Annex I

MEETING OF THE OIE

TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 17–26 September 2013

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Annex II

MEETING OF THE OIE
TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 17–26 September 2013

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Adopted agenda

A. MEETING WITH THE DIRECTOR GENERAL

Welcome – Director General

B. ADOPTION OF THE AGENDA

C. REPORT ON JOINT MEETING OF THE PRESIDENT OF THE CODE COMMISSION AND THE SCIENTIFIC COMMISSION (5 September)

D. EXAMINATION OF MEMBER COUNTRY COMMENTS AND WORK OF RELEVANT EXPERT GROUPS

Item 1 General comments of OIE Member Countries

Item 2 Horizontal issues

- a) User's Guide

Item 3 Glossary

Item 4 Notification of diseases, infections and infestations and epidemiological information (Chapter 1.1.)

- a) Notification of diseases, infections and infestations, and epidemiological information (Chapter 1.1.)
- b) Notification of 'emerging disease'

Item 5 Criteria for listing diseases (Chapter 1.2.)

Item 6 Animal health surveillance (Chapter 1.4.)

Item 7 Import risk analysis (Chapter 2.1.)

Item 8 Support for Veterinary Services

- a) Veterinary legislation (Chapter 3.4.)
- b) Report of the *ad hoc* Group on Veterinary Legislation

Item 9 Collection and processing of *in vivo* derived embryos from livestock and horses (Chapter 4.7.)

Item 10 General principles for animal disease control (Draft Chapter 4.X.)

Annex II (contd)

Item 11 Antimicrobial resistance

a) Introduction to the recommendations for controlling antimicrobial resistance (Chapter 6.6.)

b) Harmonisation of national antimicrobial resistance surveillance and monitoring programmes (Chapter 6.7.)

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

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

Item 12 Animal welfare

a) Draft new chapter on Animal Welfare and Dairy Cattle Production Systems (Chapter 7.X.)

b) Restructuring of Chapters 7.5. and 7.6.

c) Member Countries' comments on existing chapters (Chapters 7.8. and 7.10.)

d) Disaster management and preparedness: Headquarters' proposal with respect to disaster management (Chapters 3.1.–3.3.)

e) Animal Welfare Working Group Meeting Report

Item 13 Vector borne diseases

a) Infection with African horse sickness (Chapter 12.1.)

b) Infection with bluetongue virus (Chapter 8.3.)

c) Harmonisation of three vector borne diseases (bluetongue, epizootic haemorrhagic disease and African horse sickness)

Item 14 Zoonotic parasites

a) Infection with *Echinococcus granulosus* (Chapter 8.4.)

b) Infection with *Trichinella* spp. (Chapter 8.14.)

c) Collaboration with the Codex Alimentarius Commission

Item 15 Foot and mouth disease (Chapters 8.6. and 1.6.)

Item 16 Rift Valley fever (Chapter 8.12.)

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

Item 18 Infection with avian influenza viruses (Chapter 10.4.)

Item 19 Infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia) (Chapters 11.8. and 1.6.)

Item 20 Equine diseases

a) Infection with equine viral arteritis (Chapter 12.9.)

b) The high health status horse subpopulation (Draft chapter 4.X.)

c) Infection with equid herpesvirus type 1 (Equine rhinopneumonitis) (Chapter 12.8.)

Item 21 Infection with *Chlamydophila abortus* (Chapter 14.5.)

Item 22 Infection with peste des petits ruminants (Chapter 14.8.)

Item 23 Classical swine fever (Chapter 15.2.)

E. OTHER ISSUES

Item 24 Update of the Code Commission work programme

Item 25 Review of applications for recognition as OIE Collaborating Centre

a) Joint Collaborating Centre for food safety (Singapore/Japan)

Item 26 Proposed dates for meetings in 2014

Annex III

**PROPOSED AGENDA FOR THE JOINT MEETING
BETWEEN THE SCIENTIFIC AND CODE COMMISSIONS**

(5 SEPTEMBER 2013°

JOINT DISCUSSION:

1. Glossary: definition of risk-based surveillance

The Scientific Commission and the President of the Code Commission agreed that this issue will be discussed at the next full joint meeting of the two Commissions.

2. Glossary: definition of emerging disease

The Scientific Commission informed the President of the Code Commission of its decision to support the current definition of emerging diseases in the glossary and to add that for the purpose of notification, the definition excludes listed diseases. The President of the Scientific Commission noted that Dr Karim Ben Jebara (Head of the Animal Health Information Department) had supported the view of the Scientific Commission. The President of the Code Commission agreed with the proposal.

3. Horizontal chapters

a) Chapter 1.1.: The Scientific Commission agreed to the proposed amendments on notification for emerging diseases.

b) Criteria and listing (Chapter 1.2.): The Scientific Commission agreed to remove the reference to emerging diseases from the criteria for listing and maintained its position that swine vesicular disease and vesicular stomatitis should be delisted.

c) Article 1.4.6, points a) and b): Amendment proposed by the Scientific Commission in February in respect of presence of disease in wildlife vs. compliance for historical freedom. It was agreed that the entire Article 1.4.6. needs to be reviewed and the President of the Code Commission indicated that they will undertake this task.

d) The Scientific Commission sought clarification on the general principle on how horizontal chapters would apply to individual disease specific chapters (Do horizontal chapters apply to all disease chapters unless otherwise defined in disease-specific chapter?)

- Historical freedom
- Freedom and situation in wildlife
- ‘Case’ definition in the chapter related to notification (Detection of aetiological agent in animal) and definition of an infection in disease specific chapter.

e) General disease control (Chapter 4.X.): The Scientific Commission response to Member Country comments – the Scientific Commission concluded not to proceed with the request to have the draft chapter published in the *Terrestrial Code* following Member Country comments in this respect but to maintain and update the web version following Member Country comments.

Annex III (contd)

4. Disease-specific chapters

a) Classical swine fever (CSF) (Chapter 15.2.): The Scientific Commission presented the main points of discussion which was on the recommendations for the importation of meat of domestic, wild and feral pigs. There was a provision to allow import of wild and feral pigs irrespective of the status of the country but there was no specific article on the importation of domestic pig meat from infected countries which was also the case in the version in the *Terrestrial Code* prior to the adoption of the new Chapter in May 2013. Wild pig meat should in accordance with the *Terrestrial Code* be tested but it was considered that testing all domestic pig meat would be logistically unfeasible while wild pig meat was sold in small quantities and can thus be logistically managed. There also was the uncertainty of the origin of free roaming pigs even in a free country as they could have migrated from an infected area prior to be hunted. The Scientific Commission proposed combining articles of live pig importation from free and from infected countries, since from infected countries the only way allowed was originating from a free compartment, which was already included in the provisions that allow import of live pigs from a free country, zone or compartment. Since for live pigs the only way allowed from an infected country was that it originated from a free compartment, the Scientific Commission argued whether it should be specified that wild pig meat from an infected countries should only originate from a free compartment. The President of the Code Commission agreed to share these concerns with the rest of the Code Commission and would reply accordingly. With regards to historical freedom for CSF, the President of the Code Commission agreed to reconsider the horizontal chapters in Article 1.4.6, and provide the criteria for which these horizontal issues could apply.

b) Brucellosis: The Scientific Commission informed that the report was not endorsed and that the chapter was referred back to the *ad hoc* Group for a final review taking into consideration the concerns of the Scientific Commission. The aim was to circulate the chapter for a second round of comments after the February 2014 meeting of the Scientific Commission.

c) Tuberculosis: The Scientific Commission informed that the report was not endorsed and chapter was referred back to the *ad hoc* Group, for a final review taking into consideration the comments of the Scientific Commission. The aim was to circulate the chapter for a first round of comments after September 2014.

d) Contagious bovine pleuropneumonia (CBPP): The Scientific Commission discussed and endorsed the addition of an article to provide for an OIE endorsed official control programme for addition to the existing chapter. A questionnaire to assist Member Countries to apply for an OIE official control program for CBPP was also evaluated and approved for further processing by the Code Commission.

e) Foot and mouth disease (FMD) (Chapter 8.6.): The Scientific Commission commented on the most critical Member Country comments to assist the *ad hoc* Group in the review of the Member Country comments during their meeting in October 2013. The Scientific Commission suggested that the *ad hoc* Group also consider requirements for the inactivation of FMD virus in bone chips as well as the introduction of an article to provide for the movement of susceptible wild animal species from infected areas. The Code Commission was requested to consider developing a definition for the Glossary on an OIE endorsed official control program as it was obvious that Member Countries are confused between the current definition in the Glossary and an OIE endorsed control programme.

f) Avian influenza (AI) (Chapter 10.4.) (inactivation in feather and down): The Scientific Commission endorsed the scientific justification provided and concluded that the information be provided to the Code Commission for review of the relevant article in the chapter.

5. FROM the Scientific Commission to the Code Commission

a) Provision for the temporary international movement of horses: Report and draft chapter were discussed by the Scientific Commission and forwarded to the Code Commission. The document of Equine Disease Free Zones will be posted on the OIE website.

b) Rift Valley fever (RVF): the report and amended Chapter was endorsed by the Scientific Commission who shared its concern on the situation related to surveillance of free countries that were neighbouring infected countries. The Scientific Commission concluded that only 3 situations on the status for RVF are possible: Historical freedom, an epizootic status and an inter-epizootic status since a country that already had an outbreak or epizootic, cannot qualify for disease freedom.

c) Harmonisation of the *Terrestrial Code* Chapters on vector borne diseases (African horse sickness [AHS], Bluetongue [BT] and epizootic haemorrhagic disease [EHD]): Dr Thomas Mettenleiter gave an overview over the main issues discussed by the *ad hoc* Group such as the existence of subclinical infection for BT and EHD, which had a consequence for not being able to declare historical freedom; that the seasonally free period was accepted for BT and EHD but not AHS; and that attenuated vaccine virus could circulate and thus the infection definition considered the concept of infectiousness rather than the detection of the aetiological agent itself. The *ad hoc* Group succeeded in harmonising the aspects between the 3 chapters which were discussed and approved by the Scientific Commission and submitted to the Code Commission.

d) Antimicrobial resistance (AMR): Dr Elisabeth Erlacher-Vindel (Acting Head of the Scientific and Technical Department) gave an overview over the main discussion points of the *ad hoc* Group on AMR. It was agreed that the Scientific Commission would forward the revised AMR chapters which had been endorsed by the Scientific Commission.

6. Issues shared for information of the Code Commission

a) User's guide: The Scientific Commission already submitted comments on the draft text.

b) Ad hoc Group on Porcine reproductive and respiratory syndrome (PRRS): A second ad hoc Group meeting will finalise the draft chapter expected to be forwarded to the Code Commission in February 2014.

c) Ad hoc Group on Glanders: It will be convened at the end of November 2013 to update the *Terrestrial Code* chapter and discuss the possibility of official disease status recognition.

d) Ad hoc Group on Schmallenberg virus (SBV): to be convened in October 2013 to reconsider possible OIE listing of SBV.

e) Ad hoc Group on African swine fever: it will be convened after the Scientific Commission meeting in February 2014 to review current chapter in support of a decision taken at the 81st General Session.

f) Comments on atypical scrapie: the Commission suggested that the ad hoc Group on BSE consider the request for a review of the current chapter for further consideration by the Scientific Commission.

Annex III (contd)

7. Other issues

Sharing the dossiers for official status evaluation:

The President of the Scientific Commission informed the President of the Code Commission that the Scientific Commission had concluded that the dossiers of Member Countries should remain confidential and should not be made available to other Member Countries by the OIE. Member Countries could however request the Delegate of another Member Country to make its dossier available if he/her accepts to do so. He also noted that information on decisions by the Scientific Commission on country status applications is available on the OIE website for public scrutiny. The President of the Code Commission supported the Scientific Commission's approach.

Annex IV

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) The standards in the *Terrestrial Code* should be used by the Veterinary Authorities of Member Countries 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 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~~.

B. *Terrestrial Code* content

1) Key terms and expressions used in more than ~~once~~ one chapter in the *Terrestrial Code* are defined in the Glossary. When reading and using the *Terrestrial Code*, the Veterinary Authorities of Member Countries 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, including 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 for conducting import risk analysis used by an importing country in the absence of OIE trade standards or to justify import measures which result in 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. These standards are to assist the Veterinary Services of Member Countries to meet their objectives of improving terrestrial animal health and welfare and veterinary public health, as well as to establish and maintain confidence in their international veterinary certificates.

6) The standards in the chapters of Section 4 are designed for the implementation of measures for the prevention and control of pathogenic agents, including through 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.

Annex IV (contd)

7) The standards in the chapters of Section 5 are designed for the implementation of general sanitary measures for trade, in particular veterinary certification and the measures applicable by the exporting, transit and importing countries~~, especially Members of the World Trade Organization (WTO)~~. It 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, to assist Member Countries in meeting their veterinary public health objectives. This includes ante- and port-mortem inspection, control of hazards in feed, biosecurity at the animal production level, and the control of antimicrobial resistance in animals.

9) The standards in the chapters of Section 7 are designed for the implementation of animal welfare measures, including those at the level of production, transport, and slaughter or killing. 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, taking 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 provide information to the OIE on any 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 of 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. 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 this relates principally to OIE listed diseases or infections, general standards apply ~~applies~~ to all health risks. Moreover, in Chapter 4.7. diseases that are not listed diseases are included, and marked as such, ~~mentioned~~ 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*. However, where the conditions are more restrictive, they should be scientifically justified by 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, which also provide guidance for informal mediation by the OIE.

The OIE aims to include, at the beginning of each 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. Where such a list is present, there should be no trade restrictions applied to the listed commodity in relation 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., describing the animal health requirements and, where appropriate, public health requirements for the exported commodity. The quality of the exporting country's Veterinary Services, including the ethical approach 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.

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, adapted to the disease status of the exporting country, zone or compartment. Such status should be established according to the articles of the relevant disease chapter, or to Chapter 1.4. when there are no such articles.

Annex IV (contd)

c) When preparing international veterinary certificates, the importing country should endeavour to use terms and expressions in accordance with the definitions given in the Glossary. As stated in Article 5.2.2., 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 provide model certificates as a further guidance to Member Countries and that should be used as a baseline.

6) Guidance notes for 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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Annex V

GLOSSARY

For the purposes of the *Terrestrial Code*:

Emerging disease

means a new occurrence, which has a significant impact on animal or public health, of a *disease*, *infection* or *infestation* resulting from: ~~the evolution or~~

- a change of a~~n~~ known ~~existing~~ pathogenic agent ~~, a known *infection* or *infestation*~~ or its spread~~ing~~ 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~~.

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 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.

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Annex VI

CHAPTER 1.1.

NOTIFICATION OF DISEASES, INFECTIONS, INFESTATIONS AND 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.

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) 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 ~~*disease*~~.

5) In addition to notifying new findings in accordance with Article 1.1.3., Member Countries shall also provide information on the measures taken to prevent the spread of *diseases*, *infections* and *infestations*; including 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;

   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*;

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d) a sudden and unexpected change ~~increase~~ in the distribution~~,~~ or increase in incidence or virulence of, or morbidity or mortality ~~of~~ 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 for *emerging disease*, as described under point 1. These should continue until the *disease*, *infection* or *infestation* has been eradicated or the situation becomes sufficiently stable or 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.

Annex VI (contd)

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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Annex VII

CHAPTER 1.2.

CRITERIA FOR THE INCLUSION OF DISEASES, INFECTIONS AND INFESTATIONS ON 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 VII (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
- Rift Valley fever
- 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 *Chlamydophila abortus* (Enzootic abortion of ewes, ovine chlamydiosis)
   - Infection with peste des petits ruminants virus
   - Maedi–visna
   - Nairobi sheep disease
   - Ovine epididymitis (*Brucella ovis*)
   - Salmonellosis (*S.* abortusovis)
   - Scrapie
   - Sheep pox and goat pox.

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)~~

Annex VII (contd)

- 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 ~~and~~
- = ~~i~~nfection with influenza A viruses of high pathogenicity in birds other than poultry including wild birds
- Infectious bursal disease (Gumboro disease)
- Newcastle disease
- 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.

Annex VII (contd)

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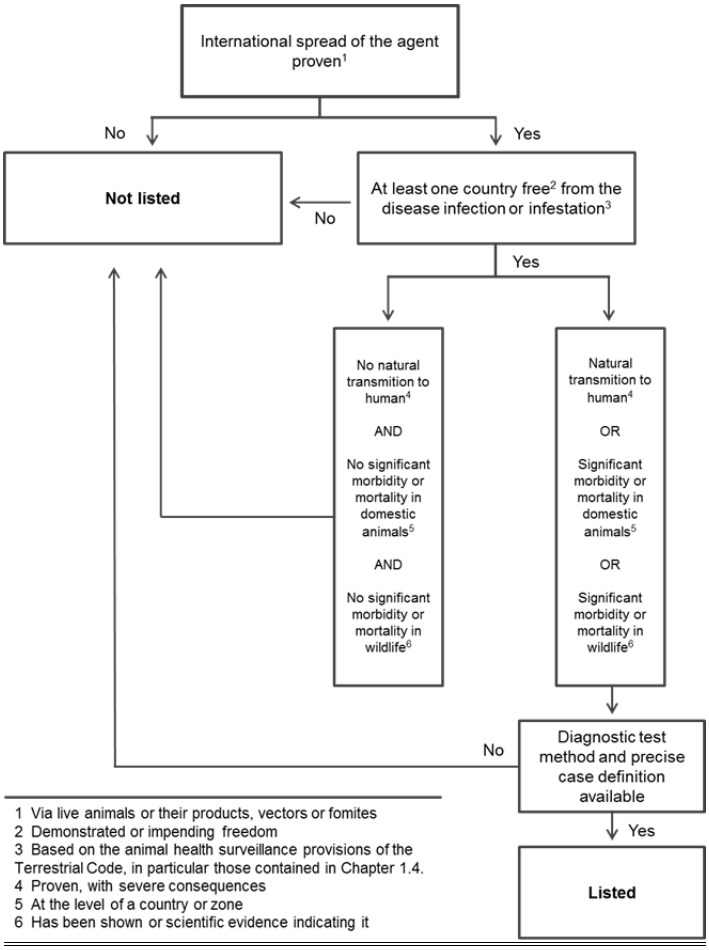

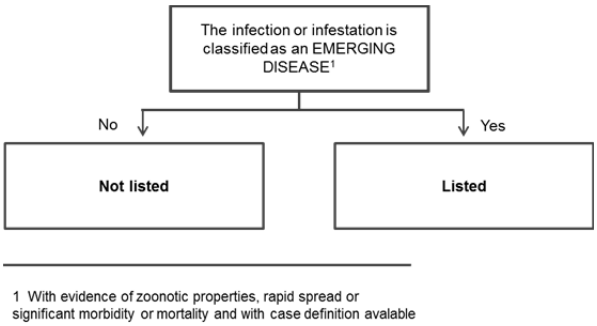

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Annex VIII

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*.

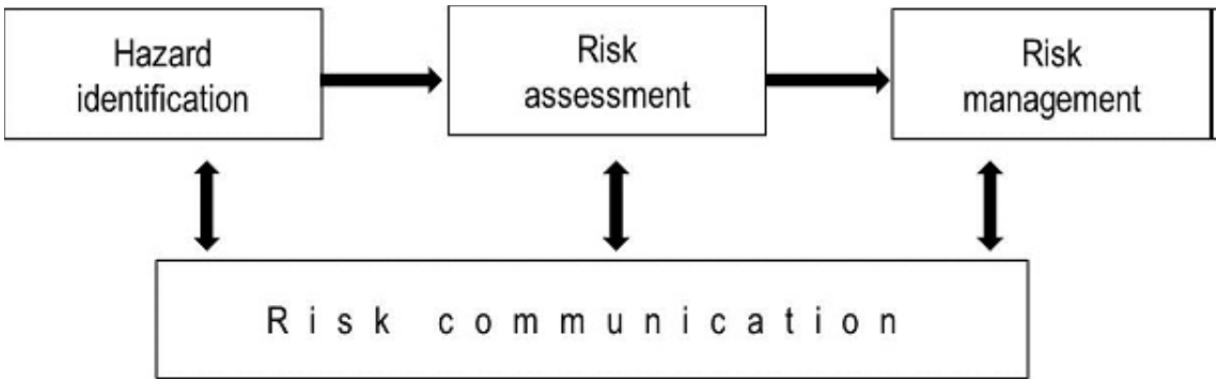
The principal aim of import *risk analysis* is to provide *importing countries* with an objective and defensible method of assessing the *disease risks* associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, biological products and *pathological material*. 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 that chapter are *hazard identification*, *risk assessment*, *risk management* and *risk communication* (Figure 1).

Fig. 1. *The four components of risk analysis*



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.

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*.

Annex VIII (contd)

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.

Annex VIII (contd)

Article 2.1.4.

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 VIII (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 achieve the Member Country's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimized. The objective is to manage *risk* appropriately to ensure that a balance is achieved between a country's desire to minimize 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 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.

Annex VIII (contd)

Article 2.1.7.

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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Annex IX

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 sector.

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.

Annex X

CHAPTER 6.7.

HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES

Article 6.7.1.

Objective

This chapter provides criteria for the:

1) development of national antimicrobial resistance surveillance and monitoring programmes,

2) harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes,

in food producing animals and in products of animal origin intended for human consumption.

Article 6.7.2.

Purpose of surveillance and monitoring

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

Surveillance and monitoring of antimicrobial resistance is necessary to:

1) assess and determine the trends and sources of antimicrobial resistance in bacteria;

2) detect the emergence of new antimicrobial resistance mechanisms;

3) provide the data necessary for conducting *risk analyses* as relevant to animal and human health;

4) provide a basis for policy recommendations for animal and human health;

5) provide information for evaluating antimicrobial prescribing practices and, for prudent use recommendations;

6) assess and determine effects of actions to combat antimicrobial resistance.

Article 6.7.3.

The development of antimicrobial resistance surveillance and monitoring programmes

1. General aspects

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

Annex X (contd)

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

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

a) statistically based surveys;

b) sampling and testing of food producing animals on the farm, at live animal market or at *slaughter*;

c) an organised sentinel programme, for example targeted sampling of food producing animals, *herds*, *flocks*, and *vectors* (e.g. birds, rodents);

d) analysis of veterinary practice and diagnostic *laboratory* records~~.~~;

e) sampling and testing of food products of animal origin.

2. Sampling strategies

a) Sampling should be conducted on a statistical basis. The sampling strategy should ensure:

- the sample is representative of the population of interest;
- the robustness of the sampling method.

b) The following criteria are to be considered:

- sample source such as food producing animal, food, animal feed;
- animal species;
- category of *animal* within species such as age group, production type;
- health status of the *animals* such as healthy, diseased;
- sample selection such as targeted, systematic random;
- type of sample (e.g. faecal, carcass, food product);
- sample size.

3. Sample size

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

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

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

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

4. Sample sources

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

a) Animal feed

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

b) Food producing animals

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

c) Food

Member Countries should consider including relevant food products originating from food producing animals in surveillance and monitoring programmes as foodborne transmission is considered to be an important route for the transfer of antimicrobial resistance.

5. Type of sample to be collected

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

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

Annex X (contd)

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

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

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

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

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

6. Bacterial isolates

The following categories of bacteria could be monitored:

a) Animal bacterial pathogens relevant to the countries' priorities

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

i) detect emerging resistance that may pose a concern for animal and human health;

ii) guide *veterinarians* in their prescribing decisions.

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

b) Zoonotic bacteria

i) *Salmonella*

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

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

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

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

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

ii) *Campylobacter*

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

iii) Other emerging bacterial pathogens

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

c) Commensal bacteria

E. coli and *enterococci* (*Enterococcus faecium* and *E. faecalis*) may be sampled from animal feed, food producing animals and animal-derived food products.

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

7. Storage of bacterial strains

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

8. Antimicrobial susceptibility testing

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

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Appropriately validated antimicrobial susceptibility testing methods should be used in accordance with Guideline ~~1.1.6.~~ 3.1. of the *Terrestrial Manual*, concerning laboratory methodologies for bacterial antimicrobial susceptibility testing. Antimicrobial susceptibility data should be reported quantitatively (minimum inhibitory concentrations [MICs] or inhibition zone diameters), rather than qualitatively.

9. Recording, storage and interpretation of data

a) Because of the volume and complexity of the information to be stored and the need to keep these data available for an undetermined period of time, careful consideration should be given to database design.

b) The storage of raw (primary, non-interpreted) data is essential to allow the evaluation in response to various kinds of questions, including those arising in the future.

c) Consideration should be given to the technical requirements of computer systems when an exchange of data between different systems (comparability or compatibility of automatic recording of laboratory data and transfer of these data between and within resistance monitoring programmes) is envisaged. Results should be collected in a suitable national database. They should be recorded quantitatively:

   i) as distributions of MICs in milligrams per litre;

   ii) or inhibition zone diameters in millimetres.

d) The information to be recorded should include, where possible, the following aspects:

   i) sampling programme;

   ii) sampling date;

   iii) animal species or type;

   iv) type of sample;

   v) purpose of sampling;

   vi) type of antimicrobial susceptibility testing method used;

   vii) geographical origin (geographical information system data where available) of *herd*, *flock* or *animal*;

   viii) *animal* factors (e.g. age, condition, health status, identification, sex).

e) The reporting of *laboratory* data should include the following information:

   i) identity of *laboratory*,

   ii) isolation date,

   iii) reporting date,

   iv) bacterial species,

   and, where relevant, other typing characteristics, such as:

   v) serotype or serovar,

   vi) phage type,

vii) antimicrobial susceptibility result or resistance phenotype,

viii) genotype.

f) The proportion of isolates regarded as resistant should be reported, including the defined interpretive criteria used.

g) In the clinical setting, breakpoints are used to categorise bacterial strains as susceptible, intermediate or resistant. These clinical breakpoints may be elaborated on a national basis and may vary between Member Countries.

h) The antimicrobial susceptibility testing standards and guidelines used should be recorded.

i) For surveillance purposes, use of the microbiological breakpoint (also referred to as epidemiological cut-off point), which is based on the distribution of MICs or inhibition zone diameters of the specific bacterial species tested, is preferred. When using microbiological breakpoints, only the bacterial population with acquired resistance that clearly deviates from the distribution of the normal susceptible population will be designated as resistant.

j) Ideally, data should be collected at the individual isolate level, allowing antimicrobial resistance patterns to be recorded.

10. Reference laboratory and annual reports

a) Member Countries should designate a national reference centre that assumes the responsibility to:

i) coordinate the activities related to the antimicrobial resistance surveillance and monitoring programmes;

ii) coordinate and collect information from participating surveillance laboratories within the country;

iii) produce an annual report on the antimicrobial resistance situation in the country.

b) The national reference centre should have access to the:

i) raw data;

ii) complete results of quality assurance and inter-laboratory calibration activities;

iii) inter-laboratory proficiency testing results;

iv) information on the structure of the monitoring system;

v) information on the chosen laboratory methods.

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Annex XI

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 agent~~(s)~~*.

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.

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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 co-operation 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.

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 agent~~(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.

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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 agent~~(s)~~

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

a) prescribed by 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*;

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 agent~~(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 agent~~(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 agent~~(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 agent~~(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 agent~~(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 agent~~(s)~~*:

a) only licensed and officially approved VMP containing *antimicrobial agent~~(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 agent~~(s)~~* directly to the food animal producer.

4. Training

The veterinary pharmaceutical industry should participate in training programmes as defined in point 14 of Article 6.9.3.

5. Research

The veterinary pharmaceutical industry should contribute to research as defined in point 15 of Article 6.9.3.

Article 6.9.5.

Responsibilities of wholesale and retail distributors

1. Distributors of VMP containing *antimicrobial agent~~(s)~~* should only do so 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*. All products should be appropriately labelled.
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 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*.

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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~~ii~~) the appropriate dosage regimen and route of administration;

      ~~i~~v) 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 VMP~~s~~ 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.

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;

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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 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 14 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 VMP~~s~~ containing *antimicrobial agent~~(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 agent~~(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 agent~~(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, 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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Annex XII

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 occuring phenomenon. However, ~~P~~problems related to antimicrobial resistance are inherently linked to *antimicrobial agent* use in any environment, including human and non-human usages. ~~However t~~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 micro-organisms 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 Member~~s~~ 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 foodborne antimicrobial resistance related to the non-human use of *antimicrobial agents* is covered by the Codex Guidelines for risk analysis of foodborne 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*.

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.~~

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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 *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*~~ apply~~ies~~ 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~~ should 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 ~~to~~ lead to the release of resistant microorganisms or resistance determinants into a particular environment due to ~~for~~ the use of a specific *antimicrobial agent* in *animals* ~~to lead to the release of resistant micro-organisms or resistance determinants into a particular environment,~~. It also estimates ~~and estimating~~ either qualitatively or quantitatively the probability of that complete process occurring. The release assessment describes the probability of the release of each of the potential *hazards* under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures.

The following factors should be considered in the release assessment:

- animal species, category such as food producing, zoo 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, age and their geographical distribution ~~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~~/pharmacokinetics~~ 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 ~~acquire~~ resistance in animal 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 estimat~~ing~~es 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 exposur ~~and the number~~, species and other characteristics of the human populations exposed.

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The following factors should be considered in the exposure assessment:

- human demographics, including population subgroups, and food consumption patterns, including traditions and cultural practices in 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 of resistant microorganisms in animal feed ~~prevalence of animal feed contaminated with resistant micro-organisms~~;
- 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 ~~-~~ host response relationships;

- 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, etc.);

- increased severity or duration of infectious *disease*;

- number of person~~/ / or~~ days of illness per year;

- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population) linked to antimicrobial resistant microorganisms;

- ~~importance~~ severity of the ~~pathology~~ *disease* ~~infection~~ caused by the target microorganisms;

- availability ~~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).

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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 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 certain bacterial diseases of *animals* will have the dual benefit of reducing the risks linked to 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 ~~its use~~ in *animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the animal *infection*.

2. Hazard identification

- m~~M~~icroorganisms that have acquired resistance, (including multiple resistance) arising from the use of an *antimicrobial agent*~~(s)~~ in *animals*;

- m~~M~~icroorganisms having obtained a resistance determinant~~(s)~~ from another microorganism~~s~~ which has~~ve~~ acquired resistance arising from the use of an *antimicrobial agent*~~(s)~~ in *animals*.

The *identification of the hazard* ~~must~~ should 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 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, age and their geographical distribution;
- 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;
- potential extra-label or off-label use;
- dosage regimen 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*;

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- ~~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 ~~in~~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;
- 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 for a random member of the population or a member of a specific more exposed sub-population) linked to antimicrobial resistant microorganisms;

- availability ~~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. ~~do~~ 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. ~~do~~ apply.

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Annex XIII

CHAPTER 7.5.

SLAUGHTER OF ANIMALS

Article 7.5.1.

General principles

1. Object

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

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

2. Personnel

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

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

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

3. Animal behaviour

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

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

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

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

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

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

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

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

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

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

4. Distractions and their removal

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

a) reflections on shiny metal or wet floors – move a lamp or change lighting;

b) dark entrances to chutes, races, stun boxes or conveyor restrainers – illuminate with indirect lighting which does not shine directly into the eyes of approaching *animals* or create areas of sharp contrast;

c) *animals* seeing moving people or equipment up ahead – install solid sides on chutes and races or install shields;

d) dead ends – avoid if possible by curving the passage, or make an illusory passage;

e) chains or other loose objects hanging in chutes or on fences – remove them;

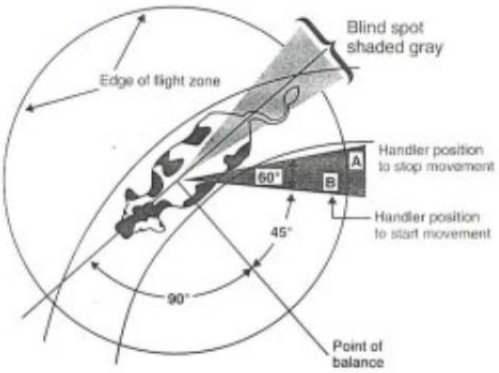
f) uneven floors or a sudden drop in floor levels at the entrance to conveyor restrainers – avoid uneven floor surfaces or install a solid false floor under the restrainer to provide an illusion of a solid and continuous walking surface;

g) sounds of air hissing from pneumatic equipment – install silencers or use hydraulic equipment or vent high pressure to the external environment using flexible hosing;

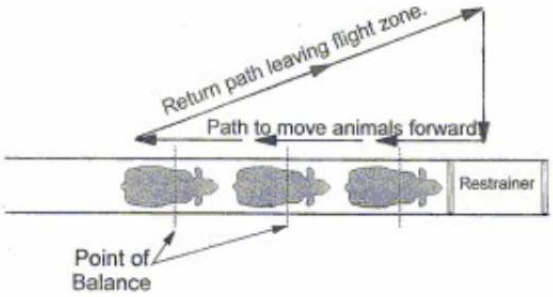
h) clanging and banging of metal objects – install rubber stops on gates and other devices to reduce metal to metal contact;

i) air currents from fans or air curtains blowing into the face of *animals* – redirect or reposition equipment.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



Article 7.5.2.

Moving and handling animals

1. General considerations

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

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

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

a) The conditions of the *animals* should be assessed upon their arrival for any *animal welfare* and health problems.

b) Injured or sick *animals*, requiring immediate *slaughter*, should be killed humanely and without delay, in accordance with the recommendations of the OIE.

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c) *Animals* should not be forced to move at a speed greater than their normal walking pace, in order to minimise injury through falling or slipping. Performance standards should be established where numerical scoring of the prevalence of *animals* slipping or falling is used to evaluate whether animal moving practices and/or facilities should be improved. In properly designed and constructed facilities with competent *animal handlers*, it should be possible to move 99 percent of *animals* without their falling.

d) *Animals* for *slaughter* should not be forced to walk over the top of other *animals*.

e) *Animals* should be handled in such a way as to avoid harm, distress or injury. Under no circumstances should *animal handlers* resort to violent acts to move *animals*, such as crushing or breaking tails of *animals*, grasping their eyes or pulling them by the ears. *Animal handlers* should never apply an injurious object or irritant substance to *animals* and especially not to sensitive areas such as eyes, mouth, ears, anogenital region or belly. The throwing or dropping of *animals*, or their lifting or dragging by body parts such as their tail, head, horns, ears, limbs, wool, hair or feathers, should not be permitted. The manual lifting of small *animals* is permissible.

f) When using goads and other aids, the following principles should apply:

   i) *Animals* that have little or no room to move should not be subjected to physical force or goads and other aids which compel movement. Electric goads and prods should only be used in extreme cases and not on a routine basis to move *animals*. The use and the power output should be restricted to that necessary to assist movement of an *animal* and only when an *animal* has a clear path ahead to move. Goads and other aids should not be used repeatedly if the *animal* fails to respond or move. In such cases it should be investigated whether some physical or other impediment is preventing the *animal* from moving.

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

   iii) Useful and permitted goads include panels, flags, plastic paddles, flappers (a length of cane with a short strap of leather or canvas attached), plastic bags and metallic rattles; they should be used in a manner sufficient to encourage and direct movement of the *animals* without causing undue stress.

   iv) Painful procedures (including whipping, kicking, tail twisting, use of nose twitches, pressure on eyes, ears or external genitalia), or the use of goads or other aids which cause pain and suffering (including large sticks, sticks with sharp ends, lengths of metal piping, fencing wire or heavy leather belts), should not be used to move *animals*.

   v) Excessive shouting at *animals* or making loud noises (e.g. through the cracking of whips) to encourage them to move should not occur, as such actions may make the *animals* agitated, leading to crowding or falling.

   vi) *Animals* should be grasped or lifted in a manner which avoids pain or suffering and physical damage (e.g. bruising, fractures, dislocations). In the case of quadrupeds, manual lifting by a person should only be used in young *animals* or small species, and in a manner appropriate to the species; grasping or lifting such *animals* only by their wool, hair, feathers, feet, neck, ears, tails, head, horns, limbs causing pain or suffering should not be permitted, except in an emergency where *animal welfare* or human safety may otherwise be compromised.

   vii) Conscious *animals* should not be thrown, dragged or dropped.

g) Performance standards should be established to evaluate the use of such instruments. Numerical scoring may be used to measure the percentage of *animals* moved with an electric instrument and the percentage of *animals* slipping or falling at a point in the *slaughterhouse*. Any risk of compromising *animal welfare*, for example slippery floor, should be investigated immediately and the defect rectified to eliminate the problem. In addition to resource-based measures, outcome-based measures (e.g. bruises, lesions, behaviour, and mortality) should be used to monitor the level of *welfare* of the *animals*.

2. Specific considerations for poultry

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

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

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

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

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

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

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

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

3. Provisions relevant to animals delivered in containers

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

b) *Animals* delivered in *containers* with perforated or flexible bottoms should be unloaded with particular care in order to avoid injury. Where appropriate, *animals* should be unloaded from the *containers* individually.

c) *Animals* which have been transported in *containers* should be slaughtered as soon as possible; mammals and ratites which are not taken directly upon arrival to the place of *slaughter* should have drinking water available to them from appropriate facilities at all times. Delivery of *poultry* for *slaughter* should be scheduled such that they are not deprived of water at the premises for longer than 12 hours. *Animals* which have not been slaughtered within 12 hours of their arrival should be fed, and should subsequently be given moderate amounts of food at appropriate intervals.

4. Provisions relevant to restraining and containing animals

a) Provisions relevant to *restraining animals* for *stunning* or *slaughter* without *stunning*, to help maintain *animal welfare*, include:

i) provision of a non-slippery floor;

ii) avoidance of excessive pressure applied by *restraining* equipment that causes struggling or vocalisation in *animals*;

iii) equipment engineered to reduce noise of air hissing and clanging metal;

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iv) absence of sharp edges in *restraining* equipment that would harm *animals*;

v) avoidance of jerking or sudden movement of *restraining* device.

b) Methods of *restraint* causing avoidable suffering should not be used in conscious *animals* because they cause severe pain and stress:

i) suspending or hoisting *animals* (other than *poultry*) by the feet or legs;

ii) indiscriminate and inappropriate use of *stunning* equipment;

iii) mechanical clamping of the legs or feet of the *animals* (other than shackles used in *poultry* and ostriches) as the sole method of *restraint*;

iv) breaking legs, cutting leg tendons or blinding *animals* in order to immobilise them;

v) severing the spinal cord, for example using a puntilla or dagger, to immobilise *animals* using electric currents to immobilise *animals*, except for proper *stunning*.

Article 7.5.3.

Lairage design and construction

1. General considerations

The *lairage* should be designed and constructed to hold an appropriate number of *animals* in relation to the throughput rate of the *slaughterhouse* without compromising the *welfare* of the *animals*.

In order to permit operations to be conducted as smoothly and efficiently as possible without injury or undue stress to the *animals*, the *lairage* should be designed and constructed so as to allow the *animals* to move freely in the required direction, using their behavioural characteristics and without undue penetration of their flight zone.

The following recommendations may help to achieve this.

2. Design of lairage

a) The *lairage* should be designed to allow a one-way flow of *animals* from *unloading* to the point of *slaughter*, with a minimum number of abrupt corners to negotiate.

b) In red meat *slaughterhouses*, pens, passageways and races should be arranged in such a way as to permit inspection of *animals* at any time, and to permit the removal of sick or injured *animals* when considered to be appropriate, for which separate appropriate accommodation should be provided.

c) Each *animal* should have room to stand up and lie down and, when confined in a pen, to turn around, except where the *animal* is reasonably restrained for safety reasons (e.g. fractious bulls). Fractious *animals* should be slaughtered as soon as possible after arrival at the *slaughterhouse* to avoid *welfare* problems. The *lairage* should have sufficient accommodation for the number of *animals* intended to be held. Drinking water should always be available to the *animals*, and the method of delivery should be appropriate to the type of *animal* held. Troughs should be designed and installed in such a way as to minimise the risk of fouling by faeces, without introducing risk of bruising and injury in *animals*, and should not hinder the movement of *animals*.

d) Holding pens should be designed to allow as many *animals* as possible to stand or lie down against a wall. Where feed troughs are provided, they should be sufficient in number and feeding space to allow adequate access of all *animals* to feed. The feed trough should not hinder the movement of *animals*.

e) Where tethers, ties or individual stalls are used, these should be designed so as not to cause injury or distress to the *animals* and should also allow the *animals* to stand, lie down and access any food or water that may need to be provided.

f) Passageways and races should be either straight or consistently curved, as appropriate to the animal species. Passageways and races should have solid sides, but when there is a double race, the shared partition should allow adjacent *animals* to see each other. For pigs and sheep, passageways should be wide enough to enable two or more *animals* to walk side by side for as long as possible. At the point where passageways are reduced in width, this should be done by a means which prevents excessive bunching of the *animals*.

g) *Animal handlers* should be positioned alongside races and passageways on the inside radius of any curve, to take advantage of the natural tendency of *animals* to circle an intruder. Where one-way gates are used, they should be of a design which avoids bruising. Races should be horizontal but where there is a slope, they should be constructed to allow the free movement of *animals* without injury.

h) In *slaughterhouses* with high throughput, there should be a waiting pen, with a level floor and solid sides, between the holding pens and the race leading to the point of *stunning* or *slaughter*, to ensure a steady supply of *animals* for *stunning* or *slaughter* and to avoid having *animal handlers* trying to rush *animals* from the holding pens. The waiting pen should preferably be circular, but in any case, so designed that *animals* cannot be trapped or trampled.

i) Ramps or lifts should be used for the *loading* and *unloading* of *animals* where there is a difference in height or a gap between the floor of the *vehicle* and the *unloading* area. Unloading ramps should be designed and constructed so as to permit *animals* to be unloaded from *vehicles* on the level or at the minimum gradient achievable. Lateral side protection should be available to prevent *animals* escaping or falling. They should be well drained, with secure footholds and adjustable to facilitate easy movement of *animals* without causing distress or injury.

3. Construction of lairage

a) *Lairages* should be constructed and maintained so as to provide protection from unfavourable climatic conditions, using strong and resistant materials such as concrete and metal which has been treated to prevent corrosion. Surfaces should be easy to clean. There should be no sharp edges or protuberances which may injure the *animals*.

b) Floors should be well drained and not slippery; they should not cause injury to the feet of the *animals*. Where necessary, floors should be insulated or provided with appropriate bedding. Drainage grids should be placed at the sides of pens and passageways and not where *animals* would have to cross them. Discontinuities or changes in floor, wall or gate colours, patterns or texture which could cause baulking in the movement of *animals* should be avoided.

c) *Lairages* should be provided with adequate lighting, but care should be taken to avoid harsh lights and shadows, which frighten the *animals* or affect their movement. The fact that *animals* will move more readily from a darker area into a well-lit area might be exploited by providing for lighting that can be regulated accordingly.

d) *Lairages* should be adequately ventilated to ensure that waste gases (e.g. ammonia) do not build up and that draughts at animal height are minimised. Ventilation should be able to cope with the range of expected climatic conditions and the number of *animals* the *lairage* will be expected to hold.

e) Care should be taken to protect the *animals* from excessively or potentially disturbing noises, for example by avoiding the use of noisy hydraulic or pneumatic equipment, and muffling noisy metal equipment by the use of suitable padding, or by minimising the transmission of such noises to the areas where *animals* are held and slaughtered.

f) Where *animals* are kept in outdoor *lairages* without natural shelter or shade, they should be protected from the effects of adverse weather conditions.

Article 7.5.4.

Care of animals in lairages

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

Annex XIII (contd)

1) As far as possible, established groups of *animals* should be kept together and each *animal* should have enough space to stand up, lie down and turn around. *Animals* hostile to each other should be separated.

2) Where tethers, ties or individual stalls are used, they should allow *animals* to stand up and lie down without causing injury or distress.

3) Where bedding is provided, it should be maintained in a condition that minimises risks to the health and safety of the *animals*, and sufficient bedding should be used so that *animals* do not become soiled with manure.

4) *Animals* should be kept securely in the *lairage*, and care should be taken to prevent them from escaping and from predators.

5) Suitable drinking water should be available to the *animals* on their arrival and at all times to *animals* in *lairages* unless they are to be slaughtered without delay.

6) Waiting time should be minimised and should not exceed 12 hours. If *animals* are not to be slaughtered within this period, suitable feed should be available to the *animals* on arrival and at intervals appropriate to the species. Unweaned *animals* should be slaughtered as soon as possible.

7) In order to prevent heat stress, *animals* subjected to high temperatures, particularly pigs and *poultry*, should be cooled by the use of water sprays, fans or other suitable means. However, the potential for water sprays to reduce the ability of *animals* to thermoregulate (especially *poultry*) should be considered in any decision to use water sprays. The risk of *animals* being exposed to very cold temperatures or sudden extreme temperature changes should also be considered.

8) The *lairage* area should be well lit in order to enable the *animals* to see clearly without being dazzled. During the night, the lights should be dimmed. Lighting should also be adequate to permit inspection of all *animals*. Subdued lighting, and for example blue light, may be useful in *poultry lairages* in helping to calm birds.

9) The condition and state of health of the *animals* in a *lairage* should be inspected at least every morning and evening by a *veterinarian* or, under the *veterinarian*'s responsibility, by another competent person, such as an *animal handler*. *Animals* which are sick, weak, injured or showing visible signs of distress should be separated, and veterinary advice should be sought immediately regarding treatment or the *animals* should be humanely killed immediately if necessary.

10) Lactating dairy *animals* should be slaughtered as soon as possible. Dairy *animals* with obvious udder distension should be milked to minimise udder discomfort.

11) *Animals* which have given birth during the *journey* or in the *lairage* should be slaughtered as soon as possible or provided with conditions which are appropriate for suckling for their *welfare* and the *welfare* of the newborn. Under normal circumstances, *animals* which are expected to give birth during a *journey* should not be transported.

12) *Animals* with horns, antlers or tusks capable of injuring other *animals*, if aggressive, should be penned separately.

13) *Poultry* awaiting *slaughter* should be protected from adverse weather conditions and provided with adequate ventilation.

14) *Poultry* in transport *containers* should be examined at the time of arrival. *Containers* should be stacked with sufficient space between the stacks to facilitate inspection of birds and air movement.

15) Forced ventilation or other cooling systems may be necessary under certain conditions to avoid build-up of temperature and humidity. Temperature and humidity should be monitored at appropriate intervals.

Recommendations for specific species are described in detail in Articles 7.5.5. ~~to~~ ~~and~~to 7.5.9~~6~~9.

Annex XIII (contd)

Article 7.5.5.

Management of foetuses during slaughter of pregnant animals

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

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

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

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

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

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

Article 7.5.6.

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

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

~~[DELETE TABLE]~~

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
No restraint	Animals are grouped	Group container	Gas stunning	Specific procedure is suitable only for gas stunning	Competent animal handlers in lairage; facilities; stocking density	Pigs, poultry
		In the field	Free bullet	Inaccurate targeting and inappropriate ballistics not achieving outright kill with first shot	Operator competence	Deer
		Group stunning pen	Head-only electrical Captive bolt	Uncontrolled movement of animals impedes use of hand operated electrical and mechanical stunning methods	Competent animal handlers in lairage and at stunning point	Pigs, sheep, goats, calves
	Individual animal confinement	Stunning pen/box	Electrical and mechanical Stunning methods	Loading of animal; accuracy of stunning Method, slippery floor and animal falling down	Competent animal handlers	Cattle, buffalo, Sheep, goats, Horses, pigs, deer, camelids, ratites

Annex XIII (contd)

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Restraining methods	Head restraint, upright	Halter/ head collar/bridle	Captive bolt Free bullet	Suitable for halter-trained animals; stress in untrained animals	Competent animal handlers	Cattle, buffalo, horses, camelids
	Head restraint, upright	Neck yoke	Captive bolt Electrical-head only Free bullet Slaughter without stunning	Stress of loading and neck capture; stress of prolonged restraint, horn configuration; unsuitable for fast line speeds, animals struggling and falling due to slippery floor, excessive pressure	Equipment; competent animal handlers, prompt stunning or slaughter	Cattle
	Leg restraint	Single leg tied in flexion (animal standing on 3 legs)	Captive bolt Free bullet	Ineffective control of animal movement, misdirected shots	Competent animal handler	Breeding pigs (boars and sows)
	Upright restraint	Beak holding	Captive bolt Electrical-head only	Stress of capture	Sufficient competent animal handlers	Ostriches
		Head restraint in electrical stunning box	Electrical-head only	Stress of capture and positioning	Competent animal handler	Ostriches
	Holding body upright-manual	Manual restraint	Captive bolt Electrical-head only Slaughter without stunning	Stress of capture and restraint; accuracy of stunning/ slaughter	Competent animal handlers	Sheep, goats, calves, ratites, small camelids, poultry
	Holding body upright mechanical	Mechanical clamp/crush/ squeeze/ V-restrainer (static)	Captive bolt Electrical methods Slaughter without stunning	Loading of animal and overriding; excessive pressure	Proper design and operation of equipment	Cattle, buffalo, sheep, goats, deer, pigs, ostriches
	Lateral restraint– manual or mechanical	Restrainer/ cradle/crush	Slaughter without stunning	Stress of restraint	Competent animal handlers	Sheep, goats, calves, camelids, cattle
	Upright restraint mechanical	Mechanical straddle (static)	Slaughter without stunning Electrical methods Captive bolt	Loading of animal and overriding	Competent animal handlers	Cattle, sheep, goats, pigs
	Upright restraint– manual or mechanical	Wing shackling	Electrical	Excessive tension applied prior to stunning	Competent animal handlers	Ostriches

Annex XIII (contd)

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Restraining and /or conveying methods	Mechanical – upright	V–restrainer	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding; excessive pressure, size mismatch between restrainer and animal	Proper design and operation of equipment	Cattle, calves, sheep, goats, pigs
	Mechanical – upright	Mechanical straddle–band restrainer (moving)	Electrical methods Captive bolt Slaughter without stunning	Loading of animal and overriding, size mismatch between restrainer and animal	Competent animal handlers, proper design and layout of restraint	Cattle, calves, sheep, goats, pigs
	Mechanical – upright	Flat bed/deck Tipped out of containers on to conveyors	Presentation of birds for shackling prior to electrical stunning Gas stunning	Stress and injury due to tipping in dump-module systems height of tipping conscious poultry broken bones and dislocations	Proper design and operation of equipment	Poultry
	Suspension and/or inversion	Poultry shackle	Electrical stunning Slaughter without stunning	Inversion stress; pain from compression on leg bones	Competent animal handlers; proper design and operation of equipment	Poultry
	Suspension and/or inversion	Cone	Electrical – head-only Captive bolt Slaughter without stunning	Inversion stress	Competent animal handlers; proper design and operation of equipment	Poultry
	Upright restraint	Mechanical leg clamping	Electrical – head-only	Stress of resisting restraint in ostriches	Competent animal handlers; proper equipment design and operation	Ostriches
Restraining by inversion	Rotating box	Fixed side(s) (e.g. Weinberg pen)	Slaughter without stunning	Inversion stress; stress of resisting restraint, prolonged restraint, inhalation of blood and ingesta Keep restraint as brief as possible	Proper design and operation of equipment	Cattle
		Compressible side(s)	Slaughter without stunning	Inversion stress, stress of resisting restraint, prolonged restraint Preferable to rotating box with fixed sides Keep restraint as brief as possible	Proper design and operation of equipment	Cattle

Annex XIII (contd)

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Body restraint	Casting/ hobbling	Manual	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; animal temperament; bruising. Keep restraint as short as possible	Competent animal handlers	Sheep, goats, calves, small camelids, pigs
		Rope casting	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent animal handlers	Cattle, camelids
Leg restraints		Tying of 3 or 4 legs	Mechanical stunning methods Slaughter without stunning	Stress of resisting restraint; prolonged restraint, animal temperament; bruising Keep restraint as short as possible	Competent animal handlers	Sheep, goats, small camelids, pigs

Article 7.5.~~7~~67.

Stunning methods

1. General considerations

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

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

   a) the *animal* is adequately restrained;

   b) *animals* in *restraint* are stunned as soon as possible;

   c) the equipment used for *stunning* is maintained and operated properly in accordance with the manufacturer's recommendations, in particular with regard to the species and size of the *animal*;

   d) the equipment is applied correctly;

   e) stunned *animals* are bled out (slaughtered) as soon as possible;

   f) *animals* are not stunned when *slaughter* is likely to be delayed; and

   g) backup *stunning* devices are available for immediate use if the primary method of *stunning* fails. Provision of a manual inspection area and simple intervention like captive bolt or cervical dislocation for *poultry* would help prevent potential *welfare* problems.

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

2. Mechanical stunning

   A mechanical device should be applied usually to the front of the head and perpendicular to the bone surface.

   For a more detailed explanation on the different methods for mechanical *stunning*, see Chapter 7.6. and Articles 7.6.~~6~~56., 7.6.~~7~~67. and 7.6.~~8~~78. The following diagrams illustrate the proper application of the device for certain species.

Cattle

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

~~**Cattle**~~

Stunning with a penetrative captive bolt stunning gun

The optimum position for stunning cattle with a penetrative captive bolt stunning gun is at the intersection of two imaginary lines drawn from the rear of the eyes to the base of the opposite horn buds or an equivalent position in polled animals. Gun has to be positioned in a right angle

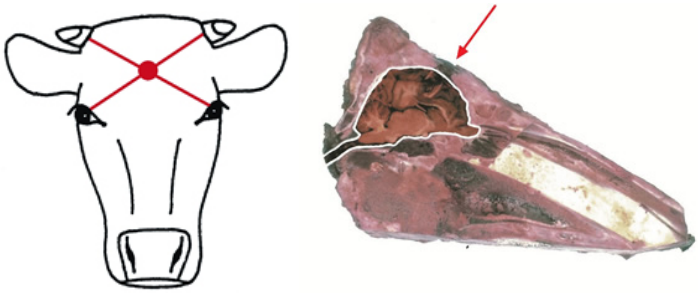


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Figure 2. Stunning with a non- penetrative captive bolt stunning gun

The optimum position for stunning cattle with a non-penetrative captive bolt stunning gun is 2 cm above the intersection of two imaginary lines drawn from the rear of the eyes to the base of the opposite horn buds or an equivalent position in polled animals. Gun has to be positioned in a right angle.

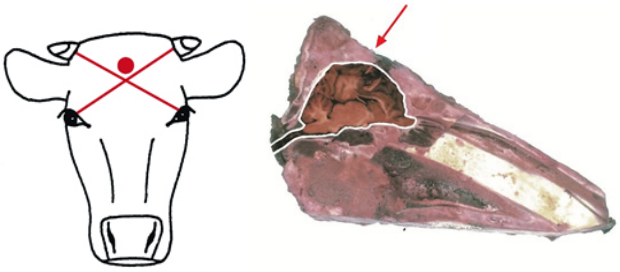


Figure source : Temple Grandin. www.grandin.com

Annex XIII (contd)

Pigs

Figure 23. The optimum position for pigs is on the midline ~~just~~ above eye level, with the shot directed down the line of the spinal cord.

~~**Pigs**~~

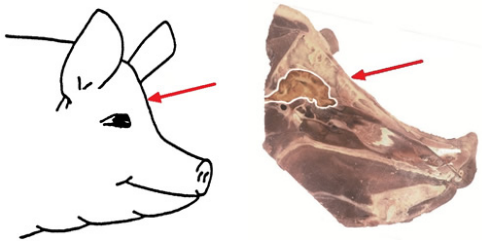
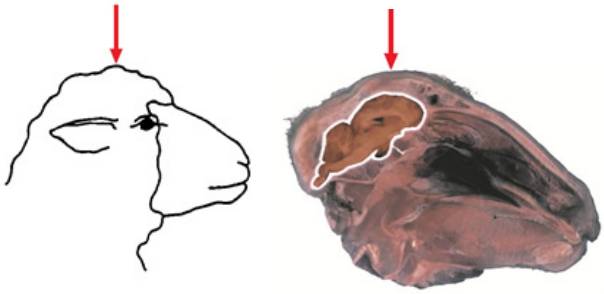


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Sheep and Goats

Figure 34. The optimum position for hornless sheep is on the midline.



~~**Sheep**~~

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

Figure 45. The optimum position for heavily horned sheep and horned goats is behind the poll, aiming towards the angle of the jaw.

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

Annex XIII (contd)

Horses

Figure ~~5~~6. The optimum position for horses is at right angles to the frontal surface, ~~well~~ above the point where imaginary lines from eyes to ears cross.

~~**Horses**~~

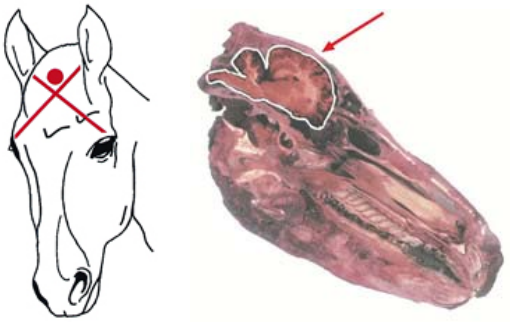


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

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

~~1) the *animal* collapses immediately and does not attempt to stand up;~~

~~2) the body and muscles of the *animal* become tonic (rigid) immediately after the shot;~~

~~3) normal rhythmic breathing stops; and~~

~~4) the eyelid is open with the eyeball facing straight ahead and is not rotated.~~

~~**Figure 6.**~~ Poultry

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

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

~~**Poultry**~~ **Figure 7**

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

Annex XIII (contd)

~~Poultry~~ Figure 8

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

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

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

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

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

b) the body and muscles of the *animal* become tonic (rigid) immediately after the shot;

c) normal rhythmic breathing stops; and

d) the eyelid is open with the eyeball facing straight ahead and is not rotated.

3. Electrical stunning

a) General considerations

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

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

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

Electrical *stunning* equipment should not be applied on *animals* as a means of guidance, movement, *restraint* or immobilisation, and shall not deliver any shock to the *animal* before the actual *stunning* or *killing*.

Electrical *stunning* apparatus should be tested prior to application on *animals* using appropriate resistors or dummy loads to ensure the power output is adequate to stun *animals*.

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

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

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

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

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

b) Electrical stunning of birds using a water bath

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

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

Birds should be hung on shackles by both legs.

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

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

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

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

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

Annex XIII (contd)

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

Using water baths, birds are stunned in groups and different birds will have different impedances. The voltage should be adjusted so that the total current is the required current per bird as shown in the table hereafter, multiplied by the number of birds in the water bath at the same time. The following values have been found to be satisfactory when employing a 50 Hertz sinusoidal alternating current.

Birds should receive the current for at least 4 seconds.

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

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

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

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

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

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

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

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

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

For direct current, parameters should be developed and applied on the basis of outcomes, such as observable stun posture, no rhythmical breathing, etc.

4. Gas stunning (under study)

a) Stunning of pigs by exposure to carbon dioxide (CO_2)

The concentration of CO_2 for *stunning* should be preferably 90 percent by volume but in any case no less than 80 percent by volume. After entering the *stunning* chamber, the *animals* should be conveyed to the point of maximum concentration of the gas as rapidly as possible and be kept until they are dead or brought into a state of insensibility which lasts until *death* occur due to bleeding. Ideally, pigs should be exposed to this concentration of CO_2 for 3 minutes. Sticking should occur as soon as possible after exit from the gas chamber.

In any case, the concentration of the gas should be such that it minimises as far as possible all stress of the *animal* prior to loss of consciousness.

The chamber in which *animals* are exposed to CO_2 and the equipment used for conveying them through it shall be designed, constructed and maintained in such a way as to avoid injury or unnecessary stress to the *animals*. The animal density within the chamber should be such to avoid stacking *animals* on top of each other.

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

It should be possible to inspect the CO_2 chamber whilst it is in use, and to have access to the *animals* in emergency cases.

The chamber shall be equipped to continuously measure and display register at the point of *stunning* the CO_2 concentration and the time of exposure, and to give a clearly visible and audible warning if the concentration of CO_2 falls below the required level.

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

b) Inert gas mixtures for stunning pigs

Inhalation of high concentration of carbon dioxide is aversive and can be distressing to *animals*. Therefore, the use of non-aversive gas mixtures is being developed.

Such gas mixtures include:

i) a maximum of 2 percent by volume of oxygen in argon, nitrogen or other inert gases, or

ii) to a maximum of 30 percent by volume of carbon dioxide and a maximum of 2 percent by volume of oxygen in mixtures with carbon dioxide and argon, nitrogen or other inert gases.

Exposure time to the gas mixtures should be sufficient to ensure that no pigs regain consciousness before *death* supervenes through bleeding or cardiac arrest is induced.

c) Gas stunning of poultry

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

Live *poultry* contained within transport modules or crates may be exposed to gradually increasing concentrations of CO_2 until the birds are properly stunned. No bird should recover consciousness during bleeding.

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

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

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

– ensure smooth entry and passage of crates or birds through the system;

– avoid crowding of birds in crates or conveyors;

– monitor and maintain gas concentrations continuously during operation;

– provide visible and audible alarm systems if gas concentrations are inappropriate to the species;

– calibrate gas monitors and maintain verifiable records;

– ensure that duration of exposure is adequate to prevent recovery of consciousness;

– make provision to monitor and deal with recovery of consciousness;

– ensure that blood vessels are cut to induce *death* in unconscious birds;

– ensure that all birds are dead before entering scalding tank;

– provide emergency procedures in the event of system failure.

i) Gas mixtures used for stunning *poultry* include:

  – a minimum of 2 minutes exposure to 40 percent carbon dioxide, 30 percent oxygen and 30 percent nitrogen, followed by a minimum of one minute exposure to 80 percent carbon dioxide in air; or

  – a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30 percent by volume and the residual oxygen concentration does not exceed 2 percent by volume; or

  – a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2 percent residual oxygen by volume; or

  – a minimum of 2 minutes exposure to a minimum of 55 percent carbon dioxide in air; or

  – a minimum of one minute exposure to 30 percent carbon dioxide in air, followed by a minimum of one minute exposure to at least 60 percent carbon dioxide in air.

ii) Requirements for effective use are as follows:

  – Compressed gases should be vaporised prior to administration into the chamber and should be at room temperature to prevent any thermal shock; under no circumstances, should solid gases with freezing temperatures enter the chamber.

  – Gas mixtures should be humidified.

  – Appropriate gas concentrations of oxygen and carbon dioxide should be monitored and displayed continuously at the level of the birds inside the chamber to ensure that anoxia ensues.

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

5. Bleeding

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

Stunning method	Maximum stun–stick interval
Electrical methods and non-penetrating captive bolt	20 seconds
CO_2	60 seconds (after leaving the chamber)

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

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

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

~~Article 7.5.8.~~Article 7.5.8.

~~**Summary analysis of stunning methods and the associated animal welfare issues**~~

Summary analysis of stunning methods and the associated animal welfare issues

~~[DELETE TABLE]~~

Method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements applicable	Species	Comment
Mechanical	Free bullet	In accurate targeting and inappropriate ballistics	Operator competence; achieving outright kill with first shot	Cattle, calves, buffalo, deer, horses, pigs (boars and sows)	Personnel safety
	Captive bolt – penetrating	Inaccurate targeting, velocity and diameter of bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, buffalo, sheep, goats, deer, horses, pigs, camelids, ratites, poultry	(Unsuitable for specimen collection from TSE suspects). A back-up gun should be available in the event of an ineffective shot
	Captive bolt – non-penetrating	Inaccurate targeting, velocity of bolt, potentially higher failure rate than penetrating captive bolt	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, deer, pigs, camelids, ratites, poultry	Presently available devices are not recommended for young bulls and animals with thick skull. This method should only be used for cattle and sheep when alternative methods are not available.

Annex XIII (contd)

Method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements applicable	Species	Comment
Mechanical (contd)	Manual percussive blow	Inaccurate targeting; insufficient power; size of instrument	Competent animal handlers; restraint; accuracy. Not recommended for general use	Young and small mammals, ostriches and poultry	Mechanical devices potentially more reliable. Where manual percussive blow is used, unconsciousness should be achieved with single sharp blow delivered to central skull bones
Electrical	Split application: 1. across head then head to chest; 2. across head then across chest	Accidental pre-stun electric shocks; electrode positioning; application of a current to the body while animal conscious; inadequate current and voltage	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats and pigs, ratites and poultry	Systems involving repeated application of head-only or head-to-leg with short current durations (<1 second) in the first application should not be used.
	Single application: 1. head only; 2. head to body; 3. head to leg	Accidental pre-stun electric shocks; inadequate current and voltage; wrong electrode positioning; recovery of consciousness	Competent operation and maintenance of equipment; restraint; accuracy	Cattle, calves, sheep, goats, pigs, ratites, poultry	
	Water bath	Restraint, accidental pre-stun electric shocks; inadequate current and voltage; recovery of consciousness	Competent operation and maintenance of equipment	Poultry only	
Gaseous	CO_2 air/O_2 mixture; CO_2 inert gas mixture	Aversiveness of high CO_2; respiratory distress; inadequate exposure	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	
	Inert gases	Recovery of consciousness	Concentration; duration of exposure; design, maintenance and operation of equipment; density management	Pigs, poultry	

~~Article 7.5.9.~~ Article 7.5.9.

~~**Summary analysis of slaughter methods and the associated animal welfare issues**~~

Summary analysis of slaughter methods and the associated animal welfare issues

~~[DELETE TABLE]~~

Annex XIII (contd)

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

Annex XIII (contd)

Bleeding with prior stunning (contd)	Manual neck cut on one side	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness under slaughter without stunning
	Oral cut	Ineffective stunning; recovery of consciousness following reversible stunning systems	Prior non-reversible stunning	Poultry only	N.B. slow induction of unconsciousness in non-stun systems
Other methods without stunning	Decapitation with a sharp knife	Pain due to loss of consciousness not being immediate		Sheep, goats, poultry	This method is only applicable to Jhatka slaughter
	Manual neck dislocation and decapitation	Pain due to loss of consciousness not being immediate; difficult to achieve in large birds	Neck dislocation should be performed in one stretch to sever the spinal cord	Poultry only	Slaughter by neck dislocation should be performed in one stretch to sever the spinal cord. Acceptable only when slaughtering small numbers of small birds.
Cardiac arrest in a waterbath electric stunner	Bleeding by evisceration		Induction of cardiac arrest	Quail	
	Bleeding by neck cutting			Poultry	

Article 7.5.~~10~~Z10.

Methods, procedures or practices unacceptable on animal welfare grounds

1) The restraining methods which work through electro-immobilisation or immobilisation by injury such as breaking legs, leg tendon cutting, and severing the spinal cord (e.g. using a puntilla or dagger) cause severe pain and stress in *animals*. Those methods are not acceptable in any species.

2) The use of the electrical *stunning* method with a single application leg to leg is ineffective and unacceptable in any species.

3) The *slaughter* method of brain stem severance by piercing through the eye socket or skull bone without prior *stunning* is not acceptable in any species.

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Annex XIV

CHAPTER 7.6.

KILLING OF ANIMALS FOR DISEASE CONTROL PURPOSES

Article 7.6.1.

General principles

These recommendations are based on the premise that a decision to kill the *animals* has been made, and address the need to ensure the *welfare* of the *animals* until they are dead.

1) All personnel involved in the humane *killing* of *animals* should have the relevant skills and competencies. Competence may be gained through formal training and/or practical experience.

2) As necessary, operational procedures should be adapted to the specific circumstances operating on the premises and should address, apart from *animal welfare*, aesthetics of the method of *euthanasia*, cost of the method, operator safety, biosecurity and environmental aspects.

3) Following the decision to kill the *animals*, *killing* should be carried out as quickly as possible, and normal husbandry should be maintained until the *animals* are killed.

4) The handling and movement of *animals* should be minimised and when done, it should be carried out in accordance with the recommendations described below.

5) Animal *restraint* should be sufficient to facilitate effective *killing*, and in accordance with *animal welfare* and operator safety requirements; when *restraint* is required, *killing* should follow with minimal delay.

6) When *animals* are killed for disease control purposes, methods used should result in immediate *death* or immediate loss of consciousness lasting until *death*; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive or the least aversive possible and should not cause avoidable anxiety, pain, distress or suffering in *animals*.

7) *Death* must be confirmed before disposal of carcasses. A combination of criteria is most reliable in confirming *death*, including absence of heartbeat and pulse, absence of respiration, absence of corneal reflex etc.

~~7~~8) For *animal welfare* considerations, young *animals* should be killed before older *animals*; for biosecurity considerations, infected *animals* should be killed first, followed by in-contact *animals*, and then the remaining *animals*.

~~8~~9) There should be continuous monitoring of the procedures by the *Competent Authorities* to ensure they are consistently effective with regard to *animal welfare*, operator safety and biosecurity.

~~9~~10) When the operational procedures are concluded, there should be a written report describing the practices adopted and their effect on *animal welfare*, operator safety and biosecurity.

~~10~~11) These general principles should also apply when *animals* need to be killed for other purposes such as after natural disasters or for culling animal populations.

Annex XIV (contd)

Article 7.6.2.

Organisational structure

Disease control contingency plans should be in place at a national level and should contain details of management structure, disease control strategies and operational procedures; *animal welfare* considerations should be addressed within these disease control contingency plans. The plans should also include a strategy to ensure that an adequate number of personnel competent in the humane *killing* of *animals* is available. Local level plans should be based on national plans and be informed by local knowledge.

Disease control contingency plans should address the *animal welfare* issues that may result from animal movement controls.

The operational activities should be led by an *official Veterinarian* who has the authority to appoint the personnel in the specialist teams and ensure that they adhere to the required *animal welfare* and biosecurity standards. When appointing the personnel, he/she should ensure that the personnel involved have the required competencies.

The *official Veterinarian* should be responsible for all activities across one or more affected premises and should be supported by coordinators for planning (including communications), operations and logistics to facilitate efficient operations.

The *official Veterinarian* should provide overall guidance to personnel and logistic support for operations on all affected premises to ensure consistency in adherence to the OIE *animal welfare* and animal health recommendations.

A specialist team, led by a team leader answerable to the *official Veterinarian*, should be deployed to work on each affected premises. The team should consist of personnel with the competencies to conduct all required operations; in some situations, personnel may be required to fulfil more than one function. Each team should contain a *veterinarian* or have access to veterinary advice at all times.

In considering the *animal welfare* issues associated with *killing animals*, the key personnel, their responsibilities and competencies required are described in Article 7.6.3.

Article 7.6.3.

Responsibilities and competencies of the specialist team

1. Team leader

   a) Responsibilities

      i) plan overall operations on affected premises;

      ii) determine and address requirements for *animal welfare*, operator safety and biosecurity;

      iii) organise, brief and manage team of people to facilitate humane *killing* of the relevant *animals* on the premises in accordance with national regulations and these recommendations;

      iv) determine logistics required;

      v) monitor operations to ensure *animal welfare*, operator safety and biosecurity requirements are met;

      vi) report upwards on progress and problems;

      vii) provide a written report at the conclusion of the *killing*, describing the practices adopted and their effect on the *animal welfare*, operator safety and biosecurity outcomes.

b) Competencies

i) appreciation of normal animal husbandry practices;

ii) appreciation of *animal welfare* and the underpinning behavioural, anatomical and physiological processes involved in the *killing* process;

iii) skills to manage all activities on premises and deliver outcomes on time;

iv) awareness of psychological effects on farmer, team members and general public;

v) effective communication skills;

vi) appreciation of the environmental impacts caused by their operation.

2. Veterinarian

a) Responsibilities

i) determine and supervise the implementation of the most appropriate *killing* method to ensure that *animals* are killed without avoidable pain and distress;

ii) determine and implement the additional requirements for *animal welfare*, including the order of *killing*;

iii) ensure that confirmation of the *death* of the *animals* is carried out by competent persons at appropriate times after the *killing* procedure;

iv) minimise the risk of disease spread within and from the premises through the supervision of biosecurity procedures;

v) continuously monitor *animal welfare* and biosecurity procedures;

vi) in cooperation with the leader, prepare a written report at the conclusion of the *killing*, describing the practices adopted and their effect on *animal welfare*.

b) Competencies

i) ability to assess *animal welfare*, especially the effectiveness of *stunning* and *killing* and to correct any deficiencies;

ii) ability to assess biosecurity risks.

3. Animal handlers

a) Responsibilities

i) review on-site facilities in terms of their appropriateness;

ii) design and construct temporary animal handling facilities, when required;

iii) move and restrain *animals*;

iv) continuously monitor *animal welfare* and biosecurity procedures.

b) Competencies

i) animal handling in emergency situations and in close confinement is required;

ii) an appreciation of biosecurity and containment principles.

Annex XIV (contd)

4. Animal killing personnel

a) Responsibilities

Humane *killing* of the *animals* through effective *stunning* and *killing* should be ensured.

b) Competencies

i) when required by regulations, licensed to use necessary equipment;

ii) competent to use and maintain relevant equipment;

iii) competent to use techniques for the species involved;

iv) competent to assess effective *stunning* and *killing*.

5. Carcass disposal personnel

a) Responsibilities

An efficient carcass disposal (to ensure *killing* operations are not hindered) should be ensured.

b) Competencies

The personnel should be competent to use and maintain available equipment and apply techniques for the species involved.

6. Farmer/owner/manager

a) Responsibilities

i) assist when requested.

b) Competencies

i) specific knowledge of his/her *animals* and their environment.

Article 7.6.4.

Considerations in planning the humane killing of animals

Many activities will need to be conducted on affected premises, including the humane *killing* of *animals*. The team leader should develop a plan for humanely *killing animals* on the premises which should include consideration of:

1) minimising handling and movement of *animals*;

2) *killing* the *animals* on the affected premises; however, there may be circumstances where the *animals* may need to be moved to another location for *killing*; when the *killing* is conducted at an *abattoir*, the recommendations in Chapter on the *slaughter* of *animals* should be followed;

3) the species, number, age and size of *animals* to be killed, and the order of *killing* them;

4) methods of *killing* the *animals*, and their cost;

5) housing, husbandry, location of the *animals* as well as accessibility of the farm;

6) the availability and effectiveness of equipment needed for *killing* of the *animals*, as well as the time necessary to kill the required number of *animals* using such methods;

7) the facilities available on the premises that will assist with the *killing* including any additional facilities that may need to be brought on and then removed from the premises;

8) biosecurity and environmental issues;

10) any legal issues that may be involved, for example where restricted veterinary drugs or poisons may be used, or where the process may impact on the environment;

11) the presence of other nearby premises holding *animals*;

12) possibilities for removal, disposal and destruction of carcasses.

The plan should minimise the negative *welfare* impacts of the *killing* by taking into account the different phases of the procedures to be applied for *killing* (choice of the *killing* sites, *killing* methods, etc.) and the measures restricting the movements of the *animals*.

Competences and skills of the personnel handling and *killing animals*.

In designing a *killing* plan, it is essential that the method chosen be consistently reliable to ensure that all *animals* are humanely and quickly killed.

~~Article 7.6.5.~~Article 7.6.5.

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

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

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

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

~~[DELETE TABLE]~~

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

Annex XIV (contd)

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Sheep and goats	all	free bullet	no	non-lethal wounding	Article 7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	Article 7.6.7.
	all except neonates	non-penetrating captive bolt, followed by bleeding	yes	ineffective stunning, regaining of consciousness before death	Article 7.6.8.
	neonates	non-penetrating captive bolt	yes	non-lethal wounding	Article 7.6.8.
	all	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	Article 7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	Article 7.6.11.
	neonates only	CO_2/air mixture	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.12.
	neonates only	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	Article 7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	Article 7.6.15.
Pigs	all, except neonates	free bullet	no	non-lethal wounding	Article 7.6.6.
	all except neonates	penetrating captive bolt, followed by pithing or bleeding	yes	ineffective stunning, regaining of consciousness before death	Article 7.6.7.
	neonates only	non-penetrating captive bolt	yes	non-lethal wounding	Article 7.6.8.
	all[1]	electrical, two-stage application	yes	pain associated with cardiac arrest after ineffective stunning	Article 7.6.10.
	all	electrical, single application (method 1)	yes	ineffective stunning	Article 7.6.11.
	neonates only	CO_2/air mixture	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.12.

Annex XIV (contd)

Species	Age range	Procedure	Restraint necessary	Animal welfare concerns with inappropriate application	Article reference
Pigs (contd)	neonates only	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.13.
	neonates only	nitrogen and/or inert gases	yes	slow induction of unconsciousness	Article 7.6.14.
	all	injection with barbiturates and other	yes	non-lethal dose, pain associated with injection site	Article 7.6.15.
Poultry	adults only	non-penetrating captive bolt	yes	ineffective stunning	Article 7.6.8.
	day-olds and eggs only	maceration	no	non-lethal wounding, non-immediacy	Article 7.6.9.
	adults only	electrical, single application (method 2)	yes	ineffective stunning	Article 7.6.11.
	adults only	electrical, single application, followed by killing (method 3)	yes	ineffective stunning; regaining of consciousness before death	Article 7.6.11.
	all	CO_2/air mixture Method 1 Method 2	- - yes no	slow induction of unconsciousness, aversiveness of induction	Article 7.6.12.
	all	nitrogen and/or inert gas mixed with CO_2	yes	slow induction of unconsciousness, aversiveness of induction	Article 7.6.13.
	all	nitrogen and/or inert gases	yes	slow induction of unconsciousness	Article 7.6.14.
	all	injection of barbiturates and other drugs	yes	non-lethal dose, pain associated with injection site	Article 7.6.15.
	all	cervical dislocation	no		Point 1 of 7.6.17.
	all	decapitation	no		Point 2 of 7.6.17.
	adults only	addition of anaesthetics to feed or water, followed by an appropriate killing method	no	ineffective or slow induction of unconsciousness	Article 7.6.16.

Article 7.6.6~~5~~6.

Free bullet

1. Introduction
   a) A free bullet is a projectile fired from a shotgun, rifle, handgun or purpose-made humane killer.
   b) The most commonly used firearms for close range use are:

Annex XIV (contd)

i) humane killers (specially manufactured/adapted single-shot weapons);

ii) shotguns (12, 16, 20, 28 bore and .410);

iii) rifles (.22 rimfire);

iv) handguns (various calibres from .32 to .45).

c) The most commonly used firearms for long range use are rifles (.22, .243, .270 and .308).

d) A free bullet used from close range should target the head and be aimed so that the projectile enters the brain, causing instant loss of consciousness. Positioning must take into account differences in brain position and skull conformation among species, as well as the energy requirement for penetrating the skull and sinus.

e) A free bullet used from long range should be aimed to penetrate the skull or soft tissue at the top of the neck of the *animals* (high neck shot) and to cause irreversible concussion and *death*. It may not be possible or appropriate, however, to target the head when killing is attempted from large distances (missed shots may result in jaw fractures or other nonfatal injuries), or when diagnostic samples of brain tissue are needed. In such cases, chest shots may need to be considered. ~~and~~ In all cases, shooting should only be used by properly trained and competent marksmen.

2. Requirements for effective use

a) The marksman should take account of human safety in the area in which he/she is operating. Appropriate vision and hearing protective devices should be worn by all personnel involved.

b) The marksman should ensure that the *animal* is not moving and in the correct position to enable accurate targeting and the range should be as short as possible (5–50 cm for a shotgun) but the barrel should not be in contact with the head of the *animals*.

c) The correct cartridge, calibre and type of bullet for the different species age and size should be used. Ideally, the ammunition should expand upon impact and dissipate its energy within the cranium.

d) Shot *animals* should be checked to ensure the absence of brain stem reflexes.

3. Advantages

a) Used properly, a free bullet provides a quick and effective method for *killing*.

b) It requires minimal or no *restraint* and can be used to kill from a distance by properly trained and competent marksmen.

c) It is suitable for *killing* agitated *animals* in open spaces.

4. Disadvantages

a) The method is potentially dangerous to humans and other *animals* in the area.

b) It has the potential for non-lethal wounding.

c) Destruction of brain tissue may preclude diagnosis of some *diseases*.

d) Leakage of bodily fluids may present a biosecurity risk.

e) Legal requirements may preclude or restrict use.

f) There is a limited availability of competent personnel.

5. Conclusion

The method is suitable for cattle, sheep, goats and pigs, including large *animals* in open spaces. For the optimum position for cattle, sheep, goats and pigs, see Figures 1 to 4 below.

Cattle

Figure 1. The optimum shooting position for cattle is at the intersection of two imaginary lines drawn from the rear of the eyes to the base of the opposite horn buds or an equivalent position in polled animal. Gun has to be positioned in a right angle.

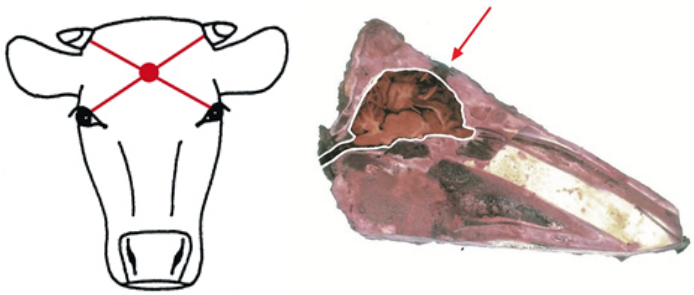

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Sheep and Goats

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

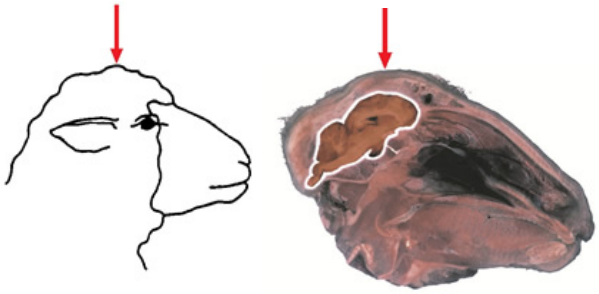

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

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

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

Annex XIV (contd)

Pigs

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

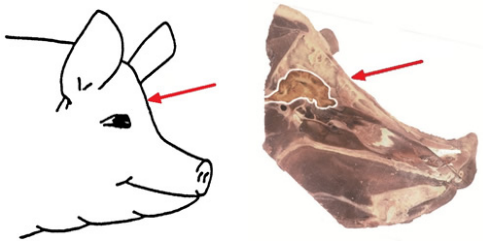

Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

Article 7.6.~~7~~67.

Penetrating captive bolt

1. Introduction

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

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

2. Requirements for effective use

a) For cartridge powered and compressed air guns, the bolt velocity and the length of the bolt should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.

b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.

d) *Animals* should be restrained; at a minimum, they should be penned for cartridge powered guns and in a race for compressed air guns.

e) The operator should ensure that the head of the *animal* is accessible.

f) The operator should fire the captive bolt at right angles to the skull in the optimal position (see figures 1, 3~~,&~~ 4 and 5. The optimum shooting position for hornless sheep is on the highest point of the head, on the midline and aim towards the angle of the jaw).

g) To ensure the *death* of the *animal*, pithing or bleeding should be performed as soon as possible after *stunning*.

h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

a) Mobility of cartridge powered equipment reduces the need to move *animals*.

b) The method induces an immediate onset of a sustained period of unconsciousness.

4. Disadvantages

a) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.

b) Post stun convulsions may make pithing difficult and hazardous.

c) The method is difficult to apply in agitated *animals*.

d) Repeated use of a cartridge powered gun may result in over-heating.

e) Leakage of bodily fluids may present a biosecurity risk.

f) Destruction of brain tissue may preclude diagnosis of some *diseases*.

5. Conclusions

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

Article 7.6.8~~7~~8.

Non-penetrating captive bolt

1. Introduction

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

The gun should be placed on the front of the skull to deliver a percussive blow ~~which~~ that produces unconsciousness in cattle (older than eight months ~~adults only~~), sheep, goats and pigs (no more than six months old), and *death* in *poultry* and neonate sheep, goats and piglets. Bleeding should be performed as soon as possible after the blow to ensure the *death* of the *animal*.

2. Requirements for effective use

a) For cartridge powered and compressed air guns, the bolt velocity should be appropriate to the species and type of *animal*, in accordance with the recommendations of the manufacturer.

b) Captive bolt guns should be frequently cleaned and maintained in good working condition.

Annex XIV (contd)

c) More than one gun may be necessary to avoid overheating, and a back-up gun should be available in the event of an ineffective shot.

d) *Animals* should be restrained; at a minimum mammals should be penned for cartridge powered guns and in a race for compressed air guns; birds should be restrained in cones, shackles, crushes or by hand.

e) The operator should ensure that the head of the *animal* is accessible.

f) The operator should fire the captive bolt at right angles to the skull in the optimal position (figures 1– 4).

g) To ensure *death* in non-neonate mammals, bleeding should be performed as soon as possible after *stunning*.

h) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

3. Advantages

a) The method induces an immediate onset of unconsciousness, and *death* in birds and neonates.

b) Mobility of equipment reduces the need to move *animals*.

4. Disadvantages

a) As consciousness can be regained quickly in non-neonate mammals, they should be bled as soon as possible after *stunning*.

b) Laying hens in cages have to be removed from their cages and most birds have to be restrained.

c) Poor gun maintenance and misfiring, and inaccurate gun positioning and orientation may result in poor *animal welfare*.

d) Post stun convulsions may make bleeding difficult and hazardous.

e) Difficult to apply in agitated *animals*; such *animals* may be sedated in advance of the *killing* procedure.

f) Repeated use of a cartridge powered gun may result in over-heating.

g) Bleeding may present a biosecurity risk.

5. Conclusions

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

Article 7.6.~~9~~89.

Maceration

1. Introduction

Maceration, utilising a mechanical apparatus with rotating blades or projections, causes immediate fragmentation and *death* in day-old *poultry* and embryonated eggs.

2. Requirements

a) Maceration requires specialised equipment which should be kept in excellent working order.

b) The rate of introducing the birds should not allow the equipment to jam, birds to rebound from the blades or the birds to suffocate before they are macerated.

c) Requires competent personnel who are appropriately trained to operate the macerator.

3. Advantages

a) Procedure results in immediate *death*.

b) Large numbers can be killed quickly.

4. Disadvantages

a) Specialised equipment is required.

b) Macerated tissues may present biosecurity or human health risks.

c) The cleaning of the equipment can be a source of contamination.

5. Conclusion

The method is suitable for *killing* day-old *poultry* and embryonated eggs.

Article 7.6.~~10~~9~~10~~10.

Electrical — two-stage application

1. Introduction

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

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

2. Requirements for effective use

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

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

b) Appropriate protective clothing (including rubber gloves and boots) should be worn.

c) *Animals* should be restrained, at a minimum free-standing in a pen, close to an electrical supply.

d) Two team members are required, the first to apply the electrodes and the second to manipulate the position of the *animal* to allow the second application to be made.

e) A *stunning* current should be applied via scissor-type *stunning* tongs in a position that spans the brain for a minimum of 3 seconds; immediately following the application to the head, the electrodes should be transferred to a position that spans the heart and the electrodes applied for a minimum of 3 seconds.

f) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.

g) *Animals* should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

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

3. Advantages

a) The application of the second stage minimises post-stun convulsions and therefore the method is particularly effective with pigs.

b) Non-invasive technique minimises biosecurity risk.

4. Disadvantages

a) The method requires a reliable supply of electricity.

b) The electrodes should be applied and maintained in the correct positions to produce an effective stun and kill.

c) Most stunner control devices utilise low voltage impedance sensing as an electronic switch prior to the application of high voltages; in unshorn sheep, contact impedance may be too high to switch on the required high voltage (especially during stage two).

d) The procedure may be physically demanding, leading to operator fatigue and poor electrode placement.

5. Conclusion

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

Figure 5. Scissor-type tongs.

Article 7.6.~~11~~~~10~~11.

Electrical — single application

1. Method 1

Method 1 comprises the single application of sufficient electrical current to the head and back, to simultaneously stun the *animal* and fibrillate the heart. Provided sufficient current is applied in a position that spans both the brain and heart, the *animal* will not recover consciousness.

a) Requirements for effective use

i) The stunner control device should generate a low frequency (30–60 Hz) current with a minimum voltage of 250 volts true RMS under load.

ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.

iii) *Animals* should be individually and mechanically restrained close to an electrical supply as the maintenance of physical contact between the *stunning* electrodes and the *animal* is necessary for effective use.

iv) The rear electrode should be applied to the back, above or behind the heart, and then the front electrode in a position that is forward of the eyes, with current applied for a minimum of 3 seconds.

v) Electrodes should be cleaned regularly between *animals* and after use, to enable optimum electrical contact to be maintained.

vi) Water or saline may be necessary to improve electrical contact with sheep.

vii) An effective stun and kill should be verified by the absence of brain stem reflexes.

b) Advantages

i) Method 1 stuns and kills simultaneously.

ii) It minimises post-stun convulsions and therefore is particularly effective with pigs.

iii) A single team member only is required for the application.

iv) Non-invasive technique minimises biosecurity risk.

c) Disadvantages

i) Method 1 requires individual mechanical animal *restraint*.

ii) The electrodes should be applied and maintained in the correct positions to produce an effective stun and kill.

iii) Method 1 requires a reliable supply of electricity.

d) Conclusion

Method 1 is suitable for calves, sheep, goats, and pigs (over one week of age).

Annex XIV (contd)

2. Method 2

Method 2 stuns and kills by drawing inverted and shackled *poultry* through an electrified water bath stunner. Electrical contact is made between the 'live' water and earthed shackle and, when sufficient current is applied, *poultry* will be simultaneously stunned and killed.

a) Requirements for effective use

i) A mobile water bath stunner and a short loop of processing line are required.

ii) A low frequency (50–60 Hz) current applied for a minimum of 3 seconds is necessary to stun and kill the birds.

iii) *Poultry* need to be manually removed from their cage, house or yard, inverted and shackled onto a line which conveys them through a water bath stunner with their heads fully immersed.

iv) The required minimum currents to stun and kill dry birds are:

– Quails – 100 mA/bird

– Chickens – 160 mA/bird

– Ducks and geese – 200 mA/bird

– Turkeys – 250 mA/bird.

A higher current is required for wet birds.

v) An effective stun and kill should be verified by the absence of brain stem reflexes.

b) Advantages

i) Method 2 stuns and kills simultaneously.

ii) It is capable of processing large numbers of birds reliably and effectively.

iii) This non-invasive technique minimises biosecurity risk.

c) Disadvantages

i) Method 2 requires a reliable supply of electricity.

ii) Handling, inversion and shackling of birds are required.

d) Conclusion

Method 2 is suitable for large numbers of *poultry*.

3. Method 3

Method 3 comprises the single application of sufficient electrical current to the head of poultry in a position that spans the brain, causing unconsciousness; this is followed by a *killing* method (see Article 7.6.~~17~~~~16~~17.).

a) Requirements for effective use

i) The stunner control device should generate sufficient current (more than 600 mA/duck and more than 300 mA/bird) to stun.

ii) Appropriate protective clothing (including rubber gloves and boots) should be worn.

iii) Birds should be restrained, at a minimum manually, close to an electrical supply.

iv) Electrodes should be cleaned regularly and after use, to enable optimum electrical contact to be maintained.

v) Birds should be monitored continuously after *stunning* until *death* to ensure the absence of brain stem reflexes.

b) Advantages

Non-invasive technique (when combined with cervical dislocation) minimises biosecurity risk.

c) Disadvantages

i) Method 3 requires a reliable supply of electricity and is not suitable for large-scale operations.

ii) The electrodes should be applied and maintained in the correct position to produce an effective stun.

iii) Birds should be individually restrained.

iv) It should be followed by a *killing* method.

d) Conclusion

Method 3 is suitable for small numbers of *poultry*.

Article 7.6.~~12~~11~~-~~12.

CO_2/air mixture

1. Introduction

Controlled atmosphere killing is performed by exposing *animals* to a predetermined gas mixture, either by placing them in a gas-filled *container* or apparatus (Method 1) or by placing transport modules or crates containing birds in a gas tight *container* and introducing a gas mixture (Method 2) or by the gas being introduced into a poultry house (Method 3). Method 3 should be used whenever possible, as it eliminates *welfare* issues resulting from the need to manually remove live birds. Although Method 2 requires handling and crating of the birds, it benefits bird *welfare* overall in comparison with Method 1 as it reduces the risk of *death* by smothering or suffocation.

Inhalation of carbon dioxide (CO_2) induces respiratory and metabolic acidosis and hence reduces the pH of cerebrospinal fluid (CSF) and neurones thereby causing unconsciousness and, after prolonged exposure, *death*. Exposure to carbon dioxide does not induce immediate loss of consciousness, therefore the aversive nature of gas mixtures containing high concentrations of CO_2 and the respiratory distress occurring during the induction phase are important considerations for *animal welfare*.

2. Method 1

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

a) Requirements for effective use in a *container* or apparatus

i) *Containers* or apparatus should allow the required gas concentration to be maintained and accurately measured.

ii) When *animals* are exposed to the gas individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.

iii) *Animals* can also be introduced to low concentrations (as low concentrations are not aversive) and the concentration could be increased afterwards and the *animals* then held in the higher concentration until *death* is confirmed.

iv) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.

v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid *animals* suffocating by climbing on top of each other.

b) Advantages

i) CO_2 is readily available.

ii) Application methods are simple.

iii) The volume of gas required can be readily calculated.

iv) As the units are operated outdoor, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator's health and safety.

v) The system uses the skilled catching teams and equipment that are in daily use by the industry.

vi) Metal *containers* can be readily cleansed and disinfected.

c) Disadvantages

i) The need for properly designed *container* or apparatus.

ii) The aversive nature of high CO_2 concentrations.

iii) No immediate loss of consciousness.

iv) The risk of suffocation due to overcrowding.

v) Difficulty in verifying *death* while the *animals* are in the *container* or apparatus.

d) Conclusion

Method 1 is suitable for use in poultry, and neonatal sheep, goats and pigs.

3. Method 2

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

The procedures for the operation of CGU include (a) position the *container* on level, solid, open ground; (b) connect the gas cylinder to the *container* (c) load birds into the *container* (d) shut and secure the door, (e) deliver the gas until a concentration of 45 percent by volume of carbon dioxide has been achieved at the top of the *container*, (f) allow time for the birds to become unconscious and die (g) open the door and allow gas to be dispersed in the air (h) remove the module (i) check each drawer for survivors (j) humanely kill any survivors; and (k) dispose of carcasses appropriately.

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

i) The birds should be caught gently and placed in crates or modules of appropriate size and at appropriate *stocking densities* to allow all birds to sit down.

ii) The crates or module full of birds should be placed inside the *container* and the door shut only when the operator is ready to administer the gas.

iii) Ensure the *container* door is locked and administer the gas until a minimum concentration of 45 percent carbon dioxide is achieved at the top of the crates.

iv) An appropriate gas meter should be used to ensure the appropriate concentration of carbon dioxide is achieved and maintained until it can be confirmed that the birds have been killed.

v) Sufficient exposure time should be allowed for birds to die before the door is opened. In the absence of a viewing window that allows direct observation of birds during killing, cessation of vocalisation and convulsive wing flapping sounds, which can be listened to by standing near the *container*, can be used to determine that the birds are unconscious and that *death* is imminent. Remove the crates or modules from the *container* and leave them in the open air.

vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing indicate *death*.

vii) Any survivors should be humanely killed.

viii) Ducks and geese are resilient to the effects of carbon dioxide and therefore require a minimum of 80 percent CO_2 and a longer period of exposure to die.

b) Advantages

i) The gas is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.

ii) Gradual increase in the concentration of CO_2 minimises the aversive nature of this method for inducing unconsciousness.

iii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house.

iv) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.

v) CO_2 is readily available.

vi) Birds are exposed to gas more uniformly and they do not smother each other when compared with Method 1.

vii) The volume of gas required can be readily calculated.

viii) As the units are operated outdoors, the gas is dispersed quickly at the end of each cycle by opening the door, improving operator's health and safety.

ix) The system uses skilled catching teams and equipment in daily use by the industry.

x) Metal *containers* can be readily cleansed and disinfected.

Annex XIV (contd)

c) Disadvantages

i) Requires trained operators, trained catchers, transport modules and fork lift. However, this equipment and suitable areas with hard surfaces are usually available.

ii) The main limiting factors are speed of catching birds.

iii) In the absence of a viewing window, visual confirmation of *death* while the birds are still in the *container* is difficult. However, cessation of vocalisation and convulsive wing flapping sounds can be used to determine onset of *death*.

d) Conclusion

i) Method 2 is suitable for use in a wide range of *poultry* systems, providing there is access to *vehicles* to carry the *containers* and equipment.

ii) Birds should be introduced into the *container* or apparatus, which is then sealed and filled as quickly as possible with the required gas concentrations, i.e. more than 40 percent CO_2. Birds are held in this atmosphere until *death* is confirmed.

iii) Method 2 is suitable for use in *poultry*, and neonatal sheep, goats and pigs. However, CO_2 is likely to cause a period of distress in the *animals* before they lose consciousness.

4. Method 3

The gas is introduced into a poultry house.

a) Requirements for effective use in a poultry house

i) Prior to introduction of the CO_2, the poultry house should be appropriately sealed to allow control over the gas concentration. The interval between sealing and gas administration should be kept to the minimum so as to avoid overheating.

Forced ventilation systems, where fitted, should only be switched off immediately prior to gas administration.

The main water supply to the poultry house may have to be turned off and water drained to avoid freezing and bursting of water pipes.

Feeders and water troughs should be lifted to avoid obstruction of the gas entry and prevent injury to birds.

ii) Gas delivery pipes or lancets should be positioned appropriately such that birds are not hit directly by very cold gas delivered at high pressures. It may be necessary to exclude birds from the area in front of the delivery pipes, for a distance of about 20 meters, by partitioning the house with nets, wire mesh or similarly perforated materials.

iii) The house should be gradually filled with CO_2 so that all birds are exposed to a concentration of >40 percent until they are dead; a vaporiser may be required to prevent freezing.

iv) Devices should be used to accurately measure the gas concentration at the maximum height accommodation of birds.

b) Advantages

i) Applying gas to birds *in situ* eliminates the need to manually remove live birds.

ii) CO_2 is readily available.

iii) Gradual raising of CO_2 concentration minimises the aversiveness of the induction of unconsciousness.

c) Disadvantages

i) It is difficult to determine volume of gas required to achieve adequate concentrations of CO_2 in some poultry houses.

ii) It is difficult to verify *death* while the birds are in the poultry house.

The extremely low temperature of liquid CO_2 entering the house and formation of solid CO_2 (dry ice) may cause concern for bird *welfare*.

d) Conclusion

Method 3 is suitable for use in *poultry* in closed-environment sheds. This method could be developed for killing pigs. However, CO_2 is likely to cause a period of distress in the birds before they lose consciousness.

Article 7.6.~~13~~12~~12~~13.

Nitrogen and/or inert gas mixed with CO_2

1. Introduction

CO_2 may be mixed in various proportions with nitrogen or an inert gas (e.g. argon), and the inhalation of such mixtures leads to hypercapnic-hypoxia and *death* when the oxygen concentration by volume is <2 percent, or <5 percent for chickens. Various mixtures of CO_2 and nitrogen or an inert gas can be administered to kill birds using Methods 1 and 2 described under Article 7.6.~~12~~11~~12~~12. Whole house gassing with mixtures of CO_2 and nitrogen, or an inert gas, has not been tested owing to the complex issues presented by mixing gases in large quantities. Such mixtures however do not induce immediate loss of consciousness, therefore the aversiveness of various gas mixtures containing high concentrations of CO_2 and the respiratory distress occurring during the induction phase, are important *animal welfare* considerations.

Pigs and *poultry* appear not to find low concentrations of CO_2 strongly aversive, and a mixture of nitrogen or argon with <30 percent CO_2 by volume and <2 percent O_2 by volume can be used for *killing poultry*, neonatal sheep, goats and pigs.

2. Method 1

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

a) Requirements for effective use

i) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O_2 and CO_2 concentrations accurately measured during the *killing* procedure.

ii) When *animals* are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.

iii) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with <2 percent O_2), and held in this atmosphere until *death* is confirmed.

Annex XIV (contd)

iv) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.

v) *Containers* or apparatus should not be overcrowded and measures are needed to avoid *animals* suffocating by climbing on top of each other.

b) Advantages

Low concentrations of CO_2 cause little aversiveness and, in combination with nitrogen or an inert gas, produces a fast induction of unconsciousness.

c) Disadvantages

i) A properly designed *container* or apparatus is needed.

ii) It is difficult to verify *death* while the *animals* are in the *container* or apparatus.

iii) There is no immediate loss of consciousness.

iv) Exposure times required to kill are considerable.

d) Conclusion

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

3. Method 2

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

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

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

i) The birds should be caught gently and placed in crates or modules of appropriate size and at appropriate *stocking densities* to allow all birds to sit down.

ii) The crates or module of birds should be placed inside the *container* and the door shut only when the operator is ready to administer the gas mixture.

iii) Ensure the *container* door is locked and administer the gas mixture until <2 percent residual oxygen is achieved at the top of the crates.

iv) An appropriate gas meter should be used to ensure a concentration of oxygen <2 percent is achieved and maintained until it can be confirmed that the birds have been killed.

v) Sufficient exposure time should be allowed for birds to die before the door is opened. In the absence of a viewing window, which allows direct observation of birds during killing, cessation of vocalisation and wing flapping sounds can be observed by standing close to the *container* and used to determine the onset of *death* in birds. Remove the crates or modules from the *container* and leave them in the open air.

vi) Each crate or module should be examined and birds checked to ensure they are dead. Dilated pupils and absence of breathing movements indicate *death*.

vii) Any survivors should be humanely killed.

viii) Ducks and geese do not appear to be resilient to the effects of a mixture of 20 percent carbon dioxide and 80 percent nitrogen or argon.

b) Advantages

i) The gas mixture is introduced quickly and quietly resulting in less turbulence and disturbance to the birds.

ii) The use of transport crates or modules to move birds minimises handling. Birds should be handled by trained, experienced catching teams at the time of depopulation of the poultry house.

iii) The modules are loaded mechanically into the CGU and a lethal mixture of gas is rapidly introduced into the chamber immediately after sealing.

iv) Mixtures containing up to 20 percent carbon dioxide in argon are readily available as welding gas cylinders.

v) Birds are exposed to gas in a more uniform manner and they do not smother each other when compared with Method 1.

vi) Two CGU can be operated in tandem and throughputs of up to 4,000 chickens per hour are possible.

vii) The volume of gas required can be readily calculated.

viii) As the units are operated outdoor the gas is dispersed quickly at the end of each cycle by opening the door, improving operators' health and safety.

ix) The system uses skilled catching teams and equipment in daily use by the industry.

x) Metal *containers* can be readily cleansed and disinfected.

c) Disadvantages

i) Requires trained operators, trained catchers, transport modules and a fork lift. However, such equipment and suitable outdoor areas with a hard surface are usually available.

ii) The main limiting factors are speed of catching birds and availability of gas mixtures.

iii) In the absence of a viewing window, visual confirmation of *death* while the birds are still in the *container* is difficult. However, cessation of vocalisation and convulsive wing flapping can be used to determine the onset of *death*.

iv) CGU could be used to kill *poultry* on small to medium farms, e.g. up to 25 thousand birds on a single farm.

d) Conclusion

i) Method 2 is suitable for use in *poultry* and in neonatal sheep, goats and pigs.

ii) Method 2 is suitable for use in *poultry* in a wide range of *poultry* systems providing that these have access to *vehicles* to carry *containers* and equipment.

iii) *Animals* should be introduced into the *container* or apparatus, which is then sealed and filled as quickly as possible with the gas mixture. A residual oxygen concentration of less than 2 percent should be achieved and maintained and birds should be held in this atmosphere until *death* is confirmed.

[DELETE THREE PICTURES]

Article 7.6.~~14~~~~13~~14.

Nitrogen and/or inert gases

1. Introduction

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

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

2. Requirements for effective use

a) *Containers* or apparatus should allow the required gas concentrations to be maintained, and the O2 concentration accurately measured.

b) When *animals* are exposed to the gases individually or in small groups in a *container* or apparatus, the equipment used should be designed, constructed, and maintained in such a way as to avoid injury to the *animals* and allow them to be observed.

c) *Animals* should be introduced into the *container* or apparatus after it has been filled with the required gas concentrations (with <2 percent O_2), and held in this atmosphere until *death* is confirmed.

d) Team members should ensure that there is sufficient time allowed for each batch of *animals* to die before subsequent ones are introduced into the *container* or apparatus.

e) *Containers* or apparatus should not be overcrowded, and measures are needed to avoid *animals* suffocating by climbing on top of each other.

3. Advantages

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

4. Disadvantages

a) A properly designed *container* or apparatus is needed.

b) It is difficult to verify *death* while the *animals* are in the *container* or apparatus.

c) There is no immediate loss of consciousness.

d) Exposure times required to kill are considerable.

5. Conclusion

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

Article 7.6.~~15~~~~14~~15.

Lethal injection

1. Introduction

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

2. Requirements for effective use

a) Doses and routes of administration that cause rapid loss of consciousness followed by *death* should be used.

b) Prior sedation may be necessary for some *animals*.

c) Intravenous administration is preferred, but intraperitoneal or intramuscular administration may be appropriate, especially if the agent is non-irritating.

d) *Animals* should be restrained to allow effective administration.

e) *Animals* should be monitored to ensure the absence of brain stem reflexes.

3. Advantages

a) The method can be used in all species.

b) *Death* can be induced smoothly.

4. Disadvantages

a) *Restraint* and/or sedation may be necessary prior to injection.

b) Some combinations of drug type and route of administration may be painful, and should only be used in unconscious *animals*.

c) Legal requirements and skill/training required may restrict use to veterinarians.

d) Contaminated carcasses may present a risk to other *wild animals* or domestic *animals*.

5. Conclusion

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

Article 7.6.~~16~~~~15~~16.

Addition of anaesthetics to feed or water

1. Introduction

An anaesthetic agent which can be mixed with *poultry* feed or water may be used to kill *poultry* in houses. *Poultry* which are only anaesthetised need to be killed by another method such as cervical dislocation.

Annex XIV (contd)

2. Requirements for effective use

a) Sufficient quantities of anaesthetic need to be ingested rapidly for effective response.

b) Intake of sufficient quantities is facilitated if the birds are fasted or water is withheld.

c) Should be followed by *killing* (see Article 7.6.~~17~~~~16~~17.) if birds are anaesthetised only.

3. Advantages

a) Handling is not required until birds are anaesthetised.

b) There may be biosecurity advantages in the case of large numbers of diseased birds.

4. Disadvantages

a) Non-target *animals* may accidentally access the medicated feed or water when provided in an open environment.

b) Dose taken is unable to be regulated and variable results may be obtained.

c) *Animals* may reject adulterated feed or water due to illness or adverse flavour.

d) The method may need to be followed by *killing*.

e) Care is essential in the preparation and provision of treated feed or water, and in the disposal of uneaten treated feed/water and contaminated carcasses.

5. Conclusion

The method is suitable for *killing* large numbers of *poultry* in houses. However, a back-up method should be available to kill birds that are anaesthetized but not killed.

Article 7.6.~~17~~~~16~~17.

Cervical dislocation and decapitation

1. Cervical dislocation (manual and mechanical)

a) Introduction

Unconscious *poultry* may be killed by either manual or mechanical cervical dislocation (stretching the neck). This method results in *death* from cerebral anoxia due to cessation of breathing and/or blood supply to the brain.

When the number of birds to be killed is small, and other methods of *killing* are not available, conscious birds of less than 3 kilograms may be killed using cervical dislocation in such a way that the blood vessels of the neck are severed and *death* is instantaneous.

b) Requirements for effective use

i) *Killing* should be performed either by manually or mechanically stretching the neck to sever the spinal cord with consequent major damage to the spinal cord.

ii) Consistent results require strength and skill so team members should be rested regularly to ensure consistently reliable results.

iii) Birds should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

i) It is a non-invasive *killing* method.

ii) It can be performed manually on small birds.

d) Disadvantages

i) Operator fatigue.

ii) The method is more difficult in larger birds.

iii) Requires trained personnel to perform humanely.

iv) Human health and safety concerns due to handling of the birds.

v) Additional stress to the *animals* from handling.

2. Decapitation

a) Introduction

Decapitation results in *death* by cerebral ischaemia using a guillotine or knife.

b) Requirements for effective use

The required equipment should be kept in good working order.

c) Advantages

The technique is effective and does not require monitoring.

d) Disadvantages

i) The working area is contaminated with body fluids, which increases biosecurity risks.

ii) Pain if consciousness is not lost immediately.

Article 7.6.~~18~~17~~-~~18.

Pithing and bleeding

1. Pithing

a) Introduction

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

b) Requirements for effective use

i) Pithing cane or rod is required.

ii) An access to the head of the *animal* and to the brain through the skull is required.

iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

Annex XIV (contd)

c) Advantages

The technique is effective in producing immediate *death*.

d) Disadvantages

i) A delayed and/or ineffective pithing due to convulsions may occur.

ii) The working area is contaminated with body fluids, which increases biosecurity risks.

2. Bleeding

a) Introduction

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

b) Requirements for effective use

i) A sharp knife is required.

ii) An access to the neck or chest of the *animal* is required.

iii) *Animals* should be monitored continuously until *death* to ensure the absence of brain stem reflexes.

c) Advantages

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

d) Disadvantages

i) A delayed and/or ineffective bleeding due to convulsions may occur.

ii) The working area is contaminated with body fluids, which increases biosecurity risks.

- - - - - - - - - - - - - -

— Text deleted.

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

Annex XV

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 *flock*s 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 following outcome-based measurable, specifically animal-based measurable, 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 XV (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 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 – an index that indicates the average daily gain (gr) 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 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.

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, 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.

Annex XV (contd)

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.

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

b) Animal health management, preventive medicine and veterinary treatment

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

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

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 speed~~s~~, 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.

Annex XV (contd)

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 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 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 broilers if carried out competently as described in Article 7.6.17.

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

n) Personnel training

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

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.

Annex XV (contd)

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

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

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

— Text deleted.

Annex XVI

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 XVI (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) animal health and welfare disaster preparedness

e ~~d~~) inspection and sampling techniques;

f ~~e~~) diagnostic tests for animal *diseases*;

g ~~f~~) preparation, production, registration and control of biological products for use in the diagnosis or prevention of *diseases*;

h ~~g~~) border controls and import regulations;

i ~~h~~) *disinfection* and *disinfestation*;

j ~~i~~) 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.

Annex XVI (contd)

13. Communication

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

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.

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Annex XVI (contd)

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.

8) An *exporting country* is entitled to expect that its *animals* and animal products will receive reasonable and valid treatment when they are subjected to import inspection in the country of destination. The country should also be able to expect that any evaluation of its standards and performance will be conducted on a non-discriminatory basis. The *importing country* should be prepared and able to defend any position which it takes as a consequence of the evaluation.

9) As the *veterinary statutory body* is not a part of the *Veterinary Services*, an evaluation of that body should be carried out to ensure that the registration or licensing of *veterinarians* and authorisation of *veterinary para-professionals* is included.

Article 3.2.2.

Scope

1) In the evaluation of *Veterinary Services*, the following items may be considered, depending on the purpose of the evaluation:

   – organisation, structure and authority of the *Veterinary Services*;
   – human resources;
   – material (including financial) resources;
   – *veterinary legislation*, regulatory frameworks and functional capabilities;
   – animal health, *animal welfare* and veterinary public health controls;
   – formal quality systems including quality policy;
   – performance assessment and audit programmes;
   – participation in OIE activities and compliance with Member Countries' obligations.

2) To complement the evaluation of *Veterinary Services*, the legislative and regulatory framework, the organisational structure and functioning of the *veterinary statutory body* should also be considered.

3) Article 3.2.14. outlines appropriate information requirements for:

   – self-evaluation by the *Veterinary Authority* which perceives a need to prepare information for national or international purposes;
   – evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;
   – verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*;
   – evaluation by third parties such as OIE PVS experts or regional organisations.

Article 3.2.3.

Evaluation criteria for the organisational structure of the Veterinary Services

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

Annex XVI (contd)

2) The organisational structure should also clearly set out the interface relationships of government Ministers and departmental Authorities with the Chief Veterinary Officer/Veterinary Director and the *Veterinary Services*. Formal relationships with statutory authorities and with industry organisations and associations should also be described. It is recognised that Services may be subject to changes in structure from time to time. Major changes should be notified to trading partners so that the effects of re-structuring may be assessed.

3) Organisational components of *Veterinary Services* which have responsibility for key functional capabilities should be identified. These capabilities include epidemiological *surveillance*, *disease* control, import controls, animal disease reporting systems, animal identification systems, traceability systems, animal movement control systems, communication of epidemiological information, training, inspection and certification. Laboratory and field systems and their organisational relationships should be described.

4) To reinforce the reliability and credibility of their services, the *Veterinary Services* may have set up quality systems that correspond with their fields of activity and to the nature and scale of activities that they carry out. Evaluation of such systems should be as objective as possible.

5) The *Veterinary Authority* alone speaks for the country as far as official international dialogue is concerned. This is also particularly important to cases where zoning and compartmentalisation are being applied. The responsibilities of the *Veterinary Authority* should be made clear in the process of evaluation of *Veterinary Services*.

6) The *Veterinary Authority* is defined in the Glossary 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.

Article 3.2.4.

Evaluation criteria for quality systems

1) The *Veterinary Services* should demonstrate a commitment to the quality of the processes and outputs of their services. Where services or components of services are delivered under a formal quality systems programme which is based on OIE recommended standards or, especially in the case of laboratory components of *Veterinary Services* other internationally recognised quality standards, the *Veterinary Services* undergoing evaluation should make available evidence of accreditation, details of the documented quality processes and documented outcomes of all relevant audits undertaken.

2) Where the *Veterinary Services* undergoing evaluation make large use of formal quality systems in the delivery of their services, it is appropriate that greater emphasis be placed on the outcomes of evaluation of these quality systems than on the resource and infrastructural components of the services.

Article 3.2.5.

Evaluation criteria for human resources

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

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.

Annex XVI (contd)

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, destruction of infected *animals* or contaminated materials, controls over the use of veterinary medicines, etc. The scope of the legislative controls should include domestic *animals* and their reproductive material, animal products, *wildlife* as it relates to the transmission of *diseases* to humans and domestic *animals*, and other products subject to veterinary inspection. Arrangements should exist for co-operation with the *Veterinary Authorities* of the neighbouring countries for the control of animal *diseases* in border areas and for establishing linkages to recognise and regulate transboundary activities. Within the structure of *Veterinary Services*, there should be appropriately qualified personnel whose responsibilities include *animal welfare*. Information on the veterinary public health legislation covering the production of products of animal origin for national consumption may be also considered in the evaluation.

2. Export and import inspection

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

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

Annex XVI (contd)

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

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

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

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

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

Article 3.2.8.

Animal health controls

1. Animal health status

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

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

2. Animal health control

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

3. National animal disease reporting systems

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

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

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.

Annex XVI (contd)

4. Veterinary medicines

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

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

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

5. Integration between animal health controls and veterinary public health

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

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

Article 3.2.10.

Performance assessment and audit programmes

1. Strategic plans

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

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

2. Performance assessment

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

3. Compliance

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

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

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

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

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 organisations. Such a programme should be used in assessing the effectiveness of the Services.

Annex XVI (contd)

e) Publications

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

f) Formal linkages with sources of independent scientific expertise

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

g) Trade performance history

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

Article 3.2.11.

Participation in OIE activities

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

Article 3.2.12.

Evaluation of the veterinary statutory 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.

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.

Annex XVI (contd)

Article 3.2.13.

1) The *Veterinary Services* of a country may undertake self-evaluation against the above criteria for such purposes as national interest, improvement of internal efficiency or export trade facilitation. The way in which the results of self-evaluation are used or distributed is a matter for the country concerned.

2) A prospective *importing country* may undertake an evaluation of the *Veterinary Services* of an *exporting country* as part of a *risk analysis* process, which is necessary to determine the sanitary or zoosanitary measures which the country will use to protect human or animal life or health from *disease* or pest threats posed by imports. Periodic evaluation reviews are also valid following the commencement of trade.

3) In the case of evaluation for the purposes of *international trade*, the authorities of an *importing country* should use the principles elaborated above as the basis for the evaluation and should attempt to acquire information according to the model questionnaire outlined in Article 3.2.14. The *Veterinary Services* of the *importing country* are responsible for the analysis of details and for determining the outcome of the evaluation after taking into account all the relevant information. The relative ranking of importance ascribed, in the evaluation, to the criteria described in this chapter will necessarily vary according to case-by-case circumstances. This ranking should be established in an objective and justifiable way. Analysis of the information obtained in the course of an evaluation study should be performed in as objective a manner as possible. The validity of the information should be established and reasonableness should be employed in its application. The assessing country should be willing to defend any position taken on the basis of this type of information, if challenged by the other party.

Article 3.2.14.

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

1. Organisation and structure of Veterinary Services

   a) National Veterinary Authority

      Organisational chart including numbers, positions and numbers of vacancies.

   b) Sub-national components of the Veterinary Authority

      Organisational charts including numbers, positions and number of vacancies.

   c) Other providers of veterinary services

      Description of any linkage with other providers of veterinary services.

2. National information on human resources

   a) Veterinarians

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

      ii) Numbers of:

         – full time government *veterinarians*: national and sub-national;

         – part time government *veterinarians*: national and sub-national;

– private *veterinarians* authorised by the *Veterinary Services* to perform official veterinary functions *[Describe accreditation standards, responsibilities and limitations applying to these private veterinarians.]*;

– other *veterinarians*.

iii) Animal health:

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

– full time government *veterinarians*: national and sub-national;

– part time government *veterinarians*: national and sub-national;

– other *veterinarians*.

iv) Veterinary public health:

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

– full time government *veterinarians*: national and sub-national;

– part time government *veterinarians*: national and sub-national;

– other *veterinarians*.

v) Numbers of veterinarians relative to certain national indices:

– per total human population;

– per farm livestock population, by geographical area;

– per livestock farming unit, by geographical area.

vi) Veterinary education:

– number of veterinary schools;

– length of veterinary course (years);

– curriculum addressing the minimum competencies of day 1 veterinary graduates and the post-graduate and continuing education topics to assure the delivery of quality veterinary services, as described in the relevant chapter(s) of the *Terrestrial Code*;

– international recognition of veterinary degree.

vii) Veterinary professional associations.

Annex XVI (contd)

b) Graduate personnel (non-veterinary)

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

c) Veterinary para-professionals employed by the Veterinary Services

i) Animal health:

– 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.

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*.

Annex XVI (contd)

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.

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 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, and control of exotic disease *outbreaks*, including *zoonoses*;

– inspection and registration of facilities;

– animal feeding;

Annex XVI (contd)

– veterinary public health controls of the production, processing, storage and marketing of *meat* for domestic consumption;

– veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other food of animal origin for domestic consumption;

– registration and use of veterinary pharmaceutical products including vaccines;

– *animal welfare*.

ii) Assessment of ability of *Veterinary Services* to enforce legislation.

b) Export and import inspection

i) Assessment of the adequacy and implementation of relevant national legislation concerning:

– veterinary public health controls of the production, processing, storage and transportation of *meat* for export;

– veterinary public health controls of production, processing, storage and marketing of fish, dairy products and other food of animal origin for export;

– animal health and veterinary public health controls of the export and import of *animals*, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;

– animal 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*.

Annex XVI (contd)

iv) Description and relevant details of animal disease emergency preparedness and response plans.

v) Recent history of animal disease status:

– animal *diseases* eradicated nationally or from defined sub-national zones in the last ten years;

– animal *diseases* of which the prevalence has been controlled to a low level in the last ten years;

– animal *diseases* introduced to the country or to previously free sub national regions in the last ten years;

– *emerging diseases* in the last ten years;

– animal *diseases* of which the prevalence has increased in the last ten years.

b) Veterinary public health

i) Food hygiene

– Annual national *slaughter* statistics for the past three years according to official data by species of *animals* (bovine, ovine, porcine, caprine, *poultry*, farmed game, wild game, equine, other).

– Estimate of total annual slaughterings which occur but are not recorded under official statistics.

– Proportion of total national *slaughter* which occurs in registered export establishments, by category of *animal*.

– Proportion of total national *slaughter* which occurs under veterinary control, by category of *animal*.

– Numbers of commercial *fresh meat* establishments in the country which are registered for export by the *Veterinary Authority*:

– *slaughterhouses* (indicate species of *animals*);

– cutting or packing plants (indicate *meat* type);

– *meat* processing establishments (indicate *meat* type);

– cold stores.

– Numbers of commercial *fresh meat* establishments in the country approved by other *importing countries* which operate international assessment inspection programmes associated with approval procedures.

– Numbers of commercial *fresh meat* establishments under direct public health control of the *Veterinary Services* (including details of category and numbers of inspection staff associated with these premises).

– Description of the veterinary public health programme related to production and processing of animal products for human consumption (including *fresh meat*, *poultry meat*, *meat products*, game *meat*, dairy products, fish, fishery products, molluscs and crustaceans and other foods of animal origin) especially including details applying to exports of these *commodities*.

– Descriptive summary of the roles and relationships of other official organisations in public health programmes for the products listed above if the *Veterinary Authority* does not have responsibility for those programmes which apply to national production destined to domestic consumption or exports of the *commodities* concerned.

ii) Zoonoses

– Descriptive summary of the numbers and functions of staff of the *Veterinary Authority* involved primarily with monitoring and control of zoonotic diseases.

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

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.

Annex XVI (contd)

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).

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.

— Text deleted.

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, and 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 XVI (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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Annex XVII

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 *infection* ~~*case*~~; 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 *infection* ~~*case,*~~.

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.~~13~~11. to 12.1.~~15~~13.

~~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.

~~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 ~~AHS~~V~~)~~ 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 XVII (contd)

a) historical freedom as described in Chapter 1.4. has demonstrated no evidence of AHSV in the country or *zone*; or

b) the country or *zone* has not reported any *case* of AHSV *infection* for at least two years and is not adjacent to an infected country or *zone*; or

c) a *surveillance* programme has demonstrated no evidence of AHSV in the country or *zone* for at least ~~twenty four months~~ two years; or

d) the country or *zone* has not reported any ~~*case of*~~ AHSV *infection* for at least 40 days and a *surveillance* programme 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.~~13~~11. to 12.1.~~15~~13. ~~*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) A~~n AHSV 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.~~13~~11. to 12.1.~~15~~13. is applied, unless historically free;

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.~~4~~3.

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*~~ free from *infection* with AHSV ~~or AHSV seasonally free *zone*~~.

Article 12.1.~~5~~4.

Establishment of a containment zone within a~~n~~ ~~AHS free~~ country or zone free from infection with AHSV

In the event of limited *outbreaks* within a~~n~~ ~~AHS free~~ country or zone free from *infection* with AHSV, ~~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;

   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~~11. to 12.1.~~15~~13. in the rest of the country or *zone* has not detected any evidence of *infection*;

Annex XVII (contd)

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~~11. to 12.1.~~15~~13. 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.~~6~~5., once the *containment zone* is recognised by the OIE.

In the event of the recurrence of AHSV 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.~~6~~5.

Article 12.1.~~6~~5.

Recovery of free status

To regain the free status when an AHS *outbreak* occurs in a~~n~~ ~~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.

Article 12.1.~~7~~6.

Recommendations for importation from ~~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 AHSV-free~~ country~~(~~ies~~)~~ or *zone~~(~~s~~)~~* 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 results on a blood samples 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.~~9~~Z.

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*

a) 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

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 test~~s~~ ~~according to the *Terrestrial Manual*~~ was carried out with a negative result~~s~~ on a blood sample~~s~~ 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~~12. and 12.1.~~15~~13, 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*~~)~~.

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Article 12.1.~~10~~8.

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 a~~n 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 antibody to 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.~~11~~9.

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:

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 a~~n 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 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 antibody to 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.~~10~~8.

Article 12.1.~~12~~10.

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*.

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.

Annex XVII (contd)

Crates, *containers* or jet stalls in which equids are being transported and the cargo hold of the aircraft should ~~must~~ be sprayed with an approved insecticide when the doors have been ~~just after the doors to 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 ~~must~~ be placed over all crates, *containers* or jet stalls.

Article 12.1.~~13~~11.

Introduction to surveillance~~: introduction~~

Articles 12.1.~~13~~11. to 12.1.~~15~~13. 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.~~14~~12.

~~Surveillance:~~ General surveillance conditions and methods

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*, have ~~include~~ an early warning system which oblige ~~for reporting suspicious *cases*. P~~persons who have regular contact with equids, as well as diagnosticians, ~~should~~ 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~~ be available ~~for~~ to those responsible for *surveillance*;

b) conduct random or targeted serological and virological *surveillance* appropriate to the *infection* status of the country or *zone* in accordance with Chapter 1.4.

Article 12.1.~~15~~13.

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 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 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, 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 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 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 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 mucosal membranes and dyspnoea.

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

Annex XVII (contd)

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 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. A~~n AHSV 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 are not vaccinated and are managed at fixed locations and observed and sampled regularly to detect new AHSV infections.

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 virus 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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Annex XVIII

CHAPTER 8.14.

INFECTION WITH *TRICHINELLA* SPP.

Article 8.14.1.

General provisions

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

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

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

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

For the purposes of the *Terrestrial Code*, *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*:

Annex XVIII (contd)

a) facilities and the surrounding environment should be managed to prevent exposure of pigs to rodents and *wildlife*;

b) raw food waste of animal origin should not be present at the farm level and should not be fed to pigs;

c) feed should comply with the requirements in Chapter 6.3. and should be stored in a manner to prevent access by rodents and *wildlife*;

d) a rodent control programme should be in place;

e) dead *animals* should be immediately removed and disposed of in accordance with 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 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.

Article 8.14.6.

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

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

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

AND

2) either:

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

   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 (under study).

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 (under study).

Annex XVIII (contd)

Article 8.14.8.

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

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

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

AND

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

Article 8.14.9.

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

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

1) has been inspected in accordance with 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.

Annex XIX

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*; or

   b) antigen or ribonucleic acid specific to RVFV, excluding vaccine strains, has been identified in a sample from an *animal* 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 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:

   "area" means a part of a country that experiences epizootics and inter-epizootic periods, but which does not correspond to the definition of *zone;*

   "epizootic of RVF" means the occurrence of *outbreaks* at an incidence substantially exceeding that during an inter-epizootic period:

   "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-Saharian~~ 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*.~~

Annex XIX (contd)

~~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.~~

~~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~~ in the whole country and either:

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

2) an ongoing pathogen-specific *surveillance* programme in accordance with Chapter 1.4 has demonstrated no evidence of RVFV *infection* in *animals* and humans in the country or *zone*.

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

~~1) the country or *zone* lies outside the historically infected regions, and is not adjacent to historically infected countries *infections*; 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 *animals* that are seropositive, so long as they are ~~which are~~ either permanently ~~marked~~ identified as such or ~~seropositive *animals* or those~~ destined for immediate ~~direct~~ *slaughter*.

Annex XIX (contd)

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 *vector*s 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 *zone*s 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~~

~~B~~a) they were vaccinated at least 14 days prior to leaving the free country or *zone*; or

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

Annex XIX (contd)

~~B~~c) they were protected from *vector* ~~mosquito~~ attacks ~~at all times~~ when transiting through an *~~infected zone~~* area experiencing an epizootic.

~~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~~ signs 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 du~~ring this time; or

ba) were vaccinated against RVF at least ~~21~~ 14 days prior to shipment with a modified live virus vaccine; or

cb) were held for at least ~~30~~ 14 days prior to shipment in a mosquito-proof *quarantine station* which is located in an area of demonstrated low *vector* activity. During this period ~~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*~~ ;

AND

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:~~

~~1) 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 signs 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 signs 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.

~~1) showed no evidence of RVF on the day of shipment;~~

~~2) were vaccinated against RVF at least 21 14 days prior to shipment with a modified live virus vaccine;~~

~~OR~~

~~3) were held in a mosquito-proof *quarantine station* for at least 30 days prior to shipment during which the *animals* showed no clinical sign of RVF and were protected from mosquito attacks between quarantine and the *place of shipment* as well as at the *place of shipment*.~~

Article 8.12.10.bis

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*;

Annex XIX (contd)

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 8.12.11.~~

~~**Recommendations for importation from RVF infected countries or zones with disease**~~

~~For meat and meat products of domestic and wild ruminants~~

~~*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~~ signs of RVF within the period from ~~28~~ 14 days prior to ~~28~~ and 14 days following collection of the semen or embryos;

2) were vaccinated against RVF at least ~~21~~ 14 days prior to collection. ~~with a modified live virus vaccine;~~ or

3) were demonstrated to be seropositive on the day of collection; or

4) 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 8.12.13.

~~(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 *zone*s 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 ongoing *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.

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Annex XX

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 percent 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 percent 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 percent 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 to H5 or H7 subtype, which have been detected in *poultry* and are not a consequence of *vaccination*, should be immediately investigated. In the case of isolated serological positive results, *infection* with avian influenza viruses may be ruled out on the basis of a thorough epidemiological and *laboratory* investigation that does not demonstrate further evidence of such an *infection*.

7) For the purposes of the *Terrestrial Code*, 'avian influenza free establishment' means an *establishment* in which the *poultry* have shown no evidence of *infection* with avian influenza viruses, based on *surveillance* in accordance with Articles 10.4.27. to 10.4.33.

8) *Infection* with influenza A viruses of high pathogenicity in birds other than *poultry*, including wild birds, should be notified according to Article 1.1.3. However, a Member Country should not impose bans on the trade in *poultry 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*.

Annex XX (contd)

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.

Annex XX (contd)

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*.

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*.

Annex XX (contd)

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*.

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*.

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

Annex XX (contd)

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 meet 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:

Annex XX (contd)

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 or,

   b) 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 100ºC for 30 minutes;

   b) fumigation with formalin (10% formaldehyde) for 8 hours;

   c) irradiation with a dose of 20 kiloGray;

   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 100ºC for 30 minutes;

   b) fumigation with formalin (10% formaldehyde) for 8 hours;

   c) irradiation with a dose of 20 kiloGray;

   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 118ºC 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 122ºC 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 74ºC;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of avian influenza viruses.

Article 10.4.25.

Procedures for the inactivation of 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:

	Core temperature (°C)	Time
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	870 seconds
Liquid egg white	56.7	232 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	20 hours
Dried egg white	54.4	513 hours

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Annex XX (contd)

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*.

	Core temperature (°C)	Time
Poultry meat	60.0	507 seconds
	65.0	42 seconds
	70.0	3.5 seconds
	73.9	0.51 second

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.4.27.

Surveillance: introduction

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 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 *infection* 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.

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:

   a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* or *infection* with avian influenza viruses should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect cases of avian influenza to a *laboratory* for avian influenza diagnosis;

c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2) The avian influenza *surveillance* programme should:

a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of avian influenza to the *Veterinary Authority*. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspected cases of avian influenza should be investigated immediately. As suspicion cannot always be resolved by epidemiological and clinical investigation alone, samples should be taken and submitted to a *laboratory* for appropriate tests. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in avian influenza diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;

b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of *animals*, such as those adjacent to an avian influenza infected country, *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.

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 characterization.

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.

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 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.

Annex XX (contd)

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 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 randomized representative sample of the populations at risk.

Article 10.4.32.

Additional surveillance 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 to haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not 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 neutralization (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 to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype influenza A viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of influenza A viruses.

Poultry can be vaccinated with a variety of influenza A vaccines including inactivated whole virus vaccines, and haemagglutinin expression-based vaccines. Antibodies to 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 to 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 to 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 to 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 to the specific HA, but not any of the other viral proteins. *Infection* is evident by antibodies to 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 to 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 to 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 to 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.

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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) characterization 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*;

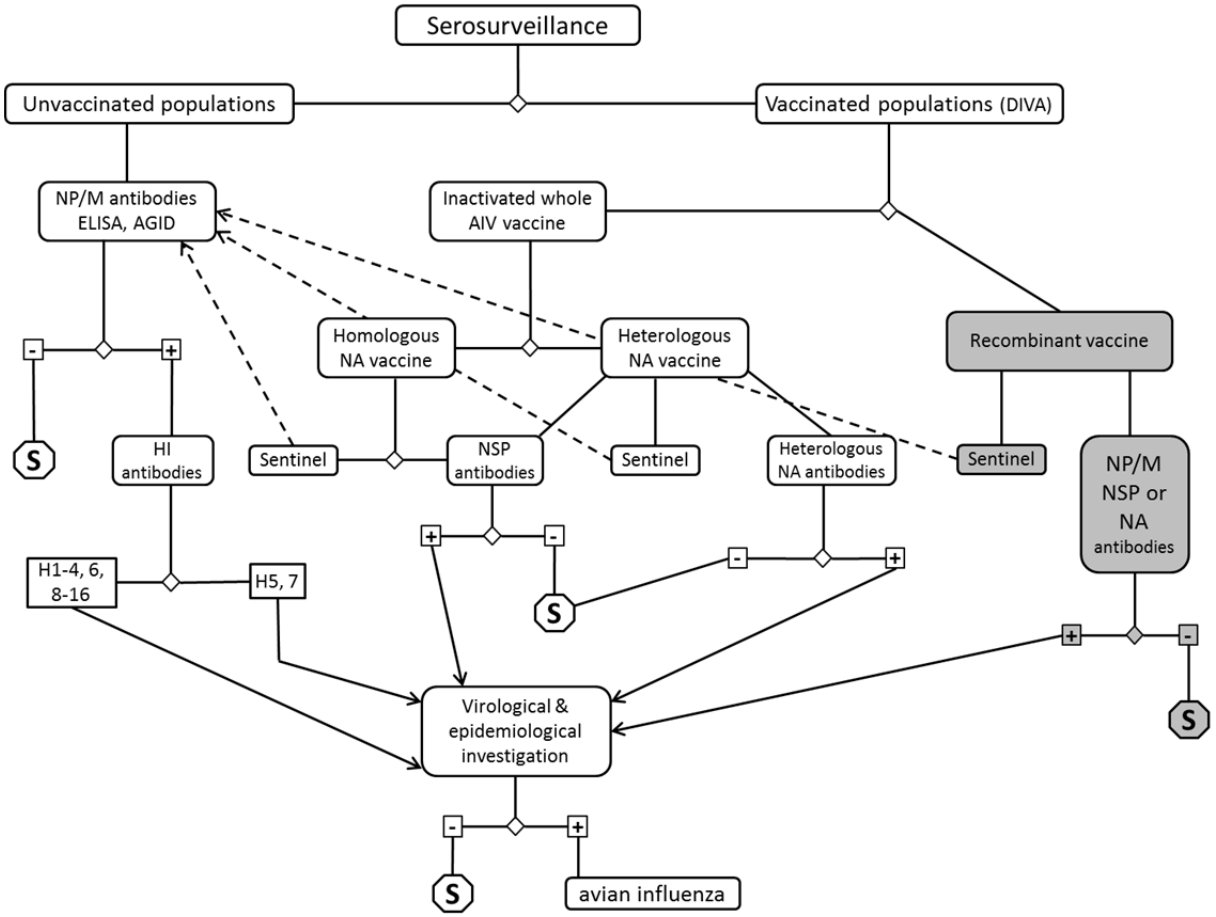
e) control of *animal identification* and movements;

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*.

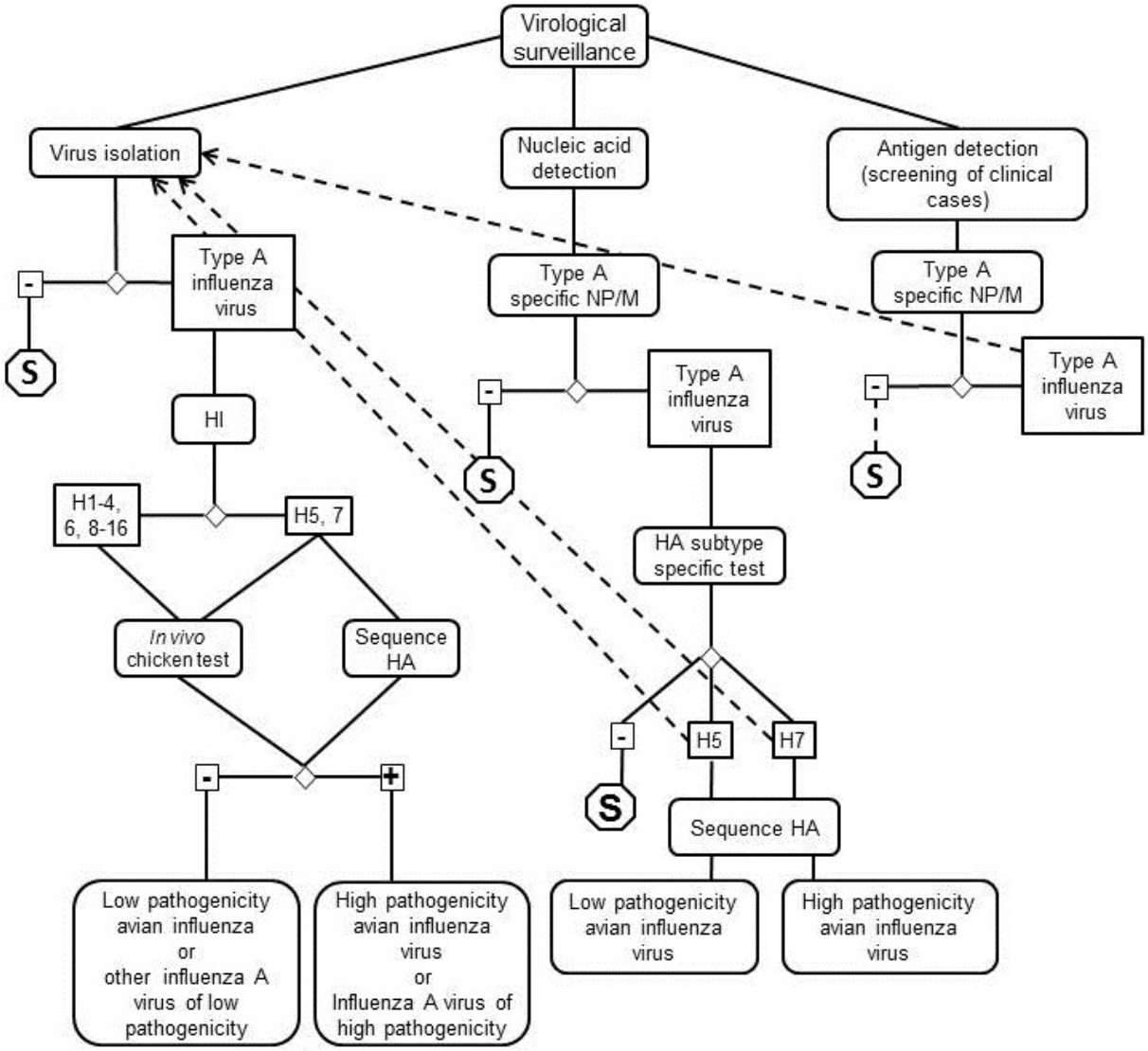
Fig. 1. *Schematic representation of laboratory tests for determining evidence of avian influenza infection through or following serological surveys*



Key:	
AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbant assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NP/M	Nucleoprotein and matrix protein
NSP	Nonstructural protein
S	No evidence of avian influenza virus

Annex XX (contd)

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



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Annex XXI

CHAPTER 10.9.

NEWCASTLE 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 virus (NDV) of 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:

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;

Annex XXI (contd)

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.

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*.

Annex XXI (contd)

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 an 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*;

OR

2) these *commodities* have been processed to ensure the destruction of NDV using ~~(under study)~~:

Annex XXI (contd)

a) pasteurisation; or

b) 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 100ºC for 30 minutes;

b) fumigation with formalin (10% formaldehyde) for 8 hours;

c) irradiation with a dose of 20 kiloGray;

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 100ºC for 30 minutes;

b) fumigation with formalin (10% formaldehyde) for 8 hours;

c) irradiation with a dose of 20 kiloGray;

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 118ºC 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 122ºC 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 74ºC 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:

	Core temperature (°C)	Time
Whole egg	55	2,521 seconds
Whole egg	57	1,596 seconds
Whole egg	59	674 seconds
Liquid egg white	55	2,278 seconds
Liquid egg white	57	986 seconds
Liquid egg white	59	301 seconds
10% salted yolk	55	176 seconds
Dried egg white	57	50.4 hours

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.9.21.

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*.

Annex XXI (contd)

	Core temperature (°C)	Time
Poultry meat	65.0	39.8 seconds
	70.0	3.6 seconds
	74.0	0.5 second
	80.0	0.03 second

The listed temperatures are indicative of a range that achieves a 7-log kill. Where scientifically documented, variances from these times and temperatures may also be suitable when they achieve the inactivation of the virus.

Article 10.9.22.

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 utilization 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 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.

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* / 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* / *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* / *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:

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.

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.

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.

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2. Additional requirements for countries, zones or compartments that practice 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.

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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Annex XXII

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 (*Mmm*SC), and freedom from CBPP means freedom from *Mmm* SC *infection*.

For the purpose of this chapter, susceptible *animals* include 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 *Mmm*SC, but also with the presence of *infection* with *Mmm*SC in the absence of clinical signs.

The following defines the occurrence of *Mmm*SC *infection*:

1) *Mmm*SC has been isolated and identified as such from an *animal*, embryos, oocytes or semen; or

2) antibodies to *Mmm*SC antigens which are not the consequence of *vaccination*, or *Mmm*SC DNA, have been identified in one or more *animals* showing pathological lesions consistent with *infection* with *Mmm*SC 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 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 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:

1) have a record of regular and prompt animal *disease* reporting;

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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 cattle and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals* showed no clinical sign of CBPP on the day of shipment.

Article 11.8.8.

Recommendations for importation from CBPP infected countries or zones

For domestic 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 bovidae 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*;

   e) AND EITHER:

      i) have not been vaccinated against CBPP;

      OR

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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 bovidae

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 bovidae

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 bovidae 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*;

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.

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*.

Article 11.8.14.

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 stand-still orders, etc.).

Annex XXII (contd)

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* 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 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 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 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 *Mmm*SC.

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 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*.

Article 11.8.17.

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.

Article 11.8.18.

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 the 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.

Annex XXII (contd)

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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Annex XXII (contd)

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° XXII (administrative procedures) and Resolution N° XXIII (financial obligations) adopted during the 76th General Session in May 2008.

[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.

Annex XXII (contd)

[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, geo-referenced map with a precise text description of the geographical boundaries of the *zones*.

   c) Provide a general description of the livestock industry in the country and any *zones*.

2. Veterinary system

   a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to 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.

Annex XXII (contd)

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. Describe any other procedures used. 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.

Annex XXII (contd)

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. lungs), 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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Annex XXIII

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 EAV, but also with the presence of *infection* with 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 stallion 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 EAV with negative results, carried out on semen collected during the six months prior to shipment; or

c) were subjected to a test for 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:

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 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 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 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

   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

Annex XXIII (contd)

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.

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Annex XXIV

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, 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 a functional separation between horses within the defined *subpopulation* and all other equids. 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 protect its health and minimise the probability of spreading *diseases* to other horses.

   These measures comprise a specific set of laboratory tests and *vaccinations* appropriate to the disease status of the horse´s region of origin and the regions that it will visit. Records of all *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 Chapter 4.2., horses in the *subpopulation* are individually identified as follows:

   a) Each horse bears an individual identification, preferably a microchip.

   b) Each horse is accompanied at all times by its individual passport that contains the horse's unique identifier.

   c) Each horse has an 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 all official tests and treatments, including *vaccinations*, are recorded and signed by the examining *veterinarian*.

Annex XXIV (contd)

b) The high health status of each horse in the *subpopulation* is maintained by ensuring compliance at all times with an international Biosecurity Plan. 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*.

d) A maximum period is set for each absence of a horse from its country of usual residence.

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. *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.

Veterinary Authorities are encouraged to recognise the biosecurity guidelines developed by the OIE in collaboration with the International Equestrian Federation (FEI) and the International Federation of Horseracing Authorities (IFHA). (Under study)

Annex XXV

CHAPTER 14.8.

INFECTION 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* can only be determined after considering the following criteria, as applicable:

   a) PPR should be notifiable in the whole territory, and all clinical signs suggestive of PPR should be subjected to appropriate field or *laboratory* investigations;

Annex XXV (contd)

b) an on-going awareness programme should be in place to encourage reporting of all cases suggestive of PPR;

c) systematic vaccination against PPR is prohibited, and importation of domestic ruminants and their semen, oocytes or embryos are carried out in accordance with this chapter;

~~c~~d) the *Veterinary Authority* should have current knowledge of, and authority over, all domestic sheep and goats in the country or *zone*;

~~d~~e) 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;

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~~.

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:

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*;

Annex XXV (contd)

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

~~3~~b) were kept in a *quarantine station* for at least the 21 days prior to shipment;

~~4~~3) 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.

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;

Annex XXV (contd)

2) were kept in a PPR free country or *zone* for at least the 21 days prior to collection.

Article 14.8.13.

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.

Article 14.8.14.

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:

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.

Annex XXV (contd)

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.

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.

Article 14.8.24.

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*.

Article 14.8.26.

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 (a_w< 0.80), or with phosphate supplemented salt containing 86.5 percent NaCl, 10.7 percent Na_2HPO_4 and 2.8 percent Na_3PO_4 (weight/weight/weight), either dry or as a saturated brine (a_w< 0.80), and kept at a temperature of ~~greater than~~ 20°C or more during this entire period.

Annex XXV (contd)

Article 14.8.27.

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 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 'pneumo-enteritis 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.

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*.

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.

Annex XXV (contd)

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 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.

Article 14.8.32.

Additional surveillance procedures 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.;

Annex XXV (contd)

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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Annex XXIX

CHAPTER 12.8.

INFECTION WITH EQUID HERPES VIRUS 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

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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