Annex I

MEETING OF THE OIE
TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 13–22 September 2011

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Annex II

MEETING OF THE OIE
TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 13–22 September 2011

Adopted agenda

A. MEETING OF THE DIRECTOR GENERAL WITH THE CODE COMMISSION

Welcome – Director General

B. ADOPTION OF THE AGENDA

C. DISCUSSION BETWEEN THE CODE COMMISSION AND THE SCIENTIFIC COMMISSION (held on 1 Sep)

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

Item 1 General comments of OIE Member countries

Item 2 Horizontal issues

a) Restructuring of *Terrestrial Code* Vol. 2 (by pathogen name)

b) Proposed OIE policy on the implications of listed diseases in *wild*life

c) Role of Veterinary Services in the detention of *wild* animals in import quarantine

d) Proposal to draft a horizontal chapter on safe commodities

Item 3 Criteria for listing diseases (Chapter 1.2.)

Item 4 Risk assessment – modification of terminology

Item 5 Support for Veterinary services

a) Evaluation of Veterinary Services (Chapter 3.2.)

b) Communication (Chapter 3.3.)

c) Revised new draft Chapter 3.4. (Veterinary Legislation)

Annex II (contd)

Item 6 Zoning and compartmentalisation

a) Chapter 4.4. (Application of compartmentalisation)

b) Generic checklist on the practical application of compartmentalisation

Item 7 Semen and embryos

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

b) Collection and processing of *in vivo* derived embryos from livestock and horses (Chapter 4 .7.)

Item 8 Salmonellosis

a) Biosecurity procedures in poultry production (Chapter 6.4.)

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

c) Cross reference to Chapter 6.4. in Article 13.2.13.

Item 9 Antimicrobial resistance (AMR)

a) Update of Chapter 6.7. (Harmonisation of AMR surveillance and monitoring programmes)

b) Update of Chapter 6.8. (Monitoring of antimicrobial use in animal husbandry)

c) Update of Chapter 6.9. (Responsible and prudent use of antimicrobial agents)

Item 10 Animal welfare

a) Chapter 7.8. Use of Animals in research and education

b) New draft Chapter 5.13. Model health certificate for laboratory animals

c) Discussion paper on Electronic certification system

d) Draft new Article 7.1.4. Animal welfare and livestock production systems – guiding principles

e) Draft new chapter on animal welfare and beef cattle production systems

f) Discussion paper on Religious slaughter

g) Welfare of working animals – proposed new work

h) Chapter 7.7. Stray dog population control

i) Request for clarification of standards for poultry stunning (Article 7.5.7.)

j) Member comments on Chapters 7.3., 7.5. and 7.6.

Item 11 Aujeszky's disease (Chapter 8.2.)

Item 12 Bluetongue (Chapter 8.3.)

Item 13 Zoonotic parasites

a) Revised Chapter 8.13.

b) Other matters arising from the report of the *ad hoc* Group on Zoonotic Parasites

Item 14 Foot and mouth disease

a) Foot and mouth disease (Chapters 8.5. and 1.6.)

b) Vaccination of zoo animals – issue raised by a Member

Item 15 Rabies

a) Rabies (Chapter 8.10)

b) Revised model certificate for dog and cats originating from rabies infected countries (Chapter 5.11.)

Item 16 Rinderpest (Chapter 8.12.)

Item 17 Vesicular stomatitis (Chapter 8.15.)

Item 18 Review of chapters on bee diseases

a) Hygiene and disease security procedures in apiaries (Chapter 4.14.)

b) Bee diseases (Chapters 9.1.to 9.6. inclusive)

Item 19 Brucellosis

a) Revised chapter on brucellosis (Chapter 11.3.)

Item 20 Bovine tuberculosis

a) Bovine tuberculosis (Chapter 11.6.)

b) Bovine tuberculosis of farmed cervidae (Chapter 11.7.)

Annex II (contd)

Item 21 Enzootic bovine leukosis (Chapter 11.9.)

Item 22 Lumpy skin disease (Chapter 11.12.)

Item 23 Equine diseases

a) African horse sickness (Chapter 12.1.)

b) Equine influenza (Chapter 12.6.)

c) Equine viral arteritis (Chapter 12.9.)

Item 24 Peste des petits ruminants (Chapter 14.8.)

Item 25 Classical swine fever (Chapter 15.2.)

Item 26 Swine vesicular disease (Chapter 15.4.)

Item 27 Report of the *ad hoc* Group on Veterinary Education

E. OTHER ISSUES

Item 28 Update of Code Commission work programme

Item 29 Risk analysis on wildlife disease

Item 30 Invasive alien species

a) Proposal to draft OIE Guidelines for assessing the risk of non-native animal species becoming invasive

b) Update of other OIE activities

Item 31 Veterinary products

Item 32 Standards for the importation of sample animal products – request from SSAFE

Item 33 Epizootic haemorrhagic disease – new chapter

Item 34 Revision of Chapter 6.11. on Zoonoses transmissible from non-human primates

Item 35 Inactivation of African swine fever virus and swine vesicular disease virus in swine casings

Item 36 Proposed dates for meetings in 2012

Annex III

CHAPTER 1.2.

CRITERIA FOR THE INCLUSION OF ~~LISTING~~ DISEASES AND INFECTIONS ON THE OIE LIST

Article 1.2.1.

Introduction

The aim of the *Terrestrial Code* is the improvement of animal health and *welfare* and veterinary public health worldwide, including by describing health measures to be used by *Veterinary Authorities* to detect, report and control pathogenic agents, and to prevent their transfer via *international trade*.

The objective of listing *diseases* is to support Members' efforts to prevent the transboundary spread of important animal *diseases*, including *zoonoses*, through transparent and consistent reporting. Each listed *disease*~~,~~ normally ~~wherever practicable,~~ has a corresponding chapter~~,~~ to ~~which~~ assists~~s~~ harmonisation of *disease* detection, prevention and control.

Article 1.2.1bis.

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

1. International spread of the agent (via live animals, their products or fomites) has been proven ~~on three or more occasions~~.

   ~~AND~~

2.~~i)~~ At least one ~~number of~~ countr~~ies~~y ~~with populations of susceptible animals~~ ~~are~~has demonstrated freedom ~~of the disease/ infection~~ or ~~face~~ impending freedom from the *disease* or *infection* in populations of susceptible *animals*, ~~(~~based on the animal health surveillance provisions of the *Terrestrial Code*, in particular those contained in Chapter 1.4., taking into account the animal health information notified in WAHIS~~)~~

   ~~OR~~

   ~~ii) OIE annual reports indicate that a number of countries with susceptible populations have reported absence of the disease for several consecutive years (based on the animal health surveillance information notified in WAHIS)~~

   ~~AND~~

Annex III (contd)

3. a~~i~~) Natural t~~T~~ransmission to humans has been proven, and human *infection* is associated with severe consequences (death or serious illness)

OR

b~~ii~~) The *disease~~/ or infection~~* has been shown to cause significant morbidity or mortality ~~production losses~~ in domestic *animals* at the level of a country or a *zone*, excepting the situation where effective prevention and control measures are commonly used ~~there is an efficient and affordable vaccine and vaccination is carried out by most Members~~

OR

c~~iii~~) The *disease~~/ or infection~~* has been shown to, or scientific evidence indicates that it would, ~~have a~~cause significant morbidity or mortality~~negative effect o~~in *wild animal* populations

~~AND~~

4.~~i~~) A ~~repeatable and~~ 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 ~~pathologies~~*diseases* and *infections*.

OR

5~~2~~. The *disease* or *infection* is an *emerging disease* with ~~apparent~~ evidence of zoonotic properties, rapid spread, or ~~possible~~ significant ~~production losses~~ morbidity or mortality and a case definition is available to clearly identify cases and allow them to be distinguished from other ~~pathologies~~*diseases* or *infections*.

Article 1.2.2.

The following *diseases* and *infections* are included in the OIE List.

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

1. The following *diseases* and *infections* are included within the category of multiple species *diseases* and *infections*:

– Anthrax

– Aujeszky's disease

– Bluetongue

- Brucellosis (*Brucella abortus*)
- Brucellosis (*Brucella melitensis*)
- Brucellosis (*Brucella suis*)
- Crimean Congo haemorrhagic fever
- Echinococcosis/hydatidosis
- Epizootic haemorrhagic disease
- Equine encephalomyelitis (Eastern)
- Foot and mouth disease
- Heartwater
- Japanese encephalitis
- New world screwworm (*Cochliomyia hominivorax*)
- Old world screwworm (*Chrysomyia bezziana*)
- Paratuberculosis
- Q fever
- Rabies
- Rift Valley fever
- Rinderpest
- Surra (*Trypanosoma evansi*)
- Trichinellosis
- Tularemia
- Vesicular stomatitis
- West Nile fever.

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

- Bovine anaplasmosis
- Bovine babesiosis
- Bovine genital campylobacteriosis
- Bovine spongiform encephalopathy

Annex III (contd)

- Bovine tuberculosis
- Bovine viral diarrhoea
- Contagious bovine pleuropneumonia
- Enzootic bovine leukosis
- Haemorrhagic septicaemia
- Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- Lumpy skin disease
- Theileriosis
- Trichomonosis
- Trypanosomosis (tsetse-transmitted).

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

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

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

- African horse sickness
- Contagious equine metritis
- Dourine
- Equine encephalomyelitis (Western)

- Equine infectious anaemia
- Equine influenza
- Equine piroplasmosis
- Equine rhinopneumonitis
- Equine viral arteritis
- Glanders
- Venezuelan equine encephalomyelitis.

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

- African swine fever
- Classical swine fever
- Nipah virus encephalitis
- Porcine cysticercosis
- Porcine reproductive and respiratory syndrome
- Swine vesicular disease
- Transmissible gastroenteritis.

6. The following *diseases* and *infections* 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
- Highly pathogenic avian influenza in birds and low pathogenicity notifiable avian influenza in poultry as defined in Chapter 10.4.
- Infectious bursal disease (Gumboro disease)
- Newcastle disease
- Pullorum disease

Annex III (contd)

– Turkey rhinotracheitis.

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

– Myxomatosis

– Rabbit haemorrhagic disease.

8. The following *diseases* and *infections* are included within the category of bee *diseases* and *infections*:

– Acarapisosis of honey bees
– American foulbrood of honey bees
– European foulbrood of honey bees
– Small hive beetle infestation (*Aethina tumida*)
– *Tropilaelaps* infestation of honey bees
– Varroosis of honey bees.

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

– Camelpox

– Leishmaniosis.

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Annex IV

CHAPTER 2.1.

IMPORT RISK ANALYSIS

Article 2.1.1.

Introduction

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

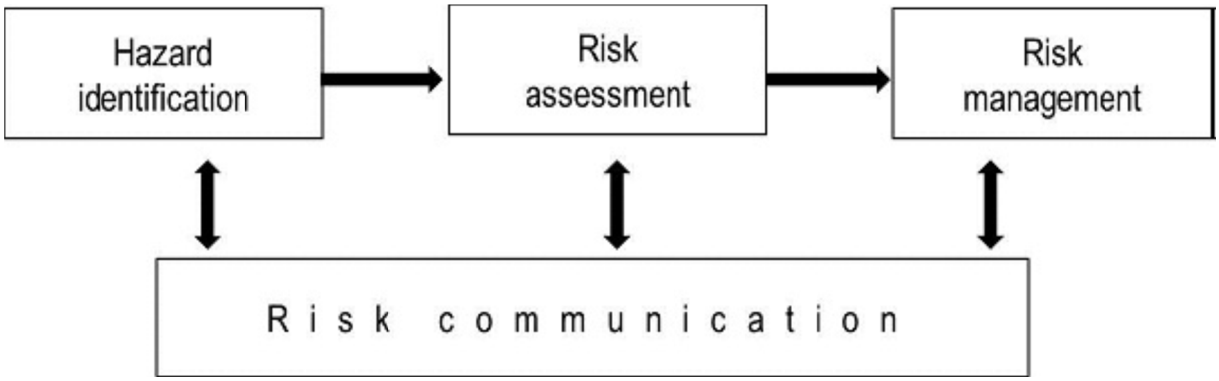
The principal aim of import *risk analysis* is to provide *importing countries* with an objective and defensible method of assessing the *disease risks* associated with the importation of *animals*, animal products, animal genetic material, feedstuffs, biological products and *pathological material*.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

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

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

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

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



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

Annex IV (contd)

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

Article 2.1.2.

Hazard identification

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

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

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

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

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

Article 2.1.3.

Principles of risk assessment

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

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

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

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

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

6. *Risk* increases with increasing volume of *commodity* imported.

7. The *risk assessment* should be amenable to updating when additional information becomes available.

Annex IV (contd)

Article 2.1.4.

Risk assessment steps

1. EntryRelease assessment

Entry Release assessment consists of describing the biological pathway(s) necessary for an importation activity to 'release' (that is, 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 release assessment describes the probability of the 'release' 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 release assessment are:

a) Biological factors

- species, age and breed of *animals*
- agent predilection sites
- vaccination, testing, treatment and quarantine.

b) Country factors

- incidence/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 release 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) released 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 (e.g. 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 IV (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 ~~release~~ 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'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'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 Members appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood and/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.

Annex IV (contd)

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.

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 V

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. 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/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 and/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*.

Annex V (contd)

7. An *importing country* has a right of assurance that information on sanitary/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/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 OIE Members' obligations.

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

3. Article 3.2.14. outlines appropriate information requirements for:

   – self-evaluation by the *Veterinary Authority* which perceives a need to prepare information for national or international purposes;

   – evaluation by a prospective or actual *importing country* of the *Veterinary Services* of a prospective or actual *exporting country*;

   – verification or re-verification of an evaluation in the course of a visit to the *exporting country* by the *importing country*;

   – evaluation by third parties such as OIE PVS experts or regional organisations.

Article 3.2.3.

Evaluation criteria for the organisational structure of the Veterinary Services

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

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

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

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

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

6. The *Veterinary Authority* is defined in the Glossary of the *Terrestrial Code*. As some countries have some relevant roles of the *Veterinary Authority* vested in autonomous sub-national (state/provincial, municipal) government bodies, there is an important need to assess the role and function of these Services. Details of their roles, relationship (legal and administrative) to each other and to the *Veterinary Authority* should be available for evaluation. Annual reports, review findings and access to other information pertinent to the animal health activities of such bodies should also be available.

7. Similarly, where the *Veterinary Authority* has arrangements with other providers of relevant services such as universities, laboratories, information services, etc., these arrangements should also be described. For the purposes of evaluation, it is appropriate to expect that the organisational and functional standards that apply to the *Veterinary Authority* should also apply to the service providers.

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.

Annex V (contd)

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.

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 (e.g. 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 (e.g. 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 (e.g. 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.

Annex V (contd)

b) Diagnostic laboratories

Analysis of the laboratory service component of *Veterinary Services*, which would include official governmental laboratories and other laboratories accredited 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/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.

This emphasis is valid whether one relates it to the actual testing performed on individual export consignments or to the more broad and 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 exercise control over all animal health 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/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/import inspection

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

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

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

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

Legislation should also provide the right to deny and/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. of the *Terrestrial Code*. They should have appropriately organised procedures which ensure that sanitary/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.

Annex V (contd)

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 an OIE Member, 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.

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.

Annex V (contd)

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/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.

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.

Annex V (contd)

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 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/zoosanitary status for evaluation purposes.

Article 3.2.12.

Evaluation of 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, autonomy and functional capacity;

   c) the composition and representation of the body's membership;

   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 *veterinary statutory body* should define its policy and objectives, including detailed descriptions of its powers and functions such as:

   a) to regulate *veterinarians* and *veterinary para-professionals* through licensing and/or registration of such persons;

   b) to determine the minimum standards of education (initial and continuing) required for degrees, diplomas and certificates entitling the holders thereof to be registered as *veterinarians* and *veterinary para-professionals*;

   c) to determine the standards of professional conduct of *veterinarians* and *veterinary para-professionals* and to ensure 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*. These controls should include, where appropriate, compulsory licensing and registration, minimum standards of education (initial and continuing) for the recognition of degrees, diplomas and certificates, setting standards of professional conduct and exercising control and the application of disciplinary procedures.

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

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

4. Evaluation of membership representation

Detailed descriptions should be available in respect of the membership of the *veterinary statutory body* and the method and duration of appointment of members. Such information includes:

a) *veterinarians* designated by the *Veterinary Authority*~~, such as the Chief Veterinary Officer~~;

b) *veterinarians* elected by members registered by the *veterinary statutory body*;

c) *veterinarians* designated or nominated by the veterinary association(s);

d) representative(s) of veterinary para-professions;

e) representative(s) of veterinary academia;

f) representative(s) of other stakeholders from the private sector;

g) election procedures and duration of appointment;

h) qualification requirements for members.

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/registration of persons should be available.

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

Descriptive summary of continuing professional development, training and education programmes should be provided, including descriptions of content, duration and participants; documented details of quality manuals and standards relating to Good Veterinary Practice should be provided.

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 V (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 e*xporting 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/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/or limitations applying tothese 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/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 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 V (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/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/export inspection.

– Education/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 and/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 accredited by government for the purposes of supporting officialor officially-endorsed animal health control or public health testing and monitoring programmes and import/export testing.

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

Annex V (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) Details of collaboration with external *laboratories* including international reference laboratories and details on numbers of samples submitted.

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

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

ix) Details of procedures for storage and retrieval of information on specimen submission and results.

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

xi) 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 control of exotic disease outbreaks, including *zoonoses*;

– inspection and registration of facilities;

– animal feeding;

– veterinary public health controls of the production, processing, storage and marketing of *meat* for domestic consumption;

– veterinary public health controls of the production, processing, storage and marketing of fish, dairy products and other foods 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/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 foods of animal origin for export;

– animal health and veterinary public health controls of the export and import of *animals*, animal genetic material, animal products, animal feedstuffs and other products subject to veterinary inspection;

– animal health controls of the importation, use and bio-containment of organisms which are aetiological agents of animal diseases, and of pathological material;

– animal health controls of importation of veterinary biological products including vaccines;

– administrative powers available to *Veterinary Services* for inspection and registration of facilities for veterinary control purposes (if not included under other legislation mentioned above);

– documentation and compliance.

ii) Assessment of ability of *Veterinary Services* to enforce legislation.

7. Animal health and veterinary public health controls

a) Animal health

i) Description of and sample reference data from any national animal disease reporting system controlled and operated or coordinated by the *Veterinary Services*.

ii) Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to *Veterinary Services*.

iii) Description and relevant data of current official control programmes including:

– epidemiological surveillance or monitoring programmes;

– officially approved industry administered control or eradication programmes for specific *diseases*.

iv) Description and relevant details of animal disease emergency preparedness and response plans.

Annex V (contd)

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/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 and/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*.

Annex V (contd)

c) Audit

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

9. Performance assessment and audit programmes

a) Strategic plans and review

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

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

b) Compliance

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

c) Annual reports of the Veterinary Authority

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

d) Other reports

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

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

e) Training

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

ii) Summary descriptions of training courses and duration.

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

f) Publications

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

g) Sources of independent scientific expertise

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

10. Membership of the OIE

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

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CHAPTER 3.3.

COMMUNICATION

Article 3.3.1.

General considerations

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

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 expertises 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.

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 be responsible for 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 V (contd)

Crisis communication: means the process of communicating information as accurately as possible, albeit~~of~~ potentially incomplete~~,~~ ~~nature~~ 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 for 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 (e.g. dedicated communication unit, 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 and/or access to appropriate material resources in order to carry out roles and responsibilities: suitable premise/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*

        ~~v) Provide guidance and expertise on communication issues to the *Veterinary Services*~~

        ~~vi~~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 communication objectives. The plan should be a long-term plan.

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 and/or interested parties, an entire community or the general public to make best possible decisions and be informed of and/or accept 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 and/or acceptance of policy decisions and subsequent change of perception, attitude and/or behaviour.

c) Operational plans for communication

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

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

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CHAPTER 3.4.

VETERINARY LEGISLATION

Article 3.4.1.

Introduction and objective

Good governance is a recognized global public good and is of critical importance to OIE Members. Legislation is a key element in achieving good governance.

Veterinary legislation should, at a minimum, provide a basis for *Competent Authorities* to meet their obligations as defined in the *Terrestrial Code* and the relevant recommendations of the Codex Alimentarius Commission.

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

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

Article 3.4.2

Definitions

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

Legal certainty: means the situation in which citizens are protected against any adverse side effects of legal instruments. The situation of legal uncertainty could arise when legislative instruments are not coherent, are overly complex or change frequently.

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

Legislative quality: means the technical relevance, acceptability to society, sustainability in technical, financial and administrative terms and effective implementation of laws.

Primary legislation: legal instruments issued by the legislature.

Secondary legislation: means the legal instruments issued by the executive and relating to the regulated domain. The equivalent term, subsidiary legislation, is used in some countries.

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

Annex V (contd)

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

Veterinary legislation: means the collection of specific legal instruments (primary and secondary legislation) required for the governance of the veterinary domain.

Article 3.4.3

General principles

1. Respect for the hierarchy of legislation

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

2. Legal basis

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

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

3. Transparency

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

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

4. Consultation

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

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

5. Legislative quality and legal certainty

   Veterinary legislation should achieve a high level of legislative quality so as to ensure legal certainty.

Article 3.4.4.

The drafting of veterinary legislation

Veterinary legislation should:

a) be drafted in a manner that establishes clear rights, responsibilities and obligations (i.e. 'normative');

b) be unambiguous, with clear and consistent syntax and vocabulary;

c) be precise and accurate even if this results in repetition and a cumbersome style;

d) contain no definitions that create any conflict or ambiguity;

e) include a clear statement of scope and objectives;

f) provide for the application of sanctions, either criminal or administrative, as appropriate to the situation; and

g) make provision for the financing needed for the execution of all activities of *Competent Authorities*.

Article 3.4.5.

Matters relating to the Competent Authority

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

Competent Authorities should be organised to ensure that all necessary actions are taken quickly and coherently to effectively address animal health and public health emergencies.

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

1. Necessary powers of the Competent Authority

   The veterinary legislation should also ensure that:

   a) officials have the legal authority to intervene in accordance with the legislation and the penal procedures in force;

   b) officials are protected against legal action and physical harm;

   c) the powers and functions of officials are explicitly and thoroughly listed to protect the rights of stakeholders and the general public against any abuse of authority. This includes respecting confidentiality, as appropriate; and

Annex V (contd)

d) at least the following powers are available through the primary legislation:

i) access to premises and vehicles for carrying out inspections;

ii) access to documents;

iii) taking samples;

iv) retention (setting aside) of *animals* and goods, pending a decision on final disposition;

v) seizure of *animals*, products and food of animal origin;

vi) suspension of one or more activities of an inspected establishment;

vii) temporary, partial or complete closure of inspected establishments; and

viii) suspension or withdrawal of authorisations or approvals.

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

2. Delegation of powers by the Competent Authority

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

For this purpose, the veterinary legislation should:

a) define the field of activities and the specific tasks covered by the delegation;

b) provide for the control, supervision and, when appropriate, financing of the delegation;

c) define the procedures for making delegation;

d) define the competencies to be held by persons receiving delegation; and

e) define the conditions of withdrawals of delegations.

Article 3.4.6.

Veterinary professionals and veterinary para-professionals

1. Veterinary medicine

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

a) provide an official definition of veterinary medicine;

b) define the prerogatives of the professionals involved in the conduct of veterinary medicine;

c) define the minimum initial and continuous educational requirements and competencies for *veterinarians* and *veterinary para-professionals*;

d) prescribe the conditions for recognition of professional qualifications for *veterinarians* and *veterinary para-professionals*;

e) define the conditions to perform the activities of veterinary medicine; and

f) identify the exceptional situations, such as epizootics, under which persons other than qualified *veterinarians* can undertake activities that are normally carried out by *veterinarians*.

2. The control of veterinary professionals and veterinary para-professionals

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

a) describe the general system of control in terms of the political, administrative and geographic configuration of the country;

b) provide for the possibility of the delegation of powers to a professional organisation such as a *veterinary statutory body*;

c) where powers have been so delegated, describe the prerogatives, the functioning and responsibilities of the mandated professional organisation; and

d) prescribe the powers to deal with conduct and competence issues, including licensing requirements, that apply to veterinary professionals and *veterinary para-professionals*.

Article 3.4.7.

Laboratories in the veterinary domain

1. Facilities

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

a) reference *laboratories*, which are responsible for controlling the veterinary diagnostic and analytical network, including the maintenance of reference methods;

b) *laboratories* designated by the *Competent Authority* for carrying out the analysis of official samples; and

c) *laboratories* recognised by the *Competent Authority* to conduct analyses required under the legislation e.g. for the purposes of quality control.

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

Annex V (contd)

2. Laboratory reagents

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

a) procedures for authorising the reagents that are used to perform official analyses;

b) quality assurance by manufacturers of the reagents used in official analyses; and

c) surveillance of marketing of reagents, where these can affect the quality of analyses required by the veterinary legislation.

Article 3.4.8.

Health provisions relating to animal production

1. Identification and traceability

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

2. Animal markets and other gatherings

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

a) registration of animal markets and other animal gatherings;

b) health measures to prevent *disease* transmission, including procedures for cleaning and *disinfection*, and animal welfare measures; and

c) provision for veterinary checks.

3. Animal reproduction

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

4. Animal feed

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

a) standards for the production, composition and quality control of animal feed;

b) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and

c) recall from the market of any product likely to present a *hazard* to human health or animal health.

5. Animal by-products

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

a) definition of the animal by-products subject to the legislation;

b) rules for collection, processing methods and authorised uses of animal by-products;

c) registration and, if necessary, approval of establishments and the provision of health requirements for relevant operations; and

d) rules to be followed by animal owners, as appropriate, concerning owners' use and disposition of animal by-products.

6. Disinfection

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

Article 3.4.9.

Animal diseases

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

1. Surveillance

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

2. Disease prevention and control

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

b) The legislation should also provide a basis for contingency plans to include the following for use in disease responses:

i) administrative and logistic organisation;

ii) exceptional powers of the *Competent Authority*; and

iii) special and temporary measures to address all identified *risks* to human or animal health.

c) Veterinary legislation should provide for the financing of animal disease control measures, such as operational expenses and, as appropriate, owners' compensation in the event of killing or slaughtering of *animals* and seizure or destruction of carcasses, meat, animal feed or other things.

Annex V (contd)

3. Emerging diseases

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

Article 3.4.10.

Animal welfare

1. General provisions

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

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

2. Stray dogs and other free-roaming animals

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

Article 3.4.11.

Veterinary medicines and biologicals

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

1. General measures

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

a) definition of veterinary medicines and biologicals, including any specific exclusions; and

b) regulation of the importation, manufacture, distribution and usage of, and commerce in, veterinary medicines and biologicals.

2. Raw materials for use in veterinary medicines and biologicals

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

a) quality standards for raw materials used in the manufacture or composition of veterinary medicines and biologicals and arrangements for checking quality;

b) establishment of the withdrawal periods and maximum residue limits for veterinary medicines and biologicals, as appropriate; and

c) requirements for substances in veterinary medicines and biological that may, through their effects, interfere with the conduct of veterinary checks.

3. Authorisation of veterinary medicines and biologicals

a) Veterinary legislation should ensure that only authorised veterinary medicines and biologicals may be placed on the market.

b) Special provisions should be made for:

i) medicated feed;

ii) products prepared by authorised *veterinarians* or authorised pharmacists; and

iii) emergencies and temporary situations.

c) Veterinary legislation should address the technical, administrative and financial conditions associated with the granting, renewal, refusal and withdrawal of authorisations.

d) In defining the procedures for seeking and granting authorisations, the legislation should:

i) describe the role of the relevant *Competent Authority*; and

ii) establish rules providing for the transparency in decision making.

e) Veterinary legislation may provide for the possibility of recognition of the equivalence of authorisations made by other countries.

4. Quality of veterinary medicines and biologicals

Veterinary legislation should address the following elements:

a) the conduct of clinical and non clinical trials to verify all claims made by the manufacturer;

b) conditions for the conduct of trials;

c) qualifications of experts involved in trials; and

d) surveillance for adverse effects arising from the use of veterinary medicines and biologicals.

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

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

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

b) definition of the responsibilities of operators;

c) good manufacturing practices as appropriate;

Annex V (contd)

d) reporting on adverse effects to the *Competent Authority*; and

e) mechanisms for traceability and recall.

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

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

a) control over the distribution of veterinary medicines and biologicals and arrangements for traceability, recall and conditions of use;

b) establishment of rules for the prescription and provision of veterinary medicines and biologicals to end users;

c) restriction to authorised professionals and, as appropriate, authorized veterinary paraprofessionals of commerce in veterinary medicines and biologicals that are subject to prescription;

d) the supervision by an authorised professional of organisations approved for holding and use of veterinary medicines and biologicals;

e) the regulation of advertising claims and other marketing and promotional activities; and

f) reporting on adverse effects to the *Competent Authority*.

Article 3.4.12.

Human food production chain

Veterinary legislation should provide a basis for actions to safeguard the human food production chain through controls at all critical steps.

1. General

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

a) recording all significant animal health events that occur during primary production;

b) prohibition of the marketing of products not fit for human consumption;

c) inspection for food safety and food composition, where this is relevant to health or safety;

d) inspection of premises;

e) controls over the implementation of the legislation at all stages of the production, processing and distribution of food of animal origin;

f) giving operators of food production premises the primary responsibility for compliance with food safety requirements established by the *Competent Authority*; and

g) provisions for recall from the marketplace of all products likely to be hazardous for human or animal health.

2. Products of animal origin intended for human consumption

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

a) arrangements for inspection;

b) the conduct of inspection on the basis of veterinary expertise;

c) health standards; and

d) the application of health identification marks that are visible to the intermediary or final user.

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

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

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

a) registration of premises and establishments by the *Competent Authority*;

b) the use of procedures based on HACCP principles; and

c) prior authorisation of operations that are likely to constitute a significant *risk* to human or animal health.

Article 3.4.13.

Import/export procedures and veterinary certification

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

Annex VI

CHAPTER 4.6.

COLLECTION AND PROCESSING OF BOVINE, SMALL RUMINANT AND PORCINE SEMEN

Article 4.6.1.

General considerations

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

1. maintain the health of *animals* on an *artificial insemination centre* at a level which permits the international distribution of semen with a negligible risk of infecting other *animals* or humans with pathogens transmissible by semen;

2. ensure that semen is hygienically collected, processed and stored.

Artificial insemination centres should comply with recommendations in Chapter 4.5.

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

Article 4.6.2.

Conditions applicable to testing of bulls and teaser animals

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

1. Prior to entering pre-entry isolation facility

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

   a) Bovine brucellosis – Point 3 or 4 of Article 11.3.5.

   b) Bovine tuberculosis – Point 3 or 4 of Article 11.6.5.

   c) Bovine viral diarrhoea-mucosal disease (BVD-MD)

      The *animals* should be subjected to:

      i) a virus isolation test or a test for virus antigen, with negative results; and

      ii) a serological test to determine the serological status of every *animal.*

   d) Infectious bovine rhinotracheitis-infectious pustular vulvovaginitis

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

      i) come from an IBR/IPV free *herd* as defined in Article 11.11.3.; or

Annex VI (contd)

ii) be subjected, with negative results, to a serological test for IBR/IPV on a blood sample.

e) Bluetongue

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

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

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

a) Bovine brucellosis

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

b) BVD-MD

i) The *animals* should be subjected to a virus isolation test or a test for virus antigen, with negative results ~~All *animals* should be tested for viraemia as described in point 1e) above~~. Only when all the *animals* in pre-entry isolation have had ~~test~~ negative results ~~for viraemia~~, may the *animals* enter the semen collection facilities ~~upon completion of the 28-day pre-entry isolation period~~.

ii) ~~After 21 days in pre-entry isolation,~~ All *animals* should be subjected to a serological test to determine the presence or absence of BVD-MD antibodies.

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

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

c) *Campylobacter fetus* subsp. *venerealis*

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

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

d) *Tritrichomonas foetus*

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

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

e) IBR-IPV

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

f) Bluetongue

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

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

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

a) Bovine brucellosis

b) Bovine tuberculosis

c) BVD-MD

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

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

d) *Campylobacter fetus* subsp. *venerealis*

i) A preputial specimen should be tested.

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

e) Bluetongue

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

f) *Tritrichomonas foetus*

i) A preputial specimen should be cultured.

Annex VI (contd)

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

g) IBR-IPV

If the *artificial insemination centre* is to be considered as IBR/IPV free, the *animals* should comply with the provisions in point 2)c) of Article 11.11.3.

4. Testing for BVD-MD prior to the initial dispatch of semen from each serologically positive bull

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

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

Each aliquot of frozen semen should be tested as per Article 11.11.7.

Article 4.6.3.

Conditions applicable to testing of rams/bucks and teaser animals

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

1. Prior to entering pre-entry isolation facility

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

a) Caprine and ovine brucellosis – Article 14.1.6.

b) Ovine epididymitis – Article 14.7.3.

c) Contagious agalactia – Points 1 and 2 of Article 14.3.1.

d) Peste des petits ruminants – Points 1, 2, and 4 or 5 of Article 14.8.7.

e) Contagious caprine pleuropneumonia – Article 14.4.7., depending on the CCPP status of the country or *zone* of origin of the *animals*.

f) Paratuberculosis – Free from clinical signs for the past two years.

g) Scrapie – Comply with Article 14.9.8. if the *animals* do not originate from a scrapie free country or *zone* as defined in Article 14.9.3.

h) Maedi-visna – Article 14.6.2.

i) Caprine arthritis/encephalitis – Article 14.2.2. in the case of goats.

j) Bluetongue

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

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

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

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

a) Caprine and ovine brucellosis – Point 1c) of Article 14.1.8.

b) Ovine epididymitis – Point 1d) of Article 14.7.4.

c) Maedi-visna and caprine arthritis/encephalitis – Test on *animals* and semen.

d) Bluetongue

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

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

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

a) caprine and ovine brucellosis;

b) ovine epididymitis;

c) Maedi-visna and caprine arthritis/encephalitis;

d) tuberculosis (for goats only);

e) bluetongue.

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

Article 4.6.4.

Conditions applicable to testing of boars

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

Annex VI (contd)

1. Prior to entering pre-entry isolation facility

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

a) Porcine brucellosis – Article 15.3.3.

b) Foot and mouth disease – Articles 8.5.12., 8.5.13. or 8.5.14.

c) Aujeszky's disease – Article 8.2.9. or Article 8.2.10.

d) Transmissible gastroenteritis – Article 15.5.2.

e) Swine vesicular disease – Article 15.4.5. or Article 15.4.7.

f) African swine fever – Article 15.1.5. or Article 15.1.6.

g) Classical swine fever – Article 15.2.5. or Article 15.2.6.

h) Porcine reproductive and respiratory syndrome – Test complying with the standards in the *Terrestrial Manual*.

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

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

a) Porcine brucellosis – Article 15.3.5.

b) Foot and mouth disease – Articles 8.5.15., 8.5.16., 8.5.17. or 8.5.18.

c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.

d) Transmissible gastroenteritis – Article 15.5.4.

e) Swine vesicular disease – Article 15.4.9. or Article 15.4.10.

f) African swine fever – Article 15.1.8. or Article 15.1.9.

g) Classical swine fever – Article 15.2.8. or Article 15.2.9.

h) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

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

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

a) Porcine brucellosis – Article 15.3.5.

b) Foot and mouth disease – Articles 8.5.15., 8.5.16., 8.5.17. or 8.5.18.

c) Aujeszky's disease – Articles 8.2.13., 8.2.14. or 8.2.15.

d) Transmissible gastroenteritis – Article 15.5.4.

e) Swine vesicular disease – Article 15.4.9. or Article 15.4.10.

f) African swine fever – Article 15.1.8. or Article 15.1.9.

g) Classical swine fever – Article 15.2.8. or Article 15.2.9.

h) Porcine reproductive and respiratory syndrome – The test complying with the standards in the *Terrestrial Manual*.

Article 4.6.5.

General considerations for hygienic collection and handling of semen

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

Article 4.6.6.

Conditions applicable to the collection of semen

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

2. The hindquarters of the teaser, whether a dummy or a live teaser animal, should be kept clean. A dummy should be cleaned completely after each period of collection. A teaser animal should have its hindquarters cleaned carefully before each collecting session. The dummy or hindquarters of the teaser animals should be sanitized after the collection of each ejaculate. Disposable plastic covers may be used.

3. The hand of the person collecting the semen should not come into contact with the *animal*'s penis. Disposable gloves should be worn by the collector and changed for each collection.

4. The artificial vagina should be cleaned completely after each collection where relevant. It should be dismantled, its various parts washed, rinsed and dried, and kept protected from dust. The inside of the body of the device and the cone should be disinfected before re-assembly using approved *disinfection* techniques such as those involving the use of alcohol, ethylene oxide or steam. Once re-assembled, it should be kept in a cupboard which is regularly cleaned and disinfected.

5. The lubricant used should be clean. The rod used to spread the lubricant should be clean and should not be exposed to dust between successive collections.

6. The artificial vagina should not be shaken after ejaculation, otherwise lubricant and debris may pass down the cone to join the contents of the collecting tube.

Annex VI (contd)

7. When successive ejaculates are being collected, a new artificial vagina should be used for each mounting. The vagina should also be changed when the *animal* has inserted its penis without ejaculating.

8. The collecting tubes should be sterile, and either disposable or sterilised by autoclaving or heating in an oven at 180°C for at least 30 minutes. They should be kept sealed to prevent exposure to the environment while awaiting use.

9. After semen collection, the tube should be left attached to the cone and within its sleeve until it has been removed from the collection room for transfer to the laboratory.

Article 4.6.7.

Conditions applicable to the handling of semen and preparation of semen samples in the laboratory

1. Diluents

   a) All receptacles used should have been sterilised.

   b) Buffer solutions employed in diluents prepared on the premises should be sterilized by filtration (0.22 µm) or by autoclaving (121°C for 30 minutes) or be prepared using sterile water before adding egg yolk (if applicable) or equivalent additive and antibiotics.

   c) If the constituents of a diluent are supplied in commercially available powder form, the water used should have been distilled or demineralised, sterilized (121°C for 30 minutes or equivalent), stored correctly and allowed to cool before use.

   d) Whenever milk, egg yolk or any other animal protein is used in preparing the semen diluent, the product should be free of pathogens or sterilised; milk heat-treated at 92°C for 3–5 minutes, eggs from SPF flocks when available. When egg yolk is used, it should be separated from eggs using aseptic techniques. Alternatively, commercial egg yolk prepared for human consumption or egg yolk treated by, for example, pasteurisation or irradiation to reduce bacterial contamination, may be used. Other additives should also be sterilized before use.

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

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

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

2. Procedure for dilution and packing

   a) The tube containing freshly collected semen should be sealed as soon as possible after collection, and kept sealed until processed.

   b) After dilution and during refrigeration, the semen should also be kept in a stoppered container.

c) During the course of filling receptacles for dispatch (such as insemination straws), the receptacles and other disposable items should be used immediately after being unpacked. Materials for repeated use should be disinfected with alcohol, ethylene oxide, steam or other approved *disinfection* techniques.

d) If sealing powder is used, care should be taken to avoid its being contaminated.

3. Conditions applicable to the storage of semen

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

Semen straws should be sealed and code marked in line with the international standards of the International Committee for Animal Recording (ICAR)[1].

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

4 Sperm sorting

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

~~1 The ICAR international standards on straws are contained in Recording Guidelines – Appendices to the international agreement of recording practices. The text of this document is available at the following web site: www.icar.org~~

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CHAPTER 4.7.

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

Article 4.7.1.

Aims of control

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

Article 4.7.2.

Conditions applicable to the embryo collection team

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

1. The team should be approved by the *Competent Authority*.

2. The team should be supervised by a team *veterinarian*.

3. The team *veterinarian* is responsible for all team operations which include verification of donor health status, sanitary handling and surgery of donors and *disinfection* and hygienic procedures.

4. Team personnel should be adequately trained in the techniques and principles of disease control. High standards of hygiene should be practiced to preclude the introduction of *infection*.

5. The collection team should have adequate facilities and equipment for:

   a) collecting embryos;

   b) processing and treatment of embryos at a permanent site or mobile laboratory;

   c) storing embryos.

   These facilities need not necessarily be at the same location.

6. The embryo collection team should keep a record of its activities, which should be maintained for inspection by the *Veterinary Authority* for a period of at least two years after the embryos have been exported.

7. The embryo collection team should be subjected to regular inspection at least once a year by an *Official Veterinarian* to ensure compliance with procedures for the sanitary collection, processing and storage of embryos.

Annex VI (contd)

Article 4.7.3.

Conditions applicable to processing laboratories

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

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

Additionally:

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

Article 4.7.4.

Conditions applicable to the introduction of donor animals

1. Donor animals

   a) The *Veterinary Authority* should have knowledge of, and authority over, the *herd*/*flock* from which the donor *animals* have been sourced.

   b) The donor *animals* should not be situated in a *herd*/*flock* subject to veterinary restrictions for OIE *listed disease* or pathogens for relevant species (see Chapter 1.2. of the *Terrestrial Code*), other than those that are in IETS Category 1 for the species of embryos being collected (see Article 4.7.14. ~~and footnote 1~~).

   c) At the time of collection, the donor *animals* should be clinically inspected by the team *veterinarian*, or by a *veterinarian* responsible to the team *veterinarian* and certified to be free of clinical signs of *diseases*.

2. Semen donors

   a) Semen used to inseminate donor *animals* artificially should have been produced and processed in accordance with the provisions of Chapter 4.6.

   b) When the donor of the semen used to inseminate donor females for embryo production is dead, and when the health status of the semen donor concerning a particular infectious *disease* or *diseases* of concern was not known at the time of semen collection, additional tests may be required of the inseminated donor female after embryo collection to verify that these infectious *diseases* were not transmitted. An alternative may be to test an aliquot of semen from the same collection date.

c) Where natural service or fresh semen is used, donor sires should meet the health conditions set out in Chapter 4.6. as appropriate to the species.

Article 4.7.5.

Risk management

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

1. The first phase, which is applicable to *diseases* not included in Category 1 of the IETS categorisation[1] (Article 4.7.14.), comprises the risk potential for embryo contamination and depends on:

   a) the disease situation in the *exporting country* and/or *zone*;

   b) the health status of the *herds/flocks* and the donors from which the embryos are collected;

   c) the pathogenic characteristics of the specified disease agents that are of concern to the *Veterinary Authority* of the *importing country*.

2. The second phase covers risk mitigation by use of internationally accepted procedures for processing of embryos which are set out in the IETS Manual[2]. These include the following:

   a) The embryos should be washed at least ten times with at least 100–fold dilutions between each wash, and a fresh pipette should be used for transferring the embryos through each wash.

   b) Only embryos from the same donor should be washed together, and no more than ten embryos should be washed at any one time.

   c) Sometimes, for example when inactivation or removal of certain viruses (e.g. bovine herpesvirus-1, and Aujeszky's disease virus) is required, the standard washing procedure should be modified to include additional washes with the enzyme trypsin, as described in the IETS Manual[2].

   d) The zona pellucida of each embryo, after washing, should be examined over its entire surface area at not less than 50X magnification to ensure that it is intact and free of adherent material.

   [NOTE: All shipments of embryos should be accompanied by a statement signed by the team veterinarian certifying that these embryo processing procedures have been completed.]

3. The third phase, which is applicable to *diseases* not included in Category 1 of the IETS categorisation[1] (Article 4.7.14.) and which are of concern to the *Veterinary Authority* of the *importing country*, encompasses the risk reductions resulting from:

   a) post-collection *surveillance* of the donors and donor *herd/flock* based on the recognized *incubation periods* of the *diseases* of concern to determine retrospectively the health status of donors whilst the embryos are stored (in species where effective storage by cryopreservation is possible) in the *exporting country*;

   b) testing of embryo-collection (flushing) fluids and non-viable embryos, or other samples such as blood, in a laboratory for presence of specified disease agents.

Annex VI (contd)

Article 4.7.6.

Conditions applicable to the collection and storage of embryos

1. Media

Any biological product of animal origin used in the media and solutions for collection, processing, washing or storage of embryos should be free of pathogenic micro-organisms. Media and solutions used in the collection and storage of embryos should be sterilized by approved methods according to the IETS Manual[2] and handled in such a manner as to ensure that sterility is maintained. Antibiotics should be added to collection, processing, washing and storage media as recommended in the IETS Manual[2].

2. Equipment

a) All equipment used to collect, handle, wash, freeze and store embryos should ideally be new or at least sterilized prior to use as recommended in the IETS Manual[2].

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

Article 4.7.7.

Optional tests and treatments

1. The testing of samples can be requested by an *importing country* to confirm the absence of pathogenic organisms that may be transmitted via *in vivo* derived embryos, or to help assess whether the degree of quality control of the collection team (with regard to adherence to procedures as described in the IETS Manual[2]) is at an acceptable level. Samples may include:

a) Non-viable embryos/oocytes

Where the viable, zona pellucida intact embryos from a donor are intended for export, all non-fertilized oocytes and degenerated or zona pellucida compromised embryos collected from that donor should be washed according to the IETS Manual[2] and pooled for testing if requested by the *importing country*. Non-viable embryos/oocytes from the donor should be processed and stored together.

b) Embryo collection (flushing) fluids

The collection fluid should be placed in a sterile, closed container and, if there is a large amount, it should be allowed to stand undisturbed for one hour. The supernatant fluid should then be removed and the bottom 10–20 ml, along with accumulated debris, decanted into a sterile bottle.

If a filter is used in the collection of embryos/oocytes then any debris that is retained on the filter should be rinsed off into the retained fluid.

c) Washing fluids

The last four washes of the embryos/oocytes should be pooled according to the (IETS Manual[2]).

d) Samples

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

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

Article 4.7.8.

Conditions applicable to the storage and transport of embryos

1. The embryos for export should be stored in sealed sterile ampoules, vials or straws under strict hygienic conditions at a storage place approved by the *Veterinary Authority* of the *exporting country* where there is no risk of contamination of the embryos.

2. Only embryos from the same individual donor should be stored together in the same ampoule, vial or straw.

3. The embryos should if possible, depending on the species, be frozen, stored with fresh liquid nitrogen in cleaned and sterilized tanks or containers under strict hygienic conditions at the approved storage place.

4. Ampoules, vials or straws should be sealed at the time of freezing (or prior to export where cryopreservation is not possible), and they should be clearly identified by labels according to the standardised system recommended in the IETS Manual[2].

5. Liquid nitrogen containers should be sealed under the supervision of the *Official Veterinarian* prior to shipment from the *exporting country*.

6. Embryos should not be exported until the appropriate veterinary certificates are completed.

Article 4.7.9.

Procedure for micromanipulation

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

Article 4.7.10.

Specific conditions applicable to porcine embryos

The *herd* of origin should be free of clinical signs of swine vesicular disease and brucellosis. The development of effective cryopreservation methods for the storage of zona pellucida-intact porcine embryos is still at a very early stage.

Annex VI (contd)

Article 4.7.11.

Specific conditions/comments applicable to equine embryos

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

Article 4.7.12.

Specific conditions/comments applicable to camelid embryos

South American camelid embryos recovered from the uterine cavity by the conventional non-surgical flushing technique at 6.5 to 7 days post-ovulation are almost invariably at the hatched blastocyst stage, and thus the zona pellucida has already been shed. Since the embryos do not enter the uterus and cannot be recovered before 6.5 to 7 days, it would be unrealistic to stipulate for these species that only zona pellucida-intact embryos can be used in *international trade*. It should be noted however that in 2008 the development of cryopreservation methods for storage of camelid embryos is still at a very early stage, and also that pathogen interaction studies with camelid embryos have not yet been carried out.

Article 4.7.13.

Specific conditions/comments applicable to cervid embryos

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

Article 4.7.14.

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

Based on the conclusions of the Research Subcommittee of the Health and Safety Advisory Committee (HASAC) of the IETS~~1~~, the following *listed diseases* and pathogenic agents are categorised into four categories, which applies only to *in vivo* derived embryos.

1. Category 1

   a) Category 1 *diseases* or pathogenic agents are those for which sufficient evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual~~2~~.

   b) The following *diseases* or pathogenic agents are in category 1:

      – Aujeszky's disease (pseudorabies) (swine): trypsin treatment required

      – Bluetongue (cattle)

      – Bovine spongiform encephalopathy (cattle)

      – *Brucella abortus* (cattle)

– Enzootic bovine leukosis

– Foot and mouth disease (cattle)

– Infectious bovine rhinotracheitis: trypsin treatment required

– Scrapie (sheep).

2. Category 2

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

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

– Bluetongue (sheep)

– Caprine arthritis/encephalitis

– Classical swine fever (hog cholera).

3. Category 3

a) Category 3 *diseases* or pathogenic agents are those for which preliminary evidence indicates that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual~~2~~, but for which additional *in vitro* and *in vivo* experimental data are required to substantiate the preliminary findings.

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

~~– Bovine immunodeficiency virus~~

~~– Bovine spongiform encephalopathy (goats)~~

– Bovine viral diarrhoea virus (cattle)

~~– *Campylobacter fetus* (sheep)~~

– Foot and mouth disease (swine, sheep and goats)

~~– *Haemophilus somnus* (cattle)~~

– Maedi-visna (sheep)

– *Mycobacterium paratuberculosis* (cattle)

~~– *Neospora caninum* (cattle)~~

~~– Ovine pulmonary adenomatosis~~

– Porcine reproductive and respiratory disease syndrome (PRRS)

Annex VI (contd)

- Rinderpest (cattle)
- Swine vesicular disease.

4. Category 4

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

i) that no conclusions are yet possible with regard to the level of transmission risk; or

ii) the risk of transmission via embryo transfer might not be negligible even if the embryos are properly handled according to the IETS Manual2 between collection and transfer.

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

- African swine fever
- ~~Akabane (~~cattle~~)~~
- Bovine anaplasmosis
- Bluetongue (goats)
- ~~Border disease (sheep)~~
- ~~Bovine herpesvirus-4~~
- *Chlamydia psittaci* (cattle, sheep)
- *Contagious* equine metritis
- ~~Enterovirus (cattle, swine)~~
- Equine rhinopneumonitis
- ~~*Escherichia coli* 09:K99 (cattle)~~
- ~~*Leptospira borgpetersenii serovar hardjobovis (cattle)*~~
- ~~*Leptospira* sp. (swine)~~
- Lumpy skin disease
- *Mycobacterium bovis* (cattle)
- *Mycoplasma* spp. (swine)
- Ovine epididymitis (*Brucella ovis*)
- ~~Parainfluenza-3 virus (cattle)~~
- ~~Parvovirus (swine)~~

- ~~Porcine circovirus (type 2) (pigs)~~
- Scrapie (goats)
- *Tritrichomonas foetus* (cattle)
- ~~*Ureaplasma/Mycoplasma* spp. (cattle, goats)~~
- Vesicular stomatitis (cattle, swine).

~~1 Based on available research and field information, the Research Subcommittee of the Health and Safety Advisory Committee (HASAC) of the International Embryo Transfer Society (IETS) has categorised some diseases based on their relative risk of dissemination by properly processed and handled *in vivo* derived embryos. This chapter that contains the complete list of IETS categorised diseases is shown in Article 4.7.14.~~

~~2 Manual of the International Embryo Transfer Society.~~

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Annex VII

CHAPTER 6.4.

BIOSECURITY PROCEDURES IN POULTRY PRODUCTION

Article 6.4.1.

Introduction

~~This chapter provides recommended biosecurity procedures in *poultry* production and is not specifically related to trade (under study).~~

Infectious agents of *poultry* are a threat to *poultry* health and, at times, human health and have significant social and economic implications. In *poultry* production, especially under intensive conditions, prevention is the most viable and economically feasible approach to the control of infectious agents.

Biosecurity procedures should be implemented with the objective of preventing the introduction and dissemination of infectious agents in the *poultry* production chain. Biosecurity will be enhanced with the adoption and implementation of the principles of Good Agricultural Practices and the Hazard Analysis Critical Control Point (HACCP) system.

Article 6.4.2.

Purpose and scope

This chapter deals with biosecurity procedures in *poultry* production. It should be read in conjunction with the Codex Alimentarius Code of Hygienic Practice for Meat (CAC/RCP 58-2005) and Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976).

This chapter identifies several biosecurity measures. The choice of measures to be implemented will vary according to national conditions, including *poultry infection* status, the risk of introduction and dissemination of infectious agents and the cost effectiveness of control measures.

Recommendations on specific infectious agents may be found in relevant *disease* chapters in the *Terrestrial Code*.

Article 6.4.3.

Definitions

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

Live bird markets: means markets where live birds from various sources and species are sold for *slaughter*, further rearing or production.

Annex VII (contd)

Article 6.4.4.

Recommendations on the location and construction of poultry establishments

1. All establishments (poultry farms and hatcheries)

   a) A suitably isolated geographical location is recommended. Factors to consider include the location of other *poultry* and livestock *establishments*, *wild* bird concentrations and the distance from roads used to transport *poultry*.

   b) *Poultry establishments* should be located and constructed to provide adequate drainage for the site. Run-off or untreated site wastewater should not discharge into waterfowl habitats.

   c) *Poultry* houses and hatcheries should be designed and constructed (preferably of smooth impervious materials) so that cleaning and *disinfection* can be carried out effectively. Ideally, the area immediately surrounding the *poultry* houses and hatcheries should be paved with concrete or other impervious material to facilitate cleaning and *disinfection*.

   d) The *establishment* should be surrounded by a security fence to prevent the entry of unwanted animals and people.

   e) A sign indicating restricted entry should be posted at the entrance to the *establishment*.

2. Additional measures for poultry farms

   a) *Establishments* should be designed to house a single species and a single production type. The design should also consider the 'all-in all-out' single age group principle. If this is not feasible, the *establishment* should be designed so that each *flock* can be managed as a separate *epidemiological unit*.

   b) *Poultry* houses, and buildings used to store feed, eggs or other material, should be constructed and maintained to prevent the entry of *wild* birds, rodents and arthropods.

   c) Where feasible, the floors of *poultry* houses should be constructed using concrete or other impervious materials and designed so that cleaning and *disinfection* can be carried out effectively.

   d) Where feasible, feed should be delivered into the farm from outside the security fence.

3. Additional measures for hatcheries

   a) The design of the hatchery should take account of work flow and air circulation needs, with 'one way flow' movement of eggs and *day-old birds* and one way air flow in the same direction.

   b) The hatchery buildings should include physical separation of areas used for the following:

      i) personnel changing, showering and sanitary facilities;

      ii) receipt, storage and transfer of eggs;

      iii) incubation;

      iv) hatching;

      v) sorting, sexing and other handling of *day-old birds*;

vi) storage of egg boxes and boxes for *day-old birds*, egg flats, chick box liners, chemicals and other items;

vii) equipment washing;

viii) waste disposal;

ix) dining facilities for personnel;

x) office space.

Article 6.4.5.

Recommendations applicable to the operation of poultry establishments

1. All establishments (poultry farms and hatcheries)

a) All *establishments* should have a written *biosecurity plan*. Personnel in the *establishments* should have access to basic training in biosecurity relevant to *poultry* production and understand the implications to animal health, human health and food safety.

b) There should be good communication between personnel involved in the *poultry* production chain to ensure that steps are taken to minimise the introduction and dissemination of infectious agents.

c) Traceability at all levels of the *poultry* production chain should be possible.

d) Records should be maintained on an individual *flock* basis and include data on bird health, production, medications, vaccination, mortality and *surveillance*. In hatcheries, records should include data on fertility, hatchability, vaccination and treatments. Records should be maintained on cleaning and *disinfection* of farm and hatchery buildings and equipment. Records should be readily available for inspection on site.

e) Monitoring of *poultry* health on the *establishment* should be under the supervision of a *veterinarian*.

f) *Establishments* should be free from unwanted vegetation and debris that could attract or harbour pests.

g) Procedures for the prevention of entry of *wild* birds into *poultry* houses and buildings, and the control of vermin such as rodents and arthropods should be implemented.

h) Access to the *establishment* should be controlled to ensure only authorised persons and *vehicles* enter the site.

i) All personnel and visitors entering an *establishment* should follow a biosecurity procedure. The preferred procedure is for visitors and personnel entering the *establishment* to shower and change into clean clothes and footwear provided by the *establishment*. Where this is not practical, clean outer garments (coveralls or overalls, head covering and footwear) should be provided.

j) Personnel and visitors should not have had recent contact with other *poultry*, *poultry* waste, or *poultry* processing plant(s). This time period should be based on the level of risk of transmission of infectious agents. This will depend on the *poultry* production purpose, biosecurity procedures and *infection* status (e.g. the time between visiting a breeder *flock* and then a broiler *flock* would be less than the time between visiting a broiler *flock* and then a breeder *flock*).

Annex VII (contd)

k) Any *vehicle* entering an *establishment* should be cleaned and disinfected according to a *biosecurity plan*. Delivery *vehicles* should be cleaned, and disinfected before *loading* each consignment of eggs or *poultry*.

2. Additional measures for all poultry farms

a) Whenever possible, the 'all-in all-out' single age group principle should be used. If this is not feasible and several *flocks* are maintained on one *establishment*, each *flock* should be managed as a separate *epidemiological unit*.

b) All personnel and visitors entering a *poultry* house should wash their hands with soap and water or sanitize them using a disinfectant. Personnel and visitors should also change footwear, use a boot spray or use a properly maintained disinfectant footbath. The disinfectant solution in the footbath should be changed on a regular basis to ensure its efficacy, according to the manufacturer's instructions.

c) Animals, other than *poultry* of the appropriate (resident) species and age, should not be permitted access to *poultry* houses. No animals should have access to other buildings (e.g. those used to store feed, eggs or other material).

d) The drinking water supply to *poultry* houses should be potable according to the World Health Organization or to the relevant national standard, and microbiological quality should be monitored if there is any reason to suspect contamination. The water delivery system should be cleaned and disinfected between *flocks* when the *poultry* house is empty.

e) Birds used to stock a *poultry* house should preferably be obtained from breeder *flocks* and hatcheries that are free from vertically transmitted infectious agents.

f) Heat treated feeds with or without the addition of other bacteriocidal or bacteriostatic treatments (e.g. addition of organic acids) are recommended. Where heat treatment is not possible, the use of bacteriostatic or bactericidal treatments is recommended.

Feed should be stored in a manner to prevent access by *wild* birds and rodents. Spilled feed should be cleaned up immediately to remove attractants for *wild* birds and rodents. The movement of feed between *flocks* should be avoided.

g) The litter in the *poultry* house should be kept dry and in good condition.

h) Dead birds should be removed from *poultry* houses as quickly as possible but at least daily. These should be disposed of in a safe and effective manner.

i) Personnel involved in the catching of birds should be adequately trained in bird handling and basic biosecurity procedures.

j) To minimise stress *poultry* should be transported in well ventilated *containers* and should not be over crowded. Exposure to extreme temperatures should be avoided.

k) *Containers* should be cleaned and disinfected between each use, or disposed of in a safe manner.

l) When a *poultry* house is depopulated, it is recommended that all faeces and litter be removed from the house and disposed of in a safe manner to minimise the risk of dissemination of infectious agents.

If litter is not removed and replaced between *flocks* then the litter should be treated in a manner to minimise the risk of dissemination of infectious agents from one *flock* to the next.

After removal of faeces and litter, cleaning and *disinfection* of the *poultry* house and equipment should be done in accordance with Chapter 4.13.

m) For *poultry flocks* that are allowed to range outdoors, feeders, feed and other items which may attract *wild* birds should be kept indoors. *Poultry* should not be allowed access to sources of contamination (e.g. household waste, litter storage areas, other animals, stagnant water and water of unknown quality). The nesting area should be inside the *poultry* house.

n) To avoid the development of antimicrobial resistance, antimicrobials should be used according to relevant directions of the *Veterinary Services* and manufacturer's instructions and in accordance with *Terrestrial Code* Chapters 6.8., 6.9., 6.10., 6.11.

3. Additional measures for layers

Refer to Section 3 of the Codex Alimentarius Code of Hygienic Practice for Eggs and Egg Products (CAC/RCP 15-1976).

4. Additional measures for breeders

a) Nest box litter and liners should be kept clean.

b) *Hatching eggs* should be collected at frequent intervals, at least daily, and placed in new or clean and disinfected packaging materials.

c) Grossly dirty, cracked, broken, or leaking eggs should be collected separately and should not be used as *hatching eggs*.

d) *Hatching eggs* should be cleaned and sanitized as soon as possible after collection using an approved sanitising agent, in accordance with the manufacturer's instructions.

e) *Hatching eggs* or their packaging materials should be marked to assist traceability and veterinary investigations.

f) The *hatching eggs* should be stored in a dedicated room as soon as possible after cleaning and sanitisation. Storage conditions should minimise the potential for microbial contamination and growth and ensure maximum hatchability. The room should be well ventilated, kept clean, and regularly disinfected using disinfectants approved for this purpose.

5. Additional measures for hatcheries

a) Dead in shell embryos should be removed from hatcheries as soon as they are found and disposed of in a safe and effective manner.

b) All hatchery waste, garbage and discarded equipment should be contained or at least covered while on site and removed from the hatchery and its environs as soon as possible.

c) After use, hatchery equipment, tables and surfaces should be promptly and thoroughly cleaned and disinfected with an approved disinfectant.

Annex VII (contd)

d) Egg handlers and sexers and handlers of *day-old birds* should wash their hands with soap and water before commencing work and between working with batches of *hatching eggs* or *day-old birds* from different breeder *flocks*.

e) *Hatching eggs* and *day-old birds* from different breeder *flocks* should be identifiable during incubation, hatching, sorting and transportation.

f) *Day-old birds* should be delivered to the farm in new *containers* or in clean, disinfected *containers*.

Article 6.4.6.

Prevention of further dissemination of infectious agents of poultry

When a *flock* is suspected or known to be infected, a *veterinarian* should be consulted immediately and, in addition to the general biosecurity measures described previously, management procedures should be adjusted to effectively isolate it from other *flocks* on the *establishment* and other epidemiologically related *establishments*. The following measures are recommended:

1. Personnel should manage *flocks* to minimise the risk of dissemination of infectious agents to other *flocks* and *establishments*, and to humans. Relevant measures include handling of an infected *flock* separately, last in sequence and the use of dedicated personnel, clothing and equipment.

~~2. A *veterinarian* should be consulted immediately.~~

2~~3~~. When *infection* has been confirmed, epidemiological investigations should be carried out to determine the origin and route of transmission of the infectious agent.

3~~4~~. *Poultry* carcasses, litter, faeces and other potentially contaminated farm waste should be disposed of in a safe manner to minimise the risk of dissemination of infectious agents. The disposal method used will depend on the infectious agent involved.

4~~5~~. Depending on the epidemiology of the *disease*, the results of a *risk assessment*, and public and animal health policies, destruction or *slaughter* of a *flock* before the end of the normal production period may be used. When infected *flocks* are destroyed or slaughtered, they should be processed in a manner to minimise exposure of humans and other *flocks* to the infectious agent, and in accordance with recommendations of the *Veterinary Service* and relevant chapters in the *Terrestrial Code*. Based on *risk assessment*, non-infected, high risk *flocks* may be destroyed or slaughtered before the end of their normal production period.

Before restocking, the *poultry* house including equipment should be cleaned, disinfected and tested to verify that the cleaning has been effective. Special attention should be paid to feed equipment and water systems.

Microbiological monitoring of the efficacy of *disinfection* procedures is recommended when pathogenic agents have been detected in the previous *flock*.

5~~6~~. Depending on the epidemiology of the *disease*, *risk assessment*, vaccine availability and public and animal health policies, vaccination is an option to minimise the dissemination of the infectious agent.

When used, vaccines should be administered in accordance with the directions of the *Veterinary Services* and the manufacturer's instructions. Recommendations in the *Terrestrial Manual* should be followed as appropriate.

Article 6.4.7.

Recommendations to prevent the dissemination of infectious agents to and from live bird markets

1. Personnel should be educated on the significance of infectious agents and the need to apply biosecurity practices to prevent dissemination of these agents. Education should be targeted to personnel at all levels of operations in these markets (e.g. drivers, owners, handlers, processors).

   Programmes should be implemented to raise consumer awareness about the risks associated with activities of live bird markets.

2. Personnel should wash their hands with soap and water before and after handling birds.

3. Birds from diseased *flocks* should not be transported to live bird markets.

4. All *containers* and *vehicles* should be cleaned and disinfected every time they leave the market.

5. Live birds that leave the market and go to a farm should be kept separately from other birds for a period of time to minimise the potential dissemination of infectious agents of *poultry*.

6. Periodically the market should be emptied, cleaned and disinfected. This is of particular importance when an infectious agent of *poultry* deemed significant by the *Veterinary Services* has been identified in the market or the region.

7. Where feasible, *surveillance* should be carried out in these markets to detect infectious agents of *poultry*. The *surveillance* programme should be determined by the *Veterinary Services*, and in accordance with recommendations in relevant chapters of the *Terrestrial Code*.

8. Efforts should be made to ensure the possibility of tracing all birds entering and leaving the markets.

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Annex VIII

CHAPTER 13.2.

RABBIT HAEMORRHAGIC DISEASE

Article 13.2.1.

General provisions

For the purposes of the *Terrestrial Code*, the *infective period* for rabbit haemorrhagic disease (RHD) shall be 60 days.

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

Article 13.2.2.

RHD free country

A country may be considered free from RHD when it has been shown that the *disease* has not been present for at least one year, that no vaccination has been carried out in the previous 12 months, and that virological or serological surveys in both domestic and *wild* rabbits have confirmed the absence of the *disease*.

This period may be reduced to six months after the last *case* has been eliminated and *disinfection* procedures completed in countries adopting a *stamping-out policy*, and where the serological survey confirmed that the *disease* had not occurred in the *wild* rabbits.

Article 13.2.3.

RHD free establishment

An *establishment* may be considered free from RHD when it has been shown, by serological testing, that the *disease* has not been present for at least one year, and that no vaccination has been carried out in the previous 12 months. Such *establishments* should be regularly inspected by the *Veterinary Authority*.

A previously infected *establishment* may be considered free when six months have elapsed after the last *case* has been eliminated, and after:

1. a *stamping-out policy* has been adopted and carcasses have been disposed of by burning;

2. the rabbitry has been thoroughly disinfected and kept empty for at least six weeks;

3. the rabbitry is properly fenced to prevent the straying of *wild* lagomorphs into the rabbitry.

Article 13.2.4.

Trade in commodities

Veterinary Authorities of RHD free countries may prohibit importation or transit through their territory, from countries considered infected with RHD, of live rabbits, semen, *meat* and non-treated pelts.

Annex VIII (contd)

Article 13.2.5.

Recommendations for importation from RHD free countries

For domestic rabbits destined for breeding

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

1. showed no clinical sign of RHD on the day of shipment;

2. were kept in a RHD free country since birth or for at least the past 60 days.

Article 13.2.6.

Recommendations for importation from RHD free countries

For day-old rabbits destined for breeding

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

1. showed no clinical sign of RHD on the day of shipment;

2. were born from female rabbits which had been kept in a country free from RHD for at least the past 60 days.

Article 13.2.7.

Recommendations for importation from countries considered infected with RHD

For domestic rabbits destined for breeding or pharmaceutical or surgical or agricultural or industrial use

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

1. showed no clinical sign of RHD on the day of shipment;

AND

2. were kept in a RHD free *establishment* where no clinical *case* of RHD was found when inspected by an *Official Veterinarian* immediately prior to shipment;

OR

3. were kept in an *establishment* where no *case* of RHD was reported during the 60 days prior to shipment and no clinical *case* of RHD was found when inspected by an *Official Veterinarian* immediately prior to shipment; and

4. were kept in an *establishment* where no *animal* has been vaccinated against RHD; and

5. were kept in an *establishment* where breeding rabbits (at least 10 percent of the *animals*) were subjected to the serological test for RHD with negative results during the 60 days prior to shipment; and

6. have not been vaccinated against RHD; or

7. were vaccinated against RHD immediately before shipment (the nature of the vaccine used and the date of vaccination shall also be stated in the certificate).

Article 13.2.8.

Recommendations for importation from countries considered infected with RHD

For day-old rabbits destined for breeding

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

1. were kept in a RHD free *establishment* where no clinical *case* of RHD was found when inspected by an *Official Veterinarian* immediately prior to shipment;

OR

2. were kept in an *establishment* where no *case* of RHD was reported during the 30 days prior to shipment and no clinical *case* of RHD was found when inspected by an *Official Veterinarian* immediately before shipment; and

3. have not been vaccinated against RHD; and

4. were born from female rabbits which were subjected to the serological test for RHD with negative results during the 60 days prior to shipment.

Article 13.2.9.

Recommendations for importation from countries considered infected with RHD

For domestic rabbits destined for immediate slaughter

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

1. showed no clinical sign of RHD on the day of shipment;

2. were kept in an *establishment* where no *case* of RHD was reported during the 60 days prior to shipment.

Article 13.2.10.

Recommendations for importation from countries considered infected with RHD

For 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 RHD on the day of collection of the semen;

2. were subjected to the serological test for RHD with negative results during the 30 days prior to collection.

Annex VIII (contd)

Article 13.2.11.

Recommendations for importation from countries considered infected with RHD

For domestic rabbit meat

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

1. were kept in an *establishment* where no *case* of RHD was reported during the 60 days prior to transport to the approved *abattoir*;

2. were subjected to ante-mortem inspections for RHD with favourable results;

3. showed no lesions of RHD at post-mortem inspections.

Article 13.2.12.

Recommendations for importation from RHD free countries

For non-treated pelts

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the pelts come from rabbits which had been kept in a country free from RHD for at least 60 days before *slaughter*.

Article 13.2.13.

Recommendations for importation from countries considered infected with RHD

For pelts

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the pelts were subjected to a drying treatment for at least one month and a formalin-based treatment by spraying at a three percent concentration, or by fumigation carried out ~~in conformity with one of the methods described in Chapter 6.4.~~, not more than seven days prior to shipment.

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Annex IX

CHAPTER 6.9.

RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

Article 6.9.1.

Purpose

This document ~~These recommendations~~ provides guidance for the responsible and prudent use of *antimicrobial agents* in veterinary medicine, with the aim of protecting both animal and human health. It defines the respective responsabilities of the *Competent Authorities* and stakeholders involved in the authorisation, production, control, distribution and use of veterinary medicinal products (VMP) containing antimicrobial agent(s) such as the national regulatory authorities, the veterinary pharmaceutical industry, veterinarians, distributors and food animal producers. ~~The *Competent Authorities* responsible for the registration and control of all groups involved in the authorisation production, distribution and use of veterinary antimicrobials have specific obligations~~.

Responsible and ~~P~~prudent use is principally determined by ~~the outcome of~~ the specifications detailed in the marketing authorisation ~~procedure~~ and by their implementation ~~of specifications~~ when antimicrobial~~s~~ agents are administered to *animals*.

Responsible and prudent use activities need to involve all stakeholders.

A 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 ~~P~~prudent use includes a set of practical measures and recommendations intended to ~~prevent and/or reduce~~ improve animal health and *animal welfare* while reducing the selection, emergence and spread of antimicrobial-resistant bacteria in *animals* to:

1. ensure the rational use ~~maintain the efficacy~~of *antimicrobial agents* ~~and to ensure the rational use of antimicrobials in *animals*~~ with the purpose of optimising both their efficacy and safety ~~in *animals*~~;

2. comply with the ethical obligation and economic need to keep *animals* in good health;

3. prevent, or reduce, as far as possible, the transfer of resistant micro-organisms and/or resistance determinants ~~(with their any resistance determinants)~~ within animal populations, their environment and from *animals* to humans;

~~4. maintain the efficacy of *antimicrobial agents* used in food producing *animals*;~~

~~5. prevent or reduce the transfer of resistant micro organisms or resistance determinants from *animals* to humans;~~

Annex IX (contd)

~~6~~4. contribute to maintaining the efficacy and usefulness of *antimicrobial agents* used in animal and human medicine ~~and prolong the usefulness of the antimicrobials~~;

~~7. prevent the contamination of animal-derived food with antimicrobial residues that exceed the established maximum residue limit (MRL);~~

~~8~~5. protect consumer health by ensuring the safety of food of animal origin with respect to residues of antimicrobial agents ~~drugs, and the ability to transfer antimicrobial drug resistant micro-organisms to humans~~.

Article 6.9.3.

Responsibilities of the regulatory authorities

1. Marketing authorisation

~~The national r~~Regulatory authorities are responsible for granting marketing authorisation. This should be done in accordance with the provisions of the *Terrestrial Code*. They have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the *veterinarian* and all the other relevant stakeholders.

2. Submission of data for the granting of the marketing authorisation

~~The pharmaceutical industry has to submit the data requested for the granting of the marketing authorisation~~. The marketing authorisation is granted on the basis of the data submitted by the pharmaceutical industry and only if the criteria of safety, quality and efficacy are met. An evaluation ~~assessment~~ of the potential risks and benefits to both animals and humans resulting from the use of antimicrobial agents in food-producing animals should be carried out. The evaluation should focus on each individual antimicrobial agents ~~product~~ and the findings not be generalised to the class of antimicrobials to which the particular active principle belongs. Guidance on usage should be provided for all target species, route of administration, dose~~age~~ regimens ~~ranges or~~ and different durations of treatment that are proposed.

3. Market approval

Regulatory authorities should ensure ~~attempt to expedite~~ that the market approval process of a ~~new~~ VMPs containing antimicrobial agent(s) occurs without undue delay in order to address a specific need for the treatment of *animal* disease.

4. Registration procedures

The *Competent Authority* should establish and implement efficient statutory registration procedures that evaluate the quality, safety and efficacy of the VMPs containing antimicrobial agent(s). According to Article 3.1.2. of Chapter 3.1. of the *Terrestrial Code*, such Authority should be free from any commercial, financial, hierarchical, political or other pressures which might affect their judgement or decisions.

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).

Member Countries lacking the necessary resources to implement an efficient registration procedure for ~~veterinary medicinal products~~ (VMPs), and whose supply principally depends on imports from foreign countries, should undertake the following measures:

a) check the efficacy of administrative controls on the import of these VMPs;

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

c) develop the necessary technical co-operation with experienced authorities to check the quality of imported VMPs as well as the validity of the recommended conditions of use.

Regulatory 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. All Member ~~c~~Countries should make every effort to actively combat the manufacture, advertisement, trade, distribution and use of unlicensed and counterfeit ~~bulk active pharmaceutical ingredients and~~ products including bulk active ingredients.

5. Quality control of antimicrobial agents

Quality controls should be performed:

a) in compliance with the provisions of good manufacturing practices;

b) to ensure that analysis specifications of *antimicrobial agents* used as active ingredients comply with the provisions of approved monographs;

c) to ensure that the quality and concentration ~~(stability)~~ of *antimicrobial agents* in the marketed dosage form(s) are maintained until the expiry date, established under the recommended storage conditions;

d) to ensure the stability of antimicrobials when mixed with feed or drinking water;

e) to ensure that all antimicrobials are manufactured to the appropriate quality and purity in order to guarantee their safety and efficacy.

6. Assessment of therapeutic efficacy

a) Preclinical trials

i) Preclinical trials should:

- establish the spectrum ~~range~~ of activity of *antimicrobial agents* on both pathogens and non-pathogens (commensals);

- assess the capacity ~~ability~~ of the *antimicrobial agent* 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* and limit the selection of antimicrobial resistance. (Pharmacokinetic and pharmacodynamic data and models can assist in this appraisal.).

ii) The activity of *antimicrobial agents* towards the targeted micro-organism 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;
- 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 ~~concentration~~ of the antimicrobial agents in the treated *animal* ~~at the site of *infection*~~ and concentration at the site of *infection* ~~its distribution in the treated *animal*~~;
- metabolism ~~that may lead to the inactivation of antimicrobials~~;
- 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, such as Veterinary International Cooperation on Harmonisation (VICH) guidelines (VICH GL-9);

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.

7. Assessment of the potential of antimicrobials~~s~~ agents to select for resistance

Other studies may be requested in support of the assessment of the potential of antimicrobials~~s~~ agents to select for resistance (Guidelines providing information for developing such studies are available, e.g. VICH GL-27). The party applying for market authorisation should, where possible, supply data derived in target animal species under the intended conditions of use.

For this the following may be considered:

a) the concentration of active compound in the gut of the *animal* (where the majority of potential food-borne pathogens reside) at the defined dosage level;

b) Pathway for the human exposure to antimicrobial resistant micro-organsims ~~the route and level of human exposure to food-borne or other resistant organisms;~~

c) the degree of cross-resistance within and between ~~the class of~~ antimicrobial~~s~~ classes ~~and between classes of antimicrobials~~;

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

8. Establishment of acceptable daily intake, maximum residue level and withdrawal periods for antimicrobial agents ~~compounds~~ in food producing animals

a) When setting the acceptable daily intake (ADI) and MRL for an antimicrobial agents ~~substance~~, the safety evaluation should also include the potential biological effects on the intestinal flora of humans (Guidelines are available, e.g. VICH GL-33).

b) The establishment of an ADI for each *antimicrobial agent*, and an MRL for each animal-derived food, should be undertaken.

c) For each VMP containing *antimicrobial agents*, withdrawal periods should be established in order to ensure ~~produce food in~~ compliance with the MRL~~s~~, taking into account:

i) the MRL~~s~~ established for the *antimicrobial agent* in the target animal and target tissues~~under consideration~~;

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

iii) the target animal species;

iii~~i~~v) the dosage regimen and the duration of treatment;

i~~v~~) the route of administration.

d) The applicant should provide methods for regulatory testing of residues in food.

9. Protection of the environment

An assessment of the impact of the proposed antimicrobial use on the environment should be conducted (Guidelines are available, e.g. VICH GL-6 and GL-38). Efforts should be made to ensure that the environmental impact of antimicrobial use is restricted to a minimum.

10. Establishment of a summary of product characteristics for each veterinary medicinal products containing antimicrobial agent(s) ~~product~~

The summary of product characteristics contains the information necessary for the appropriate use of VMPs containing ~~veterinary~~ antimicrobial agent(s)~~product (VAP)~~ 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;

Annex IX (contd)

d) target animal species and as appropriate age or production category;

e) therapeutic indications;

f) target micro-organisms;

g) dosage regimen and ~~administration~~ route of administration;

h) withdrawal periods;

i) incompatibilities;

j) 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.

11. Post-marketing antimicrobial surveillance

The information collected through existing pharmacovigilance programmes, including lack of efficacy, 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 micro-organisms resistant to *antimicrobial agents* is essential. The relevant authorities should implement a programme according to the *Terrestrial Code*.

b) Specific surveillance

Specific surveillance to assess the impact of the use of a specific antimicrobial agent may be implemented after the granting of the marketing authorisation. The surveillance programme should evaluate not only resistance ~~development~~ in target animal pathogens, but also in food-borne pathogens and~~/or~~ commensals if possible. This ~~Such a surveillance~~ will also contribute to general epidemiological surveillance of antimicrobial resistance.

12. Supply and administration of the veterinary medicinal products containing antimicrobial agent(s) ~~used in veterinary medicine~~

The relevant authorities should ensure that all the *antimicrobial agents* used in *animals* are:

a) prescribed by a *veterinarian* or other authorised person;

b) supplied only through licensed/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 destruction of unused or expired V~~A~~MPs containing antimicrobial agent(s).

13. Control of advertising

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

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

b) is restricted to authorised professionals, according to national legislation in each country.

14. Training of antimicrobial users

The training of users of antimicrobial~~s~~ agents should involve all the relevant organisations, such as regulatory authorities, pharmaceutical industry, veterinary schools, research institutes, veterinary professional organisations and other approved users such as food-animal owners. This training should focus on preserving the effectiveness of antimicrobial agents and include:

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

b) the ability of antimicrobial~~s~~ agents to select for resistant~~ce~~ micro-organisms and the relative importance of that resistance to public and animal health ~~in food-producing *animals*~~;

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

15 Research

The relevant authorities should encourage public- and industry-funded research.

Article 6.9.4.

Responsibilities of the veterinary pharmaceutical industry with regards to veterinary medicinal products containing antimicrobial agent(s)

1. Marketing authorisation ~~of VAPs~~

The veterinary pharmaceutical industry has responsibilities to:

a) supply all the information requested by the national regulatory authorities;

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 ~~of VAPs~~

For the marketing and export of VMPs containing antimicrobial agent(s) ~~VAPs~~:

Annex IX (contd)

a) only licensed and officially approved VMPs containing antimicrobial agent(s) ~~VAPs~~ 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/or 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 ~~disseminate~~ information in compliance with the provisions of the granted authorisation;

b) discourage ~~ensure that~~ the advertising of VMPs containing antimicrobial agent(s) ~~antimicrobials~~ directly to the food animal producer ~~is discouraged~~.

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 ~~Retailers distributing~~ V~~A~~MPs containing antimicrobial agent(s) should only do so on the prescription of a *veterinarian* or other suitably trained person authorised in accordance with the national legislation, and all products should be appropriately labelled.

2. The recommendations on the responsible and prudent use of VMPs containing antimicrobial~~s~~ 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.

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

Article 6.9.6.

Responsibilities of veterinarians

The ~~concern of the~~ *veterinarian*'s responsibility is to promote public health, ~~and~~ animal health and *welfare*. ~~The *veterinarian*'s responsibilities~~ including identification ~~preventing~~, prevention ~~identifying~~ and treatment~~ing~~ of animal *diseases*. The promotion of sound animal husbandry methods, hygiene procedures and vaccination strategies (good farming practice) can help to minimise the need for antimicrobial use in food-producing *animals*.

Veterinarians should only prescribe antimicrobials for *animals* under their care.

1. Use of antimicrobial agents

   The responsibilities of *veterinarians* are to carry out a proper clinical examination of the *animal(s)* and then:

   a) only prescribe antimicrobials when necessary and taking into consideration the OIE list of antimicrobials of veterinary importance;

   b) make an appropriate choice of ~~the~~ antimicrobial agent based on treatment experience and diagnostic laboratory information (pathogen isolation, identification and antibiogram) where possible~~of the efficacy of treatment~~.

2. Choosing an antimicrobial agent

   a) The expected efficacy of the treatment is based on:

      i) the clinical experience of the *veterinarian*;

      ii) known pharmacodynamics including the activity towards the pathogens involved;

      iii) the appropriate dosage regimen and route of administration;

      iv) known pharmacokinetics/tissue distribution to ensure that the selected therapeutic agent is active at the site of *infection*;

      v) 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 should be used.

   ~~To minimise the likelihood of antimicrobial resistance developing in target or other organisms, it is recommended that antimicrobials agents be targeted to pathogens likely to be the cause of *infection*.~~

   On certain occasions, a group of *animals* that may have been exposed to pathogens may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing to prevent the development of clinical *disease* and for reasons of *animal welfare*.

Annex IX (contd)

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

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

A prescription for VMPs containing antimicrobial agent(s) ~~*antimicrobial agents*~~ should indicate precisely the ~~treatment~~ dosage regimen, ~~the dose, the treatment intervals, the duration of the treatment~~, the withdrawal period where applicable and the amount of VMPs ~~drug~~ to be provided ~~delivered~~, depending on the dosage and the number of *animals* to be treated.

The off-label use of ~~a veterinary~~ VMPs containing antimicrobial agent(s) ~~drug~~ may be permitted in appropriate circumstances and should be in agreement with the national legislation in force including the withdrawal periods to be used. It is the *veterinarian*'s responsibility to define the conditions of responsible use in such a case including the dosage regimen and ~~therapeutic regimen,~~ the route of administration~~, and the duration of the treatment~~.

4. Recording

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

a) quantities of VMPs ~~medication~~ used per animal species;

b) a list of all VMPs ~~medicines~~ supplied to each food-producing animal holding;

c) treatment schedules including animal identification and withdrawal period ~~a list of medicine withdrawal period~~;

d) ~~a record of~~ antimicrobial susceptibility~~ies~~ data;

e) comments concerning the response of *animals* to treatment ~~medication~~;

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

Veterinarians should also periodically review farm records on the use of VM~~A~~Ps containing antimicrobial agent(s) to ensure compliance with their directions/prescriptions and use these records to evaluate the efficacy of treatments ~~regimens~~.

5. Labelling

All ~~medicines~~ VMPs supplied by a *veterinarian* should be labelled according to the national legislation.

6. Training/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 VM~~A~~Ps containing antimicrobial agent(s) (e.g. Guidelines for the judicious use of antimicrobials in various animal species developed by the American Veterinary Medical Association).

Annex IX (contd)

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 (good farming practice) 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 preventative measures (e.g. feedlot health plans, mastitis control plans, endo- and ectoparasite control and vaccination programmes, etc.);

   b) use VMPs containing antimicrobial agent(s) ~~*antimicrobial agents*~~ only on veterinary prescription, and according to the provisions of the prescription;

   c) use VMPs containing antimicrobial agent(s) ~~*antimicrobial agents*~~ in the species, for the uses and at the dosages on the approved/registered labels and in accordance with product label instructions, including maintenance of the storage conditions as appropriate, or the advice of a *veterinarian* familiar with the *animals* and the production site;

   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) comply with the storage conditions of antimicrobials in the rearing unit, according to the provisions of the leaflet and package insert;~~

   e~~f~~) address on-farm biosecurity measures ~~hygienic conditions~~ and take basic hygiene precautions as appropriate ~~regarding contacts between people (*veterinarians*, breeders, owners, children) and the *animals* treated~~;

   f~~g~~) comply with and record the recommended withdrawal periods to ensure that residue levels in animal-derived food do not present a risk for the consumer;

   g~~h~~) dispose of un-used and expired ~~surplus~~ VMPs containing antimicrobial agent(s) ~~antimicrobials~~ under safe conditions for the environment; ~~medicines~~ they should only be used within the expiry date~~, for the condition for which they were prescribed and, if possible, in consultation with the prescribing *veterinarian*~~;

   h~~i~~) 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~~j~~) keep adequate records of all VMPs containing antimicrobial agent(s) ~~medicines~~ used, including the following:

      i) name of the product/active substance, ~~and~~ batch number and expiry date;

      ii) name of prescriber and/or the supplier;

      iii) date of administration;

      iv) *identification of the animal* or group of *animals* to which the *antimicrobial agent* was administered;

Annex IX (contd)

v) clinical conditions treated;

vi) dosage;

vii) withdrawal periods (including date of the end of the withdrawal periods);

viii) result of laboratory tests;

ix) effectiveness of therapy;

j~~k~~) 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 VMPs containing antimicrobial agent(s).

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Annex X

CHAPTER 7.8.

USE OF ANIMALS IN RESEARCH AND EDUCATION

Preamble: The purpose of this chapter is to provide advice and assistance for OIE Members to follow when formulating regulatory requirements, or other form of oversight, for the use of live *animals* in research and education. Wherever the term "research" is used, it includes basic and applied research, testing and the production of biological materials; "education" includes teaching and training. A system of animal use oversight should be implemented in each country. The system will, in practice, vary from country to country and according to cultural, economic, religious and social factors. However, the OIE recommends that Members address all the essential elements identified in this chapter in formulating a regulatory framework that is appropriate to their local conditions. This framework may be delivered through a combination of national, regional and institutional jurisdictions and both public sector and private sector responsibilities should be clearly defined.

The OIE recognises the vital role played by the use of live *animals* in research and education. The OIE Guiding Principles for Animal Welfare state that such use makes a major contribution to the wellbeing of people and *animals* and emphasise the importance of the Three Rs (see Article 7.8.3.). Most scientists and members of the public agree that the *animals* should only be used when necessary; ethically justified (thereby avoiding unnecessary duplication of animal-based research); and when no other alternative methods, not using live *animals*, are available; that the minimum number of *animals* should be used to achieve the scientific or educational goals; and that such use of *animals* should cause as little pain and/or distress as possible. In addition, animal suffering is often recognised separately from pain and distress and should be considered alongside any lasting harm which is expected to be caused to *animals*.

The OIE emphasises the need for humane treatment of *animals* and that good quality science depends upon good *animal welfare*. It is the responsibility of all involved in the use of *animals* to ensure that they give due regard to these recommendations. In keeping with the overall approach to *animal welfare* detailed in the Guiding Principles, the OIE stresses the importance of standards based on outcomes for the *animal*.

The OIE recognises the significant role of *veterinarians* in animal-based research. Given their unique training and skills, they are essential members of a team including scientists and animal care technicians. This team approach is based on the concept that everyone involved in the use of *animals* has an ethical responsibility for the *animals*' *welfare*. The approach also ensures that animal use leads to high quality scientific and educational outcomes and optimum *welfare* for the *animals* used.

The OIE recognises that the use of live *animals* in research and education is a legitimate activity and, as a consequence, domestic and international transport of *animals* is essential to maintaining progress in advancing human and animal health. Such transport should be conducted in a legal manner, ensuring the safety of the *animal* and applying humane principles.

The OIE recommends that records on animal use should be maintained at an institutional level, as appropriate to the institution and project proposals and species used. Key events and interventions should be recorded to aid decision making and promote good science and *welfare*. A summary of these records may be gathered on a national basis and be published to provide a degree of public transparency, without compromising personnel or animal safety, or releasing proprietary information.

Article 7.8.1.

Definitions

Biocontainment: means the system and procedures designed to prevent the accidental release of biological material including allergens.

Annex X (contd)

Bioexclusion: means the prevention of the unintentional transfer of adventitious organisms with subsequent *infection* of *animals*, resulting in adverse effects on their health or suitability for research.

Biosecurity: means a continuous process of *risk assessment* and *risk management* designed to minimise or eliminate microbiological *infection* with adventitious organisms that can cause clinical *disease* in the infected *animals* or humans, or make *animals* unsuitable for biomedical research.

Cloned animal: means a genetic copy of another living or dead *animal* produced by somatic cell nuclear transfer or other reproductive technology.

Distress: means the state of an *animal*, that has been unable to adapt to stressors, and that manifests as abnormal physiological or behavioural responses. It can be acute or chronic and may result in pathological conditions.

Endangered species: means a population of organisms which is at risk of becoming extinct because it is either few in numbers, or threatened by changing environmental or predation parameters.

Environmental enrichment: means increasing the complexity (e.g. with toys, cage furniture, foraging opportunities, social housing, etc.) in a *captive animal*'s environment to foster the expression of non-injurious species-typical behaviours and reduce the expression of maladaptive behaviours, as well as provide cognitive stimulation.

Ethical review: means consideration of the validity and justification for using *animals* including: an assessment and weighing of the potential harms for *animals* and likely benefits of the use and how these balance (see harm-benefit analysis below); and consideration of experimental design; implementation of the Three Rs; animal husbandry and care and other related issues such as personnel training. Ethical judgements are influenced by prevailing societal attitudes.

Harm-benefit analysis: means the process of weighing the likely adverse effects (harms) to the *animals* against the benefits likely to accrue as a result of the proposed project.

Humane endpoint: means the point in time at which an experimental *animal*'s pain and/or distress is avoided, terminated, minimised or reduced, by taking actions such as giving treatment to relieve pain and/or distress, terminating a painful procedure, removing the *animal* from the study, or humanely killing the *animal*.

Laboratory animal: means an *animal* that is intended for use in research. In most cases, such *animals* are purpose-bred to have a defined physiological, metabolic, genetic or pathogen free status.

Operant conditioning: means the association that an *animal* makes between a particular response (such as pressing a bar) and a particular reinforcement that may be positive (for example, a food reward) or negative (e.g. a mild electric shock). As a result of this association, the occurrence of a specific behaviour of the *animal* can be modified (e.g. increased or decreased in frequency or intensity).

Pain: means an unpleasant sensory and emotional experience associated with actual or potential tissue damage. It may elicit protective actions, result in learned avoidance and distress and may modify species-specific traits of behaviour, including social behaviour.

Project proposal (sometimes called protocol): means a written description of a study or experiment, programme of work, or other activities that includes the goals of the work, characterises the use of the *animals*, and includes ethical considerations.

Suffering: means an unpleasant, undesired state of being that is the outcome of the impact on an *animal* of a variety of noxious stimuli and/or the absence of important positive stimuli. It is the opposite of good *welfare*.

Article 7.8.2.

Scope

This chapter applies to *animals* as defined in the *Terrestrial Code* (excluding bees) bred, supplied and/or used in research (including testing) and higher education. *Animals* to be used for production of biologicals and/or humanely killed for harvesting their cells, tissues and organs for scientific purposes are also covered. Members should consider both the species and the developmental stage of the *animal* in implementing these standards.

Article 7.8.3.

The Three Rs

The internationally accepted tenet, the 'Three Rs', comprises the following alternatives:

1. replacement refers to the use of methods utilising cells, tissues or organs of *animals* (relative replacement), as well as those that do not require the use of *animals* to achieve the scientific aims (absolute replacement);

2. reduction refers to the use of methods that enable researchers to obtain comparable levels of information from fewer *animals* or to obtain more information from the same number of *animals*;

3. refinement refers to the use of methods that prevent, alleviate or minimise pain, suffering, distress or lasting harm and/or enhance *welfare* for the *animals* used. Refinement includes the appropriate selection of relevant species with a lesser degree of structural and functional complexity in their nervous systems and a lesser apparent capacity for experiences that derive from this complexity. Opportunities for refinement should be considered and implemented throughout the lifetime of the *animal* and include, for example, housing and transportation as well as procedures and euthanasia.

Article 7.8.4.

The oversight framework

The role of a *Competent Authority* is to implement a system (governmental or other) for verification of compliance by institutions. This usually involves a system of authorisation (such as licensing or registering of institutions, scientists, and/or projects) and compliance which may be assessed at the institutional, regional and/or national level.

The oversight framework encompasses both ethical review of animal use and considerations related to animal care and *welfare*. This may be accomplished by a single body or distributed across different groups. Different systems of oversight may involve *animal welfare* officers, regional, national or local committees or bodies. An institution may utilise a local committee (often referred to as Animal Care and Use Committee, Animal Ethics Committee, Animal Welfare Body or Animal Care Committee) to deliver some or all of this oversight framework. It is important that the local committee reports to senior management within the institution to ensure it has appropriate authority, resources and support. Such a committee should undertake periodic review of its own policies, procedures and performance.

Ethical review of animal use may be undertaken by regional, national or local ethical review bodies or committees. Consideration should be given to ensuring the impartiality and independence of those serving on the committees.

Annex X (contd)

In providing this oversight and ensuring the implementation of the Three Rs, the following expertise should be included as a minimum:

a) one scientist with experience in animal research, whose role is to ensure that protocols are designed and implemented in accordance with sound science;

b) one *veterinarian*, with the necessary expertise to work with research *animals*, whose specific role is to provide advice on the care, use and *welfare* of such *animals*;

c) one public member, where appropriate, to represent general community interests who is independent of the science and care of the *animals* and is not involved in the use of *animals* in research.

Additional expertise may be sought from the animal care staff, as these professional and technical staff are centrally involved in ensuring the *welfare* of *animals* used. Other participants, especially in relation to ethical review, may include statisticians, information scientists and ethicists and biosafety specialists, as appropriate to the studies conducted. It may be appropriate, in teaching institutions, to involve student representation.

Oversight responsibilities include three key elements:

1. Project proposal review

   The purpose of the project proposal is to enable assessment of the quality of, and justification for, the study, work or activity.

   Project proposals, or significant amendments to these, should be reviewed and approved prior to commencement of the work. The proposal should identify the person with primarily responsibility for the project and should include a description of the following elements, where relevant:

   a) the scientific or educational aims, including consideration of the relevance of the experiment to human or animal health or *welfare*, the environment, or the advancement of biological knowledge;

   b) an informative, non-technical (lay) summary may enhance understanding of the project and facilitate the ethical review of the proposal by allowing full and equitable participation of members of the oversight body or committees who may be dealing with matters outside their specific field. Subject to safeguarding confidential information, such summaries may be made publicly available;

   c) the experimental design, including justification for choice of species, source and number of *animals*, including any proposed reuse;

   d) the experimental procedures;

   e) methods of handling and restraint and consideration of refinements such as animal training and operant conditioning;

   f) the methods to avoid or minimise pain, discomfort, distress, suffering or lasting impairment of physical or physiological function, including the use of anaesthesia and/or analgesia and other means to limit discomfort such as warmth, soft bedding and assisted feeding;

   g) application of humane endpoints and the final disposition of *animals*, including methods of euthanasia;

   h) consideration of the general health, husbandry and care of the species proposed to be used, including environmental enrichment and any special housing requirements;

i) ethical considerations such as the application of the Three Rs and a harm/benefit analysis; the benefits should be maximised and the harms, in terms of pain and distress, should be minimised;

j) an indication of any special health and safety risks; and

k) resources/infrastructure necessary to support the proposed work (e.g. facilities, equipment, staff trained and found competent to perform the procedures described in the proposed project).

The oversight body has a critical responsibility in determining the acceptability of project proposals, taking account of the *animal welfare* implications, the advancement of knowledge and scientific merit, as well as the societal benefits, in a risk-based assessment of each project using live animals.

Following approval of a project proposal, consideration should be given to implementing an independent (of those managing the projects) oversight method to ensure that animal activities conform with those described in the approved project proposal. This process is often referred to as post approval monitoring. Such monitoring may be achieved through animal observations made during the conduct of routine husbandry and experimental procedures; observations made by the veterinary staff during their rounds; or by inspections by the oversight body, which may be the local committee, *animal welfare* officer, compliance/quality assurance officer or government inspector.

l) the duration of approval of a project should normally be defined and progress achieved should be reviewed in considering renewal of a project approval.

2. Facility inspection

There should be regular inspections of the facilities, at least annually. These inspections should include the following elements:

a) the *animals* and their records, including cage labels and other methods of animal identification;

b) husbandry practices;

c) maintenance, cleanliness and security of the facility;

d) type and condition of caging and other equipment;

e) environmental conditions of the *animals* at the cage and room level;

f) procedure areas such as surgery; necropsy and animal research laboratories;

g) support areas such as washing equipment; animal feed, bedding and drug storage locations;

h) occupational health and safety concerns.

Principles of *risk management* should be followed when determining the frequency and nature of inspections.

Annex X (contd)

3. Ethical evaluation

The ethical evaluation reflects the policies and practices of the institution in complying with regulations and relevant guidance. It should include consideration of the functioning of the local committee; training and competency of staff; veterinary care; husbandry and operational conditions, including emergency plans; sourcing and final disposition of *animals*; and occupational health and safety. The programme should be reviewed regularly. A requirement for the components of such a programme should be included in relevant regulations to empower the *Competent Authority* to take appropriate action to ensure compliance.

Article 7.8.5.

Assurance of training and competency

An essential component of the animal care and use programme is the assurance that the personnel working with the *animals* are appropriately trained and competent to work with the species used and the procedures to be performed, including ethical considerations. A system (institutional, regional or national) to assure competency should be in place, which includes supervision during the training period until competence has been demonstrated. Continuing professional and paraprofessional educational opportunities should be made available to relevant staff. Senior management, given their overarching responsibility for the animal care and use programme, should be knowledgeable about issues related to the competence of staff.

1. Scientific staff

Researchers using *animals* have a direct ethical and legal responsibility for all matters relating to the *welfare* of the *animals* in their care. Due to the specialised nature of animal research, focused training should be undertaken to supplement educational and experiential backgrounds of scientists (including visiting scientists) before initiating a study. Focused training may include such topics as the national and/or local regulatory framework and institutional policies. The laboratory *animalveterinarian* is often a resource for this and other training. Scientific staff should have demonstrated competency in procedures related to their research (e.g. surgery, anaesthesia, sampling and administration, etc.).

2. Veterinarians

It is important that *veterinarians* working in an animal research environment have veterinary medical knowledge and experience in the species used. Furthermore, they should be educated and experienced in the normal behaviour, behavioural needs, stress responses and adaptability of the species, as well as research methodologies. Relevant approvals issued by the *veterinary statutory body* and appropriate national or regional schemes (where these exist) should be adopted as the reference for veterinary training.

3. Animal care staff

Animal care staff should receive training that is consistent with the scope of their work responsibilities and have demonstrated competency in the performance of these tasks.

4. Students

Students should learn scientific and ethical principles using non-animal methods (videos, computer models, etc.) when such methods can effectively reduce or replace the use of live *animals* and still meet learning objectives. Wherever it is necessary for students to participate in classroom or research activities involving live *animals*, they should receive appropriate supervision in the use of *animals* until such time that they have demonstrated competency in the related procedure(s).

5. Members of the local oversight committee or others involved with oversight

Continuing education about the use of *animals* in research and education, including associated ethics, regulatory requirements and their institutional responsibility, should be provided.

Occupational health and safety training for research animal related risks should be provided as part of the assurance of training and competency for personnel. This might include consideration of human infectious *diseases* which may infect research *animals* and thus compromise research results, as well as possible *zoonoses*. Personnel should understand that there are two categories of hazards, those that are intrinsic to working in an animal facility and those associated with the research. Specific training may be required for particular species, for specific procedures, and for the use of appropriate protective measures for personnel who may be exposed to animal allergens. Research materials, such as chemicals of unknown toxicity, biological agents and radiation sources, may present special hazards.

Article 7.8.6.

Provision of veterinary care

Adequate veterinary care includes responsibility for promoting an *animal*'s health and *welfare* before, during and after research procedures and providing advice and guidance based on best practice. Veterinary care includes attention to the physical and behavioural status of the *animal*. The *veterinarian* should have authority and responsibility for making judgements concerning *animal welfare*. Veterinary advice and care should be available at all times. In exceptional circumstances, where species unfamiliar to the veterinarian are involved, a suitably qualified non-veterinary expert may provide advice.

1. Clinical responsibilities

Preventive medicine programmes that include vaccinations, ectoparasite and endoparasite treatments and other disease control measures should be initiated according to currently acceptable veterinary medical practices appropriate to the particular animal species and source. Disease surveillance is a major responsibility of the *veterinarian* and should include routine monitoring of colony *animals* for the presence of parasitic, bacterial and viral agents that may cause overt or sub clinical *diseases*. The *veterinarian* should have the authority to use appropriate treatment or control measures, including euthanasia if indicated, and access to appropriate resources, following diagnosis of an animal *disease* or injury. Where possible, the *veterinarian* should discuss the situation with the scientist to determine a course of action consistent with experimental goals. Controlled drugs prescribed by the veterinary staff should be managed in accordance with applicable regulations.

2. Post-mortem examinations

In the case of unexpected *diseases* or *deaths*, the *veterinarian* should provide advice based on post-mortem examination results. As part of health monitoring, a planned programme of post-mortem examinations may be considered.

3. Veterinary medical records

Veterinary medical records, including post-mortem records, are considered to be a key element of a programme of adequate veterinary care for *animals* used in research and education. Application of performance standards within the veterinary medical record programme allows the *veterinarian* to effectively employ professional judgment, ensuring that the *animal* receives the highest level of care available.

Annex X (contd)

4. Advice on zoonotic risks and notifiable diseases

The use of some species of *animals* poses a significant risk of the transmission of zoonotic *disease* (e.g. some nonhuman primates). The *veterinarian* should be consulted to identify sources of *animals* that minimise these risks and to advice on measures that may be taken in the animal facility to minimise the risk of transmission (e.g. personal protective equipment, appropriate *désinfection* procedures, air pressure differentials in animal holding rooms, etc.). *Animals* brought into the institution may carry *diseases* that require notification to government officials. It is important that the *veterinarian* be aware of, and comply with, these requirements.

5. Advice on surgery and postoperative care

A programme of adequate veterinary care includes input into the review and approval process of preoperative, surgical and postoperative procedures by an appropriately qualified *veterinarian.* A *veterinarian*'s inherent responsibility includes providing advice concerning preoperative procedures, aseptic surgical techniques, the competence of staff to perform surgery and the provision of postoperative care. Veterinary oversight should include the detection and resolution of emerging patterns of surgical and post procedural complications.

6. Advice on analgesia, anaesthesia and euthanasia

Adequate veterinary care includes providing advice on the proper use of anaesthetics, analgesics, and methods of euthanasia.

7. Advice on humane endpoints

Humane endpoints should be established prior to commencement of a study in consultation with the *veterinarian* who also plays an important role in ensuring that approved humane endpoints are followed during the course of the study. It is essential that the *veterinarian* has the authority to ensure euthanasia or other measures are carried out as required to relieve pain and distress unless the project proposal approval specifically does not permit such intervention on the basis of the scientific purpose and the ethical evaluation.

Ideal humane endpoints are those that can be used to end a study before the onset of pain and/or distress, without jeopardising the study's objectives. In consultation with the *veterinarian*, humane endpoints should be described in the project proposal and, thus, established prior to commencement of the study. They should form part of the ethical review. Endpoint criteria should be easy to assess over the course of the study. Except in rare cases, *death* (other than euthanasia) as a planned endpoint is considered ethically unacceptable.

Article 7.8.7.

Source of animals

Animals to be used for research should be of high quality to ensure the validity of the data.

1. Animal procurement

Animals should be acquired legally. It is preferable that *animals* are purchased from recognised sources producing or securing high quality *animals*. The use of *wild* caught nonhuman primates is strongly discouraged.

Purpose bred *animals* should be used whenever these are available and *animals* that are not bred for the intended use should be avoided unless there is compelling scientific justification or are the only available and suitable source. In the case of farm *animals*, non traditional breeds and species, and *animals* captured in the *wild*, non purpose bred *animals* are often used to achieve specific study goals.

2. Documentation

Relevant documentation related to the source of the *animals*, such as health and other veterinary certification, breeding records, genetic status and animal identification, should accompany the *animals*.

3. Animal health status

The health status of *animals* can have a significant impact on scientific outcomes. There also may be occupational health and safety concerns related to animal health status. *Animals* should have appropriate health profiles for their intended use. The health status of *animals* should be known before initiating research.

4. Genetically defined animals

A known genetic profile of the *animals* used in a study can reduce variability in the experimental data resulting from genetic drift and increase the reproducibility of the results. Genetically defined *animals* are used to answer specific research questions and are the product of sophisticated and controlled breeding schemes which should be validated by periodic genetic monitoring. Detailed and accurate documentation of the colony breeding records should be maintained.

5. Genetically altered (also genetically modified or genetically engineered) or cloned animals

A genetically altered *animal*~~s~~ is one that has had undergone genetic modification of its nuclear or mitochondrial genomes through a deliberate human intervention, or the progeny of such an *animal*(s), where they have inherited the modification. If genetically altered or cloned *animals* are used, such use should be conducted in accordance with relevant regulatory guidance. With such *animals*, as well as harmful mutant lines arising from spontaneous mutations and induced mutagenesis, consideration should be given to addressing and monitoring special husbandry and *welfare* needs associated with abnormal phenotypes. Records should be kept of biocontainment requirements, genetic and phenotypic information, and individual identification, and be communicated by the animal provider to the recipient. Archiving and sharing of genetically altered lines is recommended to facilitate the sourcing of these customised *animals*.

6. Animals captured in the *wild*

If *wild animals* are to be used, the capture technique should be humane and give due regard to human and animal health, *welfare* and safety. Field studies have the potential to cause disturbance to the habitat thus adversely affecting both target and non-target species. The potential for such disturbance should be assessed and minimised. The effects of a series of stressors, such as trapping, handling, transportation, sedation, anaesthesia, marking and sampling, can be cumulative, and may produce severe, possibly fatal, consequences. An assessment of the potential sources of stress and management plans to eliminate or minimise distress should form part of the project proposal.

Annex X (contd)

7. Endangered species

Endangered species should only be used in exceptional circumstances where there is strong scientific justification that the desired outcomes cannot be achieved using any other species.

8. Transport, importation and exportation

Animals should be transported under conditions that are appropriate to their physiological and behavioural needs and ~~microbiological~~ pathogen free status, with care to ensure appropriate physical containment of the *animals* as well as exclusion of contaminants. The amount of time *animals* spend on a journey should be kept to a minimum. It is important to ensure that there is a well constructed journey plan, with key staff identified who have responsibility for the *animals* and that relevant documentation accompanies *animals* during transport to avoid unnecessary delays during the journey from the sender to the receiving institution.

9. Risks to biosecurity

In order to minimise the risk of contamination of *animals* with unwanted infectious microorganisms or parasites that may compromise the health of *animals* or make them unsuitable for use in research, the microbiological status of the *animals* should be determined and regularly assessed. Appropriate biocontainment and bioexclusion measures should be practised to maintain their health status and, if appropriate, measures taken to prevent their exposure to certain human or environmental commensals.

Article 7.8.8.

Physical facility and environmental conditions

A well-planned, well-designed, well-constructed, and properly maintained facility should include animal holding rooms as well as areas for support services such as for procedures, surgery and necropsy, cage washing and appropriate storage. An animal facility should be designed and constructed in accordance with all applicable building standards. The design and size of an animal facility depend on the scope of institutional research activities, the *animals* to be housed, the physical relationship to the rest of the institution, and the geographic location. For indoor housing, non-porous, non-toxic and durable materials should be used which can be easily cleaned and sanitised. *Animals* should normally be housed in facilities designed for that purpose. Security measures (e.g. locks, fences, cameras, etc.) should be in place to protect the *animals* and prevent their escape. For many species (e.g. rodents), environmental conditions should be controllable to minimise physiological changes which may be potentially confounding scientific variables and of *welfare* concern.

Important environmental parameters to consider include ventilation, temperature and humidity, lighting and noise:

1. Ventilation

The volume and physical characteristics of the air supplied to a room and its diffusion pattern influence the ventilation of an *animal*'s primary enclosure and are thus important determinants of its microenvironment. Factors to consider when determining the air exchange rate include range of possible heat loads; the species, size, and number of *animals* involved; the type of bedding or frequency of cage changing; the room dimensions; and the efficiency of air distribution from the secondary to the primary enclosure. Control of air pressure differentials is an important tool for biocontainment and bioexclusion.

2. Temperature and humidity

Environmental temperature is a physical factor which has a profound effect on the *welfare* of *animals*. Typically, animal room temperature should be monitored and controlled. The range of daily fluctuations should be appropriately limited to avoid repeated demands on the *animals*' metabolic and behavioural processes to compensate for large changes in the thermal environment as well as to promote reproducible and valid scientific data. Relative humidity may also be controlled where appropriate for the species.

3. Lighting

Light can affect the physiology, morphology and behaviour of various *animals*. In general, lighting should be diffused throughout an animal holding area and provide appropriate illumination for the *welfare* of the *animals* while facilitating good husbandry practices, adequate inspection of *animals* and safe working conditions for personnel. It may also be necessary to control the light/dark cycle.

4. Noise

Separation of human and animal areas minimises disturbance to animal occupants of the facility. Noisy *animals*, such as dogs, pigs, goats and nonhuman primates, should be housed in a manner which ensures they do not adversely affect the *welfare* of quieter *animals*, such as rodents, rabbits and cats. Consideration should be given to insulating holding rooms and procedure rooms to mitigate the effects of noise sources. Many species are sensitive to high frequency sounds and thus the location of potential sources of ultrasound should be considered.

Article 7.8.9.

Husbandry

Good husbandry practices enhance the health and *welfare* of the *animals* used and contributes to the scientific validity of animal research. Animal care and accommodation should, as a minimum, demonstrably conform to relevant published animal care, accommodation and husbandry guidelines and regulations.

The housing environment and husbandry practices should take into consideration the normal behaviour of the species, including their social behaviour and age of the *animal*, and should minimise stress to the *animal*. During the conduct of husbandry procedures, personnel should be keenly aware of their potential impact on the *animals*' *welfare*.

1. Transportation

~~Transportation is a typically stressful experience. Therefore, every precaution should be taken to avoid unnecessary stress through inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. Consignments of *animals* should be accepted into the facility without avoidable delay and, after inspection, should be transferred to clean cages or pens and be supplied with feed and water as appropriate. Social *animals* should be transported, where appropriate, in established pairs or groups and maintained in these on arrival.~~ See Article 7.8.10.

2. Acclimatisation

Newly received *animals* should be given a period for physiological and behavioural stabilisation before their use. The length of time for stabilisation will depend on the type and duration of transportation, the age and species involved, place of origin, and the intended use of the *animals*. Facilities should be available to isolate *animals* showing signs of ill health.

Annex X (contd)

3. Cages and pens

Cages and pens should be made out of material that can be readily cleaned and decontaminated. Their design should be such that the *animals* are unlikely to injure themselves. Space allocations should be reviewed and modified as necessary to address individual housing situations and animal needs (for example, for prenatal and postnatal care, obese *animals*, and group or individual housing). Both the quantity and quality of space provided is important. Whenever it is appropriate, social *animals* should be housed in pairs or groups, rather than individually, provided that such housing is not contraindicated by the protocol in question and does not pose an undue risk to the *animals*.

4. Enrichment

Animals should be housed with a goal of maximising species appropriate behaviours and avoiding or minimising stress induced behaviours. One way to achieve this is to enrich the structural and social environment of the *animals* and to provide opportunities for physical and cognitive activity. Such provision should not compromise the health and safety of the *animals* or people, nor interfere with the scientific goals.

5. Feeding

Provision should be made for each *animal* to have access to feed to satisfy its physiological needs. Precautions should be taken in packing, transporting, storing and preparing feed to avoid chemical, physical and microbiological contamination, deterioration or destruction. Utensils used for feeding should be regularly cleaned and, if necessary, sterilised.

6. Water

Uncontaminated potable drinking water should normally be available at all times. Watering devices, such as drinking tubes and automatic watering systems, should be checked daily to ensure their proper maintenance, cleanliness, and operation.

7. Bedding

Animals should have appropriate bedding provided, with additional nesting material if appropriate to the species. Animal bedding is a controllable environmental factor that can influence experimental data and *animal welfare*. Bedding should be dry, absorbent, non-dusty, non-toxic and free from infectious agents, vermin or chemical contamination. Soiled bedding should be removed and replaced with fresh material as often as is necessary to keep the animals clean and dry.

8. Hygiene

The successful operation of a facility depends very much on good hygiene. Special care should be taken to avoid spreading infection between animals through fomites, including through personnel traffic between animal rooms. Adequate routines and facilities for the cleaning, washing, decontamination and, when necessary, sterilisation of cages, cage accessories and other equipment should be established. A very high standard of cleanliness and organisation should also be maintained throughout the facility.

9. Identification

Animal identification is an important component of record keeping. Animals may be identified individually or by group. Where it is desirable to individually identify animals, this should be done by a reliable and the least painful method.

10. Handling

Staff dealing with *animals* should have a caring and respectful attitude towards the *animals* and be competent in handling and restraint. Familiarising *animals* to handling during routine husbandry and procedures reduces stress both to *animals* and personnel. For some species, for example dogs and non-human primates, a training programme to encourage cooperation during procedures can be beneficial to the *animals*, the animal care staff and the scientific programme. For certain species, social contact with humans should be a priority. However, in some cases handling should be avoided. This may be particularly the case with *wild animals*. Consideration should be given to setting up habituation and training programmes suitable for the *animals*, the procedures and length of projects.

Article 7.8.10.

Transportation

Transportation is a typically stressful experience for *animals*. Therefore, every precaution should be taken to avoid unnecessary stress through inadequate ventilation, exposure to extreme temperatures, lack of feed and water, long delays, etc. In addition, *animals* should be transported under conditions and in *containers* that are appropriate to their physiological and behavioural needs and pathogen free status, with care to ensure appropriate physical containment and safety of the *animals*.

1. The source of *animals* and therefore the mode and conditions of *transport* should be considered in the project proposal review described in point 1 c) of Article 7.8.4.

   a) The consigner and consignee should coordinate the method, route and duration of *transport* with emphasis on the potential impact on the health and *welfare* of the *animal(s)*.

   b) The potential for delays in transportation should be anticipated and avoided.

2. The documentation required to accomplish international *transport* should be based on the OIE Model Veterinary Certificate for International Trade in Laboratory Animals (Chapter 5.13.):

   a) There should be assurance that complete, relevant and legible documentation accompanies *animals* during *transport* to avoid unnecessary delays during the *journey* from the sender to the receiving institution.

   b) Electronic certificates should be implemented, wherever possible.

3. There should be a well defined *journey* plan, commencing from the point when *animals* are placed in their *containers* until they are removed from the *containers* at their final destination:

   a) The *journey* plan should be designed so that the time in transit is the shortest possible and most comfortable for the *animal*. Where *journeys* of some distance are involved, this is often best achieved through air transport, preferably by direct routes.

   b) Key staff should be identified who have responsibility for the *animals* and have the authority for making decisions in unforseen circumstances. Such staff should be contactable at all times.

Annex X (contd)

c) The *journey* plan should be under the general oversight of a *veterinarian*, knowledgeable and experienced in the biology and needs of the particular species. The following should specifically be addressed by the *veterinarian*:

i) Some *animals* (e.g. genetically altered animals) may have special requirements that should be addressed in the *journey* plan.

ii) Issues of biosecurity and bioexclusion (e.g. through *container* design and handling) should be addressed in the *journey* plan.

4)

a) Consignments of *animals* should be accepted into the facility without avoidable delay and, after inspection, should be removed from their *containers* under conditions compatible with their pathogen free status.

b) They should then be transferred to clean cages or pens and be supplied with feed and water as appropriate.

c) Where compatible, social *animals* should be transported in established pairs or groups and maintained in these on arrival.

5. In accordance with OIE Chapters 7.2 to 7.4 and IATA regulations, an appropriate environment (e.g. *container* design and construction, temperature, food, and water) should be provided to the *animal* throughout the planned *journey*. Adequate supplies of food, water and bedding should be provided to accommodate a delay of at least 24 hours.

6. Personnel handling *animals* throughout the planned *journey* should be trained in the basic needs of *animals* and in good handling practices to facilitate the *loading* and *unloading* of *animals*.

— Text deleted

Annex XI

CHAPTER 5.13.

MODEL VETERINARY CERTIFICATE FOR INTERNATIONAL TRADE IN LABORATORY ANIMALS

Article 5.13.1.

Introduction and scope

Transportation of laboratory animals between institutes is a specialised and important activity supporting scientific research. The use, and transportation, of laboratory animals is essential to some types of medical and veterinary research.

The majority of laboratory animals used and transported are rats, mice, and fish. Other species, including guinea pigs, gerbils, hamsters, rabbits, cats, dogs, pigs, amphibians, and a few species of non-human primates are used in relatively small numbers.

This chapter applies to all *animals* except bees.

Article 5.13.2.

Notes for guidance on the use of the veterinary certificate

1. General

   The certificate should be completed in capital letters to ensure legibility. To confirm an option, mark the box with a cross (X). No portion of the certificate should be left blank in a manner that would allow unauthorised amendment. Non-applicable fields should be deleted with a line through the text. Information provided on the certificate should be correct at the time of issuance of the certificate.

2. Part I. Details of consignment for export

Country:	Name of the country issuing the certificate.
Box I.1.	Name and full address of the natural or legal person dispatching the consignment. It is recommended to provide contact information, such as telephone and fax numbers or e-mail address.
Box I.2.	The certificate reference number used by the Veterinary Authority of the country issuing the certificate.
Box I.3.	Name of the Veterinary Authority.
Box I.4.	Name and full address of the natural or legal person to whom the consignment is destined.

Annex XI (contd)

Box I.5.	Name of the country from which the consignment is being exported. It is also recommended to provide the country's International Standards Organization code – see http://www.iso.org/iso/english_country_names_and_code_elements.
Box I.6.	Name of the zone or compartment of origin, if given in part III of the certificate (in accordance with Chapter 4.3. of the *Terrestrial Code*).
Box I.7.	Name of the country of destination. It is also recommended to provide the International Standards Organization (ISO) code for the country – see http://www.iso.org/iso/english_country_names_and_code_elements.
Box I.8.	Name of the zone or compartment of destination, if given in part III of the certificate (in accordance with Chapter 4.3 of the *Terrestrial Code*).
Box I.9.	Name and full address of the place(s) from which the animals are being exported; and official approval or registration number when required.
Box I.10.	Name of the air, land or sea facility from which the consignment is being shipped.
Box I.11.	Date of departure and, if known, expected time of departure.
Box I.12.	Identify the means of transport if known at the time of issuance of the certificate. The flight number, airline and airport designation (for air transport). The name and address of the carrier (for road transport).
Box I.13.	Name of border post to which the consignment is directed. It is also recommended to provide the border post's United Nations Code for Trade and Transport Locations – see http://live.unece.org/cefact/locode/service/location.html
Box I.14.	If the species is listed in the Convention on International Trade in Endangered Species of *Wild* Fauna and Flora (CITES), provide permit number(s).
Box I.15.	Description of animals. World Customs Organization HS Code, if known, see: www.wcoomd.org.
Box I.16.	Total number of animals.

Box I.17.	Temperature around the shipping container should generally be maintained in the range 10–28°C during shipment. For animals with different requirements, the specific temperature range should be listed here.
Box I.18.	The total number of units (e.g. boxes, cages or stalls) in which the animals in the consignment are being transported.
Box I.19.	Identification of the containers and seal numbers, if provided.
Box I.20.	Details of the nature of the animals. Provide: species (scientific name); identification system; identification number or other relevant details; quantity and, if required, strain/stock designation, sex, and age or weight. When available, international designation conventions should be used, see for example: http://www.informatics.jax.org/mgihome/nomen/strains.shtml http://www.informatics.jax.org/mgihome/nomen/gene.shtml . For animals with an official international animal passport, the passport number should also be provided.

3. Part II. Classification of pathogen free status

Box II.	Conventional animals are those for which the presence or absence of specific microorganisms and parasites is unknown due to the absence of testing, treatment or vaccination. This category includes *wild*-caught animals and domestic animals maintained under uncontrolled microbiological conditions. Specific Pathogen Free (SPF) animals are free of one or more parasites or infectious microorganisms. SPF animals can be further subdivided into two categories: a) Conditioned SPF animals have undergone testing, treatment and/or vaccination to ensure the absence of one or more parasites or microbial agents. The agents are most commonly of human or agricultural significance or are species-specific infectious agents that are capable of producing significant clinical disease or research effects. Conditioned SPF animals are often not maintained in specialised housing to prevent introduction of other infectious agents and are usually shipped in unfiltered containers. Larger species such as nonhuman primates, dogs, and cats are often maintained as conditioned SPF animals.

Annex XI (contd)

Box II. (contd)	b) Barrier raised SPF animals have been raised in the absence of one or more parasites or microbial agents in specialised facilities to exclude these agents as well as agents of agricultural and human significance. Their pathogen free status has been established either by testing each individual animal or by sampling representative animals from the colony. Filtered SPF shipping containers are required for transport of these animals as are special procedures and equipment for packing, unpacking, and handling them. This subcategory also includes animals that are either axenic (microbe free) or posses only a few well defined species of microorganisms. They must be produced and maintained in a sterile environment (usually isolators) without contact with human, animal, or environmental commensal infectious microorganisms.

4. Part III. Zoosanitary information

Box III.	Complete this part in accordance with the requirements agreed between the Veterinary Authorities of the importing and exporting countries in accordance with the recommendations in the *Terrestrial Code*. Attestation of fitness for transportation subject to any conditions or special requirements stated in the certificate.
Box III.a.	Certificate reference number: see box I.2.
Official veterinarian	Name, address, official position, date of signature and official stamp of the Veterinary Services for the country of export.

Article 5.13.3.

Model veterinary certificate for international trade in laboratory animals

COUNTRY:

<table>
<tr><td rowspan="11">Part I: Details of dispatched consignment</td><td>I.1. Consignor:
Name:

Address:</td><td>I.2. Certificate reference number:

I.3. Veterinary Authority:</td></tr>
<tr><td colspan="2">I.4. Consignee:
Name:

Address:</td></tr>
<tr><td>I.5. Country of origin: ISO code*</td><td>I.6. Zone or compartment of origin**:</td></tr>
<tr><td>I.7. Country of destination: ISO code*</td><td>I.8. Zone or compartment of destination**:</td></tr>
<tr><td colspan="2">I.9. Place of origin:
Name:

Address:</td></tr>
<tr><td>I.10. Place of shipment:</td><td>I.11. Date of departure:</td></tr>
<tr><td rowspan="2">I.12. Primary means of transport:

Relevant details

Aeroplane ☐

Road vehicle ☐

Vessel ☐</td><td>I.13. Expected border post:</td></tr>
<tr><td>I.14. CITES permit No(s)**:</td></tr>
<tr><td>I.15. Description of animals:

*HS Code if known :</td><td>I.16. Total number of animals:</td></tr>
<tr><td>I.17. Temperature</td><td>I.18. Total number of units:</td></tr>
<tr><td>I.19. Identification of container/seal number:</td><td></td></tr>
<tr><td colspan="2">I.20. Details of the nature of the animals and quantity of each:

Species (Scientific name) Identification system

Identification number/details

Strain/Stock (use international designation if known)* Passport number(s) if issued *

Age or Weight

Sex</td></tr>
</table>

* Optional
** If referenced in Part III.

Annex XI (contd)

COUNTRY:

. Zoosanitary information		II.a. Certificate reference number:
	II Pathogen Free Status Conventional □ Conditioned SPF □ Barrier raised SPF □ Other – specify □ III. Fitness for transportation The undersigned Official Veterinarian certifies that the consignment described above is fit for transport, subject to any conditions specified below, and that the animals satisfy the following zoosanitary requirements: Special conditions for transport: YES ☐ NO ☐ If there are special conditions for transport, provide complete information of these conditions. Name and address (in capital letters): Official position: Date: Signature: Stamp:	

r

Annex XII

CHAPTER 7.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR ANIMAL WELFARE

Article 7.1.1.

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

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

Article 7.1.2.

Guiding principles for animal welfare

1. That there is a critical relationship between animal health and *animal welfare*.

2. That the internationally recognised 'five freedoms' (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and *disease*; and freedom to express normal patterns of behaviour) provide valuable guidance in *animal welfare*.

3. That the internationally recognised 'three Rs' (reduction in numbers of *animals*, refinement of experimental methods and replacement of *animals* with non-animal techniques) provide valuable guidance for the use of *animals* in science.

4. That the scientific assessment of *animal welfare* involves diverse elements which need to be considered together, and that selecting and weighing these elements often involves value-based assumptions which should be made as explicit as possible.

5. That the use of *animals* in agriculture, education and science, and for companionship, recreation and entertainment, makes a major contribution to the wellbeing of people.

6. That the use of *animals* carries with it an ethical responsibility to ensure the *welfare* of such *animals* to the greatest extent practicable.

7. That improvements in farm *animal welfare* can often improve productivity and food safety, and hence lead to economic benefits.

8. That equivalent outcomes based on performance criteria, rather than identical systems based on design criteria, be the basis for comparison of *animal welfare* standards and recommendations.

Annex XII (contd)

Article 7.1.3.

Scientific basis for recommendations

1. *Welfare* is a broad term which includes the many elements that contribute to an *animal*'s quality of life, including those referred to in the 'five freedoms' listed above.

2. The scientific assessment of *animal welfare* has progressed rapidly in recent years and forms the basis of these recommendations.

3. Some measures of *animal welfare* involve assessing the degree of impaired functioning associated with injury, *disease*, and malnutrition. Other measures provide information on *animals*' needs and affective states such as hunger, pain and fear, often by measuring the strength of *animals*' preferences, motivations and aversions. Others assess the physiological, behavioural and immunological changes or effects that *animals* show in response to various challenges.

4. Such measures can lead to criteria and indicators that help to evaluate how different methods of managing *animals* influence their *welfare*.

Article 7.1.4.

General principles for the welfare of animals in livestock production systems

1. Genetic selection should promote the health and *welfare* of *animals*. Breeds of *animals* should be introduced only into environments to which they are genetically suited.

2. The physical environment, including the substrate (walking surface, resting surface, etc.), should be suited to the species so as not to cause injury or transmit *diseases* or parasites to *animals*.

3. The physical environment should allow comfortable resting, safe and comfortable movement including normal postural changes, and the opportunity to perform types of natural behaviour that *animals* are motivated to perform.

4. Social grouping of *animals* should allow positive social behaviour and not cause injury or chronic fear.

5. Air quality in confined spaces should support good animal health and not be aversive to *animals*. The temperature and humidity of the environment should be within the *animals*' ability to adapt. Where extreme conditions occur, *animals* should not be prevented from using their natural methods of thermo-regulation.

6. *Animals* should have access to sufficient food and water, suited to the *animals*' age and needs, to maintain normal health and vigour and to prevent serious or prolonged hunger, thirst, malnutrition or dehydration.

7. *Diseases* and parasites should be prevented as much as possible through good management practices. *Animals* with serious health problems should be isolated and treated promptly or killed humanely if treatment is not feasible or recovery is unlikely.

8. Where painful procedures cannot be avoided, the resulting pain should be managed as much as available methods and economic constraints allow.

9. The handling of *animals* should foster a positive human animal relationship and should not cause injury, panic, lasting fear or avoidable stress.

10. Owners and handlers should have sufficient skill and knowledge to ensure that *animals* are treated in accordance with these principles.

Annex XIII

DRAFT CHAPTER 7.X.

ANIMAL WELFARE AND BEEF CATTLE PRODUCTION SYSTEMS

Article 7.X.1.

Definitions

~~The *ad hoc* Group discussed the application of the OIE recommendations and decided that these should be designed with application to commercial beef production.~~ Beef cattle production systems are defined as all commercial cattle productions systems where the purpose of the operation includes some or all of the breeding, rearing and finishing of cattle intended for beef consumption.

Article 7.X.2.

Scope

~~The first priority is to~~ This chapter addresses the on-farm aspects of ~~the~~ beef cattle production systems, from birth through to finishing. The areas of emphasis are cows with calves ~~cow- calf~~, rearing, stocker~~s~~ or store cattle and finishing beef production. This scope does not include veal production.

Article 7.X.3.

Commercial beef cattle production systems

Commercial beef cattle production systems include:

1. Intensive ~~(stocker and finishing)~~

   These are systems where ~~Would include~~ cattle are in ~~that are place on~~ confinement and are fully dependent on humans to provide for basic animal needs such as food~~. Animals are depending on the daily animal husbandry for provision of feed,~~ shelter and water on a daily basis.

2. Extensive ~~(all areas)~~

   ~~Would include from a wide range grazing habitat.~~ These are systems where animals have the freedom to roam outdoors, and where the animals have some autonomy over diet selection (through grazing), water consumption and access to shelter.

3. Semi Intensive ~~(mixed)~~

   ~~Would include a combination of intensive and extensive systems.~~ These are systems where animals are exposed to any combination of both intensive and extensive husbandry methods, either simultaneously, or varied according to changes in climatic conditions or physiological state of the animals.

Annex XIII (contd)

Article 7.X.4.

Criteria or measurables for the welfare of beef cattle

The following outcome ~~(animal)~~ based measurables, specifically animal based measurables, can be useful indicators of *animal welfare*. The use of these indicators and the appropriate thresholds should be adapted to the different situations where beef cattle are managed.

1. Behaviour

   Certain behaviours could indicate an *animal welfare* problem. These include anorexia, increased respiratory rate or panting (assessed by panting score), and the demonstration of stereotypic behaviours.

2. Morbidity rates

   Morbidity rates, such as disease, lameness, post-procedural complication and injury rates, above recognised thresholds can be direct or indirect indicators of the *animal welfare* status. Understanding the aetiology of the disease or syndrome is important for detecting potential *animal welfare* problems. Scoring systems, such as lameness scoring can provide additional information.

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

3. Mortality rates

   Mortality rates, like morbidity rates, could be direct or indirect indicators of the *animal welfare* situation. Depending on the production system, estimates of mortality rates can be obtained by analysing causes of death and the rate and temporo-spatial pattern of mortality. Mortality rates can be reported daily, monthly, annually or with reference to key husbandry activities within the production cycle.

4. Changes in weight ~~gain~~ and body condition score

   In growing animals, weight gain could be an indicator of animal health and *animal welfare*. Poor body condition score and significant weight loss could be an indicator of compromised welfare in mature cattle.

5. ~~reproductive rates~~ Reproductive efficiency

   Reproductive efficiency can be an indicator of animal health and *animal welfare* situation. Poor reproductive performance can indicate *animal welfare* problems. Examples may include:

   – anoestrus or extended post-partum interval

   – low conception rates

   – high abortion rates

   – high rates of dystocia.

6. Physical appearance

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

– presence of ectoparasites

– coat that is rough or excessively soiled with faeces, mud or dirt

– dehydration

– emaciation

– depression.

7. Handling responses

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

– chute exit speed

– chute behaviour score

– percentage of animals falling

– percentage of animals moved with an electric goad

– percentage of animals striking fences or gates

– percentage of animals injured during handling, such as broken horns, broken legs, and lacerations

– percentage of animals vocalizing during restraint

8. Routine procedure management and rate of ~~post procedures~~ complications

Surgical and non-surgical procedures are commonly performed in beef cattle for improving animal performance, facilitating management, and improving human safety and *animal welfare*. However, if these procedures are not performed properly, *animal welfare* can be compromised where complications occur at levels above expected thresholds. Indicators of such problems could include:

– post procedure *infection* and swelling

– myiasis

– mortality.

~~9. post-mortem pathology~~

~~10.survivability.~~

Annex XIII (contd)

Article 7.X.5.

Recommendations

Each recommendation includes a list of relevant outcome-based measurables derived from ~~section~~ Article 7.X.4. This does not exclude other measures being used where appropriate.

1. Biosecurity and Animal Health

a) Biosecurity and disease prevention

Biosecurity means a set of measures designed to ~~protect a herd from~~ maintain a *herd* at a particular health status and to prevent the entry or spread ~~(or exit)~~ of infectious agents.

~~Biosecurity programme s should be implemented, commensurate with the risk of disease~~ Biosecurity ~~programmes~~ plans should be designed and implemented, commensurate with the desired herd health status and current disease risk and, for OIE listed diseases, in accordance with relevant recommendations found in the *Terrestrial Code* ~~chapters on OIE listed diseases.~~

These biosecurity ~~programmes~~ plans should address the control of the major sources and pathways ~~routes for~~ ~~agents~~ for spread of ~~disease and~~ pathogens ~~transmission~~, ~~as follows~~:

i) cattle
ii) other animals
iii) people
iv) equipment
v) vehicles
vi) air
vii) water supply
viii) feed.

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

b) Animal health management

Animal health management ~~is a~~ means a system designed to optimise the physical and behavioural health and *welfare* of the cattle *herd*. It includes the prevention, treatment and control of *diseases* and conditions affecting the *herd*, including the recording of illnesses, injuries, mortalities and medical treatments where appropriate. ~~prevent diseases occurring in cattle herds and also providing treatments for animals when disease occurs.~~

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

Those responsible for the care of cattle should be aware of the signs of ill-health or distress, such as reduced food and water intake, weight gain and body condition, changes in behaviour or abnormal physical appearance.

Cattle ~~with~~ at higher risk ~~for~~ ~~from~~ of *disease* will require more frequent inspection by ~~animal~~ *animal handlers*. If *animal handlers* are not able to correct the causes of ill-health or distress ~~or to correct these~~ or if they suspect the presence of a listed reportable disease they should seek advice from those having training and experience, such as ~~bovine~~ veterinarians or other qualified advisers. ~~Veterinary treatments should be prescribed by a qualified veterinarian.~~

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

Animal handlers should have experience in recognising and dealing with~~caring for~~ ~~downer~~ non-ambulatory cattle. They should also have experience in managing chronically ill or injured animals. ~~Euthanasia on n~~Non-responding ~~cattle should be killed humanely done as soon as recovery is deemed not possible~~ according to Chapter 7.5 of the *Terrestrial Animal Health Code*~~.~~

Non-ambulatory animals should have access to water at all times and be provided with feed at least once daily. They ~~Non-ambulatory animals~~ should not be transported or moved except for treatment or diagnosis. Such ~~Non-ambulatory animals should be moved~~ movement shoud be done ~~very~~ carefully using acceptable methods such as a sled, low-boy trailer or in the bucket of a loader. ~~Animals should be gently rolled on to the conveyance or lifted with a full body support.~~

When treatment is attempted, cattle that are unable to stand up unaided and refuse to eat or drink should be ~~humanely~~ killed humanely according to Chapter 7.5. as soon as recovery is deemed unlikely.

~~Non-ambulatory animals should not be transported according to Article 7.3.7 of the *Terrestrial Code.*~~

Outcome-based measurables: morbidity rate, mortality rate, reproductive efficiency, behaviour, physical appearance and body condition score.

2. Environment

a) Thermal environment

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

i) Heat stress

The risk of heat stress for cattle~~Thermal Heat Index (THI)~~ is influenced by environmental factors including air temperature, relative humidity and wind speed, and animal factors including breed, age, fatness, metabolic rate and coat color. ~~As the THI increases the risk of hyperthermia increases. Also as cattle are fed longer and become fatter are more susceptible to heat stress.~~

Animal handlers should be aware of the critical ~~THI~~ heat stress threshold for their animals. When conditions are ~~the THI is~~ expected to reach this threshold, routine daily ~~processes~~ activities that require moving cattle ~~that include cattle movement~~ should cease. If ~~As~~ the risk of heat stress ~~THI moves into emergency~~ reaches very high levels the *animal handlers* should institute an emergency action plan that could include shade, improved access to drinking water, and cooling by the use of sprinkled~~ing~~ water ~~to~~that penetrates the hair coat.

Outcome-based measurables: behaviour (including panting score and respiratory rate), morbidity rate, mortality rate,

ii) Cold stress

Protection from ~~wind and rain~~ extreme weather conditions should be provided when these conditions are likely to create a serious risk to ~~where possible, particularly for young stock outdoors for the first time~~ the welfare of animals, particularly in neonates and young animals. This could be provided by natural or man made shelter structures.

Animal handlers should also ensure that cattle have access to adequate feed and water during cold stress. During time of heavy snowfall or blizzard, *animal handlers* should institute an emergency action plan to provide cattle with shelter, feed and water.

Outcome-based measurables: Mortality rates, physical appearance, behaviour (including abnormal postures, shivering and huddling).

b) Lighting

Confined cattle that do not have access to natural light should be provided with sufficient supplementary lighting for their health and welfare, to facilitate natural behaviour patterns and to allow adequate inspection of the *animals*.

Outcome-based measurables: Behaviour, morbidity, physical appearance.

c) Air quality

Good air quality is an important factor for the health and *welfare* of cattle ~~in intensive and confined production systems~~. It is a composite variable of air constituents such as gases, dust and micro-organisms that is strongly influenced by how facilities are managed, particularly in intensive systems ~~the management of the beef producer~~. The air composition is influenced by the stocking density, the size of the cattle, flooring, bedding, waste management, building design and ventilation system.

Proper ventilation is important for effective heat dissipation in cattle and preventing the build-up of ~~CO_2~~, NH_3 and effluent gases in the confinement unit. Poor air quality and ventilation are risk factors for respiratory discomfort and *diseases*. The ammonia level in enclosed housing should not exceed 25 ppm.

Outcome-based measurables: Morbidity rate, behaviour, mortality rate, changes in weight and body condition score ~~gain~~.

d) ~~Acoustic environment~~ Noise

Cattle are adaptable to different levels and types of noise ~~acoustics environments~~. However, exposure of cattle to sudden or loud noises should be minimised where possible to prevent stress and fear reactions (e.g. stampede). 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. ~~Other irritating noises should also be taken into consideration, such as dogs barking and other outdoor sounds.~~

Outcome-based measurables: Behaviour.

e) Nutrition

The nutrient requirements of beef cattle have been well defined. Energy, protein, ~~amino acid,~~ mineral and vitamin contents of the diet are major factors determining the growth, feed efficiency, reproductive efficiency, and body composition.

~~*Animal handlers* should provide cattle a level of nutrition that meets or exceeds their maintenance requirements from the previously reference materials.~~ Cattle should be provided with access to an appropriate quantity and quality of balanced nutrition that meets their physiological needs. ~~It should be noted that cattle in certain climates and production systems may experience short term periods of below maintenance nutrition without compromise their welfare.~~ Where cattle are maintained in extensive conditions, short term exposure to climatic extremes may prevent access to nutrition that meets their daily physiological needs. In such circumstances the *animal handler* should ensure that the period of reduced nutrition is not prolonged and that mitigation strategies are implemented if *welfare* is at risk of being compromised.

Animal handlers should have adequate knowledge of appropriate body condition scores for their cattle and should not allow body condition ~~score~~ to ~~drop below~~ fall outside ~~these~~ an acceptable range ~~critical thresholds~~. ~~As a guide, assessing body condition score on a scale of 1 to 5, the target range for acceptable animal health and welfare should be between 2 and 4.~~ In times of severe drought, steps should be taken to avoid starvation of animals wherever possible~~.~~, including supplementary feeding, *slaughter*, sale or relocation of the *animals*, or humane *killing*.

~~In intensive production systems cattle should have access to adequate feed and water supply to meet their physiological needs.~~

Feedstuffs and feed ingredients should be of satisfactory quality to meet nutritional needs. ~~and under certain circumstances (e.g., drought, frost, and flood), should be tested for the presence of substances (e.g. mycotoxins and nitrates) that can be detrimental to cattle health and welfare.~~ Where appropriate, feed and feed ingredients should be tested for the presence of substances that would adversely impact on animal health.

Cattle in intensive production systems typically consume diets that contain a high proportion of grain(s) (corn, milo, barley, grain by-products) and a smaller proportion of roughages (hay, straw, silage, hulls, etc.). Diets with insufficient roughage can contribute to abnormal oral behaviour in finishing cattle, such as tongue rolling. As the proportion of grain increases in the diet, the relative risk of digestive upset in cattle increases. *Animal handlers* should understand the impact of cattle size~~,~~ and age, weather patterns, diet composition and sudden dietary changes in respect to digestive upsets and their negative consequences ~~sequelae~~ (acidosis, bloat, liver abscess, laminitis). Where appropriate beef producers should consult a cattle nutritionist ~~(private consultant, university or feed company employee)~~ for advice on ration formulation and feeding programmes.

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

The water quality and the method of supply can affect welfare. All cattle need adequate supply and access to palatable water that ~~also~~ meets their physiological requirements and free from contaminants ~~potentially~~ hazardous to cattle health.

Outcome-based measurables: Mortality rates, morbidity rates, behaviour, changes in weight ~~gain~~ and body condition scor~~c~~ing, reproductive rates.

f) Flooring, bedding, resting surfaces and outdoor areas ~~(litter quality)~~

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

Pen floor management in intensive production systems can have a significant impact on cattle welfare. Where there are areas that are not suitable for resting (e.g. excessive water / faecal accumulation), these areas should not be of a depth that would compromise *welfare* and should not comprise the whole of usable area available to the cattle.

~~Mud depth should not consistently be deeper than the ankles of cattle in pens.~~

Slopes of pens should be maintained to allow water to run off away from the feed bunks and not pool excessively in the pens.

~~If slope is not sufficient to allow for proper drainage, a mound should be constructed in each pen to allow cattle to have a dry place to lie down.~~

Pens should be ~~thoroughly cleaned after each production cycle as conditions warrant.~~cleaned as conditions warrant and, at a minimum, after each production cycle.

If animals are housed in a slatted floor shed, the slat and gap widths should be appropriate to the hoof size of the animals to prevent injuries.

In straw or other bedding systems, the bedding should be maintained to provide ~~allow~~ animals a dry and comfortable place in which to lie.

Surfaces of concrete alleys should be grooved or appropriately textured to provide adequate footing for cattle.

Outcome-based measurables: Morbidity rates (e.g. lameness, pressure sores), behaviour, changes in weight ~~gain,~~ and body condition score, and physical appearance.

g) Social environment

Management of cattle ~~in outdoor and indoor intensive production systems methods~~ should take into account the social environment ~~of cattle~~ as it relates to *animal welfare*, particularly in intensive systems. Problem areas include: ~~buller~~ agonistic and mounting activity, mixing of heifers and steers, feeding cattle of different size and age in the same pens, insufficient space at the feeder, insufficient water access and mixing of bulls.

~~In the case of buller animals, they should be identified and removed from the pen immediately. Beef producers should utilize management practices to reintroduce these animals. If reintroduction fails these animals will have to housed separately from the pen mates. *Animal handlers* should work to feed cattle of the same size and age in the same pens. Depending on feeding systems, health status of the animals and size of the animals beef producer will need to allow adequate feeder space and water access for the cattle.~~

Management of cattle in all systems should take into account the social interactions of cattle within groups. The *animal handler* should understand the dominance hierarchies that develop within different groups and focus on high risk *animals* (e.g. very young, very old, small or large size for cohort group) for evidence of bullying and excessive mounting behaviour. The *animal handler* should understand the risks of increased agonistic interactions between *animals*, particularly after mixing groups. *Animals* that are suffering from excessive agonistic activity or mounting behaviour should be removed from the group.

Where the mixing of horned and non-horned cattle is likely to increase the risk of injury, these classes of animals should not be mixed.

Adequate fencing should be provided to minimise *any animal welfare* problems that may be caused by mixing of inappropriate groups of cattle.

Outcome-based measurables: Behaviour, physical appearance, changes in weight ~~gain~~ and body condition score, morbidity and mortality rate.

h) Stocking density

High stocking densities may have an adverse effect on growth rate, feed efficiency, ~~survivability,~~ carcass quality and behaviour (e.g. locomotion, resting, feeding and drinking).

~~In extensive outdoors systems stocking density should be managed to ensure an adequate feed supply for the cattle.~~

Stocking density should be managed such that crowding does not adversely ~~impact key components of~~ affect normal behaviour of cattle. This~~ese~~ includes the ability to lie down freely without the risk of injuries, move freely around the pen and access feed and water. Stocking density should also be managed such that weight gain and duration of time spent lying is not adversely affected by crowding. ~~Excessive~~ If tongue rolling ~~can be associated with overcrowding of confined cattle.~~ is seen, measures should be taken such as reducing stocking density.

In extensive systems, stocking density should be managed to ensure an adequate feed supply for the cattle or the cattle should be moved regularly or provided with supplementary feed.

Outcome-based measurables: Behaviour, morbidity rate, mortality rate, changes in weight ~~gain~~ and body condition score, physical appearance.

~~i) Outdoor areas~~

~~Not applicable.~~

i~~t~~) Protection from predators

~~Where practical~~ ~~,~~ cCattle should be protected as much as possible from predators.

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

Annex XIII (contd)

3. Management

a) Genetic selection

Welfare and health considerations, in addition to productivity, should be taken into account when choosing a breed or subspecies for a particular location or production system. Examples of these include nutritional maintenance requirement, ectoparasite resistance and heat tolerance.

Individual animals within breed can be genetically selected to propagate offspring that exhibit ~~the following~~ traits beneficial to animal health and welfare~~:~~. These include ~~M~~maternal ability, ease of calving, birth weight, milking ability, body conformation and temperament.

Outcome-based measurables: Morbidity rate, mortality rate, behaviour, physical appearance, reproductive efficiency.

b) Reproductive management

Dystocia can be a *welfare* risk to beef cattle. Heifers should not be bred before they are physically mature enough to ensure the health and *welfare* of both dam and calf at birth. The sire has a highly heritable effect on final calf size and as such can have a significant impact on ease of calving. Sire selection should therefore account for the maturity and size of the female. Heifers and cows should not be implanted, inseminated or mated in such a way that the progeny results in increased risk to dam and calf *welfare*.

Pregnant cows and heifers should be managed during pregnancy so as not to become too fat or too thin. Excessive fatness increases the risk of dystocia, and both excessive condition gain and loss increase the risk of metabolic disorders during late pregnancy or after parturition.

Where possible, cows and heifers should be monitored when they are close to calving. *Animals* observed to be having difficulty in calving should be assisted by a competent operator as soon as possible after they are detected.

Outcome-based measurables: morbidity rate (rate of dystocia), mortality rate (cow and calf), reproductive efficiency

c) Colostrum

~~Calves are born without any immunity. Ensuring that each calf receives sufficient colostrum (first milk) immediately after calving is one of the most important factors in ensuring their survival and health. Colostrum contains both antibodies (immunoglobulins, which protect against specific diseases and anti-infective protective agents, such as lactoferrins, which prevent bacterial growth.~~ Receiving adequate immunity from colostrum generally depends on the volume and quality of colostrum ingested, and how soon after birth the calf receives it.

~~As the ability of the calf to absorb immunoglobulins starts to decline progressively after 4 to 6 hours, and ceases around 24 hours after birth, the earlier a calf is fed/suckles, the greater the level of immunoglobulin absorption.~~

Where possible, *animal handlers* should ensure that calves receive sufficient colostrum within 24 hours of birth.

Outcome-based measurables: mortality rate, morbidity rate, changes in weight.

~~b)~~d) Weaning

For the purposes of this Chapter, ~~W~~weaning means ~~is the term used to describe~~ the transfer of the calf from a milk based diet ~~(from nursing the dam or being fed with milk or milk replacer)~~ to a fibrous diet ~~from nursing the dam or being fed with milk or milk replacer~~. In beef cattle production systems, weaning can be a stressful time in the calf's life.

Calves should be weaned only when their ruminant digestive system~~s~~ has~~ve~~ developed sufficiently to enable them to maintain growth and welfare.

~~The practice of creep feeding is sometimes utilised prior to weaning to help the calf more easily adapt to a solid diet.~~

There are different weaning strategies utilised in the beef cattle production systems. These could include abrupt separation, fence line separation and the use of devices placed in the nose of the calf to discourage suckling.

Special care should be taken if abrupt weaning is immediately followed by additional stressors such as transportation~~,~~ ~~off farm~~ as ~~research has shown that~~ calves are at risk of increased morbidity under these circumstances.

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

Outcome-based measurables: Morbidity rate, mortality rate, behaviour, physical appearance, changes in weight ~~gain~~ and body condition score.

~~c)~~ e) Painful husbandry procedures

~~Surgical~~ Husbandry practices that have the potential to cause pain are routinely practiced on cattle for reasons of production efficiency, animal health and welfare and human safety. Where possible, these procedures should be performed in such a way as to minimise any pain and stress to ~~on~~ the animal. ~~Options to consider including the performing the procedure at as early an age as possible or where appropriate use of analgesia.~~ Performing these procedures at as early an age as possible or using anaesthesia and/or analgesia should be considered under the recommendation or supervision of a *veterinarian.*

Future options for enhancing *animal welfare* in relation to these procedures include: 1) ceasing the procedure and addressing the current need for the operation through management strategies; 2) breeding animals that do not require the procedure; or 3) replacing the current procedure with a non-surgical alternative that has been shown to enhance *animal welfare*~~; or 4) performing the procedure in a way that minimises pain.~~

Example of such interventions include: castration, dehorning, ovariectomy (spaying), tail docking, identification.

i) Castration

Castration of beef cattle is performed in many production systems to reduce inter-animal aggression, improve human safety, ~~remove~~ avoid the risk of unwanted pregnancies in the herd, and enhance production efficiency~~ by producing beef that better meets market requirements~~.

Annex XIII (contd)

Where it is necessary to castrate beef cattle, producers should seek guidance from veterinarians as to the optimum method and timing for their type of cattle and production system.

Methods of castration used in beef cattle include surgical (knife) removal of the testes, ischaemic methods (banding or ringing), and crushing and disruption of the spermatic cord (Burdizzo operation).

Where practical, cattle should be castrated before the age of 3 months, or at the first available handling opportunity beyond this age.

Producers should seek guidance from veterinarians on the availability and advisability of analgesia/anaesthesia for castration of beef cattle, particularly in older animals.

Operators performing castration of beef cattle should be trained and competent in the procedure used, and be able to recognise the signs of complications.

Castration			
Procedure	**Specific method**	**Key animal welfare requirements Applicable**	**Comment**
Burdizzo method	This procedure requires the male calf to be restrained as the Burdizzo device is placed on the scrotum above the testicles and is closed to crush and disrupt the spermatic cord. Each spermatic cord is crushed separately. This action severs the blood supply to the testicles causing them to degenerate.	High level of operator competency, competent operation and maintenance of equipment; restraint; accuracy.	This method shuts off the blood supply to the testicle and causes the testicle to be reabsorbed if properly done (bloodless and no open wound). The Burdizzo procedure requires certain skill to use properly and may result in only partial castration depending on competency of the operator. Post-castration discomfort or pain from the use of the Burdizzo is comparable with other castration methods. Cannot visually confirm if procedure has been successful. ~~A veterinarian should be consulted on how to control pain during such procedures.~~
Rubber ring method	Small rubber rings are used for calves less than one month of age (rubber ring castration), and for older calves heavy wall latex bands are used along with a grommet to securely fasten the mechanically tightened bands at the appropriate tension. After several weeks, the testicles and scrotum degenerate and slough from the body.	High level of operator competency, competent operation and maintenance of equipment; restraint; accuracy.	Post-castration discomfort may be prolonged by this method compared with other castration methods. High tetanus risk ~~A veterinarian should be consulted on how to control pain during such procedures.~~

Procedure	Specific method	Key animal welfare requirements Applicable	Comment
~~Banding method~~	~~A fast, easy and effective non-surgical method of castrating large animals.~~	~~High level of operator competency, competent operation and maintenance of equipment; restraint; accuracy.~~	~~Post-castration discomfort may be prolonged by this method compared with other castration methods.~~ ~~High tetanus risk.~~ ~~A veterinarian should be consulted on how to control pain during such procedures.~~
Surgical method	Removal of the testicles using sharp cutting instruments and emasculators involves opening the scrotum and removing the testicles by severing them from the spermatic cords.	High level of operator competency, competent operation and maintenance of equipment; restraint; accuracy.	Risk of haemorrhage is greater after surgical castration. Post-castration discomfort is normally not as long as it is when elastrators are used. Potential complications associated with castration include haemorrhage, excessive swelling or oedema, infection, poor wound healing, and failure ~~A veterinarian should be consulted on how to control pain during such procedures.~~
Chemical castration	Chemical castration includes injection of sclerosing or toxic agents (e.g. 88% lactic acid) into the testicular parenchyma to cause irreparable damage and loss of function.	High level of operator competency, competent operation and maintenance of equipment; restraint; accuracy. The procedures are bloodless but require extreme skill because chemical substances must be injected directly into the testicles. Chemical castration requires additional procedural time and technical skill, and almost twice the healing time compared with surgical castration.	Studies have reported that 25% of the chemically castrated calves had scrotal necrosis caused by the high pressure of injection and drug leakage from the testes. ~~A veterinarian should be consulted on how to control pain during such procedures.~~

ii) Dehorning (including disbudding)

Beef cattle ~~which~~ that are naturally horned are commonly dehorned in order to reduce animal injuries and hide damage, improve human safety, reduce damage to facilities and facilitate transport and handling. Where practical and appropriate for the production system, the selection of polled cattle is preferable to ~~can remove the need for~~ dehorning.

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

Annex XIII (contd)

Where practical, cattle should be dehorned while horn development is still at the horn bud stage, or at the first available handling opportunity beyond this age. This is because the procedure involves less tissue trauma when horn development is still at the horn bud stage, and there is no attachment of horn to the skull of the animal.

Methods of dehorning (disbudding) at the horn bud stage include removal of the horn buds with a knife, thermal cautery of the horn buds, or the application of chemical paste to cauterise the horn buds. Methods of dehorning when horn development has commenced involve the removal ~~through~~ of the horn by cutting or sawing ~~at~~ through the base of the horn close to the skull.

Producers should seek guidance from veterinarians on the availability and advisability of analgesia/anaesthesia for dehorning of beef cattle, particularly in older animals, where horn development is more advanced.

Operators performing dehorning of beef cattle should be trained and competent in the procedure used, and be able to recognise the signs of complications.

Dehorning/disbudding			
Procedure	**Specific method**	**Key animal welfare requirements applicable**	**Comment**
Disbudding (thermo-cautery)	Hot-iron disbudding is performed by applying the hot-iron device, electric or butane-gas heated to over 600°C, over the horn bud destroying the growing tissue at its base. This method is performed when horn-buds are evident by palpation which usually occurs at an age of 2–8 weeks.	High level of operator competency, competent operation and maintenance of equipment; restraint; accuracy.	The different methods of horn removal can be ranked on the basis of the acute stress (cortisol) and behavioural responses and the production effects. Methods that elicit less struggling during the procedure and lower overall distress responses are preferred. ~~A veterinarian should be consulted on how to control pain during such procedures.~~
Caustic paste	Paste disbudding is caused by the chemical burn of underlying tissue. The active ingredient used for disbudding is usually sodium hydroxide or calcium hydroxide. These strong alkalis cause liquefactive necrosis, resulting in saponification of fats and denaturation of proteins, which allows deeper penetration of the chemical. With caustic burns, tissue damage continues to increase as long as the active chemical is in contact with the tissue.	High level of operator competency, competent operation, restraint; Accuracy. The evidence indicates that caustic paste disbudding causes distress for at least 3 h and that local anaesthesia is efficient in controlling pain for the first hour but discomfort returns after the nerve blocking subsides.	A veterinarian should be consulted on how to control pain during such procedures. Inert lying is a sign of distress in young calves after caustic paste disbudding. Caustic dehorning chemicals should only be used with care. They can spread into the eyes if the skin gets wet.

Dehorning/disbudding (contd)			
Procedure	**Specific method**	**Key animal welfare requirements applicable**	**Comment**
Dehorning methods 1. Scoop dehorning 2. Guillotine shears 3. Saw 4. Foetotomy 5. Cryosurgery	Dehorning of older cattle is carried out by various methods and includes: 1. Scoop dehorning consists of two interlocking semicircular blades attached to handles that amputate the horn close to the underlying bone. Scoop dehorning which may cause either shallow or deep impact on the underlying bone and surrounding skin 2. Guillotine shears / crange device. 3. Saw - where the horn is cut close to the skull bone using a tenon saw. 4. Foetotomy wire – where the horn is cut close to the skull bones by repeated sawing with a foetotomy wire. 5. Cryosurgery	High level of operator competency, competent operation and maintenance of equipment; restraint; accuracy. The cortisol responses of male Friesian calves (5 to 6 mo of age) to amputation dehorning by each of the first 4 methods listed were similar, suggesting that the degree of distress and pain caused by the different methods of dehorning are similar.	There is a complete absence of literature available on other methods of amputation dehorning (foetotomy wire, saw, guillotine crange) and alleviation of the associated pain. ~~A veterinarian should be consulted on how to control pain during such procedures.~~
Tipping of the horn	Removal of the non-sensitive tip of the horn	High level of operator competency, competent operation, restraint; accuracy.	~~A veterinarian should be consulted on how to control pain during such procedures.~~

iii) Ovariectomy (Spaying) (ovariectomy)

Ovariectomy ~~Spaying~~ of heifers is sometimes required ~~for international trade or~~ to prevent unwanted pregnancies under extensive rangeland conditions. Surgical spaying should be performed by veterinarians or by highly trained operators. Producers should seek guidance from veterinarians on the availability and advisability of analgesia/anaesthesia for spaying of beef cattle. The use of analgesia/anaesthesia should be encouraged.

Spaying			
Procedure	**Specific method**	**Key animal welfare requirements applicable**	**Comment**
Spaying	Ovarian removal by flank incision	High level of operator competency, hygienic operation and maintenance of equipment; restraint; accuracy.	Produces a longer-lasting inflammatory response than per vagina method. Mortality rates in studies shown as comparable or slightly higher than per vagina method. Administration of local anaesthetic where applied may produce less complications than epidural block for per vagina method. Applicable to different stages of pregnancy, but results in abortion if gestation is less than 4.5 months.

Annex XIII (contd)

Spaying (contd)

Procedure	**Specific method**	**Key animal welfare requirements applicable**	**Comment**
	'Willis' dropped ovary technique (per vagina approach)	High level of operator competency, hygienic operation and maintenance of equipment; restraint; accuracy.	Produces a shorter-lasting inflammatory response than flank incision, but a comparable stress and behavioural response. Mortality rates in studies shown as comparable or slightly lower than flank method. Epidural administration of local anaesthetic where applied may produce la greater risk of complications than local or regional block for flank method. Applicable only for non-pregnant, or early pregnancy (< 4 months). Results in abortion if pregnant animal is thus spayed. Greater risk of leaving ovarian tissue intact if operator not fully experienced.
	Ovarian removal by vaginal incision	High level of operator competency, hygienic operation and maintenance of equipment; restraint; accuracy.	Similar method to Willis technique, but requires larger vaginal incision and manual manipulation removal of the ovaries. Tissue trauma is likely to be greater.

iv) Tail docking

Tail docking has been performed in beef cattle to prevent tail tip necrosis in confinement operations. Research shows that increasing space per animal and proper bedding are effectives ~~means~~ in preventing tail tip necrosis. Therefore it is not recommended for producers to dock the tails of beef cattle.

v) Identification

Ear-tagging, ear-notching, tattooing, freeze branding and radio frequency identification devices (RFID) are preferred methods of permanently identifying beef cattle from an *animal welfare* standpoint. In some situations however hot iron branding may be required or be the only practical method of permanent identifying beef cattle. If cattle are branded, it should be accomplished quickly, expertly and with the proper equipment. Identification systems should be established also according to the Chapter 4.1. of the *Terrestrial Code* on General principles on identification and traceability of live animals.

Annex XIII (contd)

Identification			
Procedure	**Specific method**	**Key animal welfare requirements applicable**	**Comment**
Ear tagging	Insertion of ear tag with visible identification marks	Hygienic operation and maintenance of equipment; restraint; Moderate level of operator competency	Ear tagging when performed well causes little distress additional to any effects of handling and restraint. Poor equipment or low operator competency can increase the risk of retention failure, requiring animals to undergo additional procedures. Visible ear tags make identification easier from a distance, potentially reducing the need for handling, but the increased tag size can increase the risk of it being caught on fences and other objects, leading to tearing of the ear pinna and tag loss.
	Insertion of radio frequency identification device	Hygienic operation and maintenance of equipment; restraint; Moderate level of operator competency	Insertion of RFID when performed well causes little distress additional to any effects of handling and restraint. Poor equipment or low operator competency can increase the risk of retention failure, requiring animals to undergo additional procedures. The risk of retention failure is lower in RFID-only tags because they are smaller, but tag reading requires specialized equipment at a short distance (< 1m).
Tattooing	Ear tattooing	Hygienic operation and maintenance of equipment; restraint; Moderate level of operator competency	Ear tattooing when performed well is permanent and causes little distress additional to any effects of handling and restraint. Because the tattoo can only be read at close quarters, animals may need to be restrained for subsequent identification checks, or the tattoo may be need to be supplemented by an additional form of identification, requiring an additional procedure.
Ear notching		Hygienic operation and maintenance of equipment; restraint; Moderate to high level of operator competency	Ear notching results in a slightly larger area of tissue damage than tagging or tattooing and therefore can cause more discomfort or pain. Has the advantage of being permanent if applied correctly. Ear notching may be more suitable for herd identification, as the number of variations available is less than for other identification methods. Subsequent hair growth or ear trauma can obscure the identification notch. Risk of infection or parasite infestations (miasis)

Annex XIII (contd)

Identification			
Specific method	**Specific method**	**Specific method**	**Specific method**
Branding	Freeze branding	High level of operator competency, hygienic operation and maintenance of equipment; restraint; accuracy.	Thermal injury and subsequent inflammatory response has the potential to cause a moderate degree of discomfort and pain, and a good result is highly dependent on operator competence. Freeze branding may be less effective on white or light coat coloured cattle. Results in a permanent brand when applied appropriately. Requires specialized equipment and can be expensive and more time-consuming than other methods.
	Hot iron branding	High level of operator competency, hygienic operation and maintenance of equipment; restraint; accuracy.	Thermal injury and subsequent inflammatory response caused by heated iron contact has the potential to cause a significant degree of discomfort and pain. A good identification marking is highly dependent on operator competence. Leaving the brand in contact with the skin for longer than the minimum time necessary can cause thermal injury to subcutaneous structures and severe tissue trauma. Hot-iron branding is permanent, and in some environments may currently be the only practical means of individual animal identification. Risk of infection or parasite infestations (miasis).

Outcome-based measurables: ~~Rate of~~ postprocedurales complications rate, ~~mortality~~ morbidity rate, behaviour, physical appearance, changes in weight ~~gain~~ and body condition score.

~~d)~~f) Handling and inspection

Beef cattle should be inspected at intervals appropriate to the production systems and the risks to the health and welfare of the animals. In intensive farming systems, animals should be inspected at least once a day.

Some animals may benefit from more frequent inspection for example: neonatal calves, cows in late gestation, newly weaned calves, and cattle experiencing environmental stress and ~~after~~ those that have undergone painful husbandry or veterinary surgical procedures.

Animal handlers need to be competent in recognising the clinical signs of health, disease and welfare of beef cattle.

Beef cattle identified as sick or injured should be given appropriate treatment at the first available opportunity by competent and trained *animal handlers*. If *animal handlers* are unable to provide appropriate treatment, then the service of veterinarians should be enlisted.

If ~~prognosis of~~ the animal's condition suggests the prognosis is poor with little chance of recovery, ~~humane euthanasia of the animal should be considered~~ the animal should be humanely killed as soon as possible. For a description of methods for the humane killing of beef cattle see Article 7.6.5. ~~of the OIE *Terrestrial Code*~~.

Recommendations on the handling of cattle are also found in Chapter 7.5. ~~and Articles 7.5.1. and 7.5.2. of the OIE T*errestrial Code*~~.

Where beef cattle are herded into a handling facility from extensive conditions, they should be moved quietly and calmly. Weather conditions should be taken into account and cattle should not be herded in excessively hot or cold conditions. Cattle should not be driven to the point of distress~~collapse~~. In situations where the gathering and handling of the cattle is likely to be stressful, consideration should be given to the avoidance of multiple handling events by combining necessary management procedures within the one handling event. Where handling itself is not stressful, management procedures should be staged over time to avoid additive stress of multiple procedures.

Properly trained dogs can be effective ~~tools~~ aids for cattle herding. Cattle are adaptable to different visual environments. However, exposure of cattle to sudden or persistent movement or visual contrasts should be minimised where possible to prevent stress and fear reactions.

Electro immobilisation should not be used.

Outcome-based measurables: Handling response, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight ~~gain~~ and body condition score.

~~e)~~g) Personnel training

All people responsible for beef cattle should be competent according to their responsibilities and should understand cattle husbandry, behaviour, biosecurity, general signs of disease, and indicators of poor *animal welfare* such as stress, pain and discomfort, and their alleviation.

Competence may be gained through formal training and/or practical experience.

Outcome-based measurables: Handling response, morbidity rate, mortality rate, behaviour, reproductive efficiency, changes in weight ~~gain~~ and body condition score.

~~f)~~ h) Emergency plans

Where the failure of power, water and feed supply systems could compromise *animal welfare*, ~~B~~beef producers should have contingency plans to cover the failure of these systems ~~power, water and feed supply.~~ These plans may include the provision of fail-safe alarms ~~devices~~ to detect malfunctions, backup generators, access to maintenance providers, ability to store water on farm, access to water cartage services, adequate on-farm storage of feed and alternative feed supply.

Plans should be in place to minimise and mitigate the effects of natural disasters or extreme climatic conditions e.g., heat stress, drought, blizzard and flooding. Humane *killing* procedures for sick or injured *animals* should be part of the emergency action plan. In drought, animal management decisions should be made as early as possible and these should include a consideration of reducing cattle numbers. Emergency plans should also cover the management of the farm in the face of an emergency disease outbreak, consistent with national programmes and recommendations of *Veterinary Services* as appropriate.

Annex XIII (contd)

~~g)~~i) Location, construction and equipment of farms

Farms for beef cattle should be situated in an appropriate geographical location for the health, welfare and productivity of the animals ~~while considering environmental sustainability~~.

All facilities for beef cattle should be constructed, maintained and operated to minimise the risk to the welfare of the animals ~~and human safety~~.

Equipment for handling and restraining beef cattle should only be used in a way that minimises the risk of injury, pain or distress.

Cattle in intensive or extensive production systems should~~must~~ be offered adequate space for comfort, and socialisation ~~and environmental management~~. ~~Whenever possible, beef cattle housed in intensive production systems should have access to pasture.~~

In intensive production systems the feeder should be sufficiently large so that animals have adequate access to feed and they should be clean and free of spoiled, moldy, sour, packed or unpalatable feed. Also cattle should have access to ~~clean and clear~~ water at all times.

Floors in housing facilities should be properly drained, and barns and handling alleys should provide traction to prevent injuries to animals and handlers.

Handling alleys and housing pens should~~must~~ be free of sharp edges and protrusions to prevent injury to animals and handlers.

~~Design and operate~~ Alleys and gates should be designed and operated to avoid impeding cattle movement. ~~Avoid~~ Slippery surfaces should be avoided, especially where cattle enter a single file alley leading to a chute or where they exit the chute. Grooved concrete, metal grating (not sharp), rubber mats or deep sand can be used to minimise slipping and falling. Quiet handling is essential to minimise slipping. When ~~operating~~ gates and catches are operated, ~~reduce~~ excessive noise should be minimised, ~~which~~ because it may cause distress to the *animals*.

Adjust hydraulic or manual restraining chutes to the appropriate size of cattle to be handled. Hydraulic or pneumatic operated restraining equipment should have pressure limiting devices to prevent injuries. Regular cleaning and maintenance of working parts is imperative to ensure the system functions properly and is safe for the cattle and handlers.

Mechanical and electrical devices used in housing facilities should~~must~~ be safe for animals ~~and humans~~.

Dipping baths are sometimes used in beef cattle production for ectoparasite control. Where these are used, they should be design and operated to minimise the risk of crowding, injury or drowning.

The loading of the animals at the farms should be conducting accordingly to Chapters 7.2., 7.3. and 7.4. ~~(Transport of animals by sea, land and air respectively).~~

Outcome-based measurables: Handling response, morbidity rate, mortality rate, behaviour, changes in weight ~~gain~~ and body condition score, physical appearance, lameness.

~~h) On farm harvesting~~

~~Refer to point 3c) of Article 7.X.5.~~

~~i)~~i) Humane killing

For sick and injured animals a ~~A~~ prompt diagnosis should be made to determine whether the animal should be humanely killed or receive additional care.

~~*Animal handlers* should provide feed and water to non-ambulatory cattle at least once daily~~

~~Non-ambulatory animals should be moved very carefully and dragging non-ambulatory animals is unacceptable.~~

~~Likewise, animals should not be lifted with chains onto transportation conveyances. Acceptable methods of transporting non-ambulatory animals include a sled, low-boy trailer or in the bucket of a loader.~~

~~When treatment is attempted, cattle that are unable to sit up unaided and refuse to eat or drink should be humanely euthanized as soon as recovery is deemed not possible.~~

~~Cattle that are non-ambulatory must not be sent to a livestock market or to a processing facility.~~

~~Humane killing should occur without pain or suffering.~~

The decision to humanely kill an animal and the procedure itself should be undertaken by a competent person.

Reasons for ~~euthanasia~~ humane *killing* may include:

i) severe emaciation, weak cattle that are non-ambulatory or at risk of becoming downers;

ii) non-ambulatory cattle that will not ~~sit~~ stand up, refuse to eat or drink, have not responded to therapy;

iii) rapid deterioration of a medical condition for which therapies have been unsuccessful;

iv) severe, debilitating pain;

v) compound (open) fracture;

vi) spinal injury;

vii) central nervous system disease; and

viii) multiple joint infections with chronic weight loss.

For a description of ~~other~~ methods for the humane *killing* of beef cattle see Article 7.6.5.~~ of the *Terrestrial Code*.~~

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Annex XIV

CHAPTER 7. 5.

SLAUGHTER OF ANIMALS

Article 7.5.1.

General principles

1. Object

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

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

2. Personnel

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

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

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

3. Animal behaviour

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

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

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

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

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

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

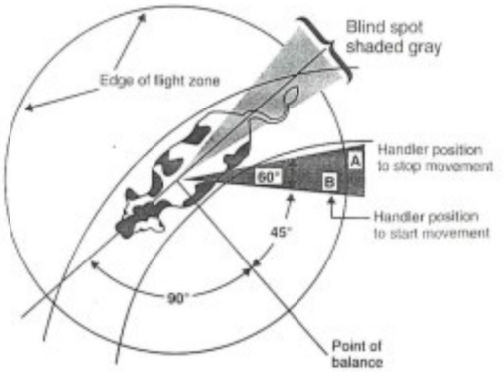
Animal handlers should use the point of balance at the *animal*'s shoulder to move *animals*, adopting a position behind the point of balance to move an *animal* forward and in front of the point of balance to move it backward.

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.

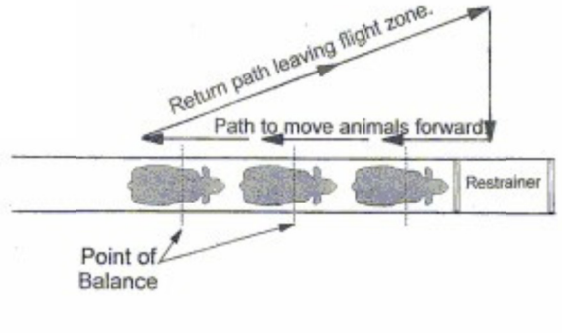
Although most domestic *animals* have a highly sensitive sense of smell, they react in different ways to the smells of *slaughterhouses*. Smells which cause fear or other negative responses should be taken into consideration when managing *animals*.

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*.

An example of a flight zone (cattle)



Handler movement pattern to move cattle forward



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.

Annex XIV (contd)

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.

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;

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* usingelectric 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*.

Annex XIV (contd)

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:

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 7.5.9.

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

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

Annex XIV (contd)

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Restraining methods (contd)	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
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

Annex XIV (contd)

	Presentation of animals	Specific procedure	Specific purpose	Animal welfare concerns/ implications	Key animal welfare requirements	Applicable species
Restraining and /or conveying methods (contd)	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
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

Annex XIV (contd)

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

Article 7.5.7.

Stunning 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., 7.6.7. and 7.6.8. The following diagrams illustrate the proper application of the device for certain species.

Cattle

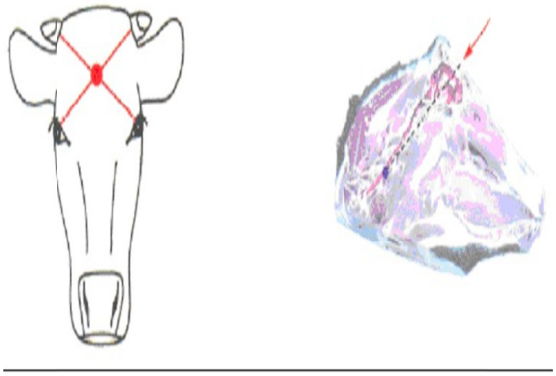


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill,

Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

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.

Pigs

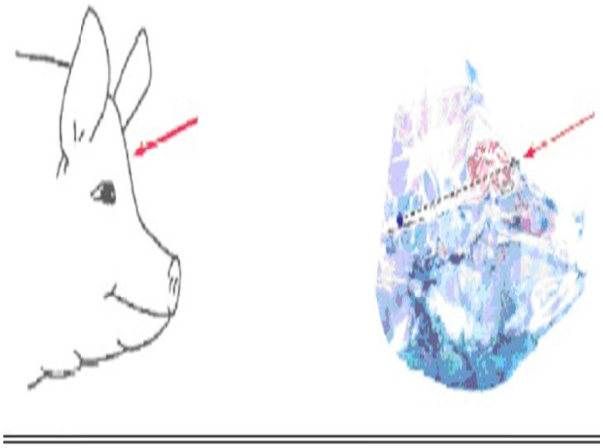


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

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

Annex XIV (contd)

Sheep

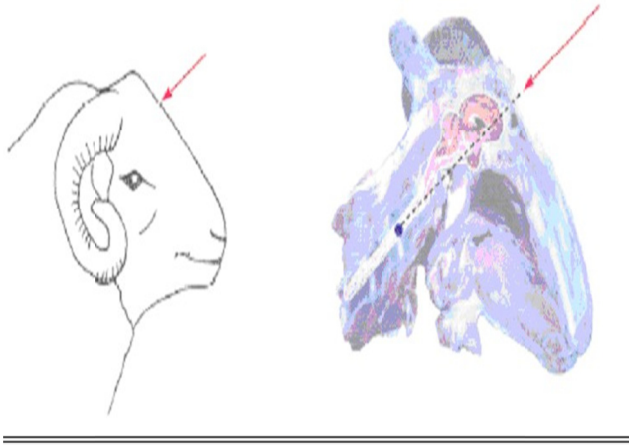


Figure source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

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

Goats

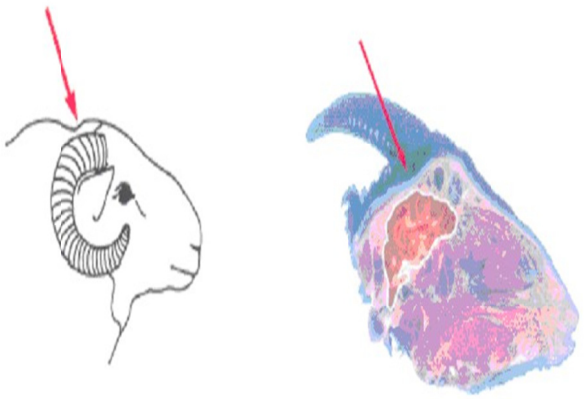
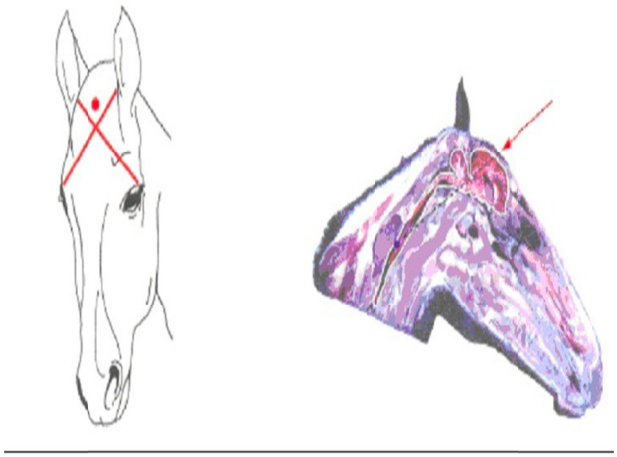


Figure Source: Humane Slaughter Association (2005) Guidance Notes No. 3: Humane Killing of Livestock Using Firearms. Published by the Humane Slaughter Association, The Old School, Brewhouse

Hill, Wheathampstead, Hertfordshire AL4 8AN, United Kingdom (www.hsa.org.uk).

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

Horses



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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.

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.

Poultry

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

Annex XIV (contd)

Poultry

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

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

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

3. Electrical stunning

a) General considerations

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

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

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

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

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

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

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

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

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

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

b) Electrical stunning of birds using a waterbath

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

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.

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

Annex XIV (contd)

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

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

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

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

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

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 waterbath stunner and/or the automatic neck-cutter are immediately stunned and/or killed immediately, and they are dead before entering scald tank.

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

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

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

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

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

	~~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~~

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.

Annex XIV (contd)

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.

Summary analysis of stunning methods and the associated animal welfare issues

Method	Specific method	Animal welfare concerns/ implications	Key animal welfare requirements applicable	Species	Comment
Mechanical	Free bullet	Inaccurate 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 XIV (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	
	Waterbath	Restraint, accidental pre-stun electric shocks; inadequate current and voltage; recovery of consciousness	Competent operation and maintenance of equipment	Poultry only	
Gaseous	CO_2 air/O_2 mixture; CO_2 inert gas mixture	Aversiveness of high CO_2; respiratory distress; inadequate exposure	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	
	Inert gases	Recovery of consciousness	Concentration; duration of exposure; design, maintenance and operation of equipment; stocking density management	Pigs, poultry	

Annex XIV (contd)

Article 7.5.9.

Summary analysis of slaughter methods and the associated animal welfare issues

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	

Annex XIV (contd)

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

Annex XIV (contd)

Cardiac arrest in a waterbath electric stunner	Bleeding by evisceration		Induction of cardiac arrest	Quail	
	Bleeding by neck cutting			Poultry	

Article 7.5.10.

Methods, procedures or practices unacceptable on animal welfare grounds

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

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

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

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Annex XV

CHAPTER 8.2.

AUJESZKY'S DISEASE

Article 8.2.1.

General provisions

Pigs are the natural host for Aujeszky's disease (AD) virus, although it can infect cattle, sheep, cats, dogs and rats causing fatal *disease*. The definition of pig includes all varieties of *Sus scrofa*, both domestic and *wild*.

For the purposes of the *Terrestrial Code*, AD is defined as an *infection* of domestic pigs ~~and~~ or *captive wild* pigs.

For the purposes of this chapter, a distinction is made between domestic pig and *captive wild* pig populations on the one hand, and *wild* ~~pig~~ and *feral* pig populations on the other hand.

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

A Member should not impose trade bans in response to a notification of *infection* with AD virus in *wild* and *feral* pigs according to Article 1.1.3. of the *Terrestrial Code*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.2.3., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the AD status of the *exporting country* or *zone*.

Article 8.2.2.

Determination of the AD status of a country or zone

The AD free or provisionally free status of a country or *zone* can only be determined after considering the following criteria in domestic and *wild* pigs, as applicable:

1. AD is notifiable in the whole country, and all clinical signs suggestive of AD should be subjected to field and/or *laboratory* investigations;

2. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of AD;

3. the *Veterinary Authority* should have current knowledge of, and authority over, all domestic and *captive wild* pigs in the country or *zone*;

4. the *Veterinary Authority* should have current knowledge about the population and habitat of *wild* and *feral* pigs in the country or *zone*;

5. 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 Chapter 1.4.

Annex XV (contd)

Article 8.2.3.

Safe commodities

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

1. *fresh meat* of domestic and *wild* pigs not containing offal (head, and thoracic and abdominal viscera);

2. *meat products* of domestic and *wild* pigs not containing offal (head, and thoracic and abdominal viscera);

3. products of animal origin not containing offal (head, and thoracic and abdominal viscera).

Article 8.2.4.

AD free country or zone

1. Qualification

   a) A country or *zone* may be considered free from the *disease* without formally applying a specific *surveillance* programme (historical freedom) if the *disease* has not been reported for at least 25 years, and if for at least the past 10 years:

      i) it has been a *notifiable disease*;

      ii) an early detection system has been in place;

      iii) measures to prevent the introduction of the AD virus into the country or *zone* have been in place;

      iv) no *vaccination* against the *disease* has been carried out;

      v) *infection* is not known to be established in *wild* and *feral* ~~swine~~ pigs, or measures have been implemented to prevent any transmission of the AD virus from *wild* and *feral* ~~swine~~ pigs to domestic and *captive wild* pigs.

   b) A country or *zone* which does not meet the conditions of the above paragraph may be considered free from AD when:

      i) animal health regulations to control the movement of *commodities* with the exception of those listed in Article 8.2.3. in order to prevent the introduction of *infection* into the *establishments* of the country or *zone* have been in place for at least two years;

      ii) *vaccination* against AD has been banned for all domestic and *captive wild* pigs in the country or *zone* for at least two years unless there are means, validated to OIE standards (Chapter 2.1.2. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs;

iii) if AD has never been reported in the country or *zone*, serological surveys, with negative results, have been conducted on a representative sample of all pig *establishments* in conformity with the recommendations in Chapter 1.4. at an acceptable level of confidence, no more than three years prior to qualification; the serological surveys should be directed at the detection of antibodies to the whole virus, and based on the breeding pig population or, for *establishments* that contain no breeding pigs, on a comparable number of fattening pigs; or

iv) if AD has been reported in the country or *zone*, a *surveillance* and control programme has been in place to detect every infected *establishment* and eradicate AD from it; the *surveillance* programme should be carried out in conformity with the recommendations in Chapter 1.4. and demonstrate that no *establishments* within the country or *zone* have had any clinical, virological or serological evidence of AD for at least two years.

v) In countries or *zones* with *wild* and *feral* ~~swine~~ pigs, measures should be implemented to prevent any transmission of the AD virus from *wild* and *feral* ~~swine~~ pigs to domestic and *captive wild* pigs.

2. Maintenance of free status

In order to maintain its free status, a country or *zone* should comply with the following requirements:

a) periodic serological surveys directed at the detection of antibodies to the whole AD virus should be carried out on a statistically significant number of breeding pigs, in conformity with the recommendations in Chapter 1.4.;

b) the importation of the *commodities* with the exception of those listed in Article 8.2.3. into the country or *zone* is carried out in conformity with the import conditions contained in the relevant Articles of the present chapter;

c) the ban on AD *vaccination* remains in force;

d) measures aimed at preventing the transmission of the AD virus from *wild* and *feral* ~~swine~~ pigs to domestic and *captive wild* pigs remain in force.

3. Recovery of free status

Should an AD *outbreak* occur in an *establishment* of a free country or *zone*, the status of the country or *zone* may be restored if either:

a) all the pigs in the *outbreak* have been slaughtered; and, during and after the application of this measure, an epidemiological investigation including clinical examination, and serological and/or virological testing has been carried out in all pig *establishments* which have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within a prescribed radius from the *outbreak*, demonstrating that these *establishments* are not infected; or

b) *vaccination* with gE- deleted vaccines has been applied and:

i) a serological testing procedure (differential ELISA) has been implemented in the *establishments* where *vaccination* has been applied to demonstrate the absence of *infection*;

ii) the movement of pigs from these *establishments* has been banned, except for immediate *slaughter*, until the above procedure has demonstrated the absence of *infection*;

Annex XV (contd)

iii) during and after the application of the measures described in points i) to ii) above, a thorough epidemiological investigation including clinical examination and serological and/or virological testing has been carried out in all pig *establishments* which have been directly or indirectly in contact with the infected *establishment* and in all pig *establishments* located within a prescribed radius from the *outbreak*, demonstrating that these *establishments* are not infected.

Article 8.2.5.

AD provisionally free country or zone

1. Qualification

A country or *zone* may be considered as provisionally free from AD if the following conditions are complied with:

a) animal health regulations to control the movement of *commodities* with the exception of those listed in Article 8.2.3. in order to prevent the introduction of *infection* into the *establishments* of the country or *zone* have been in place for at least two years;

b) if AD has never been reported in the country or *zone*, a serological survey, with negative results, has been conducted on a representative sample of all pig *establishments* in conformity with the recommendations in Chapter 1.4. (but not at an acceptable level of confidence); the serological survey should be directed at the detection of antibodies to the whole virus, and based on the breeding pig population or, for *establishments* that contain no breeding pigs, on a comparable number of fattening pigs; or

c) if AD has been reported in the country or *zone*, a *surveillance* and control programme has been in place to detect infected *establishments* and eradicate AD from these *establishments*, the *herd* prevalence rate in the country or *zone* has not exceeded one percent for at least three years (the sampling procedure described in point 1e) of the definition of 'AD free establishment' should be applied within the *establishments* of the country or *zone*), and at least 90 percent of the *establishments* in the country or *zone* are qualified free;

d) in countries or *zones* with *wild* and *feral* ~~swine~~ pigs, measures should be taken to prevent any transmission of the AD virus between *wild* and *feral* ~~swine~~ pigs and domestic and *captive wild* pigs.

2. Maintenance of provisionally free status

In order to maintain its provisionally free status, a country or *zone* should comply with the following requirements:

a) the measures described in points 1b) and 1d) above should be continued;

b) the percentage of infected *establishments* remains < one percent;

c) the importation of the *commodities* with the exception of those listed in Article 8.2.3. into the country or *zone* is carried out in conformity with the import conditions contained in the relevant articles of the present chapter.

3. Recovery of provisionally free status

Should the percentage of infected *establishments* exceed one percent in a provisionally free country or *zone*, the status of the country or *zone* is cancelled and may be restored only once the percentage of infected *establishments* has remained < one percent for at least six months, and this result is confirmed by a serological survey conducted in conformity with point 1c) above.

Article 8.2.6.

AD infected country or zone

For the purposes of this chapter, countries and *zones* which do not fulfil the conditions to be considered free or provisionally free of AD should be considered as infected.

Article 8.2.7.

AD free establishment

1. Qualification

To qualify as free from AD, an *establishment* should satisfy the following conditions:

a) it is under the control of the *Veterinary Authority*;

b) no clinical, virological or serological evidence of AD has been found for at least one year;

c) the introduction of pigs, semen and embryos/ova into the *establishment* is carried out in conformity with the import conditions for these *commodities* contained in the relevant articles of the present chapter;

d) *vaccination* against AD has not been carried out in the *establishment* for at least 12 months, and any previously vaccinated pigs are free from gE antibodies;

e) a representative sample of breeding pigs from the *establishment* has been subjected, with negative results, to serological tests to the whole AD virus, applying a sampling procedure set out in conformity with the recommendations in Chapter 1.4.; these tests should have been carried out on two occasions, at an interval of two months; for *establishments* that contain no breeding pigs, the tests should be carried out only once on a comparable number of fattening or weaning pigs;

f) a *surveillance* and control programme has been in place to detect infected *establishments* located within a prescribed radius from the *establishment* and no *establishment* is known to be infected within this *zone.*

2. Maintenance of free status

For *establishments* located in an infected country or *infected zone*, the testing procedure described in point 1e) above should be carried out every four months.

For *establishments* located in a provisionally free country or *zone*, the testing procedure described in point 1e) above should be carried out every year.

Annex XV (contd)

3. Recovery of free status

Should a free *establishment* become infected, or should an *outbreak* occur within a prescribed radius from a free *establishment*, the free status of the *establishment* should be suspended until the following conditions are met:

a) in the infected *establishment*:

i) all the pigs in the *establishment* have been slaughtered, or

ii) at least 30 days after removal of all infected *animals*, all breeding *animals* have been subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of 2 months;

b) in other *establishments* located within the prescribed radius: a number of breeding pigs from each *establishment* has been subjected, with negative results, to serological tests to the whole AD virus (non vaccinated *establishments*) or to gE antibodies (vaccinated *establishments*), applying the sampling procedure described in point 1e) above.

Article 8.2.8.

Recommendations for importation from AD free countries or zones

For domestic and *captive wild* pigs

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

1. showed no clinical sign of AD on the day of shipment;

2. come from an *establishment* located in an AD free country or *zone*;

3. have not been vaccinated against AD.

Article 8.2.9.

Recommendations for importation from AD provisionally free countries or zones

For domestic and *captive wild* pigs for breeding or rearing

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

1. showed no clinical sign of AD on the day of shipment;

2. have been kept exclusively in AD free *establishments* since birth;

3. have not been vaccinated against AD;

4. were subjected to a serological test to the whole AD virus, with negative results, within 15 days prior to shipment.

Article 8.2.10.

Recommendations for importation from AD infected countries or zones

For domestic and *captive wild* pigs for breeding or rearing

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

1. showed no clinical sign of AD on the day of shipment;

2. were kept exclusively in AD free *establishments* since birth;

3. have not been vaccinated against AD;

4. were isolated in the *establishment* of origin or a *quarantine station*, and were subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment.

Article 8.2.11.

Recommendations for importation from AD provisionally free countries or zones or AD infected countries or zones

For domestic and *captive wild* pigs for slaughter

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

1. a *surveillance* and control programme is in place in the country or *zone* to detect infected e*stablishments* and eradicate AD;

2. the *animals*:

    a) are not being eliminated as part of an eradication programme;

    b) showed no clinical sign of AD on the day of shipment;

    c) have been kept exclusively in AD free *establishments* since birth; or

    d have been vaccinated against AD at least 15 days prior to shipment.

[Note: Appropriate precautions should be taken both by the exporting country *and the* importing country *to ensure that the pigs are transported directly from the* place of shipment *to the* abattoir *for immediate* slaughter.*]*

Annex XV (contd)

Article 8.2.12.

Recommendations for importation from AD free countries or zones

For *wild* and *feral* pigs ~~swine~~

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

1. showed no clinical sign of AD on the day of shipment;

2. were captured in an AD free country or *zone*;

3. have not been vaccinated against the *disease*;

4. were isolated in a *quarantine station*, and were subjected to a serological test to the whole AD virus, with negative results, on two occasions, at an interval of not less than 30 days between each test, the second test being performed during the 15 days prior to shipment.

Article 8.2.13.

Recommendations for importation from AD free countries or zones

For semen of pigs

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

1. the donor *animals*:

    a) showed no clinical sign of AD on the day of collection of the semen;

    b) were kept in an *establishment* or *artificial insemination centre* located in an AD free country or *zone* at the time of semen collection;

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

Article 8.2.14.

Recommendations for importation from AD provisionally free countries or zones

For semen of pigs

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

1. the donor *animals*:

    a) have been kept for at least four months prior to semen collection in an *artificial insemination centre* which has the status of AD free *establishment*, and where all boars are subjected to a serological test to the whole AD virus, with negative results, every four months;

    b) showed no clinical sign of AD on the day of collection;

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

Article 8.2.15.

Recommendations for importation from AD infected countries or zones

For semen of pigs

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

1. the donor *animals*:

    a) were kept in an AD free *establishment* for at least six months prior to entering the *artificial insemination centre*;

    b) have been kept for at least four months prior to semen collection in the *artificial insemination centre* which has the status of AD free *establishment*, and where all boars are subjected to a serological test to the whole AD virus, with negative results, every four months;

    c) were subjected to a serological test to the whole AD virus, with negative results, within 10 days prior to or 21 days after semen collection;

    d) showed no clinical sign of AD on the day of collection;

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

Article 8.2.16.

Recommendations for importation from AD free countries or zones

For *in vivo* derived embryos of pigs

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

1. the donor females:

    a) showed no clinical sign of AD on the day of collection of the embryos;

    b) were kept in an *establishment* located in an AD free country or *zone* prior to collection;

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

Article 8.2.17.

Recommendations for importation from AD provisionally free countries or zones

For *in vivo* derived embryos of pigs

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

Annex XV (contd)

1. the donor females:

   a) showed no clinical sign of AD on the day of collection of the embryos;

   b) were kept in an AD free *establishment* for at least three months prior to collection;

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

Article 8.2.18.

Recommendations for importation from AD infected countries or zones

For *in vivo* derived embryos of pigs

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

1. the donor females:

   a) showed no clinical sign of AD on the day of collection of the embryos;

   b) were kept in an AD free *establishment* for at least three months prior to collection;

   c) were subjected to a serological test to the whole AD virus, with negative results, within ten days prior to collection;

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

Article 8.2.19.

Recommendations for importation from AD free countries or zones

For offal (head, and thoracic and abdominal viscera) of pigs or products containing pig offal

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of offal or products containing pig offal comes from *animals* which come from *establishments* located in an AD free country or *zone*.

Article 8.2.20.

Recommendations for importation from AD provisionally free countries or zones or from AD infected countries or zones

For offal (head, and thoracic and abdominal viscera) of pigs

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

1. which have been kept in an AD free *establishment* since birth;

2. which have not been in contact with *animals* from *establishments* not considered free from AD during their transport to the approved *abattoir* and therein.

Article 8.2.21.

Recommendations for importation from AD provisionally free countries or zones or from AD infected countries or zones

For products containing pig offal (head, and thoracic and abdominal viscera)

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

1. either the entire consignment of offal used to prepare the products complied with the conditions referred to in Article 8.2.20.; or

2. the products have been processed to ensure the destruction of the AD virus; and

3. the necessary precautions were taken after processing to avoid contact of the products with any source of AD virus.

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Annex XVI

CHAPTER 8.3.

BLUETONGUE

Article 8.3.1.

General provisions

For the purposes of the *Terrestrial Code*, the *infective period* for bluetongue virus (BTV) shall be 60 days.

Historically, the global BTV distribution has been confined between the latitudes of approximately 53°N and north of 34°S with a recent extension in Northern Europe.

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

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

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

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

Article 8.3.2.

Safe commodities

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

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

Annex XVI (contd)

Article 8.3.3.

BTV free country or zone

1. A country or a *zone* may be considered free from BTV when bluetongue is notifiable in the whole country and either:

   a) a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. has demonstrated no evidence of BTV in the country or *zone* during the past two years; or

   b) an ongoing *surveillance* programme has demonstrated no evidence of *Culicoides* in the country or *zone*.

2. A BTV free country or *zone* in which ongoing *vector surveillance*, performed according to point 5 of Article 8.3.19., has found no evidence of *Culicoides* will not lose its free status through the importation of vaccinated, seropositive or infective *animals*, or semen or embryos/ova from infected countries or *infected zones*.

3. A BTV free country or *zone* in which *surveillance* has found evidence that *Culicoides* are present will not lose its free status through the importation of vaccinated or seropositive *animals* from infected countries or *infected zones*, provided:

   a) the *animals* have been vaccinated, at least 60 days prior to dispatch, in accordance with the *Terrestrial Manual* with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and the *animals* are identified in the accompanying certification as having been vaccinated; or

   b) the *animals* are not vaccinated and, at least 60 days prior to dispatch, are demonstrated to have specific antibodies against the bluetongue virus serotypes whose presence has been demonstrated in the *exporting country* or *zone*.

4. A BTV free country or *zone* adjacent to an infected country or *infected zone* should include a *zone* as described in Article 8.3.1. in which *surveillance* is conducted in accordance with Articles 8.3.16. to 8.3.21. *Animals* within this *zone* should be subjected to continuing *surveillance*. The boundaries of this *zone* should be clearly defined, and should take account of geographical and epidemiological factors that are relevant to BTV transmission.

Article 8.3.4.

BTV seasonally free zone

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

For the application of Articles 8.3.7., 8.3.10. and 8.3.13., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides*.

For the application of Articles 8.3.7., 8.3.10. and 8.3.13., the seasonally free period is taken to conclude either:

1. at least 28 days before the earliest date that historical data show bluetongue virus activity has recommenced; or

2. immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of adult *Culicoides*.

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

Article 8.3.5.

BTV infected country or zone

For the purposes of this chapter, a BTV infected country or *infected zone* is a clearly defined area where evidence of BTV has been reported during the past two years. Such a country or *zone* may contain a BTV seasonally free *zone*.

Article 8.3.6.

Recommendations for importation from BTV free countries or zones

For ruminants and other BTV susceptible herbivores

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

1. the *animals* were kept in a BTV free country or *zone* since birth or for at least 60 days prior to shipment; or

2. the *animals* were kept in a BTV free country or *zone* for at least 28 days, then were subjected, with negative results, to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual* and remained in the BTV free country or *zone* until shipment; or

3. the *animals* were kept in a BTV free country or *zone* for at least seven days, then were subjected, with negative results, to an agent identification test according to the *Terrestrial Manual*, and remained in the BTV free country or *zone* until shipment; or

4. the *animals*:

   a) were kept in a BTV free country or *zone* for at least seven days;

   b) were vaccinated, at least 60 days before the introduction into the free country or *zone*, in accordance with the *Terrestrial Manual* against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme as described in Articles 8.3.16. to 8.3.21.;

   c) were identified as having been vaccinated; and

   d) remained in the BTV free country or *zone* until shipment;

Annex XVI (contd)

AND

5. if the *animals* were exported from a free *zone* within an infected country, either:

   a) did not transit through an *infected zone* during transportation to the *place of shipment*; or

   b) were protected from attack from *Culicoides* at all times when transiting through an *infected zone*; or

   c) had been vaccinated in accordance with point 4 above.

Article 8.3.7.

Recommendations for importation from BTV seasonally free zones

For ruminants and other BTV susceptible herbivores

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

1. were kept during the seasonally free period in a BTV seasonally free *zone* since birth or for at least 60 days prior to shipment; or

2. were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibody to the BTV group according to the *Terrestrial Manual*, with negative results, carried out at least 28 days after the commencement of the residence period; or

3. were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after the commencement of the residence period; or

4. were kept during the seasonally free period in a BTV seasonally free *zone* and were vaccinated, at least 60 days before the introduction into the free country or *zone*, in accordance with the *Terrestrial Manual* against all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21. and were identified as having been vaccinated and remained in the BTV free country or *zone* until shipment;

AND

5. either:

   a) did not transit through an *infected zone* during transportation to the *place of shipment*; or

   b) were protected from attack from *Culicoides* at all times when transiting through an *infected zone*; or

   c) were vaccinated in accordance with point 4 above.

Article 8.3.8.

Recommendations for importation from BTV infected countries or zones

For ruminants and other BTV susceptible herbivores

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

1. were protected from attack from *Culicoides* in a *vector*-protected *establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or

2. were protected from attack from *Culicoides* in a *vector*-protected *establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, carried out at least 28 days after introduction into the *vector*-protected *establishment*; or

3. were protected from attack from *Culicoides* in a *vector*-protected *establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test according to the *Terrestrial Manual*, with negative results, carried out at least 14 days after introduction into the *vector*-protected *establishment*; or

4. were vaccinated, at least 60 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 8.3.16. to 8.3.21., and were identified in the accompanying certification as having been vaccinated or, if demonstrated to have antibodies, have been protected from vectors for at least 60 days prior to shipment; or

5. demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes whose presence has been demonstrated in the source population through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21.

Article 8.3.9.

Recommendations for importation from BTV free countries or zones

For semen of ruminants and other BTV susceptible herbivores

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

1. the donor *animals*:

    a) were kept in a BTV free country or *zone* for at least 60 days before commencement of, and during, collection of the semen; or

    b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after the last collection for this consignment, with negative results; or

    c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

Annex XVI (contd)

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

Article 8.3.10.

Recommendations for importation from BTV seasonally free zones

For semen of ruminants and other BTV susceptible herbivores

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

1. the donor *animals*:

   a) were kept during the BTV seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the semen; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

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

Article 8.3.11.

Recommendations for importation from BTV infected countries or zones

For semen of ruminants and other BTV susceptible herbivores

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

1. the donor *animals*:

   a) were kept in a *vector*-protected *establishment* for at least 60 days before commencement of, and during, collection of the semen; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

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

Article 8.3.12.

Recommendations for importation from BTV free countries or zones

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

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

1. the donor females:

    a) were kept in a BTV free country or *zone* for at least the 60 days prior to, and at the time of, collection of the embryos; or

    b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

    c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

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

Article 8.3.13.

Recommendations for importation from BTV seasonally free zones

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

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

1. the donor females:

    a) were kept during the seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or

    b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

    c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

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

Article 8.3.14.

Recommendations for importation from BTV infected countries or zones

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

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

Annex XVI (contd)

1. the donor females:

   a) were kept in a *vector*-protected *establishment* for at least 60 days before commencement of, and during, collection of the embryos/oocytes; or

   b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or

   c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;

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

Article 8.3.15.

Protecting animals from Culicoides attack

1. Vector-protected establishment or facility

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

   a) Appropriate physical barriers at entry and exit points, e.g. double-door entry-exit system;

   b) openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide according to the manufacturers' instructions;

   c) *vector surveillance* and control within and around the building;

   d) measures to limit or eliminate breeding sites for *vectors* in the vicinity of the *establishment* or facility;

   e) standard operating procedures, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of *animals* to the place of *loading*.

2. During transportation

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

   Potential *risk management* strategies include:

   a) treating *animals* with insect repellents prior to and during transportation;

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

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

   d) darkening the interior of the *vehicle*, for example by covering the roof and/or sides of *vehicles* with shadecloth;

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

f) using historical information and/or information from appropriately verified and validated BTV epidemiological models to identify low risk ports and transport routes.

Article 8.3.16.

Surveillance: introduction

Articles 8.3.16. to 8.3.21. define the principles and provide a guide on the *surveillance* for BT complementary to Chapter 1.4. and for *vectors* complementary to Chapter 1.5., applicable to Members seeking to determine their BT status. This may be for the entire country or *zone*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of BT status is also provided.

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

An important component of BT epidemiology is vectorial capacity which provides a measure of *disease risk* that incorporates *vector* competence, abundance, biting rates, survival rates and extrinsic *incubation period*.

However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context. Therefore, *surveillance* for BT should focus on transmission in domestic ruminants.

The impact and epidemiology of BT differ widely in different regions of the world and therefore it is impossible to provide specific recommendations for all situations. It is incumbent upon Members to provide scientific data that explain the epidemiology of BT in the region concerned and adapt the *surveillance* strategies for defining their *infection* status (free, seasonally free or infected country or *zone*) to the local conditions. There is considerable latitude available to Members to justify their *infection* status at an acceptable level of confidence.

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

Article 8.3.17.

Surveillance: case definition

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

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

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

Annex XVI (contd)

The following defines the occurrence of BTV *infection*:

1. BTV has been isolated and identified as such from an *animal* or a product derived from that *animal*, or

2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of BTV has been identified in samples from one or more *animals* showing clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with BTV, or

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

Article 8.3.18.

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* should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspect *cases* of BT to a *laboratory* for BT diagnosis as described in the *Terrestrial Manual*;

   c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2. The BT *surveillance* programme should:

   a) in a country/*zone* free or seasonally free, include an early warning system for reporting suspicious *cases*. Farmers and workers, who have regular contact with domestic ruminants, as well as diagnosticians, should report promptly any suspicion of BT to the *Veterinary Authority*.

      They should be supported directly or indirectly (e.g. through private *veterinarians* or *Veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is BTV. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* of BT should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*;

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

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

Article 8.3.19.

Surveillance strategies

The target population for *surveillance* aimed at identification of *disease* and/or *infection* should cover susceptible domestic ruminants within the country or *zone*. Active and passive *surveillance* for BTV *infection* should be on-going. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the *infection* status of the country or *zone*.

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

Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods may be used concurrently to define the BTV status of targeted populations.

A Member should justify the *surveillance* strategy chosen as being adequate to detect the presence of BTV *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. sheep).

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

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

If a Member wishes to declare freedom from BTV *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 evidence of *infection* if it were to occur at a predetermined minimum rate. The sample size and expected prevalence determine the level of confidence in the results of the survey. The Member should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular needs to 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/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.

Annex XVI (contd)

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

1. Clinical surveillance

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

BT suspects detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

2. Serological surveillance

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

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

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

a) natural *infection* with BTV,

b) *vaccination* against BTV,

c) maternal antibodies,

d) positive results due to the lack of specificity of the test.

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

The results of random or targeted serological surveys are important in providing reliable evidence that no BTV *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 BTV transmission, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of BTV *infection*, either random or targeted sampling is suitable to select *herds* and/or *animals* for testing.

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

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

3. Virological surveillance

Isolation and genetic analysis of BTV from a proportion of infected *animals* is beneficial in terms of providing 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 in at risk populations,

b) to confirm clinically suspect *cases*,

c) to follow up positive serological results,

d) to better characterize the genotype of circulating virus in a country or *zone*.

4. Sentinel animals

Sentinel *animals* are a form of targeted *surveillance* with a prospective study design. They are the preferred strategy for BTV *surveillance*. They comprise groups of unexposed *animals* managed at fixed locations and sampled regularly to detect new BTV *infections*.

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

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

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

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

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

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

5. Vector surveillance

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

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

Long term *surveillance* can also be used to assess *vector* suppression measures.

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

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

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

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

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

Article 8.3.20.

Documentation of BTV infection free status

1. Members declaring freedom from BTV infection for the country or zone: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member declaring freedom from BTV *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, to demonstrate absence of BTV *infection* during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a *laboratory* able to undertake identification of BTV *infection* through virus detection and antibody tests described in the *Terrestrial Manual*. This *surveillance* should be targeted to non-vaccinated *animals*. Clinical *surveillance* may be effective in sheep while serological *surveillance* is more appropriate in cattle.

2. Additional requirements for countries or zones that practise vaccination

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

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

Article 8.3.21.

The use and interpretation of serological and virus detection tests

1. Serological testing

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

Annex XVI (contd)

2. Virus detection

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

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

a) The nested PCR assay detects BTV nucleic acid in ruminants long after the clearance of infectious virus. Thus positive PCR results do not necessarily coincide with active *infection* of ruminants. Furthermore, the nested PCR assay is especially prone to template contamination, thus there is considerable risk of false positive results.

b) PCR procedures other than real time PCR allow sequence analysis of viral amplicons from ruminant tissues, insect *vectors* or virus isolates. These sequence data are useful for creating data bases to facilitate important epidemiological studies, including the possible distinction of field and vaccine virus strains of BTV, genotype characterization of field strains of BTV, and potential genetic divergence of BTV relevant to vaccine and diagnostic testing strategies.

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

Fig. 1. Application of laboratory tests in serological surveillance

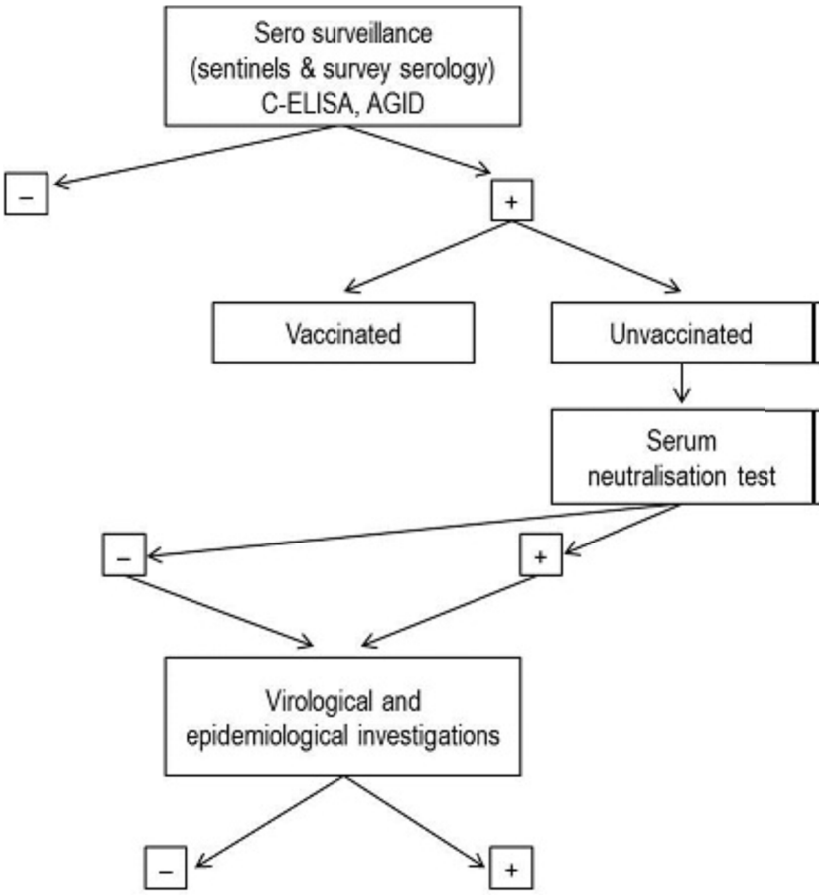
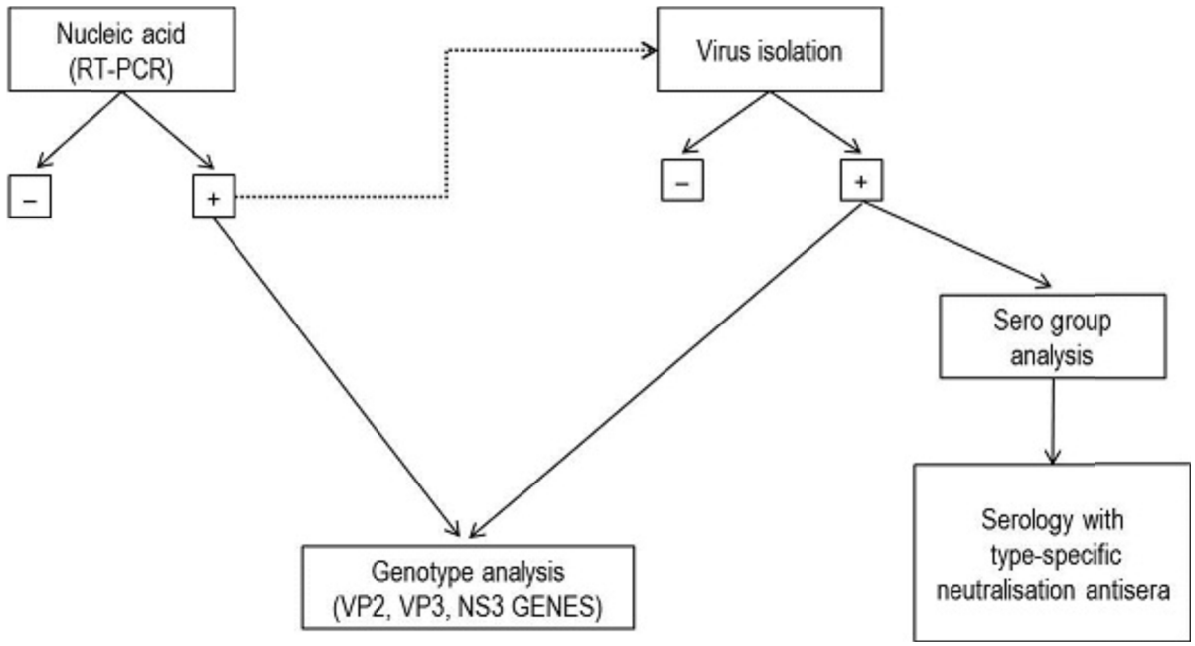


Fig 2. Application of laboratory tests in virological surveillance



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Annex XVII

CHAPTER 8.13.

INFECTION WITH *TRICHINELLA* SPP.

Article 8.13.1.

General provisions

Trichinellosis is a widely distributed *zoonosis* caused by eating raw or undercooked *meat* from *Trichinella*-infected food *animals* or game. 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. These genotypes may vary considerably between localities, districts, regions and countries.

Trichinellosis can be fatal in humans but is clinically inapparent in *animals*.

Preventing transmission to humans currently relies on the provision of *Trichinella*-free meat for human consumption. Prevention of *infection* in susceptible domestic *animals* used for human consumption currently relies on the prevention of exposure of those *animals* to the *meat* of *Trichinella*- infected *animals*, including via food waste, rodents and *wildlife*. This can be achieved by adopting appropriate biosecurity measures.

Meat and *meat products* derived from wildlife should always be considered a potential source of *infection* for humans. *Trichinella* larvae found in *meat* and *meat products* of wildlife may be resistant to freezing (depending on the*Trichinella* genotype). Therefore untested, frozen game *meat* 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 deals with methods for on-farm prevention of *Trichinella infection* in domestic pigs (*Sus scrofa*) and for safe trade of suids and equids, and their products. This chapter complements 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 the parasite's larvae in muscle samples and indirectly demonstrating their presence by detecting *Trichinella*-specific circulating antibodies.

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

Article 8.13.2.

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*:

Annex XVII (contd)

1. hides, skins, hair and bristles;

2. semen, embryos and oocytes;

3. *milk* and *milk products* of equids;

4. pig *meat* and *meat products* processed to ensure the inactivation of *Trichinella* larvae in accordance with recommendations in the [Codex working document CX/FH/11/43/6].

Article 8.13.3.

Measures to prevent infection in domestic pig *herd*s

1. Pigs kept under controlled housing

Controlled housing systems should be managed in a manner to prevent exposure of pigs to *Trichinella*.

a) Construction of buildings and environmental barriers

i) Buildings used to house pigs should be constructed to prevent entry of rodents and *wildlife*, e.g. openings, such as those for air ventilation or water pipes should be covered with wire or specific devices;

ii) areas surrounding buildings used to house pigs should be free from debris that could provide rodent harbourage;

iii) a vegetation-free perimeter consisting of concrete, gravel or a similar material should be maintained around all buildings used to house pigs to facilitate monitoring rodent and *wild* or *feral* animal incursions.

b) Feed and feed storage

i) Feed whether purchased or produced on-farm should comply with the requirements in Chapter 6.3.;

ii) feed should be stored and contained in closed silos or bins, which are constructed to prevent entry of rodents and *wildlife*.

c) Rodent control

A programme for the control of rodents should be implemented, documented and audited, and corrective actions applied as required.

d) Disposal of dead animals

Dead *animals* should be removed from buildings used to house pigs immediately after detection and disposed of as soon as possible, in accordance with the provisions of Chapter 4.12.

e) Introduction of pigs

i) Introduced pigs should originate from *Trichinella*-free *herds*;

OR

ii) if obtained from *herds* of unknown *Trichinella* status, they should be held in isolation until serologically tested to demonstrate the absence of antibodies to *Trichinella*. Adult pigs should be tested serologically on arrival and weaner pigs should be tested five weeks after arrival.

If any of these pigs test positive, the entire introduced cohort should remain in isolation until slaughtered. The *meat* should be subjected to testing by digestion to collect information on the genotype of the *Trichinella* present and to support a decision on the disposition of the *meat*. Test results should be communicated to the farm of origin.

2. Pigs exposed to outdoor environments

Pigs exposed to outdoor environments, or under conditions that facilitate contact with *wildlife* may be at higher risk of *Trichinella infection* than pigs kept in controlled housing.

To minimise the risk of *Trichinella infection*, the recommendations in Point 1 should be applied to the maximum extent possible.

Article 8.13.4.

Determination of the status of *Trichinella* infection in domestic pigs for a country, zone or herd

The status of *Trichinella infection* in domestic pigs in a country, *zone* or *herd* should be based on the following criteria:

1. *Trichinella infection* in all *animals* (domestic *animals* and *wildlife*) should be notifiable in the whole territory;
2. an *animal identification* and *traceability* system for domestic pigs should be implemented in accordance with the provisions of Chapters 4.1. and 4.2.;
3. appropriate provisions should be in place for tracing of *meat* from *wild animals* harvested for human consumption under commercial conditions;
4. the *Veterinary Authority* should have current knowledge of, and authority over, all domestic pigs in the country or *zone*;
5. the *Veterinary Authority* should have current knowledge of the population and habitat of *wild* and *feral* pigs in the country or *zone*;
6. appropriate *surveillance*, capable of detecting the presence and genotype of *Trichinella infection* in domestic pigs, and the risk posed by *wild* and *feral* pigs, and other susceptible *wildlife*, should be in place.

Communication procedures on the occurrence of *Trichinella infection*, including information about genotypes of the *cases* should be established between the *Veterinary Authority* and the Public Health Authority.

Annex XVII (contd)

Article 8.13.5.

Country or zone with a negligible risk of *Trichinella* infection in domestic pigs

A country or *zone* may be considered to be of negligible risk if the following conditions are met:

1. Article 8.13.4. has been complied with for at least 24 months;

2. the surveillance provisions in Article 8.13.11. have been complied with for a period of at least 24 months and the results demonstrate the absence of autochthonous *Trichinella infection* in domestic pigs;

3. the risk for transmission of *Trichinella infection* from *wildlife* reservoir hosts to domestic pigs has been assessed and appropriate biosecurity measures have been instituted to protect the domestic pig population; this should include the systematic monitoring of *wildlife* for *Trichinella infection* in accordance with Article 8.13.11.;

4. introduced live pigs should come from a country or *zone* with a negligible risk of *Trichinella infection* or from a *Trichinella*-free *herd*.

Article 8.13.6.

***Trichinella*-free pig herd**

The *Veterinary Authority* may officially recognise pig *herd*s complying with Article 8.13.5. as *Trichinella* -free if the following additional requirements are met:

1. at least two visits, a minimum of 6 months apart, have been made in the 12 months preceding recognition of the pig farms in the *herd* as *Trichinella* free, to verify compliance with good management practices described in Article 8.13.3.;
2. muscle samples from all pigs sent for *slaughter* during the 12 months preceding recognition of the pig *herd*s as *Trichinella*-free have been tested by a digestion method as described in the *Terrestrial Manual* and found to be negative for *Trichinella infection*;
3. an audit is carried out annually to verify compliance with good management practices described in Article 8.13.3.;
4. a survey of the pig *herd* is conducted annually including, if present, breeding pigs through the collection of sera or muscle samples on-farm or at the *slaughterhouse/abattoir* ;
5. all management practices undertaken on farm are documented;
6. introduced live pigs come from a country or *zone* with a negligible risk of *Trichinella infection* or from a *Trichinella*-free *herd*.

If a pig tests positive for *Trichinella infection* by the digestion method or serology, the *herd* loses its *Trichinella infection*-free status. Confirmation of a positive test using serology should be done by the digestion method using no less than 100 grams of *meat*, as described in the *Terrestrial Manual*. An investigation should be carried out by the *Veterinary Services* to identify the origin of the *infection* and appropriate remedial actions to be implemented.

If the outcome of an audit is unfavourable, the *Trichinella infection*-free status should be withdrawn until appropriate remedial action has been taken. To regain *Trichinella infection*-free status, the *herd* should comply with Points 1 and 2.

If the *herd* is located in a country or *zone* of negligible risk, points 2. and 4. do not apply.

Article 8.13.7.

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. comes from domestic pigs slaughtered in an approved *abattoir*;

AND

2. which:

   a) comes from domestic pigs from a negligible risk country or *zone* in accordance with Article 8.13.5.;

   OR

   b) comes from domestic pigs originating from a *Trichinella*-free *herd* in accordance Article 8.13.6.;

   OR

   c) comes from domestic pigs that tested negative by the digestion method for *Trichinella*, as described in the *Terrestrial Manual*;

   OR

   d) was processed to ensure the inactivation of *Trichinella* larvae in accordance with the recommendations in the [Codex working document CX/FH/11/43/6].

Article 8.13.8.

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. comes from *wild* or *feral* pigs inspected in accordance with the provisions in Chapter 6.2.;

AND

2. either:

   a) comes from *wild* or *feral* pigs that tested negative by the digestion method for *Trichinella*, as described in the *Terrestrial Manual*;

   OR

   b) was processed to ensure the inactivation of *Trichinella* larvae in accordance with the recommendations in the [Codex working document CX/FH/11/43/6].

Annex XVII (contd)

Article 8.13.9.

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* comes from domestic equids:

1. that were slaughtered in an approved *abattoir*;

AND

2. that tested negative by the digestion method for *Trichinella* as described in the *Terrestrial Manual*.

Article 8.13.10.

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* comes from *wild* or *feral* equids:

1. that were inspected in accordance with the provisions in Chapter 6.2;

AND

2. that tested negative by the digestion method for *Trichinella* as described in the *Terrestrial Manual*.

Article 8.13.11.

Surveillance for *Trichinella infection*

The objective of *surveillance* is to demonstrate the absence of autochthonous *Trichinella infection* in domestic pigs.

The *Veterinary Authority* should:

1. justify the choice of design, prevalence and confidence levels based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. The design should consider the prevailing, or historical, epidemiological situation, as appropriate;
2. ensure that, in addition to sampling of slaughter pigs, all breeder sows and boars and all domestic pigs exposed to outdoor environments are tested as described in the *Terrestrial Manual*;
3. ensure that all *wild* and *feral* pigs slaughtered for human consumption are tested as described in the *Terrestrial Manual*;
4. subject findings of *Trichinella infection* in *wildlife*, including *wild* and *feral* pigs, to an epidemiological investigation;
5. obtain data on *Trichinella infection* in *wildlife* through targeted *surveillance* or using samples collected for other purposes, such as hunted *wild* game, *wild* animal control programmes, studies of road kill, and independent research.

Annex XVIII

CHAPTER 8.10.

RABIES

Article 8.10.1.

General provisions

For the purpose of the *Terrestrial Code*,

1. Rabies is a *disease* caused by one~~any~~ member of the *Lyssavirus* genus; the *Rabies virus* (formerly referred to as classical rabies virus; genotype-1). All mammals ~~including human~~ are susceptible to *infection*. ~~Carnivora and Chiroptera are the reservoirs for rabies.~~

~~For the purposes of the *Terrestrial Code*:~~

2~~1~~. A~~a~~ *case* is any *animal* infected with the *Rabies virus* species;

3~~2~~. T~~t~~he *incubation period* for rabies is variable, and ~~but will be~~ considered to be ~~less than~~ 6 months or less~~;~~ . ~~and t~~The *infective period* for dogs, cats and ferrets is considered to start 10 days before the onset of the first apparent clinical signs.

Globally, the most common source of exposure of humans to rabies virus is the dog. Other mammals, particularly members of the Orders Carnivora and Chiroptera, also present a risk.

The aim of this chapter is to mitigate the risk ~~related to~~of rabies to human and animal health and to prevent the ~~for~~ international spread of the *disease* ~~trade and non-commercial movements of rabies susceptible species~~.

~~The most important species for international trade purposes are domestic carnivores (primarily dogs [*Canis familiaris*], cats [*Felis catus*] and ferrets [*Mustela putorius furo*]) and also include domestic livestock (equids, ruminants and suids).~~

~~Rabies can be suspected based on clinical signs or history of exposure to a rabid *animal*. Confirmation requires antigen detection or virus isolation.~~ Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Members ~~are encouraged to~~ should implement and maintain a programme for the management of stray dog populations consistent with Chapter 7.7.

Article 8.10.2.

Rabies free country

A country may be considered free from rabies when:

1. the *disease* is notifiable and any change in the epidemiological situation or relevant events are ~~should be~~ reported in accordance with Chapter 1.1.;

Annex XVIII (contd)

2. an ~~effective~~ ongoing system of *disease surveillance* in accordance with Chapter 1.4. has been in operation for the last two years, with a minimum requirement being an on-going early detection programme to ensure investigation and reporting of rabies suspect *animals*;

3. regulatory measures for the prevention of rabies are implemented consistent with the recommendations in the *Terrestrial Code* ~~this chapter~~, including ~~effective procedures~~ for the importation of *animals* ~~domestic dogs, cats and ferrets~~;

4. no *case* of indigenously acquired *rabies virus* infection has been confirmed during the past two years;

5. no imported *case* ~~reservoir~~ species in the Orders of Carnivora or Chiroptera has been confirmed outside a *quarantine station* for the past six months;

6. an imported human *case* of rabies does ~~will~~ not affect the rabies free status.

~~Members should implement and maintain a programme for the management of stray dog populations consistent with Chapter 7.7.~~

~~Article 8.10.3.~~

~~**Country free from dog to dog transmission of rabies**~~

~~A country may be considered free from dog to dog transmission of rabies when:~~

~~1. the *disease* is notifiable and any change in the epidemiological situation or relevant events are reported in accordance with Chapter 1.1.;~~

~~2. an effective system of *disease surveillance* has been in operation for the last 2 years, with a minimum requirement being an on going early detection programme to ensure investigation and reporting of rabies suspect *animals*;~~

~~3. regulatory measures for the prevention and control of rabies are implemented consistent with the recommendations in this chapter, including vaccination, identification and effective procedures for the importation of domestic dogs, cats and ferrets;~~

~~4. thorough epidemiological investigations have demonstrated no *case* of dog to dog transmission of rabies during the past 2 years.~~

~~Members should implement and maintain a programme for the management of stray dog populations consistent with Chapter 7.7.~~

Article 8.10.43.

Recommendations for importation from rabies free countries

For domestic mammals, and captive *wild* mammals

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

1. showed no clinical sign of rabies ~~the day prior to or~~ on the day of shipment;

2. and either:

   a) were kept since birth or at least six months prior to shipment in the free country; or

   b) were imported in conformity with the regulations stipulated in Articles 8.10.~~7~~5., 8.10.~~8~~6., 8.10.~~9~~7. or 8.10.~~10~~8.

Article 8.10.~~5~~4.

Recommendations for importation from rabies free countries

For *wild* mammals

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

1. showed no clinical sign of rabies ~~the day prior to or~~ on the day of shipment;

2. and either:

   a) have been captured at a distance 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. ~~and remained in a rabies free country, at a sufficient distance, based on the biology of species, including home range, from any infected country. The distance should be defined according to the species exported and the reservoir species in the neighbouring infected countries~~; or

   b) were kept for the six months prior to shipment in a rabies free country.

~~Article 8.10.6~~

~~**Recommendations for importation of dogs from countries free from dog to dog transmission of rabies**~~

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

~~1. were kept for at least the 6 months prior to shipment in a country free from dog to dog transmission of rabies;~~

~~2. were permanently identified (e.g., by a microchip or tattoo) and the identification number should be stated in the *certificate*;~~

~~3. received, prior to shipment, a valid anti rabies vaccination in accordance with the *Terrestrial Manual*, or revaccination if applicable, in accordance with the recommendations of the manufacturer;~~

~~4. showed no clinical sign of rabies the day prior to or on the day of shipment;~~

Annex XVIII (contd)

Article 8.10.~~7~~5.

Recommendations for importation of dogs, cats and ferrets from countries considered infected with rabies

Veterinary Authorities should require the presentation of an *international veterinary certificate* complying with the model of Chapter 5.11, attesting that the *animals*:

1. showed no clinical sign of rabies ~~the day prior to or~~ on the day of shipment;

2. were permanently identified and their identification number stated in the *certificate*;

AND EITHER:

~~2. were permanently identified (e.g., by a microchip or tattoo) and their identification number should be stated in the *certificate*; and~~

3. received, prior to shipment, a ~~valid anti-~~rabies vaccination or revaccination if applicable, in accordance with the recommendations of the manufacturer.~~;~~ The vaccine should have been produced in accordance with the *Terrestrial Manual*~~;~~ ~~or revaccination if applicable, in accordance with the recommendations of the manufacturer; vaccination~~ and

4. were subjected not less than 3 months and not more than 12 months prior to shipment to an antibody titration test as prescribed in the *Terrestrial Manual* with a positive result of at least 0.5IU/ml;

OR

5. ~~have not been vaccinated against rabies or do not meet all the conditions set out in points 2, 3 and 4 above,; in such cases, the *animals* should be~~ were quarantined for six months prior to export.

Article 8.10.~~8~~6.

Recommendations for importation of domestic ruminants, equids, camelids and suids from countries considered infected with rabies

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

1. showed no clinical sign of rabies ~~the day prior to or~~ on the day of shipment.

2. were permanently identified (e.g. by ear tag, microchip or tattoo) and the identification number should be stated in the *certificate*;

3. a) were kept for the 6 months prior to shipment in an *establishment* where no *case* of rabies was reported for at least 12 months prior to shipment;

OR

b) were vaccinated in accordance with the recommendations of the manufacturer, using a vaccine produced in accordance with the *Terrestrial Manual.*

~~Article 8.10.9.~~

~~**Recommendations for importation of domestic equids from countries considered infected with rabies**~~

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

~~1. showed no clinical sign of rabies the day prior to or on the day of shipment;~~

~~2. and either:~~

~~a) were kept for the 6 months prior to shipment in an *establishment* where no contact with reservoir species was maintained and where no *case* of rabies was reported for at least 12 months prior to shipment; or~~

~~b) were vaccinated as prescribed in the *Terrestrial Manual*.~~

Article 8.10.~~10~~7.

Recommendations for importation from countries considered infected with rabies

For rodents and lagomorphs born and reared in a biosecure facility

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

1. showed no clinical sign of rabies on the day of shipment;
2. were kept since birth in a biosecure facility where no *case* of rabies was reported for at least 12 months prior to shipment.

~~Article 8.10.11.~~

~~**Recommendations for importation from countries considered infected with rabies**~~

~~for captive *wild* animals (other than non-human primates and captive *wild* carnivores)~~

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

~~1. showed no clinical sign of rabies the day prior to or on the day of shipment;~~

~~2. were kept since birth, or for the 6 months prior to shipment, in an *establishment* where no contact with reservoir species and where no *case* of rabies was reported for at least 12 months prior to shipment.~~

Article 8.10.~~12~~8.

Recommendations for importation of *wildlife* from countries considered infected with rabies

~~for *wild* and *feral animals* (other than non-human primates and Chiroptera)~~

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

Annex XVIII (contd)

1. showed no clinical sign of rabies ~~the day prior to or~~ on the day of shipment;

2. were kept for the 6 months prior to shipment in an *establishment* where separation from susceptible ~~*wild animals* and *feral*~~ *animals* was maintained and where no *case* of rabies was reported for at least 12 months prior to shipment.

~~Article 8.10.13.~~

~~**Recommendations for importation from countries considered infected with rabies**~~

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

~~for captive non-human primates~~

~~1. the *animals* showed no clinical sign of rabies the day prior to or on the day of shipment;~~

~~2. quarantine measures were applied in accordance with Chapter 5.9. and Chapter 6.11.~~

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CHAPTER 5.11.

~~RABIES~~
MODEL ~~INTERNATIONAL~~ VETERINARY CERTIFICATE FOR ~~DOMESTIC~~ DOGS ~~(*Canis familiaris*),~~ AND CATS ~~(*Felis catus*)~~ AND FERRETS ~~(*Mustela putorius furo*)~~ ORIGINATING FROM COUNTRIES CONSIDERED INFECTED WITH RABIES ~~INFECTED COUNTRIES~~

I. OWNER

Name and address: .....
.....
.....
.....

II. DESCRIPTION

Species of animal: .....
Age or date of birth: .....
Sex: .....
Breed: .....
Colour: .....
Coat type and marking/Distinguishing marks: .....
.....
.....
.....
Identification number and location on the animal ~~(tattoo or other permanent method of identification)~~
(see note 1)

III. ADDITIONAL INFORMATION

Country of origin: .....
.....
Countries visited .....
over the past six months~~2 years~~ .....
as declared by the owner .....
(give dates) .....
.....
.....

Annex XVIII (contd)

IV. VACCINATION (Rabies)

I the undersigned declare herewith that I have vaccinated the animal described in Part II against rabies as shown below. The animal was ~~found to be~~ healthy on the day of vaccination.

Date of vaccination (dd/mm/yy)	Name of ~~inactivated virus~~ vaccine (see note 2)	1. Manufacturing laboratory 2. Batch number 3. Expiry date	~~Name (in capital letters) and signature of the veterinarian (see note 6)~~
		1.....	
		2……..	

PERIOD OF VALIDITY OF VACCINATION FOR INTERNATIONAL MOVEMENT (see note 3)		Name (in capital letters) and signature of the Certifying~~Official~~ Veterinarian (see note 6)
from (dd/mm/yy)	to (dd/mm/yy)	

V. SEROLOGICAL TESTING (Rabies)

I the undersigned declare herewith that I have taken a blood sample from the animal described in Part II and have received the following result from the official diagnostic laboratory which ~~has~~ carried out the ~~neutralising~~ antibody titration test (see note 4).

Date of sampling (dd/mm/yy)	Name and address of the official diagnostic laboratory	Result of the antibody titration test (in International Units [IU]/ml)	~~Name (in capital letters) and signature of the veterinarian (see note 6)~~

PERIOD OF VALIDITY OF SEROLOGICAL TESTING FOR INTERNATIONAL MOVEMENT (see note ~~4~~3)		Name (in capital letters) and signature of the Certifying~~Official~~ Veterinarian (see note 6)
from (dd/mm/yy)	to (dd/mm/yy)	

Annex XVIII (contd)

VI. CLINICAL EXAMINATION (Rabies)

I, the undersigned declare herewith that I have examined on the date indicated below the animal described in Part II and have found it to be free from clinical signs of rabies ~~be clinically healthy~~ (see note 5).

Date (dd/mm/yy)	Name (in capital letters) and signature of the veterinarian (see note 6)	Name (in capital letters) and signature of the Certifying ~~Official~~ Veterinarian (see note 6)

NOTE

1. The identification number should be a permanent marking. It should be stated in the certificate ~~should~~ and be identical to that ~~which can be found~~ on the animal. When electronic identification is used, the type of microchip and the name of the manufacturer should be specified.

2. Only vaccines produced in ~~that comply~~ compliance with the recommendations of the *Terrestrial Manual* should be used ~~inactivated virus vaccines are authorised for international movements of dogs and cats~~.

3. ~~In the case of a primary~~ Vaccination or re-vaccination should be carried out in accordance with the recommendations of the manufacturer ~~the animal should have been vaccinated not less than 6 months and not more than 1 year prior to its introduction into the importing country; the vaccination should have been carried out when the animal was at least 3 months old~~.

   ~~In the case of a booster vaccination, the animal should have been vaccinated not more than 1 year prior to its introduction into the importing country.~~

4. When serological testing is required, ~~T~~the animal should have been subjected not less than 3 months and not more than ~~24~~12 months prior to its introduction into the importing country, to an antibody titration test~~. It should be~~, carried out by an official diagnostic laboratory approved by the Competent Authority of the exporting country, with positive result in accordance with the *Terrestrial Manual*. ~~The animal's serum should contain at least 0.5 International Units (IU)/ml.~~

5. The clinical examination referred to in Part VI of the certificate must be carried out ~~within 48 hours~~ as per the requirements in Chapter 8.10 ~~of shipment~~.

The Competent Authority of the importing country may require the placing of the animals which do not comply with any of the above-mentioned conditions in a quarantine station located on its territory; the conditions of stay in quarantine are laid down by the legislation of the importing country.

6. The certification should be undertaken in accordance with Chapters 5.1. and 5.2. of the *Terrestrial Code*. ~~If the veterinarian whose name and signature appear on the certificate is not an official veterinarian, his signature must be authenticated in the relevant column by the signature and stamp of an official veterinarian. The expression 'Official Veterinarian' means a civil service veterinarian or a specially appointed veterinarian, as authorised by the Veterinary Authority of the country.~~

7. If so required, the certificate should be written in the language of the importing country. In such circumstances, it should also be written in a language understood by the certifying veterinarian.

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— Text deleted

Annex XIX

CHAPTER 8.12.

RINDERPEST

Article 8.12.1.

Preamble

The global eradication of rinderpest has been achieved and was announced in mid-2011 based on the following:

1. Evidence demonstrates that there is no significant risk that rinderpest virus remains in susceptible domesticated or *wild* host populations anywhere in the world.

2. All OIE Member and non-member countries have completed the pathway defined by the OIE for recognition of national rinderpest freedom and have been officially recognised by the OIE as free from the *infection*.

3. All *vaccination* against rinderpest has ceased throughout the world.

However, rinderpest virus and vaccines continue to be held in a number of institutions around the world and this poses a small risk of virus re-introduction into *animals*.

As sequestration and destruction of virus stocks proceed, the risks of reintroduction of *infection* into *animals* is expected to progressively diminish. The possibility of release of virus demands continuing vigilance, especially in the case of those countries known to be retaining the virus. This chapter takes into account the new status and provides recommendations to prevent re-emergence of the *disease* and to ensure adequate *surveillance* and protection of livestock.

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

Article 8.12.2.

General provisions

For the purposes of the *Terrestrial Code,* the *incubation period* for rinderpest (RP) shall be 21 days.

For the purpose of this chapter, a *case* is defined as an *animal* infected with rinderpest virus (RPV) whether or not showing clinical signs.

For the purpose of this chapter, the term 'susceptible *animals*' applies to domestic, *feral* and *wild* artiodactyls.

'Ban on *vaccination* against RP' means a ban on administering any vaccine containing RPV or RPV components to any *animal*.

Annex XIX (contd)

Article 8.12.3.

Ongoing surveillance post global freedom

All countries in the world, whether or not Members of the OIE, have completed all the procedures necessary to be recognised as free from RP *infection* and annual re-confirmation of RP absence is no longer required. However, countries are still required to carry out general *surveillance* in accordance with Chapter 1.4. to detect RP should it recur and to comply with OIE reporting obligations concerning the occurrence of unusual epidemiological events in accordance with Chapter 1.1. Countries should also maintain national contingency plans for responding to events suggestive of RP.

Article 8.12.4.

Recommendations for international trade in livestock and their products

When authorising import or transit of livestock and their products, *Veterinary Authorities* should not require any RP related conditions.

Article 8.12.5.

Response to recurrence of RP

In the post-eradication era, any direct or indirect detection of RPV in an *animal* or animal product confirmed in an OIE-FAO Reference Laboratory using a prescribed test, shall constitute a global emergency requiring immediate, concerted action for its investigation and elimination.

1. Definition of a suspected case of RP

   RP should be suspected if one or more *animal* of a susceptible species is found to be exhibiting clinical signs consistent with 'stomatitis-enteritis syndrome' which is defined as fever with ocular and nasal discharges in combination with any one or more of the following:

   a) clinical signs of erosions in the oral cavity; diarrhoea; dysentery; dehydration or *death*;

   b) necropsy findings of haemorrhages on serosal surfaces; haemorrhages and erosions on alimentary mucosal surfaces; lymphadenopathy.

   Stomatitis-enteritis syndrome could indicate RP as well as a number of other *diseases* which should elicit a suspicion of RP and from which RP needs to be differentiated, including bovine virus diarrhoea/mucosal disease, malignant catarrhal fever, infectious bovine rhinotracheitis, foot and mouth disease and bovine papular stomatitis.

   The detection of RP specific antibodies in an *animal* of a susceptible species with or without clinical signs is considered a suspected *case* of RP.

2. Procedures to be followed in the event of the suspicion of RP

   Upon detection of a suspected *case*, the national contingency plan should be implemented immediately. If the contingency procedure cannot rule out the suspicion of RP, samples should be submitted to an international reference laboratory. These samples should be collected in duplicate in accordance with Chapter 2.1.15. of the *Terrestrial Manual* with one set being dispatched to one of the OIE-FAO Reference Laboratories for RP to enable molecular characterisation of the virus to facilitate identification of its source. A full epidemiological investigation should simultaneously be conducted to provide supporting information and to assist in identifying the possible source and spread of the virus.

3. Definition of a case of RP

RP should be considered as confirmed when:

a) RPV has been isolated from an *animal* or a product derived from that *animal* and identified; or

b) viral antigen or viral RNA specific to RP has been identified in samples from one or more *animals*; or

c) antibodies to RPV have been identified in one or more *animals* with either epidemiological links to a confirmed or suspected *outbreak* of RP, or showing clinical signs consistent with recent *infection* with RP.

4. Procedures to be followed after confirmation of RP

Immediately following the confirmation of the presence of RP virus, viral RNA or antibody, the Reference Laboratory should inform the country concerned, OIE and FAO, allowing the initiation of the international contingency plan.

In the event of the confirmation of RP, the entire country shall be considered infected until epidemiological investigation has indicated the extent of the infected area allowing definition of *infected* and *protection zones* for the purposes of disease control. In the event of limited *outbreaks*, a single *containment zone*, which includes all *cases*, may be established for the purpose of minimising the impact on the country. The *containment zone* should be established in accordance with Chapter 4.3. and may cross international boundaries.

Emergency *vaccination* is acceptable only with live-attenuated tissue culture RP vaccine, produced in accordance with the *Terrestrial Manual*. Vaccinated *animals* should always be clearly identified at a herd or individual level.

5. Global RP freedom is suspended and the sanitary measures for trade with the infected country or countries shall revert to those in Chapter 8.12. of the *Terrestrial Animal Health Code* 2010 Edition.

Article 8.12.6.

Recovery of free status

Should there be a confirmed occurrence of RP, as defined above, a country or *zone* shall be considered as RP infected until shown to be free through targeted *surveillance* involving clinical, serological and virological *surveillance*. The country or *zone* shall be considered free only after the OIE has accepted the evidence submitted to it.

The time needed to recover RP free status of the entire country or of the *containment zone*, if one is established, depends on the methods employed to achieve the elimination of *infection*.

One of the following waiting periods applies:

1. three months after the last *case* where a *stamping-out policy* and serological *surveillance* are applied in accordance with Article 8.12.8.; or

2. three months after the *slaughter* of all vaccinated *animals* where a *stamping-out policy*, emergency *vaccination* and serological *surveillance* are applied in accordance with Article 8.12.8.

The recovery of RP free status requires an international expert mission to verify the successful application of containment and eradication measures, as well as a review of documented evidence by the OIE.

Article 8.12.7.

Recovery of global freedom

Global RP freedom shall be reinstated provided that within six months of the confirmation of an *outbreak*, the following conditions have been met:

1. the *outbreak* was recognised in a timely manner and handled in accordance with the international contingency plan;

2. reliable epidemiological information clearly demonstrated that there was minimal spread of virus;

3. robust control measures were rapidly implemented and were successful in eliminating the virus . The control measures consisted of stamping-out of infected herds and any vaccinated *animals*, combined with sanitary procedures including quarantine and other movement controls;

4. the origin of the virus was established, and it did not relate to an undetected reservoir of *infection*;

5. a risk assessment indicates that there is negligible risk of recurrence;

6. if *vaccination* was applied, all vaccinated *animals* were slaughtered or destroyed.

If the conditions above are not met, the global RP freedom is lost and Chapter 8.12 of the *Terrestrial Animal Health Code* 2010 Edition is reinstated.

Recovery of global RP freedom would require reestablishment of an internationally coordinated RP eradication programme and assessments of RP free country status.

Article 8.12.8.

Surveillance for recovery of RP free status

A country applying for reinstatement of RP free status should provide evidence demonstrating effective *surveillance* in accordance with Chapter 1.4.

1. The target for *surveillance* should be all significant populations of RP susceptible species within the country. In certain areas some *wildlife* populations, such as African buffaloes, act as sentinels for RP *infection*.

2. Given that RP is an acute *infection* with no known carrier state, virological *surveillance* using tests described in the *Terrestrial Manual* should be conducted to confirm clinically suspected *cases*. A procedure should be established for the rapid collection and transport of samples from suspect *cases* to a recognised *laboratory* for diagnosis as described in the *Terrestrial Manual*.

3. An awareness programme should be established for all animal health professionals including *veterinarians*, both official and private, and livestock owners to ensure that RP's clinical and epidemiological characteristics and risks of its recurrence are understood. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of RP.

4. Differing clinical presentations can result from variations in levels of innate host resistance *(Bos indicus* breeds being more resistant than *B. taurus),* and variations in the virulence of the attacking strain. Experience has shown that syndromic *surveillance* strategies i.e. *surveillance* based on a predefined set of clinical signs (e.g. searching for "stomatitis-enteritis syndrome") are useful to increase the sensitivity of the system. In the case of sub-acute (mild) *cases,* clinical signs are irregularly displayed and difficult to detect.

Article 8.12.9.

Annual Update on RPV-containing Material

Annual reports should be submitted to the OIE by the end of November each year by the Veterinary Authority of the Member hosting an institution holding RPV-containing material. A separate report should be produced by each institution.

For the purpose of this article, "RPV-containing material" means field and laboratory strains of RPV; vaccine strains of RPV including valid and expired vaccine stocks; tissues, sera and other clinical material from infected or suspect *animals*; and diagnostic material containing or encoding live virus. Recombinant morbilliviruses (segmented or non-segmented) containing unique rinderpest virus nucleic acid or amino acid sequences are considered to be rinderpest virus. Full length genomic material including virus RNA and cDNA copies of virus RNA is considered to be RPV-containing material. Sub-genomic fragments of morbillivirus nucleic acid that are not capable of being incorporated in a replicating morbillivirus or morbillivirus-like virus are not considered as RPV-containing material.

Annex XIX (contd)

Annual Report on Rinderpest Virus (RPV)-containing Material as of 1 November [year]

Name of Institution:

Postal Address:

Title and Name of Contact Person:

Email/phone/fax:

1. RPV-containing material currently held as of 1 November [year]

Type	Vaccine stocks	Vaccine seed virus	Other virus isolates	Other (serum, tissue etc)
Check [x] if yes	[ ]	[ ]	[ ]	[ ]
Strain/Genetic characterisation				
Quantity/doses (if applicable)				
Ownership (if other institution)				

2. RPV-containing material destroyed during the past 12 months

Type	Vaccine stocks	Vaccine seed virus	Other virus isolates	Other (serum, tissue etc)
Check [x] if yes	[ ]	[ ]	[ ]	[ ]
Strain/Genetic characterisation				
Quantity/doses (if applicable)				

3. RPV-containing material transferred to another institution during the past 12 months

Type	Vaccine stocks	Vaccine seed virus	Other virus isolates	Other (serum, tissue etc)
Check [x] if yes	[ ]	[ ]	[ ]	[ ]
Transferred to				
Strain/Genetic characterisation				
Quantity/doses (if applicable)				

4. RPV-containing material received from another institution during the past 12 months

Type	Vaccine stocks	Vaccine seed virus	Other virus isolates	Other (serum, tissue etc)
Check [x] if yes	[ ]	[ ]	[ ]	[ ]
Received from				
Strain/Genetic characterisation				
Quantity/doses (if applicable)				

5. Research or any other use conducted on RPV-containing material during the past 12 months

[Please specify]

Annex XX

CHAPTER 8.15.

VESICULAR STOMATITIS

Article 8.15.1.

General provisions and safe commodities

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

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

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

1. *milk* and *milk products*;
2. hides and skins;
3. *meat* and *meat products*;
4. tallow;
5. gelatin and collagen.

Article 8.15.2.

VS free country

A country may be considered free from VS when:

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

Article 8.15.3.

Trade in commodities

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

Article 8.15.4.

Recommendations for importation from VS free countries

For domestic cattle, sheep, goats, pigs and horses

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

Annex XX (contd)

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

2. were kept in a VS free country since birth or for at least the past 21 days.

Article 8.15.5.

Recommendations for importation from VS free countries

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

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

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

2. come from a VS free country;

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

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

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

Article 8.15.6.

Recommendations for importation from countries considered infected with VS

For domestic cattle, sheep, goats, pigs and horses

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

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

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

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

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

Article 8.15.7.

Recommendations for importation from countries considered infected with VS

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

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

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

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

3. were protected from insect *vectors* during quarantine and transportation to the *place of shipment*.

Article 8.15.8.

Recommendations for importation from VS free countries or zones

For *in vivo* derived embryos of ruminants, swine and horses

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

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

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

Article 8.15.9.

Recommendations for importation from countries or zones considered infected with VS

For *in vivo* derived embryos of ruminants, swine and horses

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

1. the donor females:

    a) were kept for the 21 days prior to, and during, collection in an *establishment* where no *case* of VS was reported during that period;

    b) were subjected to a diagnostic test for VS, with negative results, within the 21 days prior to embryo collection;

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

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Annex XXI

CHAPTER 4.14.

OFFICIAL HEALTH CONTROL OF BEE DISEASES

~~HYGIENE AND DISEASE SECURITY PROCEDURES IN APIARIES~~

Article 4.14.1

Purpose

This chapter is intended to set out guidelines for *official health control* of bee *diseases*. These are needed for the control of endemic bee *diseases* at the country level and to detect incursions of exotic *diseases*, thereby ensuring safe *international trade* of bees, bee products and used equipment associated with beekeeping. The guidelines are designed to be general in nature and more specific recommendations or requirements are made in Chapters 9.1. to 9.6. dealing with specific bee *diseases*.

Article 4.14.~~1~~2.

Overview

In each country, official health control of bee *diseases* should include:

a) official registration of the *apiaries* by the *Veterinary Authority* in the whole country;

b~~a~~) an organisation for permanent health *surveillance*;

c~~b~~) approval of breeding *apiaries* for export trade;

d~~c~~) measures for cleaning, *disinfection* and *disinfestation* of apicultural equipment;

c~~d~~) rules precisely stating the requirements for issuing an *international veterinary certificate*.

Article 4.14.3.

Official registration of the apiaries by the Veterinary Authority in the whole country

The registration of *apiaries* is the first step in developing a regional management plan for bee *disease surveillance* and control. With knowledge of bee density and location it is possible to design valid sampling schemes, to predict the spread of *disease* and to design inspection programmes to target areas of high risk.

The official registration of *apiary* sites should include:

1) the GPS coordinates of specific *apiaries*, or

   the mapping of specific *apiaries* on gridded maps of municipalities or regions;

2) the time of year when *apiary* sites are most likely to contain colonies;

3) the average number of hives expected in a given *apiary*;

4) the name and address of the principal owner of the bees in the *apiary*.

Annex XXI (contd)

The main *apiary* locations (places where the *bee hives* are located the longest time in the year) should be registered first, followed as far as possible by the seasonal *apiary* locations.

Article 4.14.~~2~~4.

Organisation for permanent official sanitary surveillance of apiaries

Veterinary Authorities of countries are requested to regulate the organisation for permanent official sanitary *surveillance* of *apiaries*.

Permanent official sanitary *surveillance* of *apiaries* should be under the authority of the *Veterinary Authority* and should be performed either by representatives of this *Authority* or by representatives of an approved organisation, with the possible assistance of bee-keepers specially trained to qualify as 'health inspectors and advisers'.

The official *surveillance* service thus established should be entrusted with the following tasks:

1. visit *apiaries*:

    a) annual visits of a representative number of *apiaries* in the whole country during the most appropriate periods for the detection of *diseases*;

    b) unexpected visits to *apiaries* where breeding or transport operations are carried out for trade or transfer to other regions, or any other purpose whereby *diseases* could be spread, as well as to *apiaries* located in the vicinity;

    c) special visits for sanitary *surveillance* to sectors where breeding *apiaries* have been approved for export purposes;

2. collect the samples required for the diagnosis of contagious *diseases* and despatch them to an ~~official~~ *laboratory*; the results of laboratory examinations ~~must~~ should be communicated within the shortest delay to the *Veterinary Authority*;

3. apply hygiene measures, comprising, in particular, treatment of colonies of bees, as well as *disinfection* of the equipment and possibly the destruction of affected or suspect colonies and of the contaminated equipment so as to ensure rapid eradication of any *outbreak* of a contagious *disease*.

Article 4.14.~~3~~5.

Conditions for approval of breeding apiaries for export trade

Veterinary Authorities of *exporting countries* are requested to regulate the conditions for approval of breeding *apiaries* for export trade.

The apiaries ~~must~~ should:

~~1. be situated in the centre of an area defined as follows and in which:~~

~~a) no *case* of varroosis has been reported for at least the past 2 years within a radius of 50 kilometres;~~

~~b) no *case* of any other contagious *disease* of bees included in this *Terrestrial Code* has been reported for at least the past 8 months within a radius of 5 kilometres~~;

21. have received, for at least the past 2 years, visits by a health inspector and adviser, carried out at least 3 two times a year (in spring, during the breeding period and the most appropriate periods for detection of *diseases* in autumn), for the systematic examination of at least 10% of the hives containing bees and of all the apicultural equipment, and for the collection of samples to be sent to an official laboratory and, depending on the situation of the *importing* and *exporting countries*, no positive results were reported to the *Veterinary Authorities* for the relevant bee *diseases* included in the *Terrestrial Code*;

2. systematically be sampled within seven days of shipment and, depending on the situation of the *importing* and *exporting countries*, found free for the relevant bee *diseases* included in the *Terrestrial Code.* To achieve this, a statistically valid number of bee colonies should be examined by any method complying with the relevant chapters of the *Terrestrial Manual.*

Bee-keepers must should:

3. immediately notify the *Veterinary Authority* of any suspicion of a contagious *disease* of bees in the breeding *apiary* and in other *apiaries* in the vicinity;

4. not introduce into the *apiary* any bee (including pre-imago larval stages) or apicultural material or product originating from another *apiary* unless health control has been previously performed by the *Veterinary Authority*;

5. apply special breeding and despatch techniques to ensure protection against any outside contamination, especially for the breeding and sending of queen-bees and accompanying bees and to enable retesting in the *importing country*;

6. collect at least every 10 30 days, during the breeding and despatch period, samples from breeding material, brood-combs, bees (including possibly separately raised accompanying bees) queen bees and or queen-bees bees (including possibly separately raised accompanying bees), to be sent to a an official laboratory and all the positive results officially reported to the *Competent Authority*.

Article 4.14.46.

Conditions for sanitation and disinfection of apicultural equipment

Veterinary Authorities of exporting countries are requested to regulate the use of products and means for sanitation and *disinfection* of apicultural equipment in their own country, taking into account the following recommendations.

1. Any apicultural equipment kept in an *establishment* which has been recognised as being affected with a contagious *disease* of bees shall be subjected to sanitary measures ensuring the elimination of pathogens.

2. In all cases, these measures comprise the initial cleaning and scraping of the equipment, followed by sanitation or *disinfection* depending on the *disease* concerned.

3. The kind of equipment (hives, small hives, combs, extractor, small equipment, appliances for handling or storage) shall also be taken into account in the choice of procedures to be applied.

34. Infected or contaminated equipment which cannot be subjected to the above-mentioned measures must should be destroyed, preferably by burning. Any equipment in bad condition, especially hives, as well as larvae in combs affected with varroosis, American foulbrood or European foulbrood, must should be destroyed by burning.

Annex XXI (contd)

45. The products and means used for sanitation and *disinfection* shall be accepted ~~recognised~~ as being effective by the *Veterinary Authority*. They shall be used in such a manner as to exclude any risk of contaminating the equipment which could eventually affect the health of bees or adulterate the products of the hive.

~~6. When these procedures are not performed, the products shall be kept away from the bees and any contact with apicultural equipment and products must should be prevented.~~

~~7. Waste water from the cleaning, sanitation and *disinfection* of apicultural equipment shall be kept away from the bees at all times and disposed of in a sewer or in an unused well.~~

Article 4.14.~~5~~7.

Preparation of the international veterinary certificate for export

This certificate covers hives containing bees, swarms, consignments of bees (worker bees or drones), queen bees (with accompanying bees), brood-combs, royal cells, etc.

This document shall be prepared in accordance with the model contained in Chapter 5.10. and taking into account the specific-disease Chapters 9.1. to 9.6. related to bee diseases.

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CHAPTER 9.1.

INFESTATION OF HONEY BEES WITH *ACARAPIS WOODI* ~~ACARAPISOSIS OF HONEY BEES~~

Article 9.1.1.

General provisions

For the purposes of this chapter, acarapisosis, acarine disease or tracheal mite infestation is a *disease* of the adult honey bee (*Apis* species), primarily *Apis mellifera L.*~~, and possibly of other *Apis* species (such as *Apis cerana*)~~. It is caused by the Tarsonemid mite *Acarapis woodi* (*A. woodi*) (Rennie)~~. The mite is~~ an internal obligate parasite of the respiratory system~~, living and reproducing mainly in the large prothoracic trachea of the bee. Early signs of *infection* normally go unnoticed, and only when *infection* is heavy does it become apparent; this is generally in the early spring. The *infection* spreads~~ which spreads by direct contact from adult bee to adult bee. ~~, with newly emerged bees under 10 days old being the most susceptible. The mortality rate may range from moderate to high.~~

Standards for diagnostic tests and general information on the *disease* are provided ~~described~~ in the *Terrestrial Manual*.

~~When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.1.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the acarapisosis status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.1.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *A. woodi* related conditions, regardless of the *A. woodi* status of the honey bee population of the *exporting country* or *zone*:

1. pre-imago (eggs, larvae and pupae) of honey bees;

~~1~~2. honey bee semen and honey bee venom;

~~2~~3. used equipment associated with beekeeping;

~~3~~4. extracted honey, pollen, propolis, royal jelly for human consumption, and processed beeswax~~, honey bee-collected pollen, propolis and royal jelly~~.

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the acarapisosis status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.1.3.

Determination of the acarapisosis status of a country or zone~~/compartment~~

The acarapisosis status of a country or *zone~~/compartment~~* ~~(under study)~~ can only be determined after considering the following criteria:

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1. a *risk assessment* has been conducted, identifying all potential factors for acarapisosis occurrence and their historic perspective;

2. acarapisosis should be notifiable in the whole country or *zone/ ~~compartment~~* ~~(under study)~~ and all clinical signs suggestive of acarapisosis should be subjected to field and laboratory investigations;

3. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of acarapisosis;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the whole country.

Article 9.1.4.

Country or zone~~/ compartment (under study)~~ free from acarapisosis

1. Historically free status

   A country or *zone ~~/ compartment~~* ~~(under study)~~ may be considered free from acarapisosis after conducting a *risk assessment* as referred to in Article 9.1.3. but without formally applying a specific *surveillance* programme if the country or *zone/ ~~compartment~~* ~~(under study)~~ complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

   A country or *zone/ ~~compartment~~* ~~(under study)~~ which does not meet the conditions of point 1 above may be considered free from acarapisosis after conducting a *risk assessment* as referred to in Article 9.1.3. and when:

   a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone/ ~~compartment~~* ~~(under study)~~;

   b) acarapisosis is notifiable in the whole country or *zone/ ~~compartment~~* ~~(under study)~~, and any clinical cases suggestive of acarapisosis are subjected to field and laboratory investigations;

   c) for the 3 years following the last reported *case* of acarapisosis, annual surveys supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone/ ~~compartment~~* ~~(under study)~~ to provide a confidence level of at least 95% of detecting acarapisosis if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards *apiaries*, areas and seasons with a higher likelihood of *disease*;

   d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with no positive ~~negative~~ results, is carried out on a representative sample of *apiaries* in the country or *zone/ ~~compartment~~* ~~(under study)~~ to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of *disease*;

   e) ~~(under study)~~ there is no self-sustaining *feral* population of *Apis* species ~~*A. mellifera* or other possible host species~~ in the country or *zone/ ~~compartment~~* ~~(under study)~~;

   f) the importation of the *commodities* listed in this chapter into the country or *zone/ ~~compartment~~* ~~(under study)~~ is carried out in conformity with the recommendations of this chapter.

Article 9.1.5.

Recommendations for the importation of live queen honey bees, worker bees and drones with or without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees come from a country or *zone/ compartment* ~~(under study)~~ free from acarapisosis or the *apiary* meets the conditions prescribed in Article 4.14.~~3.~~5. With regards to the provisions detailed in the Article 4.14.5.2., this will be achieved by a statistically valid number of bees per colony being examined by any method complying with the relevant chapter of the *Terrestrial Manual* and found free of all life stages of *A. woodi*.

~~Article 9.1.6.~~

~~**Recommendations for the importation of eggs, larvae and pupae of honey bees**~~

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:~~

~~1. were sourced from an officially free country or *zone/ compartment* (under study); or~~

~~2. were examined by an official laboratory and declared free of all life stages of *A. woodi*; or~~

~~3. have originated from queens in a *quarantine station* and were examined microscopically and found free of all life stages of *A. woodi*.~~

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Annex XXI (contd)

CHAPTER 9.4.

INFESTATION WITH *AETHINA TUMIDA* ~~SMALL HIVE BEETLE INFESTATION~~ ~~(*Aethina tumida*)~~

Article 9.4.1.

General provisions

For the purposes of this chapter, small hive beetle (SHB) is an infestation of colonies of *Apis* species, *Bombus* species and stingless bees ~~social bee colonies~~ by the beetle *Aethina tumida*, which is a free-living predator parasite and scavenger affecting bee populations ~~of the honey bee *Apis mellifera* L. It can also parasitise~~ invade ~~bumble bee *Bombus terrestris* and stingless bee *Trigona carbonaria* colonies under experimental conditions, and although infestation has not been demonstrated in *wild* populations, *Bombus* spp. must also be considered to be susceptible to infestation~~.

The adult beetle is attracted to bee colonies to reproduce, although it can survive and reproduce independently in other natural environments, using other food sources, including certain types of fruit. Hence once it is established within a localised environment, it is extremely difficult to eradicate.

~~The life cycle of *A. tumida* begins with the adult beetle laying eggs within infested hives. These are usually laid in irregular masses in crevices or brood combs. After 2-6 days, the eggs hatch and the emerging larvae begin to feed voraciously on brood comb, bee eggs, pollen and honey within the hive. The SHB has a high reproductive potential. Each female can produce about 1,000 eggs in its 4 to 6 months of life. At maturation (approximately 10-29 days after hatching), the larvae exit the hive and burrow into soil around the hive entrance. Adult beetles emerge after an average of 3-4 weeks, although pupation can take between 8 and 60 days depending on temperature and moisture levels.~~

The life span of an adult beetle depends on environmental conditions such as temperature and humidity but, in practice, adult female beetles can live for at least 6 months and, in favourable reproductive conditions, the female is capable of producing up to a thousand eggs over a lifespan of four to six months ~~laying new egg batches every 5-12 weeks~~. The beetle is able to survive at least 2 weeks without food ~~and 50 days on brood combs~~.

Early signs of infestation and reproduction in the debris may go unnoticed~~, but the growth of the beetle population is rapid, leading to high bee mortality in the hive~~. When the bees cannot prevent beetle mass reproduction on the combs, this leads to abandonment and/or collapse of the colony. Because *A. tumida* can be found and can thrive within the natural environment, and can fly up to 6-13 km from its nest site, it is capable of dispersing rapidly and directly invading new ~~colonising~~ hives. Dispersal of beetles includes following or accompanying swarms of bees. Spread of infestation does not require contact between adult bees. ~~However, t~~The movement of adult bees, honeycomb and other apiculture products and used equipment associated with bee-keeping may all cause infestations to spread to previously unaffected colonies.

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

Article 9.4.2.

~~Trade in~~ Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *A. tumida* related conditions, regardless of the *A. tumida* status of the honey bee and bumble bee population of the *exporting country* or *zone*:

1. honey bee semen and honey bee venom;

2. packaged extracted honey for human consumption, refined or rendered beeswax, propolis and frozen or dried royal jelly.

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the *A. tumida* status of the honey bee and bumble bee population of the *exporting country* or *zone*.~~

Article 9.4.3.

Determination of the *A. tumida* status of a country or zone

The *A. tumida* status of a country or *zone* can only be determined after considering the following criteria:

1. a risk assessment has been conducted, identifying all potential factors for *A. tumida* occurrence and their historic perspective;

2~~1~~. *A. tumida* infestation should be notifiable in the whole country, and all signs suggestive of *A. tumida* infestation should be subjected to field and *laboratory* investigations;

3~~2~~. on-going awareness and training programmes should be in place to encourage reporting of all cases suggestive of *A. tumida* infestation;

4~~3~~. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.4.4.

Country or zone free from *A. tumida*

1. Historically free status

   A country or *zone* may be considered free from the pest after conducting a *risk assessment* as referred to in Article 9.4.3. but without formally applying a specific *surveillance* programme if the country or *zone* complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

   A country or *zone* which does not meet the conditions of point 1 above may be considered free from *A. tumida* infestation after conducting a *risk assessment* as referred to in Article 9.4.3. and when:

   a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone*;

Annex XXI (contd)

b) *A. tumida* infestation is notifiable in the whole country or *zone*, and any clinical cases suggestive of *A. tumida* infestation are subjected to field and *laboratory* investigations; a contingency plan is in place describing controls and inspection activities;

c) for the 5 years following the last reported *case* of *A. tumida* infestation, an annual survey supervised by the *Veterinary Authority*, with negative results, has been carried out on a representative sample of *apiaries* in the country or *zone* to provide a confidence level of at least 95% of detecting *A. tumida* infestation if at least 1% of the *apiaries* were infested at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of infestation;

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* to indicate that there have been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of infestation;

e) all equipment associated with previously infested *apiaries* has been destroyed, or cleaned and sterilised to ensure the destruction of *A. tumida* spp., in conformity with one of the following ~~referred to in Chapter X.X. recommended by the OIE (under study)~~ procedures:

i) heating to 50°C core temperature and holding at that temperature for 24 hours, or

ii) freezing for 24 hours, or

iii) irradiation with 400 Gy;

f) the soil and undergrowth in the immediate vicinity of all infested *apiaries* has been treated with a soil drench or similar suitable treatment that is efficacious in destroying incubating *A. tumida* larvae and pupae;

g) the importation of the *commodities* listed in this chapter into the country or *zone* is carried out, in conformity with the recommendations of this chapter.

Article 9.4.5.

Recommendations for the importation of individual consignments containing a single live queen honey bee or queen bumble bee, accompanied by a small number of associated attendants (a maximum of 20 attendants per queen)

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

1. the bees come from a country or *zone* officially free from *A. tumida* infestation;

OR

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* including an attestation from the *Veterinary Authority* of the exporting third country stating that:~~

~~1~~2. the bees come from hives or colonies which were inspected immediately prior to dispatch and show no signs or suspicion of the presence of *A. tumida* or its eggs, larvae or pupae; and

~~2~~3. the bees come from an area of at least 100 km radius where no *apiary* has been subject to any restrictions associated with the occurrence of *A. tumida* for the previous 6 months; and

~~3~~4. the bees and accompanying packaging presented for export have been thoroughly and individually inspected and do not contain *A. tumida* or its eggs, larvae or pupae; and

45. the consignment of bees is covered with fine mesh through which a live beetle cannot enter.

Article 9.4.6.

Recommendations for the importation of live worker bees, drone bees or bee colonies with or without associated brood combs or for live bumble bees

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

1. the bees come from a country or *zone* officially free from *A. tumida* infestation; and

2. the bees and accompanying packaging presented for export have been inspected and do not contain *A. tumida* or its eggs, larvae or pupae; and

3. the consignment of bees is covered with fine mesh through which a live beetle cannot enter.

Article 9.4.7.

Recommendations for the importation of eggs, larvae and pupae of honey bees or bumble bees

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

1. the products were sourced from a country or *zone* free from *A. tumida* infestation;

OR

2. the products have been bred and kept under a controlled environment within a recognised establishment which is supervised and controlled by the *Veterinary Authority*;

3. the establishment was inspected immediately prior to dispatch and all eggs, larvae and pupae show no clinical signs or suspicion of the presence of *A. tumida* or its eggs or larvae or pupae, and

4. the packaging material, containers, accompanying products and food are new and all precautions have been taken to prevent contamination with *A. tumida* or its eggs, larvae or pupae.

Article 9.4.8.

Recommendations for the importation of used equipment associated with beekeeping

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

1. the equipment:

   EITHER

   a) comes from a country or *zone* free from *A. tumida* infestation; and

   b) contains no live honey bees or bee brood;

Annex XXI (contd)

OR

c) contains no live honey bees or bee brood; and

d) has been thoroughly cleaned, and treated to ensure the destruction of *A. tumida* ~~spp.~~, in conformity with one of the following procedures ~~referred to in Chapter X.X. recommended by the OIE (under study)~~ :

i) heating to 50°C core temperature and holding at that temperature for 24 hours, or

ii) freezing for 24 hours, or

iii) irradiation with 400 Gy; ~~and~~

AND

2. all precautions have been taken to prevent infestation/contamination.

Article 9.4.9.

Recommendations for the importation of honey-bee collected pollen and beeswax (in the form of honeycomb)

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

1. the products:

EITHER

a) comes from a country or *zone* free from *A. tumida* infestation; and

b) contains no live honey bees or bee brood;

OR

c) contains no live honey bees or bee brood; and

d) has been thoroughly cleaned, and treated to ensure the destruction of *A. tumida* ~~spp.~~, in conformity with one of the following procedures ~~referred to in Chapter X.X. recommended by the OIE (under study)~~ :

i) heating to 50°C core temperature and holding at that temperature for 24 hours, or

ii) freezing for 24 hours, or

iii) irradiation with 400 Gy;

AND

2. all precautions have been taken to prevent infestation/contamination.

Article 9.4.10.

Recommendations for the importation of comb honey

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

1. comes from a country or *zone* free from *A. tumida* infestation; and

2. contains no live honey bees or bee brood;

OR

3. were frozen ~~subjected to a treatment at a temperature of -12°C or lower~~ in the core of the product during at least 24 hours.

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Annex XXI (contd)

CHAPTER 9.5.

~~*TROPILAELAPS*~~ INFESTATION OF HONEY BEES WITH *TROPILAELAPS* SPP.

Article 9.5.1.

General provisions

For the purposes of this chapter, *Tropilaelaps* infestation of the honey bee (*Apis* species) ~~*Apis mellifera* L.~~ is caused by different species of *Tropilaelaps* (including the mites *Tropilaelaps clareae*, *T. koenigerum*, *T. thaii* and *T. mercedesae*). The mite is an ectoparasite of brood of *Apis* species ~~*Apis mellifera* L., *Apis laboriosa* and *Apis dorsata*~~, and cannot survive for periods of more than ~~7~~ 21 days away from bee brood.

Early signs of *infection* normally go unnoticed, but the growth in the mite population is rapid leading to high hive mortality. The *infection* spreads by direct contact from adult bee to adult bee, and by the movement of infested bees and bee brood. The mite can also act as a vector for viruses of the honey bee.

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

~~When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.5.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *Tropilaelaps* status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.5.2.

~~Trade in~~ Safe commodities

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

1. honey bee semen, honey bee eggs and honey bee venom;

2. extracted honey, pollen, propolis~~;~~ and royal jelly for human consumption; ~~and~~

3. processed beeswax ~~(not in the form of honeycomb)~~.

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the *Tropilaelaps* status of the honey bee population of the *exporting country* or *zone*.~~

Article 9.5.3.

Determination of the *Tropilaelaps* status of a country or zone~~/compartment~~

The *Tropilaelaps* status of a country or *zone~~/compartment~~* ~~(under study)~~ can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for *Tropilaelaps* occurrence and their historic perspective;

2. *Tropilaelaps* infestation should be notifiable in the whole country or *zone~~/compartment~~* ~~(under study)~~ and all clinical signs suggestive of *Tropilaelaps* infestation should be subjected to field and laboratory investigations;

3. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of *Tropilaelaps* infestation;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.5.4.

Country or zone~~/compartment (under study)~~ free from *Tropilaelaps* spp

1. Historically free status

   A country or *zone~~/compartment~~* ~~(under study)~~ may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.5.3. but without formally applying a specific *surveillance* programme if the country or *zone~~/compartment~~* ~~(under study)~~ complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

   A country or *zone~~/compartment~~* ~~(under study)~~ which does not meet the conditions of point 1 above may be considered free from *Tropilaelaps* infestation after conducting a *risk assessment* as referred to in Article 9.5.3. and when:

   a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone~~/compartment~~* ~~(under study)~~;

   b) *Tropilaelaps* infestation is notifiable in the whole country or *zone~~/compartment~~* ~~(under study)~~, and any clinical cases suggestive of *Tropilaelaps* infestation are subjected to field and laboratory investigations;

   c) for the 3 years following the last reported *case* of *Tropilaelaps* infestation, an annual survey supervised by the *Veterinary Authority*, with negative results, have been carried out on a representative sample of *apiaries* in the country or *zone~~/compartment~~* ~~(under study)~~ to provide a confidence level of at least 95% of detecting *Tropilaelaps* infestation if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of infestation;

Annex XXI (contd)

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* in the country or *zone/ compartment* (under study) to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of *disease*;

e) (under study) there is no self-sustaining *feral* population of *Apis* species *A. mellifera*, *A. dorsata* or *A. laboriosa*, or other possible host species in the country or *zone/ compartment* (under study);

f) the importation of the *commodities* listed in this chapter into the country or *zone/ compartment* (under study) is carried out, in conformity with the recommendations of this chapter.

Article 9.5.5.

Recommendations for the importation of live queen honey bees, worker bees, and drones and with associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *commodities* bees come from an apiary situated in a country or *zone/ compartment* (under study) officially free from *Tropilaelaps* infestation the *apiary* meets the conditions prescribed in Article 4.14.3.

In the case of the country or *zone* is not free from *Tropilaelaps* infestation, *Veterinary Authorities* of *importing countries* should only allow the importation of queen honey bees with attendants worker bees without associated brood combs and should require that the bees meet the following conditions:

1. come from an artificial broodless swarm with the caged queen, and

2. caged queen and swarm have been treated with an effective veterinary medicinal product and kept isolated for 21 days from brood prior to the shipment, and

3. were inspected by a representative of the *Veterinary Services* prior to the shipment and showed no evidence of the presence of the mites.

Article 9.5.6.

Recommendations for the importation of live queen honey bees, worker bees and drones without associated brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the bees have been held in isolation from brood and bees with access to brood, for a period of at least seven days.

Article 9.5.~~7~~6.

Recommendations for the importation of used equipment associated with beekeeping

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

1. comes from a country or *zone~~/ compartment~~* ~~(under study)~~ free from *Tropilaelaps* infestation; or
2. contains no live honey bees or bee brood and has been held away from contact with live honey bees for at least ~~7~~ 21 days prior to shipment; or
3. has been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the following procedures~~:~~ ~~referred to in Chapter X.X. recommended by the OIE (under study).~~

   a) heating to 50°C core temperature and holding at that temperature for 20 minutes, or

   b) freezing for 48 hours once the core reached -20°C, or

   c) fumigation with methyl bromide at a rate of 48 g per cubic metre at atmospheric pressure and at a temperature of 10-15°C for a period of 2 hours, or

   d) irradiation with 350 Gy.

Article 9.5.~~7~~8.

Recommendations for the importation of honey-bee collected pollen, beeswax (in the form of honeycomb), comb honey and propolis

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

1. come from a country or *zone~~/ compartment~~* ~~(under study)~~ free from *Tropilaelaps* infestation; or
2. contain no live honey bees or bee brood and has been held away from contact with live honey bees for at least ~~7~~ 21 days prior to shipment; or
3. have been treated to ensure the destruction of *Tropilaelaps* spp., in conformity with one of the following procedures ~~referred to in Chapter X.X. recommended by the OIE (under study).~~:

   a) heating to 50°C core temperature and holding at that temperature for 20 minutes, or

   b) freezing for 48 hours once the core reached -20°C, or

   c) fumigation with methyl bromide at a rate of 48 g per cubic metre at atmospheric pressure and at a temperature of 10-15°C for a period of 2 hours, or

   d) irradiation with 350 Gy.

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Annex XXI (contd)

CHAPTER 9.6.

INFESTATION ~~VARROOSIS~~ OF HONEY BEES WITH *VARROA* SPP.

Article 9.6.1.

General provisions

For the purposes of this chapter, varroosis is a *disease* of ~~the~~ honey bees~~,~~ (*Apis* species) ~~*Apis mellifera* L. It is~~ caused by ~~the Korea and Japan haplotypes of the~~ mites in the genus *Varroa* ~~*destructor*~~, primarily *Varroa destructor*. ~~the original hosts of which are the Korea and Japan haplotypes of *Apis cerana* (under study).~~ The mite is an ectoparasite of adults and brood of *Apis* spp. ~~*mellifera* L. During its life cycle, sexual reproduction occurs inside the honey bee brood cells. Early signs of *infection* normally go unnoticed, and only when *infection* is heavy does it become apparent.~~ ~~The *infection*~~ and spreads by direct contact from adult bee to adult bee, and by the movement of infested bees~~, and~~ bee brood, bee products and used equipment associated with beekeeping. The mite can also act as a vector for viruses of the honey bee.

The number of parasites steadily increases with increasing brood activity and the growth of the bee population, especially late in the season when clinical signs of infestation can first be recognised. The life span of an individual mite depends on temperature and humidity but, in practice, it can be said to last from some days to a few months.

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

~~When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 9.6.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the varroosis status of the honey bee population of the *exporting country* or *zone.*~~

Article 9.6.2.

~~Trade in~~ Safe commodities

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

1. honey bee semen, honey bee eggs and honey bee venom;

2. ~~extracted honey,~~ pollen, propolis~~,~~ and royal jelly for human consumption ~~and processed~~ beeswax ~~(not in the form of honeycomb)~~.

3. extracted honey and processed beeswax.

~~When authorising import or transit of other *commodities* listed in this Chapter, *Veterinary Authorities* should require the conditions prescribed in this Chapter relevant to the varroosis status of the honey bee population of the *exporting country* or *zone.*~~

Article 9.6.3.

Determination of the varroosis status of a country or zone~~/compartment~~

The varroosis status of a country or *zone~~/compartment~~* ~~(under study)~~ can only be determined after considering the following criteria:

1. a *risk assessment* has been conducted, identifying all potential factors for varroosis occurrence and their historic perspective;

2. varroosis should be notifiable in the whole country or *zone~~/compartment~~* ~~(under study)~~ and all clinical signs suggestive of varroosis should be subjected to field and laboratory investigations;

3. an on-going awareness programme should be in place to encourage reporting of all cases suggestive of varroosis;

4. the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees should have current knowledge of, and authority over, all domesticated *apiaries* in the country.

Article 9.6.4.

Country or zone~~/compartment (under study)~~ free from varroosis

1. Historically free status

   A country or *zone~~/compartment~~* ~~(under study)~~ may be considered free from the *disease* after conducting a *risk assessment* as referred to in Article 9.6.3. but without formally applying a specific *surveillance* programme (historical freedom) if the country or *zone~~/compartment~~* ~~(under study)~~ complies with the provisions of Chapter 1.4.

2. Free status as a result of an eradication programme

   A country or *zone~~/compartment~~* ~~(under study)~~ which does not meet the conditions of point 1 above may be considered free from varroosis after conducting a *risk assessment* as referred to in Article 9.6.3. and when:

   a) the *Veterinary Authority* or other *Competent Authority* with responsibility for reporting and control of *diseases* of honey bees has current knowledge of, and authority over, all domesticated *apiaries* existing in the country or *zone~~/compartment~~* ~~(under study)~~;

   b) varroosis is notifiable in the whole country or *zone~~/compartment~~* ~~(under study)~~, and any clinical cases suggestive of varroosis are subjected to field and laboratory investigations;

   c) for the 3 years following the last reported *case* of varroosis, an annual survey supervised by the *Veterinary Authority*, with no positive ~~negative~~ results, have been carried out on a representative sample of *apiaries* in the country or *zone~~/compartment~~* ~~(under study)~~ to provide a confidence level of at least 95% of detecting varroosis if at least 1% of the *apiaries* were infected at a within-*apiary* prevalence rate of at least 5% of the hives; such surveys may be targeted towards areas with a higher likelihood of *disease*;

Annex XXI (contd)

d) to maintain free status, an annual survey supervised by the *Veterinary Authority*, with negative results, is carried out on a representative sample of *apiaries* in the country or *zone/ ~~compartment~~* ~~(under study)~~ to indicate that there has been no new *cases*; such surveys may be targeted towards areas with a higher likelihood of *disease*;

e) ~~(under study)~~ there is no self-sustaining *feral* population of *Apis* species ~~*A. mellifera*, the Korea and Japan haplotypes of *Apis cerana* or other possible host species~~ in the country or *zone/ ~~compartment~~* ~~(under study)~~;

f) the importation of the *commodities* listed in this chapter into the country or *zone/ ~~compartment~~* ~~(under study)~~ is carried out in conformity with the recommendations of this chapter.

~~Article 9.6.4.bis~~

~~**Apiary free from varroosis**~~

~~1. The *apiary* is located in a country or *zone* complying with the requirements in points 2. a) b) and f) of Article 9.6.4.;~~

~~2. the *apiary* should be situated in an area with a radius of 50 kilometres in which no *case* of varroosis has been reported for at least the past 2 years; and~~

~~3. the *apiary* meets the conditions prescribed in Article 4.14.3.~~

Article 9.6.5.

Recommendations for the importation of live queen honey bees, worker bees, ~~and~~ drones, ~~with or without associated brood combs~~ larvae of honey bees, pupae of honey bees and brood combs

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *commodities* ~~bees~~ come from an apiary situated in a country or *zone/ ~~compartment~~* ~~(under study) officially~~ free from varroosis : ~~the *apiary* meets the conditions prescribed in Article 9.6.4. bis~~.

In the case of the country or zone is not free from varroosis, *Veterinary Authorities* of *importing countries* should only allow the importation of queen honey bees with attendants worker bees without associated brood combs and should require that the bees meet the following conditions:

1. come from an artificial broodless swarm with the caged queen, and

2. caged queen and swarm have been treated with an effective veterinary medicinal product, and

3. were inspected by a representative of the *Veterinary Services* prior to the shipment and showed no evidence of the presence of the mites.

~~Article 9.6.6.~~

~~**Recommendations for the importation of larvae and pupae of honey bees**~~

~~*Veterinary Authorities* of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:~~

~~1. were sourced from a free country or *zone/ compartment* (under study); or~~

~~2. have originated from queens in a *quarantine station* and were inspected and found free of *Varroa destructor*.~~

Article 9.6.~~7~~6.

Recommendations for the importation of used equipment associated with beekeeping

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

1. comes from a country or *zone/ ~~compartment~~* ~~(under study)~~ free from varroosis; or

2. contains no live honey bees or bee brood and has been held away from contact with live honey bees for at least ~~7~~ 21 days prior to shipment; or

3. has been treated to ensure the destruction of *Varroa* species ~~*destructor*~~, in conformity with one of the following procedures:

   a) heating to 50°C core temperature and holding at that temperature for 20 minutes, or

   b) freezing for 48 hours once the core reached -20°C, or

   c) fumigation with methyl bromide at a rate of 48 g per cubic metre at atmospheric pressure and at a temperature of 10-15°C for a period of 2 hours, or

   d) irradiation with 350 Gy.

~~referred to in Chapter X.X. recommended by the OIE (under study).~~

Article 9.6.~~8~~7.

Recommendations for the importation of honey-bee collected pollen and propolis for apiculture use, unprocessed beeswax ~~(in the form of honeycomb)~~, and comb honey ~~and propolis~~

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

1. come from a country or *zone/ ~~compartment~~* ~~(under study)~~ free from varroosis; or

2. contain no live honey bees or bee brood and has been held away from contact with live honey bees for at least ~~7~~ 21 days prior to shipment; or

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3. have been treated to ensure the destruction of *Varroa* species ~~*destructor*~~, in conformity with one of the following procedures ~~referred to in Chapter X.X. recommended by the OIE (under study)~~:

a) heating to 50°C core temperature and holding at that temperature for 20 minutes, or

b) freezing for 48 hours once the core reached -20°C, or

c) fumigation with methyl bromide at a rate of 48 g per cubic metre at atmospheric pressure and at a temperature of 10-15°C for a period of 2 hours, or

d) irradiation with 350 Gy.

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Annex XXII

CHAPTER 11.3.

INFECTION WITH *BRUCELLA ABORTUS, MELITENSIS* AND *SUIS*

Article 11.3.1.

General provisions

The aim of this chapter is to mitigate the risk of spread of, and the risk to human health from, *B. abortus, B. melitensis* and *B. suis* in *animals*.

For the purpose of this chapter, '*Brucella'* means *B. abortus, B. melitensis* or *B. suis*.

For the purpose of this chapter, 'animals' means domestic and *captive wild* animal populations of the following categories:

1. Bovidae means cattle (*Bos taurus*, *B. indicus, B. frontalis* and *B. javanicus*), yak (*B. grunniens*), bison (*Bison bison* and *B. bonasus*) and water buffalo (*Bubalus bubalis*).

2. Ovidae and Capridae mean sheep (*Ovis aries*) and goats (*Capra aegagrus*).

3. Pigs means domestic pigs and *wild* boars (*Sus scrofa*).

4. *Camelidae* means dromedary (*Camelus dromedarius*), Bactrian camel (*Camelus bactrianus*), llama (*Lama glama*), alpaca (*Lama pacos*), guanaco *(Lama guanicoe*) and vicuna (*Vicugna vicugna*).

5. *Cervidae* means red deer, wapiti, sika, samba, rusa, fallow deer, white-tailed, black-tailed, mule deer and reindeer (*Cervus elaphus, C. canadensis, C. nippon, C. unicolor unicolor, C. timorensis, Dama dama dama, Odocoileus virginianus borealis, Odocoileus hemionus columbianus, Odocoileus hemionus hemionus* and *Rangifer tarandus*).

6. European hare (*Lepus europaeus*).

The chapter deals not only with the occurrence of clinical signs caused by *Brucella infection*, but also with the presence of *Brucella infection* in the absence of clinical signs.

A *case* is an *animal* infected with *Brucella*.

The following defines a *case* of *Brucella infection*:

– *Brucella* has been isolated and/or identified as such from an *animal* or a product derived from that *animal*;

OR

– positive results to one or more tests have been obtained and there is epidemiological evidence of *Brucella infection*.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*. In the absence of sufficient scientific information, the prescribed tests for bovidae, except bovine specific indirect ELISAs, may be applied to *Cervidae* and *Camelidae*.

Article 11.3.2.

Safe commodities

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

1. skeletal muscle *meat*, brain and spinal cord, digestive tract, thymus, thyroid and parathyroid glands and derived products, provided that they are accompanied by an *international veterinary certificate* attesting that they are originating from *animals* that have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.;

2. cured hides and skins;

3. gelatine, collagen, tallow and *meat-and-bone meal*.

When authorising import or transit of other *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *Brucella* status of the animal population of the *exporting country*, *zone* or *herd* or *flock*.

Article 11.3.3.

Country or zone free from *Brucella* infection in animals without vaccination

A country or *zone* can be qualified free from *Brucella infection* without vaccination either in one or several of the animal categories listed in Article 11.3.1.

To qualify as free from *Brucella infection* without vaccination, a country or *zone* should satisfy for each relevant category of *animals* the following requirements:

1. *Brucella infection* in *animals* is a *notifiable disease* in the country;

2. a programme should be in place to ensure effective reporting of all *cases* suggestive of *Brucella infection*, particularly abortions, and regular submission of abortion material to diagnostic laboratories for investigation;

3. neither domestic nor *captive wild animals* have been vaccinated against *Brucella infection* for at least the past three years;

4. no *case* of abortion due to *Brucella infection* and no isolation of *Brucella* has been recorded in *animals* for at least the past three years;

5. except for pigs:

    a) regular and periodic testing of all *herds* or *flocks* demonstrated that *Brucella infection* was not present in at least 99.8% of the *herds* or *flocks* and 99.9% of *animals* in the country or *zone* for three consecutive years;

b) a *surveillance* programme based on regular and periodic testing of *animals* should be in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

c) if a *surveillance* programme described in Points 2 and 5 a) and b) above has not detected *Brucella infection* for the past five years, *surveillance* should be maintained in accordance with Chapter 1.4.;

6. vaccinated *animals* should not be introduced. Unvaccinated *animals* and genetic materials should comply with the recommendations in Articles 11.3.8. to 11.3.12. The free status without vaccination of the country or *zone* for a specified animal category is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* and *wild animals* provided that the relevant animal population belonging to the specified animal category free from *Brucella infection* is effectively separated from the potential source of *infection*.

Article 11.3.4.

Country or zone free from *Brucella* infection in animals with vaccination

A country or *zone* can be qualified free from *Brucella infection* with vaccination either in bovidae or ovidae and capridae as listed in Article 11.3.1.

To qualify as free from *Brucella infection* with vaccination, a country or *zone* should satisfy for each relevant category of *animals* the following requirements:

1. *Brucella infection* in *animals* is a *notifiable disease* in the country;

2. vaccinated *animals* should be identified with a permanent mark;

3. a programme should be in place to ensure effective reporting of all *cases* suggestive of *Brucella infection*, particularly abortions, and regular submission of abortion material to diagnostic laboratories for investigation;

4. no *case* of abortion due to *Brucella infection* and no isolation of *Brucella* has been recorded in *animals* during at least the past three years;

5. regular and periodic testing of all *herds* or *flocks* demonstrated that *Brucella infection* was not present in at least 99.8% of the *herds* or *flocks* and 99.9% of *animals* in the country or *zone* for three consecutive years;

6. a *surveillance* programme based on regular and periodic testing of *animals* should be in place in the country or *zone* to detect *Brucella infection* in accordance with Chapter 1.4.;

7. if a *surveillance* programme described in Points 3, 5 and 6 above has not detected *Brucella infection* for the past five years, *surveillance* should be maintained in accordance with Chapter 1.4.;

8. *animals* and genetic materials introduced should comply with the recommendations in Articles 11.3.8. to 11.3.12.

The free status with vaccination of the country or *zone* for a specified animal category is not affected by the occurrence of *Brucella infection* in other animal categories or *feral* and *wild animals* provided that the relevant animal population belonging to the specified animal category free from *Brucella infection* is effectively separated from the potential source of *infection*.

Annex XXII (contd)

Article 11.3.5.

Herd or flock free from *Brucella* infection without vaccination

1. To qualify as free from *Brucella infection* without vaccination, a *herd* or *flock* of the relevant animal category should satisfy the following requirements:

   a). the *herd* or *flock* is in a country or *zone* free from *Brucella infection* without vaccination for the relevant animal category and is certified free without vaccination by the *Veterinary Authority*;

   OR

   b). the *herd* or *flock* is in a country or *zone* free from *Brucella infection* with vaccination for the relevant animal category and is certified free without vaccination by the *Veterinary Authority*; and no *animal* of the *herd* or *flock* has been vaccinated in the past three years;

   OR

   c) the *herd* or *flock* met the following conditions:

      i) *Brucella infection* in *animals* is a *notifiable disease* in the country;

      ii) no *animal* of the *herd* or *flock* has been vaccinated during the past three years;

      iii) the *herd* or *flock* has not shown evidence of *Brucella infection* for at least the past nine months;

      iv) all suspect *cases* (such as *animals* which have aborted) have been subjected to the necessary clinical and laboratory investigations with negative results;

      v) all *animals* were subjected to a prescribed serological test with negative results on two occasions, at an interval of more than 6 and less than 12 months between each test, the first test being performed not before 3 months after the *slaughter* of the last *case*.

2. To maintain the free status, the following conditions should be met:

   a) regular prescribed tests, at a frequency depending on the prevalence of *herd* or *flock infection* in the country or *zone*, demonstrate the continuing absence of *Brucella infection*;

   b) *animals* introduced into the *herd* or *flock* should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from:

      i) a country or *zone* free from *Brucella infection* without vaccination;

      OR

      ii) a country or *zone* free from *Brucella infection* with vaccination and the *animals* have not been vaccinated during the last three years;

OR

iii) a *herd* or *flock* free from *Brucella infection* with or without vaccination, provided that the *animals* have not been vaccinated in the last 3 years and negative results were shown to a prescribed test during the 30 days prior to shipment; in the *case* of females which have given birth during the past 30 days, the test should be carried out at least 30 days after the birth. This test is not required for sexually immature *animals* or vaccinated *animals* less than 18 months of age.

c) There is no evidence of *infection* in other epidemiologically relevant animal species kept in the same *establishment*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other species kept in the same *establishment*.

Article 11.3.6.

Herd or flock free from *Brucella* infection with vaccination

A *herd* or *flock* can be qualified free from *Brucella infection* with vaccination either in bovidae or ovidae and capridae as listed in Article 11.3.1.

1. To qualify as free from *Brucella infection* with vaccination, a *herd* or *flock* of the relevant animal category should satisfy the following requirements:

   a) the *herd* or *flock* is in a country or *zone* free from *Brucella infection* with vaccination for the relevant animal category and is certified free with vaccination by the *Veterinary Authority*;

   OR

   b) the *herd* or *flock* met the following conditions:

      i) *Brucella infection* in *animals* is a *notifiable disease* in the country;

      ii) vaccinated *animals* should be permanently identified;

      iii) the *herd* or *flock* has not shown evidence of *Brucella infection* during at least the past nine months;

      iv) all suspect *cases* (such as *animals* which have aborted) have been subjected to the necessary clinical and laboratory investigations with negative results;

      v) all *animals* were subjected to a prescribed serological test with negative results on two occasions, at an interval of more than 6 and less than 12 months between each test, the first test being performed not before 3 months after the *slaughter* of the last *case*.

2. To maintain the free status, the following conditions should be met:

   a) regular prescribed tests, at a frequency depending on the prevalence of *herd* or *flock infection* in the country or *zone*, demonstrate the continuing absence of *Brucella infection*;

b) *animals* introduced into the *herd* or *flock* should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from either:

i) a country or *zone* free from *Brucella infection* with or without vaccination;

OR

ii) a *herd* or *flock* free from *Brucella infection* with or without vaccination, provided that negative results were shown to a prescribed test during the 30 days prior to shipment; in the *case* of females which have given birth during the past 30 days, the test should be carried out at least 30 days after the birth. This test is not required for sexually immature *animals* or vaccinated *animals* less than 18 months of age.

c) There is no evidence of *infection* in other epidemiologically relevant animal species kept in the same *establishment*, or measures have been implemented to prevent any transmission of the *Brucella infection* from other species kept in the same *establishment*.

Article 11.3.7.

Recovery of the *Brucella* infection free status in a country or a zone

Should a *case* of *Brucella infection* in one or more animal categories occur in a free country or *zone*, the status is suspended and may not be recovered until:

1. all infected *animals* of the relevant category were slaughtered or destroyed as soon as the result of the diagnostic test was known;

2. in animal categories other than pigs, all remaining sexually mature *animals* in the *herd* or *flocks* have been subjected to a serological test, with negative results, on three occasions, at an interval of not less than two months, a further test six months later and a final test a year later.

3. in pig *herds*, where *cases* of *Brucella infection* have occurred, all pigs were slaughtered or destroyed.

Article 11.3.8.

Recommendations for the importation of animals for breeding or rearing

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

1. showed no clinical sign of *Brucella infection* on the day of shipment;

2. originate from:

a) a country or *zone* free from *Brucella infection*;

OR

b) a *herd* or *flock* free from *Brucella infection* and were subjected to a prescribed serological test with negative results during the 30 days prior to shipment.

This test is not required for:

– pigs;

– young bovidae before the age of 12 months;

– young ovidae and capridae before the age of 6 months;

– young *Camelidae* and *Cervidae* before the age of sexual maturity;

OR

c) with the exception of pigs, a *herd* or *flock* not qualified free from *Brucella infection*:

i) in which no *Brucella infection* has been reported during the nine months prior to shipment;

ii) were isolated for 30 days prior to shipment and subjected during that period to a prescribed serological test with negative results. In the *case* of females which have given birth during the past 30 days, the test should be carried out at least 30 days after the birth. This test is not required for sexually immature *animals* or vaccinated *animals* less than 18 months of age.

Article 11.3.9.

Recommendations for the importation of animals for slaughter

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

1. showed no clinical signs of *Brucella infection* on the day of shipment;

2. originate from a country, *zone* or *herd* free from *Brucella infection* with or without vaccination;

   OR

3. were subjected to a prescribed test for *Brucella infection* with negative results during the 30 days prior to shipment and are not being eliminated as part of an eradication programme against *Brucella infection*.

Article 11.3.10

Recommendations for the importation of captive European hares (*Lepus europaeus*) for restocking

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

1. the *animals* showed no clinical signs of *Brucella infection* on the day of shipment;

2. a programme is in place to ensure effective investigation and reporting of all *cases* suggestive of *Brucella infection* in *establishments* keeping hares.

Annex XXII (contd)

Article 11.3.11.

Recommendations for the importation of semen

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

1. the donor *animals* showed no clinical signs of *Brucella infection* on the day of collection of the semen;

2. the donor *animals* were not vaccinated against *Brucella infection* and either:

   a) were kept in an *artificial insemination centre* free from *Brucella infection*;

      OR

   b) were kept in a *herd* or *flock* free from *Brucella infection* and are subjected every six months to a prescribed test with negative results;

3. the semen was collected, processed and stored in conformity with the provisions of Chapter 4.5. and Chapter 4.6.

Article 11.3.12

Recommendations for the importation of embryos and oocytes

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

1. the donor *animals* showed no clinical signs of *Brucella infection* on the day of collection;

2. the donor *animals* were not vaccinated against *Brucella infection* during the past three years and either:

   a) were kept in a country or *zone* free from *Brucella infection*;

      OR

   b) were kept in a *herd* or *flock* free from *Brucella infection* and are subjected every six months to a prescribed test with negative results;

3. the embryos and oocytes were collected, processed and stored in conformity with the provisions of Chapter 4.7. to Chapter 4.9.

Article 11.3.13.

Recommendations for the importation of fresh meat and meat products other than mentioned in Article 11.3.2.

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *meat* and *meat products* come from *animals*:

1. which have been subjected to ante-mortem and post-mortem inspections as described in Chapter 6.2.;

2. which:

   a) originate from a *herd* or *flock* free from *Brucella infection*;

   OR

   b) have not tested positive to a prescribed test for *Brucella infection*.

Article 11.3.14.

Recommendations for the importation of milk and milk products

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

1. have been derived from *animals* of a *herd* or *flock* free from *Brucella infection*;

   OR

2. were subjected to pasteurization or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Article 11.3.15

Recommendations for importation of wool and hair

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

1. have not been derived from *Brucella* infected *animals*;

   OR

2. have been processed to ensure the destruction of the *Brucella*.

Annex XXIII

CHAPTER 11.12.

INFECTION WITH *LUMPY SKIN DISEASE VIRUS* ~~(caused by group III virus, type Neethling)~~

Article 11.12.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for lumpy skin disease (LSD) shall be 28 days.

For the purpose of this chapter, susceptible *animals* include cattle (*Bos indicus* and *B. taurus*) and water buffalo (*Bubalus bubalis*).

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

When authorising import or transit of the *commodities* covered in the chapter, *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the LSD status of the cattle population of the *exporting country*.

Article 11.12.2.

LSD free country

A country may be considered free from LSD when:

1. LSD is notifiable in the country;

2. no *case* of LSD has been confirmed for at least the past three years;

3. no vaccination against LSD has been performed for at least three years;

4. *commodities* are imported in accordance with this chapter.

Article 11.12.3.

Recommendations for importation from LSD free countries

For domestic cattle and water buffaloes

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

1. showed no clinical sign of LSD on the day of shipment;

2. come from an LSD free country.

Annex XXIII (contd)

Article 11.12.4.

Recommendations for importation from LSD free countries

For *wild* cattle

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

1. showed no clinical sign of LSD on the day of shipment;

2. come from an LSD free country;

if the country of origin has a common border with a country considered infected with LSD:

3. were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.12.5.

Recommendations for importation from countries considered infected with LSD

For domestic cattle and water buffaloes

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

1. showed no clinical sign of LSD on the day of shipment;

2. either:

    a) were not vaccinated against LSD and were tested negative using tests according to the *Terrestrial Manual* within 14 days prior to shipment; or

    b) were vaccinated against LSD between 30 days and 90 days prior to shipment;

OR

3. either:

    a) were kept since birth, or for the past 28 days, in an *establishment* where no *case* of LSD was officially reported during that period; or

    b) were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.12.6.

Recommendations for importation from countries considered infected with LSD

For *wild* cattle

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

1. showed no clinical sign of LSD on the day of shipment;

2. were kept in a *quarantine station* for the 28 days prior to shipment.

Article 11.12.7.

Recommendations for importation from LSD free countries

For semen of cattle and water buffaloes

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

1. the donor *animals*:

    a) showed no clinical sign of LSD on the day of collection of the semen;

    b) were kept for at least 28 days prior to collection in an LSD free country;

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

Article 11.12.8.

Recommendations for importation from countries considered infected with LSD

For semen of cattle and water buffaloes

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

1. the donor *animals*:

    a) showed no clinical sign of LSD on the day of collection of the semen and for the following 28 days;

    b) were kept in the *exporting country* for the 28 days prior to collection, in an *establishment* or *artificial insemination centre* where no *case* of LSD was officially reported during that period, and that the *establishment* or *artificial insemination centre* was not situated in an LSD *infected zone*;

    c) and either:

        i) were vaccinated against LSD between 28 days and 90 days before semen collection and thereafter vaccinated annually at least 28 days before semen collection; or

        ii) were tested with negative results using a serum neutralisation test (SNT) or an indirect enzyme-linked immunosorbent assay (ELISA) for LSD on the day of first semen collection or up to 90 days after last collection; or

        iii) showed stable seropositivity (not more than a two-fold rise in titre) on paired samples (tested side by side) to indirect ELISA or SNT carried out in ~~quarantine~~ isolation, 28–60 days apart, with the first sample taken on the day of first semen collection;

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

Annex XXIII (contd)

Article 11.12.9.

Recommendations for importation from LSD free countries

For embryos/oocytes of cattle and water buffaloes

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

1. the donor *animals* showed no clinical sign of LSD on the day of collection of the embryos/oocytes; and

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

Article 11.12.10.

Recommendations for importation from countries considered infected with LSD

For embryos/oocytes of cattle and water buffaloes

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

1. the donor *animals*:

    a) were kept in an *establishment* where no *case* of LSD has been reported during the 28 days prior to collection; and

    b) showed no clinical sign of LSD on the day of collection;

    c) and either:

        i) were vaccinated against LSD between 28 days and 90 days before first embryo/oocyte collection and thereafter vaccinated annually at least 28 days before embryo/oocyte collection; or

        ii) were tested with negative results using a serum neutralisation test (SNT) or an indirect enzyme-linked immunosorbent assay (ELISA) for LSD on the day of embryo/oocyte collection or up to 90 days after last collection; or

        iii) showed stable seropositivity (not more than a two-fold rise in titre) on paired samples tested side by side to indirect ELISA or SNT carried out in ~~quarantine~~ isolation, 28–60 days apart with one of the samples taken on the day of embryo/oocyte collection;

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

Article 11.12.11.

Recommendations for importation from LSD free countries

For products of animal origin (from cattle) intended for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in an LSD free country since birth or for at least the past 28 days.

Article 11.12.12.

Recommendations for importation from countries considered infected with LSD

For products of animal origin (from cattle and water buffaloes) intended for agricultural or industrial use

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

Article 11.12.13.

Recommendations for importation from countries considered infected with LSD

For raw hides of cattle and water buffaloes

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products were stored for at least 40 days before shipment.

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— Text deleted

Annex XXIV

CHAPTER 12.1.

INFECTION WITH AFRICAN HORSE SICKNESS VIRUS

Article 12.1.1.

General provisions

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* ~~neighbouring~~ adjacent to~~, or considered to be at risk from,~~ 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 ~~Chapter 1.4.~~ Article 12.1.11. to 12.1.13.

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

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

   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 AHS for at least 2 years and is not adjacent to a country or *zone* not having a free status; or

   c) a *surveillance* programme has demonstrated no evidence of AHSV in the country or *zone* for at least ~~12~~24 months and includes a complete season of *vector* activity; or

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d) the country or *zone* has not reported any *case* of AHS for at least 40 days and a *surveillance* programme has demonstrated no evidence of *Culicoides* ~~likely to be competent AHSV *vectors*~~ for at least 2 years in the country or *zone*.

2. An AHS free country or *zone* adjacent to an infected country or *infected zone* should include a *zone* in which *surveillance* is conducted in accordance with Articles 12.1.11. to 12.1.13. *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.

~~2~~3. An AHSV free country or *zone* will not lose its free status through the importation of vaccinated or seropositive equids ~~equidae~~ 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 existing list of AHSV free countries or *zones*, a Member should:

a) have a record of regular and prompt animal disease reporting;

b) send a declaration to the OIE stating:

i) the section under paragraph 1 on ~~the base of~~ which the application is based~~made~~;

ii) no ~~systematic~~ vaccination against AHS has been carried out during the past 12 months in the country or *zone*;

iii) equids ~~equidae~~ are imported in accordance with paragraph 3 above;

c. supply documented evidence that:

i) *surveillance* ~~for both AHS and AHSV infection~~ in accordance with Articles 12.1.11. to 12.1.13 is ~~in operation~~ applied;

ii) regulatory measures for the early detection, prevention and control of AHS have been implemented.

5. The Member 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 should be reported to the OIE according to the requirements in Chapter 1.1., and in particular, formally state that :

~~1~~a). there has been no *outbreak* of AHS during the past 12 months in the country or *zone*;

~~2~~b) no evidence of AHSV infection has been found during the past 12 months 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* ~~likely to be competent AHSV *vectors*~~.

2. AHS is notifiable in the whole country.

~~2~~3. For the application of Articles 12.1.6., 12.1.8. and 12.1.9., 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* ~~likely to be competent AHSV *vectors*~~ 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* ~~likely to be competent AHSV~~ *vectors*.

~~3~~4. An AHSV seasonally free *zone* will not lose its free status through the importation of vaccinated or seropositive equids ~~equidae~~ 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.

AHSV infected country or zone

For the purpose of this chapter, a~~A~~n AHSV infected country or ~~*infected*~~ *zone* is one that does not fulfil the requirements to qualify as either AHSV free country or *zone* or AHSV seasonally free *zone* ~~in which the conditions of Article 12.1.2. or Article 12.1.3. do not apply~~.

Article 12.1.4.bis.

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

In the event of limited *outbreaks* within an AHS free country or *zone*, including within a *protection zone*, a single *containment zone*, which includes all *cases*, and should be large enough to contain any potentially infected vectors, can be established for the purpose of minimizing the impact on the entire country or *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 ~~equidae~~ has been imposed, and effective controls on the movement of equids ~~equidae~~ and their products ~~mentioned~~ 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;

   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 ~~*infectious*~~ *infective periods* as defined in Article 12.1.1.;

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2. the equids ~~equidae~~ within the *containment zone* should be clearly identifiable as belonging to the *containment zone*;

3. increased passive and targeted *surveillance* in accordance with Articles 12.1.11. to 12.1.13. ~~has increased~~ in the rest of the country or *zone* ~~and~~ has not detected any evidence of *infection*.

4. animal health measures that effectively prevent the spread of AHS 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 12.1.11. to 12.1.13. is in place in the *containment zone*;

The free status of the areas outside the *containment zone* is suspended pending the establishment of the *containment zone* in accordance with points 1 to 5 above. The free status of the areas outside the *containment zone* could be reinstated irrespective of the provisions of Article 12.1.4.tris, once the *containment zone* is recognised by the OIE.

The recovery of the AHS free status of the *containment zone* should follow the provisions of Article 12.1.4.tris.

Article 12.1.4.tris.

Recovery of free status

When an AHS *outbreak* occurs in an AHS free country or *zone*, to regain the free status ,the ~~following~~ provisions of Article 12.1.2. apply ~~waiting period required to regain the status of AHS free country or *zone*~~, irrespective of whether emergency vaccination has been applied~~:~~

~~1. If emergency vaccination is not carried out, the conditions of Article 12.1.2. paragraph 1b), 1c) or 1d) apply; or~~

~~2. if emergency vaccination is carried out, a waiting period of 24 months after the last *case* and completion of the emergency vaccination has elapsed, during which *surveillance* applied in accordance with Articles 12.1.11. to 12.1.13. has shown no evidence of AHSV infection.~~

Article 12.1.5.

Recommendations for importation from AHSV free countries ~~that are neither neighbouring nor considered to be at risk from an AHSV infected country~~ or ~~infected~~ zones

for ~~equidae~~ 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 or *zone* since birth or for at least 40 days prior to shipment;

4. either:

   a) did not transit through an *infected* ~~country or~~ ~~*infected*~~ *zone* during transportation to the *place of shipment*; or

   b) were protected from attacks ~~by~~ from *Culicoides* at all times when transiting through an *infected* ~~country or *infected*~~ *zone*.

Article 12.1.6.

Recommendations for importation from ~~AHSV free countries or free zones or from~~ AHSV seasonally free zones ~~(during the seasonally free period) that are neighbouring or are considered to be at risk from an AHSV infected country or infected zone~~

for ~~equidae~~ 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 ~~free country, free *zone* or~~ seasonally free *zone* during the seasonally free period since birth or for at least 40 days prior to shipment; or

   ~~4~~b. ~~in a country or *zone* considered to be at risk~~, were held in ~~quarantine~~ isolation in a *vector*-protected *establishment* ~~for at least 40 days~~ prior to shipment ~~and protected at all times from attacks by *Culicoides*; and~~

      ~~a~~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* ~~*quarantine station*~~; or

      ~~b~~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 7 days after introduction into the *vector* protected *establishment* ~~*quarantine station*~~; or

      ~~c~~iii. for a period of at least 14 days and an agent identification test~~s~~ according to the *Terrestrial Manual* ~~were~~ was carried out with a negative result~~s~~ on a blood sample~~s~~ collected ~~on two occasions with an interval of~~ not less than 14 days ~~between collection, the first sample being collected at least 7 days~~ after introduction into the *vector*-protected *establishment* ~~*quarantine station*~~;

~~5~~4. were protected from attacks ~~by~~ from *Culicoides* at all times ~~during transportation (including to and at the *place of shipment*)~~ when transiting through an *infected zone*.

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Article 12.1.7.

Recommendations for importation from AHSV infected countries or zones

for ~~equidae~~ 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 ~~continuously during the quarantine period of al least 40 days,~~ in isolation in a *vector-*~~proof~~ protected *establishment* ~~*quarantine station* and protected at all times from attacks by *Culicoides*~~; ~~and~~
   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* ~~*quarantine station*~~; 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 7 days after introduction into the *vector*-protected *establishment* ~~*quarantine station*~~; or
   c) for a period of at least 14 days and an agent identification test~~s~~ according to the *Terrestrial Manual* ~~were~~ was carried out with a negative result~~s~~ on a blood sample~~s~~ collected ~~on two occasions with an interval of~~ not less than 14 days ~~between collection, the first sample being collected at least 7 days~~ after introduction into the *vector*-protected *establishment* ~~*quarantine station*~~; 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 12.1.12 and 12.1.13, 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*).

Article 12.1.8.

Recommendations for the importation of ~~equid~~ equine semen

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

1. showed no clinical sign of AHS on the day of collection of the semen and for the following 40 days;
2. had not been immunised against AHS with a live attenuated vaccine within 40 days prior to the day of collection;
3. were either:
   a) kept in an AHSV free country or free *zone* 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- ~~proof~~ 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 7 days, during semen collection for this consignment.

Article 12.1.9.

Recommendations for the importation of *in vivo* derived equine ~~equid~~ embryos/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/oocytes and for the following 40 days;

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

c) were either:

i) kept in an AHSV free country or free *zone* 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/oocytes, or

ii) kept in an AHSV free vector- ~~proof~~ 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/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 7 days during embryos/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 fertilize the oocytes, complies at least with the requirements in Article 12.1.8.

Annex XXIV (contd)

Article 12.1.10.

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 ~~of the *establishment* or facility~~ 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 ~~aperture size (under study)~~ impregnated regularly with an approved insecticide according to manufacturers' instruction;

c) *vector surveillance* and control within and around the building;

d) measures to limit 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 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:

~~1~~i. treating animals with chemical repellents prior to and during transportation, in sanitized *vehicles* treated with appropriate residual contact insecticide;

~~2~~ii. *loading*, transporting and *unloading* animals at times of low *vector* activity (i.e. bright sunshine and low temperature);

~~3~~iii. ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;

~~4~~iv. darkening the interior of the *vehicle*, for example by covering the roof and/or sides of *vehicles* with shade cloth;

~~5~~v. monitoring for *vectors* at common stopping and offloading points to gain information on seasonal variations;

~~6~~vi. using historical, ongoing and/or AHS modelling information to identify low risk ports and transport routes.

b) Transport by air:

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

Crates, *containers* or jet stalls in which ~~equidae~~ equids are being transported and the cargo hold of the aircraft must be sprayed with an approved insecticide just after the doors to the aircraft are closed and prior to takeoff, or immediately prior to the closing of the aircraft doors after loading.

In addition, during any stop over in countries or *zones* not free of AHS, prior to, or immediately after the opening of any aircraft door and until all doors are closed ~~prior to takeoff~~, netting of appropriate ~~aperture~~ gauge ~~size~~ ~~(under study)~~ impregnated with an approved insecticide must be placed over all crates, *containers* or jetstalls.

Article 12.1.11.

Surveillance: introduction

Articles 12.1.11. to 12.1.13. define the principles and provide ~~a guide~~ guidance on ~~the~~ *surveillance* for AHS, complementary to Chapter~~s~~ 1.4. and, for *vectors*, complementary to Chapter 1.5., ~~applicable to Members seeking to determine their AHSV status. This may be for the entire country or *zone*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of AHS status is also provided.~~

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 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* ~~equid~~ 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 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.

Annex XXIV (contd)

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

~~1. AHSV has been isolated and identified as such 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 confirmed or suspected *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 *case*.~~

Article 12.1.12.

Surveillance: general 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 suspect *cases* of AHS 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 AHS *surveillance* programme should:

   a) in a country/*zone*, free or seasonally free, include an early warning system for reporting suspicious *cases*. Persons who have regular contact with equids, as well as diagnosticians, should report promptly any suspicion of AHS to the *Veterinary Authority*. 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 AHS. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* of AHS should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment are available for those responsible for *surveillance*;

   b) conduct random or targeted serological and virological *surveillance* appropriate to the *infection* status of the country or *zone* in accordance with Chapter 1.4.

Article 12.1.13.

Surveillance strategies

The target population for *surveillance* aimed at identification of *disease* and/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 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 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 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/*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/infection* are technically well defined. *Surveillance* programmes to prove the absence of AHSV infection/circulation, 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.

2. Serological surveillance

   Serological *surveillance* of equine ~~equid~~ 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* and/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 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of AHSV. An AHSV free country or *zone* 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 in at risk populations;

b) to confirm clinically suspect *cases*;

c) to follow up positive serological results;

d) to better characterize 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 ~~equid~~ 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.

~~The main purpose of v~~*Vector surveillance* is ~~to~~ aimed at demonstrating the absence of vectors or ~~define~~ 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.

Annex XXIV (contd)

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

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

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CHAPTER 1.6.

PROCEDURES FOR SELF DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE

Article 1.6.6.bis

Questionnaire on African horse sickness

AHS FREE COUNTRY

Report of a Member which applies for recognition of status, under Chapter 12.1. of the *Terrestrial Animal Health Code* (2010), as a AHS free country

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

1. Introduction

   a. Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to AHS introduction. Provide a map identifying the factors above.

   b. Equine sectors. Provide a general description of the equine sector and their relative economic importance in the country. Outline any recent significant changes observed within the sector grouping(s) (if relevant documents are available, please attach).

      i. Sport and race horses
      ii. Breeding stock equids ~~equidae~~
      iii. Working and production equids ~~equidae~~ (including horses for slaughter)
      iv. Leisure equids ~~equidae~~
      v. *Captive wild*, *wild* and *feral* equids ~~equidae~~.

2. Description of equine ~~equid~~ population

   a. Demographics of domestic equids ~~equidae~~. What is the equine ~~equidae~~ population by species within the various sectors? Provide a description of the methods of animal identification, holding and individual animal registration systems if in place. How are they distributed (e.g. density, etc.)? Provide tables and maps as appropriate.

   b. *Wild*life demographics. What *captive wild*, *wild* or *feral* equids ~~equidae~~ are present in the country? Provide estimates of population sizes and geographic distribution. ~~What are the measures in place to prevent contact between domestic and *captive wild*, *wild* or *feral* equidae?~~

Annex XXIV (contd)

3. Veterinary system

a. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to AHS.

b. Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how *Veterinary Services* supervise and control all AHS related activities. Provide maps and tables wherever possible.

c. Role of farmers, keepers, industry, regulatory bodies, and other relevant groups in AHS *surveillance* and control (include a description of training and awareness programmes on AHS).

d. Role of private veterinary profession in AHS *surveillance* and control.

e. Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS pathway

4. AHS eradication

a. History. Provide a description of the AHS history in the country if applicable, date of first detection, origin of *infection*, date of eradication (date of last *case*), and serotypes present.

b. Strategy. Describe how AHS was controlled and eradicated (e.g. isolation of cases, *stamping-out policy*, zoning), provide time frame for eradication.

c. Vaccines and vaccination. What type of vaccine was used? What equine species were vaccinated? Were vaccinated animals marked or was vaccination recorded in a unique identification document?

d. Legislation, organisation and implementation of the AHS eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines were used and give a brief summary.

e. Animal identification. Are equids ~~equidae~~ identified (individually or at a group level)?

f. Movements of equids ~~equidae~~. How are movements of equids ~~equidae~~ controlled in the country? Provide evidence on the effectiveness of ~~equidae~~ identification and movement controls of equids. Please provide information on pastoralism, transhumance and related movements.

g. Leisure and competition movements of equids ~~equidae~~. How are movements of competition and leisure equids ~~equidae~~ controlled in the country. Please provide information on systems including any use of registration. Provide information on any events that include international movements of equids ~~equidae~~.

h. Describe the market systems for equids ~~equidae~~, in particular, if markets require the international movement of equids ~~equidae~~.

5. AHS diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3., and 2.5.1. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

a. Is AHS laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.

b. Provide an overview of the AHS approved laboratories, in particular to address the following points:

i. Details on the types of tests undertaken.

ii. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO that exist in, or planned for, the laboratory system.

iii. Give details of participation in inter-laboratory validation tests (ring tests).

iv. Describe biosecurity measures applied, particularly in the case where live virus is handled.

6. AHS surveillance

Provide documentary evidence that *surveillance* for AHS in the country complies with the provisions of Articles 12.1.11. to 12.1.13. of the *Terrestrial Code*, and Chapter 2.5.1. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a. Clinical suspicion. What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom), is there a compensation system in place and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for AHS, species, type of sample, testing method(s) and results (including differential diagnosis).

b. Surveillance. Are the following undertaken?

i. Serological surveillance
ii. Virological surveillance
iii. Sentinel animals
iv. Vector surveillance.

If so, provide detailed information on the survey designs. How frequently are they conducted? Which were the equine species included? Are *wild*life species included? Provide a summary table indicating detailed results, for at least the past 2 years. Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of equids ~~equidae~~ examined and samples tested. Provide details on the methods selected and applied for monitoring the performance of the *surveillance* system.

7. AHS prevention

a. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that have been taken into account (e.g. size, distance from adjacent border to infected equids ~~equidae~~)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

If the AHS free country borders an infected country or *zone*, describe the animal health measures implemented to effectively prevent the introduction of the agent and/or *vectors*, taking into consideration the seasonal *vector* conditions and existing physical, geographical and ecological barriers.

b. Import control procedures

From what countries or *zones* does the country authorize the import of equids ~~equidae~~ or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such equids ~~equidae~~ and products, and subsequent internal movement?

Annex XXIV (contd)

What import conditions (e.g. quarantine) and test procedures are required? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports, temporary admissions or re-entry of equids ~~equidae~~ and their products for at least the past 2 years, specifying country or *zone* of origin and volume.

i. Provide a map with the number and location of ports, airports and land crossings. Is the service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the *Competent Authority*. Describe the communication systems between the *Competent Authority* 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 and/or their final destination, concerning the import and follow-up of the following:

- Equids ~~Equidae~~,
- genetic material (semen, ova and embryos of the equine species),
- equine derived (by-)products and biological.

iii. Describe the action available under legislation, and actually taken, when an illegal introduction is detected. Provide information on detected illegal introduction.

8. Control measures and contingency planning

a. Give details of any written guidelines, contingency plans (including information on vaccine banks) available to the *Competent Authority* for dealing with suspected or confirmed *cases* of AHS.

b. In the event of a suspected or confirmed AHS *outbreak*:

i. is quarantine imposed on premises with suspicious *cases*, pending final diagnosis?

ii. are movement restrictions applied on suspicion?

iii. describe the sampling and testing procedures used to identify and confirm presence of the causative agent;

iv. describe the actions taken to control the disease situation in and around any holdings found to be infected with AHS;

v. describe the control and/or eradication procedures (e.g. vaccination, modified stamping-out);

vi. describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including conditions for restocking;

vii. give details of any compensation made available when equids ~~equidae~~ are killed, for *disease* control/eradication purposes.

9. Compliance with the *Terrestrial Code*

   a. In addition to the documentary evidence that the provisions of Article 12.1.2 are properly implemented and supervised, the Delegate of the country must submit a declaration stating:

      i. The section under paragraph 1 (of Article 12.1.2.) on the base of which the application is made;

      ii. there has been no *outbreak* of AHS during the past ~~12~~24 months;

      iii. no systematic vaccination against AHS has been carried out during the past 12 months;

   b. and that vaccinated equids ~~equidae~~ were imported in accordance with Chapter 12.1.

10. Recovery of status

    Countries applying for recovery of status should comply with the provisions of Article 12.1.2. of the *Terrestrial Code* and provide detailed information as specified in sections 4(a), b), c and 6, and highlight any measures introduced to prevent a recurrence of the infection under section 7 of this questionnaire. Information in relation to other sections need only be supplied if relevant.

AHS FREE ZONE

Report of a Member which applies for recognition of status, under Chapter 12.1. of the *Terrestrial Animal Health Code* (2010), as a AHS free zone

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

1. Introduction

   a. Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to AHS introduction. Provide a map identifying the factors above. The boundaries of the *zone* must be clearly defined, including a *protection zone*, if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone* (and of the *protection zone*) established in accordance with Chapter 4.3.

   b. Equine sectors. Provide a general description of the equine sector and their relative economic importance in the country and the *zone*. Outline any recent significant changes observed within the sector grouping(s) (if relevant documents are available, please attach).

      i. Sport and race horses

      ii. Breeding stock equids ~~equidae~~

      iii. Working and production equids ~~equidae~~ (including horses for slaughter)

      iv. Leisure equids ~~equidae~~

      v. *Captive wild*, *wild* and *feral* equids ~~equidae~~.

Annex XXIV (contd)

2. Description of equine ~~equidae~~ population

   a. Demographics of domestic equids ~~equidae~~. What is the equine ~~equidae~~ population by species within the various sectors in the country and the *zone*? Provide a description of the methods of animal identification, holding and individual animal registration systems in the country and the *zone* if in place. How are they distributed (e.g. density, etc.)? Provide tables and maps as appropriate.

   b. *Wild*life demographics. What *captive wild*, *wild* or *feral* equids ~~equidae~~ are present in the country and the *zone*? Provide estimates of population sizes and geographic distribution. ~~What are the measures in place to prevent contact between domestic and *captive wild*, *wild* or *feral* equidae?~~

3. Veterinary system

   a. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to AHS.

   b. Veterinary Services. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and 1.1.3. of the *Terrestrial Manual* and describe how *Veterinary Services* supervise and control all AHS related activities in the country and in the *zone*. Provide maps and tables wherever possible.

   c. Role of farmers, keepers, industry, regulatory bodies, and other relevant groups in AHS *surveillance* and control (include a description of training and awareness programmes on AHS).

   d. Role of private veterinary profession in AHS *surveillance* and control.

4. AHS eradication

   a. History. Provide a description of the AHS history in the country and *zone*, if applicable, date of first detection, origin of *infection*, date of eradication in the *zone* (date of last *case*), and serotypes present.

   b. Strategy. Describe how AHS was controlled and eradicated in the *zone* (e.g. isolation of cases, *stamping-out policy*, zoning), provide time frame for eradication.

   c. Vaccines and vaccination. What type of vaccine was used in the *zone* and the rest of the country? What equine species were vaccinated? Were vaccinated *animals* marked or was vaccination recorded in a unique identification document?

   d. Legislation, organisation and implementation of the AHS eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines were used and give a brief summary.

   e. Animal identification. Are equids ~~equidae~~ identified (individually or at a group level)?

   f. Movements of equids ~~equidae~~. How are movements of equids ~~equidae~~ controlled in, and between *zones* of the country? Provide evidence on the effectiveness of ~~equidae~~ identification of equids and movement controls in the *zone*. Please provide information on pastoralism, transhumance and related movements.

g. Leisure and competition movements of equids ~~equidae~~. How are movements of competition and leisure equids ~~equidae~~ controlled in the country and the *zones*? Please provide information on systems including any use of registration. Provide information on any events that include international movements of equids ~~equidae~~.

h. Describe the market systems for equids ~~equidae~~ in the country and the *zones*, in particular, if markets require the international movement of equids ~~equidae~~.

5. AHS diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3., and 2.5.1. of the *Terrestrial Manual* are applied in the country and the *zone*. In particular, the following points should be addressed:

a. Is AHS laboratory diagnosis carried out in the country and the *zone*? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed.

b. Provide an overview of the AHS approved laboratories, in particular to address the following points:

i. Details on the types of tests undertaken.

ii. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO that exist in, or planned for, the laboratory system.

iii. Give details of participation in inter-laboratory validation tests (ring tests).

iv. Describe biosecurity measures applied, particularly in the case where live virus is handled.

6. AHS surveillance

Provide documentary evidence that *surveillance* for AHS in the *zone* complies with the provisions of Articles 12.1.11. to 12.1.13. of the *Terrestrial Code*, and Chapter 2.5.1. of the *Terrestrial Manual*. In particular, the following points should be addressed:

a. Clinical suspicion. What are the criteria for raising a suspicion of AHS? What is the procedure to notify (by whom and to whom), is there a compensation system in place and what penalties are involved for failure to report? Provide a summary table indicating, for the past 2 years, the number of suspect *cases*, the number of samples tested for AHS, species, type of sample, testing method(s) and results (including differential diagnosis) from the *zone*.

b. Surveillance. Are the following undertaken?

i. Serological surveillance

ii. Virological surveillance

iii. Sentinel animals

iv. Vector surveillance.

Annex XXIV (contd)

If so, provide detailed information on the survey designs. How frequently are they conducted? Which were the equine species included? Are *wild*life species included? Provide a summary table indicating detailed results, for at least the past 2 years. Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* and numbers of equids ~~equidae~~ examined and samples tested. Provide details on the methods selected and applied for monitoring the performance of the *surveillance* system.

7. AHS prevention

a. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and/or *zones* that have been taken into account (e.g. size, distance from adjacent border to infected equids ~~equidae~~)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the AHS free *zone* is established in an AHS infected country or borders an infected country or *infected zones*, describe the animal health measures implemented to effectively prevent the introduction of the agent and/or *vectors*, taking into consideration the seasonal vector conditions and existing physical, geographical and ecological barriers.

b. Import control procedures. From what countries or *zones* does the country authorize the import of equids ~~equidae~~ or their products into the free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such equids ~~equidae~~ and products, and subsequent internal movement? What import conditions (e.g. quarantine) and test procedures are required? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports, temporary admissions or re-entry of equids ~~equidae~~ and their products to the free *zone* for at least the past 2 years, specifying country or *zone* of origin and volume.

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

ii. Describe the regulations, procedures, type and frequency of checks at the points of entry into the *zone* and/or their final destination, concerning the import and follow-up of the following:

- equids ~~equidae~~,
- genetic material (semen, ova and embryos of the equine species),
- equine derived (by-)products and biologicals.

iii. Describe the action available under legislation, and actually taken, when an illegal introduction into the *zone* is detected. Provide information on detected illegal introductions into the *zone*.

8. Control measures and contingency planning

a. Give details of any written guidelines, contingency plans (including information on vaccine banks) available to the *Competent Authority* for dealing with suspected or confirmed *cases* of AHS in the country and the *zone* (including the *protection zone* if applicable).

b. In the event of a suspected or confirmed AHS *outbreak* in the *zone*:

i. is quarantine imposed on premises with suspicious *cases*, pending final diagnosis?

ii. are movement restrictions applied on suspicion?

iii. describe the sampling and testing procedures used to identify and confirm presence of the causative agent;

iv. describe the actions taken to control the disease situation in and around any holdings found to be infected with AHS;

v. describe the control and/or eradication procedures (e.g. vaccination, modified stamping-out);

vi. describe the procedures used to confirm that an *outbreak* has been successfully controlled/eradicated, including conditions for restocking;

vii. give details of any compensation made available when equids ~~equidae~~ are killed, for *disease* control/eradication purposes.

9. Compliance with the *Terrestrial Code*

a. In addition to the documentary evidence that the provisions of Article 12.1.2 are properly implemented and supervised, the Delegate of the country must submit a declaration stating:

i. The section under paragraph 1 (of Article 12.1.2.) on the base of which the application is made

ii. there has been no *outbreak* of AHS during the past ~~12~~24 months in the *zone*;

iii. no systematic vaccination against AHS has been carried out during the past 12 months in the *zone*;

b. and that vaccinated equids ~~equidae~~ were imported into the *zone* in accordance with Chapter 12.1.

10. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 12.1.2. of the *Terrestrial Code* and provide detailed information as specified in sections 4 (a), (b), (c) and 6 and highlight any measures introduced to prevent a recurrence of the *infection* under Section 7 of this questionnaire.

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Annex XXV

CHAPTER 12.6.

EQUINE INFLUENZA

Article 12.6.1.

General provisions

For the purposes of the *Terrestrial Code*, equine influenza (EI) is defined as an *infection* of domestic ~~horses, donkeys and mules~~ equids.

This chapter deals not only with the occurrence of clinical signs caused by equine influenza virus (EIV), but also with the presence of *infection* with EIV in the absence of clinical signs.

For the purposes of this chapter, isolation is defined as 'the separation of domestic equids from domestic equids of a different equine influenza health status, utilising appropriate biosecurity measures, with the purpose of preventing the transmission of *infection*'.

For the purposes of the *Terrestrial Code*, the *infective period* for EI shall be 21 days.

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 12.6.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the EI status of the equine population of the *exporting country*, *zone* or *compartment*.

Article 12.6.2.

Safe commodities

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

1. semen;

2. *in vivo* derived equine embryos collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant (under study).

Article 12.6.3.

Determination of the EI status of a country, a zone or a compartment

The EI status of a country, a *zone* or a *compartment* can be determined on the basis of the following criteria:

1. the outcome of a *risk assessment* identifying all risk factors and their historic relevance;

2. whether EI is notifiable in the whole country, an on-going EI awareness programme is in place, and all notified suspect occurrences of EI are subjected to field and, where applicable, *laboratory* investigations;

3. appropriate *surveillance* is in place to demonstrate the presence of *infection* in the absence of clinical signs in domestic equids.

Annex XXV (contd)

Article 12.6.4.

EI free country, zone or compartment

A country, *zone* or *compartment* may be considered free from EI provided the *disease* is notifiable in the whole country and it shows evidence, through an effective *surveillance* programme, planned and implemented according to the general principles in Chapter 1.4., that no *case* of EI occurred in the past two years. The *surveillance* may need to be adapted to parts of the country, *zone* or *compartment* depending on historical or geographical factors, industry structure, population data, movements of equids within and into the country, *zone* or *compartment*, *wild* equine ~~equid~~ populations or proximity to recent *outbreaks*.

A country, *zone* or *compartment* seeking freedom from EI, in which vaccination is practised, should also demonstrate that EIV has not been circulating in the population of domestic *, feral* and *wild* equids during the past 12 months, through *surveillance*, in accordance with Chapter 1.4. In a country in which vaccination is not practised, *surveillance* may be conducted using serological testing alone. In countries where vaccination is practised, the *surveillance* should include agent identification methods described in the *Terrestrial Manual* for evidence of *infection*.

A country, *zone* or *compartment* seeking freedom from EI should apply appropriate movement controls to minimise the risk of introduction of EIV in accordance with this chapter.

If an *outbreak* of clinical EI occurs in a previously free country, *zone* or *compartment*, free status can be regained 12 months after the last clinical *case*, providing that *surveillance* for evidence of *infection* has been carried out during that twelve-month period in accordance with Chapter 1.4.

Article 12.6.5.

Recommendations for the importation of domestic equids for immediate slaughter

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the domestic equids showed no clinical sign of EI on the day of shipment.

Article 12.6.6.

Recommendations for the importation of domestic equids for unrestricted movement

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

1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its vaccination status should be included in the veterinary certificate;

OR

2. came from a country, *zone* or *compartment* not known to be free from EI, were subjected to pre-export isolation for 21 days and showed no clinical sign of EI during isolation nor on the day of shipment; and

3. were immunised according to the manufacturer's instructions with a vaccine complying with the standards described in the *Terrestrial Manual* between 21 and 90 days before shipment either with a primary course or a booster; information on their vaccination status should be included in the veterinary certificate.

For additional security, countries that are free of EI or undertaking an eradication programme may also request that the domestic equids were tested negative for EIV by an agent identification test for EI described in the *Terrestrial Manual* conducted on samples collected on two occasions at 7 to 14 days and less than 5 days before shipment.

Article 12.6.7.

Recommendations for the importation of domestic equids which will be kept in isolation (see Article 12.6.1.)

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

1. came from an EI free country, *zone* or *compartment* in which they had been resident for at least 21 days; in the case of a vaccinated domestic equid, information on its vaccination status should be included in the veterinary certificate;

OR

2. showed no clinical sign of EI in any premises in which the domestic equids had been resident for the 21 days prior to shipment nor on the day of shipment; and

3. were immunised according to the manufacturer's instructions with a vaccine complying with the standards described in the *Terrestrial Manual*; information on their vaccination status should be included in the veterinary certificate.

Article 12.6.8.

Recommendations for the importation of fresh meat of equids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *fresh meat* came from equids which had been subjected to ante- and post-mortem inspections as described in Chapter 6.2.

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Annex XXV (contd)

CHAPTER 12.9.

EQUINE VIRAL ARTERITIS

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 ~~and feral members of the family, *Equidae*~~.

This chapter deals not only with the occurrence of clinical signs caused by equine arteritis virus (EAV), but also with the presence of *infection* with 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 equine viral arteritis (EVA) shall be 28 days for all categories of equids ~~equine~~ 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~~equines~~

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, as prescribed in the *Terrestrial Manual*, 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, as prescribed in the *Terrestrial Manual*:

   EITHER:

   a)~~,~~ with a negative result,

   OR

   b) with a positive result, followed at least 14 days later by a second test showing ~~carried out on two blood samples collected at least 14 days apart with~~ a stable or decreasing titre;

   and were~~,~~ immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; 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 as prescribed in the *Terrestrial Manual* on a blood sample with negative results; and

   c) were then immediately vaccinated; and

   d) were kept separated from other equids ~~equidae~~ for 21 days following vaccination; and

   e) were revaccinated regularly according to the manufacturer's instructions; or

4. have been subjected to a test for EVA, as prescribed in the *Terrestrial Manual*, 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 as prescribed in the *Terrestrial Manual* 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 equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected during the six months prior to shipment; or

   c) were subjected to a test for equine arteritis virus as prescribed in the *Terrestrial Manual* 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 manufacturer's instructions.

Article 12.9.3.

Recommendations for the importation of equids ~~equines~~ 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 were kept in an *establishment* where no *animals* have shown any signs of EVA for the 28 days prior to 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, as prescribed in the *Terrestrial Manual*, 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 manufacturer's instructions;

OR

2. were isolated for the 28 days prior to shipment and during this period the *animals* showed no sign of EVA.

Annex XXV (contd)

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 animal donors were kept for the 28 days prior to semen collection in an *establishment* where no equid ~~equine~~ 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, as prescribed in the *Terrestrial Manual*;

   Either:

   a), ~~—~~ with a negative result,

   OR

   b) with a positive result, followed at least 14 days later by a second test showing ~~on two blood samples collected at least 14 days apart with~~ a stable or decreasing titre;

   and were immediately vaccinated for EVA and regularly revaccinated according to the manufacturer's instructions; or

2. were isolated and not earlier than seven days of commencing isolation were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results, immediately vaccinated for EVA, kept for 21 days following vaccination separated from other equids ~~equidae~~ and regularly revaccinated according to the manufacturer's instructions; or

3. were subjected to a test for EVA as prescribed in the *Terrestrial Manual* on a blood sample with negative results within 14 days prior to semen collection, and had been separated from other equids ~~equidae~~ 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 as prescribed in the *Terrestrial Manual* 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 as prescribed in the *Terrestrial Manual* 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 equine arteritis virus as prescribed in the *Terrestrial Manual* 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 equine arteritis virus as prescribed in the *Terrestrial Manual* with negative results, carried out on semen collected within six months after the blood sample was tested, then immediately vaccinated, and revaccinated regularly; or

5. for frozen semen, were subjected with negative results either:

   a) to a test for EVA as prescribed in the *Terrestrial Manual* 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 equine arteritis virus as prescribed in the *Terrestrial Manual* 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.

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Annex XXVI

CHAPTER 14.8.

INFECTION WITH PESTE DES PETITS RUMINANTS VIRUS

Article 14.8.1.

General provisions

For the purposes of the *Terrestrial Code*, the *incubation period* for the peste des petits ruminants (PPR) shall be 21 days.

For the purpose of this chapter, susceptible *animals* are primarily domestic sheep and goats but also include cattle, camels, buffaloes and *wild* ruminant species.

A *case* is an *animal* infected with peste des petits ruminants virus (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*:

a) PPRV has been isolated and identified as such from an *animal* or a product derived from that *animal*; or

b) viral antigen or viral ribonucleic acid (RNA) specific to PPRV has been identified in samples from one or more *animals* showing one or more 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

c) antibodies to PPRV antigens which are not the consequence of vaccination, have been identified in one or more *animals* with either epidemiological links to a confirmed or suspected *outbreak* of PPR in susceptible *animals,* or showing clinical signs consistent with recent *infection* of PPRV.

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

The PPR status of a country or *zone* can only be determined after considering the following criteria in domestic ruminants, as applicable.

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1. PPR should be notifiable in the whole territory, and all clinical signs suggestive of PPR should be subjected to appropriate field and/or *laboratory* investigations;

2. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of PPR;

3. the *Veterinary Authority* should have current knowledge of, and authority over, all domestic ruminants in the country or *zone*;

4. for domestic ruminants, 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 Chapter 1.4.

A country or *zone* may be considered free from PPR when it has been shown that PPR has not been present for at least the past three years.

Article 14.8.4.

Recovery of status

In a newly infected country or *zone*, the recovery period shall be six months after the *slaughter* of the last affected *animal* for countries in which a *stamping-out policy* is practised with or without vaccination against PPR.

Article 14.8.5.

Recommendations for importation from PPR free countries or zones

For domestic small ruminants, cattle, camels and buffaloes

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 14.8.6.

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 PPR *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 PPR:

   have been captured at a distance 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

   were kept in a *quarantine station* for the 21 days prior to shipment.

Article 14.8.7.

Recommendations for importation from countries or zones considered infected with PPR

For domestic small ruminants

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

1. showed no clinical sign suggestive of PPR *infection* at least 21 days prior to shipment;

2. were kept since birth, or for the past 21 days, in an *establishment* where no *case* of PPR was reported during that period, and that the *establishment* was not situated in a PPR *infected zone*; and/or

3. were kept in a *quarantine station* for the 21 days prior to shipment;

4. have not been vaccinated against PPR and were submitted to a diagnostic test for PPR *infection* with negative result at least 21 days prior to shipment;

   OR

   were vaccinated against PPR with live attenuated PPRV vaccine not less than 21 days prior to shipment and attested by the presence of antibodies anti PPRV.

Article 14.8.8.

Recommendations for importation from countries or zones considered infected with PPR

For cattle, camels and buffaloes

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

1. showed no clinical sign suggestive of PPR *infection* at least 21 days prior to shipment;

2. were kept in a *quarantine station* for the 21 days prior to shipment.

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Article 14.8.9.

Recommendations for importation from countries or zones considered infected with PPR

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 PPR *infection* 21 days prior to shipment;

2. were submitted to a diagnostic test for PPR *infection* with negative results at least 21 days prior to shipment;

3. were kept in a *quarantine station* for the 21 days prior to shipment.

Article 14.8.10.

Recommendations for importation from PPR free countries or zones

For semen of domestic small ruminants, cattle, camels and buffaloes

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 collection of the semen and during the following 21 days;

2. were kept in a PPR free country or *zone* for not less than 21 days prior to collection.

Article 14.8.11.

Recommendations for importation from countries considered infected with PPR

For semen of domestic small ruminants

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

1. showed no clinical sign suggestive of PPR *infection* 21 days prior collection of the semen and during the following 21 days;

2. were kept, for 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 PPR *infected zone* and to which no *animals* had been added for the 21 days prior to collection;

3. in the absence of vaccination against PPR with the live attenuated PPRV, were submitted to a diagnostic test for PPR with negative results at least 21 days prior to collection of the semen;

OR

4. were vaccinated against PPR with the live attenuated PPRV vaccine at least 21 days prior the semen collection and attested by the presence of antibodies anti PPRV.

Article 14.8.12.

Recommendations for importation from countries considered infected with PPR

For semen of cattle, camels and buffaloes

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

1. showed no clinical sign suggestive of PPR *infection* at least 21 days prior semen collection;

2. were submitted to a diagnostic test for PPR with negative results at least 21 days prior to collection of the semen;

3. were kept for 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 PPR *infected zone* and to which no *animals* had been added for the 21 days prior to collection.

Article 14.8.13.

Recommendations for importation from PPR free countries or zones

For embryos of domestic small ruminants and captive *wild* ruminants

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

1. the donor females were kept in an *establishment* located in a PPR free country or *zone* at least 21 days prior to the time of collection of the embryos;

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

Article 14.8.14.

Recommendations for importation from countries or zones considered infected with PPR

For embryos of domestic small ruminants

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

1. the donor females:

    a) and all other *animals* in the *establishment* showed no clinical sign suggestive of PPR *infection* at the time of collection and during the following 21 days;

    b) were kept in an *establishment* for the 21 days prior to collection, where no *case* of PPR was reported during that period, and to which no susceptible *animals* had been added for the 21 days prior to collection;

    c) have not been vaccinated against PPR and were subjected to a diagnostic test for PPR with negative results at least 21 days prior to collection;

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OR

d) have been vaccinated against PPR with the live attenuated PPRV vaccine not less than 21 days prior to the embryo collection and attested by the presence of antibodies anti PPRV;

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

Article 14.8.15.

Recommendations for importation from countries or zones considered infected with PPR

For embryos of cattle, camels, buffaloes and 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 PPR *infection* 21 days prior to the embryo collection;

   b) have not been vaccinated against PPR and were subjected to a diagnostic test for PPR with negative results at least 21 days prior to collection;

   c) were kept in an *establishment* for the 21 days prior to collection, where no *case* of PPR was reported during that period, and to which no susceptible *animals* had been added for the 21 days prior to collection;

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

Article 14.8.16.

Recommendations for importation from PPR free countries or zones

For fresh meat or meat products of susceptible animals

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

1. which have been kept in a PPR free country or *zone* since birth, or for at least 21 days;

2. which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections with favourable results.

Article 14.8.17.

Recommendations for importation from countries or zones considered infected with PPR

For fresh meat of susceptible animals

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

1. showed no clinical signs of PPR within 24 hours before *slaughter*;

2. were kept in the *establishment* of origin since birth or for at least 21 days prior to shipment to the approved *abattoir*, and did not show clinical signs suggestive of PPR *infection* in the *establishment* during that period;

3. had been transported, in a *vehicle* which was cleansed and disinfected before the *animals* were loaded, directly from the *establishment* of origin to the approved *abattoir* without coming into contact with other *animals* which do not fulfil the required conditions for export;

4. were slaughtered in an approved *abattoir* in which no PPR has been detected during the period between the last *disinfection* carried out before *slaughter* and the date on which the shipment has been dispatched and have been subjected to ante-mortem and post-mortem inspections for PPR with favourable results.

Article 14.8.18.

Recommendations for importation from countries or zones considered infected with PPR

For meat products of susceptible animals

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

1. only *fresh meat* complying with the requirements in Article 14.8.17. has been used in the preparation of the *meat products*;

   OR

   the *meat products* have been processed to ensure the destruction of the PPRV in conformity with one of the procedures referred to in Article 8.5.34.;

2. the necessary precautions were taken after processing to avoid contact of the *meat products* with any possible source of PPRV.

Article 14.8.19.

Recommendations for importation from PPR free countries or zones

For milk and milk products

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* since birth or for at least 21 days.

Article 14.8.20.

Recommendations for importation from countries or zones considered infected with PPR

For milk from susceptible animals

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

Annex XXVI (contd)

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 8.5.38. and 8.5.39.;

2. the necessary precautions were taken to avoid contact of the products with any potential source of PPRV.

Article 14.8.21.

Recommendations for importation from countries or zones considered infected with PPR

For milk products from susceptible animals

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 14.8.20.;

2. the necessary precautions were taken after processing to avoid contact of the *milk products* with a potential source of PPRV.

Article 14.8.22.

Recommendations for importation from PPR free countries or zones

For products of animal origin, other than milk and fresh meat and their products from susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *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 *abattoir* and have been subjected to ante-mortem and post-mortem inspections with favourable results.

Article 14.8.23.

Recommendations for importation from countries or zones considered infected with PPR

For meal and flour from blood, meat, defatted bones, hooves, claws and horns from susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed using heat treatment to a minimum internal temperature of 70°C for at least 30 minutes. The necessary precautions were taken after processing to avoid contact of the *commodities* with a potential source of PPRV.

Article 14.8.24.

Recommendations for importation from countries or zones considered infected with PPR

For hooves, claws, bones and horns, hunting trophies and preparations destined for museums from susceptible animals

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

1. these products were completely dried and had no trace on them of skin, flesh or tendon; and/or

2. these products have been adequately disinfected;

3. the necessary precautions were taken after processing to avoid contact of the *commodities* with a potential source of PPRV.

Article 14.8.25.

Recommendations for importation from countries or zones considered infected with PPR

For wool and hair from susceptible animals

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

1. these products have been processed to ensure the destruction of the PPR virus in conformity with one of the procedures referred to in Articles 8.5.35. and 8.5.36. 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 14.8.26.

Recommendations for importation from countries or zones considered infected with PPR

For raw hides and skins from susceptible animals

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

1. the products have been 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 14.8.27.

Recommendations for importation from countries or zones considered infected with PPR

For products of animal origin from susceptible animals intended for pharmaceutical or surgical use

Annex XXVI (contd)

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

1. come from *animals* which have been slaughtered in an approved *abattoir* and have been subjected to ante-mortem and post-mortem inspections with favourable results;

2. have been processed to ensure the destruction of the PPR virus in conformity with one of the procedures referred to in Article 8.5.29. or in Articles 8.5.34. to 8.5.37. as appropriate and in premises controlled and approved by the *Veterinary Authority* of the *exporting country*.

Annex XXVII

CHAPTER 15.2.

CLASSICAL SWINE FEVER

Article 15.2.1.

General provisions

The pig is the only natural host for classical swine fever (CSF) virus. The definition of pig includes all varieties of *Sus scrofa*, both domestic and *wild*. For the purposes of this chapter, a distinction is made between domestic and *captive wild* pig ~~and~~ populations on the one hand, and *wild* ~~pig, including *captive wild*,~~ and *feral* pig populations on the other. ~~(including feral pigs) populations.~~

For the purposes of ~~*international trade*~~ the *Terrestrial Code*, classical swine fever (CSF) is defined as an *infection* of domestic or *captive wild* pigs.

Domestic pig is defined as 'all domesticated pigs, permanently *captive* or farmed free range, used for the production of *meat* for consumption, for the production of other commercial products or for breeding these categories of pigs.

~~The pig is the only natural host for classical swine fever (CSF) virus. The definition of pig includes all varieties of *Sus scrofa*, both domestic and *wild*. For the purposes of this chapter, a distinction is made between domestic pig and *wild* pig (including feral pigs) populations.~~

Pigs exposed to CSF virus prenatally may be persistently infected throughout life and may have an *incubation period* of several months before showing signs of *disease*. Pigs exposed postnatally have an *incubation period* of 2-14 days, and are usually infective between post-*infection* days 5 and 14, but up to 3 months in cases of chronic *infections*.

~~For the purposes of *international trade*, a Member should not impose trade bans in response to a notification of *infection* with classical swine fever virus in *wild* pigs according to Article 1.2.3. of the *Terrestrial Code* after the Member confirms that Article 15.2.2. is appropriately implemented.~~

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

A Member should not impose trade bans in response to a notification of *infection* with classical swine fever virus in *wild* and *feral* pigs according to Article 1.~~2~~1.3. of the *Terrestrial Code* after the Member confirms that Article 15.2.2. is appropriately implemented.

Article 15.2.2.

Determination of the CSF status of a country, zone or compartment

The CSF status of a country, *zone* or *compartment* can only be determined after considering the following criteria in domestic and *wild* pigs, as applicable:

1. CSF should be notifiable in the whole territory, and all clinical signs suggestive of CSF should be subjected to appropriate field and/or *laboratory* investigations;

2. an on-going awareness programme should be in place to encourage reporting of all *cases* suggestive of CSF;

Annex XXVII (contd)

3. the *Veterinary Authority* should have current knowledge of, and authority over, all domestic and *captive wild* pigs in the country, *zone* or *compartment*;

4. the *Veterinary Authority* should have current knowledge about the population and habitat of *wild* and *feral* pigs in the country or *zone*;

5. for domestic and *captive wild* pigs, appropriate *surveillance*, capable of detecting the presence of *infection* even in the absence of clinical signs, and the risk posed by *wild* and *feral* pigs, is in place; this may be achieved through a *surveillance* programme in accordance with Articles 15.2.23. to 15.2.28.;

6. for *wild* and *feral* pigs, if present in the country or *zone*, a *surveillance* programme is in place according to Article 15.2.28., taking into account the presence of natural and artificial boundaries, the ecology of the *wild* and *feral* pig population, and an assessment of the risks of *disease* spread.

7. Based on the assessed risk of spread within the *wild* and *feral* pig population, ~~and according to Article 15.2.26.,~~ the domestic and *captive wild* pig population should be separated from the *wild* and *feral* pig population by appropriate biosecurity measures to prevent transmission of CSF. ~~from *wild* to domestic pigs.~~

Article 15.2.3.

CSF free country, zone or compartment

A country, *zone* or *compartment* may be considered free from CSF when *surveillance* in accordance with Articles 15.2.23. to 15.2.28. has been in place for at least 12 months, and when:

1. there has been no *outbreak* of CSF in domestic or *captive wild* pigs during the past 12 months;

2. no evidence of CSFV *infection* has been found in domestic or *captive wild* pigs during the past 12 months;

3. no vaccination against CSF has been carried out in domestic or *captive wild* pigs during the past 12 months unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs;

4. imported domestic and *captive wild* pigs comply with the requirements in Article 15.2.5. or Article 15.2.6.

Article 15.2.4.

Recovery of free status

Should a CSF *outbreak* occur in a free country, *zone* or *compartment*, the free status may be restored where *surveillance* in accordance with Articles 15.2.23. to 15.2.28. has been carried out with negative results either:

1. 3 months after the last *case* where a *stamping-out policy* without vaccination is practised;

OR

2. where a *stamping-out policy* with emergency vaccination is practised:

   a) 3 months after the last *case* and the *slaughter* of all vaccinated *animals*, or

   b) 3 months after the last *case* without the *slaughter* of vaccinated *animals* where there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs;

OR

3. where a *stamping-out policy* is not practised, the provisions of Article 15.2.3. should be followed.

Article 15.2.5.

Recommendations for importation from countries, zones or compartments free of CSF

For domestic and *captive wild* pigs

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

1. showed no clinical sign of CSF on the day of shipment;

2. were kept in a country, *zone* or *compartment* free of CSF since birth or for at least the past 3 months;

3. have not been vaccinated against CSF, nor are they the progeny of vaccinated sows, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

Article 15.2.6.

Recommendations for importation from CSF infected countries or zones

For domestic and *captive wild* pigs

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

1. showed no clinical sign of CSF on the day of shipment;

2. were kept since birth or for the past 3 months in a CSF free *compartment*;

3. have not been vaccinated against CSF nor are they the progeny of vaccinated sows, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

Article 15.2.7.

Recommendations for the importation of wild and feral pigs

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the *animals*:

Annex XXVII (contd)

1. showed no clinical sign of CSF on the day of shipment;

2. were kept in a *quarantine station* for 40 days prior to shipment, and were subjected to a virological test and a serological test performed at least 21 days after entry into the *quarantine station*, with negative results;

3. have not been vaccinated against CSF, unless there are means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), of distinguishing between vaccinated and infected pigs.

Article 15.2.8.

Recommendations for importation from countries, zones or compartments free of CSF

For semen of domestic pigs

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

1. the donor *animals*:

   a) were kept in a country, *zone* or *compartment* free of CSF since birth or for at least 3 months prior to collection;

   b) showed no clinical sign of CSF on the day of collection of the semen;

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

Article 15.2.9.

Recommendations for importation from CSF infected countries or zones

For semen of domestic pigs

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

1. the donor *animals*:

   a) were kept in a *compartment* free of CSF since birth or for at least 3 months prior to collection;

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

   c) met one of the following conditions:

      i) have not been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection, with negative results; or

      ii) have been vaccinated against CSF and were subjected to a serological test in accordance with the *Terrestrial Manual* performed at least 21 days after collection and it has been conclusively demonstrated that any antibody is due to the vaccine; or

      iii) have been vaccinated against CSF and were subjected to a virological test performed in accordance with the *Terrestrial Manual* on a sample taken on the day of collection and it has been conclusively demonstrated that the boar is negative for virus genome;

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

Article 15.2.10.

Recommendations for importation from countries, zones or compartments free of CSF

For *in vivo* derived embryos of domestic pigs

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

1. the donor females showed no clinical sign of CSF on the day of collection of the embryos;

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

Article 15.2.11.

Recommendations for importation from CSF infected countries or zones

For *in vivo* derived embryos of domestic pigs

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

1. the donor females:

   a) were kept in a *compartment* free of CSF since birth or for at least 3 months prior to collection;

   b) showed no clinical sign of CSF on the day of collection of the embryos and for the following 40 days;

   c) and either:

      i) have not been vaccinated against CSF and were subjected, with negative results, to a serological test performed at least 21 days after collection; or

      ii) have been vaccinated against CSF and were subjected to a serological test performed at least 21 days after collection and it has been conclusively demonstrated by means, validated to OIE standards (Chapter 2.8.3. of the *Terrestrial Manual*), that any antibody is due to the vaccine;

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

Article 15.2.12.

Recommendations for importation from countries, zones or compartments free of CSF

For fresh meat of domestic and *captive wild* pigs

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

Annex XXVII (contd)

1. have been kept in a country, *zone* or *compartment* free of CSF, or which have been imported in accordance with Article 15.2.5. or Article 15.2.6.;

2. have been slaughtered in an approved *abattoir*, 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 CSF.

Article 15.2.13.

Recommendations for the importation of fresh meat of wild and feral pigs

Regardless of the CSF status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that ~~the entire consignment of *fresh meat* comes from *animals*~~:

1. the entire consignment of *fresh meat* comes from *animals* which have been subjected to a post-mortem inspection in accordance with Chapter 6.2. in an approved examination centre, and have been found free of any sign suggestive of CSF;

2. where the CSF-free status of the *wild* and *feral* pig population cannot be assured, the entire consignment of *meat* comes from *animals* from each of which a sample has been collected and has been subjected to a virological test and a serological test for CSF, with negative results.

Article 15.2.14.

Recommendations for the importation of meat and meat products of pigs, or for products of animal origin (from fresh meat of pigs) intended for use in animal feeding, for agricultural or industrial use, or for pharmaceutical or surgical use

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

1. have been prepared:

   a) exclusively from *fresh meat* meeting the conditions laid down in Article 15.2.12.;

   b) in a processing establishment:

      i) approved by the *Veterinary Authority* for export purposes;

      ii) processing only *meat* meeting the conditions laid down in Article 15.2.12.;

OR

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 15.2.21. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.15.

Recommendations for the importation of products of animal origin (from pigs, but not derived from fresh meat) intended for use in animal feeding

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

1. originated from domestic and *captive wild* pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in accordance with Article 15.2.20. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.16.

Recommendations for the importation of products of animal origin (from pigs, but not derived from fresh meat) intended for agricultural or industrial use

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

1. originated from domestic and *captive wild* pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.17.

Recommendations for the importation of bristles

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

1. originated from domestic and *captive wild* pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.18.

Recommendations for the importation of litter and manure

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

1. originated from domestic and *captive wild* pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus (under study) and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Annex XXVII (contd)

Article 15.2.19.

Recommendations for the importation of skins and trophies

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

1. originated from domestic and *captive wild* pigs in a CSF free country, *zone* or *compartment* and have been prepared in a processing establishment approved by the *Veterinary Authority* for export purposes; or

2. have been processed in an establishment approved by the *Veterinary Authority* for export purposes so as to ensure the destruction of the CSF virus in conformity with one of the procedures referred to in Article 15.2.22. and that the necessary precautions were taken after processing to avoid contact of the product with any source of CSF virus.

Article 15.2.20.

Procedures for the inactivation of the CSF virus in swill

For the inactivation of CSF viruses likely to be present in swill, one of the following procedures should be used:

1. the swill should be maintained at a temperature of at least 90°C for at least 60 minutes, with continuous stirring; or

2. the swill should be maintained at a temperature of at least 121°C for at least 10 minutes at an absolute pressure of 3 bar.

Article 15.2.21.

Procedures for the inactivation of the CSF virus in meat

For the inactivation of viruses present in *meat*, one of the following procedures should be used:

1. Heat treatment

   Meat shall be subjected to one of the following treatments:

   a) heat treatment in a hermetically sealed container with a Fo value of 3.00 or more;

   b) heat treatment at a minimum temperature of 70°C, which should be reached throughout the *meat*.

2. Natural fermentation and maturation

   The *meat* should be subjected to a treatment consisting of natural fermentation and maturation having the following characteristics:

   a) an aw value of not more than 0.93, or

   b) a pH value of not more than 6.0.

Hams should be subjected to a natural fermentation and maturation process for at least 190 days and loins for 140 days.

3. Dry cured pork meat

   a) Italian style hams with bone-in should be cured with salt and dried for a minimum of 313 days.

   b) Spanish style pork *meat* with bone-in should be cured with salt and dried for a minimum of 252 days for Iberian hams, 140 days for Iberian shoulders, 126 days for Iberian loin, and 140 days for Serrano hams.

Article 15.2.21.bis

Procedures for the inactivation of the CSF virus in casings of pigs

For the inactivation of CSF virus present in natural casings of pigs, the following procedures should be used: the casing should be treated ~~salting~~ for at least 30 days with dry salt mixture or saturated solution ~~phosphate supplemented dry salt~~ containing 86.5% NaCl, 10.7% Na_2HPO_4 and 2.8% Na_3PO_4 (weight/weight/weight), and kept at a temperature of greater than 12°C during this entire period.

Article 15.2.22.

Procedures for the inactivation of the CSF virus in skins and trophies

For the inactivation of CSF viruses ~~likely to be~~ present in skins and trophies, one of the following procedures should be used:

1. boiling in water for an appropriate time so as to ensure that any matter other than bone, tusks or teeth is removed;

2. gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);

3. soaking, with agitation, in a 4% (weight/volume) solution of washing soda (sodium carbonate - Na_2CO_3) maintained at pH 11.5 or above for at least 48 hours;

4. soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;

5. in the case of raw hides, salting for at least 28 days with sea salt containing 2% washing soda (sodium carbonate - Na_2CO_3).

Article 15.2.23.

Surveillance: introduction

Articles 15.2.23. to 15.2.28. define the principles and provide a guide on the *surveillance* for CSF, complementary to Chapter 1.4., applicable to Members seeking to determine their CSF status. This may be for the entire country, ~~or~~ a *zone* or a *compartment*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of CSF status is also provided.

Annex XXVII (contd)

The impact and epidemiology of CSF differ widely in different regions of the world, and it is, therefore, impossible to provide specific recommendations for all situations. The *surveillance* strategies employed for demonstrating freedom from CSF at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach should be tailored in order to prove freedom from CSF for a country or *zone* where *wild* pigs provide a potential reservoir of *infection*, or where CSF is present in adjacent countries. The method should examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is, therefore, latitude available to Members to provide a well-reasoned argument to prove that absence of classical swine fever virus (CSFV) *infection* is assured at an acceptable level of confidence.

Surveillance for CSF should be in the form of a continuing programme designed to establish that a population in a country, *zone* or *compartment* is free from CSFV *infection* or to detect the introduction of CSFV into a population already recognized as free. Consideration should be given to the specific characteristics of CSF epidemiology which include: the role of swill feeding and the impact of different production systems on *disease* spread, the role of semen in transmission of the virus, the lack of pathognomonic gross lesions and clinical signs, the frequency of clinically inapparent *infections*, the occurrence of persistent and chronic *infections*, and the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV. Serological cross-reactivity with other pestiviruses has to be taken into consideration when interpreting data from serological surveys. A common route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with bovine viral diarrhoea virus (BVDV).

For the purposes of this chapter, virus *infection* means presence of CSFV as demonstrated directly by virus isolation, the detection of virus antigen or virus nucleic acid, or indirectly by seroconversion which is not the result of vaccination.

Article 15.2.24.

Surveillance: general conditions and methods

1. A *surveillance* system, in accordance with Chapter 1.4. and under the responsibility of the *Veterinary Authority*, should address the following aspects: ~~A procedure should be in place for the rapid collection and transport of samples to an accredited *laboratory* as described in the *Terrestrial Manual*.~~

    a) formal and ongoing system for detecting and investigating *outbreaks of disease* or CSFV *infection* should be in place;

    b) a procedure should be in place for the rapid collection and transport of samples from suspect *cases* of CSF to a *laboratory* for CSF diagnosis as described in the *Terrestrial Manual*;

    c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2. The CSF *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 livestock, as well as diagnosticians, should report promptly any suspicion of CSF 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*. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated employing clinical, pathological, and *laboratory* diagnosis. ~~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 CSF diagnosis, epidemiological evaluation, and control;

b) implement, when relevant, regular and frequent clinical inspections and serological testing of high-risk groups of *animals* (for example, where swill feeding is practised), or those adjacent to a CSF infected country or *zone* (for example, bordering areas where infected *wild* pigs are present).

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 CSFV. The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot, therefore, be reliably predicted. Recognitions for freedom from CSFV *infection* should, as a consequence, provide details of the occurrence of suspicious *cases* and how they were investigated and dealt with. This should include the results of *laboratory* testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement standstill orders, etc.).

Article 15.2.25.

Surveillance strategies

1. Introduction

~~There are two basic strategies that can be employed for CSF *surveillance* depending on the purpose of the Member for seeking recognition of freedom from CSF. In countries free of CSF,~~ *S~~s~~urveillance* programmes should be designed to detect the presence ~~introduction~~ of CSFV *infection* in~~to~~ domestic or *wild* ~~swine~~ pigs. ~~The optimal strategy to meet this objective is most often targeted *surveillance*.~~

~~The population covered by *surveillance* aimed at detecting *disease* and *infection* should include domestic and *wild* pig populations within the country or *zone* to be recognised as free from CSFV *infection*. Such *surveillance* may involve opportunistic testing of samples submitted for other purposes, but a more efficient and effective strategy is one which includes targeted *surveillance*.~~

Although *surveillance* may involve opportunistic testing of samples submitted for other purposes, the optimal strategy to meet this objective is usually targeted *surveillance*, ~~*Surveillance* is targeted to~~ aimed at the domestic, ~~and~~ *wild* and *feral* pig population which presents the highest risk of *infection* (for example, swill fed farms, pigs reared outdoors, specific *wild* pig sub-populations or farms in proximity to infected *wild* pigs). ~~Each Member will need to identify its individual risk factors.~~ Targeted *surveillance* may include randomized sampling in selected high risk populations, based on the risk factors present. These may include: temporal and spatial distribution of past *outbreaks*, pig movements and demographics, etc.

For reasons of cost, the longevity of antibody levels, as well as the existence of clinically inapparent *infections* and difficulties associated with differential diagnosis of other *diseases*, serology is often the most effective and efficient *surveillance* methodology. In some circumstances, which will be discussed later, clinical and virological *surveillance* may also have value.

The *surveillance* strategy chosen ~~The Member~~ should be justif~~y~~ied ~~the *surveillance* strategy chosen~~ as adequate to detect the presence of CSFV *infection* in accordance with Chapter 1.4. and the epidemiological situation. Cumulative survey results in combination with the results of passive *surveillance*, over time, will increase the level of confidence in the *surveillance* strategy. ~~If a Member wishes to apply for recognition by other Members of a specific *zone* within the country as being free from CSFV *infection*, the design of the *surveillance* strategy and the basis for any sampling process would need to be aimed at the population within the *zone*.~~

When applying randomized sampling, either at the level of the entire population or within targeted sub-populations ~~For random surveys,~~ the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalences for the selected populations. 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 choice of design prevalence and confidence level ~~The Member~~ should be justif~~y~~ied ~~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~~ approach selected, the sensitivity and specificity of the diagnostic tests in the target populations ~~employed~~ should be considered ~~are factors~~ in the design, sample size determination and interpretation of the results obtained. ~~Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and production class of *animals* in the target population.~~

Irrespective of the testing system employed, the *surveillance* system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognized cross-reactivity with ruminant pestiviruses. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of CSFV *infection*. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as *animals* which may be epidemiologically linked.

2. Clinical ~~and virological~~ surveillance

~~Beyond their role in targeted *surveillance*, clinical and virological *surveillance* for CSF has two aims: a) to shorten the period between introduction of CSF virus into a *disease* free country or *zone* and its detection, and b) to confirm that no unnoticed *outbreaks* have occurred.~~

~~In the past,~~ The value of clinical ~~identification of *cases* was the cornerstone of early detection of CSF. However, emergence of~~ *surveillance* alone is limited due to the low virulence of some strains of CSF, as well as the emergence of new *diseases* ~~-~~(such as post-weaning multisystemic wasting syndrome, and porcine dermatitis and nephropathy syndrome ~~- have made such reliance less effective, and, in countries where such *diseases* are common, can add significant risk of masking the presence of CSF~~) which can mask the presence of CSF. Therefore, clinical *surveillance* should be supplemented, as appropriate, by serological and virological *surveillance*.

~~The spectrum of *disease* signs and gross pathology seen in CSF *infections*, along with the plethora of other agents that can mimic CSF, renders the value of clinical examination alone somewhat inefficient as a *surveillance* tool. These factors, along with the compounding effects of concurrent *infections* and *diseases* caused by ruminant pestiviruses, dictate the need for *laboratory* testing in order to clarify the status of CSF suspects detected by clinical monitoring.~~

~~Nevertheless, c~~Clinical and pathological signs ~~presentation should not be ignored as a tool~~ are useful for early detection; in particular, any *cases* where clinical signs or lesions consistent with CSF are accompanied by high morbidity and/or mortality should be investigated without delay. In CSFV *infection*s involving low virulence strains, high mortality may only be seen in young *animals*, and adult *animals* may not show clinical sign. ~~Otherwise close physical examination of susceptible *animals* is useful as a selection criteria for CSF *surveillance*, particularly in diagnostic *laboratories* or *slaughter* establishments or when applied to high risk populations such as swill feeding operations.~~

~~The difficulties in detecting chronic *disease* manifested by non specific clinical signs and delayed seroconversion and seronegativity, in persistently infected piglets, both of which may be clinically normal, makes virological investigation essential. As part of a *herd* investigation, such *animals* are likely to be in a minority and would not confound a diagnosis based on serology. Individually or as part of recently mixed batches, such *animals* may, however, escape detection by this method. A holistic approach to investigation, taking note of *herd* history, pig, personnel and *vehicle* movements and disease status in neighbouring *zones* or countries, can also assist in targeting *surveillance* in order to increase efficiency and enhance the likelihood of early detection.~~

~~The labour-intensive nature of clinical, pathological and virological investigations, along with the smaller 'window of opportunity' inherent in virus, rather than antibody detection, has, in the past, resulted in greater emphasis being placed on mass serological screening as the best method for *surveillance*. However, *surveillance* based on clinical and pathological inspection and virological testing should not be underrated. If targeted at high risk groups in particular, it provides an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. *Herds* predominated by adult *animals*, such as nucleus *herds* and artificial insemination studs, are particularly useful groups to monitor, since *infection* by low virulence viruses in such groups may be clinically inapparent, yet the degree of spread may be high.~~

~~Clinical and virological monitoring may also provide a high level of confidence of rapid detection of *disease* if a sufficiently large number of clinically susceptible *animals* is examined. In particular, molecular detection methods are increasingly able to offer the possibility of such large-scale screening for the presence of virus, at reasonable cost.~~

Wild and *feral* pigs and, in particular, those with a wholly free-living existence, rarely present the opportunity for clinical observation, but should form part of any *surveillance* scheme and should, ideally, be monitored for virus as well as antibody.

3. Virological surveillance

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

a) to monitor at risk populations;

b) to confirm clinically suspect *cases*;

c) to follow up positive serological results;

d) to test abnormal daily mortality, to ensure early detection of *infection*.

Molecular detection methods can be applied to large-scale screening for the presence of virus. If targeted at high risk groups, they provide an opportunity for early detection that can considerably reduce the subsequent spread of *disease*. Epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in *disease* free areas.

~~Vaccine design and diagnostic methodologies, and in particular methods of virus detection, are increasingly reliant on up-to-date knowledge of the molecular, antigenic and other biological characteristics of viruses currently circulating and causing *disease*. Furthermore, epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in *outbreaks* in *disease* free areas. It is therefore essential that CSFV isolates are sent regularly to the regional OIE Reference Laboratory for genetic and antigenic characterisation.~~

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~~3~~4. Serological surveillance

Serological *surveillance* aims at detecting antibodies against CSFV. Positive CSFV antibody test results can have five possible causes:

a. natural *infection* with CSFV;

b. ~~legal or illegal~~ vaccination against CSF;

c. maternal antibodies ~~derived from an immune sow (maternal antibodies) are usually found only up to 4.5 months of age, but, in some individuals, maternal antibodies can be detected for considerably longer periods~~;

d. cross-reactions with other pestiviruses;

e. non-specific reactors.

The *infection* of pigs with other pestiviruses may complicate a *surveillance* strategy based on serology. Antibodies to bovine viral diarrhoea virus (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity~~. Although persistently infected immunotolerant pigs are themselves seronegative, they continuously shed virus, so the prevalence of antibodies at the *herd* level will be high.~~

CSFV may lead to persistently infected, sero-negative young *animals*, which continuously shed virus. CSFV *infection* may also lead to c~~C~~hronically infected pigs which may have undetectable or fluctuating antibody levels. Even though serological methods will not detect these *animals*, such *animals* are likely to be in a minority and would not confound a diagnosis based on serology as part of a *herd* investigation.

It may be possible to use sera collected for other survey purposes for CSF *surveillance*. However, the principles of survey design described in this chapter and the requirement for statistical validity 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 *infection* by field strains or other pestiviruses. Because clustering may signal field strain *infection*, the investigation of all instances should be incorporated in the survey design. Clustering of positive *animals* is always epidemiologically significant and therefore should be investigated.~~

~~In countries or *zones* that are moving towards freedom, serosurveillance can provide valuable information on the disease status and efficacy of any control programme.~~ In countries, *zones* or *compartments* that are heading towards freedom from CSF and have recently discontinued the use of vaccination, ~~T~~targeted serosurveillance of young, unvaccinated *animals* ~~stock will indicate whether newly~~ can provide useful information on possible virus circulation ~~circulating virus is present, although the presence of maternal antibody will also need to be considered~~. Maternal antibodies are usually found up to four and a half months of age and can interfere with the interpretation of serological results. ~~If conventional attenuated vaccine is currently being used or has been used in the recent past, serology aimed at detecting the presence of field virus will likewise need to be targeted at unvaccinated *animals* and after the disappearance of maternal antibody. General usage in such situations may also be used to assess levels of vaccine coverage.~~

Marker v~~V~~accines ~~also exist which~~, when used in conjunction with accompanying DIVA tests as described in the *Terrestrial Manual* ~~dedicated serological tests~~, may allow discrimination between vaccinal antibody and that induced by ~~field~~ natural *infection*. ~~Such tools, described in the *Terrestrial Manual*, will need to be fully validated. They do not confer the same degree of protection as that provided by conventional vaccines, particularly with respect to preventing transplacental *infections*. Furthermore,~~ However, the interpretation of serosurveillance results using DIVA techniques is only meaningful on a *herd* level ~~such differentiation requires cautious interpretation on a *herd* basis~~.

~~The results of random or targeted serological surveys are important in providing reliable evidence that no CSFV *infection* is present in a country or *zone*. It is therefore essential that the survey be thoroughly documented.~~

~~The free status should be reviewed whenever evidence emerges to indicate that changes which may alter the underlying assumption of continuing freedom, has occurred. Such changes include but are not limited to:~~

~~f. an emergence or an increase in the prevalence of CSF in countries or *zones* from which live pigs or products are imported;~~

~~g. an increase in the volume of imports or a change in their country or *zone* of origin;~~

~~h. an increase in the prevalence of CSF in the domestic or *wild* pigs of adjacent countries or *zones*;~~

~~i. an increased entry from, or exposure to, infected *wild* pig populations of adjacent countries or *zones*.~~

Article 15.2.26.

Countries, zones or compartments declaring freedom from CSF: additional surveillance procedures

1. Country or zone free of CSF

In addition to the general conditions described above, a Member seeking recognition of CSF freedom for the country or a *zone*~~, whether or not vaccination had been practised,~~ should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances in and around the country or *zone* and will be planned and implemented according to the general conditions and methods described in this chapter.~~,~~ The objective is to demonstrate the absence of CSFV *infection* in domestic and *captive wild* pigs and ascertain the *infection* status in *wild* and *feral* pig populations, as described in Article 15.2.28. This requires the support of a national or other *laboratory* able to undertake identification of CSFV *infection* through virus detection and serological tests described in the *Terrestrial Manual*.

2. Compartment free of CSF

The objective of *surveillance* is to demonstrate the absence of CSFV *infection* in the *compartment*. The provisions of Chapters 4.3. and 4.4. should be followed. The frequency and intensity of *surveillance* should be defined and adapted to the prevailing epidemiological situation in the country or *zone*. Any deterioration in the epidemiological situation should trigger a review of the biosecurity measures and an intensification of *surveillance*. The effective separation of the ~~two~~ subpopulations should be demonstrated. To this end, a *biosecurity plan* that includes but is not limited to the following provisions should be implemented:

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a. proper containment of domestic and *captive wild* pigs;

b. control of movement of *vehicles* with cleaning and *disinfection* as appropriate;

c. control of personnel entering into the *establishments* and awareness of risk of fomite spread;

d. prohibition of introduction to the *establishments* of *wild* and *feral* caught *animals* and their products;

e. record of animal movements into and out of *establishments*;

f. information and training programmes for farmers, processors, *veterinarians*, etc.

The *biosecurity plan* implemented also requires internal and external monitoring by the *Veterinary Authority*. This monitoring should include:

g. periodic clinical and serological monitoring of *herds* in the country or *zone*, and adjacent *wild* pig populations following these recommendations;

h. *herd* registration;

i. official accreditation of *biosecurity plans*;

j. periodic monitoring and review.

Monitoring the CSF status of *wild*, *feral* and domestic pig populations outside the *compartment* will be of value in assessing the degree of risk they pose to the CSF free *compartment*. The design of a monitoring system should follow the provision described in this chapter and in Chapter 1.4. ~~is dependent on several factors such as the size and distribution of the population, the organisation of the *Veterinary Services* and resources available. The occurrence of CSF in *wild* and domestic pigs may vary considerably among countries. *Surveillance* design should be epidemiologically based, and the Member should justify its choice of design prevalence and level of confidence based on Chapter 1.4.~~

~~The geographic distribution and approximate size of *wild* pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include government *wild*life authorities, *wild*life conservation organisations, hunter associations and other available sources. The objective of a *surveillance* programme when the *disease* is already known to exist should be to determine the geographic distribution and the extent of the *infection*.~~

Article 15.2.27.

Recovery of free status: additional surveillance procedures

In addition to the general conditions described in ~~the above mentioned articles~~ this chapter, a Member seeking reestablishment of country or *zone* freedom from CSF should show evidence of an active *surveillance* programme to demonstrate absence of CSFV *infection*.

Populations under this *surveillance* programme should include:

a. *establishments* in the proximity of the *outbreak*;

b. *establishments* epidemiologically linked to the *outbreak*;

c. *animals* used to re-populate affected *establishments* and any *establishments* where contiguous culling is carried out;

d. *wild* and *feral* pig populations in the area of the *outbreak*.

In all circumstances, a Member seeking reestablishment of country or *zone* freedom from CSF ~~with vaccination or without vaccination~~ should report the results of an active and a passive *surveillance* programme. ~~in which t~~The pig population should undergo~~es~~ regular clinical, pathological, virological, and/or serological examination, planned and implemented according to the general conditions and methods described in these recommendations. ~~The *surveillance* should be based on a statistically representative sample of the populations at risk.~~ To regain CSF free status, the *surveillance* approach should provide at least the same level of confidence as demonstrated during the previous declaration of freedom.

Article 15.2.28.

Surveillance for CSFV infection in wild and feral pigs

1. The objective of a *surveillance* programme is to determine the CSFV *infection* status of *wild* and *feral* pigs, as well as the geographic distribution and prevalence, if present. While the same principles apply, *surveillance* in *wild* and *feral* pigs presents challenges beyond those encountered in domestic populations in each of the following areas:

    a) determination of the distribution, size and movement patterns associated with the *wild* and *feral* pig population;

    b) assessment of the possible presence of CSF within the population;

    c) determination of the practicability of establishing a *zone*.

~~2.~~ ~~The design of a monitoring system for *wild* pigs is dependent on several factors such as the organisation of the *Veterinary Services* and resources available.~~ The geographic distribution and approximate size of *wild* pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information to aid in the design of a monitoring system may include *wild*life conservation organisations, hunter associations ~~and other available sources~~, etc. ~~The objective of a *surveillance* programme is to determine if a given *disease* is present, and if so, at what prevalence.~~

~~3~~2. Estimates of *wild* pig populations can be made using ~~advanced~~ a variety of methods ~~(e.g.~~ including radio tracking, linear transect method, capture/recapture~~)~~ or estimates based on the number of *animals* hunted ~~traditional methods based on the number of *animals* that can be hunted to allow for natural restocking (hunting bags)~~.

~~4~~3. For implementation of the monitoring programme, it will be necessary to define the limits of the territory over which *wild* and *feral* pigs range in order to delineate the *epidemiological units* within the monitoring programme. It is often difficult to define *epidemiological units* for *wild* and *feral* *animals*. The most practical approach is based on natural and artificial barriers.

~~5~~4. The monitoring programme should also include *animals* found dead, road kills, *animals* showing abnormal behaviour or exhibiting gross lesions during dressing.

~~6~~5. There may be situations where a more targeted *surveillance* programme can provide additional assurance. The criteria to define high risk areas for targeted *surveillance* include:

    a) areas with past history of CSF;

    b) sub-regions with large populations of *wild* pigs;

    c) border regions with CSF affected countries or *zones*;

    d) interface between *wild*, *feral* and domestic pig populations;

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~~e)~~ ~~picnic and camping areas;~~

~~f~~e) farms with free-ranging pigs;

~~g)~~ ~~garbage dumps;~~

~~h~~f) other risk areas determined by the *Veterinary Authority* such as garbage dumps and picnic and camping areas.

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Annex XXVIII

FUTURE WORK PROGRAMME FOR THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Topic		
Action	**How to be managed**	**Status (September 2011)**
Restructuring of the *Terrestrial Code* Harmonisation of *Terrestrial* and *Aquatic Codes*		
1. Work with AAHSC towards harmonisation, as appropriate, of the Codes 2. CH rename by disease agents	TAHSC & ITD	1. Ongoing 2. Ongoing
Listed disease		
Criteria for listing	TAHSC & SCAD & AHG	Revised CH for MC
CWD		
Decision on listing (new CH)	TAHSC & SCAD	On hold
PRRS		
New CH	SCAD	Pending new info on diagnostics
Evaluation of VS and OIE PVS pathway		
Inclusion of legislation aspect	TAHSC & ITD	Modified new CH for MC
CSF		
Official recognition CSF	SCAD/AHG	Pending production of draft + Q
AHS		
Official recognition	SCAD&TAHSC	Revised CH & Q for MC
FMD		
Revise chapter including wildlife	SCAD&TAHSC	pending production of draft
RP		
Global freedom era	SCAD&TAHSC&AHG	Revised CH for MC
Other *Terrestrial Code* texts in need of revision		
Pet food certificate CH	TAHSC	On hold
Update CH on Brucellosis	SCAD;TAHSC	Revised CH for MC
Update CH on Rabies	SCAD&TAHSC	Revised CH for MC
Update CH on Bee diseases	New AHG/SCAD&TAHSC	Revised CH for MC
Update CH on PPR	SCAD and TAHSC	Revised CH for MC
CH on EHD	SCAD and TAHSC	TAHSC in Feb 2012
Update CH on SVD	SCAD&TAHSC	Pending SCAD revision
Update CH on ASF(SURV)	SCAD	Pending SCAD revision
CH on Paratuberculosis	BSC (diagnostic test) & STD (guidance document)	On hold pending further development in diagnostics

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Animal Production Food Safety		
1. Salmonellosis Update biosecurity procedures CH	APFSWG & AHG	1. Modified draft CH proposed for MC
Zoonotic parasitic diseases a) *Trichinella* spp. b) Echinococcosis c) *Taenia solium*	AHG&TAHSC	a) Revised CH proposed for MC b) Meeting AHG to revise CH c) Draft new CH
Animal welfare		
New texts: 1. Lab animals 2. Livestock production systems a) Broiler b) General principles c) Beef cattle 3. Working animals	AWWG & AHGs TAHSC supervision	1. Modified CH proposed for MC (new article on transport and new model certificate) 2. a) On hold b) Draft article 7.1.4.for MC c) Draft CH for MC 3. Proposed work for 2012
Commodity-based measures for trade		
1. Reviewing code text 2. Drafting horizontal CH	TAHSC, SCAD, AHG, ITD / S&T Dept	1. Ongoing 2. AHG to be convened
OIE policy on Wildlife		
Draft policy	TAHSC with WG on Wildlife & SCAD	Draft text for MC
Invasive Alien Species		
Guidance on RA	TAHSC&SCAD	Expert meeting by end 2011
Compartmentalisation		
Generic Checklist	TAHSC&SCAD	ongoing
Veterinary products (AMR)		
Updating CH 6.7 to 6.9	TAHSC&SCAD&AHG	Draft texts to MC

Note: MC; Member comments, CH: chapter, Q: questionnaire, SURV: surveillance, ITD: International Trade Department, S&T Dept: Scientific & Technical Department

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ITEM, ANNEX, CHAPTER NUMBERS AND CURRENT STATUS

Item	Annex	Chapter	Title	Provided for comments	GS80
1			General comments		
3	3	1.2.	Criteria for listing diseases	Feb 11	
4	4	2.1.	Import risk analysis		
5	5	3.2.	Evaluation of veterinary services		
		3.3.	Communication		
		3.4.	Veterinary Legislation	Sep 10	
	31		Report of AHG on veterinary legislation		
6		4.4.	Application of compartmentalisation		
			Generic checklist		
7	6	4.6.	Collection and processing of bovine, small ruminant and porcine semen		
		4.7.	Collection and processing of *in vivo* derived embryos from livestock and horses		
8	7	6.4.	Biosecurity procedures in poultry production		
		6.5.	Prevention, detection and control of *Salmonella* in poultry		
	8	13.2.	Rabbit haemorrhagic disease		
9		6.7.	Harmonisation of national antimicrobial resistance surveillance and monitoring programmes	Feb 11	
		6.8.	Monitoring of the quantities of antimicrobials used in animal husbandry		
	9	6.9.	Responsible and prudent use of antimicrobial		
	10	7.8.	Use of animals in research and education		
	11	5.13	Model health certificate for Laboratory animals		
	12	7.1.	Introduction to the recommendation for AW (General principle for production system)		
		7.X.	Broiler chicken production system	Sep09	
	13	7.X.	Beef cattle production system	Sep09	
	14	7.5.	Slaughter of animals		
		7.3. 7.6. 7.7.	Transport of animals by land Killing of animals for disease control purposes Stray dog population control		
	34		Report of AWWG Report of AHG on beef cattle production Report of AHG on Laboratory AW		

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Item	Annex	Chapter	Title	Provided for comments	GS80
11	15	8.2.	Aujeszky's disease		
12	16	8.3.	Bluetongue		
13		8.4.	Echinococcosis/Hydatidosis	Feb 11	
	17	8.13.	*Trichinella* infection	Feb 11	
	35		Report of AHG on Zoonotic Parasites		
14		8.5.	Foot and mouth disease		
		1.6.	Questionnaire on foot and mouth disease (Articles 1.6.4. and 1.6.7.)		
15	18	8.10. 5.11.	Rabies Rabies model international veterinary certificate for domestic dogs (*Canis familiaris*), cats (*Felis catus*) and ferrets (*Mustela putorius furo*)	Sep10	
16	19	8.12.	Rinderpest		
17	20	8.15.	Vesicular stomatitis		
18	21	4.14.	Hygiene and disease security procedures in apiaries	Sep10	
		9.1. 9.2. 9.3. 9.4. 9.5. 9.6.	Acarapisosis of honey bees American foulbrood of honey bees European foulbrood of honey bees Small hive beetle infestation (*Aethina tumida*) *Tropilaelaps* infestation of honey bees Varroosis of honey bees	Sep09	
19	22	11.3.	Brucellosis		
20		11.6. 11.7.	Bovine tuberculosis Bovine tuberculosis in farmed cervidae		
21		11.9.	Enzootic bovine leukosis		
22	23	11.12.	Lumpy skin disease		
23	24	12.1 1.6.	African horse sickness Questionnaire on African horse sickness (Article 1.6.6.bis)	Sep10	
	25	12.6. 12.9.	Equine influenza Equine viral arteritis		
24	26	14.8.	Peste des petits ruminants		
25	27	15.2.	Classical swine fever	Sep10	
26		15.4.	Swine vesicular disease	Mar 09	
27	36		Minimum competencies of day1 graduates	Sep10	
			Report of *ad hoc* Group on VE		
28	28		Work Programme		
33		New	Epizootic Haemorrhagic Disease		
34		6.11.	Zoonoses transmissible from non-human primates		

List of abbreviations	
AAHSC	Aquatic Animal Health Standards Commission
AHS	African horse sickness
APFSWG	Animal Production Food Safety Working Group
AWWG	Animal Welfare Working Group
EHD	Epizootic haemorrhagic disease
FMD	Foot and mouth disease
LAW	Laboratory Animal Welfare
PPR	Peste des petits ruminants
PRRS	Porcine reproductive and respiratory syndrome
SCAD	Scientific Commission for Animal Diseases
TAHSC	Terrestrial Animal Health Standards Commission
VE	Veterinary Education