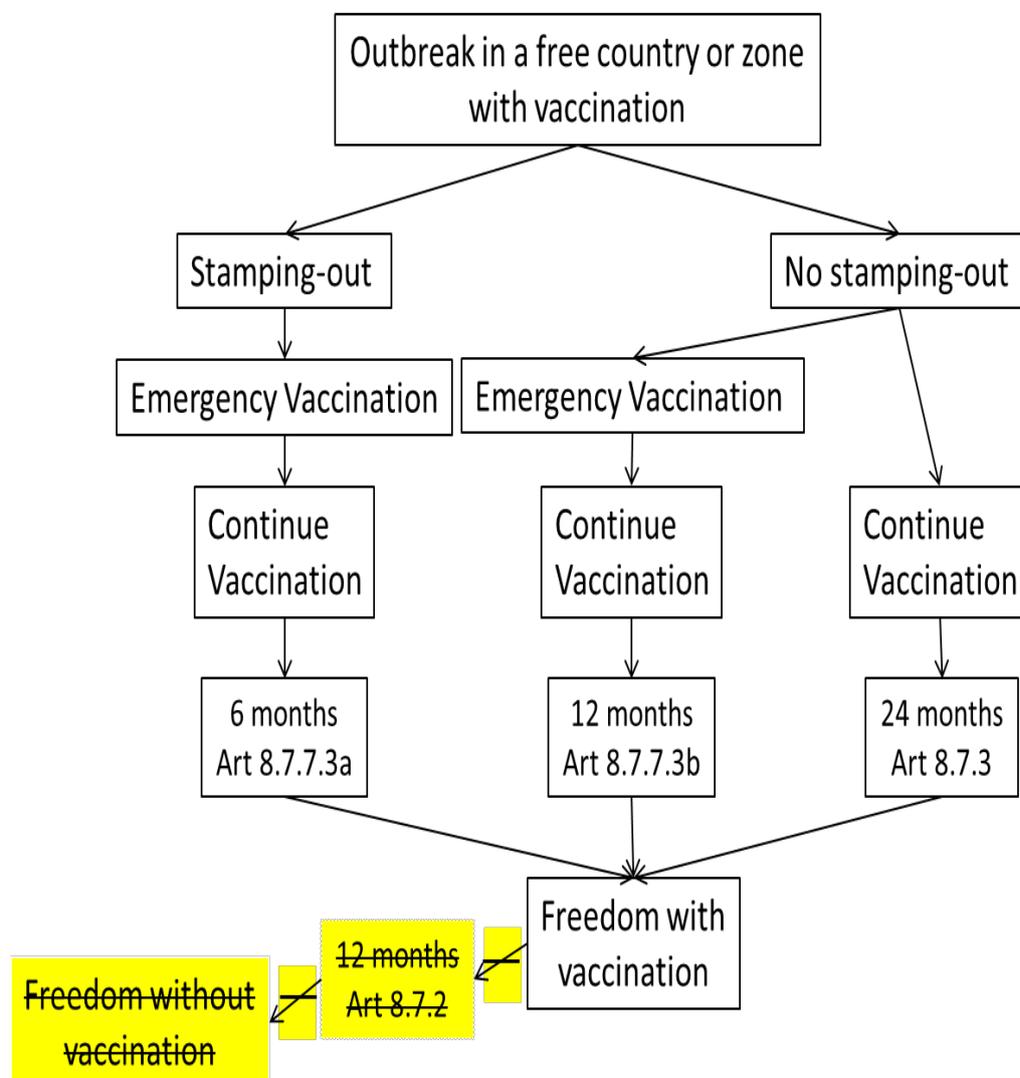
However, if the number of seropositive animals is greater than the number of false positive results expected from the specificity of the diagnostic tests used non-specific test system findings expected, susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor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

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.

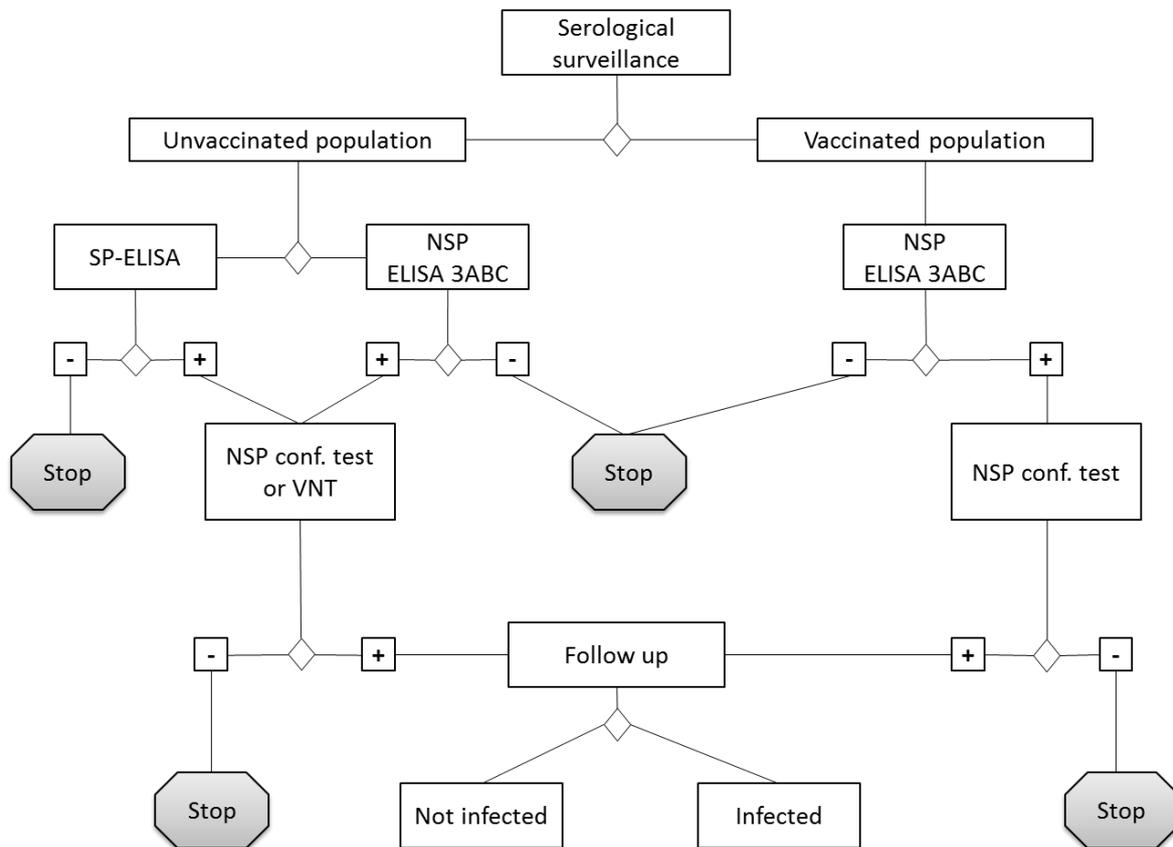
Figure 2. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak in a free country or zone where vaccination is practised



*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 (B) (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° XXVI (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.

Annex XVI (B) (contd)

[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. in the *Terrestrial Code* and Article 1.1.3. in 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*. Was FMD vaccine ever used? If so, when was the last *vaccination* carried out? When was vaccination formally prohibited? What species were vaccinated? What was the fate of these animals?

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

4. FMD diagnosis

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

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

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.7.40. to 8.7.42. in the *Terrestrial Code* and Chapter 2.1.5. in the *Terrestrial Manual*. In particular, the following points should be addressed:

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

Annex XVI (B) (contd)

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

6. FMD prevention

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

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

Annex XVI (B) (contd)

- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports detected.
 - d) Describe and justify the corrective actions that have been implemented to prevent future FMD outbreaks in response to any past disease incursions.
7. Contingency planning and outbreak response programmes
- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
 - b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases (e.g. livestock standstills)?
 - c) In the event of a FMD *outbreak*:
 - i) indicate the sampling and testing procedures to be used to identify and confirm presence of the causative agent;
 - ii) describe the actions to be taken to report and control the disease situation in and around any *establishments* found to be infected with FMD;
 - iii) indicate the control or eradication procedures (e.g. *vaccination, stamping-out policy, partial slaughter or vaccination*, methods of disposal of carcasses and other contaminated products and materials, decontamination, etc.) that would be taken. Include information on access to antigen and vaccine banks;
 - iv) describe the procedures to be used to confirm successful control or eradication, including any restocking provisions, sentinel animal and serological *surveillance* programmes;
 - v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control or eradication purposes and their prescribed timetable.
8. Compliance with the *Terrestrial Code*
- a) In addition to the documentary evidence that the provisions of Article 8.7.2. 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 Article 8.7.7., point 1) of Article 8.7.2., point 3) of Article 8.7.2. and point 4) of 8.7.2. in the *Terrestrial Code* and provide information as specified in sections 1–7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).

Annex XVI (B) (contd)**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 a 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. in the *Terrestrial Code* and Article 1.1.3. in 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. in the *Terrestrial Manual*.
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability, including *vaccination* data. How are animal movements controlled in 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 **detected**.

4. FMD diagnosis

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

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

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.7.40. to 8.7.42. in the *Terrestrial Code* and Chapter 2.1.5. in the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis).
- b) *Surveillance*. Are serological and virological surveys conducted to demonstrate freedom from *infection*, in particular applying the provisions of Article 8.7.42.? 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 **wildlife** species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- 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?

Annex XVI (B) (contd)

- 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 at risk of being contaminated with FMDV (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 8.7.3. 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 Article 8.7.7., point 1) of Article 8.7.3., point 3) of Article 8.7.3. and point 4) of Article 8.7.3. in the *Terrestrial Code* and provide information as specified in sections 1–7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).

Annex 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 a FMD free zone not practising vaccination

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

1. Introduction

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

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
- b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. in the *Terrestrial Code* and Article 1.1.3. in 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*. **#**

i) Was vaccination is ever used in the zone? If so, when was the last vaccination carried out? When was vaccination formally prohibited? What species were vaccinated? What was the fate of those animals? rest of the country,

ii) In addition, if vaccination was conducted during the past two years, provide a description and justification of the vaccination strategy, including the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the vaccination of animals was certified or reported and the records maintained. the date on which the last vaccination was performed, and the disposition of vaccinated animals (e.g. removed from or retained in the population). Provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc. Also provide evidence that the vaccine used complies with Chapter 2.1.5. in the *Terrestrial Manual*.

iii) If vaccination continues to be used in the rest of the country, give details on the post-vaccination monitoring programme.

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. in the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

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

5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.7.40. to 8.7.42. in the *Terrestrial Code* and Chapter 2.1.5. in the *Terrestrial Manual*. In particular, the following points should be addressed:

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

Annex XVI (B) (contd)

- 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 biosecurity measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

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

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

Annex XVI (B) (contd)

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

In addition to the documentary evidence that the provisions of Article 8.7.4. 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 Article 8.7.7., point 1) of Article 8.7.2., point 3) of Article 8.7.2. and point 4) of Article 8.7.2. in the *Terrestrial Code* and provide information as specified in sections 1–7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).

Annex XVI (B) (contd)

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

1. Introduction

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

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
- b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. in the *Terrestrial Code* and Article 1.1.3. in 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. in the *Terrestrial Manual*.
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.

Annex XVI (B) (contd)

- e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability, including *vaccination* data. How are animal movements controlled in 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. in the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

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

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. in the *Terrestrial Code* and Chapter 2.1.5. in the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) *Clinical suspicion*. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis).
- b) *Surveillance*. Are serological and virological surveys conducted to demonstrate freedom from *infection*, in particular applying the provisions of Article 8.7.42.? 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.

Annex XVI (B) (contd)

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

6. FMD prevention

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

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

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

From what countries or *zones* does the country authorise the import of susceptible animals or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying 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:
 - animals,
 - genetic material (semen and embryos),
 - animal products,
 - *veterinary medicinal products* (i.e. biologics),
 - other FMD-risk materials at risk of being contaminated with FMDV (e.g. stock feed and animal bedding).

Annex XVI (B) (contd)

- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports detected.
- d) Describe and justify the corrective actions that have been implemented to prevent future FMD *outbreaks* in response to any past disease incursions.

7. Contingency planning and outbreak response programmes

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

8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.7.5. 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,
- 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 Article 8.7.7., point 1) of Article 8.7.3., point 3) of Article 8.7.3. and point 4) of Article 8.7.3. in the *Terrestrial Code* and provide information as specified in sections 1–7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).

[Article 1.6.7.]

[Article 1.6.8.]

[Article 1.6.9.]

[Article 1.6.10.]

Annex XVI (B) (contd)

Article 1.6.11.

Questionnaire on FMD

<p>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 <i>Terrestrial Code</i></p>

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. in the *Terrestrial Code* and Article 1.1.3. in 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.
- 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*.

Annex XVI (B) (contd)

- 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. in the *Terrestrial Code* and Chapter 2.1.5. in the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Describe the criteria for raising a suspicion of FMD and the procedure to notify (by whom and to whom) and what penalties are involved for failure to report.
- b) Describe how clinical *surveillance* is conducted, including which levels of the livestock production system are included in clinical *surveillance*, such as farms, markets, fairs, *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.

Annex XVI (B) (contd)

- 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. in the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

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

6. FMD prevention

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

- a) Coordination with neighbouring countries, trading partners and other countries within the same region. Identify relevant factors about the adjacent countries and *zones* that should be taken into account such as size, distance from adjacent borders to affected *herds* or animals, *surveillance* carried in adjacent countries. Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*. Describe the measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation of the agent within the country or *zone* and through trade. Provide evidence that measures are in place at markets to reduce transmission of FMD such as enhancing awareness of FMD transmission mechanisms and behaviours that can interrupt transmission, implementation of good biosecurity practices, hygiene, cleaning and disinfection routines at critical points all along the production and marketing networks (typically where animals are being moved, and marketed through the country or region).

Annex XVI (B) (contd)

- b) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Are there controls in place for the feeding of swill containing animal products to pigs? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.
- c) Provide information on countries or *zones* from which the country authorises the import of susceptible animals or their products into the country or *zone*. Describe the criteria applied to approve such countries or *zones*, the controls applied on entry of such animals and products, and subsequent internal movement. Describe the import conditions and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health certificates are required. Describe any other procedures used. Provide summary statistics on imports of susceptible animals and their products for at least the past two years, specifying country or *zone* of origin, the species and the number or volume. Provide evidence that the import policy and the improved border controls have contributed to reducing the number of outbreaks or that outbreaks are not related to imports or transboundary movements of domestic animals.
- i) Provide a map with the number and location of ports, airports and land crossings. Advise whether the service responsible for import controls is part of the official services, or if it is an independent body. If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste food from international traffic, who is responsible to supervise this and provide a summary, for the past two years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and their final destination, concerning the import and follow-up of the following:
- animals,
 - genetic material (semen and embryos),
 - animal products,
 - *veterinary medicinal products*, i.e. biologics,
 - other livestock related goods potentially contaminated with FMDV including bedding, litter and feeds.
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports detected, 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;

Annex XVI (B) (contd)

- 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 no evidence** of FMDV transmission.

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

Member Countries applying for recovery of the official endorsement of the national FMD control programme should provide updated information in compliance with the provisions of Article 8.7.39. in the *Terrestrial Code*.

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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*.

Annex XVII (contd)

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;

Annex XVII (contd)

- 3) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the *animals* are held behind insect-proof netting;
- 4) using historical and current information to identify low risk ports and transport routes.

Article 8.13.7.

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.

Annex XVII (contd)

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:

Annex XVII (contd)

- 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.;

- 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;

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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;

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- 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;

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- 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 bovinds, 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. and the semen was collected and processed in accordance with Chapter 4.6.;
- 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 accordance with the provisions of Articles 4.5.3. to 4.5.5. and Articles 4.6.5. to 4.6.7.

Annex XVIII (contd)

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:

- 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 in **conformity** **accordance** 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.

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 influenza

For 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 influenza

For 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 poultryFor 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 influenzaFor 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

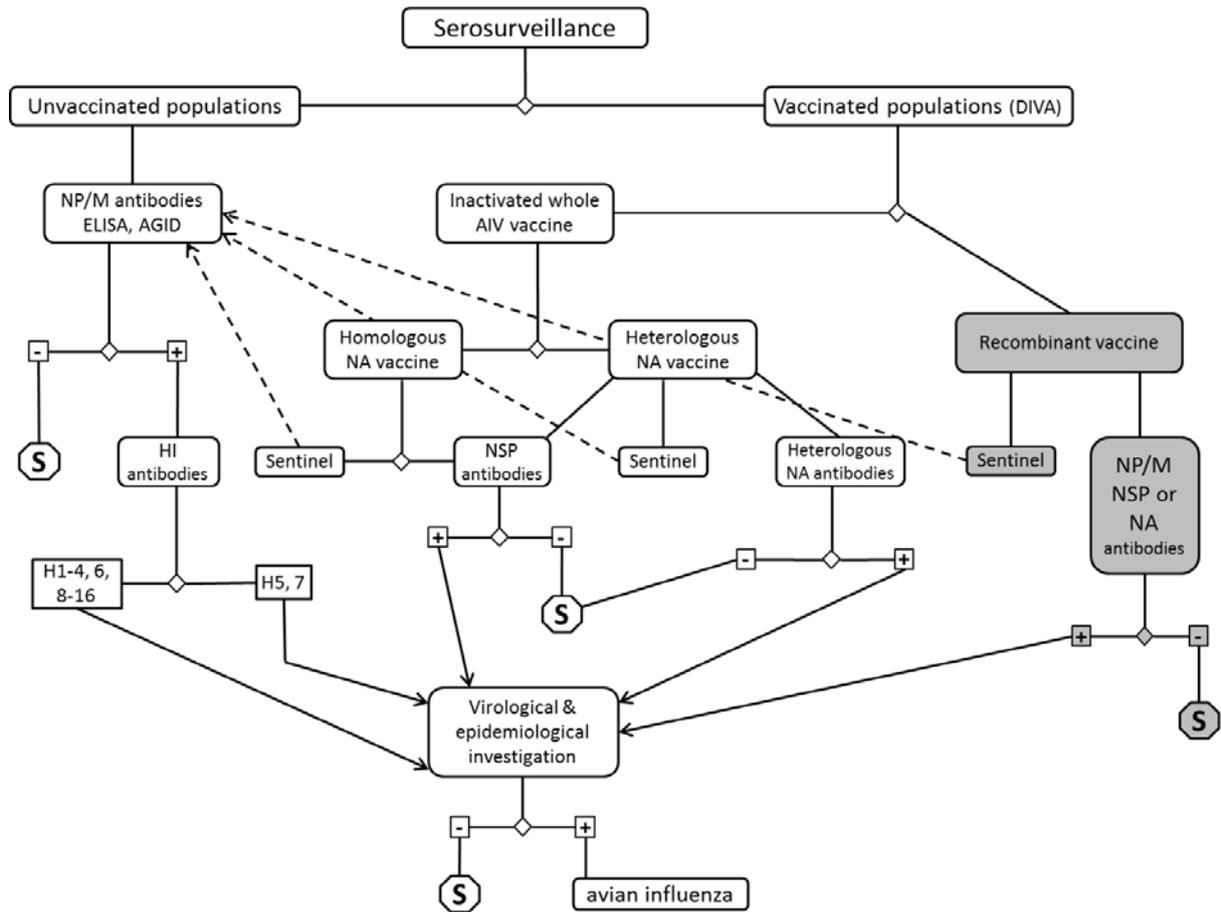
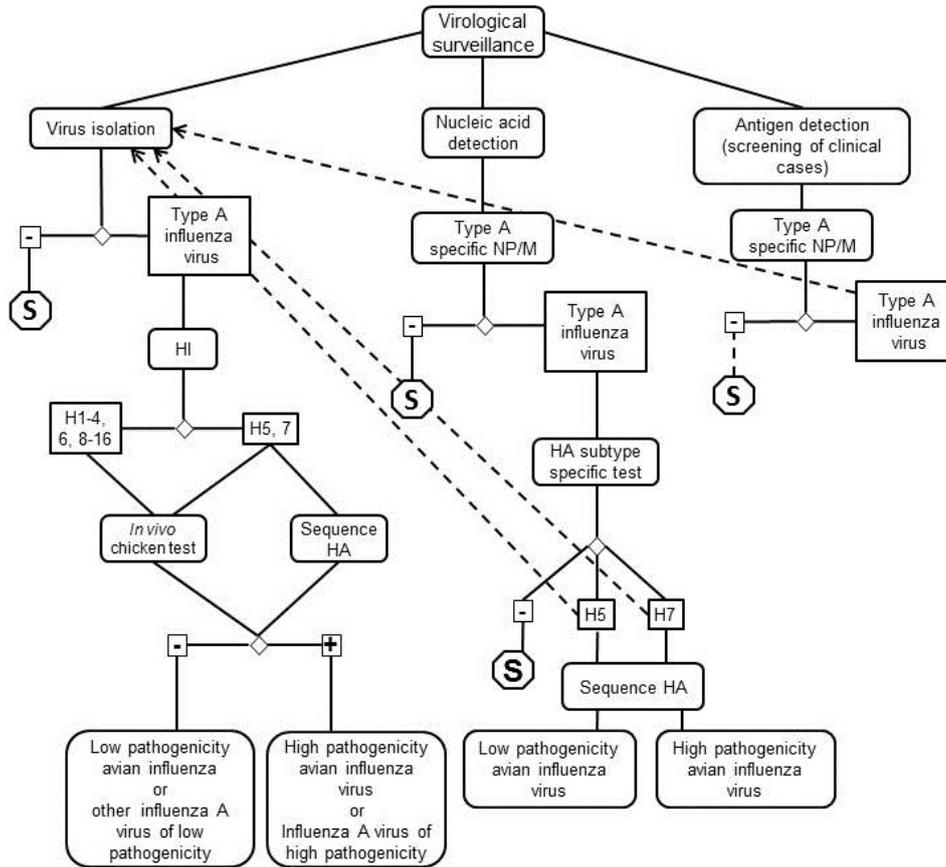


Fig. 2. Schematic representation of laboratory tests for determining evidence of avian influenza infection using virological methods



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CHAPTER 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 *listed 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 a high health status *subpopulation* and registered by the International Equestrian Federation (FEI) or the International Federation of Horseracing Authorities (IFHA) as eligible to perform take part in international competitions and races accompanied by a certificate for temporary international movement in accordance with the *Terrestrial Code*.~~

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 its health status and that of the other horses in the *subpopulation*.

These measures comprise a specific set of *laboratory tests*, treatments isolation periods and *vaccinations* appropriate to the disease status of the country or region of origin usual residence 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 examinations 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 ~~to which~~ *Veterinary Authorities* ~~should have access to this database.~~

Annex XX (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 in accordance 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 authorised for that purpose by a *Veterinary Authority*. 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 authorised 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 usual residence.

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)

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NOTE:

The Code Commission encourages Member Countries to review all relevant reports when reviewing this document including the following:

- November 2014 report of the *ad hoc* Group on the Evaluation of Bovine Spongiform Encephalopathy Risk Status of Member Countries attached to the February 2015 report of the Scientific Commission

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.4.1.

General provisions and safe commodities

The recommendations in this chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only. BSE includes 'classical' BSE and 'atypical' BSE, a condition believed to occur spontaneously in all cattle population at a similar low rate.

- 1) When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Authorities* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country, zone or compartment*:
 - a) *milk and milk products*;
 - b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;
 - c) hides and skins;
 - d) gelatine and collagen prepared exclusively from hides and skins;
 - e) tallow with maximum level of insoluble impurities of 0.15 percent in weight and derivatives made from this tallow;
 - f) dicalcium phosphate (with no trace of protein or fat);
 - g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle which were not subjected to a stunning process prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante- and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.4.14.;
 - h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.
- 2) When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BSE risk status of the cattle population of the *exporting country, zone or compartment*.
- 3) When authorising import of *commodities* according to the conditions prescribed in this chapter, the risk status of an *importing country* is not affected by the BSE risk status of the *exporting country, zone or compartment*.

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

Article 11.4.2.

The BSE risk status of the cattle population of a country, zone or compartment

The BSE risk status of the cattle population of a country, *zone* or *compartment* should be determined on the basis of the following criteria:

Annex XXI (contd)

- 1) the outcome of a *risk assessment*, based on the provisions of the *Terrestrial Code*, identifying all potential factors for 'classical' BSE occurrence and their historic perspective. Members should review the *risk assessment* annually to determine whether the situation has changed.

a) Entry assessment

Entry assessment consists of assessing, through consideration of the following, the likelihood that the 'classical' BSE agent has either been introduced into the country, *zone* or *compartment* via *commodities* potentially contaminated with it, or is already present in the country, *zone* or *compartment*.

- i) the presence or absence of the 'classical' BSE agent in the indigenous ~~ruminant~~ cattle population of the country, *zone* or *compartment* and, if present, evidence regarding its prevalence;
- ii) production of *meat-and-bone meal* or *greaves* from the indigenous ~~ruminant~~ cattle population;
- iii) imported *meat-and-bone meal* or *greaves*;
- iv) imported cattle, ~~sheep and goats~~;
- v) imported animal feed and feed ingredients;
- vi) imported products of ~~ruminant~~ bovine origin for human consumption, which may have contained tissues listed in Article 11.4.14. and may have been fed to cattle;
- vii) imported products of ~~ruminant~~ bovine origin intended for *in vivo* use in cattle.

The results of *surveillance* and other epidemiological investigations into the disposition of the *commodities* identified above should be taken into account in carrying out the assessment.

b) Exposure assessment

~~If the entry assessment identifies a risk factor, a~~ An exposure assessment should be conducted, consisting of assessing the likelihood of cattle being exposed to the BSE agent, through a consideration of the following:

- i) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ~~ruminant~~ bovine origin, or other feed or feed ingredients contaminated with these;
 - ii) the use of ~~ruminant~~ bovine carcasses (including from fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;
 - iii) the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;
 - iv) the level of *surveillance* for BSE conducted on the cattle population up to that time and the results of that *surveillance*;
- 2) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and *slaughter* of cattle to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Articles 11.4.20. to 11.4.22.;

- 3) the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;
- 4) the examination carried out in accordance with the *Terrestrial Manual* in a *laboratory* of brain or other tissues collected within the framework of the aforementioned *surveillance* and monitoring system.

When the *risk assessment* demonstrates negligible risk, the Member should conduct Type B *surveillance* in accordance with Articles 11.4.20. to 11.4.22.

When the *risk assessment* fails to demonstrate negligible risk, the Member should conduct Type A *surveillance* in accordance with Articles 11.4.20. to 11.4.22.

Article 11.4.3.

Negligible BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a negligible risk of transmitting the BSE agent if the following conditions are met:

- 1) a *risk assessment*, as described in point 1 of Article 11.4.2., has been conducted in order to identify the historical and existing risk factors, and the Member has demonstrated that appropriate specific measures have been taken for the relevant period of time defined below to manage each identified risk;
- 2) the Member has demonstrated that Type B *surveillance* in accordance with Articles 11.4.20. to 11.4.22. is in place and the relevant points target, in accordance with Table 1, has been met;
- 3) EITHER:
 - a) there has been no case of BSE or, if there has been a case, every case of BSE has been demonstrated to have been imported or has been diagnosed as 'atypical' BSE and has been completely destroyed; and
 - i) the criteria in points 2 to 4 of Article 11.4.2. have been complied with for at least seven years; ~~and~~
 - ii) it has been demonstrated through an appropriate level of control and audit, including that of cross contamination, that for at least eight years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;

OR

- b) if there has been an indigenous case of 'classical' BSE, every indigenous case was born more than 11 years ago; and
 - i) the criteria in points 2 to 4 of Article 11.4.2. have been complied with for at least seven years; ~~and~~
 - ii) it has been demonstrated through an appropriate level of control and audit, including that of cross contamination, that for at least eight years neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants;
 - iii) all BSE cases, ~~have been completely destroyed;~~
 - iv) for 'classical' BSE cases only as well as:
 - all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
 - if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE cases,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

Annex XXI (contd)

The Member or *zone* will be included in the list of negligible risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Article 11.4.4.

Controlled BSE risk

Commodities from the cattle population of a country, *zone* or *compartment* pose a controlled risk of transmitting the BSE agent if the following conditions are met:

- 1) a *risk assessment*, as described in point 1 of Article 11.4.2., has been conducted in order to identify the historical and existing risk factors, and the Member has demonstrated that appropriate measures are being taken to manage all identified risks, but these measures have not been taken for the relevant period of time;
- 2) the Member has demonstrated that Type A *surveillance* in accordance with Articles 11.4.20. to 11.4.22. has been carried out and the relevant points target, in accordance with Table 1, has been met; Type B *surveillance* may replace Type A *surveillance* once the relevant points target is met;
- 3) EITHER:
 - a) there has been no case of BSE or, if there has been a case, every case of BSE has been demonstrated to have been imported or has been diagnosed as 'atypical' BSE and has been completely destroyed, the criteria in points 2 to 4 of Article 11.4.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants, but at least one of the following two conditions applies:
 - i) the criteria in points 2 to 4 of Article 11.4.2. have not been complied with for seven years;
 - ii) it cannot be demonstrated that controls over the feeding of *meat-and-bone meal* or *greaves* derived from ruminants to ruminants have been in place for eight years;

OR

- b) there has been an indigenous case of 'classical' BSE, the criteria in points 2 to 4 of Article 11.4.2. are complied with, and it can be demonstrated through an appropriate level of control and audit, including that of cross contamination, that neither *meat-and-bone meal* nor *greaves* derived from ruminants has been fed to ruminants; and
 - i) all BSE cases; have been completely destroyed;
 - ii) for 'classical' BSE cases only as well as:
 - ⌘) all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or
 - ⌘) if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE cases,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed.

The Member or *zone* will be included in the list of controlled risk only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information for the previous 12 months on *surveillance* results and feed controls be re-submitted annually and changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

Article 11.4.5.

Undetermined BSE risk

The cattle population of a country, *zone* or *compartment* poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements of another category.

Article 11.4.6.

Recommendations for the importation of bovine commodities from a country, zone or compartment posing a negligible BSE risk

For all commodities from cattle not listed in point 1 of Article 11.4.1.

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the country, *zone* or *compartment* complies with the conditions in Article 11.4.3.

Article 11.4.7.

Recommendations for the importation of cattle from a country, zone or compartment posing a negligible BSE risk but where there has been an indigenous case of 'classical' BSE

For cattle selected for export

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

- 1) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b) ~~iii) iv)~~ of Article 11.4.3.;
- 2) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Article 11.4.8.

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

For cattle

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

- 1) the country, *zone* or *compartment* complies with the conditions referred to in Article 11.4.4.;
- 2) cattle selected for export are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as described in point 3b) of Article 11.4.4.;
- 3) cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Annex XXI (contd)

Article 11.4.9.

Recommendations for the importation of cattle from a country, zone or compartment posing an undetermined BSE riskFor cattle

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

- 1) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;
- 2) all BSE cases; have been completely destroyed;
- 3) for 'classical' BSE cases only as well as:
 - a) all cattle which, during their first year of life, were reared with the BSE cases during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or
 - b) if the results of the investigation are inconclusive, all cattle born in the same *herd* as, and within 12 months of the birth of, the BSE cases,

if alive in the country, *zone* or *compartment*, are permanently identified, and their movements controlled, and, when slaughtered or at death, are completely destroyed;

4) cattle selected for export:

- a) are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle as demonstrated in point 2 above;
- b) were born at least two years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 11.4.10.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing a negligible BSE riskFor fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.4.1.)

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

- 1) the country, *zone* or *compartment* complies with the conditions in Article 11.4.3.;
- 2) the cattle from which the *fresh meat* and *meat products* were derived passed ante- and post-mortem inspections;
- 3) in countries with negligible BSE risk where there have been indigenous cases, the cattle from which the *fresh meat* and *meat products* were derived were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Article 11.4.11.

Recommendations for the importation of meat and meat products from a country, zone or compartment posing a controlled BSE riskFor fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.4.1.)

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

Annex XXI (contd)

- 1) the country, *zone* or *compartment* complies with the conditions referred to in Article 11.4.4.;
- 2) the cattle from which the *fresh meat* and *meat products* were derived passed ante- and post-mortem inspections;
- 3) cattle from which the *fresh meat* and *meat products* destined for export were derived were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;
- 4) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
 - a) the tissues listed in points 1 and 2 of Article 11.4.14.,
 - b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age.

Article 11.4.12.

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

For *fresh meat* and *meat products* from cattle (other than those listed in point 1 of Article 11.4.1.)

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

- 1) the cattle from which the *fresh meat* and *meat products* originate:
 - a) have not been fed *meat-and-bone meal* or *greaves* derived from ruminants;
 - b) passed ante- and post-mortem inspections;
 - c) were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process;
- 2) the *fresh meat* and *meat products* were produced and handled in a manner which ensures that such products do not contain and are not contaminated with:
 - a) the tissues listed in points 1 and 3 of Article 11.4.14.,
 - b) nervous and lymphatic tissues exposed during the deboning process,
 - c) mechanically separated meat from the skull and vertebral column from cattle over 12 months of age.

Article 11.4.13.

Recommendations on ruminant-derived meat-and-bone meal or greaves

- 1) Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Article 11.4.3., but where there has been an indigenous case of BSE, should not be traded if such products were derived from cattle born before the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Annex XXI (contd)

- 2) Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country, *zone* or *compartment* defined in Articles 11.4.4. and 11.4.5. should not be traded between countries.

Article 11.4.14.

Recommendations on commodities that should not be traded

- 1) From cattle of any age originating from a country, *zone* or *compartment* defined in Articles 11.4.4. and 11.4.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.
- 2) From cattle that were at the time of *slaughter* over 30 months of age originating from a country, *zone* or *compartment* defined in Article 11.4.4., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.
- 3) From cattle that were at the time of *slaughter* over 12 months of age originating from a country, *zone* or *compartment* defined in Article 11.4.5., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull and vertebral column. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.

Article 11.4.15.

Recommendations for the importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

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

- 1) the *commodities* came from a country, *zone* or *compartment* posing a negligible BSE risk;
- OR
- 2) they originate from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and are derived from cattle which have passed ante- and post-mortem inspections; and that
- a) vertebral columns from cattle over 30 months of age at the time of *slaughter* and skulls have been excluded;
- b) the bones have been subjected to a process which includes all of the following steps:
- i) degreasing,
 - ii) acid demineralisation,
 - iii) acid or alkaline treatment,
 - iv) filtration,
 - v) sterilisation at $\geq 138^{\circ}\text{C}$ for a minimum of 4 seconds,
- or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating).

Article 11.4.16.

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

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

- 1) the tallow came from a country, *zone* or *compartment* posing a negligible BSE risk; or
- 2) it originates from a country, *zone* or *compartment* posing a controlled BSE risk, is derived from cattle which have passed ante- and post-mortem inspections, and has not been prepared using the tissues listed in points 1 and 2 of Article 11.4.14.

Article 11.4.17.

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

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

- 1) the dicalcium phosphate came from a country, *zone* or *compartment* posing a negligible BSE risk; or
- 2) it originates from a country, *zone* or *compartment* posing a controlled or undetermined BSE risk and is a by-product of bone gelatine produced according to Article 11.4.15.

Article 11.4.18.

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

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

- 1) the tallow derivatives originate from a country, *zone* or *compartment* posing a negligible BSE risk; or
- 2) they are derived from tallow meeting the conditions referred to in Article 11.4.16.; or
- 3) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

Article 11.4.19.

Procedures for the reduction of BSE infectivity in meat-and-bone meal

The following procedure should be used to reduce the infectivity of any transmissible spongiform encephalopathy agents which may be present during the production of *meat-and-bone meal* containing ruminant proteins.

- 1) The raw material should be reduced to a maximum particle size of 50 mm before heating.
- 2) The raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

Annex XXI (contd)

Article 11.4.20.

Surveillance: introduction

- 1) Depending on the risk category of a country, *zone* or *compartment* with regard to bovine spongiform encephalopathy (BSE), *surveillance* for BSE may have one or more goals:
 - a) detecting BSE, to a pre-determined design prevalence, in a country, *zone* or *compartment*;
 - b) monitoring the evolution of BSE in a country, *zone* or *compartment*;
 - c) monitoring the effectiveness of a feed ban and/or other risk mitigation measures, in conjunction with auditing;
 - d) supporting a claimed BSE status;
 - e) gaining or regaining a higher BSE status.
- 2) When the BSE agent is present in a country or *zone*, the cattle population will comprise the following sectors, in order of decreasing size:
 - a) cattle not exposed to the infective agent;
 - b) cattle exposed but not infected;
 - c) infected cattle, which may lie within one of three stages in the progress of BSE:
 - i) the majority will die or be killed before reaching a stage at which BSE is detectable by current methods;
 - ii) some will progress to a stage at which BSE is detectable by testing before clinical signs appear;
 - iii) the smallest number will show clinical signs.
- 3) The BSE status of a country, *zone* or *compartment* cannot be determined only on the basis of a *surveillance* programme but should be determined in accordance with all the factors listed in Article 11.4.2. The *surveillance* programme should take into account the diagnostic limitations associated with the above sectors and the relative distributions of infected cattle among them.
- 4) With respect to the distribution and expression of the BSE agent within the sectors described above, the following four subpopulations of cattle have been identified for *surveillance* purposes:
 - a) cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects);
 - b) cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency *slaughter* or condemned at ante-mortem inspection (casualty or emergency *slaughter* or downer cattle);
 - c) cattle over 30 months of age which are found dead or killed on farm, during transport or at an *abattoir* (fallen stock);
 - d) cattle over 36 months of age at routine *slaughter*.
- 5) A gradient is used to describe the relative value of *surveillance* applied to each subpopulation. *Surveillance* should focus on the first subpopulation, but investigation of other subpopulations will help to provide an accurate assessment of the BSE situation in the country, *zone* or *compartment*. This approach is consistent with Articles 11.4.20. to 11.4.22.

- 6) When establishing a *surveillance* strategy, authorities need to take into account the inherent difficulties of obtaining samples on farm, and overcome them. These difficulties include higher cost, the necessity to educate and motivate owners, and counteracting potentially negative socio-economic implications.

Article 11.4.21.

Surveillance: description of cattle subpopulations

1. Cattle over 30 months of age displaying behavioural or clinical signs consistent with BSE (clinical suspects)

Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioural changes such as excitability, persistent kicking when milked, changes in *herd* hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioural changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all Members with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognised that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.

This subpopulation is the one exhibiting the highest prevalence of 'classical' BSE. The accurate recognition, reporting and classification of such animals will depend on the ongoing owner/veterinarian awareness programme. This and the quality of the investigation and *laboratory* examination systems (Article 11.4.2.), implemented by the *Veterinary Services*, are essential for the credibility of the *surveillance* system.

2. Cattle over 30 months of age that are non-ambulatory, recumbent, unable to rise or to walk without assistance; cattle over 30 months of age sent for emergency slaughter or condemned at ante-mortem inspection (casualty or emergency slaughter, or downer cattle)

These cattle may have exhibited some of the clinical signs listed above which were not recognised as being consistent with BSE. Experience in Members where BSE has been identified indicates that this subpopulation is the one demonstrating the second highest prevalence. For that reason, it is the second most appropriate population to target in order to detect BSE.

3. Cattle over 30 months of age which are found dead or killed on farm, during transport or at an abattoir (fallen stock)

These cattle may have exhibited some of the clinical signs listed above prior to death, but were not recognised as being consistent with BSE. Experience in Members where BSE has been identified indicates that this subpopulation is the one demonstrating the third highest prevalence.

4. Cattle over 36 months of age at routine slaughter

Experience in Members where BSE has been identified indicates that this subpopulation is the one demonstrating the lowest prevalence. For that reason, it is the least appropriate population to target in order to detect BSE. However, sampling in this subpopulation may be an aide in monitoring the progress of the epizootic and the efficacy of control measures applied, because it offers continuous access to a cattle population of known class, age structure and geographical origin. Testing of routine slaughter cattle 36 months of age or less is of relatively very little value (Table 2).

Article 11.4.22.

Surveillance activities

In order to implement efficiently a *surveillance* strategy for BSE, a Member should use documented records or reliable estimates of the age distribution of the adult cattle population and the number of cattle tested for BSE stratified by age and by subpopulation within the country, *zone* or *compartment*.

Annex XXI (contd)

The approach assigns 'point values' to each sample, based on the subpopulation from which it was collected and the likelihood of detecting infected cattle in that subpopulation. The number of points a sample is assigned is determined by the subpopulation from which the sample is collected and the age of the animal sampled. The total points accumulation is then periodically compared to the target number of points for a country, *zone* or *compartment*.

A *surveillance* strategy should be designed to ensure that samples are representative of the *herd* of the country, *zone* or *compartment*, and include consideration of demographic factors such as production type and geographic location, and the potential influence of culturally unique husbandry practices. The approach used and the assumptions made should be fully documented, and the documentation retained for seven years.

The points targets and *surveillance* point values in this chapter were obtained by applying the following factors to a statistical model:

- 1) the design prevalence for Type A or Type B *surveillance*;
- 2) a confidence level of 95 percent;
- 3) the pathogenesis, and pathological and clinical expression of BSE:
 - a) sensitivity of diagnostic methods used;
 - b) relative frequency of expression by age;
 - c) relative frequency of expression within each subpopulation;
 - d) interval between pathological change and clinical expression;
- 4) demographics of the cattle population, including age distribution and population size;
- 5) influence of BSE on culling or attrition of animals from the cattle population via the four subpopulations;
- 5) percentage of infected animals in the cattle population which are not detected.

Although the procedure accepts very basic information about a cattle population, and can be used with estimates and less precise data, careful collection and documentation of the data significantly enhance their value. Since samples from clinical suspect animals provide many times more information than samples from healthy or dead-of-unknown-cause animals, careful attention to the input data can substantially decrease the procedure's cost and the number of samples needed. The essential input data are:

- 7) cattle population numbers stratified by age;
- 8) the number of cattle tested for BSE stratified by age and by subpopulation.

This chapter utilises Tables 1 and 2 to determine a desired *surveillance* points target and the point values of *surveillance* samples collected.

Within each of the subpopulations above in a country, *zone* or *compartment*, a Member may wish to target cattle identifiable as imported from countries or *zones* not free from BSE and cattle which have consumed potentially contaminated feedstuffs from countries or *zones* not free from BSE.

All clinical suspects should be investigated, regardless of the number of points accumulated. In addition, animals from the other subpopulations should be tested.

1. Type A surveillance

The application of Type A *surveillance* will allow the detection of BSE around a design prevalence of at least one case per 100,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95 %.

2. Type B surveillance

The application of Type B *surveillance* will allow the detection of BSE around a design prevalence of at least one case per 50,000 in the adult cattle population in the country, *zone* or *compartment* of concern, at a confidence level of 95 %.

Type B *surveillance* may be carried out by countries, *zones* or *compartments* of negligible BSE risk status (Article 11.4.3.) to confirm the conclusions of the *risk assessment*, for example by demonstrating the effectiveness of the measures mitigating any risk factors identified, through *surveillance* targeted to maximise the likelihood of identifying failures of such measures.

Type B *surveillance* may also be carried out by countries, *zones* or *compartments* of controlled BSE risk status (Article 11.4.4.), following the achievement of the relevant points target using Type A *surveillance*, to maintain confidence in the knowledge gained through Type A *surveillance*.

3. Selecting the points target

The *surveillance* points target should be selected from Table 1, which shows target points for adult cattle populations of different sizes. The size of the adult cattle population of a country, *zone* or *compartment* may be estimated or may be set at one million because, for statistical reasons, one million is the point beyond which sample size does not further increase with population size.

Table 1. Points targets for different adult cattle population sizes in a country, zone or compartment.

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	Type A surveillance	Type B surveillance
>1,000,000	300,000	150,000
1,000,000	238,400	119,200
900,001-1,000,000	214,600	107,300
800,001-900,000	190,700	95,350
700,001-800,000	166,900	83,450
600,001-700,000	143,000	71,500
500,001-600,000	119,200	59,600
400,001-500,000	95,400	47,700
300,001-400,000	71,500	35,750
200,001-300,000	47,700	23,850
100,001-200,000	22,100	11,500
90,001-100,000	19,900	9,950
80,001-90,000	17,700	8,850
70,001-80,000	15,500	7,750
60,001-70,000	13,000	6,650
50,001-60,000	11,000	5,500
40,001-50,000	8,800	4,400
30,001-40,000	6,600	3,300
20,001-30,000	4,400	2,200
10,001-20,000	2,100	1,050
9,001-10,000	1,900	950
8,001-9,000	1,600	800
7,001-8,000	1,400	700
6,001-7,000	1,200	600
5,001-6,000	1,000	500
4,001-5,000	800	400
3,001-4,000	600	300
2,001-3,000	400	200
1,001-2,000	200	100

Annex XXI (contd)

4. Determining the point values of samples collected

Table 2 can be used to determine the point values of the *surveillance* samples collected. The approach assigns point values to each sample according to the likelihood of detecting *infection* based on the subpopulation from which the sample was collected and the age of the animal sampled. This approach takes into account the general principles of *surveillance* described in Chapter 1.4. and the epidemiology of BSE.

Because precise aging of the animals that are sampled may not be possible, Table 2 combines point values into five age categories. The point estimates for each category were determined as an average for the age range comprising the group. The age groups were selected on their relative likelihoods of expressing BSE according to scientific knowledge of the incubation of the *disease* and the world BSE experience. Samples may be collected from any combination of subpopulations and ages but should reflect the demographics of the cattle *herd* of the country, *zone* or *compartment*. In addition, Members should sample at least three of the four subpopulations.

Table 2. Surveillance point values for samples collected from animals in the given subpopulation and age category.

Surveillance subpopulation			
Routine slaughter ¹	Fallen stock ²	Casualty slaughter ³	Clinical suspect ⁴
Age \geq 1 year and <2 years			
0.01	0.2	0.4	N/A
Age \geq 2 years and <4 years (young adult)			
0.1	0.2	0.4	260
Age > 4 years and <7 years (middle adult)			
0.2	0.9	1.6	750
Age \geq 7 years and <9 years (older adult)			
0.1	0.4	0.7	220
Age \geq 9 years			
0.0	0.1	0.2	45

If a country, *zone* or *compartment* determines, based on the demographics and epidemiological characteristics of its cattle population, that precise classification of the subpopulations 'casualty or emergency slaughter, or downer cattle' and 'fallen stock' is not possible, these subpopulations may be combined. In such a case, the *surveillance* point values accorded to the combined subpopulation would be that of 'fallen stock'.

The total points for samples collected may be accumulated over a period of a maximum of seven consecutive years to achieve the target number of points determined in Table 1.

Surveillance points remain valid for seven years (the 95th percentile of the incubation period).

Article 11.4.23.

BSE risk assessment: introduction

The first step in determining the BSE risk status of the cattle population of a country or *zone* is to conduct a *risk assessment* (reviewed annually), based on Section 2. of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective.

1. Entry assessment

Entry assessment consists of assessing the likelihood that a 'classical' BSE agent has been introduced via the importation of the following *commodities* potentially contaminated with it a BSE agent:

- a) *meat-and-bone meal* or *greaves*;
- b) live animals;
- c) animal feed and feed ingredients;
- d) products of animal origin for human consumption.

2. Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of cattle to the agent of 'classical' or 'atypical' the BSE agent to cattle, through a consideration of the following:

- a) epidemiological situation concerning BSE agents in the country or *zone*;
- b) recycling and amplification of the BSE agents through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;
- c) the origin and use of ruminant carcasses (including fallen stock), by-products and *slaughterhouse* waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- d) implementation and enforcement of feed bans, including measures to prevent cross-contamination of animal feed; thorough epidemiological investigations of any indigenous case born after the date of the implementation of feed bans should be conducted.

The following recommendations are intended to assist *Veterinary Services* in conducting such a *risk assessment*. They provide guidance on the issues that need to be addressed when conducting a country-based assessment of BSE risk. They apply equally to self-assessment in preparation of dossiers for categorisation of countries. The recommendations are supported by greater detail in the questionnaire used for the submission of data for country assessment.

Article 11.4.24.

The potential for the entry of the BSE agent through the importation of meat-and-bone meal or greaves

~~This point is irrelevant if the exposure assessment outlined below in Article 11.4.27. indicates that *meat-and-bone meal* or *greaves* has not been fed, either deliberately or accidentally, in the past eight years. Nevertheless, d~~Documentation should be provided on the control systems (including relevant legislation) in place to ensure that *meat-and-bone meal* or *greaves* has not been fed to ruminants in the past eight years.

Assumption: That *meat-and-bone meal* or *greaves* of ruminant origin plays the only significant role in BSE transmission.

Question to be answered: Has *meat-and-bone meal*, *greaves*, or feedstuffs containing either been imported within the past eight years? If so, where from and in what quantities?

Rationale: Knowledge of the origin of *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves*, is necessary to assess the likelihood of entry of BSE agent. *Meat-and-bone meal* and *greaves* originating in countries of high BSE risk pose a higher likelihood of entry than that from low risk countries. *Meat-and-bone meal* and *greaves* originating in countries of unknown BSE risk pose an unknown likelihood of entry.

Evidence required:

- Documentation to support claims that *meat-and-bone meal*, *greaves* or feedstuffs containing either *meat-and-bone meal* or *greaves* have not been imported, OR

Annex XXI (contd)

- Where *meat-and-bone meal*, *greaves* or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.
- Documentation on annual volume, by country of origin, of *meat*, *greaves* or feedstuffs containing them imported during the past eight years.
- Documentation describing the composition (on a species and class of stock basis) of the imported *meat-and-bone meal*, *greaves* or feedstuffs containing them.
- Documentation, from the country of production, supporting why the rendering processes used to produce *meat-and-bone meal*, *greaves* or feedstuffs containing them would have inactivated, or significantly reduced the titre of BSE agent, should it be present.
- Documentation describing the fate of imported *meat-and-bone meal* and *greaves*.

Article 11.4.25.

The potential for the entry of the BSE agent through the importation of live ~~animals~~ cattle potentially infected with BSE

Assumptions:

- Countries which have imported ~~ruminants~~ cattle from countries ~~infected~~ with 'classical' BSEs are more likely to experience 'classical' BSE.
- ~~Cattle pose the only known risk although other species are under study.~~
- ~~Animals~~ Cattle imported for breeding may pose a greater risk than ~~animals~~ cattle imported for *slaughter* because of the hypothetical risk of maternal transmission and because they are kept to a greater age than ~~animals~~ cattle imported for *slaughter*.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 2.1.3.).

Question to be answered: Have live ~~animals~~ cattle been imported within the past seven years?

Rationale: The likelihood of entry is dependent on:

- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of ~~geographical~~ the BSE risk;
- feeding and management of the ~~animals~~ cattle in the country of origin;
- ~~use to which of the commodity, has been put as apart from representing risk of developing clinical disease, †The slaughter, rendering and recycling in as meat-and-bone meal of imported animals cattle represents a potential route of exposure of indigenous livestock even if meat-and-bone meal and greaves, or feedstuffs containing them, have not been imported;~~
- ~~species;~~
- dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;
- age at *slaughter*.

Evidence required:

- Documentation on the country of origin of imports. This should identify the country of breeding of ~~animals-cattle~~, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, ~~species~~ and volume of imports.
- Documentation describing the fate of imported ~~animals~~ cattle, including their age at *slaughter*.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.4.26.

The potential for the entry of the BSE agent through the importation of products of animal bovine origin potentially infected with BSE*Assumptions:*

- ~~Semen, embryos, hides and skins or milk~~ Safe commodities as listed in Article 11.4.1. are not considered to play a role in the transmission of BSE.
- Countries which have imported products of animal-bovine origin from countries with 'classical' BSEs are more likely to experience 'classical' BSE.
- Risk is influenced by the date at which imports occurred, relative to the BSE status of the country of origin.
- Risk is proportional to volume of imports (Article 2.1.3.).

Question to be answered: What products of animal origin have been imported within the past seven years?

Rationale: The likelihood of entry is dependent on:

- ~~the species of origin of the animal products and whether these products contain tissues known to contain BSE infectivity (Article 11.4.14.);~~
- country of origin and its BSE status, which will change as more data become available; this may result from the detection of clinical *disease*, or following active *surveillance*, or assessment of ~~geographical~~ the BSE risk;
- feeding and management of the ~~animals-cattle~~ in the country of origin;
- ~~use to which of the commodity, has been put as apart from representing risk of developing clinical disease, †The slaughter, rendering and recycling in as meat-and-bone meal of imported animals cattle represents a potential route of exposure of indigenous livestock even if meat-and-bone meal and greaves, or feedstuffs containing them, have not been imported;~~
- ~~species;~~
- ~~dairy versus meat breeds, where there are differences in exposure in the country of origin because feeding practices result in greater exposure of one category;~~
- age at *slaughter*.

Annex XXI (contd)*Evidence required:*

- Documentation on the country of origin of imports. ~~This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.~~
- Documentation describing origins, ~~species~~ and volume of imports.
- Documentation confirming that these products do not contain tissues listed in Article 11.4.14.
- Documentation describing the end use of imported ~~animal~~ bovine products, and the disposal of waste.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.

Article 11.4.27.

The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of ruminant bovine origin

Assumptions:

- That the consumption by bovines of *meat-and-bone meal* or *greaves* of ruminant bovine origin plays the only significant role in BSE transmission.
- That commercially-available products of animal origin used in animal feeds may contain *meat-and-bone meal* or *greaves* of ruminant bovine origin.
- Safe commodities as listed in Article 11.4.1. Milk and blood are not considered to play a role in the transmission of BSE.

Question to be answered: Has *meat-and-bone meal* or *greaves* of ruminant origin been fed to cattle within the past eight years (see Articles 11.4.3. and 11.4.4.)?

Rationale: If cattle have not been fed products of animal origin (other than milk or blood) potentially containing *meat-and-bone meal* or *greaves* of ruminant bovine origin within the past eight years, *meat-and-bone meal* and *greaves* can be dismissed as a risk.

Article 11.4.28.

The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production

Assumptions:

- ~~BSE has a long incubation period and insidious onset of signs, so cases may escape detection.~~
- ~~Pre-clinical BSE infectivity cannot reliably be detected by any method and may enter rendering, in particular if specified risk materials are not removed.~~
- ~~Tissues most likely to contain high titres of BSE infectivity (brain, spinal cord, eyes) may not be harvested for human consumption and may be rendered.~~
- ~~BSE may manifest in sudden death, chronic disease, or recumbency, and may be presented as fallen stock or materials condemned as unfit for human consumption.~~
- BSE agent survival in rendering is affected by the method of processing. Adequate rendering processes are described in Article 11.4.19.

- BSE agent is present at much higher titres in central nervous system and reticulo-endothelial tissues (so-called 'Specified Risk Materials', or SRM).

Question to be answered: How has animal waste been processed over the past eight years?

Rationale: If potentially infected ~~animals~~ cattle or contaminated materials are rendered, there is a risk that the resulting *meat-and-bone meal* could retain BSE infectivity.

Where *meat-and-bone meal* is utilised in the production of any animal feeds, the risk of cross-contamination exists.

Evidence required:

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.
- Documentation describing the definition and disposal of specified risk material, if any.
- Documentation describing the rendering process and parameters used to produce *meat-and-bone meal* and *greaves*.
- Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of *meat-and-bone meal* in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.
- Documentation describing monitoring and enforcement of the above.

Article 11.4.29.

Conclusions of the risk assessment

The overall risk of 'classical' BSE in the cattle population of a country or *zone* is proportional to the level of known or potential exposure to BSE infectivity. 'Atypical' BSE is considered to occur at a similar low rate in all cattle populations. Both have and the potential for recycling and amplification of the infectivity through livestock feeding practices. For the risk assessment should to conclude whether that the cattle population of a country or zone is free from BSE risk, it should have demonstrated that appropriate measures have been taken to manage any risks identified.

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- Text deleted.

¹ See point 4) of Article 11.4.21.

² See point 3) of Article 11.4.21.

³ See point 2) of Article 11.4.21.

⁴ See point 1) of Article 11.4.21.

NOTE:

The Code Commission encourages Member Countries to review all relevant reports when reviewing this document including the following:

- December 2014 report of the *ad hoc* Group on Antimicrobial Resistance attached to the February 2015 report of the Scientific Commission

CHAPTER 6.7.

HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

Article 6.7.1.

Objective

This chapter provides criteria for the:

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

Article 6.7.2.

Purpose of surveillance and monitoring

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

Surveillance and monitoring of antimicrobial resistance is necessary to:

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

Article 6.7.3.

The development of antimicrobial resistance surveillance and monitoring programmes1. General aspects

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

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

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

Annex XXII (contd)

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

2. Sampling strategies

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

3. Sample size

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

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

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

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

4. Sample sources

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

a) Animal feed

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

b) Food producing animals

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

c) Food

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

5. Type of sample to be collected

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

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

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

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

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

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

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

Annex XXII (contd)6. Bacterial isolates

The following categories of bacteria could be monitored:

a) Animal bacterial pathogens relevant to the countries' priorities

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

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

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

b) Zoonotic bacteria

i) *Salmonella*

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

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

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

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

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

ii) *Campylobacter*

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

iii) Other emerging bacterial pathogens

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

c) Commensal bacteria

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

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

7. Storage of bacterial strains

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

8. Antimicrobial susceptibility testing

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

Appropriately validated antimicrobial susceptibility testing methods should be used in accordance with Guideline 4.4.6. 3.1 of the *Terrestrial Manual*, concerning laboratory methodologies for bacterial antimicrobial susceptibility testing. Antimicrobial susceptibility data should be reported quantitatively (minimum inhibitory concentrations [MICs] or inhibition zone diameters), rather than qualitatively.

9. Recording, storage and interpretation of data

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

Annex XXII (contd)

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

10. Reference laboratory and annual reports

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

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CHAPTER 6.10.

RISK ANALYSIS FOR ANTIMICROBIAL RESISTANCE ARISING FROM THE USE OF ANTIMICROBIAL AGENTS IN ANIMALS

Article 6.10.1.

Recommendations for analysing the risks to animal and human health from antimicrobial resistant microorganisms of animal origin

1. Introduction

Antimicrobial resistance is a naturally occurring phenomenon influenced by many factors. However, ~~the main driving force for the selection of antimicrobial resistance is the use of antimicrobial agents in any environment, including human, animal and other usages (under study).~~ problems related to antimicrobial resistance are inherently related to antimicrobial agent use in any environment, including human and non-human uses.

Antimicrobial resistance associated with the use of *antimicrobial agents* for therapeutic and non-therapeutic purposes has led to the selection and dissemination of antimicrobial resistant microorganisms, with a resulting loss of therapeutic efficacy in animal and human medicine of one or several *antimicrobial agents*.

2. Objective

For the purpose of this chapter, the principal aim of *risk analysis* is to provide Member Countries with a transparent, objective and scientifically defensible method of assessing and managing the human and animal health *risks* associated with the selection and dissemination of resistance arising from the use of *antimicrobial agents* in *animals*.

Guidance on the issue of food-borne antimicrobial resistance related to the non-human use of *antimicrobial agents* is covered by the Codex Guidelines for risk analysis of food-borne antimicrobial resistance (CAC/GL77-2011).

3. The risk analysis process

The components of *risk analysis* described in this chapter are hazard identification, *risk assessment*, *risk management* and *risk communication*.

The chapter includes factors to be considered at various steps of the *risk analysis* process. These factors are not intended to be exhaustive and not all elements may be applicable in all situations.

4. Hazard identification

For the purpose of this chapter, the *hazard* is the resistant microorganism or resistance determinant that emerges as a result of the use of a specific *antimicrobial agent* in *animals*. This definition reflects the potential for resistant microorganisms to cause adverse health effects, as well as the potential for horizontal transfer of genetic determinants between microorganisms. The conditions under which the *hazard* might produce adverse consequences include any scenarios through which humans or *animals* could become exposed to an antimicrobial resistant pathogen, fall ill and then be treated with an *antimicrobial agent* that is no longer effective.

5. Risk assessment

The assessment of the risk to human and animal health from antimicrobial resistant microorganisms resulting from the use of *antimicrobial agents* in *animals* should examine:

Annex XXIII (contd)

- a) the likelihood of emergence of resistant microorganisms arising from the use of an *antimicrobial agent*, or more particularly, dissemination of the resistance determinants if transmission is possible between microorganisms;
- b) consideration of all pathways and their importance, by which humans and *animals* could be exposed to these resistant microorganisms or resistance determinants, together with the likelihood of exposure;
- c) the consequences of exposure in terms of *risks* to human and animal health.

The general principles of *risk assessment* apply equally to both *qualitative* and *quantitative risk assessment*. At a minimum, a *qualitative risk assessment* should always be undertaken.

Article 6.10.2.

Analysis of risks to human health1. Definition of the risk

The infection of humans with microorganisms that have acquired resistance due to antimicrobial usage in *animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the human infection.

2. Hazard identification

- Microorganisms that have acquired resistance (including multiple resistance) arising from the use of an *antimicrobial agent* in *animals*.
- Microorganisms having obtained a resistance determinant from other microorganisms which have acquired resistance arising from the use of an *antimicrobial agent* in *animals*.

The identification of the hazard should include consideration of the class or subclass of the *antimicrobial agent*.

This definition should be read in conjunction with point 4 of Article 6.10.1.

3. Release assessment

A release assessment describes the biological pathways that may lead to the release of resistant microorganisms or resistance determinants into a particular environment due to the use of a specific *antimicrobial agent* in *animals*. It also estimates either qualitatively or quantitatively the probability of that complete process occurring. The release assessment describes the probability of the release of each of the potential *hazards* under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures.

The following factors should be considered in the release assessment:

- animal species, category such as food producing, zoo, entertainment or companion animal, and, where appropriate, production type such as veal calves or dairy cattle, broilers or laying hens, treated with the *antimicrobial agent* in question;
- number of *animals* treated and their age, geographical distribution and, where appropriate, sex;
- prevalence of *infection* or *disease* for which the *antimicrobial agent* is indicated in the target animal population;
- data on trends in *antimicrobial agent* use and changes in farm production systems;

- data on extra-label or off-label use;
- methods and routes of administration of the *antimicrobial agent*;
- dosage regimen (dose, dosing interval and duration of the treatment);
- pharmacokinetics and relevant pharmacodynamics of the *antimicrobial agent*;
- prevalence of pathogens that are likely to develop resistance in an animal species;
- prevalence of commensal bacteria which are able to transfer resistance to human pathogens;
- mechanisms and pathways of direct or indirect transfer of resistance;
- potential linkage of virulence attributes and resistance;
- cross-resistance or co-resistance with other *antimicrobial agents*;
- data on trends and occurrence of resistant microorganisms obtained through surveillance of *animals*, products of animal origin and animal waste products.

4. Exposure assessment

An exposure assessment describes the biological pathways necessary for exposure of humans to the resistant microorganisms or resistance determinants released from a given antimicrobial use in *animals*, and estimates the probability of the exposures occurring. The probability of exposure to the identified *hazards* is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure, species and other characteristics of the human populations exposed.

The following factors should be considered in the exposure assessment:

- human demographics, including population subgroups, and food consumption patterns, including traditions and cultural practices with respect to the preparation and storage of food;
- prevalence of resistant microorganisms in food at the point of consumption;
- microbial load in contaminated food at the point of consumption;
- environmental contamination with resistant microorganisms;
- occurrence in animal feed of resistant microorganisms that have the capacity to become established in the *animals*, thus leading to contamination of food of animal origin;
- transfer of resistant microorganisms and their resistance determinants between humans, *animals* and the environment;
- measures taken for microbial decontamination of food;
- survival capacity and dissemination of resistant microorganisms during the food production process (including slaughtering, processing, storage, transportation and retailing);
- disposal practices for waste products and the likelihood for human exposure to resistant microorganisms or resistance determinants through those waste products;
- capacity of resistant microorganisms to become established in humans;

Annex XXIII (contd)

- human-to-human transmission of the microorganisms under consideration;
- capacity of resistant microorganisms to transfer resistance to human commensal microorganisms and zoonotic agents;
- amount and type of *antimicrobial agents* used to treat humans;
- pharmacokinetics, such as metabolism, bioavailability and distribution to the gastrointestinal flora.

5. Consequence assessment

A consequence assessment describes the relationship between specified exposures to resistant microorganisms or resistance determinants and the consequences of those exposures. A causal process should exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring.

The following factors should be considered in the consequence assessment:

- microbial dose and subsequent host response interactions;
- variation in susceptibility of exposed populations or subgroups of the population;
- variation and frequency of human health effects resulting from loss of efficacy of *antimicrobial agents* and associated costs;
- potential linkage of virulence attributes and resistance;
- changes in food consumption patterns due to loss of confidence in the safety of food products and any associated secondary *risks*;
- interference with antimicrobial therapy in humans;
- importance of the *antimicrobial agent* in human medicine;
- prevalence of resistance in human bacterial pathogens under consideration.

6. Risk estimation

A *risk* estimation integrates the results from the release assessment, exposure assessment and consequence assessment to produce overall estimates of *risks* associated with the *hazards*. Thus, *risk* estimation takes into account the whole of the *risk* pathway from hazard identification to the unwanted consequences.

The following factors should be considered in the *risk* estimation:

- number of people falling ill and the proportion of that number infected with antimicrobial resistant microorganisms;
- adverse effects on vulnerable human sub-population (children, immunocompromised persons, elderly, pregnant, etc.);
- increased severity or duration of infectious *disease*;
- number of person/days of illness per year;

- deaths (total per year; probability per year or reduced life expectancy for a random member of the population or a member of a specific sub-population) linked to antimicrobial resistant microorganisms when compared with deaths linked to sensitive microorganisms of the same species;
- severity of the *disease* caused by the target resistant microorganisms;
- availability and cost of alternative antimicrobial therapy;
- potential impact of switching to an alternative *antimicrobial agent* (e.g. alternatives with potential increased toxicity);
- occurrence of antimicrobial resistance in target pathogens observed in humans;
- consequences of the overall *risk* impacts (e.g. illness and hospitalisation).

7. Risk management components

The OIE defines *risk management* as consisting of the steps described below.

- a) *Risk evaluation* - the process of comparing the *risk* estimated in the *risk assessment* with the reduction in *risk* expected from the proposed *risk management* measures.

- b) Option evaluation

A range of *risk management* options is available to minimise the emergence and dissemination of antimicrobial resistance and these include both regulatory and non-regulatory options, such as the development of codes of practice for the use of *antimicrobial agents* in animal husbandry. *Risk management* decisions need to consider fully the implications of these different options for human health and animal health and welfare and also take into account economic considerations and any associated environmental issues. Effective control of animal *diseases* can have the dual benefits of reducing *risks* to human health associated with both the bacterial pathogen under consideration and antimicrobial resistance.

- c) Implementation

Risk managers should develop an implementation plan that describes how the decision will be implemented, by whom and when *Competent Authorities* should ensure an appropriate regulatory framework and infrastructure.

- d) Monitoring and review

Risk management options should be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

8. Risk communication

Communication with all interested parties should be promoted at the earliest opportunity and integrated into all phases of a *risk analysis*. This will provide all interested parties, including *risk managers*, with the better understanding of *risk management* approaches. *Risk communication* should be also well documented.

Annex XXIII (contd)

Article 6.10.3.

Analysis of risks to animal health1. Definition of the risk

The *infection of animals* with microorganisms that have acquired resistance due to antimicrobial usage in *animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the animal *infection*.

2. Hazard identification

- Microorganisms that have acquired resistance (including multiple resistance) arising from the use of an *antimicrobial agent* in *animals*;
- microorganisms having obtained a resistance determinant from another microorganism which has acquired resistance arising from the use of an *antimicrobial agent* in *animals*.

The identification of the hazard should include considerations of the class or subclass of the *antimicrobial agent*.

This definition should be read in conjunction with point 4 of Article 6.10.1.

3. Release assessment

The following factors should be considered in the release assessment:

- animal species, category such as food producing, zoo, entertainment or companion animal and, where appropriate, production type, such as veal calves or dairy cattle, broilers or laying hens treated with the *antimicrobial agent* in question;
- number of *animals* treated, and their age, geographical distribution and, where appropriate, sex;
- prevalence of *infection* or *disease* for which the *antimicrobial agent* is indicated in the target animal population;
- data on trends in *antimicrobial agent* use and changes in farm production systems;
- data on extra-label or off-label use;
- dosage regimen (dose, dosing interval and duration of the treatment);
- methods and routes of administration of the *antimicrobial agent*;
- the pharmacokinetics and relevant pharmacodynamics of the *antimicrobial agent*;
- site and type of *infection*;
- development of resistant microorganisms;
- mechanisms and pathways of resistance transfer;
- cross-resistance or co-resistance with other *antimicrobial agents*;
- data on trends and occurrence of resistant microorganisms obtained through surveillance of *animals*, products of animal origin and animal waste products.

4. Exposure assessment

The following factors should be considered in the exposure assessment:

- prevalence and trends of resistant microorganisms in clinically ill and clinically unaffected *animals*;
- occurrence of resistant microorganisms in feed and in the animal environment;
- animal-to-animal transmission of the resistant microorganisms and their resistance determinants (animal husbandry practices and movement of *animals*);
- number or percentage of *animals* treated;
- quantity and trends of *antimicrobial agents* used in *animals*;
- survival capacity and dissemination of resistant microorganisms;
- exposure of *wildlife* to resistant microorganisms;
- disposal practices for waste products and the likelihood of animal exposure to resistant microorganisms or resistance determinants through those products;
- capacity of resistant microorganisms to become established in *animals*;
- exposure to resistance determinants from other sources such as water, effluent, waste pollution, etc.;
- pharmacokinetics, such as metabolism, bioavailability, distribution to the gastrointestinal flora;
- transfer of resistant microorganisms and their resistance determinants between humans, *animals* and the environment.

5. Consequence assessment

The following factors should be considered in the consequence assessment:

- microbial dose and subsequent host response interactions;
- variation in *disease* susceptibility of exposed populations and subgroups of the populations;
- variation and frequency of animal health effects resulting from loss of efficacy of *antimicrobial agents* and associated costs;
- potential linkage of virulence attributes and resistance;
- importance of the *antimicrobial agent* in animal health (see OIE list of antimicrobial agents of veterinary importance).

6. Risk estimation

The following factors should be considered in the *risk* estimation:

- additional burden of *disease* due to antimicrobial resistant microorganisms;
- number of therapeutic failures due to antimicrobial resistant microorganisms;
- increased severity and duration of infectious *disease*;
- impact on *animal welfare*;
- estimation of the economic impact and cost on animal health and production;

Annex XXIII (contd)

- deaths (total per year; probability per year or reduced life expectancy for a random member of the population or a member of a specific sub-population) linked to antimicrobial resistant microorganisms when compared with deaths linked to sensitive microorganisms of the same species;
- availability and cost of alternative antimicrobial therapy;
- potential impact of switching to an alternative *antimicrobial agent*, e.g. alternatives with potential increased toxicity.

7. Risk management options and risk communication

The relevant provisions in point 7 of Article 6.10.2. apply.

8. Risk communication

The relevant provisions in point 8 of Article 6.10.2. apply.

- Text deleted.