# MEETING OF THE OIE

**TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

Paris, 11–20 February 2014

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## List of participants

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Annex II

MEETING OF THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 11–20 February 2014

Agenda

A. MEETING WITH THE DIRECTOR GENERAL

Welcome–Director General

B. ADOPTION OF THE AGENDA

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   a) African horse sickness (Chapter 12.1.)
   b) Harmonisation of three vector-borne diseases (bluetongue, epizootic hemorrhagic disease and African horse sickness)

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Item 14 Foot and mouth disease (Chapters 8.6. and 1.6.)

Item 15 Rift Valley fever (Chapter 8.12.)

Item 16 Tularemia (Chapter 8.15.)

Item 17 Infection with *Brucella abortus*, *B. melitensis* and *B. suis* (Chapter 8.X.)

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Item 19  Newcastle disease (Chapter 10.9.)

Item 20  Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia) (Chapters 11.8. and 1.6.)

Item 21  Equine diseases
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Item 22  Infection with peste des petits ruminants virus (Chapters 14.8. and 1.6.)

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Item 27  Review of applications for recognition as OIE collaborating centre

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Item 29  Proposed dates for meetings in September 2014 and February 2015

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The Scientific Commission for Animal Diseases (the Scientific Commission) and the Terrestrial Animal Health Standards Commission (the Code Commission) convened a joint meeting chaired by the OIE Director General on Friday 14 February 2014.

The Director General welcomed and thanked both Commissions for their important work in setting OIE standards. He reiterated that close collaboration between the two Commissions is essential for setting science-based quality standards and thus the joint meeting of the two Commissions is very important.

The key issues discussed during the joint meeting are as follows:

1. **Proposed inclusion of ‘risk-based surveillance’ as a definition in the Glossary**

   The President of the Scientific Commission explained that the Scientific Commission and the ad hoc Group on Epidemiology had noted that the term is commonly used outside the OIE and decided to seek the Code Commission’s advice on its use in the Terrestrial Animal Health Code (Terrestrial Code). He added that the inclusion of this term in the Terrestrial Code might imply several changes to various chapters but it should nevertheless be discussed.

   A Code Commission member replied that while the term does not appear in the Terrestrial Code, its concept has already been introduced. He suggested that the Code Commission undertakes to consider the use of the term in the course of regular updates of the Terrestrial Code chapters and introduce it, if deemed appropriate. The President of the Code Commission stressed that since the concept of surveillance strategies based on risk, or ‘risk-based surveillance’ was already been applied in the Terrestrial Code, it is important to give sufficient justification to Member Countries when current text in the Terrestrial Code would be replaced by this term, where relevant.

   The Scientific Commission supported this approach. The Director General noted that additional definitions, such as ‘passive surveillance’ and ‘active surveillance’ were also needed on surveillance in the Terrestrial Code. He also recalled that the OIE guidelines on surveillance, to be published soon, include the concept of ‘risk-based surveillance’ and that these guidelines in the handbook should be used as a basis for both terrestrial and aquatic animal health surveillance.

2. **Historical freedom**

   The President of the Scientific Commission sought clarification from the Code Commission on whether the provisions in Chapter 1.4. with respect to historical freedom would supersede the provisions in disease-specific chapters or not, in view of the OIE official status recognition for classical swine fever and African horse sickness.

   The Code Commission responded that Article 1.4.6., in particular Article 1.4.6. point 1a, as well as all the horizontal chapters of the Terrestrial Code apply unless otherwise specified in disease-specific chapters. The Code Commission agreed to closely check the text for consistency between Chapter 1.4 and disease-specific chapters in this respect.

3. **Draft chapter on High health status horses subpopulation**

   Considering the significant number of comments from Member Countries on this draft chapter, the President of the Scientific Commission suggested that the purpose of this draft chapter be clarified in both Commissions reports. He recalled that the objective was to first agree on the concept of high health status horses by adopting the proposed generic draft chapter, and then to develop subsequent documents, more detailed and specific.
As regards the draft veterinary certificate for high health status horses subpopulation, the Scientific Commission had raised several questions to be addressed by the ad hoc Group before circulating it for Member Country comments.

The President of the Code Commission agreed with the Scientific Commission’s approach as the decision to first present a concept is similar to the one used for animal welfare (Chapter 7.1.). He also agreed not to circulate the draft certificate, which has not been reviewed by the Code Commission, for Member Country comments at this stage.

The Director General agreed with both Commissions noting that it is important to invite OIE Delegates to discuss the basic concept of the subpopulation at the forthcoming General Session to get green light from the OIE Delegates to adopt the concept and continue with the development of complementary texts.

4. Procedure for reviewing chapters in the Terrestrial Code

To expedite the review and adoption of Terrestrial Code chapters, the Code Commission proposed that the Scientific and Trade Departments share ad hoc Group reports and any relevant documents as soon as available and prior to the Scientific and Code Commission meetings. While retaining that ad hoc Group reports should remain confidential and for internal use only until the relevant Commission’s review and endorsement. Both Commissions agreed to share those reports informally. The Director General suggested that the new Deputy Director General be charged to establish clear procedures for coordination among departments. All ad hoc Group and Working Group reports endorsed by the relevant Specialist Commissions must be annexed to the reports of the relevant Specialist Commissions.

The Director General further emphasised that, whenever needed, the specialised Commissions could invite any OIE staff to ease communication and understanding on specific topics. The Code Commission also pointed out that there is a growing demand from Member Countries with respect to justification for decisions made by Commissions and ad hoc Groups from transparency point of view. It was emphasised that to be fully accountable, each Commission and ad hoc Group should enrich their meeting reports by providing clear and detailed explanation on the rationale for decisions.

5. Foot and mouth disease

The Scientific Commission viewed that Member Country comments referred to the ad hoc Group had been addressed. The Code Commission did not see it possible to devote sufficient time for careful review of this chapter, due to the length of the document and the fact that the Code Commission received the revised chapter only after its current meeting had started. It was agreed that the Code Commission would complete the review of the revised chapter at its September 2014 meeting and circulate the revised chapter for Member Countries with a view to adopting it at the General Session in May 2015. To facilitate this review, it was proposed to invite a member of the Scientific Commission to the September meeting of the Code Commission. To ease Member Countries understanding and avoid any confusion, it was also agreed that the Scientific Commission would circulate the report of the FMD ad hoc Group as an appendix to its report of the next September 2014 meeting. The draft chapter, after being revised by both Commissions, would be circulated for Member Country comments as part of the report of the September 2014 Code Commission meeting with a view to being proposed for adoption in May 2015.

6. Brucellosis

A member of the Scientific Commission who had attended the ad hoc Group meeting explained that the Group had successfully addressed outstanding technical issues in the revised chapter including ones related to surveillance for demonstrating freedom of herds. The Code Commission agreed to undertake the review of the revised chapter in the course of its meeting.
7. Classical swine fever

The Scientific Commission was of the view that the current chapter should remain as it is in view of the first round of official status recognition taking place in 2014/2015 and of further development on the revision of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals with respect to DIVA vaccine. The Code Commission agreed to review the draft chapter once the pending issues had been addressed by the Scientific and the Biological Standards Commissions.

8. Harmonisation of three vector-borne diseases chapters (African horse sickness, bluetongue and epizootic hemorrhagic disease)

The Scientific Commission recalled that the ad hoc Group had reviewed these three chapters with a view to harmonise them but that the degree of harmonisation would depend on specific characteristics of each disease, as indicated in the report of the ad hoc Group annexed to the Scientific Commission report in September 2013. The Scientific Commission proposed that the two departments (Scientific and Technical Department and International Trade Department) jointly prepare a detailed comparison among the three chapters in order to facilitate justifications for the changes to be developed by both Commissions in September 2014. The Code Commission agreed with this approach emphasising that the key is to provide Member Countries with clear justification for the decision on the harmonisation of these chapters.

9. Glanders

While endorsing the update of the current chapter in general, the Scientific Commission did not feel comfortable that the decision on the OIE official status recognition has the support from Member Countries and wider stakeholders. It was also noted that the use of diagnostic tests proposed by the ad hoc Group should be urgently reviewed by the Biological Standards Commission.

The Code Commission undertook to review the revised chapter depending on time availability since it had received the revised chapter and the report of the ad hoc Group after the Commission meeting started.

10. Schmallenberg virus infection

Based on the ad hoc Group report, the Scientific Commission concluded that Schmallenberg virus infection does not meet the criteria for being listed. The Code Commission agreed on this conclusion. The Scientific Commission suggested that the OIE consider, at an appropriate timing, replacing the fact sheet currently on the OIE website with the inclusion in the technical disease cards.

The Director General recalled that listing a disease was not only a trade consideration as animal health, public health and wildlife should also be considered.

11. Atypical bovine spongiform encephalopathy

Both Commissions agreed to discuss how to consider atypical bovine spongiform encephalopathy during their joint meeting in September 2014.

12. Ad hoc Groups to be convened

The Scientific Commission explained that meetings of ad hoc Groups on tuberculosis and African swine fever (ASF) were scheduled to revise or finalise the revision of the Terrestrial Code chapters. The Director General indicated that there was a potential request for official status recognition from ASF by some Member Countries. A Code Commission member stressed the need of updating the ASF chapter given the recent spread of the disease and its trade implications. The Scientific Commission re-iterated that the revision of the chapter has already been scheduled on the programme of the Commission some time ago pending the adoption of the amended chapter on classical swine fever.
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, 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 and available techniques. Correctly applied, the OIE standards they protect provide for animal health and welfare and veterinary public health during production and trade in animals and animal products to take place with an optimal level of animal and veterinary public health safety, based on the most recent scientific information and available techniques.

4) The absence of chapters, articles or recommendations on particular aetiological agents or commodities does not mean that Veterinary Authorities may not apply appropriate animal health and welfare measures.

5) The complete text of the Terrestrial Code is available on the OIE website and may be downloaded from: http://www.oie.int.

B. Terrestrial Code content

1) Key terms and expressions used in more than one chapter in the Terrestrial Code are defined in the Glossary. The reader should be aware of the definitions given in the Glossary. 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 yet been adopted by the World Assembly of OIE Delegates and the particular provisions are thus not yet 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, or zone or compartment.

4) The standards in the chapters of Section 2 are designed to guide the importing country in conducting import risk analysis and making decisions on import measures. The importing country may also use these standards to justify import measures which result in more trade restrictive a higher level of protection than would be achieved by measures based on 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 quality 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.
Annex IV (contd)

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, among others, animal identification, traceability, zoning, compartmentalisation, disposal of dead animals, disinfection, disinsection, disinsectisation 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.

7) The standards in the chapters of Section 5 are designed for the implementation of general sanitary measures for trade. In particular, chapters address veterinary certification and the measures applicable by the exporting, transit and importing countries, especially Members of the World Trade Organization (WTO). Section 5 also includes a range of model veterinary certificates to be used as a harmonised basis for 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 sections of 7 are designed for the implementation of animal welfare measures. The standards cover, including those at the level of production, transport, and slaughter or killing, as well as. Additional standards address 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. Although only listed and emerging diseases, as prescribed in Chapter 1.1., are compulsorily notifiable, Member Countries are encouraged to also provide information to the OIE on other animal health event of epidemiological significance.

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

2) Diagnostic tests and vaccines

The use of specified diagnostic tests and vaccines in Terrestrial Code chapters is recommended with a reference to the relevant section in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (hereafter referred to as the Terrestrial Manual). Chapter 1.3. provides a table summarising the recommended diagnostic tests for OIE listed diseases. Experts responsible for facilities responsible 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 these measures principally concern OIE listed diseases or infections, general standards apply to all health risks. Moreover, they include non-listed diseases and are marked as such for the information of OIE 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, whereas Chapter 6.5. gives an example of a specific on-farm prevention and control plan for the non-listed food borne pathogen Salmonella in poultry, including standards for introduction of live poultry and hatching eggs.

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

4) Trade requirements

International trade animal health measures should be based on OIE standards. A Member Country may authorise the importation of animals or animal products into its territory under conditions more or less restrictive than those recommended by the Terrestrial Code. To scientifically justify more trade restrictive measures, importing countries should conduct a risk analysis conducted in accordance with OIE standards, as described in Chapter 2.1. For Members of the WTO should refer to meet their obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), international trade animal health measures should be based on an OIE standard or an import risk analysis.

Chapters 5.1. to 5.3. describe the obligations and ethics in international trade. Veterinary Authorities and all veterinarians directly involved in international trade should be familiar with these chapters. These chapters also provide guidance for informal mediation by the OIE.

The OIE aims to include an article listing the commodities that are considered safe for trade without the imposition of pathogen-specific sanitary measures, regardless of the status of the country or zone for the agent in question, at the beginning of each disease-specific chapter relating to a specific aetiological agent. In Sections 8 to 15 an article listing the commodities that are considered safe for trade regardless of the status of the country or zone for the agent in question. This is a work in progress and some chapters do not yet contain articles listing safe commodities. In those chapters, where such a list of safe commodities is present, the importing countries should not apply trade restrictions applied to the listed such commodities in relation with respect to the agent in question.

5) International veterinary certificates

An international veterinary certificate is an official document drawn up by the Veterinary Authority of an exporting country in accordance with Chapter 5.1. and Chapter 5.2. Certificates list the animal health requirements and, where appropriate, public health requirements for the exported commodity. The quality of the exporting country's Veterinary Services is essential in providing assurances to trading partners regarding the safety of exported animals and products. The ethical approach of the Veterinary Services' to the provision of veterinary certificates and their history in meeting their notification obligations, is essential in providing assurance to trading partners regarding the safety of exported animals and products.
Annex IV (contd)

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

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

a) list the diseases, infections or infestations for which the importing country is justified in seeking protection in regards to its own disease 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 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, the articles except when articles of the relevant disease chapter specify otherwise, or to Chapter 1.4, when there are no such articles;

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 5.12. contain model certificates as a further guidance to Member Countries, and model certificates that should be used as a baseline.

6) Guidance notes for importers and exporters

Veterinary Authorities are recommended to prepare ‘guidance notes’ to assist importers and exporters. To provide a clear understanding of trade requirements, it is advisable that Veterinary Authorities of Member Countries prepare ‘guidance notes’ to assist importers and exporters. These notes should identify and explain the trade conditions, including the measures to be applied before and after export, during transport and unloading, 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. The guidance notes should advise on all details to be included in the health certification accompanying the consignment to its destination.

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CHAPTER 5.1.

GENERAL OBLIGATIONS RELATED TO CERTIFICATION

Article 5.1.1.

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

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

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

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

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

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

Article 5.1.2.

Responsibilities of the importing country

1) The import requirements included in the international veterinary certificate should assure that commodities introduced into the importing country comply with the standards of the OIE. Importing countries should restrict their requirements to those recommended in the relevant standards of the OIE, necessary to achieve the national appropriate level of protection. If there are no such standards or if the country wishes to establish are more trade restrictive stricter measures, these than the standards of the OIE, they should be based on an import risk analysis.

2) The international veterinary certificate should not include requirements for the exclusion of pathogens or animal diseases which are present in the importing country and are not subject to any official control programme. The measures imposed on imports to manage the risks posed by a specific pathogen or disease should not be more trade restrictive require a higher level of protection than the that provided by measures applied as part of the official control programme operating within the importing country.

3) The international veterinary certificate should not include measures against pathogens or diseases which are not OIE listed, unless the importing country has demonstrated through import risk analysis, carried out in accordance with Section 2., that the pathogen or disease poses a significant risk to the importing country.
Annex V (contd)

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

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

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

Article 5.1.3.

Responsibilities of the exporting country

1) An exporting country should, on request, supply the following to importing countries:

   a) information on the animal health situation and national animal health information systems to determine whether that country is free or has zones or compartments free from listed diseases, including the regulations and procedures in force to maintain its free status;

   b) regular and prompt information on the occurrence of notifiable diseases;

   c) details of the country's ability to apply measures to control and prevent the relevant listed diseases;

   d) information on the structure of the Veterinary Services and the authority which they exercise according to Chapters 3.1. and 3.2.;

   e) technical information, particularly on biological tests and vaccines applied in all or part of the national territory.

2) Veterinary Authorities of exporting countries should:

   a) have official procedures for authorisation of certifying veterinarians, defining their functions and duties as well as conditions of oversight and accountability, including possible suspension and termination of the authorisation;

   b) ensure that the relevant instructions and training are provided to certifying veterinarians;

   c) monitor the activities of the certifying veterinarians to verify their integrity and impartiality.

3) The Veterinary Authority of the exporting country is ultimately accountable for veterinary certification used in international trade.

Article 5.1.4.

Responsibilities in case of an incident related to importation

1) International trade involves a continuing ethical responsibility. Therefore, if within the recognised incubation periods of the various diseases subsequent to an export taking place, the Veterinary Authority becomes aware of the appearance or reappearance of a disease which has been specifically included in the international veterinary certificate, there is an obligation for this Authority to notify the importing country, so that the imported commodities may be inspected or tested and appropriate action be taken to limit the spread of the disease should it have been inadvertently introduced.
2) If a disease condition appears in imported commodities within a time period after importation consistent with the recognised incubation period of the disease, the Veterinary Authority of the exporting country should be informed so as to enable an investigation to be made, since this may be the first available information on the occurrence of the disease in a previously free herd. The Veterinary Authority of the importing country should be informed of the result of the investigation since the source of infection may not be in the exporting country.

3) In case of suspicion, on reasonable grounds, that an official certificate may be fraudulent, the Veterinary Authority of the importing country and exporting country should conduct an investigation. Consideration should also be given to notifying any third country(ies) that may have been implicated. All associated consignments should be kept under official control, pending the outcome of the investigation. The Veterinary Authorities of all countries involved should fully cooperate with the investigation. If the certificate is found to be fraudulent, every effort should be made to identify those responsible so that appropriate action can be taken according to the relevant legislation.
For the purposes of the *Terrestrial Code*:

**Emerging disease**

means a new occurrence in an animal of a disease, infection or infestation, causing which has a significant impact on animal or public health, of a disease, infection or infestation resulting from:
- a change of an known existing pathogenic agent, a known infection or infestation or its spreading to a new geographic area or species population; or
- a previously unrecognised pathogenic agent or disease diagnosed for the first time and which has a significant impact on animal or public health.

**Risk assessment**

means the scientific 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.

**Stamping-out policy**

means carrying out under the authority of the Veterinary Authority, on confirmation of a disease, the killing of the animals which are affected and those suspected of being affected in the herd and, where appropriate, those in other herds which have been exposed to infection by direct animal to animal contact, or by indirect contact of a kind likely to cause the transmission of with the causal pathogen. All susceptible animals, vaccinated or unvaccinated, on an infected premises establishments should be killed and their carcasses destroyed by burning or burial, or by any other method 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 procedures defined in the *Terrestrial Code*.

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.
CHAPTER 1.1.

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

Article 1.1.1.

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

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

Article 1.1.2.

1) Member Countries shall make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases, and their aetiological agents, and to assist in achieving better worldwide control of these diseases.

2) To achieve this, Member Countries shall comply with the notification requirements specified in Article 1.1.3. and 1.1.3.bis.

3) To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the official OIE disease reporting format.

4) The detection of the aetiological agent of a listed disease in an animal should be reported, even in the absence of clinical signs. Recognising that scientific knowledge concerning the relationship between diseases and their aetiological agents is constantly developing and that the presence of an aetiological agent does not necessarily imply the presence of a disease, Member Countries shall ensure, through their reports, that they comply with the spirit and intention of point 1 above. This means that the detection of the aetiological agent of a listed disease in an animal should be reported, even in the absence of clinical signs.

5) In addition to notifying new findings in accordance with Articles 1.1.3. and 1.1.3.bis, Member Countries shall also provide information on the measures taken to prevent the spread of diseases, infections and infestations. Information shall including include quarantine measures and restrictions on the movement of animals, animal products, biological products and other miscellaneous objects which could by their nature be responsible for their transmission. In the case of diseases transmitted by vectors, the measures taken against such vectors shall also be specified.

Article 1.1.3.

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

1) in accordance with relevant provisions in the disease-specific chapters, notification through the World Animal Health Information System (WAHIS) or by fax or e-mail, within 24 hours, of any of the following events:
   a) first occurrence of a listed disease, infection or infestation in a country, a zone or a compartment;
   b) re-occurrence of a listed disease, infection or infestation in a country, a zone or a compartment following a the final report that declared the outbreak ended;
Annex VII (contd)

c) first occurrence of a new strain of a pathogen of a listed disease, infection or infestation in a country, a zone or a compartment;

d) a sudden and unexpected change increase in the distribution, or increase in incidence or virulence of, or morbidity or mortality caused by, the aetiological agent of a listed disease, infection or and infestation prevalent present within a country, a zone or a compartment;

e) an emerging disease with significant morbidity or mortality, or zoonotic potential;

f) evidence of change in the epidemiology occurrence of a listed disease, infection or infestation in an unusual host species (including host range, pathogenicity, strain) in particular if there is a zoonotic impact;

2) weekly reports subsequent to a notification under point 1 above, to provide further information on the evolution of the event which justified the notification. These reports should continue until the disease, infection or infestation has been eradicated or the situation has become sufficiently stable so that six-monthly reporting under point 3 will satisfy the obligation of the Member Country; in any, for each event notified case, a final report on the event should be submitted;

3) six-monthly reports on the absence or presence, and evolution of listed diseases, infections or infestations and information of epidemiological significance to other Member Countries;

4) annual reports concerning any other information of significance to other Member Countries.

Although Member Countries are only required to notify listed diseases, infections and infestations and emerging diseases according to points 1 to 4 above, they are encouraged to inform the OIE of other important animal health events.

Article 1.1.3.bis

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

1) a notification through WAHIS or by fax or e-mail, when an emerging disease has been detected in a country, a zone or a compartment;

2) periodic reports subsequent to a notification of an emerging disease, as described under point 1. These should continue until:

   a) the disease, infection or infestation has been eradicated; or

   b) the situation becomes sufficiently stable; or

   c) sufficient scientific information is available to determine whether it meets the criteria for listing.

Article 1.1.4.

1) The Veterinary Authority of a country in which an infected zone was located shall inform the Headquarters when this zone is free from the disease, infection or infestation.

2) An infected zone for a particular disease, infection or infestation shall be considered as such until a period exceeding the infective period specified in the Terrestrial Code has elapsed after the last reported case, and when full prophylactic and appropriate animal health measures have been applied to prevent possible reappearance or spread of the disease, infection or infestation. These measures will be found in detail in the various chapters of Volume II of the Terrestrial Code.

3) A Member Country may be considered to regain freedom from a specific disease, infection or infestation when all relevant conditions given in the relevant chapters of the Terrestrial Code have been fulfilled.
4) The Veterinary Authority of a Member Country which sets up one or several free zones shall inform the Headquarters giving necessary details, including the criteria on which the free status is based, the requirements for maintaining the status and indicating clearly the location of the zones on a map of the territory of the Member Country.

Article 1.1.5.

1) Although Member Countries are only required to notify listed diseases, infections and infestations and emerging diseases, they are encouraged to inform the OIE of other important animal health events.

2) The Headquarters shall communicate by e-mail or World Animal Health Information Database (WAHID) to Veterinary Authorities all notifications received as provided in Articles 1.1.2. to 1.1.4. and other relevant information.

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CHAPTER 1.2.

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

Article 1.2.1.

Introduction

The aim of this chapter is to describe the criteria for the inclusion of diseases, infections and infestations on the OIE list. The objective of listing is to support Member Countries’ efforts to prevent the transboundary spread of important animal diseases, including zoonoses, through transparent and consistent reporting. Each listed disease normally has a corresponding chapter to assist Member Countries in the harmonisation of disease detection, prevention and control. Requirements for notification are detailed in Chapter 1.1. and notifications are to be made through WAHIS or, if not possible, by fax or e-mail as described in Article 1.1.3.

Article 1.2.2.

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

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

AND

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

AND

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

OR

b) The disease has been shown to cause significant morbidity or mortality in domestic animals at the level of a country or a zone.

OR

c) The disease has been shown to, or scientific evidence indicates that it would cause significant morbidity or mortality in wild animal populations.

AND

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

OR

5) The disease or infection is an emerging disease with evidence of zoonotic properties, rapid spread, or significant morbidity or mortality and a case definition is available to clearly identify cases and allow them to be distinguished from other diseases or infections.
Annex VIII (contd)

Article 1.2.3.

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

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

1) The following are included within the category of multiple species diseases, infections and infestations:
   
   - Anthrax
   - Bluetongue
   - Brucellosis (*Brucella abortus*)
   - Brucellosis (*Brucella melitensis*)
   - Brucellosis (*Brucella suis*)
   - Crimean Congo haemorrhagic fever
   - Epizootic haemorrhagic disease
   - Equine encephalomyelitis (Eastern)
   - Foot and mouth disease
   - Heartwater
   - Infection with Aujeszky's disease virus
   - Infection with *Echinococcus granulosus*
   - Infection with *Echinococcus multilocularis*
   - Infection with rabies virus
   - Infection with rinderpest virus
   - Infection with *Trichinella* spp.
   - Japanese encephalitis
   - New World screwworm (*Cochliomyia hominivorax*)
   - Old World screwworm (*Chrysomya bezziana*)
   - Paratuberculosis
   - Q fever
   - Infection with Rift Valley fever virus
   - Surra (*Trypanosoma evansi*)
   - Tularemia
   - Vesicular stomatitis (under study)
   - West Nile fever.
2) The following are included within the category of cattle diseases and infections:

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

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

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

4) The following are included within the category of equine diseases and infections:
   - Contagious equine metritis
   - Dourine
   - Equine encephalomyelitis (Western)
   - Equine infectious anaemia
   - Equine influenza
   - Equine piroplasmosis
   - Glanders
   - Infection with African horse sickness virus
   - Infection with equid herpesvirus-1 (EHV-1)
   - Infection with equine arteritis virus
   - Venezuelan equine encephalomyelitis.

5) The following are included within the category of swine diseases and infections:
   - African swine fever
   - Infection with classical swine fever virus
   - Nipah virus encephalitis
   - Porcine cysticercosis
   - Porcine reproductive and respiratory syndrome
   - Swine vesicular disease (under study)
   - Transmissible gastroenteritis.

6) The following are included within the category of avian diseases and infections:
   - Avian chlamydiosis
   - Avian infectious bronchitis
   - Avian infectious laryngotracheitis
   - Avian mycoplasmosis (*Mycoplasma gallisepticum*)
   - Avian mycoplasmosis (*Mycoplasma synoviae*)
   - Duck virus hepatitis
   - Fowl typhoid
   - Infection with avian influenza viruses
Annex VIII (contd)

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

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

- Myxomatosis
- Rabbit haemorrhagic disease.

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

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

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

- Camelpox
- Leishmaniosis.
CHAPTER 8.16.

VESICULAR STOMATITIS

Article 8.16.1.

General provisions and safe commodities

For the purposes of the Terrestrial Code, the incubation period for vesicular stomatitis (VS) shall be 21 days.

Standards for diagnostic tests are described in the Terrestrial Manual.

When authorising the import or transit of the following commodities and any products made from these commodities, Veterinary Authorities should not require any VS related conditions, regardless of the VS status of the exporting country.

1) milk and milk products;
2) hides and skins;
3) meat and meat products;
4) tallow;
5) gelatine and collagen.

Article 8.16.2.

VS free country

A country may be considered free from VS when:

1) VS is notifiable in the country;
2) no clinical, epidemiological or other evidence of VS has been found during the past two years.

Article 8.16.3.

Trade in commodities

Veterinary Authorities of countries shall consider whether there is a risk with regard to VS in accepting importation or transit through their territory, from other countries, of ruminants, swine, Equidae, and their semen and embryos.

Article 8.16.4.

Recommendations for importation from VS free countries

For domestic cattle, sheep, goats, pigs and horses

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

1) showed no clinical sign of VS on the day of shipment;
2) were kept in a VS free country since birth or for at least the past 21 days.
Annex VIII (contd)

**Article 8.16.5.**

**Recommendations for importation from VS free countries**

For wild bovine, ovine, caprine, porcine and equine animals and deer.

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

1) showed no clinical sign of VS on the day of shipment;

2) come from a VS-free country;

If the country of origin has a common border with a country considered infected with VS:

3) were kept in a quarantine station for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;

4) were protected from insect vectors during quarantine and transportation to the place of shipment.

**Article 8.16.6.**

**Recommendations for importation from countries considered infected with VS**

For domestic cattle, sheep, goats, pigs and horses.

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

1) showed no clinical sign of VS on the day of shipment;

2) were kept, since birth or for the past 21 days, in an establishment where no case of VS was officially reported during that period;

3) were kept in a quarantine station for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;

4) were protected from insect vectors during quarantine and transportation to the place of shipment.

**Article 8.16.7.**

**Recommendations for importation from countries considered infected with VS**

For wild bovine, ovine, caprine, porcine and equine animals and deer.

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

1) showed no clinical sign of VS on the day of shipment;

2) were kept in a quarantine station for the 30 days prior to shipment and were subjected to a diagnostic test for VS with negative results at least 21 days after the commencement of quarantine;

3) were protected from insect vectors during quarantine and transportation to the place of shipment.
Recommendations for importation from VS free countries or zones

For in vivo derived embryos of ruminants, swine and horses

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

1) the donor females were kept in an establishment located in a VS free country or zone at the time of collection;

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

Recommendations for importation from countries or zones considered infected with VS

For in vivo derived embryos of ruminants, swine and horses

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

1) the donor females:
   a) were kept for the 21 days prior to, and during, collection in an establishment where no case of VS was reported during that period;
   b) were subjected to a diagnostic test for VS, with negative results, within the 21 days prior to embryo collection;

2) the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.
CHAPTER 15.4.

SWINE VESICULAR DISEASE

Article 15.4.1.

General provisions

For the purposes of the Terrestrial Code, the incubation period for swine vesicular disease (SVD) shall be 28 days.

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 15.4.2.

SVD-free country

A country may be considered free from SVD when it has been shown that SVD has not been present for at least the past two years.

This period may be nine months for countries in which a stamping-out policy is practised.

Article 15.4.3.

SVD-infected zone

A zone shall be considered as infected with SVD until:

1) at least 60 days have elapsed after the confirmation of the last case and the completion of a stamping-out policy and disinfection procedures, or

2) 12 months have elapsed after the clinical recovery or death of the last affected animal if a stamping-out policy was not practised.

Article 15.4.4.

Trade in commodities

Veterinary Authorities of SVD-free countries may prohibit importation or transit through their territory, from countries considered infected with SVD, of the following commodities:

1) domestic and wild pigs;
2) semen of pigs;
3) fresh meat of domestic and wild pigs;
4) meat products of domestic and wild pigs which have not been processed to ensure the destruction of the SVD virus;
5) products of animal origin (from pigs) intended for use in animal feeding or for agricultural or industrial use which have not been processed to ensure the destruction of the SVD virus;
6) products of animal origin (from pigs) intended for pharmaceutical or surgical use which have not been processed to ensure the destruction of the SVD virus;
7) pathological material and biological products (from pigs) which have not been processed to ensure the destruction of the SVD virus.

Article 15.4.5.

Recommendations for importation from SVD free countries

For domestic pigs

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

1) showed no clinical sign of SVD on the day of shipment;
2) were kept in an SVD free country since birth or for at least the past six weeks.

Article 15.4.6.

Recommendations for importation from SVD free countries

For wild pigs

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

1) showed no clinical sign of SVD on the day of shipment;
2) come from an SVD free country;
3) were kept in a quarantine station for the six weeks prior to shipment.

Article 15.4.7.

Recommendations for importation from countries considered infected with SVD

For domestic pigs

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

1) showed no clinical sign of SVD on the day of shipment;
2) were kept since birth, or for the past six weeks, in an establishment where no case of SVD was officially reported during that period, and that the establishment was not situated in an SVD infected zone;
3) were kept in a quarantine station for the 28 days prior to shipment, and were subjected to the virus neutralisation test for SVD with negative results during that period.

Article 15.4.8.

Recommendations for importation from countries considered infected with SVD

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

1) showed no clinical sign of SVD on the day of shipment;

2) were kept in a quarantine station for the 28 days prior to shipment, and were subjected to the virus neutralisation test for SVD with negative results during that period.

Article 15.4.9.

Recommendations for importation from SVD free countries

For semen of pigs

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

1) the donor animals:
   a) showed no clinical sign of SVD on the day of collection of the semen;
   b) were kept in an SVD free country for not less than six weeks prior to collection;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 15.4.10.

Recommendations for importation from countries considered infected with SVD

For semen of pigs

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

1) the donor animals:
   a) showed no clinical sign of SVD on the day of collection of the semen, and were subjected to the virus neutralisation test for SVD with negative results;
   b) were kept in the exporting country for the 28 days prior to collection, in an establishment or artificial insemination centre where no case of SVD was officially reported during that period, and that the establishment or artificial insemination centre was not situated in an SVD infected zone;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 15.4.11.

Recommendations for importation from SVD free countries

For fresh meat of pigs

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

1) have been kept in an SVD free country since birth or for at least the past 28 days;

2) have been slaughtered in an approved abattoir, and have been subjected to ante- and post-mortem inspections for SVD with favourable results.
Article 15.4.12.

Recommendations for importation from countries considered infected with SVD

For fresh meat of pigs

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

1) have not been kept in an SVD infected zone;
2) have been slaughtered in an approved abattoir not situated in an SVD infected zone, and have been subjected to ante- and post-mortem inspections for SVD with favourable results.

Article 15.4.13.

Recommendations for importation from countries considered infected with SVD

For meat products of pigs

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

1) the entire consignment of meat products comes from animals which have been slaughtered in an approved abattoir and have been subjected to ante- and post-mortem inspections for SVD with favourable results;
2) the meat products have been processed to ensure the destruction of the SVD virus;
3) the necessary precautions were taken after processing to avoid contact of the meat with any source of SVD virus.

Article 15.4.14.

Recommendations for importation from SVD free countries

For products of animal origin (from pigs) intended for use in animal feeding or for agricultural or industrial use

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that these products come from animals which have been kept in an SVD free country since birth or for at least the past 6 weeks.

Article 15.4.15.

Recommendations for importation from SVD free countries

For products of animal origin (from pigs) intended for pharmaceutical or surgical use

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that these products come from animals which:

1) have been kept in an SVD free country since birth or for at least the past six weeks;
2) have been slaughtered in an approved abattoir, and have been subjected to ante- and post-mortem inspections for SVD with favourable results.
Annex VIII (contd)

Article 15.4.16.

Recommendations for importation from countries considered infected with SVD

For meal and flour from blood, meat, defatted bones, hooves and claws (from pigs)

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that these products have been processed to ensure the destruction of the SVD virus.

Article 15.4.17.

Recommendations for importation from countries considered infected with SVD

For bristles (from pigs)

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that these products have been processed to ensure the destruction of the SVD virus, in premises controlled and approved by the Veterinary Authority of the exporting country.

Article 15.4.18.

Recommendations for importation from countries considered infected with SVD

For fertilisers of animal origin (from pigs)

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

1) do not come from an SVD infected zone; or

2) have been processed to ensure the destruction of the SVD virus.

Article 15.4.19.

Recommendations for importation from countries considered infected with SVD

For products of animal origin (from pigs) intended for pharmaceutical or surgical use

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

1) have been processed to ensure the destruction of the SVD virus;

2) come from animals which have not been kept in an SVD infected zone;

3) come from animals which have been slaughtered in an approved abattoir and have been subjected to ante and post-mortem inspections for SVD with favourable results.

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CHAPTER 2.1.

IMPORT RISK ANALYSIS

Article 2.1.1.

Introduction

The importation of animals and animal products involves a degree of disease risk to the importing country. This risk may be represented by one or several diseases or infections.

The principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material. The analysis should be transparent. This is necessary so that the exporting country is provided with clear reasons for the imposition of import conditions or refusal to import.

Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

This chapter alludes to the role of the OIE with respect to the Agreement on the Application of Sanitary and Phytosanitary Measures (the so-called SPS Agreement) of the World Trade Organization (WTO), provides definitions and describes the OIE informal procedure for dispute mediation.

This chapter provides recommendations and principles for conducting transparent, objective and defensible risk analyses for international trade. The components of risk analysis described in this chapter are hazard identification, risk assessment, risk management and risk communication (Figure 1).

![Fig. 1. The four components of risk analysis](image)

The risk assessment is the component of the analysis which estimates the risks associated with a hazard. Risk assessments may be qualitative or quantitative. For many diseases, particularly for those diseases listed in this Terrestrial Code where there are well developed internationally agreed standards, there is broad agreement concerning the likely risks. In such cases it is more likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making. No single method of import risk assessment has proven applicable in all situations, and different methods may be appropriate in different circumstances.
Annex IX (contd)

The process of import risk analysis usually needs to take into consideration the results of an evaluation of Veterinary Services, zoning, compartmentalisation and surveillance systems in place for monitoring of animal health in the exporting country. These are described in separate chapters in the Terrestrial Code.

Article 2.1.2.

Hazard identification

The hazard identification involves identifying the pathogenic agents which could potentially produce adverse consequences associated with the importation of a commodity.

The potential hazards identified would be those appropriate to the species being imported, or from which the commodity is derived, and which may be present in the exporting country. It is then necessary to identify whether each potential hazard is already present in the importing country, and whether it is a notifiable disease or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

Hazard identification is a categorisation step, identifying biological agents dichotomously as potential hazards or not. The risk assessment may be concluded if hazard identification fails to identify potential hazards associated with the importation.

The evaluation of the Veterinary Services, surveillance and control programmes and zoning and compartmentalisation systems are important inputs for assessing the likelihood of hazards being present in the animal population of the exporting country.

An importing country may decide to permit the importation using the appropriate sanitary standards recommended in the Terrestrial Code, thus eliminating the need for a risk assessment.

Article 2.1.3.

Principles of risk assessment

1) Risk assessment should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Risk assessment should be able to accommodate the variety of animal commodities, the multiple hazards that may be identified with an importation and the specificity of each disease, detection and surveillance systems, exposure scenarios and types and amounts of data and information.

2) Both qualitative risk assessment and quantitative risk assessment methods are valid.

3) The risk assessment should be based on the best available information that is in accord with current scientific thinking. The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.

4) Consistency in risk assessment methods should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.

5) Risk assessments should document the uncertainties, the assumptions made, and the effect of these on the final risk estimate.

6) Risk increases with increasing volume of commodity imported.

7) The risk assessment should be amenable to updating when additional information becomes available.
Risk assessment steps

1. Entry assessment

Entry assessment consists of describing the biological pathway(s) necessary for an importation activity to introduce pathogenic agents into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The entry assessment describes the probability of the ‘entry’ of each of the potential hazards (the pathogenic agents) 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. Examples of the kind of inputs that may be required in the entry assessment are:

a) Biological factors
   - species, age and breed of animals
   - agent predilection sites
   - vaccination, testing, treatment and quarantine.

b) Country factors
   - incidence or prevalence
   - evaluation of Veterinary Services, surveillance and control programmes and zoning and compartmentalisation systems of the exporting country.

c) Commodity factors
   - quantity of commodity to be imported
   - ease of contamination
   - effect of processing
   - effect of storage and transport.

If the entry assessment demonstrates no significant risk, the risk assessment does not need to continue.

2. Exposure assessment

Exposure assessment consists of describing the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards (in this case the pathogenic agents) from a given risk source, and estimating the probability of the exposure(s) occurring, either qualitatively (in words) or quantitatively (as a numerical estimate).

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, such as ingestion, inhalation or insect bite, and the number, species and other characteristics of the animal and human populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are:
Annex IX (contd)

a) Biological factors
   - properties of the agent.

b) Country factors
   - presence of potential vectors
   - human and animal demographics
   - customs and cultural practices
   - geographical and environmental characteristics.

c) Commodity factors
   - quantity of commodity to be imported
   - intended use of the imported animals or products
   - disposal practices.

If the exposure assessment demonstrates no significant risk, the risk assessment may conclude at this step.

3. Consequence assessment

Consequence assessment consists of describing the relationship between specified exposures to a biological agent 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. This estimate may be either qualitative (in words) or quantitative (a numerical estimate). Examples of consequences include:

a) Direct consequences
   - animal infection, disease and production losses
   - public health consequences.

b) Indirect consequences
   - surveillance and control costs
   - compensation costs
   - potential trade losses
   - adverse consequences to the environment.

4. Risk estimation

Risk estimation consists of integrating the results from the entry assessment, exposure assessment, and consequence assessment to produce overall measures of risks associated with the hazards identified at the outset. Thus risk estimation takes into account the whole of the risk pathway from hazard identified to unwanted outcome.
For a quantitative assessment, the final outputs may include:

- estimated numbers of *herds, flocks, animals* or people likely to experience health impacts of various degrees of severity over time;

- probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates;

- portrayal of the variance of all model inputs;

- a sensitivity analysis to rank the inputs as to their contribution to the variance of the risk estimation output;

- analysis of the dependence and correlation between model inputs.

**Article 2.1.5.**

**Principles of risk management**

1) *Risk management* is the process of deciding upon and implementing measures to **address the risks identified in the risk assessment** achieve the Member Country's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage risk appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of disease incursions and their consequences and its desire to import commodities and fulfil its obligations under international trade agreements.

2) The international standards of the OIE are the preferred choice of sanitary measures for risk management. The application of these sanitary measures should be in accordance with the intentions in the standards.

**Article 2.1.6.**

**Risk management components**

1) 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 Member Country's appropriate level of protection.

2) Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the risk associated with an importation in order to bring it into line with the Member Countries' appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the risk assessment and then comparing the resulting level of risk with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the risk management options.

3) Implementation - the process of following through with the risk management decision and ensuring that the risk management measures are in place.

4) Monitoring and review - the ongoing process by which the risk management measures are continuously audited to ensure that they are achieving the results intended.
Principles of risk communication

1) *Risk communication* is the process by which information and opinions regarding hazards and risks are gathered from potentially affected and interested parties during a *risk analysis*, and by which the results of the *risk assessment* and proposed *risk management* measures are communicated to the decision-makers and interested parties in the *importing* and *exporting countries*. It is a multidimensional and iterative process and should ideally begin at the start of the *risk analysis* process and continue throughout.

2) A *risk communication* strategy should be put in place at the start of each *risk analysis*.

3) The *communication of the risk* should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.

4) The principal participants in *risk communication* include the authorities in the *exporting country* and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups.

5) The assumptions and uncertainty in the model, model inputs and the *risk* estimates of the *risk assessment* should be communicated.

6) Peer review is a component of *risk communication* in order to obtain scientific critique and to ensure that the data, information, methods and assumptions are the best available.

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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 X (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/flock from which the donor animals have been sourced.

   b) The donor animals should not be situated in a herd/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.
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 X (contd)

Article 4.7.6.

Conditions applicable to the collection and storage of embryos

1. **Media**

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

2. **Equipment**

   a) All equipment used to collect, handle, wash, freeze and store embryos should ideally be new or at least sterilised prior to use as recommended in the IETS Manual.

   b) Used equipment should not be transferred between countries for re-use by the embryo collection team.

Article 4.7.7.

**Optional tests and treatments**

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

Samples may include:

   a) **Non-viable embryos and oocytes**

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

   b) **Embryo collection (flushing) fluids**

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

   c) **Washing fluids**

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

   d) **Samples**

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

2) When treatment of the viable embryos is modified to include additional washings with the enzyme trypsin (see point 2c) 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.
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:

      - Aujeszky's disease (pigs): trypsin treatment required
      - Bluetongue (cattle)
      - Bovine spongiform encephalopathy (cattle)
      - *Brucella abortus* (cattle)
      - Enzootic bovine leukosis
      - Foot and mouth disease (cattle)
      - Infectious bovine rhinotracheitis: 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
   – Classical swine fever.

3. Category 3
   a) Category 3 diseases or pathogenic agents are those for which preliminary evidence indicates that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual, but for which additional in vitro and in vivo experimental data are required to substantiate the preliminary findings.
   b) The following diseases or pathogenic agents are in category 3:
      – Atypical scrapie (not a listed disease)
      – Bovine immunodeficiency virus (not a listed disease)
      – Bovine spongiform encephalopathy (goats) (not a listed disease of goats)
      – Bovine viral diarrhoea virus (cattle)
      – Campylobacter fetus (sheep) (not a listed disease of sheep)
      – Foot and mouth disease (pigs, sheep and goats)
      – Haemophilus somnus (cattle) (not a listed disease)
      – Maedi-visna (sheep)
      – Mycobacterium paratuberculosis (cattle)
      – Neospora caninum (cattle) (not a listed disease)
      – Ovine pulmonary adenomatosis (not a listed disease)
      – Porcine circovirus (type 2) (pigs) (not a listed disease)
      – Porcine reproductive and respiratory disease syndrome (PRRS)
      – Rinderpest (cattle)
      – Swine vesicular 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 X (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)
- Equine rhinopneumonitis
- Equine viral arteritis
- *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)
- Porcine circovirus (type 2) (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).

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CHAPTER 5.2.

CERTIFICATION PROCEDURES

Article 5.2.1.

Protection of the professional integrity of the certifying veterinarian

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

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

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

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

Article 5.2.2.

Certifying veterinarians

Certifying veterinarians should:

1) be authorised by the Veterinary Authority of the exporting country to sign international veterinary certificates;

2) only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party;

3) sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the certifying veterinarian should have verified or be in possession of that documentation before signing;

4) have no conflict of interest in the commercial aspects of the animals or animal products being certified and be independent from the commercial parties.

Article 5.2.3.

Preparation of international veterinary certificates

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

1) Certificates should be designed so as to minimize 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 XI (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 documentation sent directly from the Veterinary Authority of the exporting country to the Veterinary Authority of the importing country. Such systems also 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.

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).
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.
CHAPTER 5.4.

ANIMAL HEALTH MEASURES APPLICABLE BEFORE AND AT DEPARTURE

Article 5.4.1.

Animals for breeding, rearing or slaughter

1) Countries should only authorise the exportation from their territory of *animals for breeding or rearing or animals for slaughter* which are correctly identified and which meet the requirements of the *importing country*.

2) Biological tests and/or *vaccinations* required by the *importing country* should be carried out in accordance with the recommendations in the *Terrestrial Code* and *Terrestrial Manual*, as well as disinfection and disinfestation procedures.

3) Observation of the animals before leaving the country may be carried out either in the establishment where they were reared, or in a *quarantine station*. The animals should be transported to the *place of shipment* in specially constructed *vehicles*, previously cleansed and, if required, disinfected. This must be done without delay and without the *animals* coming into contact with other susceptible *animals*, unless these *animals* have animal health guarantees similar to those of the transported *animals*. An *international veterinary certificate* should attest that the *animals* have been found to be clinically healthy and of the health status agreed by the *importing country* and *exporting country*.

4) The transportation of the *animals for breeding or rearing or animals for slaughter* from the *establishment of origin* to the point of departure from the *exporting country* should be carried out in conformity with the conditions agreed between the *importing country* and *exporting country*.

Article 5.4.2.

Semen, embryos, *ova, oocytes* and hatching eggs

Countries should only undertake the export from its territory of:

1) semen,

2) embryos, *ova* and *oocytes*.

3) *hatching eggs*.

from *artificial insemination centres, collection centres* or farms which meet the requirements of the *importing country*.

Article 5.4.3.

Notification

Countries exporting *animals*, semen, embryos, *ova, oocytes* or *hatching eggs* should inform the country of destination and where necessary the *transit countries* if, after exportation, a *listed disease* occurs within the *incubation period* of that particular *disease*, in the *establishment of origin*, or in an *animal* which was in an *establishment* or in a *market*, at the same time as the exported *animals*.
Annex XII (contd)

Article 5.4.4.

Certificate

Before the departure of animals, semen, embryos, oocytes, hatching eggs and brood-combs of bees, an Official Veterinarian should, within the 24 hours prior to shipment, provide an international veterinary certificate conforming with the models approved by the OIE (as shown in Chapters 5.10. to 5.12.) and worded in the languages agreed upon between the exporting country and the importing country, and, where necessary, with the transit countries.

Article 5.4.5.

Live animals

1) Before the departure of an animal or a consignment of animals on an international journey, the Veterinary Authority of the port, airport or district in which the border post is situated may, if it is considered necessary, carry out a clinical examination of the animal or consignment. The time and place of the examination should be arranged taking into account customs and other formalities and in such a way as not to impede or delay departure.

2) The Veterinary Authority referred to in point 1 above should take necessary measures to:

a) prevent the shipment of animals affected or suspected of being affected with any listed disease or with any other infectious disease as agreed by the importing country and the exporting country;

b) avoid entry into the vehicle of possible vectors or causal agents of infection.

Article 5.4.6.

Products of animal origin

1) Countries should only authorise the export from their territory of meat and products of animal origin intended for human consumption, which are fit for human consumption. They must be accompanied by an international veterinary certificate conforming to the models approved by the OIE (as shown in Chapters 5.10. to 5.12.). These must be worded in the languages agreed upon between the exporting country and the importing country, and, where necessary, with the transit countries.

2) Products of animal origin intended for use in animal feeding, or for pharmaceutical or surgical or agricultural or industrial use, should be accompanied by an international veterinary certificate conforming to the models approved by the OIE (as shown in Chapters 5.10. to 5.12.).
CHAPTER 6.6.

INTRODUCTION TO THE RECOMMENDATIONS FOR CONTROLLING ANTIMICROBIAL RESISTANCE

Article 6.6.1.

Objective

The purpose of Chapters 6.7., 6.8., 6.9. and 6.10. is to provide methodologies for Member Countries to appropriately address the emergence or spread of resistant bacteria from the use of antimicrobial agents in animal husbandry and to contain antimicrobial resistance through controlling the use of antimicrobial agents.

These chapters should be read in conjunction with the standards, codes of practice and guidelines on antimicrobial resistance developed by the Codex Alimentarius Commission.

Antimicrobial agents are essential drugs for human and animal health and welfare. The OIE recognises the need for access to antimicrobial agents in veterinary medicine: antimicrobial agents are essential for treating and controlling infectious diseases in animals. The OIE therefore considers that ensuring continued access to effective antimicrobial agents is important.

The OIE recognises that antimicrobial resistance is a global public and animal health concern that is influenced by the usage of antimicrobial agents in humans, animals and elsewhere. Those working in the human, animal and plant sectors have a shared responsibility to prevent or minimise pressures for the selection of antimicrobial resistance factors in humans and animals. Arising from its mandate for the protection of animal health and food safety, the OIE developed these chapters to provide guidance to Member Countries in regard to risks in the entire animal sectors.

The application of risk assessment measures should be based on relevant international standards on risk analysis and supported by sound data and information when available. The methodologies provided in these chapters should be consulted as part of the standard approach to prevent and reduce antimicrobial resistance.

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CHAPTER 6.9.

RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

Article 6.9.1.

Purpose

This document provides guidance for the responsible and prudent use of antimicrobial agents in veterinary medicine, with the aim of protecting both animal and human health as well as the environment. It defines the respective responsibilities of the Competent Authority and stakeholders such as the veterinary pharmaceutical industry, veterinarians, animal feed manufacturers, distributors and food animal producers who are involved in the authorisation, production, control, importation, exportation, distribution and use of veterinary medicinal products (VMP) containing antimicrobial agents.

Responsible and prudent use is determined taking into account the specifications detailed in the marketing authorisation and their implementation when antimicrobial agents are administered to animals and is part of good veterinary and good agricultural practice.

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

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

Article 6.9.2.

Objectives of responsible and prudent use

Responsible and prudent use includes implementing practical measures and recommendations intended to improve animal health and animal welfare while preventing or reducing the selection, emergence and spread of antimicrobial-resistant bacteria in animals and humans. Such measures include:

1) ensuring the rational use of antimicrobial agents in animals with the purpose of optimising both their efficacy and safety;

2) complying with the ethical obligation and economic need to keep animals in good health;

3) preventing or reducing, as far as possible, the transfer of resistant micro-organisms or resistance determinants within animal populations, the environment and between animals and humans;

4) contributing to the maintenance of the efficacy and usefulness of antimicrobial agents used in animal and human medicine;

5) protecting consumer health by ensuring the safety of food of animal origin with respect to residues of antimicrobial agents.
Article 6.9.3.

Responsibilities of the Competent Authority

1. Marketing authorisation

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

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

The Competent Authority should establish and implement efficient statutory registration procedures that evaluate the quality, safety and efficacy of VMP containing antimicrobial agent(s). According to Article 3.1.2., the Competent Authority should be free from any commercial, financial, hierarchical, political or other pressures which might affect its judgement or decisions.

Member Countries lacking the necessary resources to implement an efficient registration procedure for VMP containing antimicrobial agent(s), and which are importing them, should undertake the following measures:

a) evaluate the efficacy of administrative controls on the import of these VMP;

b) evaluate the validity of the registration procedures of the exporting and manufacturing country as appropriate;

c) develop the necessary technical cooperation with experienced relevant authorities to check the quality of imported VMP as well as the validity of the recommended conditions of use.

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

Marketing authorisation is granted on the basis of the data submitted by the pharmaceutical industry or applicant and only if the criteria of safety, quality and efficacy are met.

Member Countries are encouraged to apply the existing guidelines established by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

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

The Competent Authority should expedite the process for new antimicrobial agent(s) in order to address a specific need for the treatment of animal disease.

2. Quality control of antimicrobial agent(s) and VMP containing antimicrobial agent(s)

Quality controls should be performed:

a) in compliance with the provisions of good manufacturing practices;
b) to ensure that analysis specifications of antimicrobial agent(s) used as active ingredients comply with the provisions of registration documentations (such as monographs) approved by the relevant Competent Authority;

c) to ensure that the quality of antimicrobial agent(s) in the marketed dosage form(s) are is maintained until the expiry date, established under the recommended storage conditions;

d) to ensure the stability of antimicrobial agent(s) when mixed with feed or drinking water;

e) to ensure that all antimicrobial agent(s) and the VMP containing them are manufactured to the appropriate quality and purity in order to guarantee their safety and efficacy.

3. Assessment of therapeutic efficacy

a) Preclinical trials

   i) Preclinical trials should:

   - establish the spectrum of activity of antimicrobial agent(s) against relevant pathogens and non-pathogens (commensals);

   - assess the capacity of the antimicrobial agent(s) to select for resistance in vitro and in vivo, taking into consideration intrinsically resistant and pre-existing resistant strains;

   - establish an appropriate dosage regimen (dose, dosing interval and duration of the treatment) and route of administration necessary to ensure the therapeutic efficacy of the antimicrobial agent(s) and limit the selection of antimicrobial resistance. Pharmacokinetic and pharmacodynamic data and models can assist in this appraisal.

   ii) The activity of antimicrobial agent(s) towards the targeted microorganism should be established by pharmacodynamics. The following criteria should be taken into account:

   - spectrum of activity and mode of action;

   - minimum inhibitory and bactericidal concentrations against recent isolates;

   - time- or concentration-dependent activity or co-dependency;

   - activity at the site of infection.

   iii) The dosage regimens allowing maintenance of effective antimicrobial levels should be established by pharmacokinetics. The following criteria should be taken into account:

   - bio-availability according to the route of administration;

   - distribution of the antimicrobial agent(s) in the treated animal and concentration at the site of infection;

   - metabolism;

   - excretion routes.

   Use of combinations of antimicrobial agents should be scientifically supported.
Annex XIV (contd)

b) Clinical trials

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

i) diversity of the clinical cases encountered when performing multi-centre trials;

ii) compliance of protocols with good clinical practice;

iii) eligibility of studied clinical cases, based on appropriate criteria of clinical and bacteriological diagnoses;

iv) parameters for qualitatively and quantitatively assessing the efficacy of the treatment.

4. Assessment of the potential of antimicrobial agents(s) to select for resistance

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

For this the following may be considered:

a) the concentration of either active antimicrobial agent(s) or metabolite(s) in the gut of the animal (where the majority of potential foodborne pathogens reside) at the defined dosage level;

b) pathway for the human exposure to antimicrobial resistant microorganisms;

c) the degree of cross-resistance;

d) the intrinsic and pre-existing, baseline level of resistance in the pathogens of human health concern in both animals and humans.

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

a) When setting the ADI and MRL for an antimicrobial agent, the safety evaluation should also include the potential biological effects on the intestinal flora of humans.

b) The establishment of an ADI for each antimicrobial agent, and an MRL for each animal-derived food, should be undertaken before a VMP containing it is granted marketing authorisation.

c) For all VMP containing antimicrobial agent(s), withdrawal periods should be established for each animal species in order to ensure compliance with the MRLs, taking into account:

i) the MRLs established for the antimicrobial agent in the target animal edible tissues;

ii) the composition of the product and the pharmaceutical form;

iii) the dosage regimen;

iv) the route of administration.

d) The applicant should describe methods for regulatory testing of residues in food based on the established marker residues.
6. **Protection of the environment**

An assessment of the impact of the proposed antimicrobial use on the environment should be conducted.

7. **Establishment of a summary of product characteristics for each VMP containing antimicrobial agent(s)**

The summary of product characteristics contains the information necessary for the appropriate use of VMP containing **antimicrobial agent(s)** and constitutes the official reference for their labelling and package insert. This summary should contain the following items:

- a) active ingredient and class;
- b) pharmacological properties;
- c) any potential adverse effects;
- d) target animal species and, as appropriate, age or production category;
- e) therapeutic indications;
- f) target micro-organisms;
- g) dosage regimen and route of administration;
- h) withdrawal periods;
- i) incompatibilities and interactions;
- j) storage conditions and shelf-life;
- k) operator safety;
- l) particular precautions before use;
- m) particular precautions for the proper disposal of un-used or expired products;
- n) information on conditions of use relevant to the potential for selection of resistance;
- o) contraindication.

8. **Post-marketing antimicrobial surveillance**

The information collected through existing pharmacovigilance programmes, including lack of efficacy, and any other relevant scientific data, should form part of the comprehensive strategy to minimise antimicrobial resistance. In addition to this, the following should be considered:

- a) **General epidemiological surveillance**

  The surveillance of animal microorganisms resistant to **antimicrobial agent(s)** is essential. The relevant authorities should implement a programme according to Chapter 1.4.

- b) **Specific surveillance**

  Specific surveillance to assess the impact of the use of a specific **antimicrobial agent** may be implemented after the granting of marketing authorisation. The surveillance programme should evaluate not only resistance in target animal pathogens, but also in foodborne pathogens, and commensals if relevant and possible. This will also contribute to general epidemiological surveillance of antimicrobial resistance.
9. **Supply and administration of the VMP containing antimicrobial agents(s)**

The relevant authorities should ensure that all the VMP containing antimicrobial agents(s) used in animals are:

a) prescribed by a veterinarian or other suitably trained person authorised to prescribe VMP containing antimicrobial agents(s) in accordance with the national legislation and under the supervision of a veterinarian;

b) supplied only through licensed or authorised distribution systems;

c) administered to animals by a veterinarian or under the supervision of a veterinarian or by other authorised persons.

The relevant authorities should develop effective procedures for the safe collection and disposal or destruction of unused or expired VMPs containing antimicrobial agents(s). Their labels should have appropriate instructions for disposal and destruction.

10. **Control of advertising**

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

a) complies with the marketing authorisation granted, in particular regarding the content of the summary of product characteristics;

b) is restricted to a veterinarian or other suitably trained person authorised to prescribe VMP containing antimicrobial agents(s) in accordance with the national legislation and under the supervision of a veterinarian.

11. **Training on the usage of antimicrobial agents**

The training on the usage of antimicrobial agents should include all the relevant organisations, such as the Competent Authority, pharmaceutical industry, veterinary schools, research institutes, veterinary professional organisations and other approved users such as food animal owners and manufacturers of medicated animal feed. This training should focus on preserving the effectiveness of antimicrobial agents and include:

a) information on disease prevention, management and mitigation strategies;

b) the ability of antimicrobial agents(s) to select for resistant microorganisms in animals and the relative importance of that resistance to public and animal health;

c) the need to observe responsible use recommendations for the use of antimicrobial agents(s) in animal husbandry in agreement with the provisions of the marketing authorisations;

d) appropriate storage conditions, proper disposal of unused or expired VMP;

e) record keeping.

12. **Research**

The relevant authorities should encourage public- and industry-funded research, for example on methods to identify and mitigate the public health risks associated with specific antimicrobial agent uses, or on the ecology of antimicrobial resistance.
Article 6.9.4.

Responsibilities of the veterinary pharmaceutical industry with regards to VMP containing antimicrobial agents(s).

1. **Marketing authorisation**

   The veterinary pharmaceutical industry has responsibilities to:
   
   a) supply all the information requested by the national Competent Authority;

   b) guarantee the quality of this information in compliance with the provisions of good manufacturing, laboratory and clinical practices;

   c) implement a pharmacovigilance programme and on request, specific surveillance for bacterial susceptibility and resistance data.

2. **Marketing and export**

   For the marketing and export of VMP containing antimicrobial agents(s):

   a) only licensed and officially approved VMP containing antimicrobial agents(s) should be sold and supplied, and then only through licensed/authorised distribution systems;

   b) the pharmaceutical industry should provide quality certificates prepared by the Competent Authority of the exporting and manufacturing countries to the importing country;

   c) the national regulatory authority should be provided with the information necessary to evaluate the amount of antimicrobial agents marketed.

3. **Advertising**

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

   a) distribute information in compliance with the provisions of the granted authorisation;

   b) discourage the advertising of VMP containing antimicrobial agents(s) directly to the food animal producer.

4. **Training**

   The veterinary pharmaceutical industry should participate in training programmes as defined in point 11 of Article 6.9.3.

5. **Research**

   The veterinary pharmaceutical industry should contribute to research as defined in point 12 of Article 6.9.3.

Article 6.9.5.

Responsibilities of wholesale and retail distributors

1) Distributors of VMP containing antimicrobial agents(s) should only do so on the prescription of a veterinarian or other suitably trained person authorised to prescribe VMP containing antimicrobial agents(s) in accordance with the national legislation and under the supervision of a veterinarian. All products should be appropriately labelled.
Annex XIV (contd)

2) The recommendations on the responsible and prudent use of VMP containing antimicrobial agent(s) should be reinforced by retail distributors who should keep detailed records of:
   a) date of supply;
   b) name of prescriber;
   c) name of user;
   d) name of product;
   e) batch number;
   f) expiration date;
   g) quantity supplied;
   h) copy of prescription.

3) Distributors should also be involved in training programmes on the responsible and prudent use of VMP containing antimicrobial agent(s), as defined in point 14 11 of Article 6.9.3. Article 6.9.6.

Responsibilities of veterinarians

The veterinarian’s responsibility is to promote public health, animal health and welfare, including identification, prevention and treatment of animal diseases. The promotion of sound animal husbandry methods, hygiene procedures, biosecurity and vaccination strategies can help to minimise the need for antimicrobial use in food producing animals.

Veterinarians should only prescribe antimicrobial agent(s) for animals under their care.

1. Use of antimicrobial agent(s)

   The responsibilities of veterinarians are to carry out a proper clinical examination of the animal(s) and then:
   a) administer or prescribe antimicrobial agent(s) only when necessary and taking into consideration the OIE list of antimicrobial agents of veterinary importance;
   b) make an appropriate choice of antimicrobial agent(s) based on clinical experience and diagnostic laboratory information (pathogen isolation, identification and antibiogram) where possible;
   c) provide a detailed treatment protocol, including precautions and withdrawal times, especially when prescribing extra-label or off-label use.

2. Choosing antimicrobial agent(s)

   a) The expected efficacy of the treatment is based on:
      i) the clinical experience of the veterinarians, their diagnostic insight and therapeutic judgement;
      ii) diagnostic laboratory information (pathogen isolation, identification and antibiogram);
      iii) pharmacodynamics including the activity towards the pathogens involved;
      iv) the appropriate dosage regimen and route of administration;
      iv) pharmacokinetics and tissue distribution to ensure that the selected therapeutic agent is effective at the site of infection;
vi) the epidemiological history of the rearing unit, particularly in relation to the antimicrobial resistance profiles of the pathogens involved.

Should a first-line antimicrobial treatment fail or should the disease recur, a second-line treatment should ideally be based on the results of diagnostic tests. In the absence of such results, an appropriate antimicrobial agent belonging to a different class or sub-class should be used.

In emergencies, a veterinarian may treat animals without recourse to an accurate diagnosis and antimicrobial susceptibility testing, to prevent the development of clinical disease and for reasons of animal welfare.

b) Use of combinations of antimicrobial agents should be scientifically supported. Combinations of antimicrobial agents may be used for their synergistic effect to increase therapeutic efficacy or to broaden the spectrum of activity.

3. Appropriate use of the VMPs containing antimicrobial agent(s) chosen

A prescription for VMP containing antimicrobial agent(s) should indicate precisely the dosage regimen, the withdrawal period where applicable and the amount of VMP containing antimicrobial agent(s) to be provided, depending on the dosage and the number of animals to be treated.

The extra-label or off-label use of VMP containing antimicrobial agent(s) may be permitted in appropriate circumstances and should be in agreement with the national legislation in force including the withdrawal periods to be used, as applicable. It is the veterinarian’s responsibility to define the conditions of responsible use in such a case including the dosage regimen, the route of administration and the withdrawal period.

The use of compounded VMP containing antimicrobial agent(s) and extra-label or off-label use of registered VMP containing antimicrobial agent(s) should be limited to circumstances where an appropriate registered product is not available.

4. Recording of data

Records on VMP containing antimicrobial agent(s) should be kept in conformity with the national legislation. Information records should include the following:

a) quantities of VMP used per animal species;

b) a list of all VMP supplied to each food producing animal holding;

c) treatment schedules including animal identification and withdrawal period;

d) antimicrobial susceptibility data;

e) comments concerning the response of animals to treatment;

f) the investigation of adverse reactions to antimicrobial treatment, including lack of response due to possible antimicrobial resistance. Suspected adverse reactions should be reported to the appropriate regulatory authorities.

Veterinarians should also periodically review farm records on the use of VMP containing antimicrobial agent(s) to ensure compliance with their directions or prescriptions and use these records to evaluate the efficacy of treatments.
Annex XIV (contd)

5. **Labelling**

All VMP supplied by a *veterinarian* should be labelled according to the national legislation.

6. **Training and continued professional development**

Veterinary professional organisations should participate in the training programmes as defined in point 14 of Article 6.9.3. It is recommended that veterinary professional organisations develop for their members species-specific clinical practice recommendations on the responsible and prudent use of VMP containing *antimicrobial agent*(s).

Article 6.9.7.

**Responsibilities of food animal producers**

1) Food animal producers, with the assistance and guidance of a *veterinarian*, are responsible for implementing animal health and welfare programmes on their farms in order to promote animal health and food safety.

2) Food animal producers should:
   a) draw up a health plan with the attending *veterinarian* that outlines preventive measures (e.g. feedlot health plans, mastitis control plans, endo- and ectoparasite control, *vaccination* programmes and biosecurity measures);
   b) use VMP containing *antimicrobial agent*(s) only on the prescription of a *veterinarian* or other suitably trained person authorised to prescribe VMP containing *antimicrobial agent*(s) in accordance with the national legislation and under the supervision of a *veterinarian*;
   c) use VMP containing *antimicrobial agent*(s) in accordance with product label instructions, including storage conditions, or the instructions of the attending *veterinarian*;
   d) isolate sick *animals*, when appropriate, to avoid the transfer of pathogens; dispose of dead or dying *animals* promptly under conditions approved by the relevant authorities;
   e) address on-farm biosecurity measures and take basic hygiene precautions as appropriate;
   f) comply with and record the recommended withdrawal periods to ensure that residue levels in animal-derived food do not present a risk for the consumer;
   g) use VMP containing *antimicrobial agent*(s) within the expiry date and dispose of unused and expired surplus VMP containing *antimicrobial agent*(s) under conditions safe for the environment;
   h) maintain all the *laboratory* records of bacteriological and susceptibility tests; these data should be made available to the *veterinarian* responsible for treating the *animals*;
   i) keep adequate records of all VMP containing *antimicrobial agent*(s) used, including the following:
      i) name of the product and active substance, batch number and expiry date;
      ii) name of the prescriber and the supplier;
      iii) date of administration;
      iv) identification of the *animal* or group of *animals* to which the *antimicrobial agent* was administered;
      v) clinical conditions treated;
      vi) dosage;
      vii) withdrawal periods including the end-date of the withdrawal periods;
      viii) result of *laboratory* tests;
      ix) effectiveness of therapy;
   j) inform the responsible *veterinarian* of recurrent *disease* problems.
3) Training

Food animal producers should participate in the training programmes as defined in point 11 of Article 6.9.3. It is recommended that food animal producer organisations work in cooperation with the veterinary professional organisations to implement existing guidelines for the responsible and prudent use of VMPs containing antimicrobial agents(s).

Article 6.9.8.

Responsibilities of animal feed manufacturers

1) The supply of medicated feed containing antimicrobial agents to farmers keeping food producing animals by animal feed manufacturers should be allowed only on the prescription of a veterinarian. Alternatively, such medicated feed may be prescribed by other suitably trained persons authorised to prescribe VMP containing antimicrobial agents(s) in accordance with the national legislation and under the supervision of a veterinarian. Animal feed manufacturers preparing medicated feed should do so following rules put in place by the Competent Authority in accordance with the national legislation. All medicated feed and medicated premixes should be appropriately labelled.

2) The regulations and recommendations on the responsible and prudent use of VMP containing antimicrobial agents(s) should be reinforced by animal feed manufacturers who should keep detailed records.

3) Use only approved sources of medications: Animal feed manufacturers preparing medicated feed should ensure that only approved sources of medications are added to feed at a level, and for a species and purpose and species as permitted by the drug premix label or a veterinary prescription.

4) Ensure appropriate labelling with product identification, direction for use and withdrawal time: Animal feed manufacturers preparing medicated feed should ensure that medicated animal feed are labelled with the appropriate information (e.g. level of medication, approved claim, intended species, directions for use, warning, cautions) so as to ensure effective and safe use by the producer.

5) Implement appropriate production practices to prevent contamination of other feed: Animal feed manufacturers preparing medicated feed should implement appropriate production practices to avoid unnecessary carry over and unsafe cross contamination of unmedicated feed.

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CHAPTER 6.10.

RISK ANALYSIS ASSESSMENT 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 public health from antimicrobial resistant microorganisms of animal origin

1. Introduction

Antimicrobial resistance is a naturally occurring phenomenon and the selection or dissemination of antimicrobial resistance can occur or be influenced by factors other than the use of antimicrobial agents. However, problems related to antimicrobial resistance are inherently linked to antimicrobial agent use in any environment, including human and non-human usages. However the selection, emergence or dissemination of antimicrobial resistance can occur or be influenced by through factors other than the use of antimicrobial agents.

Antimicrobial resistance associated with the use of antimicrobial agents for therapeutic and non-therapeutic purposes may lead 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.

The use of antimicrobial agents for therapy, therapeutic and non-therapeutic purposes, prophylaxis and growth promotion in animals can reduce their efficacy in animal and human medicine, through the development of antimicrobial resistant strains of pathogenic microorganisms. This risk may be represented by the loss of therapeutic efficacy of one or several antimicrobial agents drugs and includes the selection and dissemination of antimicrobial resistant microorganisms emergence of multi-resistant micro-organisms.

2. Objective

For the purpose of this chapter, the principal aim of risk analysis, for the purpose of this chapter, for antimicrobial resistance in micro-organisms from animals, is to provide Members 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 development 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 principles of risk analysis are described in Chapter 2.1, Section of this Terrestrial Code. The components of risk analysis described in this chapter are hazard identification, risk assessment, risk management and risk communication.
Annex XV (contd)

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.

A qualitative risk assessment should always be undertaken. Its outcome will determine whether progression to a quantitative risk assessment is feasible and/or necessary.

4. Hazard identification

Hazard identification is defined under the OIE Terrestrial Code in Chapter 2.1.

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 development of resistance in a species of pathogenic micro-organisms, as well as the development of a resistance determinant that may be passed from one species of micro-organisms to another 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 which contains that resistance determinant, fall ill and then be treated with an antimicrobial agent that is no longer effective because of the resistance.

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:

a) the likelihood of emergence of resistant microorganisms arising from the use of an antimicrobial agent(s), or more particularly, dissemination production 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 possible degree likelihood of exposure;

c) the consequences of exposure in terms of risks to human and/or animal health.

The general principles of risk assessment as defined in Chapter 2.1 of the Terrestrial Code applies 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 health

1. Definition of the risk

The infection of humans with microorganisms that have acquired resistance to a specific antimicrobial agent due to the antimicrobial usage used 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(s) in animals.

- Microorganisms having obtained a resistance determinant(s) from other microorganisms which have acquired resistance arising from the use of an antimicrobial agent(s) in animals.
The identification of the hazard must include consideration of the class or subclass of the antimicrobial agent(s). 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 necessary 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 to lead to the release of resistant microorganisms or resistance determinants into a particular environment. It also estimates 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 (e.g., such as veal calves or dairy cattle, broilers or laying hens), of animal treated with the antimicrobial agent(s) in question;
- number of animals treated—sex and their age and their geographical distribution and, where appropriate, sex of those animals;
- 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 potential extra-label or off-label use;
- variation in methods and routes of administration of the antimicrobial agent(s);
- dosage regimen (dose, dosing interval and duration of the treatment) including duration of use;
- the pharmacokinetics and relevant or pharmacodynamics of the antimicrobial agent(s);
- micro-organisms developing resistance as a result of the antimicrobial(s) use prevalence of pathogens that are likely to develop resistance in an animal species host;
- 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 and/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 for the existence of resistant micro-organisms.

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 and the number, species and other characteristics of the human populations exposed.
Annex XV (contd)

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 or other exposure;

- microbial load in contaminated food at the point of consumption or other exposure for quantitative risk assessment;

- environmental contamination with resistant microorganisms;

- occurrence in animal feed of resistant microorganisms in animal feed that have the capacity to become established in the animals, thus leading to contamination of food of animal origin prevalence of animal feed contaminated with resistant microorganisms;

- transfer cycling of resistant microorganisms and their resistance determinants between humans, animals and the environment;

- steps measures taken for of microbial decontamination of food;

- microbial load in contaminated food at the point of consumption;

- survival capacity and dissemination spread redistribution of resistant microorganisms during the food production process (including slaughtering, processing, storage, transportation and retailing);

- disposal practices for waste products and the likelihood opportunity for human exposure to resistant microorganisms or resistance determinants in through those waste products;

- point of consumption of food (professional catering, home cooking);

- variation in consumption and food-handling methods of exposed populations and subgroups of the population;

- capacity of resistant microorganisms to become established in humans;

- 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 in response to treat humans illness;

- pharmacokinetics, such as metabolism, bioavailability and distribution to the gastrointestinal access to intestinal 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 must 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 host response relationships 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 human medicinal practices resulting from reduced confidence in antimicrobials;
- changes in food consumption patterns due to loss of confidence in the safety of food products and any associated secondary risks;
- associated costs;
- interference with first-line or choice antimicrobial therapy in humans;
- importance of the antimicrobial agent in human medicine perceived future usefulness of the antimicrobial (time reference);
- 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 affected with antimicrobial resistant strains of microorganisms;
- adverse effects on vulnerable human sub-population (children, immunocompromised persons, elderly, pregnant, etc.);
- increased severity or duration of infectious disease;
- number of person/year days of illness per year;
- deaths (total per year; probability per year or reduced life expectancy lifetime for a random member of the population or a member of a specific more exposed sub-population) linked to antimicrobial resistant microorganisms when compared with deaths linked to sensitive microorganisms of the same species;
- importance severity of the pathology disease infection caused by the target resistant microorganisms;
- availability and cost existence or absence of alternative antimicrobial therapy;
- potential impact of switching to an alternative antimicrobial agent (e.g. alternatives with potential increased toxicity);
- occurrence incidence of antimicrobial resistance in target pathogens observed in humans;
- consequences of the overall to allow weighted summation of different risk impacts (e.g. illness and hospitalisation).
Annex XV (contd)

7. Risk management components options and risk communication

The OIE defines risk management as consisting of the steps described below. Risk management options and risk communication have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

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 Member Country’s appropriate level of protection.

b) Option evaluation

A range of risk management options is available to minimise the emergence and dissemination spread of antimicrobial resistance and these include both regulatory and non-regulatory risk management options, such as the development of codes of practice concerning 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 certain bacterial diseases of animals will can have the dual benefits of reducing the risks to human health linked to associated with both the bacterial pathogen under consideration and antimicrobial resistance, in cases where the bacterial disease pathogen under consideration has also developed antimicrobial resistance.

c) Implementation

Risk managers should develop an implementation plan that describes how the decision will be implemented, by whom and when National or regional authorities Competent Authorities should ensure an appropriate regulatory framework and infrastructure.

d) Monitoring and review

Risk management options have to 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.

Article 6.10.3.

Analysis of risks to animal health

1. Definition of the risk

The infection of animals with microorganisms that have acquired resistance to from the use of a specific antimicrobial agent(s) due to the 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(s) in animals;

- Microorganisms having obtained a resistance determinant(s) from another microorganisms which have acquired resistance arising from the use of an antimicrobial agent(s) in animals.
The identification of the hazard must include considerations of the class or subclass of the antimicrobial agent(s). 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, (e.g., such as veal calves or dairy cattle, broilers or laying hens) treated with the antimicrobial agent(s) in question;
- number of animals treated, sex, and their age, and their 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 potential extra-label or off-label use;
- dosage regimen (dose, dosing interval and duration of the treatment) including amounts used and duration of treatment use;
- variation in methods and routes of administration of the antimicrobial agent(s);
- the pharmacokinetics or and relevant pharmacodynamics/pharmacokinetics of the antimicrobial agent(s);
- site and type of infection;
- development of resistant microorganisms;
- mechanisms and pathways of resistance transfer;
- cross-resistance and/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 for the existence of resistant micro-organisms.

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 prevalence 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, methods and movement of animals);
- number or percentage of animals treated;
- dissemination of resistant micro-organisms from animals (animal husbandry methods, movement of animals);
- quantity and trends of antimicrobial agent(s) used in animals;
Annex XV (contd)

- treatment regimens (dose, route of administration, duration);
- survival capacity of resistant micro-organisms and dissemination spread of resistant microorganisms;
- exposure of wildlife to resistant microorganisms;
- disposal practices for waste products and the likelihood opportunity for animal exposure to resistant microorganisms or resistance determinants through those products;
- capacity of resistant microorganisms to become established in animals intestinal flora;
- exposure to resistance determinants from other sources such as water, effluent, waste pollution, etc.;
- dose, route of administration and duration of treatment;
- pharmacokinetics, such as metabolism, bioavailability, distribution to the gastrointestinal flora access to intestinal flora;
- transfer cycling 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 - host response relationships 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;
- changes in practices resulting from reduced confidence in antimicrobials;
- associated cost;
- perceived future importance usefulness of the drug antimicrobial agent in animal health (see OIE list of antimicrobial agents of veterinary importance) (time reference).

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;
- economic cost.
− deaths (total per year; probability per year or lifetime reduced life expectancy for a random member of the population or a member of a specific more exposed sub-population) linked to antimicrobial resistant microorganisms when compared with deaths linked to sensitive microorganisms of the same species;

− availability and cost existence or absence of alternative antimicrobial therapy;

− potential impact of switching to an alternative antimicrobial agent, e.g., alternatives with potential increased toxicity;

− estimation of the economic impact and cost on animal health and production;

− incidence of resistance observed in animals.

7. Risk management options components and risk communication

The relevant provisions contained in point 7 of Article 6.9.7, 6.10.2. de apply.

Risk management options and risk communication have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

The relevant recommendations (Articles 2.1.5., 2.1.6., and 2.1.7.) in the Terrestrial Code apply.

A range of risk management options is available to minimize the emergence and spread of antimicrobial resistance and these include both regulatory and non-regulatory risk management options, such as the development of codes of practice concerning the use of antimicrobials 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 certain bacterial diseases of animals will have the dual benefit of reducing the risks linked to antimicrobial resistance, in cases where the bacterial disease under consideration has also developed antimicrobial resistance. Appropriate communication with all stakeholders is essential throughout the risk assessment process.

8. Risk communication

The relevant provisions contained in point 8 of Article 6.9.8, 6.10.2. de apply.

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CHAPTER 7.10.

ANIMAL WELFARE AND BROILER CHICKEN PRODUCTION SYSTEMS

Article 7.10.1.

Definitions

For the purpose of this chapter:

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

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

Article 7.10.2.

Scope

These recommendations cover 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 the broiler 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. 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. Consideration should also be given to the resources provided and the design of the system.
Annex XVI (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. Broilers in commercial flocks should be assessed for gait abnormalities. 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 turns 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 (g) 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 bodyweight. Higher or lower values than expected may indicate welfare problems.

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 XVI (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.

Recommendations

1. Biosecurity and animal health

a) Biosecurity and disease prevention

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

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

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

i) direct transmission from other poultry, domesticated and wild animals and humans,

ii) fomites, such as equipment, facilities and vehicles,

iii) vectors (e.g. arthropods and rodents),

iv) aerosols,

v) water supply,

vi) feed.

b) Animal health management, preventive medicine and veterinary treatment

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

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

If persons in charge are not able to identify the causes of disease, 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 higher air speeds, provision of heat, evaporative cooling and adjusting reducing 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 also 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 be a period for gradual adjustment to lighting changes.

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

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

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

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

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

d) Noise

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

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

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

e) Nutrition

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

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

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

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

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

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

f) Flooring, bedding, resting surfaces and litter quality

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

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

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

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

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

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

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

g) Prevention of feather pecking and cannibalism

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

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

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

h) Stocking density

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

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

i) Outdoor areas

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

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

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

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

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

j) Protection from predators

Broilers should be protected from predators.

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

k) Choice of broiler strain

Welfare and health considerations, in addition to productivity and growth rate, should be taken into account when choosing a strain for a particular location or production system. For example, broilers selected with faster growth rates may have greater risks of metabolic disorders and contact dermatitis which should be mitigated by relevant management procedures. [Under study]

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

l) Painful interventions

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

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

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

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

m) Handling and inspection

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

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

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

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

Cervical dislocation is an accepted method for killing small numbers of individual broilers if carried out competently as described in Article 7.6.17.
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 disease, 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.
Annex XVI (contd)

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

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

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

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

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

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

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Chapter 3.1.

Veterinary Services

Article 3.1.1.

The quality of the Veterinary Services depends on a set of factors, which include fundamental principles of an ethical, organisational, legislative, regulatory and technical nature. The Veterinary Services shall conform to these fundamental principles, regardless of the political, economic or social situation of their country.

Compliance with these fundamental principles by the Veterinary Services of a Member Country is important to the establishment and maintenance of confidence in its international veterinary certificates by the Veterinary Services of other Member Countries.

The same fundamental principles should apply in countries where the responsibility for establishing or applying certain animal health or welfare measures, or issuing some international veterinary certificates is exercised by an organisation other than the Veterinary Services, or by an authority or agency on behalf of the Veterinary Services. In all cases, the Veterinary Services retain ultimate responsibility for the application of these principles.

These fundamental principles are presented in Article 3.1.2. Other factors affecting quality are described in Volume I of the Terrestrial Code (notification, principles of certification, etc.).

The quality of Veterinary Services, including veterinary legislation, can be measured through an evaluation, whose general principles are described in Article 3.1.3. and in Article 3.1.4.

Recommendations on the evaluation of Veterinary Services, including veterinary legislation, are described in Chapter 3.2.

A procedure for evaluating Veterinary Services by OIE experts, on a voluntary basis, is described in Article 3.1.5.

Article 3.1.2.

Fundamental principles of quality

The Veterinary Services shall comply with the following principles to ensure the quality of their activities:

1. Professional judgement

   The personnel of Veterinary Services should have the relevant qualifications, scientific expertise and experience to give them the competence to make sound professional judgements.

2. Independence

   Care should be taken to ensure that Veterinary Services' personnel are free from any commercial, financial, hierarchical, political or other pressures which might affect their judgement or decisions.

3. Impartiality

   The Veterinary Services should be impartial. In particular, all the parties affected by their activities have a right to expect their services to be delivered under reasonable and non-discriminatory conditions.
Annex XVII (contd)

4. **Integrity**

The *Veterinary Services* should guarantee that the work of each of their personnel is of a consistently high level of integrity. Any fraud, corruption or falsification should be identified and corrected.

5. **Objectivity**

The *Veterinary Services* should at all times act in an objective, transparent and non-discriminatory manner.

6. **Veterinary legislation**

_Veterinary legislation_ is prerequisite to support good governance and provide the legal framework for all key activities of the *Veterinary Services*.

Legislation should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations. In particular, it should define and document the responsibilities and structure of the organisations in charge of the _animal identification system_, control of animal movements, animal disease control and reporting systems, epidemiological _surveillance_ and communication of epidemiological information.

A similar demonstration should be made by *Veterinary Services* when they are in charge of veterinary public health activities.

7. **General organisation**

The *Veterinary Services* should be able to demonstrate by means of appropriate legislation, sufficient financial resources and effective organisation that they are in a position able to anticipate the requirements for, and have control of, the establishment and application of animal health and _animal welfare_ measures, and of international veterinary certification activities.

The *Veterinary Services* should have at their disposal effective systems for animal disease _surveillance_ and for _notification_ of disease problems wherever they occur, in accordance with the provisions of the _Terrestrial Code_. Adequate coverage of animal populations should also be demonstrated. They should at all times endeavour to improve their performance in terms of animal health information systems and animal disease control.

The *Veterinary Services* should define and document the responsibilities and structure of the organisation (in particular the chain of command) in charge of issuing _international veterinary certificates_.

Each position within the *Veterinary Services* which has an impact on their quality should be described. These job descriptions should include the requirements for education, training, technical knowledge and experience.

8. **Quality policy**

The *Veterinary Services* should define and document their policy and objectives for, and commitment to, quality, and should ensure that this policy is understood, implemented and maintained at all levels in the organisation. Where conditions allow, they may implement a quality system corresponding to their areas of activity and appropriate for the type, range and volume of work that they have to perform. The recommendations for the quality and evaluation of *Veterinary Services* propose a suitable reference system, which should be used if a Member Country choose to adopt a quality system.

9. **Procedures and standards**

The *Veterinary Services* should develop and document appropriate procedures and standards for all providers of relevant activities and associated facilities. These procedures and standards may for example relate to:
a) programming and management of activities, including international veterinary certification activities;
b) prevention, control and notification of disease outbreaks;
c) risk analysis, epidemiological surveillance and zoning;
d) emergency preparedness for disasters which could have impact on animal health and welfare disaster preparedness;
e) inspection and sampling techniques;
f) diagnostic tests for animal diseases;
g) preparation, production, registration and control of biological products for use in the diagnosis or prevention of diseases;
h) border controls and import regulations;
i) disinfection and disinestation;
j) treatments intended to destroy, if appropriate, pathogens in animal products.

Inasmuch as the OIE has adopted standards on these matters, the Veterinary Services should comply with these standards when applying animal health measures and when issuing international veterinary certificates.

10. Information, complaints and appeals

The Veterinary Authority should undertake to reply to legitimate requests from Veterinary Authorities of other Member Countries or any other authority, in particular ensuring that any requests for information, complaints or appeals that they may present are dealt with in a timely manner.

A record should be maintained of all complaints and appeals and of the relevant action taken by the Veterinary Services.

11. Documentation

The Veterinary Services should have at their disposal a reliable and up-to-date documentation system suited to their activities.

12. Self-evaluation

The Veterinary Services should undertake periodical self-evaluation especially by documenting achievements against goals, and demonstrating the efficiency of their organisational components and resource adequacy.

A procedure for evaluating Veterinary Services by OIE experts, on a voluntary basis, is described in Article 3.1.5.

13. Communication

Veterinary Services should have effective internal and external systems of communication covering administrative and technical staff and parties affected by their activities.
Annex XVII (contd)

14. Human and financial resources

Responsible authorities should ensure that adequate resources are made available to implement effectively the above activities.

Article 3.1.3.

For the purposes of the Terrestrial Code, every Member Country should recognise the right of another Member Country to undertake, or request it to undertake, an evaluation of its Veterinary Services where the initiating Member Country is an actual or a prospective importer or exporter of commodities and where the evaluation is to be a component of a risk analysis process which is to be used to determine or review sanitary measures which apply to such trade.

Any evaluation of Veterinary Services should be conducted having regard to the OIE recommendations on the evaluation of Veterinary Services presented in Chapter 3.2.

A Member Country has the right to expect that the evaluation of its Veterinary Services will be conducted in an objective manner. A Member Country undertaking evaluation should be able to justify any measure taken as a consequence of its evaluation.

Article 3.1.4.

A Member Country which intends to conduct an evaluation of another Member Country's Veterinary Services should give them notice in writing. This notice should define the purpose of the evaluation and details of the information required.

On receipt of a formal request for information to enable an evaluation of its Veterinary Services by another Member Country, and following bilateral agreement of the evaluation process and criteria, a Member Country should expeditiously provide the other country with meaningful and accurate information of the type requested.

The evaluation process should take into account the fundamental principles and other factors of quality laid down in Article 3.1.1. and in Article 3.1.2. It should also take into consideration the specific circumstances regarding quality, as described in Article 3.1.1., prevailing in the countries concerned.

The outcome of the evaluation conducted by a Member Country should be provided in writing as soon as possible, and in any case within four months of receipt of the relevant information, to the Member Country which has undergone the evaluation. The evaluation report should detail any findings which affect trade prospects. The Member Country which conducts the evaluation should clarify in detail any points of the evaluation on request.

In the event of a dispute between two Member Countries over the conduct or the conclusions of the evaluation of the Veterinary Services, the matter should be dealt with having regard to the procedures set out in Article 5.3.8.

Article 3.1.5.

Evaluation facilitated by OIE experts under the auspices of the OIE

The OIE has established procedures for the evaluation of the Veterinary Services of a Member Country, upon request by the Member Country.

The World Assembly of OIE Delegates endorses a list of approved experts to facilitate the evaluation process.

Under these procedures, the Director General of the OIE recommends an expert(s) from that list.
The expert(s) facilitate(s) the evaluation of the Veterinary Services of the Member Country based on the provisions in Chapter 3.2., using the OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool).

The expert(s) produce(s) a report in consultation with the Veterinary Services of the Member Country.

The report is submitted to the Director General of the OIE and, with the consent of the Member Country, published by the OIE.

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 XVIII (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.
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 of the Terrestrial Code. 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.

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.
Annex XVIII (contd)

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.

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 resources

1. 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 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.

Article 3.2.7.

Legislation and functional capabilities

1. 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 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 destruction of infected animals, disposal of
carcasses, or destruction of contaminted 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.
Annex XVIII (contd)

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.
Annex XVIII (contd)

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.

Article 3.2.9.

Veterinary public health controls

1. 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.
Annex XVIII (contd)

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.

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 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.
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.

Evaluation of the veterinary statutory body

1. 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.
Annex XVIII (contd)

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.

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 zoonosanitary 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:
          Numbers associated with farm livestock sector on a majority time basis in a veterinary capacity, by geographical area [Show categories and numbers to differentiate staff involved in field service, laboratory, administration, import and export and other functions, as applicable.]:
          – full time government veterinarians: national and sub-national;
          – part time government veterinarians: national and sub-national;
          – other veterinarians.
iv) Veterinary public health:

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

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

v) Numbers of veterinarians relative to certain national indices:

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

vi) Veterinary education:

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

vii) Veterinary professional associations.

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:

– 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 information

a) 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.
Annex XVIII (contd)

4. Administration details

a) Accommodation

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

b) Communications

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

c) Transport

i) Itemised numbers of types of functional transport available on a full-time basis for the Veterinary Services. In addition provide details of transport means available part-time.

ii) Details of annual funds available for maintenance and replacement of motor vehicles.

5. Laboratory services

a) Diagnostic laboratories (laboratories engaged primarily in diagnosis)

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

ii) Numbers of veterinary diagnostic laboratories operating in the country:

   – government operated laboratories;

   – 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.

iii) Descriptive summary of accreditation procedures and standards for private laboratories.

iv) Human and financial resources allocated to the government veterinary laboratories, including staff numbers, graduate and post-graduate qualifications and opportunities for further training.

v) List of diagnostic methodologies available against major diseases of farm livestock (including poultry).

vi) List of related National Reference Laboratories, if any.

vii) Details of collaboration with external laboratories including international reference laboratories and details on numbers of samples submitted.

viii) Details of quality control and assessment (or validation) programmes operating within the veterinary laboratory service.

ix) Recent published reports of the official veterinary laboratory service which should include details of specimens received and foreign animal disease investigations made.

x) Details of procedures for storage and retrieval of information on specimen submission and results.
Annex XVIII (contd)

xi) Reports of independent reviews of the laboratory service conducted by government or private organisations (if available).

xii) Strategic and operational plans for the official veterinary laboratory service (if available).

b) Research laboratories (laboratories engaged primarily in research)

i) Numbers of veterinary research laboratories operating in the country:
   - government operated laboratories;
   - private laboratories involved in full time research directly related to animal health and veterinary public health matters involving production animal species.

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

iii) Published programmes of future government sponsored veterinary research.

iv) Annual reports of the government research laboratories.

6. Veterinary legislation, regulations and functional capabilities

a) Animal health and 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 animal health and welfare disaster management of disasters which could have impact on animal health and 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.
Annex XVIII (contd)

b) Export and import inspection

i) Assessment of the adequacy and implementation of relevant national legislation concerning:
   - veterinary public health controls of the production, processing, storage and transportation of meat for export;
   - veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other food of animal origin for export;
   - animal health and veterinary public health controls of the export and import of animals, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;
   - animal 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.

7. Animal health 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;
Annex XVIII (contd)

– 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) 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.
Annex XVIII (contd)

- Descriptive summary of the role and relationships of other official organisations involved in monitoring and control of zoonoses to be provided if the Veterinary Authority does not have these responsibilities.

iii) Chemical residue testing programmes

- Descriptive summary of national surveillance and monitoring programmes for environmental and chemical residues and contaminants applied to animal-derived foodstuffs, animals and animal feedstuffs.

- Role and function in these programmes of the Veterinary Authority and other Veterinary Services to be described in summary form.

- Descriptive summary of the analytical methodologies used and their consistency with internationally recognised standards.

iv) Veterinary medicines

- Descriptive summary of the administrative and technical controls involving registration, supply and use of veterinary pharmaceutical products especially including biological products. This summary should include a focus on veterinary public health considerations relating to the use of these products in food-producing animals.

- Role and function in these programmes of the Veterinary Authority and other Veterinary Services to be described in summary form.

8. 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.

9. 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).
Annex XVIII (contd)

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.

10. Membership of the OIE

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

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CHAPTER 3.3.

COMMUNICATION

Article 3.3.1.

General considerations

In general, communication entails the exchange of information between various individual, institutional and public groups for purposes of informing, guiding and motivating action. The application of the science and technique of communication involves modulating messages according to situations, objectives and target audiences.

The recognition of communication as a discipline of the Veterinary Services and its incorporation within it is critical for their operations. The integration of veterinary and communication expertise is essential for effective communication.

Communication should be an integral part of all the activities of the Veterinary Services including animal health (surveillance, early detection and rapid response, prevention and control), animal welfare and veterinary public health (food safety, zoonoses) and veterinary medicine.

Objectives of this chapter on communication for the Veterinary Services are to provide guidance for the development of a communication system, strategic and operational communication plans and elements to assess their quality.

Article 3.3.2.

Principles of communication

1) Veterinary Services should have the authority and capability to communicate on matters within their mandate.

2) Veterinary and communication expertise should be combined, and have established linkages with relevant agencies, particularly for animal health and welfare disaster management of disasters which could have impact on animal health and welfare, and for exotic disease control.

3) Communication should be targeted and follow the fundamental criteria of transparency, consistency, timeliness, balance, accuracy, honesty and empathy and respect the fundamental principles of quality of Veterinary Services (Article 3.1.2.).

4) Communication should be a continuous process.

5) Veterinary Services should have oversight of planning, implementing, monitoring, evaluating and revising their strategic and operational communication plans.

Article 3.3.3.

Definitions

Communication: means the discipline of informing, guiding and motivating individual, institutional and public groups, ideally on the basis of interactive exchanges, about any issue under the competence of the Veterinary Services.

Crisis: means a situation of great threat, difficulty or uncertainty when issues under the competence of the Veterinary Services require immediate action.
Annex XIX (contd)

**Crisis communication:** means the process of communicating information as accurately as possible, albeit potentially incomplete, within time constraints in the event of a crisis.

**Outbreak communication:** means the process of communicating in the event of an outbreak. Outbreak communication includes notification.

Article 3.3.4.

**Communication system**

In addition to the Principles of Communication the following elements should be used in conjunction with Chapter 3.1., when planning, implementing and assessing a communication system:

1. Organisational chart indicating a direct link between the communication personnel and the Veterinary Authority, through the chain of command, such as dedicated communication unit or communication officer

2. Human resources
   a) Identified and accessible official communication focal point
   b) Job descriptions of communication personnel identifying roles and responsibilities
   c) Sufficient number of qualified personnel with knowledge, skills, attitude and abilities relevant to communication
   d) Continuous training and education on communication provided to communication personnel.

3. Financial and physical resources
   a) Clearly identified budget for communication that provides adequate funding
   b) Provision or access to appropriate material resources in order to carry out roles and responsibilities: suitable premises or accommodation that is adequately equipped with sufficient office and technical equipment, including information technology and access to the Internet.

4. Management of the communication system
   a) Roles and responsibilities of the communication personnel
      i) Report to the Veterinary Authority
      ii) Engage in decision-making process by providing guidance and expertise on communication issues to the Veterinary Services
      iii) Be responsible for the planning, implementation and evaluation of the strategic and operational plans for communication and relevant standard operating procedures
      iv) Function as contact point on communication issues for the Veterinary Services with established linkages to relevant Competent Authorities with which Veterinary Services collaborate
      v) Provide and coordinate continuous education on communication for the Veterinary Services.
b) Strategic plan for communication

A well-designed strategic plan for communication should support the Veterinary Services strategic plan and have management support and commitment. The strategic plan for communication should address all high level organization-wide long-term communication objectives.

A strategic plan for communication should be monitored, periodically reviewed and should identify measurable performance objectives and techniques to assess the effectiveness of communication.

The strategic plan for communication should consider the different types of communication: routine communication, risk communication, outbreak communication and crisis communication, to allow individuals, affected or interested parties, an entire community or the general public to make best possible decisions and be informed of policy decisions and their rationale.

The key outcomes in effectively implementing a strategic plan for communication are increased knowledge and awareness of issues by the public and stakeholders, higher understanding of the role of the Veterinary Services, higher visibility of and improved trust and credibility in the Veterinary Services. These will enhance understanding or acceptance of policy decisions and subsequent change of perception, attitude or behaviour.

c) Operational plans for communication

Operational plans for communication should be based on the assessment of specific issues and should identify specific objectives and target audiences such as staff, partners, stakeholders, media and the general public.

Each operational plan for communication should consist of a well-planned series of activities using different techniques, tools, messages and channels to achieve intended objectives and utilizing available resources within a specific timeframe.

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CHAPTER 12.1.
INFECTION WITH AFRICAN HORSE SICKNESS VIRUS

Article 12.1.1.

General provisions

For the purposes of the Terrestrial Code, African horse sickness (AHS) is defined as an infection of equids with African horse sickness virus (AHSV).

The following defines an infection with AHSV:

1) AHSV has been isolated and identified from an equid or a product derived from that equid; or

2) viral antigen or viral ribonucleic acid (RNA) specific to a serotype of AHSV has been identified in samples from an equid showing clinical signs consistent with AHS, or epidemiologically linked to a suspected or confirmed case infection; or

3) serological evidence of active infection with AHSV by detection of seroconversion with production of antibodies against structural or nonstructural proteins of AHSV that are not a consequence of vaccination have been identified in an equid that either shows clinical signs consistent with AHS, or is epidemiologically linked to a suspected or confirmed case infection.

For the purposes of the Terrestrial Code, the infective period for African horse sickness virus (AHSV) shall be 40 days for domestic horses. Although critical information is lacking for some species, this chapter applies to all equidae.

All countries or zones adjacent to a country or zone not having free status should determine their AHSV status from an ongoing surveillance programme. Throughout the chapter, surveillance is in all cases understood as being conducted as described in Article 12.1.1311 to 12.1.1513.

The following defines a case of African horse sickness (AHS):

1) AHSV has been isolated and identified from an equid or a product derived from that equid; or

2) viral antigen or viral RNA specific to one or more of the serotypes of AHSV has been identified in samples from one or more equids showing clinical signs consistent with AHS, or epidemiologically linked to a suspected or confirmed case; or

3) serological evidence of active infection with AHSV by detection of seroconversion with production of antibodies to structural or nonstructural proteins of AHSV that are not a consequence of vaccination have been identified in one or more equids that either show clinical signs consistent with AHS, or epidemiologically linked to a suspected or confirmed case.

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

Article 12.1.2.

AHS free AHSV free country or zone free from infection with AHSV

1) A country or zone may be considered free from infection with AHSV when African horse sickness (infection with AHSV) is notifiable in the whole country, systematic vaccination is prohibited, importation of equids and their semen, oocytes or embryos are carried out in accordance with this chapter, and either:
Annex XX (contd)

1) In order for a country or zone to be declared free of African horse sickness virus (AHSV), it must either:
   a) have a historical record of freedom as described in Chapter 1.4. that demonstrates no evidence of AHSV; or
   b) have not reported any case of AHSV infection for at least two years and is not adjacent to an infected country or zone; or
   c) have a surveillance programme that has demonstrated no evidence of AHSV in the country or zone for at least twenty-four months; or
   d) have not reported any case of AHSV infection for at least 40 days and a surveillance programme that has demonstrated no evidence of Culicoides for at least two years in the country or zone.

2) An AHS free country or zone free from infection with AHSV which is adjacent to an infected country or infected zone should include a zone in which surveillance is conducted in accordance with Articles 12.1.1311. to 12.1.1513. as relevant. 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 AHS transmission.

3) An AHS free country or zone free from infection with AHSV will not lose its free status through the importation of vaccinated or seropositive or vaccinated equids and their semen, oocytes or embryos from infected countries or infected zones, provided these imports are carried out in accordance with this chapter.

4) To qualify for inclusion in the list of AHSV free countries or zones, a Member Country should:
   a) have a record of regular and prompt animal disease reporting;
   b) send a declaration to the OIE stating:
      i) the section under point 1) on which the application is based;
      ii) no routine vaccination against AHS has been carried out during the past twelve months year in the country or zone;
      iii) equids are imported in accordance with this chapter;
   c) supply documented evidence that:
      i) surveillance in accordance with Articles 12.1.1311. to 12.1.1513. is applied, unless historically free in accordance with Article 1.4.6.;
      ii) regulatory measures for the early detection, prevention and control of infection with AHSV have been implemented.

5) The Member Country will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 4b)ii) and iii) and 4c) ii) above be re-submitted annually and changes in the epidemiological situation or other significant events be reported to the OIE according to the requirements in Chapter 1.1., and in particular, formally state that:
   a) there has been no outbreak of AHS during the past twelve months year in the country or zone;
   b) no evidence of infection with AHSV infection has been found during the past twelve months year in the country or zone.
Article 12.1.3.

AHSV seasonally free zone

1) An AHSV seasonally free zone is a part of an infected country or an infected zone in which for part of a year, ongoing surveillance and monitoring consistently demonstrated neither evidence of AHSV transmission nor the evidence of the presence of adult Culicoides.

2) AHS is notifiable in the whole country.

3) For the application of Articles 12.1.8., 12.1.10. and 12.1.11., the seasonally free period is:
   a) taken to commence the day following the last evidence of AHSV transmission and of the cessation of activity of adult Culicoides as demonstrated by an ongoing surveillance programme, and
   b) taken to conclude either:
      i) at least 40 days before the earliest date that historical data show AHSV activity has recommenced; or
      ii) immediately when current climatic data or data from a surveillance and monitoring programme indicate an earlier resurgence of activity of adult Culicoides vectors.

4) An AHSV seasonally free zone will not lose its free status through the importation of vaccinated or seropositive equids and their semen, oocytes or embryos from infected countries or infected zones, provided these imports are carried out in accordance with this chapter.

Article 12.1.43.

AHSV infected country or zone

For the purpose of this chapter, an AHSV infected country or zone is one that does not fulfil the requirements to qualify as either AHSV free country or zone, AHS free from infection with AHSV or AHSV seasonally free zone.

Article 12.1.54.

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

In the event of limited outbreaks within an AHS free country or zone, including within a protection zone, a single containment zone, which includes all cases, and should be large enough to contain any potentially infected vectors, can be established for the purpose of minimising the impact on the entire country or zone. Such a zone should include all cases and can be established within a protection zone. For this to be achieved, the Veterinary Authority should provide documented evidence that:

1) the outbreaks are limited based on the following factors:
   a) immediately on suspicion, a rapid response including notification has been made;
   b) standstill of movements of equids has been imposed, and effective controls on the movement of equids and their products specified in this chapter are in place;
   c) epidemiological investigation (trace-back, trace-forward) has been completed;
   d) the infection has been confirmed;
Annex XX (contd)

e) the primary outbreak and likely source of the outbreak has been identified; investigations on the likely source of the outbreak have been carried out;

f) all cases have been shown to be epidemiologically linked;

g) no new cases have been found in the containment zone within a minimum of two infective periods as defined in Article 12.1.1;

2) the equids within the containment zone should be are clearly identifiable as belonging to the containment zone;

3) increased passive and targeted surveillance in accordance with Articles 12.1.13 to 12.1.15 in the rest of the country or zone has not detected any evidence of infection;

4) animal health measures are in place to that effectively prevent the spread of AHSV infection to the rest of the country or zone, taking into consideration the establishment of a protection zone within the containment zone, the seasonal vector conditions and existing physical, geographical and ecological barriers;

5) ongoing surveillance in accordance with Articles 12.1.13 to 12.1.15 is in place in the containment zone.

The free status of the areas outside the containment zone is suspended pending the establishment of while the containment zone is being established in accordance with points 1 to 5 above. The free status of the areas outside the containment zone could may be reinstated irrespective of the provisions of Article 12.1.65, once the containment zone is recognised by the OIE.

In the event of the recurrence of AHSV infection in the containment zone, the approval of the containment zone is withdrawn.

The recovery of the AHSV free status of the containment zone should follow the provisions of Article 12.1.65.

Article 12.1.65.

Recovery of free status

To regain the free status when an AHS outbreak occurs in an AHS free country or zone previously free from infection with AHSV, to regain the free status, the provisions of Article 12.1.2. apply, irrespective of whether emergency vaccination has been applied or not.

Article 12.1.76.

Recommendations for importation from AHS free AHSV free countries or zones free from infection with AHSV

For equids

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

1) showed no clinical sign of AHS on the day of shipment;

2) have not been vaccinated against AHS within the last 40 days;

3) were kept in an AHS free, an AHSV free country, area or zone free from infection with AHSV since birth or for at least 40 days prior to shipment;
4) either:
   a) did not transit through an infected zone during transportation to the place of shipment; or
   b) were protected from attacks from Culicoides at all times when transiting through an infected zone.

Article 12.1.8.

Recommendations for importation from AHSV seasonally free zones during the seasonally free period

For equids

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

1) showed no clinical signs of AHS on the day of shipment;

2) have not been vaccinated against AHS within the last 40 days;

3) and either
   a) were kept in an AHSV seasonally free zone during the seasonally free period since birth or for at least 40 days prior to shipment; or
   b) were held in isolation in a vector-protected establishment prior to shipment
      i) for a period of at least 28 days and a serological test according to the Terrestrial Manual to detect antibodies to the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the vector-protected establishment; or
      ii) for a period of at least 40 days and serological tests according to the Terrestrial Manual to detect antibodies against AHSV were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least seven days after introduction into the vector-protected establishment; or
      iii) for a period of at least 14 days and an agent identification tests according to the Terrestrial Manual was carried out with a negative result on a blood sample collected not less than 14 days after introduction into the vector-protected establishment;

4) were protected from attacks from Culicoides at all times when transiting through an infected zone.

Article 12.1.97.

Recommendations for importation from AHSV infected countries or zones

For equids

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

1) showed no clinical sign of AHS on the day of shipment;

2) have not been vaccinated against AHS within the last 40 days;

3) were held in isolation in a vector-protected establishment
Annex XX (contd)

a) for a period of at least 28 days and a serological test according to the Terrestrial Manual to detect antibodies to against the AHSV group, was carried out with a negative result on a blood sample collected at least 28 days after introduction into the vector-protected establishment; or

b) for a period of at least 40 days and serological tests according to the Terrestrial Manual to detect antibodies against AHSV were carried out with no significant increase in antibody titre on blood samples collected on two occasions, with an interval of not less than 21 days, the first sample being collected at least seven days after introduction into the vector-protected establishment; or

c) for a period of at least 14 days and an agent identification tests according to the Terrestrial Manual was carried out with a negative results on a blood samples collected not less than 14 days after introduction into the vector-protected establishment; or

d) for a period of at least 40 days and were vaccinated, at least 40 days before shipment, in accordance with the Terrestrial Manual against all serotypes whose presence in the source population has been demonstrated through a surveillance programme in accordance with Articles 12.1.14 and 12.1.15, and were identified in the accompanying certification as having been vaccinated;

4) were protected from attacks by Culicoides at all times during transportation, (including transportation to and at the place of shipment).

Article 12.1.48.

Recommendations for the importation of equine semen

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

1) showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;

2) had not been immunised against AHS with a live attenuated vaccine within 40 days prior to the day of collection;

3) were either:

   a) kept in an AHS free AHSV free country or free zone free from infection with AHSV, or from an AHSV seasonally free zone (during the seasonally free period) for at least 40 days before commencement of, and during collection of, the semen, or

   b) kept in an AHSV free vector-protected artificial insemination centre throughout the collection period, and subjected to either:

      i) a serological test according to the Terrestrial Manual to detect antibodies to against the AHSV group, carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of semen; or

      ii) agent identification tests according to the Terrestrial Manual carried out with negative results on blood samples collected at commencement and conclusion of, and at least every seven days, during semen collection for this consignment.

Article 12.1.49.

Recommendations for the importation of in vivo derived equine embryos or oocytes

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that:
Annex XX (contd)

1) the donor animals:
   a) showed no clinical sign of AHS on the day of collection of the embryos or oocytes and for the following 40 days;
   b) had not been immunised against AHS with a live attenuated vaccine within 40 days prior to the day of collection;
   c) were either:
      i) kept in an AHS free, AHSV free country or zone free from infection with AHSV or from an AHSV seasonally free zone (during the seasonally free period) for at least 40 days before commencement of, and during collection of the embryos or oocytes, or
      ii) kept in an AHSV free vector-protected collection centre throughout the collection period, and subjected to either:
         ▪ a serological test according to the Terrestrial Manual to detect antibodies against the AHSV group carried out with a negative result on a blood sample collected at least 28 days and not more than 90 days after the last collection of embryos or oocytes; or
         ▪ agent identification tests according to the Terrestrial Manual carried out with negative results on blood samples collected at commencement and conclusion of, and at least every seven days during embryos or oocytes collection for this consignment;

2) the embryos were collected, processed and stored in conformity with the provisions of Chapter 4.7. or Chapter 4.9., as relevant;

3) semen used to fertilise the oocytes, complies at least with the requirements in Article 12.1.108.

   Article 12.1.108.

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 should at least comprise the following;

   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 manufacturers’ instruction;
   c) vector surveillance and control within and around the building;
   d) measures to limit or eliminate breeding sites for vectors in vicinity of the establishment or facility;
   e) Standard Operating Procedure, including description of back-up and alarm systems, for operation of the establishment or facility and transport of horses equids to the place of loading.
Annex XX (contd)

2. During transportation

When transporting equids through AHSV infected countries or AHSV infected zones, 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:

Potential risk management strategies include a combination of:

i) treating animals with chemical repellents prior to and during transportation, in sanitized vehicles treated with appropriate residual contact insecticide;

ii) loading, transporting and unloading animals at times of low vector activity (i.e. bright sunshine and low temperature);

iii) ensuring vehicles do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;

iv) darkening the interior of the vehicle, for example by covering the roof or sides of vehicles with shade cloth;

v) monitoring surveillance for vectors at common stopping and offloading points to gain information on seasonal variations;

vi) using historical, ongoing or AHS modelling information on AHS to identify low risk ports and transport routes.

b) Transport by air:

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

Crates, containers or jet stalls in which equids are being transported and the cargo hold of the aircraft should be sprayed with an approved insecticide when the doors have been just after the aircraft are closed and prior to take-off, or immediately prior to the closing of the aircraft doors after loading. 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 of from infection with AHSV, prior to, or immediately after 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 all crates, containers or jet stalls.

Article 12.1.4311.

Introduction to surveillance: introduction

Articles 12.1.4311 to 12.1.4513 define the principles and provide guidance on surveillance for AHSV infection, complementary to Chapter 1.4. and, for vectors, complementary to Chapter 1.5.

AHS is a vector-borne infection transmitted by a limited number of species of Culicoides insects. Unlike the related bluetongue virus, AHSV is so far geographically restricted to sub Saharan Africa with periodic excursions into North Africa, southwest Europe, the Middle East and adjacent regions of Asia. An important component of AHSV epidemiology is vectorial capacity which provides a measure of disease risk that incorporates vector competence, abundance, seasonal incidence, biting rates, survival rates and the extrinsic incubation period. However, methods and tools for measuring some of these vector factors remain to be developed, particularly in a field context.
According to this chapter, a Member Country demonstrating freedom from AHSV infection 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. This requires the support of a laboratory able to undertake identification of AHSV infection through the virus detection and antibody tests described in the Terrestrial Manual.

Susceptible captive wild, feral and wild equine populations should be included in the surveillance programme.

For the purposes of surveillance, a case refers to an equid infected with AHSV.

The purpose of surveillance is to determine if a country or zone is free from infection with AHSV or if a zone is seasonally free from AHSV. Surveillance deals not only with the occurrence of clinical signs caused by AHSV, but also with evidence of infection with AHSV in the absence of clinical signs.

Article 12.1.412.

Surveillance: General surveillance conditions and methods for surveillance

1) A surveillance system should be under the responsibility of the Veterinary Authority. In particular the following should be in place:

a) a formal and ongoing system for detecting and investigating outbreaks of disease;

b) a procedure for the rapid collection and transport of samples from suspected cases of AHSV infection to a laboratory for AHS diagnosis as described in the Terrestrial Manual;

c) a system for recording, managing and analysing diagnostic, epidemiologic and surveillance data.

2) The AHSV infection surveillance programme should:

a) In a country/zone free or seasonally free country or zone, the surveillance programme for AHS should include an early warning system which obliges persons who have regular contact with equids, as well as diagnosticians, to report promptly any suspicion of AHSV infection to the Veterinary Authority. An effective surveillance system will periodically identify suspicious suspected cases that require follow-up and investigation to confirm or exclude that the cause of the condition is AHS. 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 AHSV infection should be investigated immediately and samples should be taken and submitted to a laboratory. This requires that sampling kits and other equipment are available for those responsible for surveillance;

b) conduct in an AHS infected country or zone, random or targeted serological and virological surveillance appropriate to the epidemiological situation, infection status of the country or zone should be conducted in accordance with Chapter 1.4.

Article 12.1.513.

Surveillance strategies

The target population for surveillance aimed at identification of disease or infection should cover susceptible equids within the country or zone. Active and passive surveillance for AHSV infection should be ongoing. Surveillance should be composed of random or targeted approaches using virological, serological and clinical methods appropriate to the epidemiological situation for the infection status of the country or zone.
A Member Country should justify the surveillance strategy chosen as appropriate to detect the presence of AHSV infection 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. horses). Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. donkeys).

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

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

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

The principles for surveillance for disease or infection are technically well defined. Surveillance programmes to prove the absence of AHSV infection or circulation transmission, need to be carefully designed to avoid producing results that are either insufficiently reliable to be accepted by the OIE for official recognition of status 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 clinical signs of AHS in equids particularly during a newly introduced infection. In horses, clinical signs may include pyrexia, oedema, hyperaemia of mucous nasal membranes and dyspnoea.

**AHS suspects, Suspected cases** detected by clinical surveillance should always be confirmed by laboratory testing.

2. Serological surveillance

Serological surveillance of equine populations is an important tool to confirm absence of AHSV transmission in a country or zone. The species tested should reflect the local epidemiology of AHSV infection, and the equine species available. Management variables that may reduce the likelihood of infection, such as the use of insecticides and animal housing, should be taken into account when selecting equids to be included in the surveillance system.
Samples should be examined for antibodies against AHSV using tests prescribed in the Terrestrial Manual. Positive AHSV antibody tests results can have four possible causes:

a) natural *infection* with AHSV;

b) *vaccination* against AHSV;

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 purposes may be used for AHSV surveillance. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of AHSV infection should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no AHSV infection 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 AHSV 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 AHSV, either random or targeted sampling is suitable to select herds or animals for testing.

Serological surveillance in a free country or zone should be carried out over an appropriate distance from the border with an infected country or infected zone, based upon geography, climate, history of infection and other relevant factors. The surveillance should be carried out over a distance of at least a hundred 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 AHSV. An AHS free country or zone free from infection with AHSV may be protected from an adjacent infected country or infected zone by a protection zone.

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

3. **Virological surveillance**

Isolation and genetic analysis of AHSV from a proportion of infected animals is beneficial in terms of providing 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 comprise groups of unexposed equids that have not been vaccinated and are managed at fixed locations and observed and tested sampled regularly to detect new AHSV infections.
Annex XX (contd)

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

A sentinel equid 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 AHSV 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 AHSV activity 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 confounding factors sentinel groups should comprise animals selected to be of similar age and susceptibility to AHSV infection. 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 should reflect the equine species used and the reason for choosing the sampling site. In endemic areas virus isolation will allow monitoring of the serotypes and genotypes of AHSV circulating during each time period. The borders between infected and non-infected areas can be defined by serological detection of infection. Monthly sampling intervals are frequently used. Sentinels in declared free zones add to confidence that AHSV infections are not occurring unobserved. Here sampling prior to and after the possible period of transmission is sufficient.

Definitive information on AHSV 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 some samples are collected during the period of viraemia.

5. Vector surveillance

AHSV is transmitted between equine 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.

Vector surveillance is aimed at demonstrating the absence of vectors or defining high, medium and low-risk areas and local details of seasonality by determining the various species present in an area, their respective seasonal occurrence, and abundance. Vector surveillance has particular relevance to potential areas of spread. Long term surveillance can also be used to assess vector abatement measures, or to confirm continued absence of vectors.

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

Vector surveillance should be based on scientific sampling techniques. The choice of the number and types 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 viruses is not recommended as a routine procedure as the typically low vector infection rates mean that such detections can be rare. Other Animal-based surveillance strategies are preferred to detect virus circulation transmission.

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CHAPTER 8.14.

INFECTION WITH TRICHINELLA SPP.


General provisions

Trichinellosis is a widely distributed zoonosis caused by eating raw or undercooked meat from Trichinella infected food-producing animals or wildlife. Given that clinical signs of trichinellosis are not generally recognised in animals, the importance of trichinellosis lies exclusively in the risk posed to humans and costs of control in slaughter populations.

The adult parasite and the larval forms live in the small intestine and muscles (respectively) of many mammalian, avian and reptile host species. Within the genus Trichinella, twelve genotypes have been identified, eight of which have been designated as species. There is geographical variation amongst the genotypes.

Prevention of infection in susceptible species of domestic animals intended for human consumption relies on the prevention of exposure of those animals to the meat and meat products of Trichinella infected animals. This includes consumption of food waste of domestic animal origin, rodents and wildlife.

Meat and meat products derived from wildlife should be considered a potential source of infection for humans. Therefore untested meat and meat products of wildlife may pose a public health risk.

For the purposes of the Terrestrial Code, Trichinella infection is defined as an infection of suids or equids by parasites of the genus Trichinella.

This chapter provides recommendations for on-farm prevention of Trichinella infection in domestic pigs (Sus scrofa domesticus), and safe trade of meat and meat products derived from suids and equids. This chapter should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005).

Methods for the detection of Trichinella infection in pigs and other animal species include direct demonstration of Trichinella larvae in muscle samples. Demonstration of the presence of Trichinella-specific circulating antibodies using a validated serological test may be useful for epidemiological purposes.

When authorising the import or transit of the commodities covered in this chapter, with the exception of those listed in Article 8.14.2., Veterinary Authorities should apply the recommendations in this chapter.

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 8.14.2.

Safe commodities

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

1) hides, skins, hair and bristles;

2) semen, embryos and oocytes.
Article 8.14.3.

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

1) Prevention of infection is dependent on minimising exposure to potential sources of Trichinella:
   a) facilities and the surrounding environment should be managed to prevent exposure of pigs to rodents and wildlife;
   b) raw food waste of animal origin should not be present at the farm level and should not be fed to pigs;
   c) feed should comply with the requirements in Chapter 6.3. and should be stored in a manner to prevent access by rodents and wildlife;
   d) a rodent control programme should be in place;
   e) dead animals should be immediately removed and disposed of in accordance with provisions of Chapter 4.12.;
   f) introduced pigs should originate from herds officially recognised as being under controlled management conditions as described in point 2, or from herds of a compartment with a negligible risk of Trichinella infection, as described in Article 8.14.5.

2) The Veterinary Authority may officially recognise pig herds as being under controlled management conditions if:
   a) all management practices described in point 1 are complied with and recorded;
   b) visits by approved auditors have been made periodically to verify compliance with good management practices described in point 1; the frequency of inspections should be risk-based, taking into account historical information, slaughterhouse monitoring results, knowledge of established farm management practices and the presence of susceptible wildlife;
   c) a subsequent programme of audits is conducted, taking into account the factors described in point b.

Article 8.14.4.

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

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

1) Trichinella infection is notifiable in the whole territory and communication procedures on the occurrence of Trichinella infection are established between the Veterinary Authority and the public health authority;

2) the Veterinary Authority has knowledge of, and authority over, all domestic pigs;

3) the Veterinary Authority has current knowledge of the distribution of susceptible species of wildlife;

4) an animal identification and animal traceability system for domestic pigs is implemented in accordance with the provisions of Chapters 4.1. and 4.2.;
5) Veterinary Services have the capability to assess the epidemiological situation, detect the presence of Trichinella infection (including genotype, if relevant) in domestic pigs and identify exposure pathways.

Article 8.14.5.

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

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

1) all herds of the compartment comply with the requirements in Article 8.14.3.;

2) Article 8.14.4. has been complied with for at least 24 months;

3) the absence of Trichinella infection in the compartment has been demonstrated by a surveillance programme which takes into account current and historical information, and slaughterhouse monitoring results, as appropriate, in accordance with Chapter 1.4.;

4) once a compartment is established, a subsequent programme of audits of all herds within the compartment is in place to ensure compliance with Article 8.14.3.;

5) if an audit identifies a lack of compliance with the criteria described in Article 8.14.3. and the Veterinary Authority determines this to be a significant breach of biosecurity, the herd(s) concerned should be removed from the compartment until compliance is re-established.


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

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

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

AND

2) EITHER:

a) comes from domestic pigs originating from a compartment with a negligible risk for Trichinella infection in accordance with Article 8.14.5.;

OR

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

OR

c) was processed to ensure the inactivation of Trichinella larvae in accordance with the recommendations of the Codex Alimentarius (under study).
Annex XXI (contd)

Article 8.14.7.

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

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

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

AND

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

   OR

   b) was processed to ensure the inactivation of *Trichinella* larvae in accordance with the recommendations of the Codex Alimentarius (under study).


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

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

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

AND

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


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

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

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

AND

2) comes from wild or feral equids that tested negative by an approved method for the detection of *Trichinella* larvae.
CHAPTER 8.12.

INFECTION WITH RIFT VALLEY FEVER VIRUS

Article 8.12.1.

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 an animal a ruminant, or
   b) antigen or ribonucleic acid specific to RVFV, excluding vaccine strains, has been identified in a sample from an animal 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 an animal 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 Rift Valley fever (RVF) shall be 30 14 days.

5) In areas where RVFV is present, epizootics of RVF may occur following favorable 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, often long, duration, with intermittent low level virus activity, which is often not detected.

For the purposes of this chapter, ruminants include camels.

7) The historical distribution of RVF has been parts of is the sub-Saharan 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 can modify the temporal and spatial distribution of the infection.

Countries or zones within the historic distribution of RVF or adjacent to those that are historically infected should be subjected to surveillance.

Epidemics of RVF may occur in infected areas after flooding. They are separated by inter-epidemic periods that may last for several decades in arid areas and, during these periods, the prevalence of infection in humans, animals and mosquitoes can be difficult to detect.
Annex XXII (contd)

In the absence of clinical disease, the RVF status of a country or zone within the historically infected regions of the world should be determined by a surveillance programme (carried out in accordance with Chapter 1.4.) focusing on mosquitoes and serology of susceptible mammals. The programme should concentrate on parts of the country or zone at high risk because of historical, geographic and climatic factors, ruminant and mosquito population distribution, and proximity to areas where epidemics have recently occurred.

8) When authorising import or transit of the commodities covered in the chapter, with the exception of those listed in Article 8.12.2., Veterinary Authorities should require the conditions prescribed in this chapter relevant to the RVF status of the ruminant population of the exporting country or zone.

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

Article 8.12.2.

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 or zone:

1) hides and skins;
2) wool and fibre.

Article 8.12.3.

Country or zone free from RVFV infection free country or zone

A country or a zone may be considered free from RVFV infection when the disease is notifiable in animals throughout the whole country and either:

1) it meets the requirements for historical freedom in point 1 of Article 1.4.6.; or

2) an on-going pathogen-specific surveillance programme in accordance with Chapter 1.4 has demonstrated no evidence of RVFV infection in ruminants, animals and humans in the country or zone, and

b) no indigenous human cases have occurred in the country or zone.

No country or zone which has experienced an epizootic of RVF can ever be considered free from RVFV infection.

1) the country or zone lies outside the historically infected regions, and is not adjacent to historically infected countries; or

2) a surveillance programme as described in Article 8.12.1. has demonstrated no evidence of RVF infection in humans, animals or mosquitoes in the country or zone during the past four years following a RVF epidemic.

The provisions of the last paragraph of Article 8.12.1. may need to be complied with on a continuous basis in order to maintain freedom from infection, depending on the geographical location of the country or zone.

A country or zone free from infection with RVFV infection free country or zone in which surveillance and monitoring has found no evidence that RVF infection is present will not lose its free status through the importation of ruminants that are seropositive, so long as they are either permanently marked identified as such or seropositive animals or those destined for immediate direct slaughter.
Article 8.12.4.

**RVF infected c Country or zone infected with RVFV without disease 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.

A RVF disease free country or zone is a country or zone that is not infection free (see Article 8.12.3.) but in which disease has not occurred in humans or animals in the past six months provided that climatic changes predisposing to outbreaks of RVF have not occurred during this time.

Article 8.12.5.

**RVF infected c Country or zone infected with RVFV with disease 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.

A RVF infected country or zone with disease is one in which clinical disease in humans or animals has occurred within the past six months.

Article 8.12.5.bis

**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;

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 8.12.6.

**Recommendations for importation from countries or zones free from RVFV infection free country or zones**

For ruminants

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

1) were kept in a RVF free country or zone free from RVFV infection since birth or for at least 30 14 days prior to shipment;

AND

2) if the animals were exported from a free zone, either:

   Ba) they were vaccinated at least 14 days prior to leaving the free country or zone; or

   Ab) they did not transit through an area experiencing an epizootic an infected zone during transportation to the place of shipment; or

   Bc) they were protected from vector mosquito attacks at all times when transiting through an infected zone area experiencing an epizootic.
Annex XXII (contd)

Article 8.12.7.

Recommendations for importation from RVF infection free countries or zones

For meat and meat products of domestic and wild ruminants

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the products are derived from animals which remained in the RVF infection free country/free zone since birth or for the last 30 days.

Article 8.12.8.

Recommendations for importation from RVF infected countries/zones without disease 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 evidence sign of RVF on the day of shipment;
2) met one of the following conditions:
   a. were kept in a RVF infected country/zone free of disease since birth or for the last six months providing that climatic changes predisposing to outbreaks of RVF have not occurred during this time; or
   b)a) were vaccinated against RVF at least 21 days prior to shipment with a modified live virus vaccine; or
   cb) were held for at least 30 days prior to shipment in a mosquito-proof quarantine station which is located in an area of demonstrated low vector activity. During this period which the animals showed no clinical sign of RVFV infection and were protected from mosquitoes between quarantine and the place of shipment as well as at the place of shipment;
3) either:
   a) did not transit through an area experiencing an epizootic infected zone with disease during transportation to the place of shipment; or
   b) were protected from vector attacks when transiting through an area experiencing an epizootic.

Article 8.12.9.

Recommendations for importation from RVF infected countries or zones without disease

For meat and meat products of domestic and wild ruminants

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

4) the products are derived from animals which:
   a). remained in the RVF infected country or zone without disease since birth or for the last 30 days;
   b). were slaughtered in an approved abattoir and were subjected to ante- and post-mortem inspections for RVF with favourable results;
2) the carcasses from which the products were derived were submitted to maturation at a temperature above +2°C for a minimum period of 24 hours following slaughter.
Article 8.12.10.

Recommendations for importation from RVF infected countries or zones with disease

Recommendations for importation from countries or zones infected with RVFV disease during an epizootic

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) 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.

Recommendations for importation of fresh meat and meat products from ruminants

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

1) showed no clinical signs of RVF within 24 hours before slaughter;
2) were slaughtered in an approved slaughterhouse/abattoir and were subjected to ante- and post-mortem inspections with favourable results;
3) the carcasses from which the products were derived were submitted to maturation at a temperature above 2°C for a minimum period of 24 hours following slaughter.

Article 8.12.10.bis

Recommendations for importation from RVF infected countries or zones with disease

For meat and meat products of domestic and wild ruminants
Annex XXII (contd)

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

1) are from animals which have been slaughtered in an approved abattoir and have been subjected to ante- and post-mortem inspections for RVF with favourable results; and

2) have been fully eviscerated and submitted to maturation at a temperature above +2°C for a minimum period of 24 hours following slaughter.

Article 8.12.12.

Recommendations for importation from countries or zones not free from infection with RVFV

Recommendations for importation from countries or zones RVFV infected with disease

For 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 evidence sign of RVF within the period from 28 to 14 days prior to 28 and 14 days following collection of the semen or embryos;

AND

2) either:

   a) were vaccinated against RVF at least 21 to 14 days prior to collection with a modified live virus vaccine; 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.

   were serologically tested on the day of collection and at least 14 days following collection and showed no significant rise in titre.

Article 8.12.12.bis

Recommendations for importation of fresh meat and meat products from ruminants from countries or zones not free from infection with RVFV

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

1) ruminants which showed no clinical sign of RVF within 24 hours before slaughter;

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.


(Under study) Recommendations for importation from RVF infected countries or zones not free from infection with RVFV with disease or from RVF infected countries or zones without disease

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 8.12.14.**

**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 8.12.8. and 8.12.10.) *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.

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CHAPTER 8.15.

TULAREMIA

Article 8.15.1.

General provisions
For the purposes of the Terrestrial Code, the incubation period for tularemia (in hares, genus Lepus) shall be 15 days.

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 8.15.2.

Tularemia free country
A country may be considered free from tularemia when it has been shown that tularemia has not been present for at least the past two years and when bacteriological or serological surveys in previously infected zones have given negative results.

Article 8.15.3.

Tularemia infected zone
A zone shall be considered as infected with tularemia until:
1) until at least one year has elapsed after the last case has been confirmed;
AND
2) when a bacteriological survey on ticks within the infected zone has given negative results; or
3) when regular serological testing of hares and rabbits from that zone has given negative results.

Article 8.15.4.

Trade in commodities
Veterinary Authorities of tularemia free countries may prohibit importation or transit through their territory, from countries considered infected with tularemia, of live hares.

Article 8.15.5.

Recommendations for importation from countries considered infected with tularemia
For live hares
Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals:
1) showed no clinical sign of tularemia on the day of shipment;
2) were not kept in a tularemia infected zone;
3) have been treated against ectoparasites (ticks); and
4) were kept in a quarantine station for the 15 days prior to shipment.

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CHAPTER 8.X.

INFECTION WITH BRUCELLA ABORTUS,

B. MELITENSI S AND B. SUIS

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) For the purpose of this chapter, ‘Animals’ means domestic and captive wild animal populations of the following categories:
      i) Bovidae bovids: this term means cattle (Bos taurus, B. indicus, B. frontalis and B. javanicus), yak (and B. grunniens), bison (Bison bison and B. bonasus) and water buffalo (Bubalus bubalis);
      ii) Ovidae and Capridae mean sheep (Ovis aries) and goats (Capra aegagrus);
      iii) pigs means domestic pigs and wild boars (Sus scrofa);
      iv) Camelidae 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) Cervidae 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 dama), white-tailed, black-tailed, mule deer (Odocoileus spp.) and reindeer/caribou (Cervus elaphus elaphus, C. elaphus canadensis, C. nippon, C. unicolor unicolor, C. timorensis, Dama dama dama, Odocoileus virginianus borealis, O. docoileus hemionus columbianus, O. docoileus hemionus hemionus and 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 Brucella infection with Brucella, but also with the presence of Brucella infection with Brucella in the absence of clinical signs. A case is an animal infected with Brucella.

5) The following defines a case of Brucella infection with Brucella:
   a) Brucella has been isolated and/or identified as such from in a sample from an animal or a product derived from that animal.
   OR
   b) Positive results to one or more diagnostic tests have been obtained, and there is an epidemiological link to a confirmed case evidence of Brucella infection.
6) When authorising import or transit of commodities listed in this chapter, with the exception of those listed in Article 8.X.2., Veterinary Authorities should require the conditions prescribed in this chapter relevant to the 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. In the absence of sufficient scientific information, the prescribed tests for bovines, except bovine specific indirect ELISAs, may be applied to Cervidae and Camelidae.

Article 8.X.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, zone, herd or flock.

1) skeletal muscle meat, brain and spinal cord, digestive tract, thymus, thyroid and parathyroid glands and derived products, provided that they are accompanied by an international veterinary certificate attesting that they are originating from animals that have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.;

2) cured hides and skins;

3) gelatine, collagen, tallow and meat-and-bone meal.

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 Brucella status of the animal population of the exporting country, zone or herd or flock.

Article 8.X.2. bis

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.X.3.

Country or zone free from Brucella infection with Brucella in bovids in animals without vaccination in bovids

A country or zone can be qualified free from Brucella infection without vaccination either in one or several of the animal categories listed in Article 11.3.1.

1) To qualify as free from Brucella infection with Brucella in bovids without vaccination in bovids, a country or zone should satisfy for each relevant category of animals the following requirements:

   4a) Brucella infection with Brucella in animals is a notifiable disease in the entire country or zone;

   b) no case has been recorded in bovids for at least the past three years;
Annex XXIV (contd)

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.

2. Regulatory measures have been implemented for the early detection of Brucella infection with Brucella in bovids, particularly abortions, and including at least the regular submission of samples from abortion cases to diagnostic laboratories for investigation.

3. Neither domestic nor captive wild animals nor bovids have been vaccinated against Brucella infection with Brucella for at least the past three years, and no bovids that are introduced into the country or zone have been vaccinated during the past three years.

4. No case of abortion due to Brucella infection and no isolation of Brucella has been recorded in animals for at least the past three years.

5) except for pigs:

af) regular and periodic testing of all herds or flocks has been in place for the past three years; and this testing has demonstrated that Brucella infection was not present in at least 99.8% of the herds or flocks representing at least 99.9% of animals bovids in the country or zone for three consecutive years.

2) To maintain the status as free from Brucella infection with Brucella in bovids without vaccination in bovids, a country or zone should satisfy the following requirements:

a) the requirements in points 1a), 1b) and 1d) to 1e) above are met;

b) a surveillance programme based on regular and periodic testing of animals should be in place in the country or zone to detect Brucella infection with Brucella in accordance with Article Chapter 1.4.4.

c) if a surveillance programme described in Points 2 and 5a) and b) above has not detected Brucella infection with Brucella for the past five two consecutive years, surveillance should be maintained in accordance with Article Chapter 1.4.5.

6.3) Vaccinated animals should not be introduced. Unvaccinated animals and genetic materials should comply with the recommendations in Articles 11.3.8. to 11.3.12. The country or zone free status of free from Brucella infection with Brucella in bovids without vaccination in bovids a specified animal category is not affected by the occurrence of Brucella infection with Brucella in other animal categories or feral and wild animals provided that effective measures have been implemented to prevent transmission of Brucella infection with Brucella to the relevant animal population bovids belonging to the specified animal category free from Brucella infection is effectively separated from the potential source of infection.

Article 8.X.4.

Country or zone free from Brucella infection with Brucella in bovids in animals with vaccination in bovids

A country or zone can be qualified free from Brucella infection with vaccination either in bovines or ovicaprines as listed in Article 11.3.1.
1) To qualify as free from *Brucella infection with Brucella in bovids* with vaccination in bovids, a country or zone should satisfy for each relevant category of animals the following requirements:

4.a) *Brucella infection with Brucella* in animals is a notifiable disease in the entire country or zone;

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;

2) Regulatory measures have been implemented for the early detection a programme should be in place to ensure effective reporting of all cases suggestive of *Brucella infection with Brucella* in bovids, particularly abortions, and including at least the regular submission of samples from abortion cases material to diagnostic laboratories for investigation, have been implemented.

3) Vaccinated animals should be permanently identified as such with a permanent mark;

4) no case of abortion due to *Brucella infection* and no isolation of *Brucella* has been recorded in animals for at least the past three years;

5) Regular and periodic testing of all herds or flocks has been in place for the past three years; and this testing has demonstrated that *Brucella infection* was not present in at least 99.9% of the herds or flocks and representing at least 99.9% of animals in the country or zone three consecutive years;

2) To maintain the status as free from *Brucella infection with Brucella in bovids* with vaccination in bovids, a country or zone should satisfy the following requirements:

a) the requirements in points 1a), 1b) and 1d) to 1ef) above are met;

b, if a surveillance programme described in Points 2 and 5 a) and b) above has not detected *Brucella infection with Brucella* for the past five two consecutive years, surveillance should may be maintained in accordance with Article Chapter 1.4.5.

7) The country or zone free status of free from *Brucella infection with Brucella in bovids* with vaccination of the country or zone for bovids a specified animal category is not affected by the occurrence of *Brucella infection with Brucella* in other animal categories or feral and or wild animals provided that effective measures have been implemented to prevent transmission of *Brucella infection with Brucella* to the relevant animal population bovids belonging to the specified animal category free from *Brucella infection* is effectively separated from the potential source of infection.

4) In addition, if The status of A country or zone free from *Brucella infection with Brucella in bovids with vaccination in bovids* wishes to change its status to country or zone free from *Brucella infection without 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.X.3. are met, the status of this country or zone remains unchanged for a period of at least three years after vaccination has ceased, at which time this status may be changed to free from infection with *Brucella in bovids without vaccination* provided that the requirements in point 1c) of Article 8.X.3. are met during that period.
Annex XXIV (contd)

Article 8.X.5.

Country or zone free from Brucella infection with Brucella in sheep and goats without vaccination in sheep and goats

1) To qualify as free from Brucella infection with Brucella in sheep and goats without vaccination in sheep and goats, a country or zone should satisfy the following requirements:

a) Brucella infection with Brucella in animals is a notifiable disease in the entire country or zone;

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 Brucella infection with Brucella in sheep and goats, including at least the regular submission of samples from abortion cases material to diagnostic laboratories for investigation; have been implemented;

e) no sheep and goats have been vaccinated against Brucella infection with Brucella for at least the past three years and no sheep and goats that are introduced into the country or zone, have not been vaccinated in during the past three years;

f) regular and periodic testing of all flocks has been in place for the past three years; and this testing has demonstrated that Brucella infection 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.

2) To maintain the status as free from Brucella infection with Brucella in sheep and goats without vaccination in sheep and goats, a country or zone should satisfy the following requirements:

a) the requirements in points 1a), 1b) and 1d) to 1e) above are met;

b) a surveillance programme based on regular and periodic testing of sheep and goats is in place in the country or zone to detect Brucella infection with Brucella in accordance with Chapter 1.4. Article 1.4.4.;

c) if the surveillance programme described in b) above has not detected Brucella infection with Brucella for two consecutive years, surveillance may be maintained in accordance with Chapter 1.4. Article 1.4.5.

3) The country or zone free status of free from infection with Brucella in sheep and goats without vaccination of the country or zone in sheep and goats is not affected by the occurrence of Brucella infection with Brucella in other animal categories or feral or wild animals provided that effective measures have been implemented to prevent transmission of Brucella infection with Brucella to sheep and goats.
Annex XXIV (contd)

**Article 8.X.6.**

**Country or zone free from Brucella infection with Brucella in sheep and goats with vaccination in sheep and goats**

1) To qualify as free from Brucella infection with Brucella in sheep and goats with vaccination in sheep and goats, a country or zone should satisfy the following requirements:
   
   a) Brucella infection with Brucella in animals is a notifiable disease in the entire country or zone;
   
   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 Brucella infection with Brucella in sheep and goats, including at least the regular submission of samples from abortion cases material to diagnostic laboratories for investigation, have been implemented;
   
   e) vaccinated sheep and goats should be permanently identified as such with a permanent mark;
   
   f) no case of Brucella infection has been recorded in sheep and goats for at least the past three years;
   
   g) sheep and goats and their genetic materials introduced into the country or zone comply with the recommendations in Articles 8.X.13. and 8.X.15. to 8.X.17.
   
   h) regular and periodic testing of all flocks have been in place for the past three years; and this testing has demonstrated that Brucella infection 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.

2) To maintain the status as free from Brucella infection with Brucella in sheep and goats with vaccination in sheep and goats, a country or zone should satisfy the following requirements:

   a) the requirements in points 1a), 1b) and 1d) to 1e) above are met;
   
   b) a surveillance programme based on regular and periodic testing of sheep and goats is in place in the country or zone to detect Brucella infection with Brucella in accordance with Chapter 1.4., Article 1.4.4.;
   
   c) if the surveillance programme described in b) above has not detected Brucella infection with Brucella for two consecutive years, surveillance may be maintained in accordance with Chapter 1.4., Article 1.4.5.

3) The free country or zone status of free from infection with Brucella in sheep and goats with vaccination of the country or zone in sheep and goats is not affected by the occurrence of Brucella infection with Brucella in other animal categories or feral or wild animals provided that effective measures have been implemented to prevent transmission of Brucella infection with Brucella to sheep and goats.

4) In addition, if Aa The status of a country or zone free from Brucella infection with Brucella in sheep and goats with vaccination remains unchanged for a period of three years after vaccination has ceased, in sheep and goats wishes to change its status to country or zone free from Brucella infection without vaccination, provided that the requirements in points 1a), 1b) and 1d) to 1f) of Article 8.X.5. are met, the status of this country or zone remains unchanged for a period of at least three years after vaccination has ceased, at which time this status may be changed to free from infection with Brucella in sheep and goats without vaccination provided that the requirements in point 1c) of Article 8.X.5. are met during that period.
Country or zone free from *Brucella* infection with *Brucella* in camelids

1) To qualify as free from *Brucella* infection with *Brucella* in camelids, a country or zone should satisfy the following requirements:

a) *Brucella* infection with *Brucella* in animals is a notifiable disease in the entire country or zone;

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 *Brucella* infection with *Brucella* in camelids, including at least the regular submission of samples of abortion cases material to diagnostic laboratories for investigation, have been implemented;

e) no camelids have been vaccinated against *Brucella* 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;

d) no case of *Brucella* infection has been recorded in camelids for at least the past three years;

e) camelids and their genetic materials introduced into the country or zone comply with the recommendations in Articles 8.X.13. and 8.X.15. to 8.X.17.;

f) regular and periodic testing of all herds has been in place for the past three years; and this testing has demonstrated that *Brucella* infection was not present in at least 99.8% of the herds representing at least 99.9% of camelids in the country or zone;

2) To maintain the status as free from *Brucella* infection with *Brucella* in camelids, a country or zone should satisfy the following requirements:

a) the requirements in points 1a), 1b) and 1d) to 1e) above are met;

b) a surveillance programme based on regular and periodic testing of camelids is in place in the country or zone to detect *Brucella* infection with *Brucella* in accordance with Chapter 1.4. Article 1.4.4.;

c) if the surveillance programme described in b) above has not detected *Brucella* infection with *Brucella* for two consecutive years, surveillance may be maintained in accordance with Chapter 1.4. Article 1.4.5.

3) The free country or zone status of free from infection with *Brucella* in the country or zone in camelids is not affected by the occurrence of *Brucella* infection with *Brucella* in other animal categories or feral or wild animals provided that effective measures have been implemented to prevent transmission of *Brucella* infection with *Brucella* to camelids.

Country or zone free from *Brucella* infection with *Brucella* in cervids

1) To qualify as free from *Brucella* infection with *Brucella* in cervids, a country or zone should satisfy the following requirements:
Brucella infection with Brucella in animals is a notifiable disease in the entire country or zone.

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.

bd) regulatory measures have been implemented for the early detection of Brucella infection with Brucella in cervids, including at least the regular submission of samples from abortion cases material to diagnostic laboratories for investigation, have been implemented.

ea) no cervids have been vaccinated against Brucella 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.

d) no case of Brucella infection has been recorded in cervids for at least the past three years.

ef) cervids and their genetic materials introduced into the country or zone comply with the recommendations in Articles 8.X.13. and 8.X.15. to 8.X.17.

f) regular and periodic testing of all herds has been in place for the past three years; and this testing has demonstrated that Brucella infection was not present in at least 99.8% of the herds representing at least 99.9% of cervids in the country or zone.

2) To maintain the status as free from Brucella infection with Brucella in cervids, a country or zone should satisfy the following requirements:

a) the requirements in points 1a), 1b) and 1d) to 1ef) above are met;

b) a surveillance programme based on regular and periodic testing of cervids is in place in the country or zone to detect Brucella infection with Brucella in accordance with Chapter 1.4. Article 1.4.4.;

c) if the surveillance programme described in b) above has not detected Brucella infection with Brucella for two consecutive years, surveillance may be maintained in accordance with Chapter 1.4. Article 1.4.5.

3) The country or zone free status of free from infection with Brucella the country or zone in cervids is not affected by the occurrence of Brucella infection with Brucella in other animal categories or feral or wild animals provided that effective measures have been implemented to prevent transmission of Brucella infection with Brucella to cervids.

Article 8.X.9.

Herd or flock free from Brucella infection with Brucella without vaccination in bovids, sheep and goats, camels or cervids without vaccination

1) To qualify as free from Brucella infection with Brucella without vaccination, a herd or flock of the relevant animal category bovids, sheep and goats, camels or cervids should satisfy the following requirements:
a) the herd or flock is in a country or zone free from Brucella infection with Brucella without vaccination in for 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 Brucella infection with Brucella with vaccination in for 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) Brucella 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 during in the past three years;

iii) no case of Brucella infection has been detected in the herd or flock has not shown evidence of Brucella infection for at least the past nine past 12 months;

iv) animals showing clinical signs consistent with Brucella infection with Brucella are suspected cases (such as animals which have aborted or abscission) have been subjected to the necessary clinical and laboratory investigations diagnostic tests with negative results.

v) for at least the past year 12 months, there has been no evidence of Brucella infection with Brucella in other susceptible animals herds or flocks of the same epidemiological unit establishment, or measures have been implemented to prevent any transmission of the Brucella infection with Brucella from these other susceptible animals herds or flocks;

wii) all sexually mature animals of the relevant category except castrated males were subjected to a prescribed serological tests for Brucella infection two tests have been performed with negative results on two occasions on all sexually mature animals present in the herd at the time of testing, at an interval of more than 6 and less than 12 months between each test, the first test being performed not before 3 three months after the slaughter of the last case and the second test at an interval of more than six 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;

ab) regular prescribed tests, at a frequency depending on the prevalence of herd or flock infection in the country or zone, demonstrate the continuing absence of Brucella infection with Brucella;

b) animals of the relevant category introduced into the herd or flock are should be accompanied by a certificate from an Official Veterinarian attesting that they come from:

i) a country or zone free from Brucella infection with Brucella in the relevant category without vaccination;

OR

ii) a country or zone free from Brucella infection with Brucella with vaccination and the animals of the relevant category have not been vaccinated during in the past three years;
Annex XXIV (contd)

iii) a herd or flock free from *Brucella infection with Brucella* with or without vaccination, and provided that the animals have not been vaccinated in the past 3 years and were subjected to a prescribed test for *Brucella infection with Brucella* during within the 30 days prior to shipment with negative results; in the case of post-parturient females which have given birth during the past 30 days, the test is should be carried out at least 30 days after giving the birth. This test is not required for sexually immature animals or vaccinated animals less than 18 months of age.

e) There is no evidence of infection in other epidemiologically relevant animal species kept in the same establishment, or measures have been implemented to prevent any transmission of the *Brucella infection from other species kept in the same establishment.*

Article 8.X.10.

**Herd or flock free from *Brucella infection with Brucella* with vaccination in bovids, sheep and goats with vaccination**

A herd or flock can be qualified free from *Brucella infection with Brucella* with vaccination either in bovines or ovidae and capridae as listed in Article 11.3.1.

1) To qualify as free from *Brucella infection with Brucella* with vaccination, a herd of bovids or flock of sheep and goats the relevant animal category should satisfy the following requirements:

   a) the herd or flock is in a country or zone free from *Brucella 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) *Brucella infection with Brucella* in animals is a notifiable disease in the entire country;

      ii) vaccinated animals of the relevant categories should be are permanently identified as such;

      iii) no case of *Brucella infection* has been detected in the herd or flock has not shown evidence of *Brucella infection* for at least the past nine years; months;

      iv) animals of the relevant category showing clinical signs consistent with *Brucella infection with Brucella* all suspect cases (such as animals which have aborted abortions) have been subjected to the necessary clinical and laboratory investigations diagnostic tests with negative results;

      v) for at least the past year, there has been no evidence of *Brucella infection with Brucella* in other susceptible animals herds or flocks of the same epidemiological unit establishment, or measures have been implemented to prevent any transmission of the *Brucella infection with Brucella* from these other susceptible animals herds or flocks;

      vi) all sexually mature animals of the relevant category except castrated males were subjected to a prescribed serological test for *Brucella infection* two tests have been performed with negative results on two occasions on all sexually mature animals present in the herd at the time of testing, at an interval of more than 6 and less than 12 months between each test; the first test being performed not before 3 three months after the slaughter of the last case and the second test at an interval of more than six 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 prescribed tests, at a frequency depending on the prevalence of herd or flock infection in the country or zone, demonstrate the continuing absence of Brucella 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 Brucella infection with Brucella in the relevant category with or without vaccination;

OR

ii) a herd or flock free from Brucella infection with Brucella with or without vaccination, and provided that the animals have not been vaccinated in the past 3 years and were subjected negative results were shown to a prescribed tested for Brucella infection with Brucella within during the 30 days prior to shipment with negative results, in the case of post-parturient females which have given birth during the past 30 days, the test is should be carried out at least 30 days after giving the birth. This test is not required for sexually immature animals or vaccinated animals less than 18 months of age.

c) There is no evidence of infection in other epidemiologically relevant animal species kept in the same establishment, or measures have been implemented to prevent any transmission of the Brucella infection from other species kept in the same establishment.

Article 8.X.11.

Herd free from Brucella infection with Brucella in pigs

1) To qualify as free from Brucella infection with Brucella a herd of pigs should satisfy the following requirements:

a) Brucella infection with Brucella in animals is a notifiable disease in the entire country;

b) no pigs of the herd have been vaccinated;

c) no case of Brucella infection has been detected in the herd for at least the past three years;

d) animals showing clinical signs consistent with Brucella infection with Brucella (such as abortions or orchitis) have been subjected to the necessary diagnostic tests with negative results;

e) 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;

f) for at least the past three years, there has been no evidence of Brucella infection with Brucella in other susceptible animals herds or flocks of the same epidemiological unit establishment, or measures have been implemented to prevent any transmission of the Brucella infection with Brucella from these other susceptible animals herds or flocks.
Annex XXIV (contd)

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 Brucella 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 Chapter 1.4. Article 1.4.4., was subjected to a prescribed tested within 30 days prior to shipment, demonstrating the absence of Brucella infection with Brucella;
       
       OR
       
iii) they were subjected to a prescribed tested within 30 days prior to shipment with negative results.

Article 8.X.12.

Recovery of the Brucella infection free status in a country or a zone

Should a case of Brucella infection with Brucella in one or more animal categories occur in a free country or zone as described in Articles 8.X.3. to 8.X.8., the status is suspended the free status and may not be recovered until once the following requirements are met:

1) all infected animals of the relevant category were are have been slaughtered or destroyed as soon as Brucella infection with Brucella is confirmed the result of the diagnostic test was known;

2) an epidemiological investigation has been is performed within 60 days of Brucella infection confirmation 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 Brucella infection has spread to less than 0.2% of herds or flocks.

3) in the index herd or flock and herds or flocks identified by the epidemiological investigation:
   
a) whole herd or flock depopulation has been is practised; or,
   
   2 b) whole herd or flock depopulation has not been practised in animal categories other than pigs, and all remaining sexually mature animals in the herd or flocks except castrated males have been subjected to a serological prescribed tested, with negative results, on three occasions, at an interval of not less than two months, then a further fourth test six months later and a final fifth test a year later;
   
c) no animals are moved from the herds or flocks except for directly for slaughter until the processes in point a) or b) above are completed;

3.4) in pig herds, where cases of Brucella infection have occurred, all pigs were slaughtered or destroyed cleansing and disinfection procedures have been applied at the end of the slaughter process and before new animals are introduced.

If When these requirements have not been are not met, the status is not recovered and Articles 8.X.3. to 8.X.8. apply as relevant.
Recommendations for the importation of animals bovids, sheep and goats, camels 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 signs of *Brucella* infection with *Brucella* on the day of shipment;

2) originate from:

   a) a country or zone free from *Brucella* infection with *Brucella* as relevant;

   OR

   b) a herd or flock free from *Brucella* infection with *Brucella* and all sexually mature animals were subjected to a prescribed serological test for *Brucella* infection with *Brucella* with negative results during within the 30 days prior to shipment.

   This test is not required for:

   - pigs;
   - young bovines before the age of 12 months;
   - young ovidae and capridae before the age of 6 months;
   - young Camelidae and Cervidae before the age of sexual maturity;

   OR

   c) with the exception of pigs, a herd or flock not qualified free from *Brucella* infection with *Brucella*:

   i) in which no *case Brucella infection* has been reported during the nine 12 months year prior to shipment;

   ii) the animals were isolated for 30 days prior to shipment and all animals in isolation were subjected during tested for infection with *Brucella* within that period with negative results within that period to a prescribed serological test for *Brucella infection* with negative results; in the case of post-parturient females which have given birth during the past 30 days, the test was is should be carried out at least 30 days after giving the birth. This test is not required for sexually immature animals or vaccinated animals less than 18 months of age.

**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 signs of *Brucella* infection with *Brucella* on the day of shipment;
Annex XXIV (contd)

2) either:
   a) originate from a *herd* free from *Brucella 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 Chapter 1.4, Article 1.4.4., was subjected to a prescribed tested within 30 days
      prior to shipment, demonstrating the absence of *Brucella infection with Brucella*;
   OR
   c) were isolated for 30 days prior to shipment and all pigs in isolation were subjected to a prescribed
      tested for *Brucella infection with Brucella* within that period 30 days prior to shipment with negative
      results.

Article 8.X.15.

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 signs of *Brucella infection with Brucella* on the day of shipment;

2) originate from a country, zone, *herd* or *flock* free from *Brucella infection with Brucella* with or without
   *vaccination*;

OR

3) are not being culled eliminated as part of an eradication programme against *Brucella infection* and in the
   case of sexually mature bovids, sheep and goats, camelids or cervids, were subjected to a prescribed tested
   for *Brucella infection with Brucella* with negative results during within the 30 days prior to shipment and are
   not being eliminated as part of an eradication programme against *Brucella infection*.

Article 11.3.10.

Recommendations for the importation of captive European hares (*Lepus europaeus*) for restocking

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

1) the animals showed no clinical signs of *Brucella infection* on the day of shipment;

2) a programme is in place to ensure effective investigation and reporting of all cases suggestive of *Brucella
   infection* in establishments keeping hares.

Article 8.X.16.

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 signs of *Brucella infection with Brucella* on the day of collection of the
   semen;
Annex XXIV (contd)

2) the donor animals were not vaccinated against \textit{Brucella infection with Brucella} and either:

a) were kept in an \textit{artificial insemination centre} complying with the provisions of Chapter 4.5 free from \textit{Brucella infection},

OR

b) were kept in a \textit{herd or flock} free from \textit{Brucella infection with Brucella} and are \textit{subjected tested} every six months to a prescribed test for \textit{Brucella infection with Brucella} with negative results, and the semen was collected, processed and stored in conformity with the provisions of Articles 4.5.3. to 4.5.5. and Articles 4.6.5. to 4.6.7.

3) the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

Article 8.X.17.

Recommendations for the importation of embryos and oocytes

Veterinary Authorities of importing countries should require the presentation of an \textit{international veterinary certificate} attesting that:

1) the donor animals showed no clinical signs of \textit{Brucella infection with Brucella} on the day of collection;

2) the donor animals were not vaccinated against \textit{Brucella infection with Brucella} during in the past three years and either:

a) were kept in a country or \textit{zone} free from \textit{Brucella infection with Brucella}, as relevant;

OR

b) were kept in a \textit{herd or flock} free from \textit{Brucella infection with Brucella} and are tested subjected every six months to a prescribed test for \textit{Brucella infection with Brucella} with negative results;

3) the embryos and oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7. to Chapter 4.9.

Article 8.X.18.

Recommendations for the importation of fresh meat and meat products other than mentioned in Article 8.X.2.

Veterinary Authorities of importing countries should require the presentation of an \textit{international veterinary certificate} attesting that the \textit{meat} and \textit{meat products} come from animals:

1) which have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.;

2) which:

a) originate from a country or \textit{zone} free from \textit{Brucella infection with Brucella}, as relevant;

OR

ab) originate from a \textit{herd or flock} free from \textit{Brucella infection with Brucella};

OR

bc) have not been \textit{culled eliminated} as part of an eradication programme against \textit{Brucella infection with Brucella} have not tested positive to a prescribed test for \textit{Brucella infection}.
Annex XXIV (contd)

Article 8.X.19.

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 of a herd or flock free from Brucella 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.X.20.

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 Brucella infected animals culled eliminated as part of an eradication programme against Brucella infection with Brucella.

OR

2) have been processed to ensure the destruction of the Brucella.

Article 8.X.21.

Procedures for the inactivation of Brucella in casings of bovids, sheep and goats, and pigs

For the inactivation of Brucella in casings of bovids, sheep and goats, and pigs, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine (Awa < 0.80), and kept at a temperature of greater than 20°C or above during this entire period.
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 (RNA) 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.
Annex XXV (contd)

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 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.

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 have been 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 the 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 have been should be to the certificate.
Annex XXV (contd)

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:

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 have been *should be* to the *certificate*.

Article 10.4.8.

Recommendations for importation from a country, zone or compartment free from infection with high pathogenicity avian influenza viruses in poultry

For day-old live poultry

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

1) the *poultry* were kept in a country, *zone or compartment* free from infection with high pathogenicity avian influenza viruses in *poultry* since they were hatched;

2) the *poultry* were derived from parent *flocks* which had been kept in an avian influenza free *establishment* for at least 21 days prior to and at the time of the collection of the eggs;

3) the *poultry* are transported in new or appropriately sanitized *containers*.

If the *poultry* or the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of vaccination have been *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 have been *should be* attached to the *certificate*.

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Article 10.4.10.

Recommendations for importation from a country, zone or compartment free from avian influenza

For hatching eggs of poultry

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

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 have been 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 have been 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 have been should be attached to the certificate.
Annex XXV (contd)

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:

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 free 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 the 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

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 the 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 the 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.;

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 (under study):
   a) pasteurisation;
   b) moist heat treatment for 30 minutes at 56°C;

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 (under study) 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 (under study) 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

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.
Annex XXV (contd)

Article 10.4.25.

Procedures for the inactivation of the 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:

<table>
<thead>
<tr>
<th></th>
<th>Core temperature (°C)</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole egg</td>
<td>60</td>
<td>188 seconds</td>
</tr>
<tr>
<td>Whole egg blends</td>
<td>60</td>
<td>188 seconds</td>
</tr>
<tr>
<td>Whole egg blends</td>
<td>61.1</td>
<td>94 seconds</td>
</tr>
<tr>
<td>Liquid egg white</td>
<td>55.6</td>
<td>870 seconds</td>
</tr>
<tr>
<td>Liquid egg white</td>
<td>56.7</td>
<td>232 seconds</td>
</tr>
<tr>
<td>10% salted yolk</td>
<td>62.2</td>
<td>138 seconds</td>
</tr>
<tr>
<td>Dried egg white</td>
<td>67</td>
<td>20 hours</td>
</tr>
<tr>
<td>Dried egg white</td>
<td>54.4</td>
<td>513 hours</td>
</tr>
</tbody>
</table>

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 the avian influenza viruses in meat

The following times for industry standard temperatures are suitable for the inactivation of avian influenza viruses present in meat:

<table>
<thead>
<tr>
<th></th>
<th>Core temperature (°C)</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poultry meat</td>
<td>60.0</td>
<td>507 seconds</td>
</tr>
<tr>
<td></td>
<td>65.0</td>
<td>42 seconds</td>
</tr>
<tr>
<td></td>
<td>70.0</td>
<td>3.5 seconds</td>
</tr>
<tr>
<td></td>
<td>73.9</td>
<td>0.51 second</td>
</tr>
</tbody>
</table>

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 will need to 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;

b) 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, serological and virological testing of high-risk groups of animals, such as those adjacent to an avian influenza infected country, or zone or compartment, 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.
Annex XXV (contd)

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.).

Article 10.4.29.

Surveillance strategies

1. 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. 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 will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to 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 clearly needs to 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 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 needs to 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) false positive results due to the 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.
Annex XXV (contd)

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.

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 poultry

1. Additional surveillance procedures 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 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 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 will depend 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 procedures 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 procedures 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), non-structural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will be 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 categorisation 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.

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*.
Annex XXV (contd)

**Fig. 1. Schematic representation of laboratory tests for determining evidence of avian influenza infection through or following serological surveys**

Key abbreviations and acronyms:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Acronym</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>AGID</td>
<td>Agar gel immunodiffusion</td>
<td></td>
</tr>
<tr>
<td>DIVA</td>
<td>Differentiating infected from vaccinated animals</td>
<td></td>
</tr>
<tr>
<td>ELISA</td>
<td>Enzyme-linked immunosorbent assay</td>
<td></td>
</tr>
<tr>
<td>HA</td>
<td>Haemagglutinin</td>
<td></td>
</tr>
<tr>
<td>HI</td>
<td>Haemagglutination inhibition</td>
<td></td>
</tr>
<tr>
<td>NA</td>
<td>Neuraminidase</td>
<td></td>
</tr>
<tr>
<td>NP/M</td>
<td>Nucleoprotein and matrix protein</td>
<td></td>
</tr>
<tr>
<td>NSP</td>
<td>Nonstructural protein</td>
<td></td>
</tr>
<tr>
<td>S</td>
<td>No evidence of avian influenza virus</td>
<td></td>
</tr>
</tbody>
</table>
**Fig. 2.** Schematic representation of laboratory tests for determining evidence of avian influenza infection using virological methods

Key abbreviations and acronyms:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGID</td>
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</tr>
</tbody>
</table>

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CHAPTER 10.9.

INFECTION WITH NEWCASTLE DISEASE VIRUS

NEW CASTLE DISEASE

Article 10.9.1.

General provisions

1) For the purposes of the Terrestrial Code, Newcastle disease (ND) is defined as an infection of poultry caused by a Newcastle disease virus (NDV), which is an avian paramyxovirus serotype 1 (APMV-1) that meets one of the following criteria for virulence:

   a) the virus has an intracerebral pathogenicity index (ICPI) in day-old chicks (Gallus gallus) of 0.7 or greater; or

   b) multiple basic amino acids have been demonstrated in the virus (either directly or by deduction) at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term ‘multiple basic amino acids’ refers to at least three arginine or lysine residues between residues 113 and 116. Failure to demonstrate the characteristic pattern of amino acid residues as described above would require characterisation of the isolated virus by an ICPI test.

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

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

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

3) For the purposes of the Terrestrial Code, the incubation period for ND shall be 21 days.

4) This chapter deals with NDV infection of poultry as defined in Point 2 above, in the presence or absence of clinical signs.

5) The occurrence of infection with NDV is defined as the isolation and identification of NDV as such or the detection of viral RNA specific for NDV.

6) Standards for diagnostic tests, including pathogenicity testing, are described in the Terrestrial Manual. When the use of ND vaccines is appropriate, those vaccines should comply with the standards described in the Terrestrial Manual.

7) A Member Country should not impose bans on the trade in poultry commodities in response to information on the presence of any APMV-1 in birds other than poultry, including wild birds.

Article 10.9.2.

Determination of the Newcastle disease status of a country, zone or compartment

The ND status of a country, a zone or a compartment can be determined on the basis of the following criteria:
Annex XXVI (contd)

1) ND is notifiable in the whole country, an on-going ND awareness programme is in place, and all notified suspect occurrences of ND are subjected to field and, where applicable, laboratory investigations;

2) appropriate surveillance is in place to demonstrate the presence of NDV infection in the absence of clinical signs in poultry, this may be achieved through an ND surveillance programme in accordance with Articles 10.9.22. to 10.9.26.;

3) consideration of all epidemiological factors for ND occurrence and their historical perspective.

Article 10.9.3.

Newcastle disease free country, zone or compartment

A country, zone or compartment may be considered free from ND when it has been shown that NDV infection in poultry has not been present in the country, zone or compartment for the past 12 months, based on surveillance in accordance with Articles 10.9.22. to 10.9.26.

If infection has occurred in poultry in a previously free country, zone or compartment, ND 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 10.9.22. to 10.9.26. has been carried out during that three-month period.

Article 10.9.4.

Recommendations for importation from a Newcastle disease free country, zone or compartment as defined in Article 10.9.3.

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 suggestive of ND on the day of shipment;

2) the poultry were kept in an ND 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 ND, the nature of the vaccine used and the date of vaccination have been should be attached to the certificate.

Article 10.9.5.

Recommendations for the importation of live birds other than poultry

Regardless of the ND status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1) the birds showed no clinical sign suggestive of infection by NDV on the day of shipment;

2) the birds were kept in isolation approved by the Veterinary Services since they were hatched or for at least the 21 days prior to shipment and showed no clinical sign of infection during the isolation period;

3) a statistically valid sample of the birds, selected in accordance with the provisions of Article 10.9.24., was subjected to a diagnostic test within 14 days prior to shipment to demonstrate freedom from infection with NDV;
4) the birds are transported in new or appropriately sanitized containers.

If the birds have been vaccinated against ND, the nature of the vaccine used and the date of vaccination have been should be attached to the certificate.

Article 10.9.6.

Recommendations for importation from a Newcastle disease free country, zone or compartment

For day-old live poultry

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

1) the poultry were hatched and kept in an ND free country, zone or compartment since they were hatched;

2) the poultry were derived from parent flocks which had been kept in an ND 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 parent flocks have been vaccinated against ND, the nature of the vaccine used and the date of vaccination have been should be attached to the certificate.

Article 10.9.7.

Recommendations for the importation of day-old live birds other than poultry

Regardless of the ND status of the country of origin, Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1) the birds showed no clinical sign suggestive of infection by NDV on the day of shipment;

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 NDV;

4) the birds are transported in new or appropriately sanitized containers.

If the birds or parent flocks have been vaccinated against ND, the nature of the vaccine used and the date of vaccination have been should be attached to the certificate.

Article 10.9.8.

Recommendations for importation from a Newcastle disease free country, zone or compartment

For hatching eggs of poultry

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

1) the eggs came from an ND free country, zone or compartment;

2) the eggs were derived from parent flocks which had been kept in an ND 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.
Annex XXVI (contd)

If the parent flocks have been vaccinated against ND, the nature of the vaccine used and the date of vaccination have been should be attached to the certificate.

Article 10.9.9.

Recommendations for the importation of hatching eggs from birds other than poultry

Regardless of the ND 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 NDV;
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 ND, the nature of the vaccine used and the date of vaccination have been should be attached to the certificate.

Article 10.9.10.

Recommendations for importation from a Newcastle disease free country, zone or compartment

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 an ND free country, zone or compartment;
2) the eggs are transported in new or appropriately sanitized packaging materials.

Article 10.9.11.

Recommendations for importation of egg products of poultry

Regardless of the ND 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 Article 10.9.10.; or
2) the commodity has been processed to ensure the destruction of NDV in accordance with Article 10.9.20.;

AND

3) the necessary precautions were taken to avoid contact of the egg products with any source of NDV.

Article 10.9.12.

Recommendations for importation from a Newcastle disease free country, zone or compartment

For poultry semen

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the donor poultry:
1) showed no clinical sign suggestive of ND on the day of semen collection;

2) were kept in an ND free country, zone or compartment for at least the 21 days prior to and at the time of semen collection.

Article 10.9.13.

Recommendations for the importation of semen of birds other than poultry

Regardless of the ND 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 the 21 days prior to and on the day of semen collection;

2) showed no clinical sign suggestive of infection with NDV during the isolation period and on the day of semen collection;

3) were subjected to a diagnostic test within 14 days prior to semen collection to demonstrate freedom from infection with NDV.

Article 10.9.14.

Recommendations for importation from a Newcastle disease free country, zone or compartment

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 an ND free country, zone or compartment since they were hatched or for at least the past 21 days;

2) which have been slaughtered in an approved abattoir in an ND free country, zone or compartment and have been subjected to ante- and post-mortem inspections in accordance with Chapter 6.2. and have been found free of any sign suggestive of ND.

Article 10.9.15.

Recommendations for importation of meat products of poultry

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

1) the commodity is derived from fresh meat which meet the requirements of Article 10.9.14.; or

2) the commodity has been processed to ensure the destruction of NDV in accordance with Article 10.9.21.;

AND

3) the necessary precautions were taken to avoid contact of the commodity with any source of NDV.

Article 10.9.16.

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 ND 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 a ND free country, zone or compartment from poultry which were kept in a ND 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;
Annex XXVI (contd)

OR

2) these commodities have been processed to ensure the destruction of NDV using (under study):
   a) pasteurisation; or
   b) moist heat treatment for 30 minutes at 56°C;

AND

3) the necessary precautions were taken to avoid contact of the commodity with any source of NDV.

Article 10.9.17.

Recommendations for the importation of feathers and down of poultry

Regardless of the ND 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 10.9.14. and were processed in a ND free country, zone or compartment; or

2) these commodities have been processed to ensure the destruction of NDV (under study) 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 NDV;

AND

3) the necessary precautions were taken to avoid contact of the commodity with any source of NDV.

Article 10.9.18.

Recommendations for the importation of feathers and down of birds other than poultry

Regardless of the ND 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 NDV (under study) 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 NDV;

and

2) the necessary precautions were taken to avoid contact of the commodity with any source of NDV.
Article 10.9.19.

Recommendations for the importation of feather meal and poultry meal

Regardless of the ND 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 a ND free country, zone or compartment from poultry which were kept in a ND 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 for a minimum of 280 seconds;

AND

3) the necessary precautions were taken to avoid contact of the commodity with any source of ND virus.

Article 10.9.20.

Procedures for the inactivation of the Newcastle disease virus in eggs and egg products

The following times and temperatures are suitable for the inactivation of ND virus present in eggs and egg products:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Core temperature (°C)</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole egg</td>
<td>55</td>
<td>2,521 seconds</td>
</tr>
<tr>
<td>Whole egg</td>
<td>57</td>
<td>1,596 seconds</td>
</tr>
<tr>
<td>Whole egg</td>
<td>59</td>
<td>674 seconds</td>
</tr>
<tr>
<td>Liquid egg white</td>
<td>55</td>
<td>2,278 seconds</td>
</tr>
<tr>
<td>Liquid egg white</td>
<td>57</td>
<td>986 seconds</td>
</tr>
<tr>
<td>Liquid egg white</td>
<td>59</td>
<td>301 seconds</td>
</tr>
<tr>
<td>10% salted yolk</td>
<td>55</td>
<td>176 seconds</td>
</tr>
<tr>
<td>Dried egg white</td>
<td>57</td>
<td>50.4 hours</td>
</tr>
</tbody>
</table>

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.
Annex XXVI (contd)

Article 10.9.21.

Procedures for the inactivation of the Newcastle disease virus in meat

The following times for industry standard temperatures are suitable for the inactivation of ND virus present in meat.

<table>
<thead>
<tr>
<th>Core temperature (°C)</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poultry meat</td>
<td></td>
</tr>
<tr>
<td>65.0</td>
<td>39.8 seconds</td>
</tr>
<tr>
<td>70.0</td>
<td>3.6 seconds</td>
</tr>
<tr>
<td>74.0</td>
<td>0.5 second</td>
</tr>
<tr>
<td>80.0</td>
<td>0.03 second</td>
</tr>
</tbody>
</table>

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 10.9.22.

Introduction to surveillance: introduction

Articles 10.9.22. to 10.9.26. define the principles and provide a guide on the surveillance for ND as defined in Article 10.9.1. and is complementary to Chapter 1.4. It is applicable to Member Countries seeking to determine their ND 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 ND status is also provided.

Surveillance for ND is complicated by the known occurrence of avian paramyxovirus serotype 1 (APMV-1) infections in many bird species, both domestic and wild, and the widespread utilisation of ND vaccines in domestic poultry.

The impact and epidemiology of ND differ widely in different regions of the world and therefore it is not possible to provide specific recommendations for all situations. Therefore, surveillance strategies employed for demonstrating freedom from ND at an acceptable level of confidence will need to should be adapted to the local situation. Variables such as the frequency of contacts of poultry with wild birds, different biosecurity levels, production systems and the commingling of different susceptible species 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 ND 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 freedom from NDV infection.

Surveillance for ND 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 NDV infection.

Article 10.9.23.

General conditions and methods for surveillance: general conditions and methods

1) A surveillance system in accordance with Chapter 1.4. should be under the responsibility of the Veterinary Authority. In particular there should be in place:
   a) a formal and ongoing system for detecting and investigating outbreaks of disease or NDV infection;
   b) a procedure for the rapid collection and transport of samples from suspect cases of ND to a laboratory for ND diagnosis;
   c) a system for recording, managing and analysing diagnostic and surveillance data.
2) The ND 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 ND 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 ND should be investigated immediately. As suspicion cannot 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 to those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in ND diagnosis and control;

b) implement, when relevant, regular and frequent clinical, virological and serological surveillance of high risk groups of poultry within the target population (e.g. those adjacent to an ND infected country, zone, compartment, places where birds and poultry of different origins are mixed, or other sources of NDV).

An effective surveillance system may identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is due to NDV infection. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from NDV infection should 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.).

Article 10.9.24.

Surveillance strategies

1. Introduction

Any surveillance programme requires inputs from professionals competent and experienced in this field and should be thoroughly documented. The design of surveillance programmes to prove the absence of NDV infection or circulation needs to be carefully followed to avoid producing results that are either unreliable, or excessively costly and logistically complicated.

If a Member Country wishes to declare freedom from NDV infection in a country, zone or compartment, the subpopulation used for the surveillance for the disease and infection should be representative of all poultry within the country, zone or compartment. Multiple surveillance methods should be used concurrently to accurately define the true ND status of poultry populations. Active and passive surveillance for ND should be ongoing with the frequency of active surveillance being appropriate to the disease situation in the country. Surveillance should be composed of random and/or targeted approaches, dependent on the local epidemiological situation and using clinical, virological and serological methods. If alternative tests are used they should have been validated as fit-for-purpose in accordance with OIE standards. A Member Country should justify the surveillance strategy chosen as adequate to detect the presence of NDV infection in accordance with Chapter 1.4. and the prevailing epidemiological situation.

In surveys, the sample size selected for testing should be statistically justified to detect infection at a predetermined target prevalence. The sample size and expected prevalence determine the level of confidence in the results of the survey. The survey design and frequency of sampling should be dependent on the historical and current local epidemiological situation. The Member Country should justify the choice of survey design and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Chapter 1.4.

Targeted surveillance (e.g. based on the increased likelihood of infection in a population) may be an appropriate strategy.
It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g., unvaccinated chickens). Similarly, virological and serological testing could target species that may not show clinical signs (Article 10.9.2.) of ND and are not routinely vaccinated (e.g., ducks). Surveillance may also target poultry populations at specific risk, for example direct or indirect contact with wild birds, multi-age flocks, local trade patterns including live poultry markets, the presence of more than one species on the holding and poor biosecurity measures in place. In situations where wild birds have been shown to play a role in the local epidemiology of ND, surveillance of wild birds may be of value in alerting Veterinary Services to the possible exposure of poultry and, in particular, of free ranging poultry.

The sensitivity and specificity of the diagnostic tests are key factors in the choice of survey design, which should anticipate the occurrence of false positive and false negative reactions. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination and infection history and for the different species in the target population. If the characteristics of the testing system are known, the rate at which these false reactions are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of infection 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 results of active and passive surveillance are important in providing reliable evidence that no NDV infection is present in a country, zone or compartment.

2. Clinical surveillance

Clinical surveillance aims to detect clinical signs suggestive of ND at the flock level and should not be underestimated as an early indication of infection. Monitoring of production parameters (e.g., a drop in feed or water consumption or egg production) is important for the early detection of NDV infection in some populations, as there may be no, or mild clinical signs, particularly if they are vaccinated. Any sampling unit within which suspicious animals are detected should be considered as infected until evidence to the contrary is produced. Identification of infected flocks is vital to the identification of sources of NDV.

A presumptive diagnosis of clinical ND in suspect infected populations should always be confirmed by virological testing in a laboratory. This will enable the molecular, antigenic and other biological characteristics of the virus to be determined.

It is desirable that NDV isolates are sent promptly to an OIE Reference Laboratory for archiving and further characterisation if required.

3. Virological surveillance

Virological surveillance should be conducted to:

a) monitor at risk populations;

b) confirm suspect clinical cases;

c) follow up positive serological results in unvaccinated populations or sentinel birds;

d) test ‘normal’ daily mortalities (if warranted by an increased risk e.g. infection in the face of vaccination or in establishments epidemiologically linked to an outbreak).

4. Serological surveillance

Where vaccination is carried out, serological surveillance is of limited value. Serological surveillance cannot be used to discriminate between NDV and other APMV-1. Positive NDV antibody test results can have five possible causes:
Annex XXVI (contd)

a) natural infection with APMV-1;

b) vaccination against ND;

c) exposure to vaccine virus;

d) 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;

e) non-specific test reactions.

It may be possible to use serum collected for other survey purposes for ND surveillance. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of NDV should not be compromised.

Discovery of seropositive, unvaccinated flocks should be investigated further by conducting a thorough epidemiological investigation. Since seropositive results are not necessarily indicative of infection, virological methods should be used to confirm the presence of NDV in such populations. Until validated strategies and tools to differentiate vaccinated animals from those infected with field APMV-1 are available, serological tools should not be used to identify NDV infection in vaccinated populations.

5. Use of sentinel poultry

There are various applications of the use of sentinel poultry as a surveillance tool to detect virus circulation. They may be used to monitor vaccinated populations or species which are less susceptible to the development of clinical disease for the circulation of virus. Sentinel poultry should be immunologically naïve and may be used in vaccinated flocks. In case of the use of sentinel poultry, the structure and organisation of the poultry sector, the type of vaccine used and local epidemiological factors will determine the type of production systems where sentinels should be placed, the frequency of placement and monitoring of the sentinels.

Sentinel poultry should be in close contact with, but should be identified to be clearly differentiated from, the target population. Sentinel poultry should be observed regularly for evidence of clinical disease and any disease incidents investigated by prompt laboratory testing. The species to be used as sentinels should be proven to be highly susceptible to infection and ideally develop clear signs of clinical disease. Where the sentinel poultry do not necessarily develop overt clinical disease a programme of regular active testing by virological and serological tests should be used (the development of clinical disease may be dependent on the sentinel species used or use of live vaccine in the target population that may infect the sentinel poultry). The testing regime and the interpretation of the results will depend on the type of vaccine used in the target population. Sentinel birds should be used only if no appropriate laboratory procedures are available.

Article 10.9.25.

**Additional surveillance requirements for declaration of freedom Documentation of Newcastle disease free status: additional surveillance procedures**

The requirements for a country, zone or compartment to declare freedom from ND are given in Article 10.9.3.

A Member Country declaring freedom of a country, zone or compartment with or without vaccination should report the results of a surveillance programme in which the ND susceptible poultry population undergoes regular surveillance planned and implemented according to the general conditions and methods described in these recommendations.
Annex XXVI (contd)

1. **Member Countries declaring freedom from Newcastle disease for the country, zone or compartment**

In addition to the general conditions described in the *Terrestrial Code*, a Member Country declaring freedom from ND for the entire country, or a *zone* or a *compartment* should provide evidence for the existence of an effective *surveillance* programme. The *surveillance* programme should be planned and implemented according to general conditions and methods described in this chapter to demonstrate absence of NDV *infection* in *poultry* during the preceding 12 months.

2. **Additional requirements for countries, zones or compartments that practise vaccination**

*Vaccination* against ND may be used as a component of a disease prevention and control programme. In vaccinated populations there is a need to perform *surveillance* to ensure the absence of NDV circulation. The use of sentinel *poultry* may provide further confidence of the absence of virus circulation. The *surveillance* should be repeated at least every six months or at shorter intervals according to the risk in the country, *zone* or *compartment*, or evidence to show the effectiveness of the *vaccination* programme is regularly provided.

**Article 10.9.26.**

**Additional surveillance requirements for regaining freedom** Countries, zones or compartments regaining freedom from Newcastle disease following an outbreak: additional surveillance procedures

A Member Country regaining country, *zone* or *compartment* freedom from ND should show evidence of an active *surveillance* programme depending on the epidemiological circumstances of the *outbreak* to demonstrate the absence of the *infection*.

A Member Country declaring freedom of a country, *zone* or *compartment* after an *outbreak* of ND with or without *vaccination* should report the results of a *surveillance* programme in which the ND susceptible *poultry* population undergoes regular *surveillance* planned and implemented according to the general conditions and methods described in these recommendations.

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CHAPTER 11.8.

INFECTION WITH MYCOPLASMA MYCOIDES SUBSP. MYCOIDES SC (CONTAGIOUS BOVINE PLEUROPNEUMONIA)

Article 11.8.1.

General provisions

For the purposes of the Terrestrial Code, the incubation period for contagious bovine pleuropneumonia (CBPP) shall be six months.

For the purpose of this chapter, a case of CBPP means an animal infected with Mycoplasma mycoides subsp. mycoides SC (MmmSC), and freedom from CBPP means freedom from MmmSC infection.

For the purpose of this chapter, susceptible animals include bovids cattle (Bos indicus, B. taurus and B. grunniens) and water buffaloes (Bubalus bubalis).

For the purposes of international trade, this chapter deals not only with the occurrence of clinical signs caused by MmmSC, but also with the presence of infection with MmmSC in the absence of clinical signs.

The following defines the occurrence of MmmSC infection:

1) MmmSC has been isolated and identified as such from an animal, embryos, oocytes or semen; or

2) antibodies to MmmSC antigens which are not the consequence of vaccination, or MmmSC DNA, have been identified in one or more animals showing pathological lesions consistent with infection with MmmSC with or without clinical signs, and epidemiological links to a confirmed outbreak of CBPP in susceptible animals.

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

When authorising import or transit of the commodities listed in this chapter, with the exception of those listed in Article 11.8.2., Veterinary Authorities should require the conditions prescribed in this chapter relevant to the CBPP status of the domestic bovids cattle and water buffalo population of the exporting country, zone or compartment.

Article 11.8.2.

Safe commodities

When authorising import or transit of the following commodities, Veterinary Authorities should not require any CBPP related conditions, regardless of the CBPP status of the domestic bovids cattle and water buffalo population of the exporting country, zone or compartment:

1) milk and milk products;

2) hides and skins;

3) meat and meat products (excluding lung).

Article 11.8.3.

CBPP free country or zone

To qualify for inclusion in the existing list of CBPP free countries and zones, a Member should:
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1) have a record of regular and prompt animal disease reporting;

2) send a declaration to the OIE stating that:
   a) there has been no outbreak of CBPP during the past 24 months;
   b) no evidence of CBPP infection has been found during the past 24 months;
   c) no vaccination against CBPP has been carried out during the past 24 months,

   and supply documented evidence that surveillance for CBPP in accordance with this chapter is in operation
   and that regulatory measures for the prevention and control of CBPP have been implemented;

3) not have imported since the cessation of vaccination any animals vaccinated against CBPP.

The country or zone will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 2a), 2b), 2c) and 3 above 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 11.8.4.

Recovery of free status

When a CBPP outbreak occurs in a CBPP free country or zone, one of the following waiting periods is required to regain the status of CBPP free country or zone:

1) 12 months after the last case where a stamping-out policy and serological surveillance and strict movement control are applied in accordance with this chapter;

2) if vaccination was used, 12 months after the slaughter of the last vaccinated animal.

Where a stamping-out policy is not practised, the above waiting periods do not apply but Article 11.8.3. applies.

Article 11.8.5.

CBPP infected country or zone

When the requirements for acceptance as a CBPP free country or zone are not fulfilled, a country or zone shall be considered as infected.

Article 11.8.6.

CBPP free compartment

The bilateral recognition of a CBPP free compartment should follow the principles laid down in this chapter and in Chapters 4.3. and 4.4.

Article 11.8.7.

Recommendations for importation from CBPP free countries or zones, or from CBPP free compartments

For domestic bovids, cattle and water buffaloes

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals...
1) showed no clinical sign of CBPP on the day of shipment;
2) were kept in a CBPP free country, zone or compartment since birth or for at least the past six months.

Article 11.8.8.

Recommendations for importation from CBPP infected countries or zones

For domestic bovids, cattle and water buffaloes for slaughter

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals:
1) showed no clinical sign of CBPP on the day of shipment;
2) originate from an establishment where no case of CBPP was officially reported for the past six months, and
3) are transported directly to the slaughterhouse in sealed vehicles.

Article 11.8.9.

Recommendations for importation from CBPP free countries or zones, or from CBPP free compartments

For bovine semen

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:
1) the donor animals:
   a) showed no clinical sign of CBPP on the day of collection of the semen;
   b) were kept in a CBPP free country, zone or compartment since birth or for at least the past six months;
2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.8.10.

Recommendations for importation from CBPP infected countries

For bovine semen

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:
1) the donor animals:
   a) showed no clinical sign of CBPP on the day of collection of the semen;
   b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;
   c) were isolated from other domestic bovids and water buffaloes from the day of the first complement fixation test until collection;
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d) were kept since birth, or for the past six months, in an establishment where no case of CBPP was reported during that period, and that the establishment was not situated in a CBPP infected zone;

e) AND EITHER:

i) have not been vaccinated against CBPP;

OR

ii) were vaccinated using a vaccine complying with the standards described in the Terrestrial Manual not more than four months prior to collection; in this case, the condition laid down in point b) above is not required;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 11.8.11.

Recommendations for importation from CBPP free countries or zones, or from CBPP free compartments

For in vivo derived or in vitro produced embryos or oocytes of domestic bovidae and water buffaloes

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

1) the donor animals:

   a) showed no clinical sign of CBPP on the day of collection of the embryos or oocytes;

   b) were kept in a CBPP free country, zone or compartment since birth or for at least the past six months;

2) the oocytes were fertilised with semen meeting the conditions of Article 11.8.9.;

3) 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 11.8.12.

Recommendations for importation from CBPP infected countries

For in vivo derived or in vitro produced embryos or oocytes of domestic bovidae and water buffaloes

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

1) the donor animals:

   a) showed no clinical sign of CBPP on the day of collection of the embryos or oocytes;

   b) were subjected to the complement fixation test for CBPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to collection;

   c) were isolated from other domestic domestic bovidae and water buffaloes from the day of the first complement fixation test until collection;

   d) were kept since birth, or for the past six months, in an establishment where no case of CBPP was reported during that period, and that the establishment was not situated in a CBPP infected zone;
Annex XXVII (contd)

e) AND EITHER:
   i) have not been vaccinated against CBPP;
   OR
   ii) were vaccinated using a vaccine complying with the standards described in the Terrestrial Manual not more than four months prior to collection; in this case, the condition laid down in point b) above is not required;

2) the oocytes were fertilised with semen meeting the conditions of Article 11.8.10.;

3) 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 11.8.13.

Introduction to surveillance: introduction

Articles 11.8.13. to 11.8.17. define the principles and provide a guide for the surveillance of CBPP in accordance with Chapter 1.4. applicable to Member Countries seeking establishment of freedom from CBPP. Guidance is provided for Member Countries seeking reestablishment of freedom from CBPP for the entire country or for a zone, following an outbreak and for the maintenance of CBPP free status.

The impact and epidemiology of CBPP 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 CBPP at an acceptable level of confidence will need to be adapted to the local situation. It is incumbent upon the applicant Member Country to submit a dossier to the OIE in support of its application that not only explains the epidemiology of CBPP in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically-based supporting data. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that the absence of CBPP infection is assured at an acceptable level of confidence.

Surveillance for CBPP should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from CBPP infection.


General conditions and methods for surveillance: general conditions and methods

1) A surveillance system in accordance with Chapter 1.4. should be under the responsibility of the Veterinary Authority. A procedure should be in place for the rapid collection and transport of samples from suspect cases of CBPP to a laboratory for CBPP diagnoses.

2) The CBPP surveillance programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers (such as community animal health workers) who have day-to-day contact with livestock, meat inspectors as well as laboratory diagnosticians, should report promptly any suspicion of CBPP. They should be integrated directly or indirectly (e.g. through private veterinarians or veterinary para-professionals) into the surveillance system. All suspect cases of CBPP should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a laboratory. 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 CBPP diagnosis and control;
b) implement, when relevant, regular and frequent clinical inspection and testing of high-risk groups of animals, such as those adjacent to a CBPP infected country or infected zone (for example, areas of transhumant production systems);

c) take into consideration additional factors such as animal movement, different production systems, geographical and socio-economic factors that may influence the risk of disease occurrence.

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 CBPP. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from CBPP infection 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 standstill orders, etc.).

Article 11.8.15.

Surveillance strategies

1. Introduction

The target population for surveillance aimed at identifying disease and infection should cover all the susceptible species (Bos taurus, B. indicus, B. grunniens, and Bubalus bubalis) within the country or zone.

Given the limitations of the diagnostic tools available, the interpretation of surveillance results should be at the herd level rather than at the individual animal level.

Randomised surveillance may not be the preferred approach given the epidemiology of the disease (usually uneven distribution and potential for occult foci of infection in small populations) and the limited sensitivity and specificity of currently available tests. Targeted surveillance (e.g. based on the increased likelihood of infection in particular localities or species, focusing on slaughter findings, and active clinical surveillance) may be the most appropriate strategy. The applicant Member Country should justify the surveillance strategy chosen as adequate to detect the presence of CBPP infection in accordance with Chapter 1.4. and the epidemiological situation.

Targeted surveillance may involve testing of the entire target subpopulation or a sample from it. In the latter case the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection 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 applicant 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 clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated.

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

Clinical **surveillance** aims at detecting clinical signs of CBPP in a **herd** by close physical examination of susceptible **animals**. Clinical inspection will be is an important component of CBPP **surveillance** contributing to reach the desired level of confidence of detection of disease if a sufficiently large number of clinically susceptible **animals** is examined.

Clinical **surveillance** and laboratory testing should always be applied in series to clarify the status of CBPP suspects detected by either of these complementary diagnostic approaches. Laboratory testing and post-mortem examination may contribute to confirm clinical suspicion, while clinical **surveillance** may contribute to confirmation of positive serology. Any sampling unit within which suspicious **animals** are detected should be classified as infected until contrary evidence is produced.

3. **Pathological surveillance**

Systematic pathological **surveillance** for CBPP is the most effective approach and should be conducted at **slaughterhouses** and other **slaughter** facilities. Suspect pathological findings should be confirmed by agent identification. Training courses for **slaughter** personnel and **meat** inspectors are recommended.

4. **Serological testing**

Serological **surveillance** is not the preferred strategy for CBPP. However, in the framework of epidemiologic investigations, serological testing may be used.

The limitations of available serological tests for CBPP will make the interpretation of results difficult and useful only at the **herd** level. Positive findings should be followed-up by clinical and pathological investigations and agent identification.

Clustering of seropositive reactions should be expected in CBPP **infections** and is will be usually accompanied by clinical signs. As clustering may signal field strain infection, the investigation of all instances should be incorporated in the **surveillance** strategy.

Following the identification of a CBPP infected **herd**, contact herds need to should be tested serologically. Repeated testing may be necessary to reach an acceptable level of confidence in **herd** classification.

5. **Agent surveillance**

Agent **surveillance** should be conducted to follow-up and confirm or exclude suspect **cases**. Isolates should be typed to confirm **MmmSC**.

**Article 11.8.16.**

**Countries or zones applying for recognition of freedom from CBPP**

In addition to the general conditions described in this chapter, a Member Country applying for recognition of CBPP freedom for the 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 will should be planned and implemented according to general conditions and methods in this chapter, to demonstrate absence of CBPP infection, during the preceding 24 months in susceptible populations. This requires the support of a national or other **laboratory** able to undertake identification of CBPP infection.
Countries or zones re-applying for recognition of freedom from CBPP following an outbreak

In addition to the general conditions described in this chapter, a Member re-applying for recognition of country or zone freedom from CBPP should show evidence of an active surveillance programme for CBPP, following the recommendations of this chapter.

Two strategies are recognised by the OIE in a programme to eradicate CBPP infection following an outbreak:

1) slaughter of all clinically affected and in-contact susceptible animals;
2) vaccination used without subsequent slaughter of vaccinated animals.

The time period before which an application can be made for re-instatement of freedom from CBPP depends on which of these alternatives is followed. The time periods are prescribed in Article 11.8.4.

OIE endorsed official control programme for CBPP

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

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

For an official control programme for CBPP 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 CBPP; this evidence can be provided by countries following the OIE PVS Pathway;
3) submit a detailed plan of the programme to control and eventually eradicate CBPP 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) submit documentation indicating that the official control programme for CBPP has been implemented and is applicable to the entire territory;
4) submit a dossier on the epidemiology of CBPP in the country describing the following:
   a) the general epidemiology in the country highlighting the current knowledge and gaps;
   b) the measures to prevent introduction of infection, the rapid detection of, and response to, all CBPP outbreaks in order to reduce the incidence of CBPP outbreaks and to eliminate CBPP in at least one zone in the country;
   c) the main livestock production systems and movement patterns of CBPP susceptible animals and their products within and into the country.
5) submit evidence that CBPP 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 in accordance with the *Terrestrial Manual* including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC;

6) where vaccination is practised as a part of the official control programme for CBPP, 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;
      iii) technical specification of the vaccines used and description of the licensing procedures in place;
      iv) the proposed timeline and strategy for the cessation of vaccination;

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

The Member Country’s official control programme for CBPP will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the official control programme and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

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

= non-compliance with the timelines or performance indicators of the programme; or
= significant problems with the performance of the Veterinary Services; or
= an increase in the incidence of CBPP that cannot be addressed by the programme.

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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 1.6.4. (for BSE), 1.6.5. (for FMD), 1.6.6. (for CBPP), 1.6.7. (for AHS), 1.6.8. (for PPR) or 1.6.9. (for CSF).

The OIE framework for the official recognition and maintenance of disease status is described in Resolution N° XXX (administrative procedures) and Resolution N° XXXI (financial obligations) adopted during the 81st General Session in May 2013.

[Article 1.6.2.]

[Article 1.6.3.]
Article 1.6.3.bis

Endorsement by the OIE of an official control programme for CBPP

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

When requesting endorsement by the OIE of an official control programme for CBPP, the Member Country should submit to the OIE Scientific and Technical Department a dossier providing the information requested in Article 1.6.12.

[Article 1.6.4.]

[Article 1.6.5.]

[Article 1.6.6.]

[Article 1.6.7.]

[Article 1.6.8.]

[Article 1.6.9.]

[Article 1.6.10.]

[Article 1.6.11.]

Article 1.6.12.

COUNTRY WITH AN OIE ENDORSED OFFICIAL CONTROL PROGRAMME FOR CBPP

Report of a Member Country which applies for the OIE endorsement of its official control programme for CBPP under Chapter 11.8. of the Terrestrial Code

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

1. Introduction

a) Geographical factors. Provide a general description of the country and zones including physical, geographical and other factors that are relevant to CBPP 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 in specific parts of the country, the boundaries of the zones should be clearly defined, including the protection zone, if applied. Provide a digitalised, georeferenced 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.
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2. Veterinary system

   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to CBPP 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 1.1.3., of the Terrestrial Manual and describe how the Veterinary Services supervise and control all CBPP related activities in the country and any zones. Provide maps and tables wherever possible.

   c) Provide a description of 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 CBPP surveillance and control. Include a description of training and awareness programmes on CBPP.

   d) Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS Pathway.

3. CBPP control

   a) Provide a description of CBPP 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 MmmSC present.

   b) Describe the general epidemiology of CBPP in the country and the surrounding countries or zones highlighting the current knowledge and gaps.

   c) Describe how CBPP is controlled in the country or any zones.

   d) Provide a description of the legislation, organisation and implementation of the current CBPP control programme. Indicate if detailed operational guidelines exist and give a brief summary.

   e) Provide information on types of vaccines used and species vaccinated. Provide information on the licensing process for 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. Provide information on pastoralism, transhumance and related paths of movement. Describe measures to prevent introduction of CBPP from neighbouring countries or zones and through trade.

4. CBPP surveillance

   Provide documentary evidence that surveillance for CBPP in the country complies with the provisions of Articles 11.8.12., to 11.8.17., of the Terrestrial Code and Chapter 2.4.9., of the Terrestrial Manual. In particular, the following points should be addressed:

   a) Describe the criteria for suspecting a case of CBPP and the procedure for notifying (by whom and to whom) and what penalties are involved for failure to report.

   b) Provide a description of the means employed to detect the presence of any MmmSC strain in the susceptible population of the zone. Provide criteria for selection of populations for targeted surveillance and numbers of animals examined and samples tested. Provide details of the methods applied for monitoring the performance of the surveillance system including indicators.
c) 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/abattoir 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 of the methods applied for monitoring the performance of the surveillance system including indicators. Explain whether serological and slaughterhouse/abattoir surveys are conducted and, if so, how frequently and for what purpose.

d) Slaughterhouses/abattoirs, slaughter slabs. What are the criteria for suspecting a lesion is CBPP? What is the procedure for notifying (by whom and to whom)? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for CBPP agent, species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details on follow-up actions taken on suspicious and positive results.

e) Provide details of training programmes for personnel involved in clinical and slaughterhouses/abattoirs surveillance, and the approaches used to increase community involvement in CBPP surveillance programmes.

f) In countries where a significant proportion of animals in the country or zone are not slaughtered in controlled slaughterhouses/abattoirs, what are the alternative surveillance measures applied to detect CBPP (e.g. active clinical surveillance programme, laboratory follow-up).

g) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many herds of each susceptible species are in the country or zone? How are they distributed (e.g. herd density, etc.)? Provide tables and maps as appropriate.

h) Slaughterhouses/abattoirs and markets. Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country and the zone? How are the animals transported and handled during these transactions?

5. CBPP laboratory diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.4.9. of the Terrestrial Manual are applied. In particular, the following points should be addressed:

a) Is CBPP laboratory diagnosis carried out in the country? If so, provide a list of laboratories approved by the Competent Authority to diagnose CBPP. If not, provide the names of and the arrangements with the laboratories to which samples are sent, the follow-up procedures and the time frame for obtaining results. If applicable, indicate the laboratories 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 laboratories approved to test for CBPP, 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 of participation in inter-laboratory validation tests (ring tests).

iii) Biosecurity measures applied.

iv) Details of the type of tests undertaken including procedures to isolate and identify *M. mycoides* subsp. *mycoides* SC as opposed to *M. mycoides* subsp. *mycoides* LC.
6. CBPP prevention

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

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.

b) Import control procedures

Provide information on countries, zones or compartments from which the country authorises the import of susceptible animals or their products into the country or zone. Describe the criteria applied to approve such countries, zones or compartments. Describe the controls applied to 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. Provide summary statistics of imports of susceptible animals and their products for at least the past two years, specifying country, zone or compartments of origin, the species and the number or volume.

i) Provide a map with the number and location of ports, airports and land border 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) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or zone or their final destination, concerning the import and follow-up of the following:

- animals,
- semen, embryos and oocytes,
- veterinary medicinal products, i.e. biologics.

iii) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

7. Control measures and emergency response

a) Give details of any written guidelines, including contingency plans, available to the Veterinary Services for dealing with suspected or confirmed outbreaks of CBPP.

b) Advise whether quarantine is imposed on premises with suspected cases, pending final diagnosis? What other procedures are followed regarding suspected cases?

c) In the event of a CBPP outbreak:

i) Provide a detailed description of procedures that are followed in case of an outbreak including forward and backward tracing.

ii) Indicate the sampling and testing procedures used to identify and confirm presence of the causative agent.
iii) describe the actions taken to control the disease situation in and around any holdings found to be infected with CBPP;

iv) indicate the control or eradication procedures, such as vaccination, stamping-out policy, partial slaughter with vaccination, movement control, pastured livestock and livestock as pets, control of the livestock waste (e.g. offal, especially lungs, and carcasses), 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.

8. Official control programme for CBPP 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 CBPP in the Member Country, including:

a) objectives,

b) expected status to be achieved; for zones (if applicable) and for the whole country,

c) timelines of the control programme including cessation of vaccination,

d) performance indicators, including methods for measurement and verification,

e) description of the funding for the control programme and annual budgets for its duration.

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

Member Countries applying for recovery of the official endorsement of the national CBPP control programme should provide updated information in compliance with the provisions of Article 11.8.18. of the Terrestrial Code.

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DRAFT CHAPTER 4.X.

HIGH HEALTH STATUS HORSE SUBPOPULATION

Article 4.X.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 certified 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.

In line with the provisions in Chapter 4.4., the subpopulation is established 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. The separation, at all times, of high health status horses from all other equids is essential to maintain their membership in the subpopulation.

Horses that are moved internationally for the purpose of breeding or any other purpose not linked to competitions are not included in this subpopulation.

Article 4.X.2.

Criteria for the inclusion of horses in the high health status subpopulation

1. High health status

   Each horse in the subpopulation is subjected to specific measures to establish and maintain protect its health status, and preserve minimise the probability of spreading diseases to that of the other horses in the subpopulation.

   These measures comprise a specific set of laboratory tests, treatments and vaccinations appropriate to the disease status of the horse’s region of origin, regions visited and the regions that it will visit. Records of all treatments and vaccinations, and results of tests and clinical inspections are documented in an individual passport that complies with Chapter 5.12.

2. Identification and traceability

   Consistent with the provisions of Chapters 4.1. and 4.2., horses in the subpopulation are individually identified as follows:

   a) Each horse bears a permanent unique identifier individual identification, 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 individual document that identifies it as a member of the high health status subpopulation and refers to the passport and the identifier.

   d) Horses are registered in an international database that contains relevant information linked to the passport and the identifier. Veterinary Authorities should have access to this database.
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 all official 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.

   b) The high health status of each horse in the subpopulation is maintained by ensuring compliance at all times with an international biosecurity plan approved by the Veterinary Authorities of the importing and exporting countries, in accordance with the relevant recommendations of the OIE. This compliance is assured and validated through continual veterinary supervision of horses at the establishment of usual residence, during transport and at competition venues. This supervision is provided by authorised veterinarians. Non-compliance results in suspension of the high health status of the horse.

   c) An appropriate qualification period is required for entry or re-entry of a horse into the subpopulation. The procedures for qualification should be described in the international biosecurity plan.

   d) A maximum period is set for each absence of a horse from its country of usual residence, as specified in the international biosecurity plan.

   

   Article 4.X.3.

**Recommendations for the Veterinary Authorities**

Veterinary Authorities are encouraged to officially recognise organisations that will be responsible for ensuring compliance with this chapter should be approved and supervised by the Veterinary Authorities. Veterinary Authorities are also encouraged to develop specific protocols for the temporary importation of horses of high health status entering the country solely for the purpose of competition at equestrian events and for their return to their country of origin.

Veterinary Authorities are encouraged to recognise the international biosecurity plan guidelines developed by the OIE in collaboration with the International Equestrian Federation (FEI) and the International Federation of Horseracing Authorities (IFHA) on the basis of the relevant OIE guidelines. (Under study.)

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CHAPTER 12.8.

INFECTION WITH EQUID HERPESVIRUS TYPE 1
(EQUINE RHINOPNEUMONITIS)

Article 12.8.1.

General provisions

Equine rhinopneumonitis (ER) is a collective term for any one of several highly contagious, clinical disease entities of equids that may occur as a result of infection by either of two closely related herpesviruses, equid herpesvirus-1 and -4 (EHV-1 and EHV-4).

Infection by either EHV-1 or EHV-4 is characterised by a primary respiratory tract disease of varying severity that is related to the age and immunological status of the infected animal. Infections by EHV-1 in particular are capable of progression beyond the respiratory mucosa to cause the more serious disease manifestations of abortion, perinatal foal death, or neurological dysfunction.

For the purpose of international trade, recommendations are provided for EHV-1 (abortigenic and paralytic forms) only.

Standards for diagnostic tests are described in the Terrestrial Manual.

Article 12.8.2.

Recommendations for the importation of equines equids

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

1) showed no clinical sign of EHV-1 equine herpes virus type 1 infection (abortigenic and paralytic forms) on the day of shipment and during the 21 days prior to shipment;

2) were kept for the 21 days prior to shipment in an establishment where no case of EHV-1 equine herpes virus type 1 infection (abortigenic and paralytic forms), was reported during that period.

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CHAPTER 12.9.

INFECTION WITH EQUINE ARTERITIS VIRUS

Article 12.9.1.

General provisions

For the purposes of the Terrestrial Code, equine viral arteritis (EVA) is defined as an infection of domestic equids with equine arteritis virus (EAV).

This chapter deals not only with the occurrence of clinical signs caused by equine arteritis virus EAV, but also with the presence of infection with equine arteritis virus EAV in the absence of clinical signs.

For the purposes of this chapter, isolation is defined as the separation of domestic equids from those of a different EVA health status, utilising appropriate biosecurity measures, with the objective of preventing the transmission of infection.

The infective period for EVA shall be 28 days for all categories of equids except sexually mature stallions where the infective period may be for the life of the animal. Because the infective period may be extended in the case of virus shedding in semen, the status of seropositive stallions should be checked to ensure that they do not shed virus in their semen.

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

Article 12.9.2.

Recommendations for the importation of uncastrated male equids

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the animals showed no clinical sign of EVA on the day of shipment and during the 28 days prior to shipment and met one of the following requirements:

1) were isolated for the 28 days prior to shipment and were subjected to a test for EVA carried out on a single blood sample collected during the 21 days prior to shipment with negative result; or

2) were subjected between six and nine months of age to a test for EVA:

   EITHER:

   a) with a negative result,

   OR

   b) with a positive result, followed at least 14 days later by a second test showing a stable or decreasing antibody titre;

   and were immediately vaccinated against EVA and regularly revaccinated according to the recommendations of the manufacturer; or

3) met the following requirements:

   a) were isolated; and

   b) not earlier than seven days of commencing isolation were subjected to a test for EVA on a blood sample with negative results; and
c) were then immediately vaccinated; and 
d) were kept separated from other equids for 21 days following vaccination; and 
e) were revaccinated regularly according to the recommendations of the manufacturer; or

4) have been subjected to a test for EVA carried out on a blood sample with positive results and then: either
   a) were subsequently test mated to two mares within six months prior to shipment which were subjected
to two tests for EVA with negative results on blood samples collected at the time of test mating and
again 28 days after the mating; or
   b) were subjected to a test for EVA\textsuperscript{EAV} with negative results, carried out on semen collected during
the six months prior to shipment; or
   c) were subjected to a test for EVA\textsuperscript{EAV} with negative results, carried out on semen collected within six
months after the blood sample was tested, then immediately vaccinated, and revaccinated regularly in
accordance with the recommendations of the manufacturer.

Article 12.9.3.

Recommendations for the importation of equids other than uncastrated males

Veterinary Authorities of importing countries should require the presentation of an international veterinary
certificate attesting that the animals showed no clinical sign of EVA on the day of shipment and

EITHER

1) were kept in an establishment where no animals have shown any signs of EVA for the 28 days prior to
shipment; and
   a) were subjected to a test for EVA carried out on blood samples collected either once within 21 days
prior to shipment with negative result, or on two occasions at least 14 days apart within 28 days prior to
shipment, which demonstrated stable or declining antibody titres; or
   b) were regularly vaccinated according to the recommendations of the manufacturer;

OR

2) were isolated for the 28 days prior to shipment and during this period the animals showed no sign of EVA.

Article 12.9.4.

Recommendations for the importation of equine semen

Veterinary Authorities of importing countries should require the presentation of an international veterinary
certificate attesting that the donors were kept for the 28 days prior to semen collection in an establishment where
no equid has shown any clinical sign of EVA during that period and showed no clinical sign of EVA on the day of
semen collection; and

1) were subjected between six and nine months of age to a test for EVA:
Annex XXX (contd)

EITHER:

a) with a negative result,

OR

b) with a positive result, followed at least 14 days later by a second test showing a stable or decreasing antibody titre;

and were immediately vaccinated for EVA and regularly revaccinated according to the recommendations of the manufacturer; or

2) were isolated and not earlier than seven days of commencing isolation were subjected to a test for EVA on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equids and regularly revaccinated according to the recommendations of the manufacturer; or

3) were subjected to a test for EVA on a blood sample with negative results within 14 days prior to semen collection, and had been separated from other equids not of an equivalent EVA status for 14 days prior to blood sampling until the end of semen collection; or

4) have been subjected to a test for EVA carried out on a blood sample with positive results and then: either

a) were subsequently test mated to two mares within six months prior to semen collection, which were subjected to two tests for EVA with negative results on blood samples collected at the time of test mating and again 28 days after the test mating; or

b) were subjected to a test for EVA EAV with negative results, carried out on semen collected within six months prior to collection of the semen to be exported; or

c) were subjected to a test for EVA EAV with negative results, carried out on semen collected within six months after the blood sample was collected, then immediately vaccinated, and revaccinated regularly; or

5) for frozen semen, were subjected with negative results either:

a) to a test for EVA carried out on a blood sample taken not earlier than 14 days and not later than 12 months after the collection of the semen for export; or

b) to a test for EVA EAV carried out on an aliquot of the semen collected immediately prior to processing or on an aliquot of semen collected within 14 to 30 days after the first collection of the semen to be exported.

Article 12.9.5.

Recommendations for the importation of in vivo derived equine embryos

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the donor animals showed no clinical sign of EVA on the day of embryo collection; and

EITHER

1) were kept in an establishment where no animals have shown any signs of EVA for the 28 days prior to collection; and
Annex XXX (contd)

a) were subjected to a test for EVA carried out on blood samples collected either once within 21 days prior to collection with negative result, or on two occasions at least 14 days apart within 28 days prior to collection, which demonstrated stable or declining antibody titres; or

b) were regularly vaccinated according to the recommendations of the manufacturer;

OR

2) were isolated for the 28 days prior to collection and during this period the animals showed no sign of EVA;

AND

3) semen used to fertilise the oocytes complies with the requirements in Article 12.9.4.

Text deleted.
CHAPTER 14.8.

INFECTI ON WITH PESTE DES PETITS RUMINANTS VIRUS

Article 14.8.1.

General provisions

Peste des petits ruminants (PPR) susceptible animals are primarily domestic sheep and goats although cattle, camels, buffaloes and some wild ruminant species can also be infected and may act as sentinels indicating the spill over of peste des petits ruminants virus (PPRV) from domestic small ruminants. Even if some wild small ruminants can be infective, only domestic sheep and goats play a significant epidemiological role.

For the purpose of the Terrestrial Code, PPR is defined as an infection of domestic sheep and goats with PPRV.

This chapter deals not only with the occurrence of clinical signs caused by PPRV, but also with the presence of infection with PPRV in the absence of clinical signs.

The following defines the occurrence of PPRV infection:

1) PPRV, excluding vaccine strains, has been isolated and identified as such from a domestic sheep or goat or a product derived from it; or

2) viral antigen or viral ribonucleic acid (RNA) specific to PPRV, excluding vaccine strains, has been identified in samples from a domestic sheep or goat showing clinical signs consistent with PPR, or epidemiologically linked to an outbreak of PPR, or giving cause for suspicion of association or contact with PPR; or

3) antibodies to PPRV antigens which are not the consequence of vaccination, have been identified in a domestic sheep or goat with either epidemiological links to a confirmed or suspected outbreak of PPR or showing clinical signs consistent with recent infection of PPRV.

For the purposes of the Terrestrial Code, the incubation period for PPR shall be 21 days.

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

Article 14.8.2.

Safe commodities

When authorising import or transit through their territory of the following commodities, Veterinary Authorities should not require any PPR related conditions regardless of PPR status of the exporting country or zone: semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather, e.g. wet blue and crust leather), which have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 14.8.3.

PPR free country or zone

1) The PPR status of a country or zone should only be determined on the basis of after considering the following criteria, as applicable:
Annex XXXI (contd)

a) PPR is should be notifiable in the whole territory, and all clinical signs suggestive of PPR should be subjected to appropriate field or laboratory investigations;

b) an on-going awareness programme is should be in place to encourage reporting of all cases suggestive of PPR;

c) systematic vaccination against PPR is prohibited; and

d) importation of domestic ruminants and their semen, oocytes or embryos are is carried out in accordance with this chapter;

cde) the Veterinary Authority should has current knowledge of, and authority over, all domestic sheep and goats in the country or zone;

def) appropriate surveillance, capable of detecting the presence of infection even in the absence of clinical signs, is in place; this may be achieved through a surveillance programme in accordance with Articles 14.8.27. to 14.8.33.

2) To qualify for inclusion in the list of PPR free countries or zones, a Member Country should either:

a) declare apply for recognition of historical freedom as described in point 1 of Article 1.4.6.; or

b) apply for recognition of freedom and submit to the OIE:

   i) a record of regular and prompt animal disease reporting;

   ii) a declaration stating that:

      – there has been no outbreak of PPR during the past 24 months;

      – no evidence of PPRV infection has been found during the past 24 months;

      – no vaccination against PPR has been carried out during the past 24 months;

      – importation of domestic ruminants and their semen, oocytes, or embryos is carried out in accordance with this chapter;

   iii) supply documented evidence that surveillance in accordance with Chapter 1.4, is in operation and that regulatory measures for the prevention and control of PPR have been implemented;

   iv) evidence that no animals vaccinated against PPR have been imported since the cessation of vaccination.

The Member Country will be included in the list only after the application and submitted evidence has been accepted by the OIE. Changes in the epidemiological situation or other significant events should be reported to the OIE according to the requirements in Chapter 1.1. Retention on the list requires annual reconfirmation of point 2 above that the information in points b)i) to b)iv) above be re-submitted annually.
Annex XXXI (contd)

Article 14.8.4.

PPR free compartment

A PPR free compartment can be established in either a PPR free country or zone or in an infected country or infected zone. In defining such a compartment the principles of Chapters 4.3. and 4.4. should be followed. Domestic sheep and goats in the PPR 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 PPR free compartment should:

1) have a record of regular and prompt animal disease reporting and if not PPR free, have an official control programme and a surveillance system for PPR in place according to Articles 14.8.27. to 14.8.33. that allows an accurate knowledge of the prevalence of PPR in the country or zone;

2) declare for the PPR free compartment that:
   a) there has been no outbreak of PPR during the past 24 months;
   b) no evidence of PPRV infection has been found during the past 24 months;
   c) vaccination against PPR is prohibited;
   d) no small ruminant in the compartment has been vaccinated against PPR within the past 24 months;
   e) animals, semen and embryos should only enter the compartment in accordance with relevant articles in this chapter;
   f) documented evidence shows that surveillance in accordance with Articles 14.8.27. to 14.8.33. is in place;
   g) an animal identification and traceability system in accordance with Chapters 4.1. and 4.2. is in place;

3) describe in detail the animal subpopulation in the compartment and the biosecurity plan for PPRV infection.

The compartment should be approved by the Veterinary Authority.

Article 14.8.5.

Infected country or zone

A country or zone shall be considered as PPR infected when the requirements for acceptance as a PPR free country or zone are not fulfilled.

Article 14.8.6.

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

In the event of limited outbreaks within a PPR free country or zone, including within a protection zone, a single containment zone, which includes all cases, can be established for the purpose of minimising the impact on the entire country or zone.

For this to be achieved and for the Member Country to take full advantage of this process, the Veterinary Authority should submit documented evidence as soon as possible to the OIE that:
Annex XXXI (contd)

1) the outbreaks are limited based on the following factors:
   a) immediately on suspicion, a rapid response including notification has been made;
   b) standstill of animal movements has been imposed, and effective controls on the movement of other commodities mentioned in this chapter are in place;
   c) epidemiological investigation (trace-back, trace-forward) has been completed;
   d) the infection has been confirmed;
   e) the primary outbreak has been identified, and investigations on the likely source of the outbreak have been carried out;
   f) all cases have been shown to be epidemiologically linked;
   g) no new cases have been found in the containment zone with a minimum of two incubation periods as defined in Article 14.8.1. after the stamping-out of the last detected case is completed;

2) a stamping-out policy has been applied;

3) the susceptible animal population within the containment zones is clearly identifiable as belonging to the containment zone;

4) increased passive and targeted surveillance in accordance with Articles 14.8.27. to 14.8.33. in the rest of the country or zone has not detected any evidence of infection;

5) animal health measures that effectively prevent the spread of the PPRV to the rest of the country or zone, taking into consideration physical and geographical barriers, are in place;

6) ongoing surveillance is in place in the containment zone.

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 14.8.7., once the containment zone is clearly established, by complying with points 1 to 6 above. It should be demonstrated that commodities for international trade have originated outside the containment zone.

The recovery of the PPR free status of the containment zone should follow the provisions of Article 14.8.7.

Article 14.8.7.

Recovery of free status

When a PPR outbreak or PPRV infection occurs in a PPR free country or zone and when a stamping-out policy is practised with or without vaccination, the recovery period shall be six months after the slaughter of the last affected animal case provided that Article 14.8.32. has been complied with.

If a stamping-out policy is not applied, the provisions of Article 14.8.3. apply.

Article 14.8.8.

Recommendations for importation from PPR free countries or zones

For domestic sheep and goats

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals:
1) showed no clinical sign of PPR on the day of shipment;
2) were kept in a PPR free country or zone since birth or for at least the past 21 days.

Article 14.8.9.

Recommendations for importation from PPR free countries or zones

For wild ruminants

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals:
1) showed no clinical sign suggestive of PPRV infection on the day of shipment;
2) come from a PPR free country or zone;
3) if the country or zone of origin has a common border with a country considered infected with PPRV:
   a) were captured at a distance from the border that precludes any contact with animals in an infected country, the distance should be defined according to the biology of the species exported, including home range and long distance movements;
   OR
   b) were kept in a quarantine station for at least the 21 days prior to shipment.

Article 14.8.10.

Recommendations for importation from countries or zones considered infected with PPRV

For domestic sheep and goats

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals:
1) showed no clinical sign suggestive of PPRV infection for at least the 21 days prior to shipment;
2) either
   a) were kept since birth, or for at least the 21 days prior to shipment, in an establishment where no case of PPR was reported during that period, and that the establishment was not situated in a PPRV infected zone; or
   b) were kept in a quarantine station for at least the 21 days prior to shipment;
4) either
   a) were not vaccinated against PPR and were submitted to a diagnostic test for PPRV infection with negative result no more than 21 days prior to shipment; or
   OR
   b) were vaccinated against PPR with live attenuated PPRV vaccines at least 21 days prior to shipment.
Annex XXXI (contd)

Article 14.8.11.

Recommendations for importation from countries or zones considered infected with PPRV

For wild ruminants

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

1) showed no clinical sign suggestive of PPRV infection for at least the 21 days prior to shipment;

2) were submitted to a diagnostic test for PPRV infection with negative results no more than 21 days prior to shipment;

3) were kept in a quarantine station for at least the 21 days prior to shipment.

Article 14.8.12.

Recommendations for importation from PPR free countries or zones

For semen of domestic sheep and goats

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

1) showed no clinical sign of PPR on the day of the collection of the semen and during the following 21 days;

2) were kept in a PPR free country or zone for at least the 21 days prior to collection.


Recommendations for importation from countries considered infected with PPRV

For semen of domestic sheep and goats

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

1) showed no clinical sign suggestive of PPR for at least the 21 days prior to collection of the semen and during the following 21 days;

2) were kept, for at least the 21 days prior to collection, in an establishment or artificial insemination centre where no case of PPR was reported during that period, which was not situated in a PPRV infected zone and to which no animals had been added during the 21 days prior to collection;

3) were not vaccinated against PPR and were submitted to a diagnostic test for PPRV infection with negative results at least 21 days prior to collection of the semen;

OR

4) were vaccinated against PPR with live attenuated PPRV vaccines at least 21 days prior to semen collection.
 Annex XXXI (contd)


Recommendations for importation from PPR free countries or zones

For embryos of domestic sheep and goats and captive wild ruminants

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

1) the donor animals were kept in an establishment located in a PPR free country or zone at least 21 days prior to embryo collection;

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

3) semen of domestic sheep and goats used to fertilise the oocytes complies at least with the requirements in Article 14.8.12. or Article 14.8.13.

Article 14.8.15.

Recommendations for importation from countries or zones considered infected with PPRV

For embryos of domestic sheep and goats

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

1) the donor animals:
   a) and all other animals in the establishment showed no clinical sign suggestive of PPRV infection at the time of collection and during the following 21 days;
   b) were kept, for at least the 21 days prior to collection, in an establishment where no case of PPR was reported during that period, and to which no susceptible animals had been added during the 21 days prior to collection;
   c) were not vaccinated against PPR and were subjected to a diagnostic test for PPRV infection with negative results at least 21 days prior to collection;
   OR
   d) were vaccinated against PPR with live attenuated PPRV vaccines at least 21 days prior to embryo collection;

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

3) semen of domestic sheep and goats used to fertilise the oocytes complies at least with the requirements in Article 14.8.12. or Article 14.8.13.

Article 14.8.16.

Recommendations for importation from countries or zones considered infected with PPRV

For embryos of captive wild ruminants

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:
Annex XXXI (contd)

1) the donor animals:
   a) showed no clinical signs suggestive of infection with PPRV for at least the 21 days prior to embryo collection;
   b) were not vaccinated against PPR and were subjected to a diagnostic test for PPRV infection with negative results at least 21 days prior to collection;
   c) were kept, for at least the 21 days prior to collection, in an establishment where no case of PPR or of infection with PPRV was reported during that period, and to which no susceptible animals had been added during the 21 days prior to collection;

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

Article 14.8.17.

Recommendation for importation of fresh meat and meat products from sheep and goats

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

1) showed no clinical signs of PPR within 24 hours before slaughter;

2) have been slaughtered in an approved slaughterhouse/abattoir and have been subjected to ante- and post-mortem inspections with favourable results.

Article 14.8.18.

Recommendations for importation from PPR free countries or zones

For milk and milk products from sheep and goats

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that these products come from animals which have been kept in a PPR free country or zone for at least the 21 days prior to milking.

Article 14.8.19.

Recommendations for importation from countries or zones considered infected with PPRV

For milk from sheep and goats

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

1) the milk:
   a) originates from herds or flocks which were not subjected to any restrictions due to PPR at the time of milk collection;

   OR

   b) has been processed to ensure the destruction of the PPRV in conformity with one of the procedures referred to in Articles 8.6.38. and 8.6.39.;

2) the necessary precautions were taken to avoid contact of the products with any potential source of PPRV.
Annex XXXI (contd)

Article 14.8.20.

Recommendations for importation from countries or zones considered infected with PPRV

For milk products from sheep and goats

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:
1) these products are derived from milk complying with the requirements of Article 14.8.19.;
2) the necessary precautions were taken after processing to avoid contact of the milk products with any potential source of PPRV.

Article 14.8.21.

Recommendations for importation from PPR free countries or zones

For products of sheep and goats, other than milk, fresh meat and their products

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that these animals:
1) which have been kept in a PPR free country or zone since birth or for at least the past 21 days;
2) which have been slaughtered in an approved slaughterhouse/abattoir and have been subjected to ante- and post-mortem inspections with favourable results.

Article 14.8.22.

Recommendations for importation from countries or zones considered infected with PPRV

For meal and flour from blood, meat, defatted bones, hooves, claws and horns from sheep and goats

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:
1) the products were processed using heat treatment to a minimum internal temperature of 70°C for at least 30 minutes;
2) the necessary precautions were taken after processing to avoid contact of the commodities with any potential source of PPRV.

Article 14.8.23.

Recommendations for importation from countries or zones considered infected with PPRV

For hooves, claws, bones and horns, hunting trophies and preparations destined for museums from sheep and goats

Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:
1) the products were completely dried and had no trace on them of skin, flesh or tendon or were adequately disinfected; and
2) the necessary precautions were taken after processing to avoid contact of the commodities with any potential source of PPRV.

Recommendations for importation from countries or zones considered infected with PPRV

For wool, hair, raw hides and skins from sheep and goats

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

1) the products were adequately processed in conformity with one of the procedures referred to in Article 8.5.37. in premises controlled and approved by the Veterinary Authority of the exporting country;

2) the necessary precautions were taken after processing to avoid contact of the commodities with any potential source of PPRV.

Article 14.8.25.

Recommendations for importation from countries or zones considered infected with PPRV

For products of animal origin from sheep and goats intended for pharmaceutical or surgical use

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

1) come from animals which were slaughtered in an approved slaughterhouse/abattoir and have been subjected to ante- and post-mortem inspections with favourable results;

2) were processed to ensure the destruction of the PPRV in conformity with one of the procedures referred to in Article 8.6.29. or in Articles 8.6.34. to 8.6.37. as appropriate and in premises controlled and approved by the Veterinary Authority of the exporting country.


Procedures for the inactivation of the PPRV in casings of sheep and goats

For the inactivation of viruses present PPRV in casings of sheep and goats, the following procedures should be used: treatment salting for at least 30 days either with dry salt (NaCl) or with saturated brine (aw< 0.80), or with phosphate supplemented salt containing 86.5% percent NaCl, 10.7% percent NaHPO_4, and 2.8% percent Na_3PO_4 (weight/weight/weight), either dry or as a saturated brine (aw< 0.80), and kept at a temperature of greater than 20°C or more during this entire period.

Article 14.8.27.

Introduction to Surveillance: introduction

Articles 14.8.27. to 14.8.33. define the principles and provide a guide for the surveillance of PPR in accordance with Chapter 1.4. applicable to Member Countries seeking recognition of country or zonal freedom from PPR. Guidance is provided for Member Countries seeking reestablishment of freedom following an outbreak and for the maintenance of PPR free status.

Surveillance strategies employed for demonstrating freedom from PPR at an acceptable level of confidence will need to should be adapted to the local situation. Outbreaks of PPR may vary in severity with differing clinical presentations believed to reflect variations in host resistance and variations in the virulence of the attacking strain. Experience has shown that surveillance based on a predefined set of clinical signs (e.g. searching for ‘pneumoperitoneum syndrome’) increases the sensitivity of the system. In the case of peracute cases the presenting sign may be sudden death. In the case of sub-acute (mild) cases, clinical signs are displayed irregularly and are difficult to detect.
Where they exist, susceptible domestic species, and feral populations of these species, should be included in the design of the surveillance strategy.

Surveillance for PPR should be in the form of a continuing programme designed to establish that the whole country or zone is free from PPRV infection.

Article 14.8.28.

General conditions and methods for surveillance: general conditions and methods

1) A surveillance system in accordance with Chapter 1.4. should be under the responsibility of the Veterinary Authority. A procedure should be in place for the rapid collection and transport of samples from suspected cases to a laboratory for PPR diagnosis.

2) The PPR surveillance programme should:

a) include an early warning system throughout the production, marketing and processing chain for reporting suspected cases. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of PPR. 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 significant epidemiological events consistent with PPR, such as pneumo-enteritis syndrome, should be reported and investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a laboratory. This requires that sampling kits and other equipment be available to those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in PPR diagnosis and control;

b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of animals, such as those adjacent to a PPRV infected country.

An effective surveillance system will periodically identify animals with signs suggestive of PPR that require follow-up and investigation to confirm or exclude that the cause of the condition is PPRV. The rate at which such suspected cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from PPRV infection should, in consequence, provide details of the occurrence of suspected 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.).

Article 14.8.29.

Surveillance strategies

1. Clinical surveillance

Clinical surveillance aims to detect clinical signs of PPR by close physical examination. Clinical surveillance and epidemiological investigations are the cornerstone of all surveillance systems and should be supported by additional strategies such as virological and serological surveillance. Clinical surveillance may be able to provide a high level of confidence of detection of disease if sufficiently large numbers of clinically susceptible animals are examined. It is essential that clinical cases detected be followed up by the collection of appropriate samples such as ocular and nasal swabs, blood or other tissues for virus isolation or virus detection by other means. Sampling units within which suspicious animals are detected should be classified as infected until fully investigated.

Active search for clinical disease can include participatory disease searching, tracing backwards and forwards, and follow-up investigations. Participatory surveillance is a form of targeted active surveillance based upon methods to capture livestock owners' perceptions on the prevalence and patterns of disease.
Annex XXXI (contd)

The labour requirements and the logistical difficulties involved in conducting clinical examinations should be taken into account.

PPRV isolates may be sent to an OIE Reference Laboratory for further characterisation.

2. Virological surveillance

Given that PPR is an acute infection with no known carrier state, virological surveillance should only be conducted as a follow-up to clinically suspected cases.

3. Serological surveillance

Serological surveillance aims to detect antibodies against PPRV. Positive antibody test results can have four possible causes:

a) natural infection with PPRV;

b) vaccination against PPR;

c) maternal antibodies derived from an immune dam (maternal antibodies in small ruminants can be found only up to six months of age);

d) heterophile (cross) and other non-specific reactions.

It may be possible to use serum collected for other survey purposes for PPR surveillance. However, the principles of survey design described in this chapter and the requirement for a statistically valid survey for the presence of PPRV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain infection. As clustering may signal field strain infection, the investigation of all instances must be incorporated in the survey design.

The results of random or targeted serological surveys are important in providing reliable evidence that PPRV infection is not present in a country or zone. It is therefore essential that the survey be adequately documented.

Article 14.8.30.

Surveillance in wildlife

Where a population of a susceptible wildlife species may act as sentinels indicating the spill over of PPRV from domestic sheep and goats, serosurveillance data should be collected.

Obtaining meaningful data from surveillance in wildlife can be enhanced by close coordination of activities in a region. Both purposive and opportunistic samplings are used to obtain material for analysis in national or reference laboratories. The latter are required because many countries do not have adequate facilities to perform the full testing protocol for detecting antibodies against PPRV in wildlife sera.

Targeted sampling is the preferred method to provide wildlife data to evaluate the status of infection with PPRV. In reality, the capacity to perform wildlife sampling is minimal in most countries. However, samples can be obtained from hunted animals, and these may provide useful background information.
Article 14.8.31.

Additional surveillance requirements procedures for Member Countries applying for OIE recognition of PPR free status

The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances in and around the country or zone and should be planned and implemented according to the conditions for status recognition described in Article 14.8.3. and methods in this chapter, to demonstrate absence of PPRV infection during the preceding 24 months. This requires the support of a laboratory able to undertake identification of PPRV infection through virus, antigen or viral nucleic acid detection and antibody tests.

The target population for surveillance aimed at identifying disease and infection should cover significant populations within the country or zone to be recognised as free from PPRV infection.

The strategy employed should be based on an appropriate combination of randomised and targeted sampling requiring surveillance consistent with demonstrating the absence of PPRV infection at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Risk-based approaches (e.g. based on the increased likelihood of infection in particular localities or species) may be appropriate to refine the surveillance strategy. The Member Country should justify the surveillance strategy chosen as adequate to detect the presence of PPRV infection in accordance with Chapter 1.4. and the epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular subpopulations likely to exhibit clear clinical signs.

Consideration should be given to the risk factors for the presence of PPRV, including:

1) historical disease patterns;
2) critical population size, structure and density;
3) livestock husbandry and farming systems;
4) movement and contact patterns, such as market and other trade-related movements;
5) virulence and infectivity of the strain.

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

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained.

Irrespective of the testing system employed, surveillance design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to subsequently 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 herds or flocks which may be epidemiologically linked to it.

The principles involved in surveillance for disease or infection are technically well defined in Chapter 1.4. The design of surveillance programmes to demonstrate the absence of PPRV infection needs to be carefully followed to ensure the reliability of results. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.
Annex XXXI (contd)

Article 14.8.32.

Additional surveillance requirements for recovery of free status

Following an outbreak of PPR in a Member Country at any time after recognition of PPR freedom, the origin of the virus strain should be thoroughly investigated. In particular it is important to determine if this is due to the re-introduction of virus or re-emergence from an undetected focus of infection. Ideally, the virus should be isolated and compared with historical strains from the same area as well as those representatives of other possible sources.

After elimination of the outbreak, a Member Country wishing to regain the free status should undertake surveillance according to this chapter to demonstrate the absence of PPRV infection.

Article 14.8.33.

The use and interpretation of serological tests for serosurveillance of PPR

Serological testing is an appropriate tool to use for PPR surveillance where vaccination has not been practised. There is only one serotype of virus and the tests will detect antibodies elicited by infection with all PPRV but the tests cannot discriminate between antibodies against field infection and those from vaccination with attenuated vaccines. This fact compromises serosurveillance in vaccinated populations and meaningful serosurveillance can only commence once vaccination has ceased for several years. Antibodies against virulent and vaccine strains of PPRV can be detected in small ruminants from about 14 days post infection or vaccination and peak around 30 to 40 days. Antibodies then persist for many years, possibly for life, although titres decline with time.

It is necessary to demonstrate that positive serological results have been adequately investigated.

Article 14.8.34.

OIE endorsed official control programme for PPR

The objective of an OIE endorsed official control programme for PPR is for Member Countries to progressively improve the situation in their territories and eventually attain free status for PPR.

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

For a Member Country’s official control programme for PPR to be endorsed by the OIE, the Member Country should:

1) submit documented evidence on the capacity of its Veterinary Services to control PPR; this evidence can be provided by countries following the OIE PVS Pathway;

2) submit documentation indicating that the official control programme for PPR is applicable to the entire territory (even if it is on a zonal basis);

3) have a record of regular and prompt animal disease reporting according to the requirements in Chapter 1.1.;

4) submit a dossier on the status of PPR in the country describing the following:

a) the general epidemiology of PPR in the country highlighting the current knowledge and gaps;

b) the measures implemented to prevent introduction of infection, the rapid detection of, and response to, all PPR outbreaks in order to reduce the incidence of outbreaks and to eliminate virus circulation in domestic sheep and goats in at least one zone in the country;
c) the main livestock production systems and movement patterns of sheep and goats and their products within and into the country and, where applicable, the specific zone(s);

5) submit a detailed plan of the programme to control and eventually eradicate PPR in the country or zone including:
   a) the timeline for the programme;
   b) the performance indicators that will be used to assess the efficacy of the control measures;

6) submit evidence that PPR surveillance is in place, taking into account the provisions in Chapter 1.4. and the provisions on surveillance in this chapter;

7) have diagnostic capability and procedures in place, including regular submission of samples to a laboratory;

8) where vaccination is practised as a part of the official control programme for PPR, provide evidence (such as copies of legislation) that vaccination of sheep and goats in the country or zone is compulsory;

9) if applicable, provide detailed information on vaccination campaigns, in particular on:
   a) the strategy that is adopted for the vaccination campaign;
   b) monitoring of vaccination coverage, including serological monitoring of population immunity;
   c) serosurveillance in other susceptible species, including wildlife to serve as sentinels for PPRV circulation in the country;
   d) disease surveillance in sheep and goat populations;
   e) the proposed timeline for the transition to the cessation of the use of vaccination in order to enable demonstration of absence of virus circulation;

10) provide an emergency preparedness and contingency response plan to be implemented in case of PPR outbreak(s).

The Member Country’s official control programme for PPR will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the official control programme and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

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

– non-compliance with the timelines or performance indicators of the programme; or

– significant problems with the performance of the Veterinary Services; or

– an increase in the incidence of PPR that cannot be addressed by the programme.

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CHAPTER 6.5.

PREVENTION, DETECTION AND CONTROL OF SALMONELLA IN POULTRY

Article 6.5.1.

Introduction

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

Salmonellosis is one of the most common foodborne bacterial diseases in the world. The great majority of *Salmonella* infections in humans are foodborne 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 foodborne 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) and 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 foodborne 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.
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/caecal samples collected from different areas in the *poultry* house.

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

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

2. **Sample size**

   Refer to the *Terrestrial Manual* *(under development).*

3. **Laboratory methods**

   Refer to the *Terrestrial Manual* *(under development).*

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 after depopulation, cleaning and disinfection.
Annex XXXII (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. Enteriditis*.

2) In layer *flocks*, control measures will reduce and may eliminate contamination of eggs with *Salmonella*.

3) In *poultry* for *meat* production, control measures may be implemented at slaughter or further down the food chain.

Article 6.5.5.

**Prevention and control measures**

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

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

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

1) *Day-old birds* used to stock a *poultry* house should be obtained from breeder *flocks* and hatcheries that have been monitored according to this chapter and in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected.

2) Layer and breeder *flocks* should be stocked from *flocks* that have been monitored according to this chapter and in which no evidence of *S. Enteritidis* and *S. Typhimurium* has been detected.

3) Feed contamination with *Salmonella* is known to be a source of *infection* for *poultry*. Therefore, it is recommended to monitor the *Salmonella* status of *poultry* feed, and if found positive to take corrective measures. Heat treated feeds with or without the addition of other bactericidal or bacteriostatic treatments, e.g. organic acids, are recommended. Where heat treatment is not possible, the use of bacteriostatic or bactericidal treatments is recommended. Feed should be stored in clean closed containers to prevent access by wild birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for wild birds and rodents.

4) Competitive exclusion may be used in *day-old birds* to reduce colonisation by *Salmonella*.

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

5) Vaccines are used against *Salmonella infections* caused by different serotypes in various *poultry* species, including single or combined vaccines. Vaccines produced according to the *Terrestrial Manual* should be used.

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

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

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

7) S. Enteritidis is characterised by its ovarian transmission pattern. Countries should set targets for eradicating (or significantly reducing) S. Enteritidis from egg-producing flocks through a guided policy for eradication from the top of the production pyramid, i.e. from grandparent flocks through breeder flocks to layer flocks.

8) The responsible veterinarian should evaluate the results of surveillance testing for Salmonella and supervise the implementation of appropriate control measures. These results should be available to the veterinarian before marketing if a veterinary certificate for flock Salmonella status is required. When required by the Competent Authority, the veterinarian or other person responsible for notification should notify the Competent Authority if the presence of Salmonella of the relevant serotype is confirmed.

Article 6.5.6.

Prevention of Salmonella spread from infected flocks

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

1) According to the epidemiological situation, investigations should be carried out to determine the origin of the infection.

2) Movement of poultry flocks at the end of the production cycle should only be allowed for slaughter or destruction.

Special precautions should be taken in the transport, slaughter and processing of the birds, e.g. they could be sent to a separate slaughterhouse or processed at the end of a shift before cleaning and disinfection of the equipment.

3) Litter should not be reused as such. Used poultry litter, carcasses and other potentially contaminated farm waste should be disposed of in a safe manner to prevent the direct or indirect exposure of humans, livestock and wildlife to Salmonella. Particular care needs to be taken when utilising used poultry litter to fertilise plants intended for human consumption. If litter is not removed, it should be treated in a manner to inactivate infectious agents, to prevent the spread from one flock to the next.
Annex XXXII (contd)

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.

Article 6.5.7.

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

Introduced live poultry (other than day-old birds) should Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1) the poultry originated from a flock that participates in a Salmonella surveillance programme in accordance with the recommendations in Article 6.5.4.;

2) the poultry originated from a flock in which no evidence of S. Enteritidis and S. Typhimurium has been detected prior to movement shipment and have had no contact with birds or other material from flocks that do not comply with this chapter;

3) the poultry originated from a flock that complies with the recommendations in Chapter 6.4.

Article 6.5.8.

Recommendations for introduction importation of day-old birds

Introduced day-old birds should Veterinary Authorities should require the presentation of an international veterinary certificate attesting that:

1) the day-old birds showed no clinical signs of salmonellosis on the day of movement shipment;

2) the day-old birds originated 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) the day-old birds originated 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) the day-old birds originated from a breeder flock and a hatchery that comply with the recommendations in Chapter 6.4.;

5) the day-old birds were shipped be transported in new and clean containers.

Article 6.5.9.

Recommendations for introduction importation of hatching eggs

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

1) the hatching eggs originated from a breeder flock that participates in a Salmonella surveillance programme in accordance with the recommendations in Article 6.5.4.;

2) the hatching eggs originated 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) **the hatching eggs** originated from a breeder *flock* that complies with the recommendations in of Chapter 6.4.;

4) **the hatching eggs were shipped** be transported in new and clean packaging materials.

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CHAPTER 4.13.

GENERAL RECOMMENDATIONS ON DISINFECTION AND DISINSECTISATION DISINSECTION

Article 4.13.1.

General provisions

Veterinary Authorities are requested to draw up regulations in their respective countries concerning the use of disinfectants and insecticides on the basis of the principles described below:

1) The choice of disinfectants and of procedures for disinfection should be made taking into account the causal agents of infection and the nature of the premises, vehicles and objects which are to be treated.

2) Disinfectants and insecticides should be authorised only after thorough tests have been carried out under field condition.

3) The following should be considered:

   a) few universal disinfectants exist;
   b) whereas hypochlorite, which is very often used, may be regarded as a universal disinfectant, its effectiveness is diminished by prolonged storage and it is therefore necessary to check its activity before use; a concentration of 0.5% active chlorine appears necessary for satisfactory disinfection;
   c) no matter what substances are used, disinfection techniques should comprise the following:
      i) thorough soaking of bedding and litter as well as faecal matter with the disinfectant;
      ii) washing and cleaning by careful brushing and scrubbing of the ground, floors and walls;
      iii) then further washing with the disinfectant;
      iv) washing and disinfecting the outside of vehicles; these procedures will be carried out, if possible, with liquids applied under pressure and the washing, disinfecting or destroying of articles used for tying up the animals (ropes, reins, etc.) should not be omitted.

Article 4.13.2.

Pathogen-specific disinfection

1) Foot and mouth disease virus is easily destroyed by a high or low pH but the disinfectants used may be caustic or corrosive in concentrated form.

2) Mycobacteria are very resistant to disinfectants and a high concentration is required to destroy the organisms, as well as prolonged action.
Annex XXXIII (contd)

3) **Bacillus anthracis**

a) In situations in which manure, dung or bedding may be contaminated with *Bacillus anthracis* (*B. anthracis*) spores, the following are recommended:

i) small volumes by incineration; or

ii) chemothermal treatment by composting as follows:
   - mix with one of the following at a rate of 1–1.5 litre/m³:
     - 10% formaldehyde (approximately 30 % formalin), or
     - 4% glutaraldehyde (pH 8.0–8.5);
   - turn the material after five weeks;
   - leave for a further five weeks.

   [Note: Spontaneous combustion of the composting pile is possible. Also note: Formalin is a dangerous chemical and as such the appropriate personal protective equipment should be used and safety training on the handling of this chemical should be provided.]

b) In situations in which liquid manure (slurry) may be contaminated with *B. anthracis* spores, disinfection with formalin (35% aqueous solution of formaldehyde) with stirring for one hour daily is recommended:

i) for slurry up to 5 % dry matter, 50 kg formalin per m³ for 4 days;

ii) for slurry >5 % and <10% dry matter, 100 kg formalin per m³ for 4 days.

   [Note: Formalin is a dangerous chemical and as such the appropriate personal protective equipment should be used and safety training on the handling of this chemical should be provided.]

c) In situations in which surfaces in animal houses, stables, vehicles, etc. may be contaminated with *B. anthracis* spores, the following three-step approach is recommended:

i) a preliminary disinfection should be carried out using one of the following disinfectants at a rate of 1–1.5 litres/m² for 2 hours:
   - 10 % formaldehyde (approximately 30 % formalin); or
   - 4 % glutaraldehyde (pH 8.0–8.5);

ii) all surfaces should be washed and scrubbed using ample hot water and, when cleaned and waste water is free from dirt particles, dried;

iii) a final disinfection step should be carried out using one of the following disinfectants applied at a rate of 0.4 litre/m² for 2 hours:
   - 10 % formaldehyde (approximately 30 % formalin), repeated after one hour; or
   - 4 % glutaraldehyde (pH 8.0–8.5), repeated after one hour; or
   - 3 % hydrogen peroxide; or
   - 1 % peracetic acid, repeated after one hour; or
   - 5–10 % sodium hypochloride solution.
d) Contaminated rooms which cannot be cleared before cleaning and disinfection can be fumigated to eliminate B. anthracis spores. The following procedure is recommended:

i) all windows, doors and vents to the outside should be sealed with heavy adhesive tape; and

ii) for rooms up to 30 m³, 4 litres of water containing 400 ml of concentrated formalin (37 % w/v formaldehyde) in an electric kettle (with a timing switch to turn it off) should be boiled away and the room left overnight. Room temperature should be >15°C.

[Note: Formaldehyde fumigation is hazardous and proper respirators should be on hand for operator safety. The effectiveness of the fumigation process should be verified by exposing dried discs of filter paper which have been dipped in a suspension of spores of B. subtilis var. globigii or B. cereus or Sterne vaccine strain of B. anthracis and placed in the room before fumigation is started. At the end of fumigation, the discs should be placed on nutrient agar plates containing 0.1 % histidine and incubated overnight at 37°C. If fumigation has been effective, there will be no bacterial growth.]